Agenda
Minnetonka City Council
Regular Meeting, Monday, Sept. 17, 2018
6:30 p.m.
Council Chambers

1. Call to Order
2. Pledge of Allegiance
3. Roll Call: Schack-Acomb-Happe-Calvert-Bergstedt-Ellingson-Wiersum
4. Approval of Agenda
5. Approval of Minutes: None
6. Special Matters: None
7. Reports from City Manager & Council Members
8. Citizens Wishing to Discuss Matters Not on the Agenda
9. Bids and Purchases: None
10. Consent Agenda - Items Requiring a Majority Vote:
    A. Resolution concerning a multi-family residential development by Dominium, at 11001 Bren Road East
11. Consent Agenda - Items Requiring Five Votes:
    A. Conditional use permit, with variances, for a restaurant with on-sale liquor at 14725 Excelsior Blvd.
12. Introduction of Ordinances: None
13. Public Hearings:
    A. Resolutions for special assessment of 2017-2018 projects
       Recommendation: Hold the public hearing and adopt the resolutions (4 votes)
14. Other Business:
    A. Ordinances related to tobacco-related products
       Recommendation: Adopt the ordinances (4 votes)
B. Concept plan review for redevelopment of the property at 1809 Plymouth Road

Recommendation: Provide comments and feedback. No formal action is required.

C. Concept plan review for Hennepin County Medical Examiner’s Office at 14300 Co. Rd. 62

Recommendation: Discuss the concept plan with the applicant. No formal action required.

D. Ordinances related to franchise fees

Recommendation: Adopt the ordinances (4 votes)

E. Items related to the 2019 preliminary tax levy

1) Resolution setting a preliminary 2018 tax levy and preliminary 2018 HRA levy, collectible in 2019, and a preliminary 2019 budget, and consenting to a special benefit tax levy of the Minnetonka Economic Development Authority

2) Resolution setting a preliminary 2018 tax levy, collectible in 2019, for the Bassett Creek Watershed Management Tax District

Recommendation: Adopt the resolutions (4 votes)

F. Items related to the Green Line Extension (Southwest LRT)

Recommendation: Approve the following agreements and adopt the resolutions related to Southwest LRT (4 votes):

1) Resolution approving the reaffirmation of previous approvals for Southwest LRT

2) Subordinate Funding Agreement (SFA) 6 – Change Orders for Locally Requested Capital Improvements (LRCI’s)

3) Subordinate Funding Agreement (SFA) Amendments – SFA 4 and SFA 5

4) Resolution approving real estate conveyances

15. Appointments and Reappointments: None

16. Adjournment
Brief Description     Resolution concerning a multi-family residential development by Dominium, at 11001 Bren Road East

Recommendation     Adopt the resolution

Background

On Aug. 27, 2018, the Minnetonka City Council and Economic Development Authority approved the planning entitlements and items related to the financing for the Legends of Minnetonka (senior housing) and Preserve at Shady Oak (workforce housing).

Current Financing Request

The developer, Dominium, is now requesting that the city approve a change to the documents that indicate an additional allocation of $3 million to assist with the workforce housing portion of the project due to an increase in project costs. The attached resolution amends the previous resolution for the tax-exempt bonds and increases the total amount of tax-exempt bonds from $30,500,000 to $33,500,000.

Additional information regarding this request is included in the attached memos from the city’s bond counsel, Gina Fiorini, of Kennedy & Graven. Julie Eddington of Kennedy & Graven will be attending the city council meeting on Sept. 17, 2018 and can answer any questions that may arise during the meeting.

Next Steps

The tentative timeline for financing the two developments is as follows:

- Closing on senior housing bonds on or before Sept. 15, 2018
- Closing on workforce housing bonds on or before Oct. 31, 2018

Staff Recommendation

Staff recommends that the city council adopt the resolution authorizing the issuance of tax-exempt multifamily housing revenue notes and bonds for the benefit of Minnetonka Leased Housing Associates II, LLLP; and authorize city officials to approve non-substantive changes to the related documents.

Submitted through:
    Julie Wischnack, AICP, Community Development Director
    Merrill King, Finance Director

Originated by:
    Alisha Gray, EDFP, Economic Development and Housing Manager
Supplemental Information:

Location Map

List of Senior Housing and Workforce Housing Project Documents

- Link to view documents on website

Previous Resolutions related to this action (attached)

Memo from Gina Fiorini – Kennedy & Graven

City Council Meeting – Aug. 27, 2018
City Council Meeting – July 23, 2018
EDAC Meeting- April 19, 2018
City Council Meeting – April 16, 2018
City Council Meeting – Dec. 18, 2017
City Council Meeting– Dec. 4, 2017
EDAC Meeting – Nov. 27, 2017
Location Map

Project: Dominium
Address: 11001 Bren Rd E
SENIOR HOUSING AND WORK FORCE HOUSING PROJECT DOCUMENTS

Summary of Financing (two series of tax-exempt notes and two series of taxable notes)
Under Project Loan Agreement, Borrower provides the Project Notes. Construction Lenders (U.S. Bank and BMO Harris) fund the Project Notes and the proceeds of the Project Notes are given to the City to fund the Tax-Exempt Funding Loan and Taxable Funding Loan. The proceeds of the Funding Loans pay for the costs of constructing both projects. Once the projects are completed, the “conversion date” occurs and if all conditions of conversion are met, Freddie Mac buys and becomes the lender for the tax-exempt notes and Freddie Mac makes a supplemental loan to take the place of the taxable notes.

Documents relating to Tax-Exempt Notes and Taxable Notes (one set of documents for each of the workforce housing project and the senior housing project)
- Multifamily Notes each with designation as Multifamily Housing Revenue Note (Legends of Minnetonka Project), Series A-1, Series A-2, Series B-1 and Series B-2
  - Sets forth the terms of the Note, including repayment requirements, interest rates, and redemption provisions
- Allonge Endorsement of Multifamily Notes
  - Each allonge assigns all the City’s right, title, and interest in the Notes to the Fiscal Agent for the benefit of the purchasers of the Notes
- Funding Loan Agreement
  - Provides for the issuance of the Notes by the City and creates the various funds and accounts relating to the use of the proceeds of the Notes and assigns all the City’s rights under the Project Loan Agreement, the Notes, and certain other moneys and securities to the Fiscal Agent on behalf of the Lender
- Project Loan Agreement
  - Provides the terms for the loan of proceeds of the Notes to the Borrower, sets forth the City’s administrative fees, and indemnifies the City for any costs, fees, expenses and liability of the Notes
- Mortgage, Assignment of Leases and Rents, Security Agreement and Fixture Financing Statement (one for Taxable and Tax-Exempt Notes)
  - Grants a mortgage, security and assignment of leases and rents in the project to the City as security for the Notes
- Assignment of Mortgage, Assignment of Leases and Rents, Security Agreement and Fixture Financing Statement
  - Assigns all the City’s right, title and interest in the Mortgage to the Fiscal Agent, to the Lenders
- Regulatory Agreement
  - Sets forth the certain rental and occupancy restrictions that the project must meet to comply with state law and federal tax law applicable to tax-exempt bonds
- Housing Program
  - Required by Minnesota Statutes, Chapter 462C and sets forth the proposed plan for the acquisition, construction and equipping of the project and the issuance of conduit revenue obligations to finance the project. The program also explains what the proceeds of the conduit obligations will be used for, the amount and general terms of the conduit revenue obligations, and the affordability requirements relating to the project
- Resolutions
  - The resolution approving each bond transaction also provides authorization for the Minnetonka EDA and the City to sign various closing certificates and other documents necessary to carry out the purposes of the documents approved and the resolutions adopted.
Tax Increment Revenue and Subordinate Multifamily Housing Revenue Bonds, Series 2018C

Documents

- Subordinate Indenture of Trust
  - Issues the Subordinate Bonds and creates the various funds and accounts relating to the use of the proceeds of the Subordinate and for the repayment of the Subordinate Bonds

- Subordinate Loan Agreement
  - Provides for the terms for the loan of proceeds of the Subordinate Bonds to the Borrower, sets forth the City’s administrative fees, and indemnifies the City for any costs, expenses and liability of the Subordinate Bonds

- Subordinate Combination Mortgage, Security Agreement, Fixture Financing Statement, and Assignment of Leases and Rents
  - Provides the Trustee on behalf of bondholders with a subordinate mortgage, assignment of leases and rents relating to the project

- Assignment, Pledge, and Security Agreement
  - Pursuant to this document, the Borrower will pledge and assign its interest in the TIF Note issued by the Minnetonka EDA to the Trustee in order to secure its repayment obligations under the Subordinate Loan Agreement

- Subordinate Guaranty Agreement of Dominium Holdings II, LLC
  - A subordinate guaranty of payments of debt service by an affiliate of the Borrower relating to the Subordinate Bonds

- Subordination Agreement (for Mortgage and Pledge of Surplus Cash)
  - Subordinates the Subordinate Mortgage, Subordinate Guaranty, and the use of surplus cash for repayment of debt service on the Subordinate Bonds to the senior financing

- Bond Purchase Agreement
  - Sets forth the terms of the sale and purchase of the Subordinate Bonds

- Resolutions
  - The resolution approving each bond transaction also provides authorization for the Minnetonka EDA and the City to sign various closing certificates and other documents necessary to carry out the purposes of the documents approved and the resolutions adopted.

TIF and Development Documents

- Construction Addendum to Contract for Private Development (one for each project)
  - Sets forth, among other items, certain construction obligations under the Contract for Private Development including timelines, the payment of certain fees and charges, design and construction of various site improvements, landscaping, the submission of engineering reports, the installation of utilities, erosion and grading requirements, and the ownership of various site improvements and utilities.

- Subordination Agreements related to the Tax-Exempt Notes and Taxable Notes (for Contract for Private Development, Declaration of Restrictive Covenants and Minimum Assessment Agreement) (two agreements for each project – one for tax-exempt notes and one for taxable notes)
  - Subordinates the EDA’s rights in the Minimum Assessment Agreement setting forth a minimum market value for the project, Declaration of Restrictive Covenants relating to the affordability of the project and the Contract for Private Development setting forth terms of providing tax increment financing assistance to the borrower to the rights of the Fiscal Agent on behalf of the Lenders under the financing documents relating to the Tax-Exempt Notes and the Taxable Notes. The subordination agreement subordinates the right of the City to require replacement of the property manager. The City and EDA may exercise the remedies of specific performance or injunctive relief to enforce covenants
and agreements of Borrower relating to income, rent, or affordability restrictions contained in the Subordinate Agreements. The EDA has the right to exercise its remedies under the Contract for Private Development upon default by the developer.
Resolution No. 2018-112

Resolution authorizing the issuance of multifamily housing revenue notes for the benefit of Minnetonka Leased Housing Associates II, LLLP; approving a housing program for a workforce housing development; and authorizing the execution of documents in connection therewith

Be it resolved by the City Council (the “Council”) of the City of Minnetonka, Minnesota (the “City”) as follows:

Section 1. Recitals.

1.01. Pursuant to Minnesota Statutes, Chapter 462C, as amended (the “Act”), the City is authorized to carry out the public purposes described in the Act by providing for the issuance of revenue obligations to provide funds to finance multifamily housing developments located within the City, including workforce housing developments.

1.02. On May 7, 2018, the City issued its Multifamily Housing Revenue Note (Preserve at Shady Oak Project), Series 2018 (the “Prior Note”), in the original aggregate principal amount of $30,500,000, and loaned the proceeds thereof to Minnetonka Leased Housing Associates II, LLLP, a Minnesota limited liability limited partnership (the “Borrower”). The Prior Note was issued to provide short-term financing for the acquisition, construction, and equipping of approximately 220 units of workforce housing to be located at 10987 and 11015 Bren Road East in the City (the “Project”). The Borrower intended to refinance the Prior Note with the proceeds of long-term financing to be secured by a mortgage loan, tax credit investor contributions, and/or other security.

1.03. In conjunction with the issuance of the Prior Note, the State of Minnesota, through Minnesota Management & Budget, allocated bonding authority in the amount of $30,500,000 to the City with respect to the Prior Note to finance the Project in accordance with the requirements of Minnesota Statutes, Chapter 474A, as amended (the “Allocation Act”).

1.04. The Borrower has now proposed that the City issue its revenue obligations, in one or more series, as taxable and tax-exempt obligations (the “Obligations”), in an estimated aggregate principal amount not to exceed $55,000,000, for the benefit of the Borrower for the purposes of (i) refunding the Prior Note and financing the acquisition, construction, and equipping of the Project; (ii) funding one or more reserve funds to secure the timely payment of the Obligations, if necessary; (iii) financing interest on the Obligations during the construction of the Project, if necessary; and (iv) paying the costs of issuing the Obligations. The Project will be owned and operated by the Borrower.

1.05. In accordance with the Act, the City has prepared an amended and restated housing program (the “Amended Housing Program”) to authorize the issuance by the City of the Obligations to provide financing for the acquisition, construction, and equipping by the Borrower of the Project. The Amended Housing Program was prepared and submitted to Metropolitan Council for its review and comment.
1.06. A notice of public hearing (the “Public Notice”) was published in the Lakeshore Weekly News, the official newspaper of and a newspaper of general circulation in the City, with respect to the required public hearing under Section 147(f) of the Internal Revenue Code of 1986, as amended (the “Code”), and Section 462C.04, subdivision 2 of the Act.

1.07. The Public Notice was published at least fifteen (15) days before the regularly scheduled meeting of the Council of the City, and on the date hereof, the Council conducted a public hearing on the Housing Program and the issuance of the Obligations at which a reasonable opportunity was provided for interested individuals to express their views, both orally and in writing.

Section 2. Amended Housing Program.

2.01. The Amended Housing Program, in the form substantially on file with the City, is hereby approved.

Section 3. The Notes.

3.01. The Borrower has requested that the City issue, sell, and deliver a portion of the Obligations, in one or more series, as taxable and tax-exempt obligations, in the estimated aggregate principal amount of $51,430,000 (the “Notes”). On the date hereof, the Council will also consider authorizing a separate portion of the Obligations, in one or more series, as taxable or tax-exempt obligations, in the estimated aggregate principal amount of $3,570,000 (the “Subordinate Bonds”). In no event shall the combined principal amount of the Notes and the Subordinate Bonds exceed $55,000,000. Furthermore, in no event shall the combined principal amount of the Notes and the Subordinate Bonds to be issued on a tax-exempt basis exceed $30,500,000.

3.02. The Notes will be issued pursuant to a Funding Loan Agreement (the “Funding Loan Agreement”), between the City, U.S. Bank National Association, a national banking association, in its capacity as fiscal agent (the “Fiscal Agent”), and U.S. Bank National Association, a national banking association, as administrative agent (the “Administrative Agent”) for U.S. Bank National Association, a national banking association, and BMO Harris Bank N.A., a national banking association (together, the “Funding Lender”). The proceeds derived from the sale of the Notes (the “Funding Loans”) will be loaned by the City to the Borrower (the “Project Loans”) pursuant to the terms of a Project Loan Agreement (the “Project Loan Agreement”) between the City, the Fiscal Agent, and the Borrower.

3.03. The principal of and interest on the Project Loans will be paid from loan repayments to be made by the Borrower under the terms of the Project Loan Agreement, and as security for the repayment of principal of and interest on the Project Loans, the Borrower will execute and deliver to the City one or more mortgage agreements (the “Mortgages”) to be assigned by the City to the Fiscal Agent pursuant to one or more assignments of mortgage (the “Mortgage Assignments”). Additionally, the Borrower will issue one or more project notes (the “Project Notes”) to the City to be endorsed by the City to the Fiscal Agent as security for the Funding Loans.
3.04. The Notes will be issued pursuant to this resolution and the Act, and the Notes and the interest thereon (i) shall be payable solely from the revenues pledged therefor under the Funding Loan Agreement and the Project Loan Agreement and additional sources of revenues provided by or on behalf of the Borrower; (ii) shall not constitute a debt of the City within the meaning of any constitutional or statutory limitation; (iii) shall not constitute nor give rise to a pecuniary liability of the City or a charge against its general credit or taxing powers; (iv) shall not constitute a charge, lien, or encumbrance, legal or equitable, upon any property of the City other than the City's interest in the Funding Loan Agreement and the Project Loan Agreement; and (v) shall not constitute a general or moral obligation of the City.

3.05. The loan repayments to be made by the Borrower under the Funding Loan Agreement and the Project Loan Agreement will be fixed so as to produce revenue sufficient to pay the principal of, premium, if any, and interest on the Notes when due. Pursuant to the Funding Loan Agreement, the City will assign its rights to the basic payments and certain other rights under the Project Loan Agreement, the Project Loans, the Project Notes, the Mortgages, and certain moneys and securities held by the Fiscal Agent in the funds and accounts established under the Funding Loan Agreement to the Fiscal Agent.

3.06. The City acknowledges, finds, determines, and declares that the issuance of the Notes is authorized by the Act and is consistent with the purposes of the Act and that the issuance of the Notes, and the other actions of the City under the Funding Loan Agreement and the Project Loan Agreement and this resolution constitute a public purpose and are in the interests of the City. In authorizing the issuance of the Notes for the financing of the Project and the related costs, the City's purpose is and the effect thereof will be to promote the public welfare of the City and its residents by providing multifamily housing developments for individuals and families of low or moderate income and otherwise furthering the purposes and policies of the Act.

3.07. For the purposes set forth above, there is hereby authorized the issuance, sale, and delivery of the Notes in the approximate aggregate principal amount of $51,430,000, subject to Section 3.01 hereof.

The Notes shall bear interest at the rates, shall be designated, shall be numbered, shall be dated, shall mature, shall be in the aggregate principal amount, shall be subject to redemption prior to maturity, shall be in such form, and shall have such other terms, details, and provisions as are prescribed in the form of Notes now on file with the City, with the amendments referenced herein. The City hereby authorizes a portion of the Notes be issued, in whole or in part, as "tax-exempt obligations," the interest on which is not includable in gross income for federal and State of Minnesota income tax purposes (the "Tax-Exempt Notes").

All of the provisions of the Notes, when executed as authorized herein, shall be deemed to be a part of this resolution as fully and to the same extent as if incorporated verbatim herein and shall be in full force and effect from the date of execution and delivery thereof. The Notes shall be substantially in the forms on
file with the City, which forms are hereby approved, with such necessary and appropriate variations, omissions, and insertions (including changes to the aggregate principal amount of the Notes, the stated maturities of the Notes, the interest rates on the Notes and the terms of redemption of the Notes) as the Mayor and the City Manager, in their discretion, shall determine. The execution of the Notes with the manual or facsimile signatures of the Mayor and the City Manager and the delivery of the Notes by the City shall be conclusive evidence of such determination.

3.08. The Notes shall be special, limited obligations of the City payable solely from the revenues provided by the Borrower pursuant to the Project Loan Agreement, including revenues derived from the Project. The Council hereby authorizes and directs the Mayor and the City Manager to execute the Notes in accordance with the terms thereof.

3.09. The Mayor and the City Manager are hereby authorized and directed to execute and deliver the Funding Loan Agreement and the Project Loan Agreement. All of the provisions of the Funding Loan Agreement and the Project Loan Agreement, when executed and delivered as authorized herein, shall be deemed to be a part of this resolution as fully and to the same extent as if incorporated verbatim herein and shall be in full force and effect from the date of execution and delivery thereof. The Funding Loan Agreement and the Project Loan Agreement shall be substantially in the forms on file with the City which are hereby approved, with such omissions and insertions as do not materially change the substance thereof, and as the Mayor and the City Manager, in their discretion, shall determine, and the execution thereof by the Mayor and the City Manager shall be conclusive evidence of such determinations.

3.10. To ensure compliance with certain rental and occupancy restrictions imposed by the Act and Section 142(d) of the Code, and to ensure compliance with certain restrictions imposed by the City, the Mayor and City Manager are hereby authorized and directed to execute and deliver a Regulatory Agreement (the "Regulatory Agreement") between the City, the Borrower, the Fiscal Agent, and U.S. Bank National Association, a national banking association, as the trustee for the Subordinate Bonds. All of the provisions of the Regulatory Agreement, when executed and delivered as authorized herein, shall be deemed to be a part of this resolution as fully and to the same extent as if incorporated verbatim herein and shall be in full force and effect from the date of execution and delivery thereof. The Regulatory Agreement shall be substantially in the form on file with the City which is hereby approved, with such omissions and insertions as do not materially change the substance thereof, or as the Mayor and the City Manager, in their discretion, shall determine, and the execution thereof by the Mayor and the City Manager shall be conclusive evidence of such determination.

3.11. The Mayor and the City Manager are hereby authorized to execute and deliver, on behalf of the City, such other documents and certificates as are necessary or appropriate in connection with the issuance, sale, and delivery of the Notes, including the Mortgage Assignments, the endorsement of the Project Notes to the Fiscal Agent, various certificates of the City, an Information Return for Tax-Exempt Private Activity Bond Issues, Form 8038 (Rev. April 2011), with
respect to the Tax-Exempt Notes, an endorsement of the City to the tax certificate of the Borrower, and similar documents, and all other documents and certificates as shall be necessary and appropriate in connection with the issuance, sale, and delivery of the Notes. The City hereby authorizes Kennedy & Graven, Chartered, as bond counsel ("Bond Counsel"), to prepare, execute, and deliver its approving legal opinions with respect to the Notes.

3.12. The City hereby authorizes the Borrower to provide such security for payment of its obligations under the Funding Loan Agreement and the Project Loan Agreement and for payment of the Notes, including the Mortgages, one or more guaranties, or any other security agreed upon by the Borrower, Fiscal Agent, the Administrative Agent, and the Funding Lender, and the City hereby approves the execution and delivery of such security.

Section 4. Additional Findings and Certifications.

4.01. Except as otherwise provided in this resolution, all rights, powers, and privileges conferred and duties and liabilities imposed upon the City or the Council by the provisions of this resolution or of the aforementioned documents shall be exercised or performed by the City or by such members of the Council, or such officers, board, body or agency thereof as may be required or authorized by law to exercise such powers and to perform such duties.

No covenant, stipulation, obligation or agreement herein contained or contained in the aforementioned documents shall be deemed to be a covenant, stipulation, obligation or agreement of any member of the Council of the City, or any officer, agent or employee of the City in that person's individual capacity, and neither the Council of the City nor any officer or employee executing the Notes shall be personally liable on the Notes or be subject to any personal liability or accountability by reason of the issuance thereof.

No provision, covenant or agreement contained in the aforementioned documents, the Notes, or in any other document relating to the Notes, and no obligation therein or herein imposed upon the City or the breach thereof, shall constitute or give rise to a general or moral obligation of the City or any pecuniary liability of the City or any charge upon its general credit or taxing powers. In making the agreements, provisions, covenants, and representations set forth in such documents, the City has not obligated itself to pay or remit any funds or revenues, other than funds and revenues derived from the Funding Loan Agreement and the Project Loan Agreement which are to be applied to the payment of the Notes, as provided therein.

4.02. Except as herein otherwise expressly provided, nothing in this resolution or in the aforementioned documents expressed or implied is intended or shall be construed to confer upon any person or firm or corporation, other than the City, any holder of the Notes issued under the provisions of this resolution, any right, remedy or claim, legal or equitable, under and by reason of this resolution or any provisions hereof, this resolution, the aforementioned documents, and all of their provisions being intended to be and being for the sole and exclusive benefit of
the City, and any holder from time to time of the Notes issued under the provisions of this resolution.

4.03. In case any one or more of the provisions of this resolution, other than the provisions contained in the first sentence of Section 3.08 hereof, or of the aforementioned documents, or of the Notes issued hereunder shall for any reason be held to be illegal or invalid, such illegality or invalidity shall not affect any other provision of this resolution, or of the aforementioned documents, or of the Notes, but this resolution, the aforementioned documents, and the Notes shall be construed and endorsed as if such illegal or invalid provisions had not been contained therein.

4.04. The Notes, when executed and delivered, shall contain a recital that they are issued pursuant to the Act, and such recital shall be conclusive evidence of the validity of the Notes and the regularity of the issuance thereof, and that all acts, conditions, and things required by the laws of the State of Minnesota relating to the adoption of this resolution, to the issuance of the Notes, and to the execution of the aforementioned documents to happen, exist, and be performed precedent to the execution of the aforementioned documents have happened, exist, and have been performed as so required by law.

4.05. The officers of the City, Bond Counsel, other attorneys, engineers, and other agents or employees of the City are hereby authorized to do all acts and things required of them by or in connection with this resolution, the aforementioned documents, and the Notes, for the full, punctual, and complete performance of all the terms, covenants, and agreements contained in the Notes, the aforementioned documents, and this resolution. If for any reason the Mayor or the City Manager is unable to execute and deliver the documents referred to in this resolution, such documents may be executed by any member of the Council or any officer of the City delegated the duties of the Mayor or the City Manager with the same force and effect as if such documents were executed and delivered by the Mayor or the City Manager.

4.06. The Borrower shall pay the administrative fee of the City for the issuance of conduit debt. The Borrower will also pay, or, upon demand, reimburse the City for payment of, any and all costs incurred by the City in connection with the Project and the issuance of the Notes, whether or not the Notes are issued, including any costs for reasonable attorneys' fees.

4.07. This resolution shall be in full force and effect from and after its approval. The approvals contained in the resolution are effective for one year after the date hereof.
Adopted by the City Council of the City of Minnetonka, Minnesota on Aug. 27, 2018.

Brad Wiersum, Mayor

ATTEST:

David E. Maeda, City Clerk

ACTION ON THIS RESOLUTION:

Motion for adoption: Acomb
Seconded by: Calvert
Voted in favor of: Ellingson, Acomb, Happe, Schack, Calvert, Bergstedt, Wiersum
Voted against: 
Abstained: 
Absent: 
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on Aug. 27, 2018.

David E. Maeda, City Clerk
Resolution authorizing the issuance of tax increment revenue and subordinate multifamily housing revenue bonds for the benefit of Minnetonka Leased Housing Associates II, LLLP; approving a housing program for a workforce housing development; and authorizing the execution of documents in connection therewith

Be it resolved by the City Council (the "Council") of the City of Minnetonka, Minnesota (the "City") as follows:

Section 1. Recitals.

1.01. Pursuant to Minnesota Statutes, Chapter 462C, as amended (the "Act"), the City is authorized to carry out the public purposes described in the Act by providing for the issuance of revenue obligations to provide funds to finance multifamily housing developments located within the City, including workforce housing developments.

1.02. On May 7, 2018, the City issued its Multifamily Housing Revenue Note (Preserve at Shady Oak Project), Series 2018 (the "Prior Note"), in the original aggregate principal amount of $30,500,000, and loaned the proceeds thereof to Minnetonka Leased Housing Associates II, LLLP, a Minnesota limited liability limited partnership (the "Borrower"). The Prior Note was issued to provide short-term financing for the acquisition, construction, and equipping of approximately 220 units of workforce housing to be located at 10987 and 11015 Bren Road East in the City (the "Project"). The Borrower intended to refinance the Prior Note with the proceeds of long-term financing to be secured by a mortgage loan, tax credit investor contributions, and/or other security.

1.03. In conjunction with the issuance of the Prior Note, the State of Minnesota, through Minnesota Management & Budget, allocated bonding authority in the amount of $30,500,000 to the City with respect to the Prior Note to finance the Project in accordance with the requirements of Minnesota Statutes, Chapter 474A, as amended (the "Allocation Act").

1.04. The Borrower has now proposed that the City issue its revenue obligations, in one or more series, as taxable and tax-exempt obligations (the "Obligations"), in an estimated aggregate principal amount not to exceed $55,000,000, for the benefit of the Borrower for the purposes of (i) refunding the Prior Note and providing financing for the acquisition, construction, and equipping of the Project; (ii) funding one or more reserve funds to secure the timely payment of the Obligations, if necessary; (iii) financing interest on the Obligations during the construction of the Project, if necessary; and (iv) paying the costs of issuing the Obligations. The Project will be owned and operated by the Borrower.

1.05. In accordance with the Act, the City has prepared an amended and restated housing program (the "Amended Housing Program") to authorize the issuance by the City of the Obligations to provide financing for the acquisition, construction, and equipping by the Borrower of the Project. The Amended Housing Program was prepared and submitted to Metropolitan Council for its review and comment.
1.06. A notice of public hearing (the “Public Notice”) was published in the Lakeshore Weekly News, the official newspaper of and a newspaper of general circulation in the City, with respect to the required public hearing under Section 147(f) of the Internal Revenue Code of 1986, as amended (the “Code”), and Section 462C.04, subdivision 2 of the Act.

1.07. The Public Notice was published at least fifteen (15) days before the regularly scheduled meeting of the Council of the City, and on the date hereof, the Council conducted a public hearing on the Housing Program and the issuance of the Obligations at which a reasonable opportunity was provided for interested individuals to express their views, both orally and in writing.

Section 2. Amended Housing Program.

2.01. The Amended Housing Program, in the form substantially on file with the City, is hereby approved.

Section 3. The Subordinate Bonds.

3.01. The Borrower has requested that the City issue, sell, and deliver a portion of the Obligations, in one or more series, as taxable or tax-exempt obligations, in the estimated aggregate principal amount of $3,570,000 (the “Subordinate Bonds”). On the date hereof, the Council will also consider authorizing a separate portion of the Obligations, in one or more series, as taxable and tax-exempt obligations, in the estimated aggregate principal amount of $51,430,000 (the “Notes”). In no event shall the combined principal amount of the Notes and the Subordinate Bonds exceed $55,000,000. Furthermore, in no event shall the combined principal amount of the Notes and the Subordinate Bonds to be issued on a tax-exempt basis exceed $30,500,000.

3.02. The Subordinate Bonds will be issued pursuant to a Subordinate Indenture of Trust (the “Indenture”) between the City and U.S. Bank National Association, a national banking association (the “Trustee”). The proceeds of the Subordinate Bonds will be loaned to the Borrower pursuant to a Subordinate Loan Agreement (the “Loan Agreement”) between the City and the Borrower.

3.03. The principal of and interest on the Subordinate Bonds will be paid from loan repayments to be made by the Borrower under the terms of the Loan Agreement. As security for the repayment of principal of and interest on the Subordinate Bonds, the Borrower will pledge its interest in the pay-as-you-go note (the “TIF Note”) to be issued by the Economic Development Authority in and for the City of Minnetonka, Minnesota (the “Authority”) in the maximum principal amount of $3,648,000 to the Trustee. In addition, the Borrower will execute and deliver to the City a subordinate mortgage agreement (the “Subordinate Mortgage”) to be assigned by the City to the Trustee pursuant to an assignment of mortgage (the “Subordinate Mortgage Assignment”). In addition to the revenues and security granted for the repayment of the Subordinate Bonds in the Loan Agreement, the Indenture, and the Subordinate Mortgage, the Subordinate Bonds will also be secured by (i) an assignment of the TIF Note under the provisions of an Assignment, Pledge, and Security Agreement (the “Pledge Agreement”),
between the Borrower and the Trustee, and (ii) a Subordinate Guaranty Agreement (the "Guaranty") by Dominium Holdings II, LLC, a Minnesota limited liability company, in favor of the Trustee.

3.04. The Subordinate Bonds will be issued pursuant to this resolution, the Act, and the Indenture, and the Subordinate Bonds and the interest thereon (i) shall be payable solely from the revenues pledged therefor under the Indenture and the Loan Agreement and additional sources of revenues provided by or on behalf of the Borrower; (ii) shall not constitute a debt of the City within the meaning of any constitutional or statutory limitation; (iii) shall not constitute nor give rise to a pecuniary liability of the City or a charge against its general credit or taxing powers; (iv) shall not constitute a charge, lien, or encumbrance, legal or equitable, upon any property of the City other than the City’s interest in the Indenture and the Loan Agreement; and (v) shall not constitute a general or moral obligation of the City.

3.05. The loan repayments to be made by the Borrower under the Loan Agreement will be fixed so as to produce revenue sufficient to pay the principal of, premium, if any, and interest on the Subordinate Bonds when due. Pursuant to the Indenture, the City will assign its rights to the basic payments and certain other rights under the Loan Agreement and the Subordinate Mortgage and certain moneys and securities held by the Trustee in the funds and accounts established under the Indenture to the Trustee.

3.06. The City acknowledges, finds, determines, and declares that the issuance of the Subordinate Bonds is authorized by the Act and is consistent with the purposes of the Act and that the issuance of the Subordinate Bonds, and the other actions of the City under the Indenture and the Loan Agreement and this resolution constitute a public purpose and are in the interests of the City. In authorizing the issuance of the Subordinate Bonds for the financing of the Project and the related costs, the City’s purpose is and the effect thereof will be to promote the public welfare of the City and its residents by providing multifamily housing developments for seniors of low or moderate income and otherwise furthering the purposes and policies of the Act.

3.07. For the purposes set forth above, there is hereby authorized the issuance, sale, and delivery of the Subordinate Bonds in the approximate aggregate principal amount of $3,570,000, subject to Section 3.01 hereof.

The Subordinate Bonds shall bear interest at the rates, shall be designated, shall be numbered, shall be dated, shall mature, shall be in the aggregate principal amount, shall be subject to redemption prior to maturity, shall be in such form, and shall have such other terms, details, and provisions as are prescribed in the form of Subordinate Bonds now on file with the City, with the amendments referenced herein. The City hereby authorizes a portion of the Subordinate Bonds be issued, in whole or in part, as "tax-exempt bonds," the interest on which is not includable in gross income for federal and State of Minnesota income tax purposes (the "Tax-Exempt Subordinate Bonds").
All of the provisions of the Subordinate Bonds, when executed as authorized herein, shall be deemed to be a part of this resolution as fully and to the same extent as if incorporated verbatim herein and shall be in full force and effect from the date of execution and delivery thereof. The Subordinate Bonds shall be substantially in the forms on file with the City, which forms are hereby approved, with such necessary and appropriate variations, omissions, and insertions (including changes to the aggregate principal amount of the Subordinate Bonds, the stated maturities of the Subordinate Bonds, the interest rates on the Subordinate Bonds and the terms of redemption of the Subordinate Bonds) as the Mayor and the City Manager, in their discretion, shall determine. The execution of the Subordinate Bonds with the manual or facsimile signatures of the Mayor and the City Manager and the delivery of the Subordinate Bonds by the City shall be conclusive evidence of such determination.

3.08. The Subordinate Bonds shall be special, limited obligations of the City payable solely from the revenues provided by the Borrower pursuant to the Indenture and the Loan Agreement, including revenues derived from the Project. The Council hereby authorizes and directs the Mayor and the City Manager to execute the Subordinate Bonds in accordance with the terms thereof.

3.09. The Mayor and the City Manager are hereby authorized and directed to execute and deliver the Indenture, the Loan Agreement, the Subordinate Bonds Subordination Agreement, and a Bond Purchase Agreement (the “Bond Purchase Agreement”) between the City, the Borrower, and Dougherty & Company LLC, as the original purchaser of the Subordinate Bonds. All of the provisions of the Indenture, the Loan Agreement, and the Bond Purchase Agreement, when executed and delivered as authorized herein, shall be deemed to be a part of this resolution as fully and to the same extent as if incorporated verbatim herein and shall be in full force and effect from the date of execution and delivery thereof. The Indenture, the Loan Agreement, and the Bond Purchase Agreement shall be substantially in the forms on file with the City which are hereby approved, with such omissions and insertions as do not materially change the substance thereof, and as the Mayor and the City Manager, in their discretion, shall determine, and the execution thereof by the Mayor and the City Manager shall be conclusive evidence of such determinations.

3.10. To ensure compliance with certain rental and occupancy restrictions imposed by the Act and Section 142(d) of the Code, and to ensure compliance with certain restrictions imposed by the City, the Mayor and City Manager are also hereby authorized and directed to execute and deliver a Regulatory Agreement (the “Regulatory Agreement”) between the City, the Borrower, the Trustee, and U.S. Bank National Association, a national banking association, as the fiscal agent for the Notes. All of the provisions of the Regulatory Agreement, when executed and delivered as authorized herein, shall be deemed to be a part of this resolution as fully and to the same extent as if incorporated verbatim herein and shall be in full force and effect from the date of execution and delivery thereof. The Regulatory Agreement shall be substantially in the form on file with the City which is hereby approved, with such omissions and insertions as do not materially change the substance thereof, or as the Mayor and the City Manager,
in their discretion, shall determine, and the execution thereof by the Mayor and
the City Manager shall be conclusive evidence of such determination.

3.11. The Mayor and the City Manager are hereby authorized to execute and deliver,
on behalf of the City, such other documents and certificates as are necessary or
appropriate in connection with the issuance, sale, and delivery of the Subordinate
Bonds, including the Subordinate Mortgage Assignment, various certificates of
the City, an Information Return for Tax-Exempt Private Activity Bond Issues,
Form 8038 (Rev. April 2011), with respect to the Tax-Exempt Subordinate
Bonds, an endorsement of the City to the tax certificate of the Borrower with
respect to the Tax-Exempt Subordinate Bonds, and similar documents, and all
other documents and certificates as shall be necessary and appropriate in
connection with the issuance, sale, and delivery of the Subordinate Bonds. The
City hereby authorizes Kennedy & Graven, Chartered, as bond counsel ("Bond
Counsel"), to prepare, execute, and deliver its approving legal opinions with
respect to the Subordinate Bonds.

3.12. The City has not participated in the preparation of the Preliminary Official
Statement (the "Preliminary Official Statement") or the Official Statement (the
"Official Statement") relating to the Subordinate Bonds and has made no
independent investigation with respect to the information contained therein,
including the appendices thereto, and the City assumes no responsibility for the
sufficiency, accuracy, or completeness of such information. Subject to the
foregoing, the City hereby consents to the distribution and the use by the
Underwriter in connection with the sale of the Subordinate Bonds of the
Preliminary Official Statement and the Official Statement. The Preliminary
Official Statement and the Official Statement are the sole materials consented to
by the City for use in connection with the offer and sale of the Subordinate
Bonds. The Council ratifies the distribution of the Preliminary Official Statement
in connection with the public offering of the Subordinate Bonds.

3.13. The City hereby authorizes the Borrower to provide such security for payment of
its obligations under the Indenture and the Loan Agreement and for payment of
the Subordinate Bonds, including the Subordinate Mortgage, the Pledge
Agreement, the Guaranty, or any other security agreed upon by the Borrower,
the Trustee, and the City hereby approves the execution and delivery of such
security.

3.14. The Trustee is hereby appointed as Paying Agent and Bond Registrar for the
Subordinate Bonds.

Section 4. Additional Findings and Certifications.

4.01. Except as otherwise provided in this resolution, all rights, powers, and privileges
conferred and duties and liabilities imposed upon the City or the Council by the
provisions of this resolution or of the aforementioned documents shall be
exercised or performed by the City or by such members of the Council, or such
officers, board, body or agency thereof as may be required or authorized by law
to exercise such powers and to perform such duties.
No covenant, stipulation, obligation or agreement herein contained or contained in the aforementioned documents shall be deemed to be a covenant, stipulation, obligation or agreement of any member of the Council of the City, or any officer, agent or employee of the City in that person’s individual capacity, and neither the Council of the City nor any officer or employee executing the Subordinate Bonds shall be personally liable on the Subordinate Bonds or be subject to any personal liability or accountability by reason of the issuance thereof.

No provision, covenant or agreement contained in the aforementioned documents, the Subordinate Bonds, or in any other document relating to the Subordinate Bonds, and no obligation therein or herein imposed upon the City or the breach thereof, shall constitute or give rise to a general or moral obligation of the City or any pecuniary liability of the City or any charge upon its general credit or taxing powers. In making the agreements, provisions, covenants, and representations set forth in such documents, the City has not obligated itself to pay or remit any funds or revenues, other than funds and revenues derived from the Indenture and the Loan Agreement which are to be applied to the payment of the Subordinate Bonds, as provided therein.

4.02. Except as herein otherwise expressly provided, nothing in this resolution or in the aforementioned documents expressed or implied is intended or shall be construed to confer upon any person or firm or corporation, other than the City, any holder of the Subordinate Bonds issued under the provisions of this resolution, any right, remedy or claim, legal or equitable, under and by reason of this resolution or any provisions hereof, this resolution, the aforementioned documents, and all of their provisions being intended to be and being for the sole and exclusive benefit of the City, and any holder from time to time of the Subordinate Bonds issued under the provisions of this resolution.

4.03. In case any one or more of the provisions of this resolution, other than the provisions contained in the first sentence of Section 3.08 hereof, or of the aforementioned documents, or of the Subordinate Bonds issued hereunder shall for any reason be held to be illegal or invalid, such illegality or invalidity shall not affect any other provision of this resolution, or of the aforementioned documents, or of the Subordinate Bonds, but this resolution, the aforementioned documents, and the Subordinate Bonds shall be construed and endorsed as if such illegal or invalid provisions had not been contained therein.

4.04. The Subordinate Bonds, when executed and delivered, shall contain a recital that they are issued pursuant to the Act, and such recital shall be conclusive evidence of the validity of the Subordinate Bonds and the regularity of the issuance thereof, and that all acts, conditions, and things required by the laws of the State of Minnesota relating to the adoption of this resolution, to the issuance of the Subordinate Bonds, and to the execution of the aforementioned documents to happen, exist, and be performed precedent to the execution of the aforementioned documents have happened, exist, and have been performed as so required by law.

4.05. The officers of the City, Bond Counsel, other attorneys, engineers, and other agents or employees of the City are hereby authorized to do all acts and things
required of them by or in connection with this resolution, the aforementioned documents, and the Subordinate Bonds, for the full, punctual, and complete performance of all the terms, covenants, and agreements contained in the Subordinate Bonds, the aforementioned documents, and this resolution. If for any reason the Mayor or the City Manager is unable to execute and deliver the documents referred to in this resolution, such documents may be executed by any member of the Council or any officer of the City delegated the duties of the Mayor or the City Manager with the same force and effect as if such documents were executed and delivered by the Mayor or the City Manager.

4.06. The Borrower shall pay the administrative fee of the City for the issuance of conduit debt. The Borrower will also pay, or, upon demand, reimburse the City for payment of, any and all costs incurred by the City in connection with the Project and the issuance of the Subordinate Bonds, whether or not the Subordinate Bonds are issued, including any costs for reasonable attorneys’ fees.

4.07. This resolution shall be in full force and effect from and after its approval. The approvals contained in the resolution are effective for one year after the date hereof.

Adopted by the City Council of the City of Minnetonka, Minnesota on Aug. 27, 2018.

Brad Wiersum, Mayor

ATTEST:

David E. Maeda, City Clerk

ACTION ON THIS RESOLUTION:

Motion for adoption: Acomb
Seconded by: Calvert
Voted in favor of: Ellingson, Acomb, Happe, Schack, Calvert, Bergstedt, Wiersum
Voted against:
Abstained:
Absent:
Resolution adopted.
I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on August 27, 2018.

David E. Maeda, City Clerk
September 10, 2018

Alisha Gray  
Economic Development and Housing Manager  
City of Minnetonka  
14600 Minnetonka Boulevard  
Minnetonka, MN 55345-1502

Re: Resolution authorizing the issuance of tax-exempt multifamily housing revenue notes and bonds for the benefit of Minnetonka Leased Housing Associates II, LLLP

Dear Alisha,

As you know, Minnetonka Leased Housing Associates II, LLLP, a Minnesota limited liability limited partnership (the “Borrower”), is working with the City of Minnetonka (the “City”) to provide permanent financing for the acquisition, construction, and equipping of approximately 262 units of workforce housing to be located at 10987 and 11015 Bren Road East in the City (the “Workforce Housing Project”). The Workforce Housing Project will be adjacent to the senior housing project (the “Senior Housing Project”) being developed by Minnetonka Leased Housing Associates III, LLLP. To finance the Workforce Housing Project, the Borrower has requested that the City issue multifamily housing revenue bonds in multiple series, as both taxable and tax-exempt obligations.

On December 18, 2017, the City Council adopted a resolution authorizing the submission of an application to the office of Minnesota Management & Budget for an allocation of bonding authority with respect to the revenue bonds to finance the Project in accordance with the requirements of Minnesota Statutes, Chapter 474A, as amended (the “Allocation Act”), and providing preliminary approval for the sale and issuance of the revenue bonds or other obligations for the Project and the Senior Housing Project in an amount not to exceed $120,000,000. On May 7, 2018, the City issued a portion of the revenue bonds for the Project in the form of its Multifamily Housing Revenue Note (Preserve at Shady Oak Project), Series 2018 in the original aggregate principal amount of $30,500,000 to provide short-term tax-exempt financing for the Workforce Housing Project. In conjunction with the issuance of the Prior Note, the State of Minnesota, through Minnesota Management & Budget, allocated tax-exempt bonding authority in the amount of $30,500,000 to the City with respect to the Prior Note to finance the Project in accordance with the requirements of the Allocation Act.

On August 27, 2018, the City Council adopted two resolutions (the “Prior Resolutions”) approving the issuance of its revenue obligations, in or more series, as taxable and tax-exempt obligations (the “Obligations”) to refinance the Prior Note and to finance the Project in an amount not to exceed $55,000,000. In addition, the Prior Resolutions limited the issuance of Obligations on a tax-exempt basis to an amount not to exceed $30,500,000. The Borrower has determined that there are additional costs
associated with the Project and has requested that the Prior Resolutions be amended to allow additional Obligations to be issued on a tax-exempt basis in an amount not to exceed $33,500,000, representing an increase of $3,000,000. The total amount of Obligations to be issued on a taxable and tax-exempt basis will remain $55,000,000.

In connection with the increase in the amount of tax-exempt Obligations to be issued by the City, there has been requested from the State of Minnesota, through Minnesota Management & Budget, additional allocated tax-exempt bonding authority in the amount of $3,000,000 representing the increase in the amount of tax-exempt Obligations to be issued.

The City Council will be asked to consider the enclosed resolution, which amends the Prior Resolutions to provide approval of the issuance of tax-exempt Obligations in an amount not to exceed $33,500,000. All the other provisions of the Prior Resolutions and the overall financing structure will remain the same.

Julie Eddington will be attending the City Council meeting on September 17, 2018 and can answer any questions that may arise during the meeting. Please contact me with any questions you may have prior to the City Council meeting.

Sincerely,

Gina A. Fiorini
Be it resolved by the City Council (the “Council”) of the City of Minnetonka, Minnesota (the “City”) as follows:

Section 1. Recitals.

1.01. Pursuant to Minnesota Statutes, Chapter 462C, as amended (the “Act”), the City is authorized to carry out the public purposes described in the Act by providing for the issuance of revenue obligations to provide funds to finance multifamily housing developments located within the City, including workforce housing developments.

1.02. On December 18, 2017, the Council adopted a resolution authorizing the submission of an application to the office of Minnesota Management & Budget for an allocation of bonding authority with respect to the revenue bonds or other obligations to finance the Project (as hereinafter defined) in accordance with the requirements of Minnesota Statutes, Chapter 474A, as amended (the “Allocation Act”), and providing preliminary approval for the sale and issuance of such revenue bonds or other obligations for the Project in an amount not to exceed $120,000,000.

1.03. On May 7, 2018, the City issued its Multifamily Housing Revenue Note (Preserve at Shady Oak Project), Series 2018 (the “Prior Note”), in the original aggregate principal amount of $30,500,000, and loaned the proceeds thereof to Minnetonka Leased Housing Associates II, LLLP, a Minnesota limited liability limited partnership (the “Borrower”). The Prior Note was issued to provide short-term financing for the acquisition, construction, and equipping of approximately 220 units of workforce housing to be located at 10987 and 11015 Bren Road East in the City (the “Project”). At the time of issuance, the Borrower intended to refinance the Prior Note with the proceeds of long-term financing to be secured by a mortgage loan, tax credit investor contributions, and/or other security.

1.04. In conjunction with the issuance of the Prior Note, the State of Minnesota, through Minnesota Management & Budget, allocated bonding authority in the amount of $30,500,000 to the City with respect to the Prior Note to finance the Project in accordance with the requirements of Minnesota Statutes, Chapter 474A, as amended (the “Allocation Act”).

1.05. On August 27, 2018, after a duly noticed public hearing, the Council adopted its “Resolution authorizing the issuance of tax increment revenue and subordinate multifamily housing revenue bonds for the benefit of Minnetonka Leased Housing Associates II, LLLP; approving a housing program for a workforce housing development; and authorizing the execution of documents in connection therewith” and its “Resolution authorizing the issuance of multifamily housing
revenue notes for the benefit of Minnetonka Leased Housing Associates II, LLLP; approving a housing program for a workforce housing development; and authorizing the execution of documents in connection therewith (collectively, the “Prior Resolutions”)."

1.06. The Prior Resolutions authorized the City to issue its revenue obligations, in or more series, as taxable and tax-exempt obligations (the “Obligations”), in an estimated aggregate principal amount not to exceed $55,000,000, for the benefit of the Borrower for the purposes of (i) refunding the Prior Note and financing the acquisition, construction, and equipping of the Project; (ii) funding one or more reserve funds to secure the timely payment of the Obligations, if necessary; (iii) financing interest on the Obligations during the construction of the Project, if necessary; and (iv) paying the costs of issuing the Obligations. The Project will be owned and operated by the Borrower. The resolutions separately authorized the issuance of Obligations in the form of the multifamily housing revenue obligations (the “Notes”) and tax increment revenue and subordinate multifamily housing revenue bonds (the “Bonds”) to finance the Project and stated that the combined principal amount of the Notes and the Subordinate Bonds issued on a tax-exempt basis would not exceed $30,500,000.

1.07. The Borrower has determined that the cost of the Project has increased and has requested that the amount of the Notes and Subordinate Bonds issued on a tax-exempt basis authorized by the Prior Resolutions be increased to an amount not to exceed $33,500,000. In connection with the increase in the amount of tax-exempt obligations to be issued by the City, there has been requested from the State of Minnesota, through Minnesota Management & Budget, additional allocated tax-exempt bonding authority in the amount of $3,000,000 to finance the Project in accordance with the Allocation Act.

Section 2. Increase in Tax-Exempt Obligations.

2.01. The City hereby authorizes the issuance, sale, and delivery of the Obligations, in one or more series, as taxable and tax-exempt obligations, in an amount not to exceed $55,000,000 to finance the Project. In no event, shall the combined principal amount of the Notes and the Subordinate Bonds to be issued on a tax-exempt basis exceed $33,500,000. The Prior Resolutions are hereby amended in all respects to allow for an increase in the amount of tax-exempt Obligations to be issued in a combined amount not to exceed $33,500,000 in the form of the Notes and the Subordinate Bonds.

2.01. All other provisions of the Prior Resolutions shall remain in full force and effect.
Adopted by the City Council of the City of Minnetonka, Minnesota on Sept. 17, 2018.

Brad Wiersum, Mayor

ATTEST:

David E. Maeda, City Clerk

ACTION ON THIS RESOLUTION:

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on Sept.17, 2018.

David E. Maeda, City Clerk
City Council Agenda Item #11A  
Meeting of Sept. 17, 2018

**Brief Description**  
Conditional use permit, with variances, for a restaurant with on-sale liquor at 14725 Excelsior Blvd.

**Recommendation**  
Adopt the resolution approving the request

**Introduction**

DelSur L.L.C. (DelSur) formed in 2014. Since that time, the business has expanded from selling empanadas online to include the DelSur Empanadas Food Truck (a mobile food vendor). Earlier this year, DelSur began operating its commissary kitchen in the former Glen Lake Café space at the Glen Lake Shopping Center. Since this did not include the sale of food to customers within the tenant space, a conditional use permit was not required.

A number of food businesses have operated in the space over the years including a pastry shop, coffee house and most recently the Glen Lake Café. The Glen Lake Café had seating for 55 serving breakfast, lunch and dinner including a liquor license for beer and wine.

**Proposal**

DelSur has recently submitted a proposal to reconfigure a portion of the existing tenant space. No changes are proposed for the commissary kitchen area. To accommodate the restaurant, the interior would be reconfigured to allow for restaurant seating for up to 50 people, a bar area and a new food display case. Generally, the restaurant would operate from 11 a.m. to 9 p.m. Monday through Sunday and would employ up to 12 people. The applicant has submitted an application to serve beer and wine. The city council will review the final liquor application on Oct. 8, 2018.

The proposal requires:

- **Conditional Use Permit**, with a residential setback variance. By City Code §300.18, Subd. 4(i), restaurants with an on-sale intoxicating liquor license are conditionally permitted uses within the B-2 zoning district. One of the conditional use permit standards is a minimum distance from low-density residential properties. The proposed restaurant would be located within the required 100-foot setback from residential properties. As such, a variance is required.

- **Parking variance**. The neighborhood commercial center would not contain the total number of parking stalls as required by ordinance. As such, a parking variance is necessary.

**Planning Commission Hearing**

The planning commission considered the request on Sept. 6, 2018. The commission report and plans are attached. Staff recommended approval noting:

- The restaurant would be located within a tenant space previously used for a number of food-related users.
• The restaurant would be located more than 200-feet from the nearest residential structure and would be visually screened by an existing vegetative buffer.

• The parking and restaurant entrance would be on the north side of the shopping center and orientated away from the residential properties.

• The existing tenants and proposed restaurant would have varied hours of operation and peak parking demands. Additionally, based on parking observations of the site, the parking demands of the restaurant could be accommodated onsite. Should the parking demands exceed the site’s available amount of parking, staff believes that there are opportunities in the surrounding area for shared parking agreements. As a condition of approval, a revised conditional use permit that includes a solution to the parking issue would be required if the city observes that parking demand related to the restaurant typically exceeds parking supply.

At the commission meeting, a public hearing was opened to take comment. One area resident appeared and generally expressed support of the proposed restaurant, but requested additional information on the amount of available parking.

Following the public hearing, the commission discussed the proposal and generally discussed the parking demand compared to the amount of available parking. Ultimately, the commission was comfortable with the proposal with the inclusion that a revised conditional use permit would be required should the parking demand exceed the amount of available parking.

**Planning Commission Recommendation**

On a 5-0 vote, the commission recommended that the city council approve the conditional use permit, with variances. Meeting minutes are attached. There have been no changes to the proposal or additional information received since the planning commission’s meeting on this item.

**Staff Recommendation**

Staff recommends the city council adopt the resolution approving the conditional use permit, with variances for DelSur, a restaurant with on sale liquor, at 14725 Excelsior Blvd.

Through: Geralyn Barone, City Manager  
Julie Wischnack, AICP, Community Development Director  
Loren Gordon, AICP, City Planner  

Originator: Ashley Cauley, Senior Planner
Introduction

DelSur L.L.C. (DelSur) originally formed in 2014. Since that time, the business has expanded from selling empanadas online to include the DelSur Empanadas Food Truck (a mobile food vendor). Earlier this year, DelSur began operating their commissary kitchen in the former Glen Lake Café space at the Glen Lake Shopping Center. Since this did not include the sale of food to customers within the tenant space, a conditional use permit was not required. DelSur has recently submitted a proposal to reconfigure the interior of the space to accommodate a restaurant, with on-sale liquor. The proposal requires a conditional use permit with parking and setback from residential property variances.

Proposal Summary

The following is intended to summarize the applicant’s proposal. Additional information associated with the proposal can be found in the “Supporting Information” section of this report.

- **Existing Site Conditions.**

  The subject property is located in the southwest corner of the Excelsior Boulevard/Eden Prairie Road intersection. The site is improved with a roughly 31,200 square foot neighborhood commercial center – originally constructed in 1958 – and a surrounding parking lot.

- **Proposed Use.**

  The DelSur tenant space is roughly 2,000 square feet in size. No changes are proposed for the commissary kitchen area. To accommodate the restaurant space, the interior would be reconfigured to allow for restaurant seating for up to 50 people, a bar area, and a new food display case. Generally, the restaurant would operate from 11 a.m. to 9 p.m. Monday through Sunday and would employ up to 12 people. The applicant has submitted a liquor license application to serve beer and wine.

Primary Questions and Analysis

A land use proposal is comprised of many details. In evaluating a proposal, staff first reviews these details and then aggregates them into a few primary questions or issues. The following outlines both the primary questions associated with the DelSur proposal and staff’s findings.
• **Is the proposed restaurant use appropriate?**

Yes. The restaurant would be located within a tenant space previously used for food-related users. Since the shopping center’s construction in 1958, a number of food-related uses including a coffee shop, pastry shop and most recently a restaurant, with an on-sale liquor license, have occupied the tenant space.

• **Is the variance to the residential setback reasonable?**

Yes. By code, restaurants should not be located within 100-feet of a low-density residential use. The ordinance does allow for a reduced amount of separation when the use and associated parking and lighting would be reasonably screened or be unobtrusive to the surrounding residential uses.

While the proposed restaurant use would be within 100-feet of residential properties to the south, the restaurant would be located more than 100-feet from the closest residential structure. Additionally, the parking and restaurant entrance would be on the north side of the shopping center and orientated away from the residential properties, which are further separate from the site by a vegetative buffer.

• **Can the anticipated parking demands be accommodated?**

Yes. The neighborhood commercial center currently contains 133 parking spaces. The Institute of Transportation Engineers (ITE) parking demand data suggests that the average parking demand of the center would require 153 parking stalls. However, the existing tenants of the shopping center have varying hours of operation and, therefore, the parking demand of the site also varies. Staff conducted parking observations during times when the restaurant would have the highest anticipated parking demand. Ultimately, during these observations, the existing lot was less than 50-percent occupied. This would suggest that the parking demand of the restaurant could be accommodated within the existing parking lot.

**Staff Recommendation**

Recommend the city council adopt the resolution approving a conditional use permit, with variances, for a restaurant with an on-sale liquor at 14725 Excelsior Boulevard.

Originator: Ashley Cauley, Senior Planner  
Through: Loren Gordon, AICP, City Planner
Supporting Information

**Project No.** 91043.18a

**Property** 14725 Excelsior Blvd

**Applicant** Diego Montero, on behalf of DelSur, L.L.C.

**Surrounding Land Uses**
- Northerly: Excelsior Boulevard, daycare under construction
- Easterly: Eden Prairie Road, commercial buildings beyond
- Southerly: single-family home
- Westerly: neighborhood commercial center

**Planning**
- Guide Plan designation: Commercial
- Existing Zoning: B-2, limited business

**City Actions**
The proposal requires the following applications:

- Conditional Use Permit, with a residential setback variance. By City Code §300.18, Subd. 4(i), restaurants having on-sale intoxicating liquor license are conditionally permitted uses within the B-2 zoning district. One of the conditional use permit standards is a minimum distance from low-density residential properties. The proposed restaurant would be located within the 100-foot setback to residential properties. As such, a variance is required.

- Parking variance. The neighborhood commercial center would not contain the total number of parking stalls as required by ordinance. As such, a parking variance is required.

**Outdoor Seating**
The submitted plans include four outdoor tables located on the adjacent sidewalk. Customers would be able to take their food out of the restaurant to eat on these table. However, staff would not serve the outdoor tables. No liquor would be allowed to be consumed outside of the restaurant. In the past, staff has not considered these types of informal seating areas as “conditionally permitted outdoor seating area/patios.” If the applicant desires more formalized the seating area, a conditional use permit is required.

**Parking**
In 2016, the city approved a parking variance to reduce the amount of required parking from 178 to 132 for Unmapped Brewery. Currently there is 133 parking spaces onsite.

By city code, the existing tenants and uses would require 209 parking stalls. As such, a parking variance is required.

ITE suggests that the parking demand rates for the commercial center would be less than city code requires.
<table>
<thead>
<tr>
<th>CODE</th>
<th>Use</th>
<th>Area</th>
<th>Rate</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unmapped (brewery)</td>
<td>5,125 sf</td>
<td>1/1000 sf</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Unmapped (taproom)</td>
<td>3,600</td>
<td>1/50 sf</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td>Commercial Center</td>
<td>20,480 sf</td>
<td>4.5/1000</td>
<td>92</td>
</tr>
<tr>
<td></td>
<td>DelSur</td>
<td>2,000 sf</td>
<td>1/50 sf</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td><strong>209</strong></td>
</tr>
<tr>
<td>ITE AVERAGE</td>
<td>Brewery</td>
<td>5,125 sf</td>
<td>1.02/1000 sf</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Taproom*</td>
<td>3,600</td>
<td>16.3/1000 sf</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>Commercial Center*</td>
<td>20,480 sf</td>
<td>3.02/1000 sf</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>DelSur</td>
<td>50 seats</td>
<td>0.47/per seat</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td><strong>150</strong></td>
</tr>
</tbody>
</table>

* Friday p.m. peak hour = highest demand rate.

Actual parking observations on the site suggest that the parking demand is lower than what ITE standards. Staff believes that this is likely the result of the varied hours of operation of the users within the center. Please note that there is one vacant tenant space that is not included below. This chart below summarizes the current tenants and hours of operation:

<table>
<thead>
<tr>
<th>Mon</th>
<th>Tues</th>
<th>Wed</th>
<th>Thurs</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unmapped</strong></td>
<td>4 –10 p.m.</td>
<td>3-10 p.m.</td>
<td>3-11 p.m.</td>
<td>Noon – 11 p.m.</td>
<td>Noon – 6 p.m.</td>
<td></td>
</tr>
<tr>
<td><strong>State Farm</strong></td>
<td>9 a.m. – 5 p.m.</td>
<td>9 a.m. – 4:30 p.m.</td>
<td>Closed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>E Cig</strong></td>
<td>10 a.m. – 9 p.m.</td>
<td>10 a.m. – 9 p.m.</td>
<td>Noon – 9 p.m.</td>
<td>11 a.m. – 8 p.m.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gina Maria’s</strong></td>
<td>9 a.m. – 11 p.m.</td>
<td>3 – 11 p.m.</td>
<td>Noon – 11 p.m.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Studio 13</strong></td>
<td>9:30 a.m. – 8:30 p.m.</td>
<td>9 a.m. – 6 p.m.</td>
<td>9 a.m. – 4 p.m.</td>
<td>Closed</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Annie’s nails</strong></td>
<td>9:30 a.m. – 6 p.m.</td>
<td>9 a.m. – 4 p.m.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ken’s barber shop</strong></td>
<td>-</td>
<td>7 a.m. – 5 p.m.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DelSur</strong></td>
<td>11 a.m. – 9 p.m.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sir Knights</strong></td>
<td>7 a.m. – 7 p.m.</td>
<td>7 a.m. – 3 p.m.</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Based on actual parking observations of the site, the parking demands of the restaurant could be accommodated onsite. Should the parking demands exceed the site’s available amount of parking, staff believes there are opportunities within the surrounding area for shared parking agreements.

Traffic

The proposed restaurant would be located within a neighborhood shopping center located at the intersections of Excelsior Blvd/ Willison Road and Excelsior Blvd/ Eden Prairie Road.

<table>
<thead>
<tr>
<th>Roadway classification</th>
<th>Designed capacity</th>
<th>2015 Traffic volumes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Williston Road</td>
<td>Collector</td>
<td>1,000 – 15,000</td>
</tr>
<tr>
<td>Excelsior Blvd</td>
<td>Minor Arterial</td>
<td>5,000 – 30,000</td>
</tr>
<tr>
<td>Eden Prairie Rd</td>
<td>Minor Arterial</td>
<td>5,000 – 30,000</td>
</tr>
</tbody>
</table>

By ITE standards, the proposed restaurant would generate roughly 37 trips during the p.m. peak hour. Based on existing traffic volumes of the adjacent roadways, the anticipated impact of the proposed restaurant would be minimal.

CUP Standards

The proposal would meet the general conditional use permit standards as outlined in City Code §300.16 Subd.2:

1. The use is consistent with the intent of this ordinance;
2. The use is consistent with the goals, policies and objectives of the comprehensive plan;
3. The use does not have an undue adverse impact on governmental facilities, utilities, services or existing or proposed improvements; and
4. The use does not have an undue adverse impact on the public health, safety or welfare.

The proposal would meet the general conditional use permit standards as outlined in City Code §300.21 Subd. 4(i) for restaurants having on-sale liquor or dance hall licenses:

1. parking shall be in compliance with the requirements of Section 300.28 of this ordinance;

Finding: The commercial center would not meet the parking requirements and a variance is required. Staff finds the parking
variance request reasonable as noted in the variance section of this report.

2. shall only be permitted when it can be demonstrated that the operation will not significantly lower the existing level of service as defined by the Institute of Traffic Engineers on streets and intersections; and

Finding: Based on ITE standards, the proposed restaurant use is not anticipated to significantly impact existing traffic volumes or levels of service.

3. shall not be located within 100 feet of any low density residential parcel or adjacent to medium or high density residential parcels. The city may reduce separation requirements if the following are provided:

   a. landscaping and berming to shield the restaurant use;
   b. parking lots not located in proximity to residential uses; and
   c. lighting plans which are unobtrusive to surrounding areas.

Finding: The proposed restaurant would be located within 100-feet of the low density residential to the south. However, the nearest residential structure would be more than 100-feet away. Additionally, the restaurant would be screened by existing vegetation separating the shopping center and the single family homes. The parking lot and restaurant entrance would be located on the north side of the shopping center further separating the most intense part of the restaurant use from the single family homes.

Variance Standard

A variance may be granted from the requirements of the zoning ordinance when: (1) it is in harmony with the general purposes and intent of the ordinance; (2) it is consistent with the comprehensive plan; and (3) when an applicant establishes that there are practical difficulties in complying with the ordinance. Practical difficulties mean that the applicant proposes to use a property in a reasonable manner not permitted by the ordinance, the plight of the landowner is due to circumstances unique to the property not created by the landowner, and, the variance if granted, would not alter the essential character of the locality. (City Code §300.07)

The requested variances would meet the variance standard:

Intent of the ordinance:

- The intent of the ordinance as it relates to parking requirements is to ensure adequate parking is provided to
meet anticipated parking demands. Based on ITE standards, the shopping center would have a much lower parking demand than city code requirements. Further, parking observations suggest that the site’s actual parking demand is even less than anticipated by the ITE standards. While staff does not anticipate parking issues, staff does believe that if issues should arise in the future there are opportunities for shared parking agreements within the area.

- The intent of the ordinance as it relates to the location of restaurant and residential uses is to ensure appropriate separation of uses which are known to have much different levels of activity and intensities. In this case, the shopping center building is located 40-feet from the shared property line, however, the restaurant entrance would be 200 feet from the nearest residential structure. Additionally, the restaurant is screened by existing vegetation and topography.

Consistency with the comprehensive guide plan:

The subject property is located within the Glen Lake village center. One of the overall themes outlined in the guide plan is to “provide development and redevelopment opportunities to increase vitality, promote identity and improve livability” within village centers. The requested variances would allow for the reuse of a space previously occupied by a restaurant user. Further, the restaurant use would be compatible to existing uses within the village center.

Practical difficulties:

- Reasonable and Unique Circumstance:

  The requested parking variances is reasonable. Based on the center’s users and ITE standards, the parking ordinance would require more stalls than needed to accommodate the anticipated parking demand. Further, parking observations suggest that the parking demands of the site are even lower than ITE standards anticipate. Staff finds that this is likely the result of the diversity of the center’s tenants and varied hours of operation. In combination, these circumstances are unique and not common to other similarly zoned properties.

  The requested variance to reduce the required separation between the restaurant and residential uses is reasonable. Construction of the original Glen Lake Center occurred in 1958. This predates the adoption of the city’s first zoning ordinance. The variance would allow a restaurant user to occupy a space previously occupied by restaurant and other food-related uses. The restaurant entrance and parking would be orientated away from the residential uses and would be
visually separated from them by existing vegetation and topography.

- Character of the locality:

The requested variances would not significantly impact the character of the locality. Rather, the variance would allow for reuse of a space previously occupied by a restaurant and a use generally compatible to existing uses within the shopping center.

**Liquor License**

DelSur, L.L.C. is requesting a liquor license. The city council has the authority to approve or deny liquor licenses. The final hearing for the liquor license is scheduled for the October 8, 2018 city council meeting.

**Pyramid of Discretion**

This proposal:

**Voting Requirement**

The planning commission will make a recommendation to the city council. A recommendation for approval requires an affirmative vote of a simple majority. The city council’s approval requires an affirmative vote of five members, due to the requested variances.

**Motion Options**

The planning commission has three options:

1. Concur with staff recommendation. In this case, a motion should be made recommending the city council adopt the resolution approving the request.

2. Disagree with staff’s recommendation. In this case, a motion should be made recommending the city council deny the request. This motion must include a statement as to why denial is recommended.

3. Table the requests. In this case, a motion should be made to table the item. The motion should include a statement as to why the request is being tabled with direction to staff, the applicant, or both.
<table>
<thead>
<tr>
<th>Neighborhood Comments</th>
<th>The city sent notices to 162 area property owners and received no comments.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deadline for Decision</td>
<td>December 1, 2018</td>
</tr>
</tbody>
</table>
Business Plan

OWNERS
Nicolas Nikolov and Diego Montero
Business name: DelSur LLC
Address: 14725 Excelsior Blvd Minnetonka, MN 55345
Telephone: (612) 554-4615
E-mail: contact@delsurempanadas.com

Form of ownership: Partnership L.L.C.

DelSur L.L.C. was formed in June of 2014. Initially, selling ready-to-bake empanadas online. In December 2014, DelSur started doing pop-ups at craft breweries in Minneapolis. In March 2016, DelSur Empanadas Food Truck started operating in the City of Minneapolis serving mostly local breweries and special events. In February 2017, DelSur expanded to serve the greater Metro area by obtaining the Minnesota Mobile Food Vendor License and participated in all (5) Food Truck festivals around the Twin Cities. February 2018, DelSur leased a former Café Space in Minnetonka and has been using the space as commissary kitchen since. The store will become DelSur Cocina Argentina and will have seating for a maximum of 50 people. The core menu will be empanadas but will also include, salads, traditional sandwiches, dessert, wine and beer. Target opening is October 2018.

General Company Description

Mission statement: to provide the Twin Cities area with authentic, affordable, freshly made Argentinian cuisine with a strong focus on empanadas.

We operate the only Argentinian Food Truck in Minnesota and are expanding our business to include a sit-down restaurant in Minnetonka were we currently have our commissary kitchen. The restaurant will include an expanded selection of empanadas as well as other items not currently offered in the Food Truck. Made from scratch and handcrafted individually, our food meets the highest standards of quality, freshness and seasonality combining both modern-creative and traditional Argentinian styles of cooking. Argentina is well known for its meat, soccer, tango, and Malbec wine amongst other things. As the first empanada focused and Argentinian restaurant in the twin Cities area, we plan on having a small selection of wines and local craft beers to satisfy the customers that enjoy having their food with a glass of wine or a local craft brew.
Our Target
Food Truck target:
- Downtown Minneapolis and Saint Paul Lunch
- Craft Breweries
- Corporate Campuses Lunch
- Private Parties (graduations, Weddings, Birthdays, corporate fundraisers, etc)
- Festivals (community, food truck festivals, Art, Music)

Our Minnetonka Restaurant:
- Capacity for seating 50 people inside and 4 tables outside
- Hours of Operation: 11am to 9pm Monday through Sunday
- 8 to 12 employees
- Food to wine/beer ratio: 90-95% food to 5-10% wine/beer
- DelSur will participate in the Best Practices Program “Project Smart Choice” offered by the city of Minnetonka to train all new hires (servers and Managers) within 60 days from hire. DelSur shares and fully supports the goal of this program to keep alcohol out of the hands of young adults. DelSur will be responsible for clearing tables of any left behind alcohol as soon as the customer leaves the premises.
- DelSur is committed to provide a clean and comfortable space for our customers and for the customers of surrounding businesses, we will be responsible for keeping our premises free of litter generated by the operation of the restaurant or left behind by our customers.

Most important strengths and core competencies: Making empanadas from scratch is labor intensive. Over the years, we have developed a system that allows us to optimize the empanada making process to be more efficient and productive. Besides being the only Argentinian Food Truck in MN, we are the only ones selling “Baked” empanadas as well as the only ones that make our own dough mitigating the dependency on suppliers or availability of the product and adding the craftsmanship and uniqueness of our product. Food aside, our operating model gives us an advantage over other food trucks because the serving time from the moment our customers order until they get their food is second to none without compromising the quality of our product. This is super advantageous in situations such as lunch hour in Downtown or Food Truck festivals where customers do not want to wait 15+ minutes for their food.

Significant challenges the company faces now and in the near future: The biggest challenge we might be facing, as well as many food businesses, will be to get the right talent to be able to produce the amount of empanadas required to supply the Food Truck and the retail shop, we estimate we will need to produce 10000 empanadas a month.

Short-Mid term: DelSur is ready for growth. Having a dedicated commercial kitchen (commissary) allowed us to significantly increase production while also facilitating the addition of a sit-down restaurant
**Long Term:** DelSur will be able to continue to grow by offering our product wholesale to restaurants, caterers and grocery stores. To achieve this level of production we would need to scale our operation even further (~8000 empanadas/week). This will be achieved by hiring more talent and acquiring the appropriate production equipment (already identified).

In the 5-year horizon and depending on demand, we envision DelSur to replicate the model we are using in the first sit-down restaurant into smaller, satellite stores with minimal investment (not full kitchen required) without compromising the quality and freshness of the product. To sum up the 5-yr plan, DelSur will have these different revenue streams:

a) Food Truck(s)
b) Catering
c) Sit-down
d) Take-out, delivery
e) Wholesale
f) Small empanada shops

**Products and Services**

Empanadas are simple, tasty and convenient. Their popularity has spread beyond the traditional countries like Argentina to become truly international. Empanada literally means “wrapped in bread” but this description does not do justice to the wonder of this Argentine staple. But don’t make the mistake of believing all empanadas are created equal. Made from scratch and handcrafted individually, our empanadas meet the highest standards of quality, freshness and seasonality combining both modern-creative and traditional Argentinian styles of cooking.

**Products**

For the past 3 years we have gathered customer’s feedback and it has been great. Some customers would write something on social media, some will come back to the truck to tell us how the food was, we haven’t received any negative feedback thus far. We have received requests for different types of empanadas, for example another vegetarian option beside Spinach, we listened and incorporated the Caprese and sweet corn to the menu, more to come. We are working on gluten free and vegan options and have tested those options with great results and feedback. Overall customers seemed to be happy and satisfied with both, quality and price of product.

**Features and Benefits**

**Empanadas:** Our Core product. Hand-crafted, Freshness,
growing in popularity, convenient (finger food), ethnic. The customer experience is all about eating something new to them but yet with familiar ingredients.

**Lomitos**: Simple, new, familiar ingredients and yet no many customers had eaten a sandwich prepared in this manner. The options for the lomito sandwich include: steak, chicken and a vegetarian option (eggplant).

**Choripan**: Traditional and popular Argentinian Sausage sandwich

**Saladas**

**Quiche**

**Customers**

As a mobile food vendor, customer vary depending upon where we are located. For example, Downtown Minneapolis would be professionals with the core group being between 24 and 40. At a brewery the crowd can range from College students to 60 with varying income and education levels. For the sit-down in Minnetonka our customers will be mostly families looking for more food options that currently are very limited to American style pub or pizza, craft brewery goers (we are in the same shopping center as Unmapped Brewing Co.), Argentinians and people from Latin America looking for and empanada shop in the cities.

**Competition**

**Sit-Down:**
Currently there are three places to eat around our location: Gold Nugget, an American style bar, and Gina Maria’s a take-out Pizza place and Dragon Jade, a typical Chinese food restaurant.

**Food Truck:**
Every Food Truck parked around us is competition. The difference is that we are selling a unique, high quality product and are the only Argentinian Food Truck in the cities. We are not the only empanada truck in the cities but competition with the other truck is minimal since our products are very different (baked vs. deep fried; from scratch vs, store bought dough; ethnic vs. generic).

**Distribution Channels**

- Retail Shop
- Food Truck
• Food delivery services
• Catering or private events
• Food Truck Festivals
DEMOlarIZATION PLAN NOTES

1. SEE ALL DRAWINGS FOR ADDITIONAL NOTES AND SPECIFICATIONS.
2. IN ALL CASES IF THERE ARE CONFLICTING CONDITIONS BETWEEN THE CONTRACT DOCUMENTS AND THE BUILDING RULES, THE CONTRACTOR IS TO NOTIFY THE ARCHITECT IMMEDIATELY.
3. ASBESTOS: THE ABATEMENT OF ASBESTOS MATERIAL IS EXCLUDED FROM THIS PROJECT AND WILL BE CONTRACTED SEPARATELY, IF REQUIRED.
4. GENERAL CONTRACTOR TO CONSULT WITH BUILDING OWNER WHEN REMAINING ASBESTOS CONTAINING MATERIALS COULD BE A MESA TO THE SURROUNDING AREAS CAUSED BY DEMOLITION AND CONSTRUCTION IN 'AREA OF WORK'.
5. FIRE AND SMOKE DETECTION SYSTEM (EXISTING) TO REMAIN IN OPERATION DURING DEMOLITION AND CONSTRUCTION TO REMAIN.
6. FIRE AND SMOKE DETECTION SYSTEM (EXISTING) TO REMAIN IN OPERATION DURING DEMOLITION AND CONSTRUCTION INCLUDING ALL STROBES.
7. CUSTOMER INSTALLATION OF FIRE AND SMOKE DETECTION SYSTEM (EXISTING) TO REMAIN IN OPERATION DURING DEMOLITION AND CONSTRUCTION INCLUDING ALL STROBES.
8. GENERAL CONTRACTOR TO REMOVE ANY OR ALL OUTLETS IN ANY EXISTING WALLS, EXCEPT WHERE THEY ARE IN CONFLICT WITH APPLICABLE CODES AND ORDINANCES.
9. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
10. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
11. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
12. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
13. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
14. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
15. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
16. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
17. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
18. RELATED SYSTEMS TO REMAIN IN SERVICE AND WILL BE ACTIVE DURING THE COURSE OF THE WORK.
LIFE SAFETY PLAN GENERAL NOTES

1. SEPARATE PERMIT AND SHOP DRAWINGS FOR FIRE SUPPRESSION SYSTEM BY CONTRACTOR.
2. SEPARATE PERMIT AND SHOP DRAWINGS FOR FIRE ALARM SYSTEM BY CONTRACTOR.
3. ALL DOORS IN THE MEAN OF EGRESS SHALL BE SINGLE ACTION RELEASE AND SHALL NOT REQUIRE THE USE OF A KEY, TOOL, OR SPECIAL KNOWLEDGE TO OPEN FROM EGRESS SIDE.
4. A KNOX BOX WILL BE SUPPLIED AND SHALL BE MOUNTED 5' A.F.F. NEAR THE MAIN ENTRY DOOR, UNDER OVERHANG TO PROTECT FROM WEATHER DAMAGE FOR ACCESS TO FIRE ALARM PANEL.
5. ALL FIRE EXTINGUISHERS SHALL BE INSPECTED AND TAGGED BY A LICENSED FIRE EQUIPMENT COMPANY.

LIFE SAFETY PLAN LEGEND

LIFE SAFETY PLAN KEY NOTES

1. KNOX BOX

3. BUTTON FOR EXTINGUISHING GAS FIRES

5. WINE ROOM

7. SERVICE STATION

9. MECHANICAL

11. MEN'S RESTROOM

13. KITCHEN

15. STORAGE

17. OFFICE

19. WOMEN'S RESTROOM

21. BATHROOM

23. EXIT SIGN LIGHTS

SEE MEP FOR MORE INFORMATION.

5# ABC EXTINGUISHERS REQUIRED AT ALL COMMON AREAS.

FIRE EXTINGUISHER CABINET W/ FIRE EXTINGUISHER, SEE G SPECIFICATION SHEETS. LOCATION TO BE VERIFIED BY THE AUTHORITY HAVING JURISDICTION.
Sewall looks at each project on its own unique basis and its reasonableness.

Powers appreciated Chair Kirk’s thoughts. The neighborhood seems to agree with the applicant. Commissioners agreed that the proposal would be more aesthetically appealing. He was not worried about a precedent. This is a unique setting. The homeowner is being sensitive to the neighbors.

Chair Kirk preferred to vote to deny the variance application, but he will vote to approve the application since the motion to approve the application would most likely have passed if a few more commissioners were in attendance. He understood that commissioners felt that because of the natural rooflines of the house, it would make more sense to keep the rooflines in alignment and keep the same architectural conditions that exist on neighboring houses by allowing the addition to encroach two-and-a-half feet into the existing setback. The findings of fact include that the proposal would be aesthetically consistent with the character of the neighborhood.

_Hanson moved, second by Sewall, to adopt a resolution approving a variance application to allow a front yard setback of 23.9 feet to construct a garage addition to the single-family house at 5039 Clear Spring Drive._

_Henry, Powers, Sewell, Hanson, and Kirk voted yes. Knight was absent. Motion carried._

_B. Resolution approving a conditional use permit with variances for a restaurant at 14725 Excelsior Blvd._

Chair Kirk introduced the proposal and called for the staff report.

Cauley reported. She recommended approval of the application based on the findings and subject to the conditions listed in the staff report.

Henry asked why the results were different for the ITE parking study and the city’s parking study. Cauley explained that the ITE study is based on parking studies throughout the United States and the city’s number is generated by a study of the parking on the actual site. Cauley stated that the applicant has been discussing parking options with surrounding property owners if additional parking would be needed.

Chair Kirk asked if the Glen Lake Animal Hospital was included. Cauley answered that the Glen Lake Animal Hospital has a parking agreement in place with the shopping center.

Diego Montero, applicant, stated that he was excited to use the space that has been empty for four years and bring Argentinian food to Minnetonka.

Chair Kirk stated that he counted 42 chairs. Mr. Montero stated that the maximum seating would be 50 patrons. The property owner has been talking with neighboring property owners regarding additional parking options.
The public hearing was opened.

Anne Hossfeld, 14616 Glendale Street, stated that she had no objections. She had questions about parking. The parking lot has been completely full in the evenings since Unmapped opened. She questioned where the patrons would park. That was a concern. She noticed that vehicles were parking on the side of Eden Prairie Road before it was signed “no parking.” She questioned where those vehicles would now park. She questioned if it would be o.k. for patrons of a restaurant to park on neighboring residential streets.

No additional testimony was submitted and the hearing was closed.

Hanson was happy to see the application prompting an interest in finding additional parking. The parking lot is usually full in the evenings and that is without The Copper Cow. People park across the street which creates a safety issue. The east side of the lot is usually full and the west side of the lot is usually two-thirds full. Vehicles are usually parallel parked along the retaining wall on the north side.

Henry has found the east side of the parking lot full during peak times. The west side generally is not full. Cauley agreed. The stalls in front of the tenant a patron wants to visit may be full, but there may still be available parking further away.

Henry asked if a condition of approval requiring parking agreements was considered. Cauley responded that there is a condition of approval that states that if a parking issue would arise that parking agreements would be required to be implemented.

*Powers moved, second by Henry, to recommend that the city council adopt the resolution approving a conditional use permit with variances for a restaurant with on-sale liquor at 14725 Excelsior Blvd.*

*Henry, Powers, Sewell, Hanson, and Kirk voted yes. Knight was absent. Motion carried.*

C. Concept plan for redevelopment of the property at 1809 Plymouth Road.

Chair Kirk introduced the proposal and called for the staff report. Staff recommends the planning commission provide comments and feedback on the identified key issues and any others the planning commission deems appropriate.

9. Adjournment

*Sewall moved, second by Powers, to adjourn the meeting at 9 p.m. Motion carried unanimously.*
Resolution No. 2018-

Resolution approving a conditional use permit, with variances, for a restaurant at 14725 Excelsior Boulevard

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01 DelSur L.L.C. is requesting a conditional use permit to allow a restaurant having on-sale intoxicating liquor license within the B-2 zoning district. The request includes the following variances:

1. Parking variance from 209 to 133 spaces; and
2. Setback variance from a residential area from 100 feet to 41 feet.

1.02 The property is located at 14725 Excelsior Boulevard. It is legally described on Exhibit A.

1.03 On Sept. 6, 2018, the planning commission held a hearing on the proposal. The applicant was provided the opportunity to present information to the commission. The commission considered all of the comments received and the staff report, which are incorporated by reference into this resolution. The commission recommended that the city council approve the permit.

Section 2. Standards.

2.01 City Code §300.21 Subd.2 lists the following general conditional use permit standards:

1. The use is consistent with the intent of this ordinance;
2. The use is consistent with the goals, policies and objectives of the comprehensive plan;
3. The use does not have an undue adverse impact on governmental facilities, utilities, services or existing or proposed improvements;
4. The use is consistent with the city's water resources management plan;
5. The use is in compliance with the performance standards specified in section 300.28 of this ordinance; and

6. The use does not have an undue adverse impact on the public health, safety or welfare.

2.02 City Code §300.21, Subdivision 4(i) lists the following specific standards for restaurants having an on-sale intoxicating liquor license must be met for granting the permit:

1. Parking shall be in compliance with the requirements of section 300.28 of this ordinance.

2. Shall only be permitted when it can be demonstrated that the operation will not significantly lower the existing level of service as defined by the institute of traffic engineers on streets and intersections.

3. Shall not be located within 100 feet of any low density residential parcel or adjacent to medium or high density residential parcels. The city may reduce the separation requirements if the following are provided:
   a) Landscaping and berming to shield the restaurant use;
   b) Parking lots not located in proximity to residential uses; and
   c) Lighting plans which are unobtrusive to surrounding uses.

2.03 By City Code §300.07 Subd.1, a variance may be granted from the requirements of the zoning ordinance when: (1) the variance is in harmony with the general purposes and intent of this ordinance; (2) when the variance is consistent with the comprehensive plan; and (3) when the applicant establishes that there are practical difficulties in complying with the ordinance. Practical difficulties means:
   (1) The proposed use is reasonable; (2) the need for a variance is caused by circumstances unique to the property, not created by the property owner, and not solely based on economic considerations; and (3) the proposed use would not alter the essential character of the surrounding area.

Section 3. Findings.

3.01 The proposal meets the general conditional use permit standards outlined in City Code §300.21 Subd.4.

3.02 The proposal requires variances from the specific conditional use permit standards outlined in City Code §300.21, Subdivision 4(i):

1. The commercial center would not meet the parking requirements and a variance is required. The parking variance request reasonable, as is outlined following section of this resolution.
2. Based on Institute of Transportation Engineers (ITE) standards, the proposed restaurant use is not anticipated to significantly impact existing traffic volumes or levels of service.

3. The proposed restaurant would be located within 100 feet of the low density residential to the south. However, the nearest residential structure would be more than 100 feet away. Additionally, the restaurant would be screened by existing vegetation separating the shopping center and the single-family homes. The parking lot and restaurant entrance would be located on the north side of the shopping center further separating the most intense part of the restaurant use from the single-family homes.

3.03 The proposed restaurant would meet the variance standard as outlined in City Code §300.07 Subd. 1:

1. Intent of the ordinance:
   a) The intent of the ordinance as it relates to parking requirements is to ensure adequate parking is provided to meet anticipated parking demands. Based on ITE standards, the shopping center would have a much lower parking demand than city code requirements. Further, parking observations suggest that the site’s actual parking demand is even less than anticipated by the ITE standards. While the city does not anticipate parking issues, if issues should arise in the future there are opportunities for shared parking agreements within the area.
   b) The intent of the ordinance as it relates to the location of restaurant and residential uses is to ensure appropriate separation of uses which are known to have much different levels of activity and intensities. In this case, the shopping center building is located 40-feet from the shared property line, however, the restaurant entrance would be 200 feet from the nearest residential structure. Additionally, the restaurant is screened by existing vegetation and topography.

2. Consistency with the comprehensive guide plan: The subject property is located within the Glen Lake village center. One of the overall themes outlined in the guide plan is to “provide development and redevelopment opportunities to increase vitality, promote identity and improve livability” within village centers. The requested variances would allow for the reuse of a space previously occupied by a restaurant user. Further, the restaurant use would be compatible to existing uses within the village center.

3. There are practical difficulties in complying with the ordinance:
   a) Reasonable and Unique Circumstance:
1) The requested parking variances are reasonable. Based on the center’s users and ITE standards, the parking ordinance would require more stalls than needed to accommodate the anticipated parking demand. Further, parking observations suggest that the parking demands of the site are even lower than ITE standards anticipate. This is likely the result of the diversity of the center’s tenants and varied hours of operation. In combination, these circumstances are unique and not common to other similarly zoned properties.

2) The requested variance to reduce the required separation between the restaurant and residential uses is reasonable. Construction of the original Glen Lake Center occurred in 1958. This predates the adoption of the city’s first zoning ordinance. The variance would allow a restaurant user to occupy a space previously occupied by restaurant and other food-related uses. The restaurant entrance and parking would be orientated away from the residential uses and would be visually separated from them by existing vegetation and topography.

b) Character of the locality: The requested variances would not significantly impact the character of the locality. Rather, the variances would allow for reuse of a space previously occupied by a restaurant and a use generally compatible to existing uses within the shopping center.

Section 4. City Council Action.

4.01 The above-described conditional use permit is approved, subject to the following conditions:

1. Subject to staff approval, the property must be developed and maintained in general conformance with the plans dated July 16, 2018 and the business plan date-stamped Aug. 21, 2018.

2. This resolution must be recorded with Hennepin County.

3. The restaurant must obtain all applicable food and liquor licenses.

4. The building must be comply with all requirements of the Minnesota state building code, fire code, and health code.

5. This resolution does not approve any signs. Sign permits are required.

6. The outdoor tables must not obstruct pedestrian or vehicular traffic.

7. No table service or liquor is allowed under this conditional use permit for
the outdoor tables. A conditional use permit is required for formal outdoor seating.

8. The city council may reasonably add or revise conditions to address any future unforeseen problems.

9. Any change to the approved use that results in a significant increase in traffic or a significant change in character will require a revised conditional use permit. Specifically, if the approved use is observed to create a parking demand that exceeds the parking availability onsite, a revised conditional use permit that includes a solution to the parking issue will be required.

Adopted by the City Council of the City of Minnetonka, Minnesota, on Sept. 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on Sept. 17, 2018.

David E. Maeda, City Clerk
EXHIBIT A

Tract I

That part of Section 33, Township 117, Range 22, described as follows: That part of the Northeast Quarter of the Northeast Quarter of said Section bounded on the North by the Excelsior Road and on the South by the Southerly line of the abandoned right-of-way of the Minneapolis & St. Paul Suburban Railroad company and on the East by the Eden Prairie Road, also sometimes known as County Road No. 4, and on the West line of the Northeast Quarter of the Northeast Quarter of said Section 33, according to United States Government Survey thereof and situate in Hennepin County, Minnesota.

Tract II

That part of Lot 21, “Glen Oak Addition”, and that part of the abandoned right-of-way of the Minneapolis & St. Paul Suburban Railroad company running through the Northeast Quarter of Section 33, Township 117, Range 22, described as follows: Commencing at the Northeast corner of said Lot 21; thence Southwesterly along the Northerly line of said Lot 21 a distance of 231.25 feet; thence Southeasterly to a point on the Southerly line of said right-of-way line and the East line of said Northwest Quarter of the Northeast Quarter of said Section 33; Thence North along the East line of said Northwest Quarter of the Northeast Quarter and along the East Line of said Lot 21 to the point of beginning, according to the plat thereof on file and of record in the office of the Register of Deeds in and for Hennepin County, Minnesota.

The above described tracts are subject to easements of record, if any and existing roads.
City Council Agenda Item #13A
Meeting of Sept. 17, 2018

Brief Description: Resolutions for special assessment of 2017-2018 projects

Recommended Action: Hold the public hearing and adopt the resolutions

Background

The process for special assessment includes numerous communications with parcel owners and opportunities for prepayments of the assessments. Prior to determining the property must be assessed, division staff associated with the specific type of assessment have notified or worked with the property owners regarding the associated work financed by the city. After determination of assessment, staff sends a notice of public hearing to each property owner and publishes a notice in the newspaper in late August.

At its meeting of August 27, 2018, the city council adopted the necessary resolutions pertaining to the levying of 2018 special assessments and scheduled the public hearing for 6:30 p.m. on September 17, 2018. Staff has received payment to prepay two (2) assessments since the August 27, 2018 meeting date. After the public hearing this evening, property owners are given thirty (30) days to prepay assessments or partial assessments without an interest charge. After this first prepayment deadline, property owners are given up to forty-four (44) additional days to pay the full amount with interest until required certification to the county on December 1st.

Attached are the resolutions necessary for adopting the special assessments for these projects. These resolutions are separated by type of project and length of time to spread the special assessments in each category.

- Privately Installed Sewer and Water Improvement Projects. No projects to be assessed this year.

- Nuisance Abatement Projects. There are 37 nuisance abatement projects (including diseased tree removals) in which the city has incurred costs totaling $75,334.52. Three of the projects were completed through the use of a Nuisance Abatement Agreement signed by the property owners for extensive work that was needed on the properties at 10301 Cedar Lake Road 317, 3424 Robinwood Spur and 11829 Shady Oak Drive. These projects are proposed to be specially assessed in accordance with Minnesota statutes and city council policies regarding the levying of these nuisance abatement projects. These interest rates are benchmarked to the current Aaa municipal bond rate. The term and interest rate for each assessment is as follows:

<table>
<thead>
<tr>
<th>Assessment Amount</th>
<th>Term</th>
<th>Interest Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$1,000</td>
<td>1 year</td>
<td>3.48%</td>
</tr>
<tr>
<td>$1,000-$2,999</td>
<td>3 years</td>
<td>3.78%</td>
</tr>
<tr>
<td>$3,000-$5,000</td>
<td>5 years</td>
<td>3.99%</td>
</tr>
<tr>
<td>&gt;$5,000</td>
<td>10 years</td>
<td>4.48%</td>
</tr>
</tbody>
</table>
## 2018 Nuisance Abatements – Project No. 4894 (1-year term)

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-550</td>
<td>1511</td>
<td>Oakways</td>
<td>04-117-22-41-0037</td>
<td>$84.00</td>
</tr>
<tr>
<td>N-539</td>
<td>9900</td>
<td>Cedar Lake Rd</td>
<td>12-117-22-41-0027</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-542</td>
<td>4705</td>
<td>Diane Dr</td>
<td>26-117-22-21-0035</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-543</td>
<td>4552</td>
<td>Ellerdale Rd</td>
<td>22-117-22-34-0031</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-552</td>
<td>11921</td>
<td>Bradford Rd</td>
<td>23-117-22-43-0064</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-553</td>
<td>14300</td>
<td>Orchard Rd</td>
<td>15-117-22-33-0047</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-555</td>
<td>3670</td>
<td>Robin La</td>
<td>14-117-22-34-0046</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-546</td>
<td>14222</td>
<td>Bellevue Dr</td>
<td>27-117-22-32-0014</td>
<td>$362.50</td>
</tr>
<tr>
<td>N-540</td>
<td>14010</td>
<td>Minnehaha Pl</td>
<td>15-117-22-22-0035</td>
<td>$884.68</td>
</tr>
<tr>
<td>N-551</td>
<td>13015</td>
<td>Lake St Extension</td>
<td>22-117-22-41-0005</td>
<td>$884.68</td>
</tr>
<tr>
<td>N-549</td>
<td>4717</td>
<td>Karen Cir</td>
<td>26-117-22-12-0064</td>
<td>$940.68</td>
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<tr>
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<td></td>
<td></td>
<td><strong>Subtotal</strong></td>
</tr>
</tbody>
</table>

## 2018 Nuisance Abatements – Project No. 4894 (3-year term)

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-548</td>
<td>709</td>
<td>Plymouth Rd</td>
<td>03-117-22-14-0053</td>
<td>$1,915.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Subtotal</strong></td>
</tr>
</tbody>
</table>

## 2018 Nuisance Abatements – Project No. 4894 (5-year term)

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-544</td>
<td>10301</td>
<td>Cedar Lake Rd 317</td>
<td>12-117-22-42-0074</td>
<td>$3,980.55</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Subtotal</strong></td>
</tr>
</tbody>
</table>
There are 22 properties in the diseased tree removals project this year in which the city has incurred costs. Some property owners have paid part of the total cost. It is proposed that these projects be specially assessed for the remaining cost of the abatement in accordance with Minnesota statutes and city council policies regarding the levying of these nuisance abatement projects. The terms for the 2018 diseased tree assessments will be based on the assessment amount similar to the nuisance abatement assessments. The special assessment amount on each parcel is as follows:
### 2018 Diseased Tree Removal – Project No. 4902 (3-year term)

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-52</td>
<td>n/a</td>
<td>Stone &amp; Oakland Rd</td>
<td>10-117-22-34-0005</td>
<td>$1,120.76</td>
</tr>
<tr>
<td>T-35</td>
<td>3205</td>
<td>Co Rd No 101</td>
<td>17-117-22-23-0057</td>
<td>$1,678.32</td>
</tr>
<tr>
<td>T-54</td>
<td>5068</td>
<td>Holiday Cir</td>
<td>29-117-22-41-0012</td>
<td>$1,770.29</td>
</tr>
<tr>
<td>T-18</td>
<td>11405</td>
<td>Timberline Rd</td>
<td>02-117-22-44-0036</td>
<td>$1,779.02</td>
</tr>
<tr>
<td>T-2</td>
<td>4721</td>
<td>Deerwood Dr</td>
<td>27-117-22-12-0016</td>
<td>$1,914.86</td>
</tr>
<tr>
<td>T-37</td>
<td>5101</td>
<td>Boarshead Rd</td>
<td>30-117-22-32-0044</td>
<td>$1,943.01</td>
</tr>
<tr>
<td>T-60</td>
<td>2325</td>
<td>Sheridan Hills Rd</td>
<td>09-117-22-24-0008</td>
<td>$2,482.58</td>
</tr>
<tr>
<td>T-51</td>
<td>17510</td>
<td>Co Rd No 101</td>
<td>08-117-22-33-0027</td>
<td>$2,697.70</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Subtotal</strong></td>
</tr>
</tbody>
</table>

### 2018 Diseased Tree Removal – Project No. 4902 (5-year term)

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-48</td>
<td>5520</td>
<td>Glenavon Ave</td>
<td>34-117-22-12-0019</td>
<td>$3,041.25</td>
</tr>
<tr>
<td>T-50</td>
<td>15112</td>
<td>Glen Oak St</td>
<td>33-117-22-12-0036</td>
<td>$3,161.24</td>
</tr>
<tr>
<td>T-53</td>
<td>4941</td>
<td>West La</td>
<td>30-117-22-23-0053</td>
<td>$3,266.53</td>
</tr>
<tr>
<td>T-56</td>
<td>4728</td>
<td>Coventry Rd E</td>
<td>27-117-22-21-0061</td>
<td>$4,177.35</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Subtotal</strong></td>
</tr>
</tbody>
</table>

### 2018 Diseased Tree Removal – Project No. 4902 (10-year term)

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-31</td>
<td>11924</td>
<td>Sunrise La</td>
<td>23-117-22-43-0062</td>
<td>$5,477.18</td>
</tr>
<tr>
<td>T-58</td>
<td>11505</td>
<td>Lakeview La W</td>
<td>11-117-22-11-0027</td>
<td>$5,362.81</td>
</tr>
<tr>
<td>T-55</td>
<td>3622</td>
<td>Steele St</td>
<td>17-117-22-44-0022</td>
<td>$6,288.60</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Subtotal</strong></td>
</tr>
</tbody>
</table>
• **City Court Fines.** Listed below is the city court fine imposed in 2018 that is proposed to be specially assessed over a one-year term, bearing an interest rate of 10 percent. This assessment is categorized as city court fines. The interest is calculated from October 1, 2018 to December 31, 2019. Hennepin County charges an additional administrative fee prior to the final certification. The following is the proposed parcel to be assessed:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1020</td>
<td>709</td>
<td>Plymouth Rd</td>
<td>03-117-22-14-0053</td>
<td>$600.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total: $600.00</td>
</tr>
</tbody>
</table>

- **Deferred Hook-up Fee, 3533 and 3535 Orchard Lane.** On February 26, 2018, the city council approved a conditional use permit, setback variance and floodplain alteration to allow the construction of a new home on a single parcel created by combination of the properties at 3533 and 3535 Orchard Lane. The development triggered the obligation to pay deferred hook-up fees in the total amount of $39,999.58, which the owner has elected to have specially assessed against the properties. Because the amount to be assessed includes accrued interest of $24,006.32, the staff recommends that no interest be charged on the assessed amount; otherwise the owner would be paying interest on accrued interest. The proposed resolution approves the petition and waiver agreement for the special assessment and provides for payment over a term of ten years at zero percent interest.

- **Fire Sprinkler Retrofit.** The city received a petition from Chris Bjorling of Copper Estates LLC dba The Copper Cow, the owner of the building at 5445 Eden Prairie Rd, for a fire sprinkler retrofit. At the council meeting on March 19, 2018, the City Council adopted a resolution approving the petition and waiver agreement, which provided for city payment of the construction cost for a fire sprinkler system retrofit and related improvements, up to a maximum of $42,350, and the levy of an assessment equal to the city’s payments. The city incurred costs of $42,350 for the improvements, which is the amount of the proposed assessment. The assessment will accrue interest at 3.87% per annum over a ten-year period as provided in the March resolution.

- **Cancelation of Deferred Cedar Ridge HIA Fee and Reassessment.** In 2012, the city council established the Cedar Ridge Condominium Housing Improvement Area (“HIA”) for the purpose of providing financing assistance for major improvements to the Cedar Ridge Condominiums, including replacement of roofs, hot water boilers, elevators and decks. The city recoups those costs through a HIA fee, which the city levied against the condominium properties by special assessment. The assessments vary based upon the unit size.
As with other special assessments, the city allows owners to defer payment of their assessments if they meet certain age or disability and income requirements established by city ordinance. The owner of Unit 205 qualified for and obtained a deferment. In 2018, that owner sold Unit 205 and paid the city the total of all deferred payments, plus accrued interest. Due to technical issues in the law, the city needs to cancel the existing assessment for Unit 205 and reassess the remaining balance over the remainder of the original term. By doing so, the city can accept the payment of the deferred amount, and the annual assessment amount against Unit 205 will remain the same as contemplated by the original assessment schedule. Without cancelation and reassessment, the deferred amount would be added to the existing assessment, and the prior owner would have needed to pay the deferred amounts to the new owner instead of the city.

The new owner has submitted a petition and waiver agreement for the cancelation and reassessment. The original 2012 assessment against Unit 205 was $3,378.15, payable in equal annual installments of $225.21 over a term of 15 years, at 4.50% annual interest. The city collected six years of deferred payments, plus interest. The new assessment is $2,026.89, to be paid in annual installments of $225.21 over a term of 9 years, at 4.50% annual interest.

**Annual Report on Deferred Assessments.**

Pursuant to City Council Policy 2.17, Deferment of Special Assessments and Storm Sewer Charges, the following is a summary of the deferred assessments for 2017:

<table>
<thead>
<tr>
<th>No. of Applications submitted</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Applications granted</td>
<td>1</td>
</tr>
<tr>
<td>Outstanding amounts as of 12/31/2016 Cedar Ridge HIA</td>
<td>$6,172.78</td>
</tr>
</tbody>
</table>

**Recommendation**

Hold the public hearing and adopt the following attached resolutions:

1. Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, one-year assessment term.
2. Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, three-year assessment term.
3. Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, five-year assessment term.
4. Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, ten-year assessment term.
5. Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902, one-year assessment term.


7. Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902, five-year assessment term.


9. Resolution adopting special assessments for 2018 City Court Fines Project No. 1020, one-year assessment term.

10. Resolution adopting special assessment for Connection Charge, 3535 Orchard Lane Project No. 5110, ten-year assessment term.

11. Resolution adopting special assessment for the “Copper Cow” Fire Sprinkler Project, 5445 Eden Prairie Road, Project No. 4874, ten-year assessment term.

12. Resolution canceling and reassessing special assessment of Housing Improvement Area Fee for 10211 Cedar Lake Road, Unit 205, Project No. 4318, 9-year assessment term.

Submitted through:
Geralyn Barone, City Manager
Corrine Heine, City Attorney
Merrill King, Finance Director
Julie Wischnack, Community Development Director
Colin Schmidt, City Assessor
John Weinand, Environmental Health Supervisor
Jo Colleran, Natural Resource Manager

Originated by:
Denise Ostlund, Assessment Specialist
PETITION FOR REASSESSMENT OF SPECIAL ASSESSMENTS
AND WAIVER OF SPECIAL ASSESSMENT APPEAL

This Agreement is entered into this 24th day of August, 2018, by and between the CITY OF MINNETONKA ("City"), 14600 Minnetonka Boulevard, Minnetonka, Minnesota 55345 and KAMANA KARKI, a single person ("Owner").

Recitals

A. Owner is the fee owner of certain property located within the Cedar Ridge condominium development, at 10211 Cedar Lake Road, Unit 205, Minnetonka, MN 55305, which is legally described on attached Exhibit A (the "Property").

B. On March 5, 2012, the Minnetonka city council adopted Ordinance 2012-01, establishing the Cedar Ridge Condominium Housing Improvement Area ("HIA") and Resolution 2012-017, establishing a fee for the Cedar Ridge HIA.

C. The purpose of establishing the Cedar Ridge HIA and fee was to assist in financing major improvements to the Cedar Ridge Condominiums, including the Property. The improvements included, among other things, replacement of roofs, hot water boilers, elevators and decks.

D. On September 18, 2012, the Minnetonka city council adopted Resolution No. 2012-087, levying a special assessment against the Property in the amount of $3,378.15, equal to the HIA fees for the Property. The assessments are payable in equal annual installments of $225.21 over a term of 15 years, plus interest at 4.50%.

E. In accordance with Resolution No. 2012-017, City Code section 220.010 and Minn. Stat. section 435.193, the Minnetonka city council deferred the payment of installments of the special assessments against the Property that would otherwise have been payable in the years 2013 through 2018, based on the age and disability of the former owner of the Property.
F. Owner purchased the Property in 2018. At the time of sale, the former owner of the Property paid to the City the total of all deferred assessments, in the amount of $1,351.26, plus accrued interest of $775.08, for a total payment of $2,126.34.

G. In order to credit the payment of $2,126.34 against the special assessments for the Property, it is necessary for the City to cancel the existing assessment and reassess the remaining principal balance of $2026.89 against the Property. In the absence of a reassessment, the deferred amount would be paid to Owner, but the assessment installments of principal would increase to $375.35 per year, plus accrued interest interest.

In consideration of the mutual covenants contained herein, the parties agree as follows:

1. Owner requests that the City accept the payment of the deferred installments, cancel the existing assessment against the Property, and reassess the Property in the principal amount of $2,026.89, to be paid over a nine year term, together with annual interest at the rate of 4.5%.

2. Owner represents and warrants that it is the owner of 100 percent of the Property, that it has full legal power and authority to encumber the Property as provided in this Agreement.

3. Owner waives notice of hearing and hearing provided in Minn. Stat. Sections 429.031 and 429.061, or any other right notice and hearing, on the reassessment of the HIA fee.

5. Owner waives the right to appeal the levy of the special assessments in accordance with this Agreement pursuant to Minn. Stat. Section 429.081.

10. The covenants, waivers and agreements contained in this Agreement bind the successors and assigns of the Developer and run with the Subject Property and bind all successors in interest. It is the intent of the parties that this Agreement be in a form that is recordable among the land records of Hennepin County, Minnesota; and they agree to make any changes in this Agreement that may be necessary to effect the recording and filing of this Agreement against the title of the Subject Property.

[Signature pages follow]
CITY SIGNATURE PAGE
Dated: _____________  

CITY OF MINNETONKA

By ____________________________________________

Its Mayor

By ____________________________________________

Its City Manager

STATE OF MINNESOTA  ]

ss.  

COUNTY OF HENNEPIN  ]

This instrument was subscribed and sworn to before me this _____________ day of ________, 20_____, by Brad Wiersum, the Mayor of the City of Minnetonka, a Minnesota municipal corporation.

______________________________________________

Notary Public

STATE OF MINNESOTA  ]

ss.  

COUNTY OF HENNEPIN  ]

This instrument was subscribed and sworn to before me this _____________ day of ________, 20_____, by Geralyn Barone, the City Manager of the City of Minnetonka, a Minnesota municipal corporation.

______________________________________________

Notary Public
STATE OF MINNESOTA ]
COUNTY OF HENNEPIN ] ss.

This instrument was subscribed and sworn to before me this 24th day of August, 2018, by Kamana Karki, a single person.

Notary Public

THIS INSTRUMENT WAS DRAFTED BY:

City Attorney
City of Minnetonka
14600 Minnetonka Boulevard
Minnetonka, MN 55345
952-939-8200
Exhibit A

Legal Description of Subject Property

Unit No. 323, Condominium No. 0357 Cedar Ridge Condominium, Hennepin County, Minnesota
Resolution No. 2018-
Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, one-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Nuisance Abatement Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-550</td>
<td>1511</td>
<td>Oakways</td>
<td>04-117-22-41-0037</td>
<td>$84.00</td>
</tr>
<tr>
<td>N-539</td>
<td>9900</td>
<td>Cedar Lake Rd</td>
<td>12-117-22-41-0027</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-542</td>
<td>4705</td>
<td>Diane Dr</td>
<td>26-117-22-21-0035</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-543</td>
<td>4552</td>
<td>Ellerdale Rd</td>
<td>22-117-22-34-0031</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-552</td>
<td>11921</td>
<td>Bradford Rd</td>
<td>23-117-22-43-0064</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-553</td>
<td>14300</td>
<td>Orchard Rd</td>
<td>15-117-22-33-0047</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-555</td>
<td>3670</td>
<td>Robin La</td>
<td>14-117-22-34-0046</td>
<td>$84.68</td>
</tr>
<tr>
<td>N-546</td>
<td>14222</td>
<td>Bellevue Dr</td>
<td>27-117-22-32-0014</td>
<td>$362.50</td>
</tr>
<tr>
<td>N-540</td>
<td>14010</td>
<td>Minnehaha Pl</td>
<td>15-117-22-22-0035</td>
<td>$884.68</td>
</tr>
<tr>
<td>N-551</td>
<td>13015</td>
<td>Lake St Extension</td>
<td>22-117-22-41-0005</td>
<td>$884.68</td>
</tr>
<tr>
<td>N-549</td>
<td>4717</td>
<td>Karen Cir</td>
<td>26-117-22-12-0064</td>
<td>$940.68</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Subtotal</strong></td>
</tr>
</tbody>
</table>

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 3.48 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.
2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.

2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

__________________________________________
Brad Wiersum, Mayor

Attest:

__________________________________________
David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

__________________________________________
David E. Maeda, City Clerk
Resolution No. 2018-

Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, three-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Nuisance Abatement Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-548</td>
<td>709</td>
<td>Plymouth Rd</td>
<td>03-117-22-14-0053</td>
<td>$1,915.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subtotal</td>
<td>$1,915.00</td>
</tr>
</tbody>
</table>

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 3.78 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.

2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.
Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

David E. Maeda, City Clerk
Resolution No. 2018-
Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, five-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Nuisance Abatement Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-544</td>
<td>10301</td>
<td>Cedar Lake Rd 317</td>
<td>12-117-22-42-0074</td>
<td>$3,980.55</td>
</tr>
</tbody>
</table>

Subtotal $3,980.55

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 3.99 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.

2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.
Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

David E. Maeda, City Clerk
Resolution No. 2018-
Resolution adopting special assessments for 2018 Nuisance Abatement Project No. 4894, ten-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Nuisance Abatement Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-545</td>
<td>3424</td>
<td>Robinwood Spur</td>
<td>14-117-22-41-0044</td>
<td>$7,200.90</td>
</tr>
<tr>
<td>N-547</td>
<td>11829</td>
<td>Shady Oak Dr</td>
<td>26-117-22-12-0032</td>
<td>$9,940.35</td>
</tr>
</tbody>
</table>

Subtotal $17,141.25

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 4.48 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.

2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.
Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

________________________________________
Brad Wiersum, Mayor

Attest:

________________________________________
David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

________________________________________
David E. Maeda, City Clerk
Resolution No. 2018-
Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902,
one-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Diseased Tree Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-38</td>
<td>14101</td>
<td>Council Cir</td>
<td>10-117-22-22-0008</td>
<td>$66.91</td>
</tr>
<tr>
<td>T-14</td>
<td>14806</td>
<td>Walker Pl</td>
<td>21-117-22-12-0039</td>
<td>$81.10</td>
</tr>
<tr>
<td>T-6</td>
<td>14021</td>
<td>Minnehaha Pl</td>
<td>15-117-22-23-0028</td>
<td>$93.94</td>
</tr>
<tr>
<td>T-59</td>
<td>4905</td>
<td>Mayview Rd</td>
<td>27-117-22-24-0050</td>
<td>$105.00</td>
</tr>
<tr>
<td>T-47</td>
<td>4441</td>
<td>Gaywood Dr</td>
<td>22-117-22-34-0004</td>
<td>$658.94</td>
</tr>
<tr>
<td>T-57</td>
<td>5990</td>
<td>Covington Ter</td>
<td>31-117-22-42-0054</td>
<td>$675.39</td>
</tr>
<tr>
<td>T-61</td>
<td>15120</td>
<td>Stone Ridge Trace</td>
<td>09-117-22-13-0015</td>
<td>$790.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Subtotal</td>
</tr>
</tbody>
</table>

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 3.48 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.
2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:  
Seconded by:  
Voted in favor of:  
Voted against:  
Abstained:  
Absent:  
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

David E. Maeda, City Clerk
Resolution No. 2018-
Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902,
three-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council
has met on September 17, 2018 to hear and to pass upon all objections to the
proposed special assessments for 2018 Diseased Tree Projects at the following
properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-52</td>
<td>n/a</td>
<td>Stone &amp; Oakland Rd</td>
<td>10-117-22-34-0005</td>
<td>$1,120.76</td>
</tr>
<tr>
<td>T-35</td>
<td>3205</td>
<td>Co Rd No 101</td>
<td>17-117-22-23-0057</td>
<td>$1,678.32</td>
</tr>
<tr>
<td>T-54</td>
<td>5068</td>
<td>Holiday Cir</td>
<td>29-117-22-41-0012</td>
<td>$1,770.29</td>
</tr>
<tr>
<td>T-18</td>
<td>11405</td>
<td>Timberline Rd</td>
<td>02-117-22-44-0036</td>
<td>$1,779.02</td>
</tr>
<tr>
<td>T-2</td>
<td>4721</td>
<td>Deerwood Dr</td>
<td>27-117-22-12-0016</td>
<td>$1,914.86</td>
</tr>
<tr>
<td>T-37</td>
<td>5101</td>
<td>Boarshead Rd</td>
<td>30-117-22-32-0044</td>
<td>$1,943.01</td>
</tr>
<tr>
<td>T-60</td>
<td>2325</td>
<td>Sheridan Hills Rd</td>
<td>09-117-22-24-0008</td>
<td>$2,482.58</td>
</tr>
<tr>
<td>T-51</td>
<td>17510</td>
<td>Co Rd No 101</td>
<td>08-117-22-33-0027</td>
<td>$2,697.70</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subtotal</td>
<td>$15,386.54</td>
</tr>
</tbody>
</table>

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each
tract of land is found to be benefited by the improvement in the amount of the
assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this
resolution, or may be paid in a single installment in the same time and manner as
the payment of real estate taxes with interest at the rate of 3.78 percent per annum.
To the first installment of each assessment will be added interest on the entire
assessment from the date of this resolution to December 31 of the year in which
the first payment is payable. Subsequently, one year's interest on the remaining
balance will be added to each subsequent installment. Any property owner may
pay the entire unpaid balance of the assessment against his/her property at any
time with interest accrued to December 31 of the year in which the payment is
made, provided the payment is made before November 30 in the first year and
before November 15 in subsequent years.
2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.

2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

________________________
David E. Maeda, City Clerk
Resolution No. 2018-

Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902, five-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Diseased Tree Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-48</td>
<td>5520</td>
<td>Glenavon Ave</td>
<td>34-117-22-12-0019</td>
<td>$3,041.25</td>
</tr>
<tr>
<td>T-50</td>
<td>15112</td>
<td>Glen Oak St</td>
<td>33-117-22-12-0036</td>
<td>$3,161.24</td>
</tr>
<tr>
<td>T-53</td>
<td>4941</td>
<td>West La</td>
<td>30-117-22-23-0053</td>
<td>$3,266.53</td>
</tr>
<tr>
<td>T-56</td>
<td>4728</td>
<td>Coventry Rd E</td>
<td>27-117-22-21-0061</td>
<td>$4,177.35</td>
</tr>
</tbody>
</table>

Subtotal $13,646.37

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 3.99 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year’s interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.
2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

__________________________
Brad Wiersum, Mayor

Attest:

__________________________
David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

__________________________
David E. Maeda, City Clerk
Resolution No. 2018-
Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902, ten-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Diseased Tree Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-31</td>
<td>11924</td>
<td>Sunrise La</td>
<td>23-117-22-43-0062</td>
<td>$5,477.18</td>
</tr>
<tr>
<td>T-58</td>
<td>11505</td>
<td>Lakeview La W</td>
<td>11-117-22-11-0027</td>
<td>$5,362.81</td>
</tr>
<tr>
<td>T-55</td>
<td>3622</td>
<td>Steele St</td>
<td>17-117-22-44-0022</td>
<td>$6,288.60</td>
</tr>
</tbody>
</table>

Subtotal: $17,128.59

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 4.48 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.
2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

________________________________________
Brad Wiersum, Mayor

Attest:

________________________________________
David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

________________________________________
David E. Maeda, City Clerk
Resolution No. 2018-

Resolution adopting special assessments for 2018 City Court Fines
Project No. 1020, one-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by its charter and ordinances, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed assessments for civil penalties at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1020</td>
<td>709</td>
<td>Plymouth Rd</td>
<td>03-117-22-14-0053</td>
<td>$600.00</td>
</tr>
</tbody>
</table>

Subtotal $600.00

Section 2. Council Action.

2.01. The proposed special assessment listed above is hereby adopted, and the tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 10 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.

2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.
Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

David E. Maeda, City Clerk
Resolution No. 2018-
Resolution adopting special assessment for Connection Charge, 3535 Orchard Lane
Project No. 5110, ten-year assessment term

BE IT RESOLVED by the city council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. The city is authorized by Minnesota Statutes chapter 444 to establish fees for connection to the municipal sewer and water utility systems. Prior to 2009, the city used connection charges or “deferred hookup fees” as means of ensuring that undeveloped properties which benefited from public sewer and water improvements would reimburse the city for an appropriate portion of that cost, at the time the properties developed.

1.02. The city installed public sewer and water facilities in 1995 as part of Project No. 4804U, for the benefit of multiple properties on Orchard Lane. The city established a connection charge at the time against an undeveloped parcel that consisted of what is now 3533 and 3535 Orchard Lane (the “Property”). The original amount of the connection charge in 1995 was $15,993.26.

1.03. Pursuant to City Council Policy 12.4, the amount of any connection charge must be increased annually by an amount equal to the amount that would have been payable as interest, if the improvement costs had been specially assessed; however, after 20 years, there are no additional increases in the amount of the connection charge. In accordance with City Council Policy 12.4, the connection charge against the Property is now $39,999.58.

1.04. As provided by council policy, connection charges must be paid in full at the time the Property connects to municipal sewer and water. The current owner of the Property has signed a Petition and Waiver Agreement, requesting that the connection charges be specially assessed against the Property.

1.05. The Property currently consists of two tax parcels. However, as a condition of the development approvals given in Resolution No. 2018-014, the city has required that the two parcels be combined as a single tax parcel. That combination has not yet occurred. The assessment is therefore proposed to be levied against the parcel for which a building permit has issued, 3535 Orchard Lane, PID No. 14-117-22-32-0049

1.06. Minnesota Statute 444.075 authorizes the city council to certify unpaid charges to the county auditor for collection with property taxes. The charges are certified in the same manner as special assessments.

Section 2. Council Action.

2.01. The Petition and Waiver of Special Assessment Agreement is approved, and the mayor and city manager are authorized to execute the same.
2.02. The amount to be certified for collection with taxes is as follows:

<table>
<thead>
<tr>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>3535</td>
<td>Orchard Lane</td>
<td>14-117-22-32-0049</td>
<td>$39,999.58</td>
</tr>
</tbody>
</table>

2.03. The proposed special assessment listed above is hereby adopted against the land listed above, and the tract of land is found to be benefited by the improvement in the amount of the total assessment stated above.

2.04. The special assessment may be paid within 30 days from the date thereof, or may be paid in ten (10) equal annual installments in the same time and manner as the payment of real estate taxes with interest at the rate of zero percent per annum. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time, provided the payment is made before November 30 the first year and before November 15 in subsequent years.

2.05. At any time within 30 days following the adoption of this resolution, the owner of any property assessed may pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100. Thereafter, the owner may at any time pay to the city the entire unpaid balance of the assessment.

2.06. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the city council of the City of Minnetonka, Minnesota, on September 17, 2018.

__________________________
Brad Wiersum, Mayor

ATTEST:

__________________________
David E. Maeda, City Clerk

ACTION ON THIS RESOLUTION:

Motion for adoption: 
Seconded by: 
Voted in favor of: 
Voted against: 
Abstained: 
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the city council of the City of Minnetonka, Minnesota at a duly authorized meeting held on September 17, 2018.

David E. Maeda, City Clerk
BE IT RESOLVED by the city council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. On March 19, 2018, by Resolution No. 2018-025, the city council approved a petition and waiver agreement for the installation of a fire sprinkler system to serve the building located at 5445 Eden Prairie Road.

1.02. Minnesota Statute 429.031 authorizes the city council to specially assess the cost of installing fire sprinkler systems in existing buildings.

Section 2. Council Action.

2.01. The cost of such work to be specially assessed is as follows:

<table>
<thead>
<tr>
<th>2018 Fire Sprinkler– Project No. 4874 (10 year term)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street No.</td>
</tr>
<tr>
<td>5445</td>
</tr>
</tbody>
</table>

2.02. The proposed special assessment listed above is hereby adopted against the land listed above, and the tract of land is found to be benefited by the improvement in the amount of the assessment stated above.

2.03. The special assessment may be paid within 30 days from the date thereof, or may be paid in ten (10) equal annual installments in the same time and manner as the payment of real estate taxes with interest at the rate of 3.87% per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest to December 31 of the year in which the payment is made, provided the payment is made before November 30 the first year and before November 15 in subsequent years.

2.04. Within 30 days following the adoption of this resolution, the owner of any property assessed may pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100. No interest will be charged on the portion of the assessment paid within the 30 days following the adoption of this resolution. Thereafter, the owner may at any time pay to the city the entire unpaid balance of the assessment, with interest accrued to December 31 of the year in which such payment is made.
2.05. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the city council of the City of Minnetonka, Minnesota, on September 17, 2018.

________________________________________
Brad Wiersum, Mayor

ATTEST:

________________________________________
David E. Maeda, City Clerk

ACTIONS ON THIS RESOLUTION:

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the city council of the City of Minnetonka, Minnesota at a duly authorized meeting held on September 17, 2018.

________________________________________
David E. Maeda, City Clerk
Resolution No. 2018-

Resolution canceling and reassessing special assessment of Housing Improvement Area Fee for 10211 Cedar Lake Road, Unit 205, Project No. 4318, 9-year assessment term

BE IT RESOLVED by the city council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. On March 5, 2012, the Minnetonka city council adopted Ordinance 2012-01, establishing the Cedar Ridge Condominium Housing Improvement Area (“HIA”) and Resolution 2012-017, establishing a fee for the Cedar Ridge HIA.

1.02. On September 18, 2012, the Minnetonka city council adopted Resolution No. 2012-087, levying the Cedar Ridge HIA fees as a special assessment against the units in the Cedar Ridge HIA. The assessment was certified to the county auditor as Levy No. 99999.

1.03. The assessment levied against 10211 Cedar Lake Road, Unit 205 (the “Property”) is in the amount of $3,378.15, in equal annual installments of $225.21 over a term of 15 years, plus interest at 4.50%.

1.04. In accordance with Resolution No. 2012-017, City Code § 220.010 and Minn. Stat. § 435.193, the Minnetonka city council deferred the payment of installments of the special assessments against the Property that would otherwise have been payable in the years 2013 through 2018, based on the age and disability of the former owner of the Property.

1.05. The former owner sold the Property in 2018, which automatically terminated the deferral and caused the previously deferred installments, plus accrued interest, in the total amount of $2,126.34, to become payable. The former owner has paid that amount to the city.

1.06. In order to credit the payment of $2,126.34 against the special assessments for the Property, it is necessary for the city to cancel the existing assessment and reassess the remaining principal balance of $2,026.89 against the Property. In the absence of a reassessment, the former owner’s payment would be remitted to the new owner of the Property, but the assessment installments of principal would increase to $375.35 per year, plus accrued interest.

1.07. By petition and waiver agreement, the new owner of the Property has requested that the city cancel the existing assessment against the Property, credit the payment of $2,126.34 for the benefit of the Property, and reassess the remaining balance against the Property over or the remaining term of nine years. As a result, the annual installments will remain at $225.21, plus interest at 4.50%.

1.08. Minn. Stat. § 479.071 allows the city to make reassessments or new assessments when it determines that an assessment is excessive.
Section 2. Council Action.

2.01. The petition and waiver agreement is approved, and the mayor and city manager are authorized to execute the agreement.

2.02. The council finds that the existing assessment would be excessive if the city allowed the previously deferred installments to be spread over the remaining term of nine years, because that would increase the amount of the annual installments to $375.35, even though the city has received payment in full of the deferred installments plus interest. Therefore, the assessment levied against 10211 Cedar Lake Road, Unit 205, by Resolution No. 2012-87, in the amount of $3,378.15, is hereby canceled.

2.03. There is levied against the property at 10211 Cedar Lake Road, Unit 205, a reassessment as follows:

<table>
<thead>
<tr>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>10211</td>
<td>Cedar Lake Road Unit 205</td>
<td>12-117-22-42-0182</td>
<td>$2,026.89</td>
</tr>
</tbody>
</table>

2.04. The proposed special assessment listed above is hereby adopted against the land listed above, and the tract of land is found to be benefited by the improvement in the amount of the assessment stated above.

2.05. The special assessment may be paid in nine (9) equal annual installments in the same time and manner as the payment of real estate taxes with interest at the rate of 4.50% per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year’s interest on the remaining balance will be added to each subsequent installment.

2.06. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the city council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

ATTEST:

David E. Maeda, City Clerk
ACTION ON THIS RESOLUTION:

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the city council of the City of Minnetonka, Minnesota at a duly authorized meeting held on September 17, 2018.

David E. Maeda, City Clerk
Brief Description  Ordinances related to tobacco-related products

Recommendation  Adopt the ordinances

Background

On July 23, 2018, the city council introduced several ordinances relating to tobacco products regulated by Minnetonka. The city council provided direction to have the three ordinance changes, identified below, presented at this meeting.

- Minimum Age 21 Ordinance
- Prohibition of Flavored Products Ordinance
- General Housekeeping Ordinance

The council recommended the effective date of the ordinances, if adopted, should be Jan. 1, 2019. The previous staff report and supporting information may be found on the July 23, 2018 City Council meeting website page (starting on page 25).

Public Input

The city continues to receive public comments relating to various ordinances that are being considered. All comments received after the July 23, 2018 meeting are attached.

Recommendation

Staff recommends adopting the following ordinances:

1) Ordinance amending sections 625.040 and 625.045 of the Minnetonka City Code, relating to the minimum age for sales of tobacco-related products
2) An Ordinance amending sections 625.005 and 625.040 of the Minnetonka City Code, relating to flavored tobacco-related products
3) Ordinance amending sections 625.010, 625.015, 625.025, and 625.040 of the Minnetonka City Code, relating to tobacco-related products – general changes.

Submitted through:
Geralyn Barone, City Manager

Originated by:
Julie Wischnack, AICP, Community Development Director
Corrine Heine, City Attorney
From: Julie Wischnack
To: Kathy Leervig
Subject: FW: Let’s Stop the Start in Minnetonka
Date: Monday, July 30, 2018 8:46:45 AM

Begin forwarded message:

From: Ray Lewis
Date: July 23, 2018 at 12:44:52 PM CDT
To: Tony Wagner <twagner@eminnetonka.com>
Subject: Let’s Stop the Start in Minnetonka
Reply-To: 

Dear Council Member Tony Wagner,

As a resident of Minnetonka and a volunteer for the American Heart Association, I am writing to urge you to stop the start in Minnetonka and support raising the minimum age to purchase tobacco products from 18 to 21, restricting flavored tobacco to adult-only tobacco shops and setting a minimum price for cheap cigars.

We can do more to prevent kids from becoming addicted to tobacco. A national consensus is growing to prevent addictions and future health problems by ensuring that those who sell tobacco products do so to adults who are 21 and older. Let’s make Minnetonka join Edina, St. Louis Park, Bloomington, Plymouth, North Mankato, Shoreview, Falcon Heights, Minneapolis, Richfield and Roseville in becoming the first cities in Minnesota to raise the minimum age to purchase tobacco from 18 to 21!

The National Academy of Medicine reports that there would be a 25 percent reduction in smoking initiation among 15-to-17-year-olds if the age to purchase tobacco was raised to 21. Preventing youth from starting to smoke is essential to reducing smoking prevalence, considering that almost 95 percent of addicted adult smokers started before age 21. Increasing the age gap between kids and those who can legally buy tobacco will help remove access to tobacco products from the high-school environment and stop the start.

Several states and local governments throughout the country have already passed this life-saving policy to protect youth. Hawai’i and California were the first states to raise the age to purchase tobacco to 21. And more than 300 municipalities, and growing, in the United States have raised the age to purchase tobacco to 21 including the city of Chicago. In 2005, Needham, MA increased the tobacco purchase age to 21 and saw the smoking rates among high school students fell by nearly half!

That is why I urge you to protect our youth and pass this life-saving policy in Minnetonka. Let’s create a movement in our state to stop the start!

Thank you for your service to our community.
Regards,
Ray Lewis
10521 Cedar Lake Rd
Minnetonka, MN 55305
From: Julie Wischnack
To: Kathy Leervig
Subject: FW: Support raising the tobacco sales age to 21
Date: Friday, August 03, 2018 1:59:35 PM
Attachments: MCA LOS Minnetonka .pdf

From: Brad Wiersum
Sent: Friday, August 3, 2018 12:46 PM
To: Julie Wischnack ; Geralyn Barone
Subject: Fw: Support raising the tobacco sales age to 21
Attachment included...sorry!
BJW

From: Katie Engman
Sent: Thursday, July 26, 2018 12:06 PM
To: Brad Wiersum; Deborah Calvert; Bob Ellingson; Mike Happe; Tim Bergstedt; Patty Acomb
Subject: Support raising the tobacco sales age to 21
Dear Mayor Wiersum and Members of the council,
On behalf of the Minnesota Cancer Alliance, please see the attached letter of support around your proposed tobacco ordinance changes.
Thank you,
Katie
Katie H. Engman, MCHES
Program Director
Association for Nonsmokers-MN (ANSR)
2395 University Ave W. #310, Saint Paul, MN 55114
Office- 651-646-3005,
July 25, 2018

Minnetonka City Hall
14600 Minnetonka Boulevard
Minnetonka, MN 55345

Mayor Wiersum and Members of the Minnetonka City Council:

Congratulations on your leadership in introducing an ordinance that will protect youth from tobacco addiction. Nearly 95% of adult smokers start before they turn 21. If youth do not smoke before 21, they likely never will. Increasing the tobacco sales age to 21 is a prudent action for you to be taking to protect youth. Tobacco use is a preventable cause of 15 cancers and other chronic diseases.

The Minnesota Cancer Alliance (MCA) is committed to reducing the burden of cancer for all people living in Minnesota. We are a coalition of over 100 organizations from diverse backgrounds and disciplines dedicated to reducing the burden of cancer across the continuum; from prevention and detection, to treatment, survivorship, and end-of-life care.

Our members include Masonic Cancer Center at the U of M, Fairview Health Services, MN Hospital Association, Park Nicollet Cancer Center, MN Medical Association, Mayo Clinic Cancer Center, Health Partners, Medica, Blue Cross Blue Shield of MN, Susan G. Komen Minnesota, MN Breast Cancer Coalition, Park Nicollet Cancer Center, MN Ovarian Cancer Alliance, and the MN Society for Clinical Oncology – to name just a few.

Cancer is the leading cause of death among Minnesotans and tobacco use is of course a very significant contributor to many forms of cancer. According to the 2017 Minnesota Youth Tobacco Survey, 26.7% of high school students reported using a tobacco product in the past 30 days. In 2017, this number increased for the first time in 17 years. Increasing the age gap between young people and those who can legally buy tobacco will reduce youth access to tobacco, remove these products from our high schools and ensure Minnetonka youth don’t suffer from a lifetime of tobacco addiction.

The Minnesota Cancer Alliance fully supports the ordinance you are considering and we urge you to take final action to adopt it. We hope you will serve as an example for other Minnesota communities in our shared desire to reduce tobacco related cancers.

Sincerely,

Cathy Skinner, MA
Chair, MN Cancer Alliance Steering Committee

cc: Donna McDuffie
Comprehensive Cancer Control Program
Minnesota Department of Health
From: Molly Moilanen  
Sent: Thursday, August 9, 2018 2:53 PM  
To: Brad Wiersum ; Deborah Calvert ; Patty Acomb ; Bob Ellingson ; Tony Wagner ; Mike Happe ; Tim Bergstedt ; Rebecca Schack  
Cc: Julie Wischnack  
Subject: New federal warning labels on e-cigarettes

Dear Mayor Wiersum and Council Members:

Thank you for the opportunity last month to testify in support of the proposed changes to Minnetonka’s tobacco ordinance, including e-cigarettes. I wanted to let you know that e-cigarettes, which have surged in popularity among Minnesota youth, will soon carry a federal warning. Beginning August 10, 2018, the U.S. Food and Drug Administration (FDA) will require warning labels on e-cigarettes and certain other tobacco products. I will be on TPT’s Almanac on Friday night to talk about this topic. The warning label is a needed and overdue step but it’s not sufficient. States and localities need to do more to prevent youth addiction. That is why I’m proud that my city, Minnetonka, is considering increasing the tobacco age to 21 and restricting the sale of flavored tobacco products to adult-only stores. Together, these two policies will reduce the visibility of and access to tobacco products that are addicting young people in our community and across the state. Please let me know if you would like more information on these new warnings or the proposed policies.

Thank you,

Molly Moilanen, M.P.P.
Director of Public Affairs
ClearWay Minnesota
952-767-1421 (o) / 612-619-3273 (m)
Dear Ms. Cook:

Thank you for your note and for sharing your experience with students and with their use of e-cigarettes. I concur with your perspective. Delivering addictive and harmful substances to young adults under the age of 21 is something that I do not support. Whether smoked or vaped, I am concerned about the harmful impacts of these products to our youth. I think that prohibiting the sale of these products to people under 21 is likely the right thing for our city. I work to keep an open mind until all of the public input is in, but I am leaning toward supporting T21 in Minnetonka. Thank you, again!

Sincerely,
Brad Wiersum
Mayor
City of Minnetonka
gentlemen who spoke mentioned that kids usually do not repeat use. We have students who cannot go more than 15 minutes without taking a "hit." Teenagers do not only use vapes and JUULs, but have access to more serious mixes and sources such as Fire Stick Vape Pens, and Black Magic juice.

Last winter we had an instance occur on campus that was especially unsettling for faculty and students. Three of our English teachers heard a student moaning in the bathroom. They found him unconscious and seizing on the floor. He had taken a hit from another student's JUUL and immediately passed out. The JUUL had been laced with bath salts and Fentanyl. When the student left our campus in the ambulance he was unresponsive.

We had several other instances of students passing out in the hallways, or becoming unresponsive in class. It will look like a student is napping, but they are actually unconscious.

In our community students are mainly accessing their vapes and JUULs at a convenient store up the road. The manager of the store will make his own mixes. A teenager can walk in and ask for the "special mix" and he will sell it to them no questions asked.

This epidemic as becoming so severe among our teenagers our School Resource Officer has trained our faculty and staff on what vapes and JUULs look like. We are aware of what the signs of a student vaping look like, what an overdose looks like, and have been asked to increase monitoring in the hallways and particularly the student bathrooms.

In my experience, I have seen how quickly a teenager's addiction to vaping, and JUULing can take hold. They do not understand the severity of what they are doing. Posting photos of them vaping on social media, joking about "vape lung," and buying and selling from one another has become part of their culture.

Thank you for considering this ordinance. I see Minnesota as a leader in strong and effective public health policies and saw first-hand at the meeting in July that leadership from the state always starts at the local level. Please reach out if you have any questions.

Thank you,
Lisa Cook
From: Annie Krapek  On Behalf Of TCMS

Sent: Wednesday, September 05, 2018 10:44 AM

To: Brad Wiersum ; Deborah Calvert ; Patty Acomb ; Bob Ellingson ; Rebecca Schack ; Mike Happe ; Tim Bergstedt
Cc: Julie Wischnack

Subject: Letter of Support- Tobacco 21

Dear Mayor Wiersum and Members of the Minnetonka City Council,

Thank you for considering raising the tobacco sales age in Minnetonka to 21. Tobacco 21 is a critical prevention policy that protects the health of our communities. Please find a letter of support from Twin Cities Medical Society and supporting materials attached to this email.

Thank you,

Annie Krapek, Program Manager
Physician Advocacy Network, Twin Cities Medical Society
1300 Godward Street, NE Suite 2000
Minneapolis, MN 55413

612-362-3715
www.panmn.org

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September 5, 2018

Mayor Wiersum and Members of the City Council
City of Minnetonka
14600 Minnetonka Boulevard
Minnetonka, MN 55345

Dear Mayor Wiersum and Members of the Minnetonka City Council,

I am writing on behalf of the Twin Cities Medical Society in reiterate our support for raising the legal age for tobacco sales in Minnetonka from 18 to 21. The Twin Cities Medical Society is an organization that represents approximately 4,500 physicians and medical students living and working in the seven-county Twin Cities metropolitan area.

Our physician members have shared with us that they are deeply concerned about the rapid increase in youth e-cigarette use. The popularity of JUUL and other high-nicotine e-cigarettes among youth, as outlined in the attached New England Journal of Medicine article, is particularly alarming. Adolescence is a critical time in brain development, and youth’s brains are particularly vulnerable to nicotine addiction. Exposure to nicotine during this time can cause life-long problems with learning, memory and attention. Research also shows that teens who use high-nicotine e-liquids, like those in JUUL pods, are more likely to begin smoking cigarettes¹.

While many youth believe e-cigarettes are “safe” or “no big deal,” research shows that e-cigarettes contain many of the same dangerous and cancer-causing chemicals as cigarettes, including heavy metals like lead, volatile organic chemicals, formaldehyde and diacetyl²,³,⁴. Simply put, e-cigarettes are not safe, and no youth should be vaping or using other tobacco products.

By restricting the sale of all tobacco products to those 21 and older, you have the opportunity to prevent today’s teens from a future of nicotine addiction and tobacco-related illnesses. We hope that you will join the growing group of Minnesota communities who have prioritized the health of our youth by passing Tobacco 21.

Sincerely,

Tom Kottke, MD
President of the Twin Cities Medical Society

Adolescents' Use of “Pod Mod” E-Cigarettes — Urgent Concerns

Jessica L. Barrington-Trimis, Ph.D., and Adam M. Leventhal, Ph.D.

Adolescents’ use of electronic cigarettes initially took the public health community by surprise. In 2011, less than 2% of U.S. high school students reported having used e-cigarettes in the previous month. But by 2015, the percentage had jumped to 16%. The following year, the U.S. Surgeon General issued a report concluding that e-cigarette use among young people was “a public health concern.” Ensuing public education campaigns and policies helped bring the prevalence of past-month e-cigarette use among U.S. high school students down to 11% in 2016.

A recent evolution in technology and marketing may threaten this progress. A new product class called “pod mods” — small, rechargeable devices that aerosolize liquid solutions containing nicotine, flavoring, and other contents encapsulated in cartridges (see image) — appears to be gaining traction. Media stories about Juul, a popular pod mod brand, highlight anecdotal reports from students, parents, teachers, and school superintendents indicating that use of these products is rampant among young people. According to Nielsen data, as of January 27, 2018, Juul had captured 49.6% of the e-cigarette market. There is reason to be concerned that adolescents’ use of pod mods is not a passing trend and could bring a host of adverse health consequences to the current generation of adolescents and young adults.

Pod mods may deliver high levels of nicotine with few of the deterrents that are inherent in other tobacco products. Traditional e-cigarette products use solutions with free-base nicotine formulations in which stronger nicotine concentrations can cause aversive user experiences. Juul and other pod mods use protonated nicotine formulations derived from the nicotine salts in loose-leaf tobacco. According to their advertisements, nicotine salt solutions contain nicotine concentrations 2 to 10 times those found in most free-base-nicotine e-cigarette products. Juul’s website indicates that there is 0.7 ml of nicotine per pod (concentration, 59 mg per milliliter [5%]) — equivalent to approximately 20 combustible cigarettes. According to a patent application, the combination of salt-based nicotine and other additives results in a satisfying experience even at high nicotine concentrations.

This innovation in nicotine chemistry may be critical with regard to the addictiveness of pod mods. Combustible cigarettes deliver high doses of nicotine as well, but the noxious taste and sensations of the initial smoking
Adolescents’ Use of “Pod Mod” E-Cigarettes

Pod mods may deliver an addictive dose of nicotine without an aversive user experience or other tobacco-related deterrents — which may be one reason why 80% of 15-to-24-year-olds who try Juul continue using the product and why social media posts saying “addicted to my Juul” are common. Pod mods are easy to conceal from authority figures. As compared with many e-cigarette devices, they generally need less electrical power to deliver high doses of nicotine and so are compact. Juul vaporizers measure 93.98 cm by 1.52 cm by 0.76 cm and weigh only 0.01 kg. They are inconspicuous, closely resembling computer USB drives. Young people can therefore readily conceal them, and teen use of pod mods on school grounds, including use during class time, is reportedly widespread (see photo). Furthermore, pod mods may appeal to a wide audience. They have a sleek, modern design, and their packaging resembles that of a smartphone. Customizable adhesive covers for Juul (like mobile-phone cases) are marketed as “skins” — the same term used for the visual personae that videogame players can select to represent their gaming characters. Juuls are available in attractive-sounding flavors, including “creme,” “fruit medley,” “mango,” and “cool mint,” and are easy to use. Many e-cigarette devices require purchase of solutions from independent manufacturers, manual refilling, and user calibration. With most pod mods, consumers merely open their starter kit package, slide a flavor pod into the device, and start vaping.

Although there may be far less diversity and quantity of toxins in e-cigarette aerosol than in combustible cigarette smoke, e-cigarettes are not without risks. Their aerosol can include metals, volatile organic compounds, and flavoring additives, which may be harmful when inhaled, particularly to adolescent users, who in fact are more likely than nonusers to report having respiratory symptoms. Moreover, nicotine adversely affects the developing brain and causes addiction. Adolescent exposure to nicotine is associated with an increased risk of mood and attention problems. Nicotine is the principal constituent responsible for the substantial addictiveness of tobacco products. Symptoms of nicotine addiction, such as drug withdrawal and forfeiture of social, occupational, or recreational activities in favor of nicotine use, cause substantial distress and impairment. Given the high nicotine concentrations in pod mods, the nicotine-related health consequences of use by young people could be worse than those from most e-cigarette products. Yet 63% of 15-to-24-year-olds surveyed did not know that nicotine is present in all Juul products.

E-cigarette use may increase the risk for combustible-cigarette smoking. A consensus report of the National Academies of Sciences, Engineering, and Medicine concluded that adolescents and young adults who use e-cigarettes are more likely than nonusers to start smoking combustible cigarettes, and it cited evidence that higher nicotine concentrations may heighten the risk of such a transition. It’s important to study how and to what extent the increased popularity of pod mods among adolescents affects the prevalence of combustible-tobacco use among young people.

Since many pod mods are virtually indistinguishable from USB drives, some schools have banned all USB drives from their grounds. School districts have launched par-
Adolescents’ Use of “Pod Mod” E-Cigarettes

Teen Using a Pod Mod at School.
The design of the pod mod makes it easy to conceal its use in the classroom.

health organizations urged the Food and Drug Administration (FDA) — the federal agency charged with regulating e-cigarettes — to take action to prevent “Juul-ing” by young people.3 The group urged the FDA to act to suspend Internet sales of Juul until stronger regulations can be implemented to prevent online purchases by young people and to increase enforcement of restrictions against e-cigarette sales to minors in brick-and-mortar stores. It also encouraged the FDA to advance the deadline (currently set for 2022) for determinations of whether existing e-cigarette products may remain on the market. A coalition of 11 U.S. senators also recently wrote to the FDA with similar concerns and called for the prohibition of sales of e-cigarettes in “kid-friendly” flavors.

The FDA has begun to take action. On April 24, 2018, the agency announced recently initiated, nationwide, undercover operations to identify and intervene with retailers that sell e-cigarettes to minors, restrictions against third-party resale of Juuls on the popular shopping website eBay, and detailed requests for information from the manufacturer of Juul to aid FDA efforts to prevent Juul-ing by young people. Comprehensive actions are urgently needed to counteract adolescents’ use of pod mods and other e-cigarettes. In the meantime, we advise physicians and parents to remain on alert regarding this emerging public health concern.

Disclosure forms provided by the authors are available at NEJM.org.

From the Department of Preventive Medicine, Keck School of Medicine (J.L.B.-T., A.M.L.), and the Department of Psychology (A.M.L.), University of Southern California, and the USC Norris Comprehensive Cancer Center (J.L.B.-T., A.M.L.) — all in Los Angeles.

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Hello Julie,

I hope you are doing well, enjoying your last bits of summer – it has gone by fast! Attached is a letter to the council regarding the city’s consideration of tobacco retail prevention strategies. If you would please forward it on to the Mayor and Council members. Thank you. If there is any information or resources I can assist you with please don’t hesitate to reach out.

Warm regards, and have a nice weekend.

Ruth

Ruth Tripp, MPH, RN
Principal Health Promotion Specialist
Hennepin County Public Health|525 Portland Ave., MC 963|Minneapolis, MN 55415
Phone: 612-348-5367|E-Mail: [link removed]

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August 30, 2018

RE: Proposed restrictions on tobacco sales

Dear Minnetonka City Council:

We commend the City of Minnetonka for identifying ways that your city can limit youth access to tobacco and help protect them from the harms of tobacco and a possible lifetime of addiction. Increasing the minimum age for sales of tobacco-related products from 18 to 21 and restricting the sale of all flavored tobacco-related products are two effective mechanisms to prevent and reduce tobacco use. Done together, as the city has proposed, is efficient and can dramatically curtail initiation by youth and prevent targeting of populations that experience disproportionate negative health impacts from tobacco.

Tobacco use is still the No. 1 preventable cause of death and disease in Minnesota. One in seven Hennepin County deaths is tobacco-related, resulting in $585 million in excess medical costs annually. Hennepin County Public Health works to decrease tobacco's harm and tobacco-related disparities by reducing exposure to secondhand smoke, helping people quit, and preventing youth and young adults from starting. We have been, and will continue to be, available as a resource to your city staff as these measures are considered, implemented, monitored and evaluated. This work is supported by funds from the MN Department of Health’s (MDH) Statewide Health Improvement Partnership.

For years, adolescent tobacco use rates have been declining. 2016 MN Student Survey data for Minnetonka and Hopkins school districts, where many Minnetonka youth attend, shows that 10 percent of 11th grade students use conventional tobacco products—cigarettes, cigars, and chewing tobacco. This is down from 15 percent in 2013. However, adolescents’ use of e-cigarettes has gone up dramatically. These products, which are almost always flavored, are now the most popular of tobacco products and threatening to erase tobacco prevention progress. When e-cigarette products are included we find that over 1 in 5, or 21 percent of Minnetonka and Hopkins 11th graders report using a tobacco product in the past 30 days. In fact, four times as many Minnetonka and Hopkins 11th graders are using e-cigarettes compared to conventional cigarettes.
Nearly all electronic tobacco products contain nicotine, which is highly addictive. According to the MDH Health Advisory, nicotine in electronic cigarettes is harmful to adolescent brain development and compromises learning, memory and attention. Perhaps most concerning is that nicotine is highly addictive. Newer electronic cigarette technologies are available with high concentrations of nicotine. Developing brains are particularly susceptible. With many 18-year-olds being in high school, raising the sales age to 21 will decrease younger teens' access to tobacco products through this social network at school. For these reasons, it is important to include electronic and emerging tobacco products in any changes considered.

One of the key drivers of tobacco use is the availability of flavored products. Tobacco companies use candy, fruit, menthol, and minty-flavoring in their products that mask the harsh taste of tobacco and are appealing to youth. Menthol, a mint-based additive, is particularly threatening because it increases tobacco use initiation, facilitates addiction by suppressing the cough reflexes and irritation of cigarette smoke, decreases cessation, and affects vulnerable populations at higher rates. In Minnetonka and Hopkins school districts, over 40 percent of students in 9th and 11th grades who use tobacco use a flavored product and 25 percent of them use menthol products.

Nearly 90 percent of retailers in Minnetonka sell menthol or other flavored tobacco products. Even with increasing the age for tobacco sales to 21, flavored products, if available for sale, are still advertised in retailers that youth and young adults frequent. Marketing exposure is a strong indicator of tobacco initiation and use. Restricting the availability of all flavored tobacco products will reduce youth exposure to these products, as well as the marketing and promotion that accompanies them.

Thank you for your consideration and leadership regarding this important public health issue. Please feel free to contact me if you have questions or would like additional information.

Sincerely,

Ruth Tripp, MPH, RN
Principal Health Promotion Specialist


Attached please find the comments for the upcoming City Council meeting on the 17th.
Thank you,
Tom Madden
Owner E-Cig POD USA
Minnetonka City Council,

Thank you for taking the time to hear all sizes of the Tobacco 21 issue.

As an owner of an electronic cigarette establishment in Minnetonka there are 3 points I would like to address regarding the ordinances in front of the City Council.

**Prohibiting Sale of Flavored Products**

“flavored tobacco-related products” is generally defined to include any tobacco-related product that contains a taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen.

This definition of what I would be allowed to sell to the community would directly lead to people reverting to cigarettes. Currently I have over 50 eliquid flavors to offer my customers. To restrict the number of flavors I offer the community would reduce the effectiveness of electronic cigarettes, turning people away from this product and back to cigarettes. The longer we can keep people off cigarettes the higher the probability they will stay off. We have learned through over 15 years of electronic cigarettes being in the market (we have been in business 5 years this coming October) that people learn they like the taste of other flavors more than the taste of tobacco. They also get tired of a certain flavor, they may for example switch from a fruit flavor to a spice flavor or any number of different flavors. Having a multiple variety of flavors helps adults stay off cigarettes.

**Exemption if 90% of sales are nicotine related products**

My customers have been demanding other products. As people remove cigarettes from their lives they start to realize the benefits of a healthy lifestyle. For example; my customers asked me to bring in a line of essential oils, which I have done. In addition, they asked me to carry CBD products, similar products are sold at Lakewinds Co-Op. The essential oils have been helping people with allergies, sleep deprivation as well as detoxifying the body. CBD products are helping our seniors with Arthritis.

If I am restricted to only having 10% non-nicotine related products in my store I am significantly reducing the positive health benefits I can offer my customers.

**Minimum Age 21 Ordinance**

To raise the minimum age for customers who purchase tobacco-related products from 18 years to 21 years.

As the ordinance includes electronic cigarettes in “tobacco-related products” it will restrict young adults from trying vaping to quiet cigarettes. Current teens under the age of 18 who are illegally smoking cigarettes will not be able to try vaping once they turn 18, which they currently can do. They will have to wait until they turn 21, 3 additional years of abuse, 3 more years of over 3,500 chemicals polluting their bodies threw the burning of tobacco cigarettes as this ordinance is currently written. This will have the opposite effect of its intended purpose. If we simply remove the words “electronic cigarettes” from
the definition of what a “tobacco-related product” is young adults will have any easier way going forward to remove cigarettes from their lives for good.

**Conclusion:**

By removing “e-cigarettes” from the definition of “tobacco-related products” we will be significantly closer to what all of us want in the community. Fewer people smoking cigarettes. If we choose to leave the wording as it is currently stated, we are sending a message that it is ok for our young adults to pour cancer causing agents into their bodies for a longer period of time, regardless of what the world of science is telling us.

It is my hope the city council will remove these two words from the “tobacco-related products” definition for the benefit of all of us.

Regards,

Tom Madden
Owner
E-Cig POD
14645 Excelsior Blvd
Minnetonka, MN 55345
Dear Mayor and Council Members-

I am writing regarding the proposed changes to tobacco ordinances. I work with small business owners across the state that manufacture and sell vapor products. I was present and the last hearing.

You should be aware that despite statements made at the last hearing. The vapor industry is comprised mostly of small business owners and NOT Big tobacco companies. In fact, Big tobacco comprises less than 15% of the market. While it may be easy to lump vapor in with products sold by Big tobacco this strategy has caused the American Cancer Society to issue a statement that Vapor products in their current forms are "markedly less harmful than tobacco products" and they are concerned that about the growing misunderstanding of harm being promoted by many.

According to the 2014 MN Dept of Health Adult Tobacco Survey vapor was the most popular method for adults looking to quit (45.7%) or reduce (50.1%) smoking. This coincided with an all-time low smoking rate of 14.4% and an all-time high successful quit rate of 15.6%. This is all despite that fact that Minnesota is one of only a handful of state that tax these products and does so at an astonishingly high rate of 95% wholesale.

Adults in Minnesota, U.S. and across the globe are choosing vapor as the primary method to quit. The UK recently released a report directly attributing the new low in smoking rates being directly attributable to an increase in vaping and has supported the prescription of vapor devices and promotion of them as smoking cessation options. This includes products with non-tobacco flavoring as many adults have found regular use of flavored products helpful in their quit attempts.

Health Concerns

Since the vapor products there have been numerous questions raised about the potential health effects of vaping but in recent years there have been a number of comprehensive studies showing little evidence for concern. Most recently the National Academy of Sciences found:

- There is substantial evidence that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes.

- There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."

- There is moderate evidence that risk and severity of dependence are lower for e-cigarettes than combustible tobacco cigarettes.

- There is no available evidence whether or not e-cigarette use is associated with clinical cardiovascular outcomes (coronary heart disease, stroke, and peripheral artery disease) and subclinical atherosclerosis (carotid intima media-thickness and coronary artery
calcification)."

There is insufficient evidence that e-cigarette use is associated with long-term changes in heart rate, blood pressure, and cardiac geometry and function."

There is no available evidence whether or not e-cigarettes cause respiratory diseases in humans.

There is limited evidence for improvement in lung function and respiratory symptoms among adult smokers with asthma who switch to e-cigarettes completely or in part (dual use)."

The Royal College of Physicians, the first medical organization to warn of the dangers of smoking in 1962, published a review of current science and studies, supported by British health agency Public Health UK, stating that vapor products are at least 95% less harmful than cigarettes and they should be widely supported as a cessation method. Additionally, leading anti-smoking nonprofits across England have embraced vaping as a cessation method and attributed it to their record low smoking rates.

Youth Use

Along with the popularity of vapor amongst adults, we have also seen an increase in youth experimentation of vapor products since 2011. While the concerns have been persistent the reality is there is no empirical evidence to support this claim. For instance, in Minnesota, the rate of teens trying vapor products has continued to rise since 2011 yet the rate of smoking has continually dropped. This mirrors data from the CDC that show that since the introduction of vapor products not only has the youth smoking rate continued it decline it has done so at a faster rate during this period.

Opponents of vaping need only to look to their one research to explain this phenomenon. Traditionally determining a regular smoker was done by asking if they had used a product within the last 30 days.

In June of 2015, a study funded by Clearway MN was published stating that “prevalence as any use in the past 30 days may include experimenters unlikely to continue use, and is of questionable utility for population surveillance of public health trends over time.” Looking further into the most recent data released by the Dept of Health that shows that that majority of students using vapor products in 2016 only did so for a handful of days. The CDC notes regular use as 20 of the last 30 days. In this context, you can see that less than 5% of students are regular users and they likely were regular smokers before.

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Additionally, the most recent “Monitoring the Future” report which has been tracking youth use of tobacco and drugs since 1991 found of t students who have tried vaping in the last 30 days (12%) the majority 8% did not use liquids with Nicotine.
The reality is that while there have been studies that show increased odds that youth who vape will also smoke there is little data to show that kids who vaped became regular smokers. Raising the age to purchase will likely make it more difficult for 18-21 year olds who unfortunately have already become smokers to switch to vaping.

By prohibiting flavors you are essentially removing the most popular method to quit smoking in Minnesota from the shelves while leaving cigarettes. This action seems counter to your expressed health impacts of this ordinance. Allowing cigarettes in your community yet enacting a de facto ban on vaping seems to indicate you as a council prefers people smoke and oppose a product that has been shown to be significantly safer and supported as an alternative.

Cap O'Rourke
President
O'Rourke Strategic Consulting
@ORourkeSc
Acknowledgements
The Tobacco Advisory Group acknowledges the help of the UK Centre for Tobacco and Alcohol Studies (www.ukctas.net), which is funded by the UK Clinical Research Collaboration, in writing this report; and thanks Natalie Wilder, Claire Daley, Jane Sugarman and James Partridge in the Royal College of Physicians Publications Department for their work in producing the report.

The Royal College of Physicians
The Royal College of Physicians (RCP) plays a leading role in the delivery of high-quality patient care by setting standards of medical practice and promoting clinical excellence. The RCP provides physicians in over 30 medical specialties with education, training and support throughout their careers. As an independent charity representing 32,000 fellows and members worldwide, the RCP advises and works with government, patients, allied healthcare professionals and the public to improve health and healthcare.

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Contributors

Amanda Amos  Professor of health promotion, University of Edinburgh

Deborah Arnott  Chief executive, Action on Smoking and Health (UK)

Richard Ashcroft  Professor of bioethics, Queen Mary University of London

Paul Aveyard  Professor of behavioural medicine, University of Oxford

Linda Bauld  Professor of health policy, University of Stirling and CRUK/BUPA chair in behavioural research for cancer prevention, Cancer Research UK

Ilze Bogdanovica  Research fellow, University of Nottingham

John Britton  Professor of epidemiology, University of Nottingham

Meghan Chenoweth  Postdoctoral fellow, University of Toronto, Canada

Jeff Collin  Professor of global health policy, University of Edinburgh

Martin Dockrell  Head of tobacco control, Public Health England

Peter Hajek  Professor of clinical psychology, Queen Mary University of London

Nick Hopkinson  Reader in respiratory medicine and honorary consultant physician, National Heart and Lung Institute, Imperial College London

Tessa Langley  Assistant professor in health economics, University of Nottingham

Sarah Lewis  Professor of medical statistics, University of Nottingham

Ann McNeill  Professor of tobacco addiction, King’s College London
Tobacco harm reduction

Hayden McRobbie  Professor of public health interventions, Queen Mary University of London

Marcus Munafó  Professor of biological psychology, University of Bristol

Magdalena Opazo Breton  Research statistician, University of Nottingham

Rachel F Tyndale  Professor of pharmacology and toxicology, and psychiatry, Centre for Addiction and Mental Health, University of Toronto

Jennifer Ware  Research fellow, University of Bristol

Robert West  Professor of health psychology, University College London
Paul Aveyard is the chief investigator of a trial of nicotine preloading in which NRT is donated by GlaxoSmithKline to the NHS.

Peter Hajek has received research funding from and provided consultancy to Pfizer, Johnson & Johnson, Novartis and GlaxoSmithKline.

Hayden McRobbie has received honoraria for speaking at smoking cessation educational and advisory group meetings, which have been organised by Johnson & Johnson and Pfizer; he has received funding for investigator-led research from Pfizer and was an investigator on a 2008 study of e-cigarettes sponsored by manufacturer Ruyan Group and conducted independently at the University of Auckland.

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Amanda Amos, Deborah Arnott, Richard Ashcroft, Linda Bauld, Ilze Bogdanovica, John Britton, Meghan Chenoweth, Jeff Collin, Martin Dockrell, Nick Hopkinson, Tessa Langley, Sarah Lewis, Ann McNeill and Magdalena Opazo Breton have no interests to declare.
Members of the Tobacco Advisory Group of the Royal College of Physicians

John Britton (chair)
Sanjay Agrawal
Deborah Arnott
Richard Ashcroft
Paul Belcher
Tim Coleman
Linda Cuthbertson
Helen Donovan
Anna Gilmore
Nick Hopkinson
Martin Jarvis
Jo Leonardi-Bee
Ann McNeill
The Royal College of Physicians (RCP) exists to improve the care of individual patients, and the health of the population. As tobacco smoking generates more illness and premature death than any other avoidable cause, preventing smoking has been a high priority for the RCP since the health harm of smoking was first recognised over 60 years ago. In the more than 50 years since our first report, *Smoking and health*, in 1962, we have argued consistently for more and better policies and services to prevent people from taking up smoking, and help existing smokers to quit.

Smoking is far less prevalent today than it was in 1962, but remains common, particularly among more disadvantaged individuals in our society. There are still almost nine million smokers in the UK, half of whom will die prematurely unless they quit. The evidence in this report demonstrates sustained progress over recent decades in preventing young people from becoming smokers, but also shows that much more must be done to increase the number of existing smokers who succeed in stopping smoking.

In 2007 the RCP published a report, *Harm reduction in nicotine addiction*, which argued for the application of harm-reduction strategies to tobacco dependence. We suggested that making effective, affordable, socially acceptable, low-hazard nicotine products available to smokers as a market alternative to tobacco could generate significant health gains, by allowing smokers to stop smoking tobacco, without having to stop using the nicotine to which they are addicted. Our report was published just as the prototypes of a new consumer alternative to tobacco, the electronic cigarette (e-cigarette), were first appearing on the UK market.

The rapid growth in use of e-cigarettes by smokers since 2007 demonstrates that many smokers want reduced-harm products, and it is also clear that many smokers have succeeded in quitting simply by substituting electronic for tobacco cigarettes. However, e-cigarettes have also proved to be highly controversial, attracting much criticism as well as support within medicine and public health, and indeed in wider society.
This report therefore aims to provide a fresh update on the use of harm reduction in tobacco smoking, in relation to all non-tobacco nicotine products but particularly e-cigarettes. It concludes that, for all the potential risks involved, harm reduction has huge potential to prevent death and disability from tobacco use, and to hasten our progress to a tobacco-free society. With careful management and proportionate regulation, harm reduction provides an opportunity to improve the lives of millions of people. It is an opportunity that, with care, we should take.

Professor Jane Dacre
President, Royal College of Physicians
### Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ASA</td>
<td>Advertising Standards Authority</td>
</tr>
<tr>
<td>ASH</td>
<td>Action on Smoking and Health</td>
</tr>
<tr>
<td>BAT</td>
<td>British American Tobacco</td>
</tr>
<tr>
<td>BSI</td>
<td>British Standards Institute</td>
</tr>
<tr>
<td>CO</td>
<td>carbon monoxide</td>
</tr>
<tr>
<td>COP</td>
<td>FCTC Conference of the Parties</td>
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<tr>
<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CTADS</td>
<td>Canadian Tobacco, Alcohol and Drugs Survey</td>
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<tr>
<td>CYP2A6</td>
<td>cytochrome P450 2A6 enzyme</td>
</tr>
<tr>
<td>e-cigarette</td>
<td>electronic cigarette</td>
</tr>
<tr>
<td>ECITA</td>
<td>Electronic Cigarette Industry Trade Association</td>
</tr>
<tr>
<td>EFTA</td>
<td>European Free Trade Association</td>
</tr>
<tr>
<td>ENDS</td>
<td>electronic nicotine delivery system</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FCA</td>
<td>Framework Convention Alliance</td>
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<td>FCTC</td>
<td>Framework Convention on Tobacco Control</td>
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<td>FDA</td>
<td>US Food and Drug Administration</td>
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<tr>
<td>FM03</td>
<td>flavin-containing monooxygenase 3</td>
</tr>
<tr>
<td>GABA</td>
<td>γ-aminobutyric acid</td>
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<tr>
<td>GRPs</td>
<td>gross rating points</td>
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<td>HAZ</td>
<td>Health Action Zones</td>
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<tr>
<td>HMRC</td>
<td>HM Revenue and Customs</td>
</tr>
<tr>
<td>IGTC</td>
<td>Institute for Global Tobacco Control</td>
</tr>
<tr>
<td>ITC</td>
<td>International Tobacco Control policy evaluation project</td>
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<tr>
<td>MAO</td>
<td>monoamine oxidase</td>
</tr>
<tr>
<td>MCA</td>
<td>Medicines Control Agency</td>
</tr>
<tr>
<td>MHRA</td>
<td>UK Medicines and Healthcare products Regulatory Agency</td>
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<tr>
<td>MMC</td>
<td>mass media campaign</td>
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<tr>
<td>MPOWER</td>
<td>Monitor, Protect, Offer, Warn, Enforce, Raise</td>
</tr>
<tr>
<td>nAChR</td>
<td>nicotinic acetylcholine receptor</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>NMR</td>
<td>nicotine metabolite ratio</td>
</tr>
<tr>
<td>NNN</td>
<td>N′-nitrosonornicotine</td>
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### Tobacco harm reduction

<table>
<thead>
<tr>
<th>Acronym</th>
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<tr>
<td>NNS</td>
<td>nicotine nasal spray</td>
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<tr>
<td>NO</td>
<td>nitric oxide</td>
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<tr>
<td>NRT</td>
<td>nicotine replacement therapy</td>
</tr>
<tr>
<td>ONS</td>
<td>Office for National Statistics</td>
</tr>
<tr>
<td>PET</td>
<td>positron emission tomography</td>
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<tr>
<td>PHE</td>
<td>Public Health England</td>
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<tr>
<td>PMI</td>
<td>Philip Morris International</td>
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<td>RCP</td>
<td>Royal College of Physicians</td>
</tr>
<tr>
<td>SALSUS</td>
<td>Schools Adolescent and Lifestyle and Substance Use Survey</td>
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<tr>
<td>SES</td>
<td>socio-economic status</td>
</tr>
<tr>
<td>SHARE</td>
<td>Smoking Harm Reduction Education Programme</td>
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<td>SHS</td>
<td>second-hand smoke</td>
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<td>SPECT</td>
<td>single-photon emission computed tomography</td>
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<tr>
<td>SSS</td>
<td>Stop Smoking Service</td>
</tr>
<tr>
<td>STS</td>
<td>Smoking Toolkit Study</td>
</tr>
<tr>
<td>TAPA</td>
<td>UK Tobacco Advertising and Promotion Act 2002</td>
</tr>
<tr>
<td>TPD</td>
<td>EU Tobacco Products Directive</td>
</tr>
<tr>
<td>TSNAs</td>
<td>tobacco-specific nitrosamines</td>
</tr>
<tr>
<td>UGT</td>
<td>uridine diphosphate (UDP) glucuronosyltransferase</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Harm reduction is a strategy used in medicine and social policy to minimise harm to individuals and/or wider society from hazardous behaviours or practices that cannot be completely avoided or prevented. Examples include providing clean needles and syringes to intravenous drug users to reduce the risk of infection, promoting condom use by sex workers, drink-driving laws, protective clothing in sport, and motor vehicle safety measures and emission controls. Sometimes by appearing to condone or perpetuate hazardous behaviours that could in theory be prevented, harm-reduction approaches can be controversial, particularly in medicine. To their proponents, however, they represent pragmatic solutions to a range of otherwise intractable causes of avoidable death and disability.

Tobacco smoking is addictive and lethal. Half of all lifelong smokers in the UK die as a direct consequence of their smoking, and smokers lose an average of about 3 months of life expectancy for every year smoked after the age of 35; in sustained smokers this amounts to a total loss of around 10 years of life. Tobacco smoking harms others, through passive exposure of both adults and children to exhaled and sidestream smoke, while smoking in pregnancy impairs fetal growth and development, in some cases to the point of fetal death. Smoking causes fires and litter, reduces economic productivity and social engagement, and exacerbates poverty. Together these effects make smoking responsible for more loss of quality and quantity of life in the UK than any other avoidable cause. As smoking is strongly related to social disadvantage, the burden of ill health caused by smoking falls particularly on the most disadvantaged individuals, making smoking the largest cause of social inequalities in health in the UK.

Smoking is completely preventable, yet, more than half a century after the health harm of smoking first became widely known, almost 1 billion people worldwide still smoke. They do so primarily because they are addicted to the nicotine in tobacco smoke and, as this addiction can be extremely difficult to overcome, many will continue to smoke until they die. Conventional tobacco control policies, embodied in the World Health Organization’s (WHO’s) Framework Convention on Tobacco Control (FCTC) and MPOWER policy framework
Tobacco harm reduction

(Monitor tobacco use and prevention policies, Protect people from tobacco smoke, Offer help to quit tobacco use, Warn about the dangers of tobacco, Enforce bans on tobacco advertising, promotion and sponsorship, and Raise taxes on tobacco)\textsuperscript{12} aim to prevent the uptake of smoking and to help as many existing smokers to quit as possible. These approaches have contributed to a 50% reduction in UK smoking prevalence in the past 35 years,\textsuperscript{13} as well as increasing global success in smoking prevention.\textsuperscript{9,14} However, although smoking prevalence in the UK is now down to 18%,\textsuperscript{15} this figure translates into around 8.7 million current smokers\textsuperscript{16,17} sustaining significant harm from smoking. Harm reduction provides an additional strategy to protect this group, and their counterparts in other countries, from the burden of disability and early death that will continue to accumulate until and unless they stop smoking.

In 2007 the RCP published a report promoting the principle of harm reduction in nicotine addiction,\textsuperscript{18} arguing that, as most of the harm caused by smoking arises not from nicotine but from other components of tobacco smoke, the health and life expectancy of today’s smokers could be radically improved by encouraging as many as possible to switch to a smoke-free source of nicotine. While recognising the primacy of complete cessation of all tobacco and nicotine use as the ultimate goal to prevent harm from smoking, the report argued that promoting widespread substitution of cigarettes and other tobacco combustion products would, for smokers who made the change, achieve much the same thing.\textsuperscript{18} Harm reduction, as a complement to conventional tobacco control policies, could therefore offer a means to prevent millions of deaths among tobacco smokers in the UK alone.\textsuperscript{18} This argument was accepted and integrated into national tobacco control strategies published by the then Labour and subsequent coalition governments in 2010 and 2011,\textsuperscript{19,20} through the extension of the licence for nicotine replacement therapy (NRT) to include harm reduction by the Medicines and Healthcare products Regulatory Agency in 2010,\textsuperscript{21} and in guidance issued by the National Institute for Health and Care Excellence in 2013.\textsuperscript{22}

At the time of the 2007 report, the product categories available as potential smoking substitutes comprised smokeless tobacco, the least hazardous forms of which were then and still are illegal in the UK,\textsuperscript{18} and conventional NRT, which, although effective as a smoking cessation therapy, has proved to have limited appeal to many smokers.\textsuperscript{18} E-cigarettes, which appeared in the UK at around the time the 2007 report was published, have transformed this market, becoming the most popular choice of product for smokers hoping to quit or cut down on their smoking\textsuperscript{23,24} (see Chapter 5). In the UK and many other countries, however, e-cigarettes have proved highly controversial, attracting both widespread concern and disapproval, and strong support, from individuals and organisations both within and outside medicine. Policies on e-cigarettes vary widely between countries with some, such as the UK, currently allowing their sale as consumer products whereas others, eg Australia, prohibit the product\textsuperscript{25} (see Chapter 10).
Harm reduction, and in particular the role of e-cigarettes, has probably split global and, to some extent, national opinion on tobacco control more than any other issue. This report therefore aims to provide an update on harm reduction in the UK, particularly but not exclusively in relation to the role of e-cigarettes.

1.1 The harm of smoking

The harm that smoking causes to individuals and society is extensive and has been reviewed comprehensively in reports published by the RCP over the past 15 years, by the US surgeon general and by many other authorities. The main effects of smoking on health and wellbeing, particularly in the context of the UK population, are as follows.

1.1.1 Mortality

The most recent detailed analysis of mortality caused by smoking in the UK uses data from 2010, when tobacco smoking caused an estimated 122,000 deaths in adults, equivalent to more than one in six of all deaths, in the UK. Although due to a wide range of diseases, 70% of these deaths were from three causes: lung cancer, chronic obstructive pulmonary disease (COPD) and vascular disease (Fig 1.1).

![Fig 1.1 Deaths attributable to smoking by disease in men and women, UK, 2009. (Data for figure from Peto et al.)](image-url)
Deaths caused by passive smoking are more difficult to estimate with precision, but in 2003 over 10,000 adults in the UK were estimated to have died from lung cancer, cardiovascular disease or COPD caused by passive smoking. The figure today is likely to be lower, as a result of declining smoking prevalence and legislation making UK public places and workplaces smoke free. Among children, around 40 cases of sudden infant death syndrome are caused by smoking in the UK each year, whereas passive exposure of the fetus arising from maternal smoking during pregnancy causes over 5,000 fetal or perinatal deaths each year.

1.1.2 Morbidity

Smoking during pregnancy accounts for around 2,000 premature births and 19,000 cases of low birth weight each year, and increases the risk of fetal anomalies. Among children, passive smoking has been estimated to cause around 165,000 new cases of disease, predominantly middle-ear disease and respiratory infections in 2008, generating over 300,000 primary care consultations and 9,500 hospital admissions in the UK each year. In adults, combined morbidity and mortality from smoking accounted for the loss of around 2 million disability-adjusted life years in the UK in 2010. In 2014 smoking caused over 450,000, or about 4% of all, admissions to hospitals in England. Most of these admissions were for cancer, or respiratory or vascular disease.

1.1.3 NHS and wider societal costs

Smoking costs the NHS more than £2 billion in direct costs, or more than 2% of the total NHS budget, every year. Costs of inpatient and primary care caused by passive smoking in children in 2007 exceeded £20 million. The total cost of smoking to society, including healthcare, social care, lost productivity, litter and fires, was conservatively estimated in 2015 to be around £14 billion per year.

1.1.4 Smoking and deprivation

Smoking prevalence is strongly and directly related to all measures of deprivation. Smoking prevalence among those in higher managerial and professional occupations in the UK is now close to 12%, whereas among those in routine and manual occupations the figure is over 28%. Among unemployed people, almost 40% smoke, as do around 40% of people with longstanding mental health problems and more than 70% of people who are homeless or imprisoned.
1.5 Normalisation effects

Smoking harms the health of others through behavioural effects, independent of tobacco exposure. It was estimated that, in the UK in 2011, over 200,000 11- to 15-year-olds started smoking\(^34\) and, although smoking rates have since fallen, it is still the case that, every day, hundreds of children become smokers. These new smokers are more likely to come from households that include a smoker\(^35\) or to have been exposed to smoking behaviour in the media\(^36\) or in their wider social environment.\(^36\) These effects tend to perpetuate addiction to smoking among successive generations of families and social groups, and hence also the consequent inequality in quantity and quality of life in disadvantaged groups.

1.2 Principles of tobacco harm reduction

Tobacco smoke contains thousands of constituents that determine the flavour and other characteristics of the smoke; but, crucially, they also combine to deliver nicotine to the lung in an aerosol, with physical properties that allow rapid absorption into the pulmonary circulation. Although other components of tobacco smoke may enhance the addictiveness of tobacco smoke, the main driver of tobacco smoking is addiction to nicotine.\(^10,18\) The mechanisms of nicotine addiction are complex, but it is evident that smokers experience an initial sensation of reward from exposure to nicotine; after sustained use and consequent desensitisation to nicotine’s effects, smokers seek nicotine primarily to relieve the symptoms of nicotine withdrawal.\(^10,18\) Regular nicotine use also confers rewards in some of the stimuli and behaviours associated with nicotine delivery, such as the sense of smoke in the throat, and the physical acts that are integral to smoking, such as unwrapping, sharing or handling cigarettes.

Nicotine is not, however, in itself, a highly hazardous drug (see Chapters 4 and 5). It increases heart rate and blood pressure, and has a range of local irritant effects, but is not a carcinogen.\(^37\) Of the three main causes of mortality from smoking, lung cancer arises primarily from direct exposure of the lungs to carcinogens in tobacco smoke, COPD from the irritant and proinflammatory effects of smoke, and cardiovascular disease from the effects of smoke on vascular coagulation and blood vessel walls. None is caused primarily by nicotine. For practical purposes, as argued by Mike Russell in the 1970s, ‘smokers smoke for nicotine but are killed by tar’.\(^38\) Although the nature and extent of any long-term health hazard from inhaling nicotine remain uncertain, because there is no experience of such use other than from cigarettes, it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided.
It is also clear that many smokers would prefer not to have to smoke to get nicotine, provided that they can access the drug in doses and formulations that they find satisfying and acceptable. The availability and use of an oral tobacco product known as *snus* in Sweden, documented in more detail in our 2007 report (and revisited in Chapter 7), demonstrates proof of the concept that a substantial proportion of smokers will, given the availability of a socially acceptable and affordable consumer alternative offering a lower hazard to health, switch from smoked tobacco to the alternative product. Particularly among men, the availability of *snus* as a substitute for smoking has helped to reduce the prevalence of smoking in Sweden, which is now by far the lowest in Europe. The magnitude of the contribution made by the availability of *snus* over and above conventional tobacco control measures is difficult to quantify, but a recent study of the effect of withdrawal of *snus* from the market in Finland in 1995, when both Finland and Sweden joined the EU, but only Sweden was allowed to continue its use, estimates that over the following 10 years the availability of *snus* reduced smoking prevalence in Sweden by an additional 3.7 percentage points. Trends in *snus* use in Norway are similar to, and perhaps stronger than, those in Sweden, and there the use of *snus* is strongly associated with quitting smoking.

### 1.3 Role of harm reduction in tobacco control policy

In 1962, the RCP’s *Smoking and health* report promoted a range of smoking prevention measures, including a list of policies that, under the heading ‘Possible action by the government’, probably represented the first published comprehensive tobacco control strategy. The core components – preventing tobacco advertising, increasing prices, making public places smoke free, providing treatment for smokers, educating the public and restricting young people’s access to cigarettes – remain at the centre of modern tobacco control strategy as promoted by the WHO and the FCTC.

These policies are effective and, when countries and states adopt them comprehensively, the prevalence of smoking falls slowly. Australia, Canada and the UK have implemented increasingly extensive ranges of tobacco control policies over recent decades and, in these countries, over the past 10 years or so, prevalence has fallen respectively by around 0.6, 0.75 and 0.7 percentage points per year. Adult smoking prevalence is now below 20% in all of these countries, but, even if these rates of decline can be sustained, it will take more than two decades before rates start to approach zero. Meanwhile, substantial numbers of people in these countries continue to smoke: nearly 9 million in the UK, 4.6 million in Canada and 3 million in Australia remain exposed to the harm of smoking. Tobacco control policies may have a greater effect when introduced together for the first time in a high-prevalence setting: in Uruguay,
for example, a comprehensive package of tobacco control measures was introduced in 2005, when adult smoking prevalence was around 34%, and led to a reduction in smoking prevalence of around 1.1 percentage points per year for the next 6 years. However, even if this rate of decline can be sustained, it will take three decades to eradicate smoking, during which most current smokers will continue to be harmed or killed by their addiction. It is therefore important to complement this approach with strategies to reduce or prevent harm in those who will otherwise continue to smoke.

To date, harm-reduction strategies have tended to focus on reducing emissions and absorption of toxins from conventional cigarettes, eg through the use of filters and attempts to limit tar yields, although the latter proved to be more of a marketing device for the tobacco industry than a genuine reduction in harm potential. More radical strategies, such as promoting alternative sources of nicotine as a sustained substitute for smoking, have until recently been pursued only in the context of therapies for individual smokers attempting to quit. The potential for more widespread nicotine product substitution at a population level, with the primary objective of changing the source of nicotine used by smokers rather than ending all nicotine use, has not to date been widely adopted as a public health policy. The evidence from Sweden suggests that the harm reduction could add a further 0.4 percentage points per year to the rate of decline in smoking prevalence, and hence make a substantial contribution to public health.

**1.4 Developments since the publication of the 2007 RCP report and the need for this update**

When the RCP published its last report on harm reduction in 2007, options for alternative nicotine products for use in a population-level harm-reduction strategy were limited to smokeless tobacco, the supply of which in the UK is subject to severe constraints under the terms of legislation passed in 1992, and medicinal NRT products, which many smokers find unsatisfactory as a long-term substitute for smoking. However, the nicotine harm-reduction landscape has since been transformed by the emergence of e-cigarettes which, as documented later in this report, have demonstrated a popularity among smokers akin to that of snus in Sweden. The emergence of e-cigarettes has also provoked substantial controversy among those involved in tobacco control, wider public health policy and practice, and the general population, and a spectrum of regulatory responses in different countries that range from free market access to outright prohibition. This report has been produced to review developments relevant to tobacco harm reduction since the publication of the 2007 RCP report *Harm reduction in nicotine addiction*, to look in particular at the effect that this new product category has had on smoking and nicotine use in the UK, and to make further
Tobacco harm reduction

recommendations as to how the potential for this approach to prevent death and disability from tobacco use might be realised, within an appropriate and proportionate regulatory framework.

1.5 Summary

> Tobacco smoking is addictive, and causes an extensive range of harm to health and wellbeing in individuals and wider society.
> Tobacco smoking contributes more to social inequalities in health, and to overall death and disability, than any other avoidable cause.
> Smoking is preventable, and smoking prevalence falls progressively when countries implement a comprehensive range of tobacco control policies.
> The rate of decline is slow, however, with millions of smokers in the UK alone continuing to be exposed to the immediate and long-term hazards of smoking.
> Harm reduction aims to reduce or prevent harm in those smokers who do not respond to conventional tobacco control approaches by quitting smoking.
> Harm reduction works by providing smokers with the nicotine to which they are addicted without the tobacco smoke that is responsible for almost all of the harm caused by smoking.
> E-cigarettes are a new product class that has proved popular with smokers and offers a viable harm-reduction option.
> E-cigarettes have proved highly controversial and have provoked widely different regulatory responses in different countries.
> It is therefore important to look carefully at the role that these and other novel nicotine products might play in helping to prevent death and disability caused by smoking, and to consider how regulation should be applied proportionately to maximise this benefit.

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Smoking in Britain

2.1 Recent trends and current prevalence of smoking in the UK

Reliable national data on the prevalence of smoking among adults in Britain were collected from 1972 to 2011 in the General Household Survey,1 and since that date in the Opinions and Lifestyle Survey1 and the Integrated Household Survey.2 Data from these sources demonstrate that, over the more than four decades for which survey data are available, smoking prevalence fell from 51% of men and 41% of women in 1972,1 to 21% of men and 16% of women in 20142 (Fig 2.1). Applying age- and gender-specific smoking rates to the 2013 population estimates of the Office for National Statistics (ONS),3 there are approximately 8.7 million adult smokers in the UK, of whom 4.8 million are men and 3.9 million women.

Fig 2.1 Smoking prevalence in men and women in Britain, 1972–20131 and 2014,2 (Adapted with permission from the Office for National Statistics1,2 under Open Government Licence.)
Smoking has always been more common among men than women, and is also related to age and socio-economic status. Especially over the past two decades, smoking tends to be most common among young adults, and least so among older people, but is following a predominantly downward trend in all age groups (Fig 2.2).

Fig 2.2 Smoking among men and women in Britain, by age 1974–2013.\textsuperscript{1} (Adapted with permission from the Office for National Statistics\textsuperscript{1} under Open Government Licence.)
Cross-sectional prevalence data by age demonstrate that smoking is currently most common among young adults, and particularly among men aged 25–34 (Fig 2.3). Age-group data also demonstrate marked falls in smoking prevalence.
over the decade from 2004 to 2014 in all age groups, but particularly in younger adults (Fig 2.4).

Smoking among children is also falling, even more markedly than among young adults. Figure 2.5 shows that the proportion of children aged 11–15 in England who report that they currently smoke at least one cigarette a week has fallen by around two-thirds since the 1990s, to figures of 4% and 3%, respectively, in girls and boys. Over the past 10 years the prevalence of smoking in all people aged 11–15 has fallen from 9% to 3%, with smoking among the youngest participants (those aged 11 and 12) falling to almost zero (Fig 2.6). Similarly substantial declines in smoking prevalence among young people have also occurred in Scotland.

2.2 Smoking and disadvantage

Smoking is strongly associated with socio-economic disadvantage, however defined or measured. Figure 2.7 shows prevalence trends over time in Britain according to occupational socio-economic status, and demonstrates a falling prevalence in all groups since 2001, but also prevalence that is twice as high, and falling more slowly, among those in routine and manual occupations relative to the managerial and professional group.
A more detailed breakdown of smoking by occupation, from the Integrated Household Survey, demonstrates a clear and direct relationship between smoking...
prevalence and occupational social group, being highest in the least skilled occupations (Fig 2.8).

In 2013, smoking in Britain was almost twice as prevalent among unemployed people (35%) as among those in employment (19%), and in those with incomes below £20,000 per year (23%) than those with incomes greater than £40,000 (11%).\(^1\) Smoking is about twice as prevalent among those with a long-standing mental health condition than in those without (Fig 2.9), and similar among those with schizophrenia or other psychosis in 2010\(^6\) to those in the general population in the 1970s.\(^1\) Among other severely deprived groups, such as those who are homeless, imprisoned, or dependent on other drugs or other substances, most smoke.\(^6\) The strong relationship between smoking and deprivation means that passive exposure to tobacco smoke, particularly in children, tends to be much higher among children living in relatively deprived households.\(^7\)

Socio-economically disadvantaged people not only are more likely to be smokers, but also tend to be more heavily dependent on smoking. Levels of cotinine, a metabolite of nicotine (see Chapter 4) and a marker of nicotine dependence, are consistently higher among relatively disadvantaged smokers across all age groups\(^8\) (Fig 2.10).

Fig 2.8  Smoking by occupation in Britain 2014.\(^2\) (Adapted with permission from the Office for National Statistics\(^2\) under Open Government Licence.)
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Fig 2.9 Smoking prevalence among people with a long-standing mental health problem, and in the general population, UK 1993–2013. (Updated for this report from the RCP.6)

Fig 2.10 Saliva cotinine levels in smokers in relation to age and deprivation (data from 1998 to 2003).8 (Adapted with permission from Action on Smoking and Health.8)
2.3 Trends in the uptake and progression of smoking in the UK

2.3.1 Smoking uptake

Most smokers in the UK start smoking during their teenage or early adult years. In Britain in 2011, the most recent year for which data are accessible, 68% of male and 65% of female current smokers, respectively, reported that they started smoking before age 18, and 95% and 93%, respectively, before age 25. Children in lower socio-economic status households tend to start smoking at an earlier age: 43% of smokers in 2011 who grew up in households in which the main wage earner was employed in a manual or routine occupation took up smoking before age 16, compared with 31% of those from professional and managerial households. Uptake after age 25 is rare in men and women, and in all socio-economic groups.

Smoking status in young people tends to be less dichotomous than in adults, because much early use is occasional and experimental, with a relatively low likelihood of leading to sustained smoking. Comparison of smoking behaviour between children and adults is also complicated by the different survey questions used to define smoking in national surveys in these groups. Thus, by the age of 15 in 2014, 35% of children in England had tried smoking at least once, 5% had smoked occasionally but less than once per week and 8% were smoking regularly, which in this survey is defined as smoking at least once a week. From age 16, the question used to define regular smoking changes to 'Do you smoke cigarettes at all nowadays?' and by this definition 17% of those aged 16–19 in 2014 were regular smokers. Among those aged 20–24, smoking prevalence was 25% (see Fig 2.4).

However, these are cross-sectional data, so the prevalence of smoking in those aged 20–24 in 2014 will not necessarily apply to younger cohorts when they reach that age. As Figs 2.6 and 2.7 demonstrate, uptake of smoking among children and young people is falling rapidly, indicating that children born since the early 1990s may be substantially less likely than their predecessors to take up smoking, at least in their teens; and, unless these cohorts take up smoking in their 20s to a much greater degree than has typically been the case in the past, it appears that today's children and young people in the UK are much less likely than their predecessors to become smokers. The marked decline in smoking prevalence among 11- to 15-year-olds began in 2006 (see Fig 2.6) and is likely to be attributable primarily to the major tobacco control interventions of the decade: the phased removal of tobacco advertising in the UK from 2002 and smoke-free legislation, which was in place across the UK by the end of 2007.

2.3.2 Quitting

The proportion of people who have smoked regularly in the past but do not smoke now increases progressively with age. Taking data for 2011, around 2% of
men and 4% of women aged 16–19 describe themselves as ex-smokers, whereas, of those aged 60 and over, the respective proportions are 45% and 30%. Although the latter figures are likely to be biased upwards by the higher mortality in continuing smokers, this bias will be less marked among those aged 50–59. In this age group in 2011, 27% of men and 24% of women were ex-smokers, whereas 20% and 18%, respectively, were still smoking. These data therefore indicate that over half of those who had ever been regular smokers quit before they reached the age of 60, but that over 40% continue to smoke beyond that age.

2.3.3 Uptake and quitting within birth cohorts

Cross-sectional data on current smoking prevalence and past quitting are not representative of trends within cohorts of UK individuals born at different times. Figure 2.11 shows General Household/General Lifestyle Survey data from 1972 to 2011, provided by the UK Data Service, analysed to estimate smoking prevalence within 5-year birth cohorts over the duration for which data are available. Figure 2.11 demonstrates that, in more recent birth cohorts, smoking prevalence tends to be highest at around 25 years of age, but also that the peak within-cohort

![Fig 2.11](image-url)

Fig 2.11 Smoking prevalence in Britain from 1972 to 2011, by 5-year birth cohort in people born since 1920.
prevalence has fallen progressively in successive cohorts from almost 50% in those born between 1951 and 1955, to under 30% in those born since 1986. Peak prevalence levels in earlier cohorts are not known, but the steady downward trend in prevalence in all of them indicates that they were probably substantially higher. After age 24 the prevalence of smoking declines in all cohorts, and this decline is likely to be attributable primarily to quitting smoking during mid-adult life, and also to earlier mortality among smokers in older age groups. The rate of this decline in smoking prevalence within recent cohorts is of the order of 1 percentage point per year, which, if sustained, indicates that, by the time today’s 20- to 24-year-olds reach the age of 50, their smoking prevalence is likely to have fallen from around 30% (see Fig 2.4) to about 5%.

### 2.4 Current and expected future mortality and morbidity from smoking

Mortality from smoking tends to lag behind smoking prevalence by several decades, and reached a peak of around 151,000 deaths per year in the UK in the mid-1980s (Fig 2.12). This total has since declined progressively to 103,000 in 2009. Data for England since 2009 suggest that this trend has continued, with an estimated 78,200 people, equivalent to about 93,000 in the UK, killed by smoking in 2014. The decline has to date been due predominantly to a relatively marked fall in cardiovascular mortality (Fig 2.13), although modest

![Fig 2.12 Deaths from smoking, total and by gender, UK 1950–2009. (Data for figure from Peto et al.)](image-url)
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Generating estimates of morbidity from smoking is a more complex process and direct data are not available. However, figures on hospital admissions attributable to smoking provide a proxy for morbidity, and demonstrate a sustained rise over the past decade, from 1.38 million in 2003–4 to 1.63 million in 2013–14.12

2.5 Summary

- Smoking prevalence has been falling for several decades in the UK, in all age groups, in both men and women.
- Smoking prevalence has fallen particularly markedly since 2007 among children and young people.
- Smoking remains much more prevalent among socio-economically disadvantaged individuals and those with mental health problems.
- Uptake of smoking appears to be falling progressively, whereas quit rates appear to be remaining relatively constant across successive cohorts.
- Smoking remains most prevalent among disadvantaged individuals, and addiction to nicotine tends to be higher in more disadvantaged smokers.
This means that the approximately 8.7 million smokers in the UK today include a high proportion of the most disadvantaged individuals in society, who as a result of higher levels of addiction are likely to find it particularly difficult to quit smoking.

Smoking is likely to be rare among today’s young people as they approach older age, but continuing efforts to reduce child uptake of smoking are vital.

However, smoking continues to cause significant mortality and morbidity, in part as a consequence of higher smoking rates in past decades.

Helping disadvantaged smokers to quit or else reduce the harm caused by smoking is therefore a key priority to prevent current and future death and disability.

References


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3 Effectiveness of current and future tobacco control policy

3.1 Background

In 1962, when most men and almost half of all women in the UK were regular smokers, the RCP’s report, *Smoking and health*, identified tobacco smoking as the primary cause of the twentieth-century global epidemic of lung cancer and proposed a range of policies to reduce smoking prevalence.\(^1\) Progress with implementation of these policies remained slow, however, until the first comprehensive UK tobacco control policy document, *Smoking kills*, was published in 1998.\(^2\) *Smoking kills* recognised the devastating effect of tobacco smoking on UK public health, and committed to reduce smoking in children and young people, help adults to stop smoking, prioritise reducing the prevalence of smoking in manual occupational groups as a means of decreasing health inequalities, and offer particular help to pregnant smokers. Drawing heavily on the policy recommendations of *Smoking and health*, *Smoking kills* defined a package of tobacco control policies including the following:

- a ban on tobacco advertising and sponsorship
- tobacco tax rises
- enforcement of underage sales laws
- reducing point-of-sale tobacco advertising
- introducing smoking cessation services
- facilitating access to smoking cessation medication
- voluntary measures to reduce passive smoke exposure in public places and workplaces.

Shortly after *Smoking kills* was published, powers for key policy areas, including health, were devolved to the newly established Scottish Parliament, Welsh Assembly and Northern Ireland Assembly, although some powers relevant to tobacco, such as fiscal policy (via the Treasury), remained within the remit of the Westminster government. However, *Smoking kills* had set the scene for tobacco policy changes throughout the UK and, in the years that followed, the main policies it recommended were implemented throughout England and the devolved nations. These new measures included comprehensive smoke-free
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legislation, which was implemented in Scotland in 2006 and throughout the rest of the UK by the end of 2007. Each of the UK nations has since produced their own tobacco control strategies, with some variation in emphasis and the timing of how policies were introduced. The core strategies are, however, broadly similar and articulated in the most recent tobacco control plan for England, which was published in March 2011. This plan committed to:

- implementing legislation to end tobacco displays in shops
- considering and consulting on plain packaging of tobacco products
- continuing to defend tobacco legislation against legal challenges by the tobacco industry
- continuing to follow a policy of using tax to maintain the high price of tobacco products
- promoting effective local enforcement of tobacco legislation
- encourage more smokers to quit by using the most effective forms of support, through local stop smoking services
- publish a 3-year marketing strategy for tobacco control.

Progress has been made on all these objectives, particularly in ending point-of-sale tobacco displays and passing legislation mandating standardised packaging for tobacco products. The plan also proposed adopting a harm-reduction strategy based on helping tobacco users who cannot or are unwilling to quit smoking to substitute alternative safer sources of nicotine for tobacco, to be supported by guidance from the National Institute for Health and Care Excellence (NICE), which was in development at the time but published in due course in 2013, and undertook to encourage the development of new, affordable and acceptable nicotine products. The UK government elected in 2015 has committed to a new tobacco strategy, although a publication date has not been set.

In addition to national and devolved government actions, tobacco control policy in the UK is significantly influenced by international treaties and initiatives. UK tobacco policy is shaped by the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), a global health treaty ratified by most of the world’s countries, including the UK, that defines a comprehensive range of tobacco control policies and practices that all political parties undertake to implement. At the European level, European Union (EU) single market rules have also been a driver of significant policy initiatives across all EU member states in recent years, including legislation banning tobacco advertising (2003/33/EC) and mandating health warnings on tobacco packs (2001/37/EC, known as the Tobacco Products Directive, or TPD). A revision of the TPD (2014/40/EU), which comes into force in 2016, will impose a minimum pack size of 20 cigarettes (and 50 g hand-rolling tobacco), require combined pictorial and text health warnings to cover 65% of the front and back of the pack, and end
cigarette flavouring. The new TPD will also set out product standards and regulations on the sale of e-cigarettes (see Chapter 9). UK tobacco control policy thus continues to be shaped by both national initiatives and international agreements and legislation. The combination of these processes has led to the UK becoming the European leader in tobacco control policy implementation.

3.2 Tobacco control policy effectiveness and implementation in the UK

3.2.1 Increasing the price of tobacco products

Fiscal measures, including tobacco taxation, are a key element of tobacco control. In the UK, tobacco tax increased in the mid- to late 1990s, through an escalator of 3% above inflation from 1993 to 1997 and 5% above inflation from 1997 to 2000. From 2001 to 2008 taxes rose in line with inflation, until, in 2009, a tax escalator was reintroduced, which is currently set at 2% above inflation, a commitment that runs until the end of the current parliament in 2020. Overall, between 1980 and 2012 the affordability of tobacco declined by 28%, although, relative to the 1960s’ prices, tobacco was approximately 50% more affordable in 2006 than when Smoking and health was published in 1962, and remains more affordable today. The price of the most popular price category cigarettes, a metric that initially reflected the price of the most popular brand or brands on the market, but now typically represents the prices of the more expensive (premium-brand) cigarettes, has increased consistently over the last three decades (Fig 3.1), with the result that the UK now has some of the highest premium-brand prices in Europe. However, the price of cigarettes in the ultra-low price category favoured by younger and more disadvantaged smokers has remained virtually static in recent years, thus undermining the effects of tobacco tax rises.

The World Bank suggests that price increases through higher taxation are the single most effective and cost-effective tobacco control measure. Its estimates from the late 1990s suggested that a price increase of 10% typically decreases adult consumption by around 4% in developed countries. A 1996 study in the UK produced an estimate consistent with the World Bank figure, with a price increase of 10% reducing consumption by 5% and with evidence that lower socio-economic groups were more responsive than those in higher socio-economic groups to changes in the price of cigarettes. These figures were disputed in a recent paper by HM Revenue and Customs (HMRC), which estimated that the price elasticity of demand for cigarettes increased in the period from 1982 to 2009, suggesting that a 10% increase in price now reduces consumption by 10%. However, this study included duty-paid manufactured cigarettes only, and did not take into account other types of tobacco, such as...
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Evidence from a wide range of settings consistently demonstrates the effectiveness of price increases as a tobacco control measure. From 1990 to 2005, France tripled inflation-adjusted cigarette prices by raising taxes 5% or more every year in excess of inflation and, during the same period, cigarette consumption halved and smoking prevalence fell by a quarter. Comparable price increases in South Africa achieved similar reductions in consumption. However, the available evidence relates predominantly to the effects of relatively small, incremental price rises over time; the effects of sudden large price rises are less well defined. Data from France indicate that a single large increase in tobacco taxation in 2003, which caused the price of a packet of premium-brand cigarettes to rise in real terms by almost 20%, resulted in a 13.5% decline in sales. This implies that sudden large price increases may be more effective than repeated smaller rises.

There is also consistent international evidence that raising taxes to increase the price of tobacco reduces smoking among young people, who as a group are more responsive than adults to price increases. The US surgeon general’s report on preventing youth smoking concluded that increases in cigarette prices reduce

Fig 3.1 Price and affordability of tobacco, 1980–2012. (Adapted from the Health and Social Care Information Centre under Open Government Licence.)

hand-rolling tobacco, to which many smokers downtrade when prices for manufactured cigarettes rise.
initiation, prevalence and intensity of smoking among both children and young adults.\textsuperscript{23} Evidence from developed countries indicates that a 10% increase in price reduces youth consumption by between 5 and 12%.\textsuperscript{24} There is also evidence from high-income countries that low socio-economic status (SES) groups are more responsive to price increases, indicating that tobacco price increases have a key role to play in reducing inequalities in health caused by tobacco use.\textsuperscript{25} Two systematic reviews have recently assessed the equity impact of tobacco control in high-income countries, in terms of differential impact on SES groups, in both young people and adults.\textsuperscript{26,27} The reviews found that the clearest and most consistent evidence of a positive equity impact (ie reduced inequalities in smoking) for all types of tobacco control in adults, and to a lesser extent in young people (as there are fewer studies on this), related to price increases.

Although UK tobacco prices increased throughout the 1990s, the effects of increasing taxation during this period were undermined by, among other things, a rapid increase in the market share for illicit cigarettes, which rose from 3\% in 1996–7 to 21\% by 2000–1.\textsuperscript{28,29} This meant that smokers were switching to cheap, illicit cigarettes rather than quitting in response to price rises. This and a relative absence of other tobacco control measures during this period resulted in little change in UK smoking prevalence, despite year-on-year price rises. From 2000, however, a comprehensive anti-smuggling strategy reduced the supply of illicit cigarettes from 21\% in 2000–1 to 9\% in 2012–13. This included, from 2006, legislation imposing substantial fines on manufacturers who failed to prevent their products from being smuggled into the UK.\textsuperscript{28} Since then, however, tax increases have been undermined by new developments in tobacco industry pricing strategy, with the creation of a range of ultra-low-price cigarettes and the practice of ‘overshifting’ tax on to more profitable premium brands, leaving ultra-low brand prices relatively unchanged.\textsuperscript{12} The consequence of this strategy is that many smokers who might otherwise quit smoking or else reduce their consumption in response to price rises now ‘downtrade’ to lower-price brands, or indeed switch to hand-rolling tobacco.

\subsection*{3.2.2 Restrictions on smoking in public places, workplaces and cars}

The health effects of passive smoke exposure are well documented\textsuperscript{30} and, to protect workers and the public from these effects, bans or restrictions on smoking in public places and workplaces are a key component of tobacco control policy. In the UK, smoke-free legislation was introduced first in Scotland in March 2006, in Wales and Northern Ireland in April 2007, and in England in July 2007.

There is now extensive international and UK evidence that smoke-free laws are effective in reducing passive exposure to smoke. Before the 2007 smoke-free legislation, the highest levels of occupational passive exposure to smoke in the
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UK occurred in serving staff in bars and pubs.\textsuperscript{31} A study of bar workers in England, Scotland and Wales showed that their exposure was reduced on average by between 84\% and 93\% after introduction of the legislation.\textsuperscript{32} Children are particularly vulnerable to the effects of tobacco smoke, and research in Scotland, Wales and Northern Ireland found that passive exposure of children to smoke declined after the introduction of the legislation in these countries.\textsuperscript{33} Between 1998 and 2012 in England, passive smoke exposure among children declined by 79\%, and the most rapid decline occurred in the period immediately before smoke-free legislation came into force, thus coinciding with national mass media campaigns highlighting the dangers of passive smoke exposure.\textsuperscript{34} Smoke-free legislation in the UK has also had positive effects on child and adult health, with substantial reductions in preterm deaths, childhood admissions to hospital with asthma and adult admissions for myocardial infarction.\textsuperscript{35–38}

Smoke-free legislation also acts as an incentive to smokers to quit smoking. The Smoking Toolkit Study found that, at the time of the legislation in England, the number of smokers trying to quit smoking increased significantly, with approximately 300,000 additional quit attempts made.\textsuperscript{39} Scottish data suggest that quit attempts increased in the 3 months leading up to Scotland’s smoke-free legislation,\textsuperscript{40} after which there was a temporary fall in prevalence in addition to the secular reducing trend.\textsuperscript{40} A further study has suggested that, although smoke-free legislation was not associated with additional reductions in smoking prevalence, existing decreasing trends continued in the 18 months following implementation of the ban.\textsuperscript{41}

Two systematic reviews have recently assessed the equity impact of smoke-free policy in high-income countries on young people and adults.\textsuperscript{26,27} A youth review found that, of the six studies that had looked at the equity impact of comprehensive smoke-free legislation, two had a neutral effect and four were negative in terms of second-hand smoke (SHS) exposure.\textsuperscript{26} Declines in SHS exposure occurred predominantly among children who had low SHS exposure before smoke-free legislation, and who were from more affluent families. Thus, the substantial SES gradients in children’s SHS exposure levels remained unchanged. Welsh data showed that, although there was a significant decline among high-SES children perceiving adult smoking as the norm, there was no change among children from low-SES households.\textsuperscript{42} Thus, SES disparities in children’s perceptions of adult smoking as normative increased, which is of concern because social norms are important influences on smoking uptake. An adult equity systematic review found that comprehensive national smoke-free legislation was much more likely to have a neutral or positive equity impact than voluntary partial policies.\textsuperscript{27}

Following the success of smoke-free legislation in the UK, there are continuing efforts to extend smoke-free policies to other settings. Some cities are considering
extending smoke-free laws to outdoor public places including parks or other open spaces. Since October 2015 it has been illegal for drivers in England and Wales to smoke in private cars in the presence of children, and Scotland and Northern Ireland are in the process of introducing similar legislation. Recent UK research suggests that around one-fifth to one-third of 11- to 15-year-olds are exposed to SHS in cars sometimes or often, and that this is concentrated among those from more deprived backgrounds. Around three-quarters of adolescents reported disliking being exposed to SHS in cars. Around one-third of 8- to 15-year-olds who reported ever being exposed to SHS in cars felt too embarrassed or frightened to ask someone smoking in a car when they were present to stop. Most children, adults and adult smokers in the UK support a ban on smoking in cars where children are present.

3.2.3 Mass media campaigns

Tobacco control mass media campaigns (MMCs) use television, radio, newspapers and other media channels to reach large numbers of smokers and encourage them to quit smoking, reduce harm to self or others from tobacco use, and prevent young people from taking up smoking. Large-scale MMCs have been a key component of UK tobacco control strategy since the early 2000s, and there is strong evidence that tobacco control MMCs can increase adult smoking cessation and reduce youth uptake. Campaigns in England have varied in informational content; approximately half of the adverts between 2004 and 2010 warned of the negative consequences of smoking, whereas half contained information on how to quit smoking. In April 2010, the government ceased spending on national public health MMCs in England. A tobacco control MMC was reintroduced in England in September 2011, but at a much lower rate of funding. Mass media are also used to promote the ‘Stoptober’ campaign, which has run every year since 2012 and encourages smokers to quit for the month of October. Examples are shown in Fig 3.2.

The magnitude of the independent effect of MMCs on smoking behaviour is difficult to establish when, as is usually the case, they are used together with other tobacco control policies. However, several recent studies have assessed the impact of MMCs on a range of measures of quitting behaviour in England (and, to a lesser extent, Wales), including quit-line calls, hits on the national Smokefree website, and measures of cigarette consumption and smoking prevalence. Over the period from 2002 to 2009, when adult smoking prevalence in Britain fell from 26% to 21%, an estimated 13.5% of this decline was attributable to the effect of MMCs. A further study showed that positive emotive campaigns – predominantly those promoting the use of NHS Stop Smoking Services – and negative emotive campaigns – generally those containing negative health effects messages – played a statistically indistinguishable role in
triggering this effect. More recently, the annual English Stoptober campaign, which aims to create a positive quitting trigger around a specific call to action – stopping for 28 days – and which uses a combination of traditional and new
media, was estimated to have generated an additional 350,000 quit attempts and
9,000 permanent quitters in October 2012.63

Research from Australia has suggested that the level of exposure to MMCs
required to obtain a detectable reduction in smoking prevalence is the equivalent
of four exposures per person per month (390 gross rating points, known as
GRPs).47 Between 2004 and the spring of 2010, campaign exposure in England
exceeded this threshold in around 40% of months; in other months, exposure
was lower, with no campaign at all during 1 in every 5 months.54 A recent study
found that, below 400 GRPs per month, there was little impact of campaigns on
quit-line calls in England, and that the effect increased significantly above the
400 GRP threshold,59 suggesting that efforts should be made to maintain
exposure above this level.

The US surgeon general’s report on prevention of smoking in youth concluded
that MMCs can be one of the most effective strategies in changing social norms
and preventing youth smoking.23 The surgeon general concluded that the
characteristics of effective campaigns included evoking strong negative emotions
(eg health effects, deceptiveness of the tobacco industry), an appealing format,
clear messages, intensity and adequate repetition (at least four advertising
exposures per month over a 4-month period). There was strong evidence that
MMCs aimed at adults also decreased smoking among young people.

Two recent systematic reviews have looked at the equity impact of MMCs on
youth and adults. The youth equity review found only one study that had
assessed the equity impact of MMCs on young people by SES.26 This was an
evaluation of the US Truth campaign, which had mixed equity effects depending
on the outcome measure used.65 The adult review found 30 studies that had
looked at the equity impact of MMCs.27 These studies included a diverse range
of approaches and messages, including some aimed at increasing quit
motivations and/or attempts, and some aimed at increasing calls to quit-lines or
uptake of free nicotine replacement therapy (NRT). The equity impact of these
campaigns was inconsistent. This is perhaps not surprising given the diversity of
messages, media formats and levels of exposure. There was some evidence that
certain types of message, such as those with a higher emotional narrative, are
more effective with low-SES smokers. A previous review also found that the
impact of campaigns can vary by SES depending on the type of message, media
format and mechanisms of engagement.66,67

3.2.4 Health warnings

Health warnings on tobacco packages are a means of communicating the risks of
tobacco use to smokers. Text warnings became a legal requirement in the UK in
1971, and since 2008 graphic pictorial warnings covering 40% of the back of the pack, and text warnings covering 30% of the front of the pack, have been required (Fig 3.3). The new EU TPD will see a further increase in the prominence of health warnings, with picture and text warnings covering at least 65% of the front and back of tobacco packaging by May 2016.

Studies from a wide range of countries indicate high levels of awareness of pack health warnings among both smokers and non-smokers. Large text warnings have been shown to be linked to increased knowledge about the health risks of smoking and increased motivation to quit. In the UK, a study of text-only warnings found that they were noticed by over half of smokers, and that those noticing warning labels were more likely to know about the health risks of smoking. Pictorial warnings are likely to be most effective because they are more likely to be noticed, improve memory for the health message, and are associated with stronger beliefs about the risks of smoking and increased motivation to quit.

Determining whether exposure to health warnings is causally related to changes in smoking behaviour has been difficult, owing to the challenges of disentangling their effect from those of other interventions. Research has suggested that pictorial health warnings increase the likelihood of a quit attempt and that health warnings can help to prevent relapse. Some studies have investigated the effect of health warnings on smoking prevalence, with some suggesting positive effects, although other factors may also have contributed. The US surgeon general’s report on prevention of smoking in youth concluded that small text-only health warning labels have limited impact on youth and...
young adults, but that larger text or pictorial warnings that elicit strong emotional reactions are significantly more effective at discouraging tobacco use.23

Systematic reviews of the equity impact of tobacco control policies found no studies that had assessed the equity impact of health warnings in young people,26 and five studies of the effect of health warning labels in adults.27 EU text-only health warnings and the addition of a quit-line number to new pictorial health warnings were found to have had a greater impact on low-SES groups, and the rest were equity neutral.

3.2.5 Comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names

Prohibiting advertising and promotion of tobacco products is a key element of tobacco control. Television advertising for tobacco products was banned in the UK in 1965 under the Television Act 1964, almost 25 years earlier than an EU directive that prohibited television advertising across the EU in 1989 (Television without Frontiers Directive (89/552/EEC)).85 This directive was replaced by the Audiovisual Media Services Directive (2007/65/EC) adopted in December 2007.86 Subsequently, the UK Tobacco Advertising and Promotion Act 2002 (TAPA) banned print media and billboard advertising from February 2003, tobacco direct marketing from May 2003 and sponsorship within the UK in July 2003.

Advertising bans have been shown to reduce smoking uptake in children by lessening its social desirability, and also to reduce tobacco consumption in adults. The introduction of comprehensive advertising bans in Norway, Finland and France resulted in significant reductions in tobacco sales in the period following the introduction of the legislation.87 The US surgeon general’s report on prevention of smoking among youth concluded that there is a causal relationship between tobacco advertising and promotion, and the initiation and progression of smoking in young people.23 It also concluded that comprehensive cigarette advertising bans reduce youth smoking. The World Bank has estimated that comprehensive advertising bans can reduce consumption by around 7%.88

A recent systematic review found four studies that had assessed the equity impact of restrictions and bans on advertising and promotion, all of which had a neutral equity effect.27 A similar review on the equity impact on young people found four US studies indicating that, when there is no enforced control of advertising, promotion or marketing of tobacco, there is the potential for increased inequality in youth smoking.26

The main exclusions from TAPA, and hence the key remaining forms of promotion, were displays of tobacco packs at the point of sale in shops, and the
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Pack itself. Legislation ending both of these exclusions has now been passed in the UK. Point-of-sale displays were removed from large retailers such as supermarkets in England, Northern Ireland and Wales from April, October and December 2012, respectively, and April 2013 in Scotland. Point-of-sale displays in smaller shops were prohibited across the UK from April 2015 (Fig 3.4). Studies of the removal of point-of-sale displays in Iceland and Ireland suggest that the policy is supported by the public and that there are signs that prohibition helps to denormalise smoking. A recent systematic review of the impact of point-of-sale promotion on youth smoking found that there was a positive association between exposure and smoking-related outcomes, including smoking and smoking susceptibility. The review also found that point-of-sale bans may contribute to a shift in youth perceptions about peer smoking prevalence, but found no evidence of short-term population-level impacts on smoking.

Fig 3.4 Examples of tobacco point-of-sale displays in small retailers in England, before and after prohibition.
Legislation to introduce standardised tobacco packaging in the UK was approved in March 2015, and from May 2016 imposes a standard plain dark-green/brown design and a large graphic health warning on all tobacco packaging, and limits branding to a name and descriptor in a specified and standard plain font (Fig 3.5). A systematic review published in 2012 found that plain packs were rated as less attractive than branded equivalent packs, or unattractive, by young people.91 An independent review into standardised packaging published in 2014 concluded that the measure is likely to lead to a modest but important reduction in smoking, including among children.92 Public support for the measure is also reported to be high: in January 2015, a YouGov survey conducted for Cancer Research UK found that 72% of those polled supported standardised packaging.93

In 2012, Australia became the first country to introduce standardised packaging, and early evaluations suggest that the removal of branding from packaging has reduced the ability of the tobacco industry to use the pack to communicate to
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young people and adults, and made products less appealing.\textsuperscript{94–96} There is also evidence that standardised packaging has increased both thoughts about quitting and quit attempts in adult smokers, and reduced smoking prevalence.\textsuperscript{97,98} Concerns that standardised packaging would lead to reductions in the price of cigarettes and increases in illicit tobacco consumption appear not to have been borne out.\textsuperscript{99,100}

With point-of-sale and standardised packaging legislation complementing TAPA, there are few remaining means by which smoking can be promoted in the UK. However, tobacco and related imagery remains prevalent in the media, including films, television programmes, magazines and social media. Although paid-for product placement is illegal under the terms of TAPA, smoking imagery remains common in popular films, computer games and on prime-time UK television.\textsuperscript{101,102} Evidence suggests that there is a clear association between exposure to such imagery in the media and young people starting smoking.\textsuperscript{103} Smoking in the media thus remains a major driver of smoking uptake among children and young people, and needs to be addressed.

3.2.6 Restricting young people’s access to tobacco products

Measures to reduce young people’s access to tobacco have been recommended as a means of reducing uptake of smoking. Evidence arising mostly from the USA indicates that reducing youth access to tobacco by implementation of the minimum age-of-sale laws reduces smoking prevalence among young people, although this is highly dependent on levels of enforcement and access to alternative non-retail sources of cigarettes.\textsuperscript{104,105} European evidence indicates that access to cigarette-vending machines was significantly associated with regular smoking by young people.\textsuperscript{106}

Across the UK, the minimum age at which young people are permitted to purchase tobacco was raised from 16 to 18 in 2007, and legislation prohibiting vending machines was implemented between 2011 and 2013.\textsuperscript{107} The increase in minimum purchase age in England was associated with a significant reduction in regular smoking among 11- to 15-year-olds\textsuperscript{107} and a decline in smoking prevalence among 16- to 17-year-olds.\textsuperscript{108} The percentage difference in current smoking pre- and post-legislation was significantly greater among those under 18 than in older age groups. However, the effect of the legislation is undermined by substitution of other means of access, particularly proxy purchasing by adults.\textsuperscript{109,110} Scotland banned such sales in 2010 and England from 2015, although the Scottish legislation appears not to have been successful in reducing proxy sales.\textsuperscript{111}

A recent systematic review of the equity impact of tobacco control policies found only five studies that have assessed the equity impact of such measures on
Two were equity positive (greater impact on low-SES youth), two neutral (no difference by SES) and one negative (greater impact on high-SES youth). Thus, no overall conclusion can be drawn about their equity impact. However, stronger (i.e., comprehensive and enforced) US state-level, age-of-sale laws were associated with lower smoking initiation and a reduction in low-SES adolescent girls moving on to regular smoking. In England, raising the age of sale from 16 to 18 was associated with a significant reduction in regular smoking among those aged 11–15 years, with no difference by SES (measured by eligibility for free school meals). However, although the percentage of high-SES pupils who found it difficult to buy cigarettes from a shop increased, this was not the case for low-SES pupils.

### 3.2.7 Treatments to help dependent smokers stop, including increasing access to medications

Evidence-based smoking cessation treatments typically comprise behavioural interventions, delivered as brief advice from healthcare professionals, telephone quit-lines, more intensive one-to-one or group counselling, and pharmacotherapies, including NRT, bupropion and varenicline. The UK was one of the first countries to make these services easily available to all smokers as a tobacco control policy. In England and Wales, NHS Stop Smoking Services (NHS SSSs), free at the point of use, were launched in areas of high deprivation defined as Health Action Zones (HAZs) in 1998–9, and extended to the rest of England and Wales in 2000–1. The number of people using NHS SSSs grew year on year, rising to over 800,000 in 2011–12, although they have fallen each year since then to a total of 450,582 in 2014–15.

These services, which use evidence-based guidelines and strongly recommend the use of pharmacotherapy, have been shown to be effective over a number of years. A national evaluation conducted in the early years after their establishment found that 53% of attendees confirmed abstinence at 4 weeks, with 15% still abstinent at 1 year. This study has recently been updated, and 1-year abstinence rates are now lower, at 8%; however, some of this change may be attributable to the growth of less intensive and hence less effective forms of support, such as one-to-one interventions in pharmacies rather than individual or group behavioural support delivered by smoking cessation specialists. In the UK, cessation support is also available to smokers through stop smoking helplines and websites where smokers can speak to or converse online with a trained expert adviser. In a recent trial using the NHS Stop Smoking helpline, approximately 20% of smokers who agreed to set a quit date were abstinent at 6 months. The number of calls to the NHS quit-line is small, however, averaging 20,000 per month between 2005 and 2010.
Pharmacological therapies such as NRT, bupropion and varenicline are highly effective when delivered with behavioural support (see Chapter 5), and initiatives to increase access to these treatments by smokers should improve the success of quit attempts. Making cessation therapies available on reimbursable prescriptions and NRT products available on general sale, which occurred in the UK between 1999 and 2002, resulted in a rapid increase in the proportion of quit attempts supported by medication from 28% to 61%. However, a great deal more could be done to extend delivery of stop smoking interventions, particularly by making intervention a component of all NHS care delivery, including secondary care.

Smoking cessation services tend to be more effective in adults than in young smokers. The US surgeon general’s report on prevention of smoking in youth concluded that several cessation programmes for youth are efficacious in the short term but that, in contrast to adults, there is little evidence of the efficacy of pharmacotherapies in youth cessation. Data from the NHS SSSs indicate that relatively few under-18-year-olds access these services, and that those who do have lower quit rates than other age groups. A recent systematic review found only two studies that had assessed the equity impact on youth of cessation services. Participants in both studies were mobile phone owners in their late teens / early 20s, who were motivated to quit and received text messaging support. Only one study demonstrated a long-term effect on quitting and this was significant only in low-SES intervention participants.

The contribution of NHS SSSs to the reduction in smoking prevalence over recent years has been estimated at between 0.1 and 0.3% above the background quit rate per year. Although the impact on prevalence of policies and initiatives to improve access to treatment is modest, these interventions have been successful in reaching smokers in the most disadvantaged areas, who tend to be more addicted and have the most difficulty stopping. A recent systematic review of cessation studies concluded that untargeted smoking cessation interventions across Europe are, on balance, likely to have increased inequalities in smoking. However, the same review found that the comprehensive UK stop smoking services, which are targeted at low-SES smokers, have reduced inequalities in the harm caused by smoking, because higher reach among low-SES smokers compensates for lower quit rates.

### 3.3 Cumulative impact of conventional tobacco control policies and future challenges

Although evidence of the impact of individual interventions on smoking prevalence is limited by the difficulty of separating out the independent effects on smoking prevalence of individual components from a wider package of measures, the multi-component approach adopted in the UK appears to be
effective, for both adults and young people. The effectiveness of comprehensive packages of tobacco control policies has been further demonstrated in a recent study of the association between MPOWER policies – a list of measures developed by the WHO that are intended to assist in the implementation of interventions required by the FCTC (Monitor tobacco use and prevention policies, Protect people from tobacco smoke, Offer help to quit tobacco use, Warn about the dangers of tobacco, Enforce bans on tobacco advertising, promotion and sponsorship, and Raise taxes on tobacco) – and changes in prevalence, by scoring countries according to their implementation of MPOWER measures. The study showed that countries with higher MPOWER composite scores experienced greater decreases in current tobacco smoking between the years 2006 and 2009, and therefore underlines the need to implement the widest possible range of policies.\(^{125}\) The study also assessed the effect of changes in each MPOWER measure on changes in current tobacco smoking, and confirmed existing evidence that price increases are the most effective tobacco control measure.

Figure 3.6 demonstrates the declines that have occurred in smoking prevalence among adults and young people in Britain since *Smoking kills* was published in 1998, in relation to the timeline of policies introduced. The reduction of adult
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smoking by around one-third, and by almost twice that proportion among young people, represents a substantial success for tobacco control policy. However, these figures also demonstrate that, despite this progress, smoking remains a significant public health problem in the UK, with around one in five adults still smoking regularly.61,128 These smokers, who are increasingly predominantly from the more deprived SES groups in UK society,61 have by definition proved resistant to policies applied to date, and also by definition are in desperate need of measures to help them stop smoking.

The Scottish Government has recently set a target for Scotland to become ‘tobacco free’, defined as a smoking prevalence below 5%, by 2034. Figure 3.7 demonstrates how challenging it will be to meet this objective given current trends in smoking prevalence, particularly among low-SES groups, and it will be equally challenging in the rest of the UK. If such an ambition is to be realised, new tobacco control approaches that can bring about substantial declines in smoking among the most deprived individuals in society are urgently needed.

3.4 Developing a more effective tobacco control policy approach

There are many ways in which existing UK tobacco control policies could be improved and complemented to achieve faster declines in smoking.
In addition to policy measures already in place, greater investment in innovative MMCs, reversing declines in the uptake of SSSs and wider integration of smoking cessation interventions into NHS service delivery, extending smoke-free policies to a wider range of public places, preventing smoking promotion through media imagery and other loopholes in advertising and promotion legislation, and tighter measures to prevent youth access would all make contributions to this end.

However, the most effective policy measure is price. Repeated substantial increases in tobacco price, and removal of the price differentials for premium cigarettes, budget cigarettes and hand-rolling tobacco, would have a substantial impact, particularly among low-SES groups. The effect of taxes can be further enhanced if some of the revenue generated is used to support comprehensive tobacco control strategies. However, the negative effect of price rises on the incomes of those who continue to smoke, as well as the need to do more in general to provide smokers with alternative means to stop smoking, demands additional alternative approaches. Making non-tobacco nicotine products available to smokers, as envisaged in the Tobacco Control Plan for England and advocated in this report, could not only reduce the prevalence of smoking but also offset the negative effect of increased tax on continuing smokers by providing a more affordable and acceptable alternative product.

3.5 Summary

- Increasing the price of cigarettes reduces smoking prevalence, particularly among young and relatively disadvantaged smokers.
- Price increases may be more effective if introduced in single large rather than multiple small increments.
- The effect of price increases is undermined by the availability of illicit tobacco, and the option for smokers to downtrade to ultra-low-price cigarettes and hand-rolling tobacco.
- Smoke-free legislation has reduced passive exposure of children and adults to smoke, and may also have generated some further reduction in smoking prevalence.
- MMCs reduce smoking in all age groups and are an important factor in enhancing the effectiveness of other interventions, but are effective only if sufficiently well funded.
- Graphic health warnings on packs discourage smoking uptake, and encourage and sustain quit attempts.
- Removal of tobacco advertising is particularly effective in reducing smoking uptake, and both point-of-sale display prohibition and standardised packaging of tobacco products further reduce exposure to tobacco branding.
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- Smoking imagery in the media, both branded and unbranded, remains a strong promotional driver of smoking, particularly among young people.
- Raising the minimum age of sale, and prohibiting vending machine sales, reduces smoking among young people.
- Providing cessation support to smokers helps them to quit smoking and, if widely available, increases the rate at which smoking prevalence declines.
- Smokers from low-SES groups are particularly likely to respond to price increases and graphic health warnings.
- Existing tobacco control policy could be enhanced by: further reducing the affordability of tobacco, particularly of budget cigarettes and hand-rolling tobacco; investing in MMCs; preventing smoking imagery in the media, including social media; and extending smoke-free policies to outdoor areas.
- NHS SSSs need to be expanded, and appropriately funded to be integrated and actively promoted in clinical care pathways.
- However, even with all such measures in place, millions of people in the UK will continue to smoke for the foreseeable future. Alternative approaches, particularly for young and disadvantaged smokers, are urgently needed.
- Promoting the use of alternative, acceptable and more affordable nicotine products as a harm-reduction strategy has the potential to complement existing tobacco control policy, and in particular to offset the potentially regressive nature of tobacco tax rises.

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Effectiveness of current and future tobacco control policy


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Nicotine pharmacology and pathophysiology

4.1 Nicotine chemistry and absorption

Nicotine is a naturally occurring alkaloid present in the leaves of the tobacco plant, and is the major psychoactive compound and mediator of addiction to tobacco use.1 Nicotine absorption across cell membranes is highly pH dependent, because only non-ionised nicotine can cross biological membranes and be absorbed into the bloodstream.2 Nicotine is a weak base with a pKₐ of approximately 8,² so, in the relatively acidic medium of cigarette smoke with a pH typically ranging from 6.0 to 7.8, more than half of the nicotine in tobacco smoke is protonated³ and cannot be absorbed. Manipulating the pH of tobacco smoke to make it more alkaline thus increases nicotine absorption.⁴

The average nicotine content of commercially available manufactured cigarettes is around 10 mg, but, as a result of loss in sidestream smoke, retention in the cigarette stub and delivery of nicotine in ionised form, only about 1 mg is absorbed from each cigarette smoked.⁵ When tobacco smoke is inhaled, nicotine passes through the alveolar membranes of the lung into the pulmonary venous circulation. It is then carried into the heart, and then directly into the arterial system, reaching the brain within 10–20 s. The rate of increase in arterial nicotine concentration achieved by inhaling nicotine is thus faster even than that achieved by intravenous administration, with peak arterial concentrations occurring at around 20 and 30 s, respectively.⁶ After smoking a single cigarette, arterial nicotine concentrations differ according to the type of cigarette and the way in which it is smoked. Thus, one study reported arterial levels of only about 20 ng/mL,⁶ but some smokers can achieve arterial nicotine concentrations of about 60 ng/mL with just a few puffs⁷ and arterial concentrations of 100 ng/mL have been reported after smoking a single cigarette.⁸ The arterial blood nicotine levels achieved by inhaling nicotine are much higher than in the venous circulation⁸ (Fig 4.1). As the rate at which an addictive drug reaches the brain influences its addictive potential,⁹ the fast absorption and delivery of nicotine after inhaling tobacco smoke underpin the rapid behavioural reinforcement of smoking.¹⁰
In contrast, when nicotine is swallowed, it is absorbed from the gastrointestinal tract into blood that flows into the portal veins and hence to the liver, where it undergoes substantial first-pass metabolism. Oral nicotine therefore generates very low and similar systemic venous and arterial blood levels. Conventional nicotine replacement therapy (NRT) products avoid this first-pass metabolism by delivering nicotine via the skin, mouth or nose, blood from which drains directly into the systemic venous system. NRT thus generates higher arterial nicotine levels than those achieved by gastrointestinal absorption, but levels in arterial blood are similar to those in venous blood and much lower than those achieved by inhalation. There are also marked differences in venous plasma concentrations of nicotine achieved, depending on the form and dose of NRT used\(^1\) (Fig 4.2). The variation in time to reach maximal nicotine plasma concentration is due, in part, to differences in administration duration as well as absorption time that occur with each route of delivery.\(^1\)

The relatively slow delivery of nicotine to the brain achieved by NRT is much less reinforcing, and hence much less likely to generate dependence, than cigarette smoking.\(^2\) However, forms of NRT that deliver nicotine relatively quickly, such as the nasal spray, are thought to be more likely to generate dependence than others. Overall, however, the addictive potential of cigarettes is much higher than that of NRT or other non-inhaled nicotine products.\(^3\) Clinically, very few users of NRT become dependent on it.
4.2 Nicotine metabolism

Around 70–80% of absorbed nicotine is metabolised to cotinine, and around 90% of this metabolism is via the hepatic cytochrome P450 (CYP) 2A6 enzyme. The majority of cotinine is then further metabolised to 3′-hydroxycotinine in a reaction mediated exclusively by CYP2A6. Both nicotine and its metabolites are excreted in urine. As most nicotine clearance occurs via metabolic (i.e., non-renal) means, variability in nicotine metabolism is likely to cause substantial variation in the rate of nicotine clearance between individuals. The ratio 3′-hydroxycotinine: cotinine is known as the nicotine metabolite ratio (NMR), which serves as a phenotypic indicator of CYP2A6 enzymatic activity. As CYP2A6 represents the major route of nicotine clearance, the NMR is also strongly correlated with the rate of nicotine clearance.
Variation in the CYP2A6 gene, which has an impact on the functionality of the CYP2A6 enzyme, is common and associated with alterations in the rate of nicotine clearance, together with a variety of smoking behaviours. Slower nicotine metabolism, as inferred from CYP2A6 genotypes or as measured directly by the NMR, is associated with lower cigarette consumption, lower nicotine dependence, lower smoking-related reward and lower risk of being a current smoker. Slower nicotine metabolism is also associated with an increased likelihood of unaided cessation (ie cessation without behavioural or pharmacological support) and cessation in clinical trials, in which slow metabolisers are typically more likely to achieve abstinence on both placebo and NRT. A separate study that used an alternative CYP2A6 phenotype measure also found associations between slow nicotine metabolism and higher abstinence rates. The prevalence of slower nicotine metabolism differs according to ethnicity, predominantly owing to interethnic variability in patterns of CYP2A6 allele expression. The frequency of CYP2A6 alleles conferring reduced or loss of CYP2A6 activity is generally higher in African and East Asian populations than in European populations, as reflected by a higher prevalence of reduced nicotine metabolism in populations of African and East Asian descent (approximately 40–50%) versus European descent (approximately 10–25%).

In addition to CYP2A6-mediated nicotine inactivation, nicotine can be inactivated through N-glucuronidation and N'-oxidation, through metabolism by uridine diphosphate (UDP) glucuronosyltransferase (UGT) 2B10 and flavin-containing monooxygenase (FMO) 3, respectively. The resulting minor nicotine metabolites, nicotine N-glucuronide and nicotine N'-oxide, account for up to 5% and 7% of a nicotine dose that can be recovered from urine, respectively. In individuals with no functional CYP2A6 activity, FMO3- and UGT-mediated nicotine metabolism may be more important for nicotine clearance; however, reduced FMO3 function did not substantially affect nicotine metabolism in individuals with reduced CYP2A6 activity. UGT2B10 can also metabolise cotinine to cotinine N-glucuronide, comprising 12–17% of a nicotine dose recovered from urine. A second UGT enzyme, UGT2B17, metabolises 3'-hydroxycotinine to 3'-hydroxycotinine O-glucuronide, and accounts for about 9% of a nicotine dose recovered from urine.

Several of these minor enzymes involved in the nicotine and cotinine metabolic pathway (FMO3, UGT2B10 and UGT2B17) are highly polymorphic, with some genetic variants leading to altered activity of these enzymes. Variation in FMO3 is associated with minor alterations in nicotine metabolism, but appears to be of insufficient magnitude to alter cigarette consumption or total tobacco dose in light smokers of African-American ancestry. In heavy smokers of European ancestry, variation in FMO3 has little effect on consumption, unless restricted to those with faster CYP2A6 activity (a difference of about three cigarettes a day). The influence of UGT genetic variation, tested to date on variation in nicotine
metabolism, is also relatively modest and does not appear to alter smoking behaviours substantially.\(^{35,36}\) Although \textit{UGT2B17} genetic variation is associated with altered \(^3\)-hydroxycotinine metabolism,\(^{36}\) variation in genes for UGTs that alters cotinine and \(^3\)-hydroxycotinine metabolism is unlikely to affect smoking behaviours because cotinine and \(^3\)-hydroxycotinine are essentially inactive metabolites of nicotine.

### 4.3 Systemic and central nervous system effects

#### 4.3.1 Nicotinic acetylcholine receptors

Nicotine exerts its pharmacological effects through binding to nicotinic acetylcholine receptors (nAChRs). These receptors are universally expressed in cells throughout the body,\(^{37}\) including the central and peripheral nervous systems, where they play a key role in mediating nicotine dependence and addiction. The nAChRs are ligand-gated ion channels composed of five transmembrane subunit proteins arranged around a central pore. Neuronal nAChRs consist of $\alpha$ ($\alpha_2$–$\alpha_{10}$) and $\beta$ ($\beta_2$–$\beta_4$) subunits,\(^{38}\) each of which is encoded by a single gene (denoted with a ‘\textit{CHRN}’ prefix), and may be homomeric or heteromeric in terms of subunit composition. Different combinations of subunits result in receptors differing in pharmacological and physiological profiles.\(^{39,40}\) Individual subtypes differ, eg in their affinity for nicotine, and sensitivity to upregulation and desensitisation after nicotine exposure.\(^{40}\)

Each nAChR subtype has a distinct distribution profile within the brain, which can be determined through assessment of subunit mRNA using techniques such as \textit{in situ} hybridisation, and through imaging techniques such as positron emission tomography (PET) and single-photon emission computed tomography (SPECT), using subtype-selective radioligands.\(^{40}\) The differential expression of specific subunits, with distinct biological functions in brain regions mediating specific behaviours, allows nicotine to exert a broad range of effects.\(^{41}\) The $\alpha_4\beta_2$ receptor is the most commonly expressed subtype in the human brain, and historically has been implicated through animal models as critical to the experience of nicotine’s reinforcing effects (eg Picciotto et al\(^ {42}\)). In recent years, however, the importance of the less studied $\alpha_3$- and $\alpha_5$-receptor subunits in mediating nicotine dependence has been recognised. The $\alpha_5$-receptor subunit appears to play a key role in determining aversive responses to high doses of nicotine.\(^{43}\)

#### 4.3.2 Systemic and central nervous system effects

Nicotine, at relatively low doses, is a stimulant. It increases heart rate, and has been reported to have beneficial effects on cognition and performance,
improving attention, memory and fine motor skills.\textsuperscript{44} Tolerance to nicotine can develop rapidly (within a few days of use), and cessation of use then results in the experience of withdrawal symptoms, both somatic and affective, such as anxiety, restlessness, inability to concentrate, irritability and change in appetite.\textsuperscript{45} Chronic exposure to nicotine results in a number of neuroadaptions,\textsuperscript{46} including desensitisation of nAChRs and upregulation in their expression,\textsuperscript{47} both of which are linked to nicotine tolerance and withdrawal.

### 4.3.3 Mechanisms of effect

Nicotine exerts its complex effects (including arousal, mood modulation and pleasure) via several neurotransmitter pathways. Once bound to neuronal nAChRs, nicotine facilitates the release of dopamine, serotonin and a host of other neurotransmitters including $\gamma$-aminobutyric acid (GABA), glutamate, noradrenaline, acetylcholine and endorphins.\textsuperscript{47} The mesolimbic dopamine pathway has, perhaps, been the most widely studied in relation to nicotine dependence.\textsuperscript{46} Dopamine release in the nucleus accumbens, resulting from nicotinic stimulation of dopaminergic neurons in the ventral tegmental area, is crucial to the processing of rewarding and reinforcing the effects of nicotine. Indeed, dopamine release in the nucleus accumbens appears to be critical in the experience of the rewarding effects of many drugs of abuse. Continued pairing of the rewarding/reinforcing effects of nicotine with specific sensory and environmental stimuli (which could include, for example, the smell of tobacco smoke or the sight of a pack of cigarettes – smoking-related behaviours) results in these stimuli also acquiring reinforcing properties. These cues (conditioned reinforcers) have been linked to the maintenance of smoking, smoking-related cravings and relapse.\textsuperscript{47}

### 4.4 Toxicity and potential hazards

#### 4.4.1 Toxicity of nicotine

Although nicotine is a toxic compound, overdosing on nicotine products used as directed is almost impossible, given the individual ability to titrate dose and the short half-life of nicotine (see Development of addiction below – Section 4.5). However, ingestion of high doses (purposeful or accidental) can be fatal. Historically, the lethal dose of nicotine for a human adult has consistently been stated to be about 60 mg,\textsuperscript{48} corresponding to an oral median lethal dose (LD\textsubscript{50}) of approximately 0.8 mg/kg. However, this figure has recently been disputed in the light of reports of non-fatal suicide attempts or accidents involving nicotine ingestion, leading to an estimate that the lower dose limit for fatal outcomes is likely to be 500–1,000 mg ingested nicotine, equivalent to an oral LD\textsubscript{50} of 6.5–13 mg/kg.\textsuperscript{48}
4.4.2 Potential hazards of short- and long-term nicotine use

At commonly used dose levels, short-term nicotine use does not result in clinically significant harm. The safety of NRT products, which have typically been used for days or weeks in the context of an attempt to quit smoking, is well established\(^49\) (see Chapter 5 for further detail), with no evidence of any increase in the risk of heart attack, stroke or death.\(^50,51\)

Evidence about long-term nicotine or NRT use is relatively scarce, and concerns have been raised that long-term NRT use may increase cancer risk, in part owing to endogenous formation of carcinogens such as N\(^\prime\)-nitrosonornicotine (NNN).\(^52\) However, studies carried out in experimental animals largely indicate that nicotine alone is not carcinogenic.\(^53\) In vitro and in vivo studies in animals do, however, suggest that nicotine can have tumour-promoting effects through activation of intracellular signalling pathways. Such effects include cell proliferation, enhanced angiogenesis and decreased apoptosis.\(^37,49\) However, it is important to note that many studies in this area have used nicotine at higher doses than those achieved in heavy smokers.\(^54\) In vitro research suggests that nicotine can have a negative impact on the function of some cells within the cardiovascular system,\(^55\) and adverse effects on glucose metabolism.\(^56\) However, robust evidence on the safety of long-term nicotine use in humans from the 5-year Lung Health Study, in which participants were actively encouraged to use NRT for several months and many continued to consume NRT for a much longer period, demonstrates no association between sustained NRT use and the occurrence of cancer (lung, gastrointestinal or any cancer) or cardiovascular disease.\(^57,58\) In addition, a recent clinical trial comparing 8, 24 and 52 weeks of NRT treatment found that treatment duration was not associated with any adverse effects, further supporting the safety of long-term NRT use.\(^59\)

Although there is little evidence on the safety of using nicotine for periods longer than 5 years, and no data on the safety of long-term use of nicotine by inhalation other than when delivered by tobacco smoke, it is widely accepted that any long-term hazards of nicotine are likely to be of minimal consequence in relation to those associated with continued tobacco use. Notably, and in recognition of this fact, the UK Medicines and Healthcare products Regulatory Agency (MHRA) recently approved an extension to the indication of NRT to include ‘harm reduction’,\(^60\) defined as ‘for use as a substitute or partial substitute for smoking tobacco, both for those making an attempt to quit and those not currently intending to make a quit attempt, without any restriction on its duration of use’.\(^61\) Guidelines on harm-reduction approaches to smoking from the National Institute for Health and Care Excellence (NICE) further state that ‘it is safer to use licensed nicotine-containing products than to smoke’ and ‘there is reason to believe that lifetime use of licensed nicotine-containing products will be considerably less harmful than smoking’.\(^62\)
Research from animal studies suggests that fetal exposure to nicotine may lead to adverse postnatal health consequences and that cognitive function and development are adversely affected by nicotine exposure during both the fetal and the adolescent periods. The relevance of these findings to human brain development remains uncertain, however. There is evidence that smoking in adolescence is associated with cognitive and attentional impairments in later life, and possibly an increased risk of mental health problems, but it is difficult to exclude the effects of confounders of this association in the observational studies available.

### 4.5 Development of addiction

Nicotine is the primary addictive component in cigarettes and other tobacco products. It establishes and maintains addiction, thereby sustaining use, through a range of complex actions on brain neurochemistry, which have been reviewed in detail elsewhere. However, the addictiveness of any nicotine-containing product depends on several factors beyond merely the presence of nicotine. These factors primarily include the rate at which nicotine is absorbed and delivered to the brain, and the dose of nicotine delivered. Other factors, such as the speed at which the drug is metabolised and how soon withdrawal symptoms occur, play a role. This is particularly relevant to nicotine, given its short half-life (about 2 h), but this is a feature of the drug more than the product delivering the drug. A nicotine-containing product will therefore be more or less addictive depending on the dose and rate at which the nicotine is delivered. Essentially, a product that delivers a high dose rapidly will have a greater liability for addiction than one that delivers a low dose slowly. In this section, we describe the importance of these factors.

#### 4.5.1 Dose effects on addiction potential

Dose is an important factor in the development of nicotine dependence. Animal models clearly demonstrate an inverted-U relationship between nicotine dose and self-administration, although there is interindividual variability in the shape of this curve, some of which is under a genetic influence. Therefore, increasing the dose is associated with increased self-administration up to a point, after which higher doses become increasingly aversive and ultimately toxic. One advantage of the short half-life of nicotine is, however, that it enables consumers to self-titrate their achieved dose. The dose (ie plasma concentration) of nicotine achieved via use of different nicotine-containing products varies considerably (see Fig 4.1 – the total dose achieved is reflected by the area under the curve for each product). Figure 4.1 also illustrates the considerable variability in speed of delivery across these products which, as discussed above, also contributes to addiction liability.
4.5.2 Rate of nicotine clearance

Nicotine is metabolised principally in the liver, with a half-life for elimination of approximately 2 h (although, as discussed above, this varies considerably between individuals). As a result of this short half-life, plasma nicotine concentrations drop rapidly after nicotine administration, leading to withdrawal symptoms, prompting further nicotine administration in regular users, eg in a typical heavy, dependent smoker, nicotine levels increase rapidly after smoking a cigarette (by about 5–30 ng/mL), then drop before increasing again after smoking the next cigarette. Over the course of a day, plasma nicotine concentrations rise gradually to a steady state of between about 10 and 50 ng/mL. The combination of a short half-life and regular administration via frequent smoking (eg hourly) results in a distinctive pattern of nicotine concentrations, as represented in Fig 4.3. Critically, overnight abstinence leads to the almost-complete elimination of nicotine from the body, leading to marked withdrawal on waking, and the need to consume nicotine in order to reverse these symptoms.

Fig 4.3 Simulated plasma nicotine concentrations obtained after smoking a cigarette every hour for 16 h. (Adapted and reprinted from Le Houezec with the permission of the International Union Against Tuberculosis and Lung Disease. Copyright © The Union.)
4.6 Smoke constituents influencing the addictive potential of cigarette smoke

The addictive potency of cigarettes (and indeed other tobacco products) is influenced by not only their nicotine content but also other aspects of product design, including substances added to the cigarette to enhance nicotine delivery and absorption. Monoamine oxidase (MAO) inhibitors in tobacco smoke increase the levels of amines in the brain, such as dopamine and serotonin, and may subsequently potentiate the reinforcing effects of nicotine. Indeed, animal studies have demonstrated that MAO inhibitors facilitate nicotine self-administration and enhance its motivational properties. These findings may also contribute to the strong reinforcing properties of nicotine from cigarettes.

Sugars and polysaccharides are commonly added to tobacco products to increase the formation of aldehydes, including formaldehyde and acetaldehyde, in tobacco smoke. Acetaldehyde itself has addictive potential, as demonstrated through self-administration experiments in animals, but it also enhances the addictive potential of nicotine. The interaction between these compounds also generates a rewarding effect that exceeds the additive effects of either component in rodent studies.

Menthol and other flavourings (including cloves and liquorice) increase the palatability of cigarette smoke and, in the case of menthol and cloves, facilitate deeper inhalation and therefore a higher nicotine dose (owing to their cooling/local anaesthetic effects). These are widely added at levels below those used in what are conventionally considered to be ‘flavoured’ cigarettes. Flavours may also become conditioned reinforcers in themselves, as a consequence of their repeated pairing with nicotine. In addition, menthol inhibits metabolism of nicotine to cotinine, purportedly through inhibition of CYP2A6 enzyme activity, thus increasing the effect of nicotine. Cocoa and chocolate, which contain theobromine, are also common additives in tobacco. Theobromine is a bronchodilator, and thus has been proposed to enhance nicotine absorption in the lungs. However, the theobromine content of cigarettes was deemed too low to exert bronchodilatation in a recent review. Levulinic acid is an additive with a sweet caramel taste, but it also alters the pH and so reduces the ‘harshness’ of inhaled smoke. This, similarly to menthol, facilitates a higher nicotine dose.

Alkaline additives such as ammonia compounds are among the most common additives used in cigarette manufacture. These substances are added to cigarettes (and other tobacco products) to manipulate the pH. As discussed above, increasing the pH increases the proportion of non-ionised, or freebase, nicotine, which is more physiologically active than the ionised form, crossing biological membranes more readily. Tobacco industry scientists have extensively investigated the potential of pH manipulation to optimise nicotine delivery (see...
Hurt and Robinson\textsuperscript{79}). Curing methods used in the production of tobacco can also influence the pH of tobacco smoke. In particular, air-cured tobacco, as used in cigars, generates nicotine at a relatively high pH, facilitating absorption from oral and upper airway mucosa. Cigarette tobacco is largely flue cured, resulting in nicotine at a lower pH and lower upper airway absorption, hence requiring inhalation into the much larger surface area of the lung alveoli to achieve significant absorption.

4.7 Impact of cigarette design characteristics on nicotine delivery

A number of physical characteristics of cigarettes have been engineered to influence nicotine delivery, including cigarette dimensions, filtration, ventilation, paper porosity and tobacco shred size.\textsuperscript{79} Ventilation, for example, serves to manipulate nicotine, tar and carbon monoxide levels through dilution of tobacco smoke, and is achieved through the introduction of holes in both the filter and the paper wrap.\textsuperscript{77} Ventilation technology was used in the production of ‘light’ or ‘low-tar’ cigarettes, which were promoted by the tobacco industry as healthier alternatives to full-strength cigarettes. However, these descriptions have been shown to be misleading and for this reason have been banned in the UK. Although smoking machine assessments give readings indicating that these cigarettes yield lower doses of nicotine, studies in humans have shown that smokers compensate by altering their smoking topography (ie the way in which people smoke their cigarettes). Thus, smokers use deeper inhalation, increased number of puffs per cigarette, etc when smoking these cigarettes, in order to achieve the same dose of nicotine attained when smoking stronger brands.\textsuperscript{80} This results in equivalent levels of exposure to the harmful constituents of tobacco smoke.\textsuperscript{81}

Smoking topography also affects nicotine delivery. Smokers can make changes to their blood nicotine levels by altering depth and frequency of inhalation and volume of smoke inhaled. A 20-a-day smoker can halve the number of cigarettes that they smoke, but sustain the same plasma nicotine levels by taking larger and deeper puffs. It is this compensatory behaviour that leads to a lack of association between machine-determined nicotine levels in cigarettes and the nicotine dose and quantity of toxic smoke inhaled by a smoker (see below). This may be why reductions in the amount individuals smoke, although making it easier for them to go on to quit, have a relatively limited impact on health outcomes compared with quitting altogether. There are also sex differences in smoking topography (women typically take smaller puffs than men) and ethnicity (African-American individuals typically smoke more of their cigarette than people of European descent).\textsuperscript{2} Mood may also affect the way in which people smoke, with positive effect being associated with a greater increase in blood nicotine levels.\textsuperscript{82}
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4.8 Lessons from cigarette design for harm-reduction product development

Nicotine is the primary addictive component sustaining tobacco use, but is not the cause of the vast majority of harm associated with tobacco use. Therefore, a product that delivers nicotine in the absence of other constituents of tobacco will be associated with dramatically less harm. The safety of NRT demonstrates this and, although long-term use is relatively uncommon, there is sufficient evidence to conclude that any harm from long-term nicotine use will still be negligible compared with the harm of tobacco use. However, nicotine-containing products such as NRT, although very low in harm, are also substantially less satisfying to smokers than, for example, cigarettes, as evidenced by their modest efficacy as smoking cessation products. As discussed above, this is due to the favourable nicotine delivery characteristics and unique range of behavioural reinforcers associated with cigarette smoking. The ideal harm-reduction device should therefore deliver nicotine in a manner as similar as possible to cigarettes, while at the same time maximising palatability and nicotine delivery to approximate the experience of cigarette smoking more closely.

4.8.1 Targeting the determinants of addictiveness

The principal determinants of the addictiveness of a nicotine-containing product are the dose that it delivers, and the speed with which the dose is delivered. Given that most cigarette smokers are dependent (at least to some degree) on nicotine, targeting these determinants is a critical requirement of any harm-reduction product. The use of additives in tobacco products and the design of the cigarette are both engineered to enhance nicotine delivery from the cigarette, by modifying both the palatability of the cigarette smoke (and therefore the ease with which it can be inhaled, facilitating rapid delivery and self-titration) and the bioavailability of the nicotine contained within it. Other factors, such as the taste and smell of cigarette smoke, and the behavioural action of smoking, can themselves become conditioned reinforcers over time and, although secondary to the effects of nicotine, are important drivers of continued smoking.

4.8.2 E-cigarettes and harm reduction

E-cigarettes meet many of the criteria for an ideal tobacco harm-reduction product. Although nicotine delivery from e-cigarettes depends on a number of factors, including level of user experience and device characteristics,83 they can in principle deliver a high dose of nicotine, in the absence of the vast majority of the harmful constituents of tobacco smoke (or at least at negligible levels), in a way that enables accurate self-titration (see Chapter 5). They also provide some of the
cues associated with cigarette smoking, such as taste and throat rasp, as well as behavioural actions such as hand-to-mouth movement. At present therefore, although little is known of the kinetics of nicotine uptake from e-cigarettes into arterial blood, e-cigarettes offer a substitute to smoking that is more likely, on theoretical grounds, to prove satisfying and acceptable to smokers than NRT.

4.9 Summary

> Nicotine is the primary addictive component of tobacco smoke.
> When inhaled into the lungs, nicotine from tobacco smoke is absorbed and delivered to the brain much more quickly, and in higher doses, than can be achieved by other routes of absorption.
> This rapid delivery of repeated high doses of nicotine to the brain is thought to underpin the addictive nature of cigarettes.
> Nicotine is metabolised quickly, causing blood levels to fall rapidly after dosing. People who metabolise nicotine more slowly, and therefore maintain more constant blood levels, tend to be less heavily addicted.
> Nicotine is a stimulant that improves concentration and fine motor skills. However, once tolerance is acquired, unpleasant withdrawal symptoms occur when nicotine blood levels fall.
> Sustained use of nicotine is reinforced by some of the co-stimuli of smoking, such as the taste and sensation of tobacco in the throat, and the smells and behaviours associated with smoking.
> The tobacco industry has manipulated other constituents and additives in tobacco to enhance the addictiveness of nicotine in smoke.
> NRT products may not be effective in some smokers because they replicate few of the delivery, sensory or behavioural characteristics of cigarettes.
> E-cigarettes have the capacity to replace more of the characteristics of tobacco cigarettes than conventional NRT, and therefore have potential as effective smoking substitutes.

References

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Tobacco harm reduction


Tobacco harm reduction


5.1 Introduction

For many years, the range of non-tobacco nicotine products available in the UK has been dominated by nicotine replacement therapy (NRT) products, developed and licensed as medicines to aid smoking cessation. The range of NRT products available has grown to include transdermal patches, chewing gum, lozenges, nasal spray, oral pouch, oral spray, oral strips and the ‘inhalator’, a device that provides a nicotine vapour for oral absorption. In recent years the licences for these products have been extended in several countries, including the UK, to include use to assist smoking reduction and temporary abstinence.

There is strong evidence from randomised controlled clinical trials that NRT can be an effective smoking cessation therapy. A Cochrane review carried out in late 2012 identified 150 such trials, and concluded that all commercially available forms of NRT increase the likelihood of successful cessation among smokers making a quit attempt. NRT products also have a very good safety record. The products differ in the speed of nicotine delivery and the degree of behavioural replacement for smoking that they provide, but are fairly similar in the amount of nicotine that their strongest formulation delivers. Some require specific techniques for correct use (eg chewing gum and nasal spray), whereas others (eg the transdermal patch) are very simple to use. None, however, reproduces the rapid delivery of high doses of nicotine achieved by inhaling tobacco smoke, and few smokers find them enjoyable or satisfying.

NRT products have traditionally been produced and marketed by the pharmaceutical industry, but in recent years tobacco companies have also begun to acquire or develop products manufactured to standards similar to those of NRT products. Examples of these ‘clean’, non-tobacco nicotine products include Zonnic nicotine gum, marketed by Niconovum, part of Reynolds American Inc, and Verve nicotine-containing discs marketed by NuMark, part of Philip Morris. In the past 5 years, however, the non-tobacco nicotine market has been transformed by the emergence of e-cigarettes, which are now the most widely used form of non-tobacco nicotine. Unlike NRT, they have been marketed as
consumer products rather than therapeutic goods, and also, unlike most forms of NRT, they retain several important features of smoking other than nicotine delivery, including similar hand-to-mouth movements, behavioural rituals, an inhaled sensory stimulus and a range of flavours. These characteristics make e-cigarettes attractive to a wide range of smokers, including many who do not or would not use NRT; hence, they provide a potentially viable, lower-hazard market competitor to tobacco cigarettes. As consumer products, they are subject to varying degrees of regulation in different countries, and are evolving quickly as the technology improves. Most e-cigarettes are marketed by independent companies importing products from China, but some production is now based in the UK. Several leading brands have now been bought by tobacco companies (see Chapter 8).

The non-tobacco nicotine market in the UK and many other countries is thus in a state of rapid change, with use of e-cigarettes already eclipsing that of pharmaceutical NRT (see Chapter 7), and an increasingly wide range of new products that deliver nicotine at or close to medicinal standards, some of them marketed by the tobacco industry, becoming available. Indeed the status quo of the nicotine market, whereby medicines have to date been made exclusively by pharmaceutical companies, has recently been challenged by the award of medicines licences to two new products: a nicotine-metered dose inhaler (Voke), and an e-cigarette (E-Voke), both of which are being brought to market by Nicoventures, a subsidiary of British American Tobacco.

This chapter provides a summary of currently available non-tobacco nicotine products, their pharmacokinetic profile, safety, addiction potential and trends in their use. Where blood or plasma nicotine levels are given, they relate to those in venous blood (see Chapter 4) unless stated otherwise.

5.2 NRT products

5.2.1 Transdermal nicotine

5.2.1.1 Doses and pharmacokinetics

Commercially available transdermal nicotine patches provide nicotine at a controlled rate for absorption through the skin into the systemic venous circulation. Products vary in dose from around 7 to 25 mg per patch, and deliver nicotine for either 16 or 24 h. High-dose examples include patches that deliver 25 mg over 16 h, or 21 mg over 24 h; lower doses, which are intended for weaning some weeks after smoking cessation, deliver (for example) 15 or 10 mg over 16 h, or 14 or 7 mg over 24 h. The rationale behind the 24-h patch is that it delivers nicotine during sleep and thus provides some protection against urges to smoke immediately after waking. The occasional drawback of 24-h delivery,
which is avoided by 16-h formulations, is that nicotine can cause vivid dreams or otherwise disturbed sleep.

The rate of absorption of nicotine from transdermal patches is slow, although there are some differences in pharmacokinetic profile between available products. In general, after application of the patch there is a delay of up to 2 h before plasma nicotine levels start to rise. High-dose products can generate maximum venous plasma concentrations of 16–18 ng/mL at around 6–12 h. Plasma nicotine levels at 24 h are about 11 ng/mL with the 24-h patch, and 3 ng/mL with the 16-h patch. During use a small reservoir of nicotine accumulates in the skin under the patch, which means that nicotine continues to be absorbed into the blood for an hour or so after the patch has been removed.

5.2.1.2 Safety profile

The nicotine patch has a good safety profile, even when more than one high-dose patch is applied simultaneously. In addition to the generic nicotine effects outlined briefly in Chapter 4, which apply to all the products described in this section, the most common side effects of the nicotine patch are insomnia, abnormal dreams, and skin irritation at the application site. There were early case reports of cardiovascular adverse effects, but more robust reviews suggest that these were not caused by NRT.

5.2.1.3 Addiction potential

The addiction potential of nicotine products is generally related to the speed of nicotine delivery, with faster delivery systems more likely to be used long term. As transdermal patches deliver nicotine very slowly, long-term dependence is not expected to be a problem, and empirical evidence confirms that this is indeed the case.

5.2.2 Oral and nasal nicotine

5.2.2.1 Doses and pharmacokinetics

Oral and nasal NRT products deliver nicotine more rapidly than nicotine patches, typically achieving peak plasma nicotine concentrations within 30–60 min. However, this kinetic profile is due in part to the sustained-release formulations used in many oral products, and faster absorption is possible. Formulations that spray nicotine solutions directly on to the mouth or nasal linings are among the most quickly absorbed NRT products, achieving peak levels within about 10 min of dosing. Nicotine absorption is influenced by the pH of the oral lining, being faster in relatively alkaline conditions. As with all oral or nasal products, nicotine that is swallowed undergoes extensive first-pass
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metabolism (see Chapter 4) and makes no appreciable contribution to levels of nicotine in the blood.

Nicotine gum

Nicotine gum is available in two strengths, 2 mg and 4 mg, with the higher dose recommended for more dependent smokers. The nicotine contained within the gum is released on chewing and absorbed through the tissues lining the mouth. After chewing a single 2-mg piece of gum, peak plasma concentrations of 3–5 ng/mL are observed within 30–60 min,10,11 and chewing a 2-mg piece of gum every hour results in plasma nicotine concentrations of between 12 and 16 ng/mL. The maximum concentration ($C_{\text{max}}$) for a single dose of 4-mg gum is around 10 ng/mL, and regular dosing can generate plasma nicotine concentrations of between 27 and 32 ng/mL.11

Nicotine oral disc

A recently developed nicotine oral disc has similar characteristics to the gum. It is a non-dissolving polymer disc containing 1.5 mg tobacco-derived nicotine, which is released when it is chewed. Chewing for 15 min results in an increase in plasma nicotine concentration of around 2 ng/mL.12

Nicotine oral pouch

The nicotine in this product is in a powder, contained in a small pouch designed to be held in the mouth. A single 4-mg pouch, if held against the inner lining of the cheek for 30 min, produces a peak plasma concentration of approximately 10 ng/mL.13

Nicotine lozenges and sublingual tablets

Products in this NRT category differ in how quickly they dissolve in the mouth, and in their dose and pharmacokinetic profile. A single 1-mg lozenge creates a peak plasma concentration of around 2 ng/mL,10 a 2-mg lozenge between 4 and 5 ng/mL and a 4-mg lozenge about 10 ng/mL, all within about 60 min. A study of a 2.5-mg nicotine lozenge showed that single use resulted in a maximum plasma concentration of 10.8 ng/mL in 30 min.14 Regular use of lozenges (eg one every 1–1.5 h) results in plasma nicotine concentrations of between 10 and 15 ng/mL for the 1- and 2-mg lozenges10,11 and 20 and 26 ng/mL for the 4-mg lozenge.11 The pharmacokinetic profile of the 2-mg sublingual tablet is similar to that of the 2-mg lozenge.15

Nicotine oral film

This product contains 2.5 mg nicotine in a thin film, designed to be applied to the roof of the mouth, where it dissolves in less than 5 min. Use of a single strip
produces a peak plasma nicotine concentration, similar to the 2-mg lozenge and gum, of between 4 and 5 ng/mL.

**Nicotine inhalator**

The nicotine inhalator consists of a plastic tube holding a replaceable cartridge containing either 10 or 15 mg nicotine. When the user inhales through the device, nicotine vapour is generated, which deposits on and is absorbed through the lining of the mouth. Although used by inhalation, this product does not achieve appreciable pulmonary delivery or absorption, and the pharmacokinetic profile is similar to that of other oral NRT products.

After 20 min intensive use, around 2 mg nicotine is released from the device, resulting in peak plasma concentrations of up to 8 ng/mL and, if this use is repeated hourly for 10 h, levels of around 20–25 ng/mL are achieved. Most users do not, however, use the device with this level of intensity, so lower plasma levels, similar to those achieved by 2-mg gum, are more typical. Nicotine release from this device decreases with ambient temperature so, in cold conditions (<15°C), users should be advised to keep the inhalator warm.

**Nicotine nasal and mouth sprays**

The nasal spray delivers nicotine solution to the nasal mucosa and, after a single 1-mg dose (two sprays containing 0.5 mg nicotine), a peak plasma nicotine concentration of about 5–6 ng/mL is observed within 10–15 min. Taking an hourly dose results in a steady-state plasma concentration of about 10 ng/mL. Although one of the fastest-acting NRT products, the nasal spray is also one of the most aversive to use initially.

The nicotine mouth spray also delivers nicotine quickly. Each spray delivers 1 mg nicotine and results in a peak plasma concentration of around 3–4 ng/mL within 10 min. A 2-mg dose gives a plasma concentration of around 5–6 ng/mL. Another mouth spray formulation has shown higher maximum plasma concentration (10 ng/mL) with a 2-mg dose, but with a slightly longer time (15 min) to reach this.

**5.2.2.2 Safety profile**

Similar to the nicotine patch, oral and nasal nicotine products have a good safety profile. The most commonly reported adverse effects are related to mouth and throat irritation, and hiccups. The nasal spray is a local irritant to the nasal lining.
5.2.2.3 Addiction potential

Some 5% of smokers who use oral nicotine products to stop smoking will continue to use them for a year or longer.9 With the nicotine nasal spray, this figure is closer to 10%,9 which probably reflects the faster nicotine delivery of this product. Long-term users are usually people who were highly dependent on nicotine from their cigarettes and who would be relatively unlikely to maintain long-term abstinence from smoking without such help.21 There are no documented cases of non-smokers becoming dependent on NRT.

5.2.3 Dual use of NRT and smoked tobacco products

NRT appears to be safe and well tolerated when used together with smoking.22,23 Randomised placebo-controlled trials of dual use indicate that the occurrence of expected symptoms of nicotine overdose, such as nausea and palpitations, is uncommon.24,25 A meta-analysis of NRT use before quitting found no increase in adverse events in patch users compared with those on placebo.26 No reported concerns over the use of NRT while smoking have arisen from post-marketing surveillance. Smokers who also use NRT (known as ‘dual users’) are approximately twice as likely in the following months to make a quit attempt, and to quit smoking, than those who do not.27,28

5.3 E-cigarettes

E-cigarettes provide nicotine for inhalation in a vapour generated by heating a solution containing water, nicotine, propylene glycol, vegetable glycerine and typically also some flavouring. E-cigarettes were developed and first marketed in China in around 2003, and appeared on the market in the UK about 4 years later. The quality of early devices was variable, as was the consistency of the nicotine solutions (e-liquid) that they contained29 and their ability to deliver nicotine, which, in some cases at least, was poor.30 Newer studies have demonstrated some improvements in quality, at least in relation to declared nicotine content.31,32

The many brands and models of e-cigarettes available can be grouped into three broad categories of different appearance (Fig 5.1). The original or first-generation e-cigarettes were designed to be of similar size and appearance to a conventional cigarette, and hence are sometimes known as ‘cigalikes’. These devices typically comprise two components: a battery and a ‘cartomiser’, a section of the device that contains nicotine solution and a vaporiser. Although some cartomisers are refillable, most are disposable, ie designed for single use and replacement when empty. Second-generation e-cigarettes are larger,
Fig 5.1 The three generations of e-cigarettes: (a) first generation; (b) second generation; and (c) third generation. (Images provided by Anna Phillips.)
typically the size of a large fountain pen, and incorporate a more powerful battery linked to a permanent vaporiser, and a tank system that users can refill with nicotine solution. Third-generation devices are typically larger still, with a still more powerful battery, usually with two heating elements (coils), and allow users to vary power and sometimes also the draw resistance of the device. Third-generation devices are also designed to allow modifications and substitution of individual components according to preference. Second- and third-generation devices generally deliver nicotine more effectively than first-generation devices (see below). The nicotine, propylene glycol, glycerine and flavouring contents of e-liquids also vary substantially, particularly in relation to nicotine content (with some being nicotine free), and in the ratio propylene glycol:glycerine.

5.3.1 Pharmacokinetics

Nicotine delivery from e-cigarettes is influenced by the concentration of nicotine and other constituents of the e-liquid, and the puffing (‘vaping’) technique used, and has generally increased with successive generations of the technology.\(^3\) The earliest first-generation devices delivered little or no nicotine, eg two early products containing a 16 mg/mL nicotine solution; when tested in smokers who had not previously used e-cigarettes, it was found that the devices delivered either very little nicotine, achieving a maximum blood level of 1.3 ng/mL at 20 min,\(^3\) or none at all.\(^3\) However, with improved technology and more experienced users, nicotine delivery is improved, eg whereas one study found that, among naive users, 5 min free use of an e-cigarette containing 24 mg/mL nicotine produced a peak plasma concentration of 4.6 ng/mL within 5 min, after 4 weeks’ practice the same users were achieving levels of 5.7 ng/mL.\(^3\) A study of a more advanced first-generation e-cigarette containing 18 mg/mL nicotine, and using a longer puffing (vaping) regimen (10 puffs 30 s apart on six occasions every 30 min), resulted in a maximum plasma nicotine concentration of 7.4 ng/mL at 2.5 h after the first puffing bout.\(^3\) In experienced users, using the same 10 puffs in a 5-min regimen, plasma nicotine levels can rise by around 8–16 ng/mL within 5 min of the first puff.\(^3\)

Use of higher nicotine concentrations in the e-liquid increases nicotine delivery, as does the inclusion of propylene glycol. In a study that examined nicotine delivery from a first-generation e-cigarette containing either 16 or 24 mg/mL nicotine, in either 75% glycerine or a 50% glycerine:20% propylene glycol e-liquid, peak plasma nicotine concentrations after 30 min of controlled puffing were highest (18 ng/mL) with the 24 mg/mL nicotine in the mixed glycerine:propylene glycol formulation, and lowest (10 ng/mL) with the 16 mg/mL nicotine in 75% glycerine solution\(^4\) (Fig 5.2). The propylene glycol:glycerine mix formulation delivered more nicotine at either dose than the
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75% glycerine solution. This higher delivery is thought to result from the lower boiling point of propylene glycol (187.6°C) than of glycerine (290°C).

Nicotine delivery is generally better from second- and third-generation devices, eg in a direct comparison with first-generation devices using a prescribed 5-min puffing regimen, second-generation e-cigarettes produced significantly higher rises in plasma nicotine concentration (by 4 ng/mL vs 2 ng/mL) at 5 min⁴¹ (Fig 5.3), and with repeated use these devices can sustain venous blood levels comparable with those expected in smokers.⁴² In a study examining the nicotine delivered by a third-generation device, experienced vapers were able to achieve a greater rise in blood nicotine levels than naive users under the same prescribed 5-min puffing regimen (5.8 ng/mL vs 2.7 ng/mL at 5 min),⁴³ although the speed of nicotine delivery remains much slower than from cigarettes.

Levels of the nicotine metabolite cotinine, which reflect nicotine intake over the past 3–4 days,⁴⁴ are similar in experienced e-cigarette users to those observed in smokers,⁴⁵–⁴⁷ indicating that e-cigarettes are capable of delivering...
5.3.2 Safety profile

E-cigarettes are generally well tolerated. Similar to oral NRT products, reported short-term adverse effects relate predominantly to mouth and throat irritation, and tend to be self-limiting.\textsuperscript{29,48,49} As with all new products, however, long-term or rare adverse effects will remain uncertain until e-cigarettes have been in widespread use for several decades. Discussion of the potential long-term adverse effects of e-cigarette use is therefore limited to consideration of the likely effects of sustained inhalation of the known constituents of e-cigarette vapour.

Analysis of vapour generated by e-cigarettes has identified a number of potentially harmful constituents delivered alongside the nicotine and other
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e-liquid components. These include volatile organic compounds, carbonyls, aldehydes, tobacco-specific nitrosamines (TSNAs) and metal particles, but all at much lower levels than in cigarette smoke.\textsuperscript{50–64} Levels of formaldehyde and other aldehydes can be relatively high when vaporisation occurs at high temperatures,\textsuperscript{65,66} although in practice this overheating generates an aversive taste known as a ‘dry puff’, which vapers avoid.\textsuperscript{66,67} Recent reviews of the health effects of toxins inhaled during normal use of e-cigarettes have expressed concerns over potential adverse effects based on the presence of these contaminants,\textsuperscript{68–70} but not their levels, which are generally the more important determinant of toxicity. In normal conditions of use, toxin levels in inhaled e-cigarette vapour are probably well below prescribed threshold limit values for occupational exposure,\textsuperscript{71} in which case significant long-term harm is unlikely. Some harm from sustained exposure to low levels of toxins over many years may yet emerge, but the magnitude of these risks relative to those of sustained tobacco smoking is likely to be small. However, consideration of the potential harm of long-term e-cigarette use should serve as a guide to evidence-based product development, regulation and monitoring.

5.3.3 Areas of potential concern over hazards arising from vapour exposure

Areas of potential concern over the long-term effects of e-cigarette use include the effects of vapour constituents depositing in the mouth, upper airway and lungs, and systemic effects of vapour components absorbed as a result of swallowing or inhalation. The vapour constituents to be considered consist of those that should be present in e-liquids, and hence also the vapour, including: nicotine, propylene glycol, glycerine and flavours; those arising from impurities and contaminants in the e-liquid, which vary between batches and suppliers;\textsuperscript{72} and toxins, particles and other components created by the vaporisation process. The long-term adverse effects of nicotine are likely to be minimal\textsuperscript{73} (see also Chapters 4 and 7), although it is acknowledged that the effects of sustained inhalation of nicotine, in isolation from tobacco smoke and as opposed to absorption by another route, have not been studied. There are, however, no grounds to suspect that inhaled nicotine will have an appreciably different risk profile from nicotine delivered via other routes of absorption. The following discussion therefore relates to the effects of other constituents of e-cigarette vapour.

Inhaled vapours deposit first, and often substantially, in the mouth and upper airway. Much of this deposition is then swallowed, absorbed from the gastrointestinal tract and excreted, mostly in urine, either unchanged or after metabolism. This process of deposition, absorption and excretion of TSNAs and other carcinogens in tobacco smoke probably accounts for the increased risks of
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cancer of the oropharynx, stomach, bladder and other organs involved in the absorption and excretion process in smokers. The presence of carcinogens in e-cigarette vapour therefore increases the risk of similar outcomes but, in view of the very low levels of exposure generated by e-cigarette vapour, the magnitude of any increase in risk, in either relative or absolute terms, is likely to be low.

After passing through the mouth and upper airway into the lungs, larger particles and droplets in inhaled vapours deposit substantially throughout the intrapulmonary airways, to be either absorbed and excreted as above, or expectorated. Vapour components <5 µm in diameter reach the alveoli, where they either deposit and are then absorbed or cleared through phagocytosis or other processes, or are exhaled. In tobacco smoking, the deposition of carcinogens carried in tobacco smoke results in an increased risk of lung cancer, whereas oxidants and other toxins and irritants in smoke cause direct and inflammation-induced damage to lung tissues, which leads to chronic bronchitis and emphysema (chronic obstructive pulmonary disease (COPD)) and to pulmonary fibrosis. Smoke components absorbed from the lung, including particles and carbon monoxide, contribute to the increased risk of cardiovascular disease in smokers and, together with local effects, to an increased risk of infection. Although e-cigarette vapour contains a far less extensive range of toxins, and those present are typically at much lower levels, than in tobacco smoke, it is appropriate to consider potential hazards of e-cigarettes in relation to this spectrum of harm.

5.3.3.1 Generic effects of vapour

Data on the effects of e-cigarette vapour on the airways are limited to studies of short-term exposure. Use of an e-cigarette in healthy individuals for 5 min has been shown to reduce exhaled nitric oxide (NO) and increase airway resistance, consistent with an irritant effect on the airways resulting in mucosal oedema, smooth muscle contraction or increased production of lung secretions in response to the vapour. Another study reported a reduction in exhaled NO after inhaling vapour from an e-cigarette, with or without nicotine, of an order of magnitude similar to that provoked by conventional cigarette smoke. However, short-term e-cigarette use has been found to have no effect on spirometric markers of lung function, and another study found no difference in reported adverse events over 12 weeks’ use of an e-cigarette with or without nicotine, or conventional NRT. It is therefore far from clear whether these short-term airway effects will translate into long-term airway damage. Furthermore, as smoking cessation is associated with a reduction in respiratory symptoms in people with respiratory disease, many smokers who switch to an e-cigarette are likely to experience improvements in respiratory symptoms. This is illustrated in a study that followed a small cohort of patients with asthma, in whom improvements in symptoms and respiratory function were observed after
switching from smoking to vaping. These observations therefore provide reassurance about short-term use of e-cigarettes in relation to adverse respiratory effects. One survey from Hong Kong has reported a higher prevalence of respiratory symptoms among Chinese adolescents who were ex- or never-smokers, and reported any use of an e-cigarette in the preceding month. However, e-cigarettes were used by only 1.1% of the total sample and 0.1% of never-smokers and, as use of e-cigarettes was not quantified, there is no evidence that those reporting symptoms were using the product regularly.

E-cigarette vapour has been reported to influence resistance to infection, and to delay recovery from influenza infection, in an animal model, although the validity of these findings and relevance to the effects in humans are far from clear. At the time of writing we are not aware of any published evidence on cardiovascular effects of e-cigarette use other than those attributable to nicotine. It is known, however, that the vapour does not deliver appreciable amounts of carbon monoxide, which represents a significant advantage relative to tobacco smoke. A study of carcinogen excretion in participants’ urine after use of e-cigarettes or tobacco cigarettes found significantly lower levels of TSNAs, benzene and polyaromatic hydrocarbons with e-cigarettes, demonstrating systemic absorption of these carcinogens and hence some degree of potential cancer risk, although clearly much less than that associated with smoking.

5.3.3.2 Propylene glycol and glycerine

Propylene glycol is an active ingredient of the solutions used to generate the synthetic smoke widely used in the performing arts and nightclubs, and in this context is generally considered to be safe. In animal studies, a month of exposure to propylene glycol vapour produced no apparent tissue toxicity of the lung, liver or kidney in beagles or rats, although 90 days’ nasal inhalation in rats was associated with an increase in the number of goblet cells and mucin production in the nasal mucosa at levels of exposure >1.0 mg/L. An early study examined long-term exposure to propylene glycol vapour over 12–18 months in rats and monkeys, and identified no lung or other adverse effects. However, acute exposure to propylene glycol has been shown to induce airway irritation and cough in humans, together with minor airflow obstruction. One study also found an association between levels of propylene glycol exposure in the home, and asthma and rhinitis in children.

Evidence on the adverse effects of inhaled glycerine is limited to a single case report of lipoid pneumonia with onset of symptoms associated with commencing e-cigarette use. The pneumonia was attributed to glycerine-based oils in the e-liquid, although commentators pointed out that glycerine is an alcohol and not a lipid. There have been no further reported cases of this
outcome. Studies of repeated inhalation in rats found no evidence of damage to the lungs.97,98

5.3.3.3 Flavours

Although the flavours used in the e-cigarette liquid are generally those considered safe when ingested orally, some are irritant to the airways and the safety of most flavours after heating and inhalation is unknown.99 Diacetyl is an example of a flavour used in popcorn, and some other foods, that is safe for oral consumption but which, when heated and inhaled in large doses over long periods of time, can cause irreversible bronchiolitis.100 Vapour produced from e-liquids containing flavours has been demonstrated to be more cytotoxic than unflavoured vapour101 and, although both are far less so than tobacco smoke, this exposure may increase airway inflammation.102 In vitro experimental studies have also reported increased susceptibility of airway cells to viral infection after direct contact with e-liquid103 and evidence of cytotoxicity from cinnamon flavours, although the relevance of direct effects of contact with e-liquid, as opposed to vapour, is unclear.50 Although no study so far shows any clear hazards of flavours in e-cigarette vapour, those derived from flavours seem the most likely to pose appreciable health risks from long-term use.

5.3.3.4 Components generated by vaporisation

Heating propylene glycol or glycerine can cause decomposition to low-molecular-mass carbonyl compounds including formaldehyde and acetaldehyde, which can be carcinogenic in large doses.104 A study investigating the effect of varying the heating element voltage in e-cigarettes found that, at low voltage, levels of these compounds were up to 800-fold lower than in tobacco smoke, but that, at higher voltage (4.8 V), the levels were similar.56 In a study involving a third-generation – or variable-voltage – e-cigarette, negligible levels of formaldehyde were generated at lower (normal) power settings, but, when used at maximum power with 3- or 4-s puffs, levels 5–15 times higher than those found in cigarette smoke were observed.65 However, in a study simulating this ‘dry puff’ use, generating high levels of formaldehyde (up to 355 µg), acetaldehyde (up to 206 µg) and acrolein (up to 210 µg), experienced vapers were easily able to detect dry puffs and none could tolerate them.66 Under normal conditions of use, the levels were negligible.66

Two studies have examined urinary levels of aldehydes in vapers. One was a cross-sectional study that demonstrated considerably lower levels of urinary acrolein and crotonaldehyde in vapers than in smokers.89 The other was a cohort study that examined the change in urinary acrolein level when smokers switched to vaping. Significant decreases in acrolein concentrations were observed in smokers who switched completely to e-cigarettes as well as in those who were
both smoking and vaping, showing that ‘dual use’ of tobacco cigarettes and e-cigarettes leads to a reduction in smoke intake.\(^8\)

In addition to the vaporised liquid, e-cigarette devices include metals, ceramics and rubber, all of which may become aerosolised in the process of vapour generation,\(^6\),\(^2\),\(^10\),\(^5\),\(^10\) eg copper particles of respirable size (0.450–2.02 \(\mu\)m) have been demonstrated in e-cigarette vapour at a level six times that seen in conventional cigarette smoke;\(^5\) levels of nickel and silver that are also higher than those in tobacco smoke have been noted.\(^6\) Whether these exposures comprise a significant health hazard remains uncertain. Potential toxicity of metal and other fine particles include carcinogenicity, cardiovascular disease and diseases such as COPD and interstitial lung disease, which are characterised by sensitisation, chronic inflammation or tissue remodelling.\(^10\) Inhalation of small particles, over both the short and the long term, also increases the risk of cardiovascular events.\(^10\) However, this is probably not a major concern because levels of exposure are well below recognised safety thresholds,\(^10\) and could be reduced still further by improving manufacturing processes and standards.

### 5.3.3.5 Hypersensitivity reactions

Hypersensitivity pneumonitis has been described in response to a range of inhaled organic materials. Allergy to nickel, which can be present in very small amounts in e-cigarette vapour, is a relatively common problem in clinical practice,\(^11\) although there has been no reported case of this problem in e-cigarette users. A case of eosinophilic pneumonia has been reported in a smoker who tried an e-cigarette,\(^11\) but again this has not been replicated and hence is of uncertain relevance.

### 5.3.3.6 Relevance to potential long-term harms

The above observations indicate that e-cigarettes deliver a much smaller range of toxins at much lower concentrations than cigarettes, and therefore indicate that harm from e-cigarette use is likely to be far less than that from smoking. They also demonstrate a possibility that some harm from long-term e-cigarette use cannot be dismissed. From first principles, we would expect repeated and sustained inhalation of the generally low concentrations of particulates, oxidants, carcinogens and other constituents to pose some risks to health, particularly in relation to COPD and lung cancer. However, the absolute magnitude of any risk attributable to e-cigarette use is likely to be very small in absolute terms, and hence substantially smaller than that arising from tobacco smoking. A recent evidence review concluded that e-cigarette vapour can contain some of the toxins present in tobacco smoke, but at much lower levels, and that the long-term health effects of e-cigarette use, although unknown, are likely to be much less, if
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at all, harmful to users or bystanders than cigarette smoke. An analysis based on expert opinion quantified the likely harm to health and society of e-cigarettes at about 5% of the burden caused by tobacco smoking, and a recent report by Public Health England supported this conclusion.

With appropriate product standards to minimise toxin and contaminant exposure in e-cigarette vapour, it should be possible to reduce risks of physical health still further. It is also possible, although unlikely, that other, unexpected harm from inhaling e-cigarette vapour over the longer term might yet emerge. Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

5.3.3.7 Effects of passive exposure to e-cigarette vapour

Users of e-cigarettes exhale the vapour, which may therefore be inhaled by others, leading to passive exposure to nicotine. There is, so far, no direct evidence that such passive exposure is likely to cause significant harm, although one study has reported levels of polycyclic aromatic hydrocarbons that were outside defined safe-exposure limits. It is clear that passive exposure will vary according to fluid, device and the manner in which it is used. Nicotine from exhaled vapour can be deposited on surfaces, but at such low levels that there is no plausible mechanism by which such deposits could enter the body at doses that would cause physical harm.

5.3.4 Addiction potential

Speed of nicotine delivery seems to be important for smokers’ satisfaction and addiction potential. As outlined in Chapter 4, as a consequence of pulmonary absorption, cigarettes deliver nicotine to the brain very quickly. Although there are no available data on arterial nicotine levels after e-cigarette use, its venous delivery kinetics appear similar to those of products delivering to the mouth or upper airway, suggesting that pulmonary absorption from currently available e-cigarettes is low. In addition to this, the addictiveness of cigarettes is probably also related to other chemicals in tobacco smoke that enhance nicotine’s effects. These observations tally with other evidence, eg e-cigarette users report that they feel less dependent on them than on tobacco cigarettes, and empirical evidence from adolescent use suggests that, although adolescents experiment with e-cigarettes, few – if any – never-smokers who do so become regular e-cigarette users. The addiction potential of currently available e-cigarettes is therefore likely to be low. NRT and e-cigarettes may satisfy smokers who are already using nicotine, but they have little appeal for never-smokers. This may...
change in the future, however, if e-cigarette and other nicotine inhalation technology improves sufficiently to achieve significant pulmonary absorption.

5.3.5 Dual use of e-cigarettes and tobacco cigarettes

Observational population-level evidence indicates that dual users of both tobacco and e-cigarettes are more likely to make an attempt to stop smoking than smokers who do not also use e-cigarettes, but it is not yet clear whether they are more likely to succeed\textsuperscript{119,120} (see Chapter 6). Some researchers have found a lower subsequent cessation rate among smokers who tried e-cigarettes but continued to smoke than among smokers who did not try e-cigarettes, but this could be explained by self-selection and exclusion of smokers who switched completely to e-cigarettes. One study found that daily users of the more advanced models had a higher cessation rate.\textsuperscript{120} Experience with NRT suggests that e-cigarette use is likely to increase the proportion of smokers making a quit attempt, but appropriate evidence on this effect is not yet available. A recent study has shown that dual users maintain their intake of nicotine, but reduce their intake of smoke and related toxins significantly.\textsuperscript{88} Obtaining nicotine from an alternative source leads to a reduction in smoking.\textsuperscript{22}

5.3.6 Use to inhale other drugs

Refillable e-cigarettes can be used to inhale other materials including cannabis oil or narcotics. Although such use is outside the scope of this report, use of e-cigarettes to deliver cannabis is likely, as is the case for nicotine, to be substantially less hazardous than conventional inhalation of cannabis smoke either alone or mixed with tobacco.

5.4 Products in development

At the time of writing there is a range of non-tobacco nicotine products in development, most of which are variations on the formulations outlined above, but some of which represent genuinely novel approaches, with the potential to deliver nicotine by inhalation with significant pulmonary absorption. As this is the route of absorption that generates the fastest increases in arterial blood levels, this range of products may prove to be the most effective, and also possibly the most addictive, smoking substitutes.

A metered-dose inhaler using propellants to deliver small droplets of nicotine to the respiratory tract has been developed.\textsuperscript{121} Ten puffs of a 50-µg nicotine/puff inhaler, inhaled via a spacer, resulted in peak plasma nicotine concentrations of
12.5 ng/mL within 6 min of finishing the 10 puffs. A 100-µg dose was also tested and resulted in slightly lower peak nicotine concentrations (9.4 ng/mL), most probably owing to the greater adverse effect of coughing at the higher dose. Voke is an inhaler device that is similar in shape and size to a conventional cigarette; it is charged and recharged with an aerosol containing nicotine, propylene glycol and a propellant from a small pressurised canister (similar to those used in asthma inhalers), housed in a pack about the size of a pack of 20 cigarettes. Inhalation of the entire contents of the device provides 0.45 mg of nicotine to the user, with nicotine measurable in arterial blood (mean 2.06 ng/mL) within 2 min of the first inhalation, suggesting at least some pulmonary absorption. A \(C_{\text{max}}\) of 3.7 ng/mL in arterial blood was reached in 7 min. A \(C_{\text{max}}\) in venous blood of approximately 3 ng/mL was reached within 15–20 min. Hourly use results in steady-state plasma nicotine levels of between 8 and 10 ng/mL.\(^{122}\) The product has now been awarded a medicines licence, and hence is likely to be brought to market, although at the time of writing no date has been set.

Nicotine pyruvate is formed from the combination of nicotine and pyruvic acid. Its salts are small (similar in size to the particulate matter in cigarette smoke) and so can be carried deeper into the respiratory tract in the process of inhalation, and are less harsh than pure nicotine to inhale. An inhaler has been developed that contains pyruvic acid and nicotine, which are combined when the user draws air through the device. In participants taking 10 controlled inhalations over 5 min, plasma nicotine levels rose to 5 ng/mL within 5 min when using a dose of 20 µg nicotine pyruvate per puff, and to 8.3 ng/mL with a 30-µg dose.\(^{123}\) This technology was purchased by Philip Morris International Inc in 2011,\(^{124}\) but has not yet been brought to market.

The Aradigm AERx system, which was developed for inhalation of insulin, has also been tested for nicotine delivery.\(^ {125}\) There are limited published data about nicotine delivery, but those that are available on the company website\(^ {126}\) suggest that nicotine delivery is rapid. The product has not, however, yet been commercialised.

5.5 Summary

- The market in non-tobacco nicotine products in the UK has been dominated for several decades by NRT.
- NRT is licensed as a medicine to help smokers quit smoking, and there is strong clinical trial evidence of effectiveness in this role.
- NRT is also licensed for use to help smokers cut down on smoking, and for temporary abstinence.
- NRT products have an excellent safety profile and present negligible risks to users.
- However, NRT products do not reproduce the rapid, high-dose delivery of...
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tobacco smoke, and reproduce few if any of the behavioural components of
tobacco smoking.

► The dominance of NRT has been challenged in recent years by a growing
range of consumer nicotine products, some of which are made to high
standards of purity but not necessarily licensed as medicines, and by
e-cigarettes, which are now more widely used than NRT.
► Unlicensed nicotine products made to high standards of purity are also likely
to have very little risk for users.
► Currently available e-cigarettes are manufactured to variable standards, and
many are therefore likely to be more hazardous than NRT.
► Nicotine delivery from e-cigarettes is variable and, with some first-
generation devices, very low.
► However, e-cigarette design is evolving quickly, with newer models delivering
higher doses of nicotine than their predecessors, and hence being more
satisfying for smokers.
► Some of the carcinogens, oxidants and other toxins present in tobacco
smoke have also been detected in e-cigarette vapour, raising the possibility
that long-term use of e-cigarettes may increase the risks of lung cancer,
COPD, cardiovascular and other smoking-related diseases.
► However, the magnitude of such risks is likely to be substantially lower than
those of smoking, and extremely low in absolute terms.
► These potential health risks arise primarily from contaminants and
components generated by the vaporisation process, which should be
amenable to reduction through technological and purity improvements.
► New nicotine products in development are likely to extend the range of
choices available to smokers further, increasing purity and safety, and, in
those achieving greater pulmonary absorption, addictiveness.
► Although it is not possible to precisely quantify the long-term health risks
associated with e-cigarettes, the available data suggest that they are unlikely
to exceed 5% of those associated with smoked tobacco products, and may
well be substantially lower than this figure.

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6 Quitting smoking

6.1 Introduction

Quitting smoking is the most effective means by which smokers can avoid the premature death and disability caused by smoking. This chapter describes current patterns of smoking cessation in the UK, to provide context in which to consider the position and role of harm-reduction policies. As in Chapter 5, data are again drawn from the Smoking Toolkit Study (STS: www.smokinginengland.info),¹ the only national survey within the UK that provides detailed data on smoking cessation behaviour in a representative general population sample. Although limited to smokers in England, STS data are likely to be broadly representative of trends across the UK. This chapter uses STS and other data to explore recent trends in quitting behaviour, and the association between e-cigarette use and smoking prevalence, and to consider approaches to increasing the number of quit attempts made. It also describes patterns of use of e-cigarettes among young people.

6.2 Quit attempts and quit success

STS data indicate that the proportion of smokers making at least one quit attempt each year has fallen over the past 8 years, from 43% in 2007 to 32% in the first 9 months of 2015 (Fig 6.1). This overall trend was reversed in 2012 and 2013, when 34% and 39% made quit attempts, but has since fallen again. These attempts were slightly more likely to occur in women and younger adults and, in 2014 and 2015, among those in non-manual occupations (Fig 6.2).

The proportion of these attempts that are successful in the short term, which can be identified as survey responses from individuals reporting that they have made a quit attempt in the past year and are now not smoking, is around 16%, a slight increase since 2011 (Fig 6.3). There were no marked differences in the proportion of successful attempts in relation to age or gender, but success was more likely among those in higher occupational groups (Fig 6.4).
Fig 6.1 Proportion of people who have smoked in the past year who made at least one serious quit attempt in that year (data from 42,386 people who smoked in the past 12 months; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)
Fig 6.2 Proportions of people who have smoked in the past year making at least one serious quit attempt in that year, by gender, age and occupational group (data details as per Fig 6.1).1 (Adapted from the Smoking Toolkit Study1 with permission.)
Fig 6.3 Proportion of people who have tried to stop in the past year and are currently not smoking\(^1\) (data from 15,720 people who tried to stop smoking in the past 12 months; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\(^1\) with permission.)

Fig 6.4 Proportion of people who have tried to stop in the past year and are currently not smoking by occupational social group (data details as per Fig 6.3).\(^1\) (Adapted from the Smoking Toolkit Study\(^1\) with permission.)
6.3 Methods used to quit

The methods chosen by smokers in England to help them to quit, reported in the STS study between 2007 and 2015, are represented in Fig 6.5. Until 2013, the most commonly used aid to cessation was nicotine replacement therapy (NRT) bought over the counter, but NRT has been displaced as the most popular choice by a rapid increase in the use of e-cigarettes in England since 2012 (see also Chapter 5). The proportion of smokers who use no aid to cessation has fallen progressively over recent years, but remains above 40%.

Evidence from randomised trials and English population data indicate that there are three main categories of quit attempt in terms of aids used; these are grouped below in relation to their relative likelihood of success.
6.3.1 Lowest likelihood of success

The approaches to quitting associated with the lowest likelihood of success are those that are unaided, including use of over-the-counter NRT and use of NRT without professional support. STS data suggest that there is little or no difference in the likelihood of quitting using either of these methods. This observation contrasts with randomised trial evidence that NRT can increase the likelihood of cessation, and suggests that trial procedures, and perhaps in particular an element of professional instruction and follow-up, may be crucial to NRT effectiveness. This, in turn, indicates that providing even minimal behavioural support to purchasers of NRT could improve the likelihood of successful quitting. As one in five smokers who tried to quit smoking in 2015 did so using NRT purchased from a shop or pharmacy, the low effectiveness of this approach represents a considerable lost opportunity to promote cessation.

6.3.2 Intermediate likelihood of success

Quit attempts among STS participants are around 50% more likely to succeed if they involve NRT, varenicline or bupropion obtained on prescription (and hence involving at least some contact with a health professional), or an e-cigarette bought from a shop. These methods are typically used by more heavily addicted smokers who would otherwise be expected to have a lower chance of success than those using the methods of lowest effectiveness. The fact that NRT obtained on prescription yields higher success rates than over-the-counter NRT suggests that, again, with this product, some form of clinical supervision or involvement is required for NRT to have an effect. This may be because without supervision smokers use NRT incorrectly, eg by using too little, or use the therapy for too short a time. However, this in turn raises the question of why use of e-cigarettes, which in the limited clinical trials available to date appear to be of similar efficacy to NRT, appears to be effective even without this supervision. There are, however, a number of possible explanations, as follows.

6.3.2.1 Nicotine delivery kinetics

Although early-generation e-cigarettes delivered relatively little nicotine, experienced e-cigarette users, particularly when using a later-generation product, can achieve venous blood levels similar to those obtained from smoking (see Chapter 5). Although this is also possible with NRT, it generally requires very frequent dosing with a short-acting product used in combination with a nicotine transdermal patch, and few consumers of NRT are likely to be aware of the need to follow this kind of dosing regimen. It is therefore possible that users
adopting e-cigarettes without direction on optimal use are more likely to achieve satisfactory nicotine substitution than those choosing NRT.

### 6.3.2.2 Duration of use

There is a tendency for e-cigarettes to be used for longer than NRT. Although some smokers who use NRT to stop smoking continue to use NRT for months or even years after quitting, they are in a minority; most discontinue the product within a few weeks. In contrast, many users of e-cigarettes continue using the product both before and after quitting smoking, and for a longer period after quitting than most NRT users.\(^{12-15}\)

### 6.3.2.3 Sensory replacement

Unlike NRT, e-cigarettes replicate many of the sensory characteristics of smoking. As outlined in Chapter 4, nicotine addiction is sustained not only by the rewarding characteristics of nicotine itself, but also by reward given to the stimuli and behaviours associated with nicotine delivery.\(^{16}\) As sensory replacement can reduce tobacco withdrawal symptoms,\(^{17}\) the sensation of vapour in the back of the throat, the plume of exhaled vapour, the hand-to-mouth action, and various other sensory and behavioural similarities with cigarettes may help to make e-cigarettes a closer sensory substitute for tobacco smoking than NRT products.

### 6.3.2.4 Cultural acceptability

Particularly among smokers, e-cigarettes are a socially and culturally accepted direct substitute for smoking. E-cigarette users can still share smoking breaks with and be accepted by other smokers, thus sustaining a social identity as a smoker, but can also tap into the enthusiasm, knowledge sharing and social support for e-cigarette use generated via online user groups and vaping websites. Also, unlike NRT, e-cigarettes are not medicalised, and use does not imply rejection of smoking or a commitment to quitting.

### 6.3.2.5 Confounding

People who choose to purchase e-cigarettes may differ from those who choose NRT in relation to factors that also influence the likelihood of successful quitting. Although STS analysis suggests that differences in characteristics known to predict smoking cessation outcome, including nicotine dependence, age, social grade and recent history of quit attempts, do not account for the difference in quit rates between those using e-cigarettes and those using NRT,\(^{3-6}\) it is still possible that unmeasured confounding variables could account for the apparent advantage of e-cigarettes.
Clarifying whether and why over-the-counter e-cigarettes appear to be more effective than NRT purchased in the same way clearly requires further research, comparing e-cigarettes and other cessation pharmacotherapy in head-to-head pragmatic trials, and exploring the importance of sensory replacement and other characteristics of the products involved.

6.3.3 Highest likelihood of success

STS data indicate that the greatest improvement in quit rates comes from use of NRT, varenicline or bupropion together with multi-session, face-to-face specialist behavioural support from a qualified stop smoking adviser. This method tends to be used by the most heavily addicted smokers, who would therefore be expected to have the lowest success rates of the three categories but, after adjustment for characteristics associated with likelihood of cessation, this approach appears to increase success rates by between two- and threefold. As NHS Stop Smoking Services (SSSs) have only recently started to support quit attempts using e-cigarettes, the available data on success rates are limited, but early experience estimates quit rates to be at least as high as among those using other medication. In the year to March 2015 in England, only 2,221 SSS users made a quit attempt using an unlicensed nicotine product (ie an e-cigarette), from a total of 445,979 setting a quit date. The average quit rate in all smokers using SSSs was around 51%, and among e-cigarette users it was 66%; although factors other than the product itself are likely to be involved in this difference, the finding is certainly consistent with high efficacy as a cessation therapy.

6.3.4 Trends in uptake of different quitting methods over time

Figure 6.6 shows the proportions of quit attempts using these three groups of quitting methods among smokers in England from 2009 to 2015. It demonstrates that use of specialist services is rare among smokers and that, although most of those making a quit attempt still use the least effective methods to do so, the proportion using methods of intermediate effectiveness is increasing, largely as a consequence of increased use of e-cigarettes.

Through use of estimates of relative effectiveness based on Cochrane reviews of trials of medication and behavioural support, supplemented by the data from smokers in England described above, the growth in use of intermediate effectiveness methods between 2012 and 2015 from 18% to 40% is likely to have generated many thousands of additional successful quit attempts by 2015; the figure for 2014 is likely to be around 19,000. However, these trends also demonstrate that much more needs to be done to increase the number of smokers attempting to quit, and to increase the proportions...
6.4 What motivates smokers to try to quit and what are the obstacles?

Smokers make a quit attempt when the desire to quit and confidence in success reach an action threshold. Environmental factors can trigger a quit attempt by either momentarily raising motivation above this threshold or reducing the level of the threshold. In this context, the environment includes social norms about the desirability of smoking, as well as triggers such as health campaigns or advice on smoking from health professionals.

Survey data suggest that, in Britain, motivation to quit is driven primarily by health concerns and the financial cost of smoking, whereas factors such as
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concern about the effect of smoking on one’s family, not liking being addicted to smoking and feeling stigmatised are present but less frequently cited.\textsuperscript{26,27} The most important environmental trigger identified from smokers’ reports is health professional advice.\textsuperscript{26} Mass media campaigns can also play an important role,\textsuperscript{28} although this does not appear to be explicitly recognised by smokers.\textsuperscript{26} The introduction of a comprehensive ban on smoking in indoor public areas appears to have had a short-term, but not a sustained long-term, effect on quitting.\textsuperscript{29}

The main personal barriers to making an attempt to quit smoking appear to be enjoyment of smoking, having a positive smoker identity and low confidence in success.\textsuperscript{27,30} Motivation may also be reduced by smoking among other people who are important to the smoker, such as a partner or friends, colleagues and wider family, although evidence for this influence is less strong.\textsuperscript{27}

6.5 Why do more smokers not try to quit and how could the numbers be increased?

The figures outlined in this chapter thus far relate to the approximately one in three smokers who make a quit attempt each year. Although it is essential to ensure that as many of those as possible succeed in quitting, it is at least as important to increase quit attempts among the remaining majority of smokers who do not make a quit attempt in any given year. Measures are therefore required to increase the proportion of smokers making any attempt to quit smoking, as well as to increase the likelihood of success among those who try.

Chapter 3 outlined the population measures that can influence both quitting and uptake of smoking, and identified price rises and media campaigns as among the most effective. As studies of smokers also identify that the main drivers of motivation to quit are concerns about the health consequences of smoking and the cost of smoking,\textsuperscript{26,27} the evidence is consistent in indicating that the most effective approaches to increase quit attempt numbers in the UK are likely to comprise price rises and media campaigns using health messages. However, advice from a health professional is also identified by smokers as a key trigger for quit attempts,\textsuperscript{26} and it would appear that a great deal more could be done to increase the delivery of such advice. Figure 6.7 shows the proportion of smokers in England who report having received advice to stop smoking from their GP in the past year during 2010–15, and reveals that fewer than 40\% of smokers recall having received advice to quit; of these, only two-thirds recall having received an offer of help with quitting. Equivalent data from people accessing NHS secondary care services are not available, but anecdotal evidence suggests that delivery of smoking cessation advice and support is also low. As over 1 million
smokers are admitted to hospitals in the UK each year,\textsuperscript{31} this also represents a substantial missed opportunity to initiate and support quit attempts.

These findings indicate that guidance from the National Institute for Health and Care Excellence (NICE), which recommends that health professionals should offer help to quit at every opportunity,\textsuperscript{32,33} and support of harm-reduction initiatives among those unwilling to quit,\textsuperscript{34} is not being implemented sufficiently widely. Clinical trial evidence also suggests that, although simple advice from a physician to quit is effective, offers of support are more effective, generating quit attempts in around 40\% of those receiving the offer.\textsuperscript{35} Therefore, there is substantial scope for healthcare professionals to increase the rate of quit attempts by integrating advice and support to quit smoking in all healthcare consultations.

Since 2004, GPs in the UK have received financial incentives to record smoking status and provide advice on smoking, which, although unspecified, is generally interpreted as advice to quit.\textsuperscript{36} This scheme applied initially only to smokers with smoking-related conditions and people with serious mental health disorders, but in 2012 was extended to cover everyone who smokes. Moreover, in 2012, the contracted requirement was changed from an offer of advice to an offer of pharmacotherapy and referral for smoking cessation support. Early evidence on the scheme demonstrated that it led to marked increases in the recording of both

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**Fig 6.7** Proportion of people who smoked in the past year who reported receiving any advice on stopping or offer of help with stopping from their GP\textsuperscript{1} (data from 27,000 smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\textsuperscript{1} with permission.)
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smoking status and delivery of advice, but no increase in the prescription of pharmacotherapy\(^\text{36}\) over the background trend.\(^\text{37}\) A later evaluation of the 2012 change showed a similar result for all smokers, with increased recording by GPs of smoking status, delivery of advice to quit and referral to smoking cessation services, but no actual increase in prescription of pharmacotherapy.\(^\text{38}\) A similar scheme that rewarded hospitals for ensuring that opportunistic advice on smoking was given to patients was introduced in 2012, and there is also no evidence that this initiative has had any effect.\(^\text{39}\) Reform of these schemes would therefore appear appropriate.

6.6 How could changes in the availability of nicotine products influence quitting behaviour?

Evidence from time-series analyses indicates that increasing the availability of NRT, and introducing new smoking cessation medications to the market, increases the use of these products by smokers trying to stop smoking, but does not increase the proportion of smokers attempting to quit.\(^\text{40}\)

Evidence from placebo-controlled trials indicates that use of an NRT product while continuing to smoke can increase the likelihood of a quit attempt (see Chapter 5), and that this effect is due to the nicotine in the products rather than being a placebo response.\(^\text{41}\) Population-level data confirm that smokers who use an NRT product while smoking are more likely to try to stop, and eventually to succeed in quitting.\(^\text{42-45}\) Although the mechanism for this effect does not appear to involve increased confidence in quitting,\(^\text{43}\) it is possible that nicotine from the NRT product interferes with the maintenance of the association between smoking and nicotine reward, and hence reduces the motivation to smoke. It is also possible that encouraging smokers to experiment with nicotine products, including e-cigarettes, would generate more quit attempts and hence increase smoking cessation. The limited available evidence on this indicates that quit attempts are indeed more common among daily e-cigarette users who continue to smoke, but that successful quitting using the early-generation ‘cigalike’ devices is less common.\(^\text{46,47}\) Research into methods of increasing quit rates among people experimenting with alternative nicotine sources, perhaps by finding ways to deliver quitting advice and behavioural support, is therefore needed.

6.7 Summary

> Approximately one in three smokers in the UK currently attempts to quit each year, but only about one in six of those who try to quit remains abstinent for more than a few weeks or months.
Most smokers who try to quit do so without accessing professional help, preferring either to use no help or support, or else to use NRT or e-cigarettes bought over the counter.

Those who use over-the-counter NRT appear to be no more likely to quit than those getting no help.

Smokers who use over-the-counter e-cigarettes or prescribed medications are more likely to succeed.

The greatest increase in the chances of stopping successfully occurs with prescribed medications used together with specialist behavioural support.

The effectiveness of e-cigarettes used with behavioural support is uncertain, but early data demonstrate a relatively high quit rate.

Smokers are motivated to make a quit attempt in particular by cost and health concerns.

Price rises, media campaigns and brief advice from health professionals are therefore likely to increase the numbers of smokers trying to quit.

Health professional advice and support to quit smoking should be offered as a routine component of healthcare consultations.

Smokers who use nicotine products as a means of cutting down on smoking are more likely to make quit attempts. Promoting wider use of consumer nicotine products, such as e-cigarettes, could therefore substantially increase the number of smokers who quit.

New research is needed to improve the effectiveness of over-the-counter NRT, and to find ways of providing behavioural support to smokers who choose e-cigarettes.

References

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Quitting smoking


7 Trends in use of non-tobacco nicotine in Britain

7.1 Sources of data

Although detailed data on the prevalence of smoking in Britain have been collected for some decades (see Chapter 2), sources of survey data on the use of nicotine replacement therapy (NRT) or unlicensed nicotine products are relatively limited. The most detailed source is the Smoking Toolkit Study (STS: www.smokinginengland.info), a monthly, household, face-to-face survey of representative samples of the population of England aged 16 and over, in operation since 2007. Data on all smoking and non-tobacco nicotine-containing products, including e-cigarettes, have been collected since 2007 for smokers, since 2011 for recent ex-smokers (<1 year), and since 2013 for never-smokers and long-term (>1 year) ex-smokers. Other large national surveys have added questions on e-cigarettes much more recently, e.g. in 2014 in the Opinions and Lifestyle Survey and Scottish Health Survey. Data on use of e-cigarettes by children have also begun to be collected only relatively recently in national surveys in England, Scotland and Wales. Action on Smoking and Health (ASH) UK has commissioned annual surveys of e-cigarette use among adults since 2010 and children since 2013, and these extend beyond simple measures of prevalence to include reasons for use, and a range of other factors. The STS is the only source of data on NRT use. This chapter draws on all these sources to review trends in use of NRT and e-cigarettes in Britain over recent years. Most of the data presented are drawn from samples of smokers and recent ex-smokers participating in the STS.

7.2 Trends in the use of non-tobacco nicotine products among adults

Before the widespread uptake of e-cigarette use began in around 2011, NRT was being used by between 15% and 20% of smokers in England (Fig 7.1). However, use of non-tobacco nicotine products has risen sharply since 2011, primarily as a result of a marked increase in e-cigarette use, which has more than offset a more sustained decline in use of licensed NRT. In 2015 about 28% of smokers were
using at least one non-tobacco nicotine product, and more than 20% an e-cigarette (Fig 7.1).

Among recent (<1 year) ex-smokers, use of non-tobacco nicotine products also rose between 2012 and 2015, despite a fall in the use of NRT (Fig 7.2). In 2015 more than half of all recent ex-smokers were using a non-tobacco nicotine product, with more than 40% of these being e-cigarette users.

**Fig 7.1** Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among current cigarette smokers in England 2007–15 (data from 36,896 cigarette smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)

**Fig 7.2** Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among recent ex-smokers in England 2011–14 (data from 2,318 people who stopped smoking in the past year; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)
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Fig 7.3 Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among long-term ex-cigarette smokers in England 2013–15¹ (data from 6,487 long-term ex-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study⁹ with permission.)

Data for longer-term (>1 year) ex-smokers, which are available since 2013, show a slightly different pattern, with generally lower levels of prevalence of use and stable NRT prevalence, whereas e-cigarette use has increased (Fig 7.3).

The explanation for these trends is not certain, but is likely to be mainly due to continued e-cigarette use among people who have used them to quit smoking, because the proportion of smokers in England who have stopped smoking but then take up an e-cigarette within a year of stopping is only about 10%.¹ The ASH survey in 2015 found that the principal reasons given by ex-smokers who are currently vaping are ‘to help me stop smoking entirely’ (61%) and ‘to help me keep off tobacco’ (53%). The principal reasons given by current vapers who still smoke are ‘to help me reduce the amount of tobacco I smoke, but not stop completely’ (43%) and ‘to help me stop smoking entirely’ (41%).⁷ Whether some of these individuals would otherwise have relapsed back to cigarette smoking, had e-cigarettes not been available, is not clear. Exploration of the explanations for these trends is an important area for future research.

Among never-smokers, non-tobacco nicotine use is extremely uncommon. In 2015, 0.1% of never-smokers were using NRT and 0.3% an e-cigarette, and these figures have remained virtually unchanged since 2013 (Fig 7.4).
Among current smokers and recent ex-smokers, e-cigarettes tend to be used by a slightly higher proportion of younger than older smokers (Fig 7.5), but this use does not differ by socio-economic status (Fig 7.6) or gender.

**Fig 7.4** Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among never-smokers in England, 2013–15\(^1\) (data from 24,041 never-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\(^9\) with permission.)

**Fig 7.5** Age distribution of e-cigarette or NRT users in 2013–15\(^1\) (data from 11,186 smokers and <1 year ex-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\(^9\) with permission.)
Fig 7.6 Social grade distribution of e-cigarette and NRT users in 2013–15\(^1\) (from 11,186 smokers and <1 year ex-smokers; 2015 figures based on January to September data). AB, professional managerial; C1, clerical; C2, skilled manual; D, semi-skilled manual; E, unskilled manual/unemployed. (Adapted from the Smoking Toolkit Study\(^9\) with permission.)

Fig 7.7 Proportion of adults in Scotland in 2014 who had ever used an e-cigarette, by age and sex.\(^3\) (Adapted from the Scottish Government\(^3\) with permission under Open Government Licence.)
The Opinions and Lifestyle Survey estimated that, in the first quarter of 2014, e-cigarettes were being used by 11.8% of smokers, 4.8% of ex-smokers and 0.14% of never-smokers. Data from Scotland indicate that, in 2014, around 15% of men and women reported ever having used an e-cigarette, and about 5% reported current use. This current use was entirely restricted to current smokers (of whom 15% were current e-cigarette users) and ex-smokers (7%). Of never-smokers, 1% reported ever using an e-cigarette, and none were current users. ‘Ever use’ was much more prevalent among younger people (Fig 7.7).

Annual surveys by ASH demonstrate data consistent with STS findings, with almost 60% of smokers in Britain ever having tried an e-cigarette, and just under 18% reporting current use in 2015. Similar to the STS findings, current use had remained unchanged between 2014 and 2015 after rapid growth since 2010 (Fig 7.8).

As in the Scottish data, however, this use of e-cigarettes has occurred almost entirely among current and ex-smokers; in 2015, the prevalence of current use of e-cigarettes among never-smokers was 0.2%. The most frequently reported reasons for using e-cigarettes were to quit smoking, to help maintain abstinence having already quit and, among dual users, to cut down on smoking. The ASH survey in 2015 also explored the type of e-cigarettes that respondents were using, and demonstrated that most had started use with first-generation disposable or ‘cigalike’ devices, but then migrated to second- and third-generation refillable or tank designs (Fig 7.9).
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Over 80% of e-cigarette users surveyed by ASH in 2015 were using flavoured e-liquids. Tobacco was the most popular flavour (35% of users), but fruit (25%) and menthol (19%) were also popular.7

7.3 Trends in the use of non-tobacco nicotine products among children

Data on the use of non-tobacco nicotine among children are limited to e-cigarette use. Annual surveys by ASH of young people in the UK since 2013 demonstrate that awareness of e-cigarettes has grown substantially, such that, in 2015, only 7% of young people reported no knowledge of these products, and the proportion of young people who had tried e-cigarettes increased over these three surveys from 5% to 13% (Fig 7.10).8

However, of the 13% of young people who reported in 2015 ever having tried an e-cigarette, most (80%) had done so only once or twice.8 Only 2.4% of all participants in the survey had used e-cigarettes once or more a month, and 0.5% once or more a week. The Scottish SALSUS (Schools Adolescent and Lifestyle and Substance Use Survey) study5 reported similar findings among 13- and 15-
Trends in use of non-tobacco nicotine in Britain

7 year-olds in 2013, with 7% and 17%, respectively, reporting ever having tried to use or used an e-cigarette, and only 1% in each age group using the product more than ‘once or a few times’. In 2014, the Welsh Health Behaviour in School-aged Children survey of 11- to 16-year-olds in Wales reported that 12.3% of participants had ever used an e-cigarette, and 1.5% were using e-cigarettes at least once a month.6 The 2014 Smoking, Drinking and Drug Use survey of children aged 11–15 in England found that 22% of participating children had ever used an e-cigarette, but only 1% reported regular use.4 Regular use of e-cigarettes among young people in the UK thus appears to be very rare. As in adults, it appears that it occurs predominantly among those who are using, or have used, tobacco cigarettes. In 2013 in the Scottish study, all of those who reported having used e-cigarettes more than a few times had been, or were still, smokers (Fig 7.11).5

The 2014 Welsh survey reports very similar findings, with young people aged 11–15 who had ever used an e-cigarette being over 20 times more likely than never-users to have ever smoked; those using e-cigarettes more than once a month were more than 100 times more likely to be smoking cigarettes at least once a week.6 The 2015 ASH survey also reports a strong association between use of e-cigarettes and tobacco cigarettes (Fig 7.12), with almost all e-cigarette users either being current smokers, or having tried or been regular smokers in the past.8 Regular e-cigarette use in the 2014 English Smoking, Drinking and Drug Use survey was exclusive to children who had at least tried smoking.4

Fig 7.10 Prevalence of awareness and frequency of use of e-cigarettes among young people aged 11–18, UK, 2013–15.8 (Adapted from ASH8 with permission under Open Government Licence.)

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Of those using e-cigarettes in the ASH survey, most used a tank or other refillable device, and most used e-liquids with fruit (42%), tobacco (23%) or menthol (13%) flavours.8

Fig 7.11 Use of e-cigarettes, by smoking status, among 13- and 15-year-olds in Scotland in 2013.5 (Adapted from NHS National Services Scotland5 with permission under Open Government Licence.)

Fig 7.12 Young people aged 11–18 who have ever tried an e-cigarette, by smoking status, UK, 2015.8 (Adapted from ASH8 with permission under Open Government Licence.)
7.4 Summary

- Use of e-cigarettes among adults in the UK was rare before 2010, but has since increased to the point that up to one in five smokers now uses an e-cigarette, more than twice as many as use NRT.
- The proportion of smokers using NRT has fallen by about half over this period, but the proportion using any non-tobacco nicotine product has increased to just under 30%.
- These trends are similar but more marked among recent ex-smokers, 40% of whom use an e-cigarette.
- Use of e-cigarettes among adults who have never been regular smokers is very rare.
- There is a slightly greater likelihood that younger adult smokers will use e-cigarettes than NRT; in Scotland, younger men are more likely to use them.
- Adult regular e-cigarette users tend to use tank or other refillable devices, rather than first-generation ‘cigalikes’, and tobacco-, fruit- or menthol-flavoured nicotine.
- The proportion of young people in Britain aged <18 who have ever used an e-cigarette is increasing, but remains low.
- Most use among young people appears to be single or very occasional experimentation. Use more than once a month is relatively rare and more than once a week extremely rare.
- Regular use is almost exclusively limited to young people who are already either regular or occasional smokers, or have experimented with smoking in the past.
- Young regular users of e-cigarettes also favour later-generation devices, and fruit, tobacco or menthol flavours.
- In adults and young people in the UK, therefore, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.

References

Tobacco harm reduction


8.1 The need for harm reduction

Prevention of smoking is vital to public health, and much progress has been made in reducing the prevalence of smoking in the UK over recent decades (see Chapter 2). However, the data presented in Chapter 2 also demonstrate that this success has been achieved primarily by reducing uptake of smoking among younger people, more than improvements in the rate at which established smokers quit smoking. It is, however, these established smokers in middle and older age who will generate most of the population burden of morbidity and premature mortality caused by smoking over the next two decades.\(^1,2\) As established smokers today are more likely to be socio-economically disadvantaged or to have mental health problems (see Chapter 2), this burden of disease will fall disproportionately on these groups who, as a result of higher levels of addiction to nicotine, also find it particularly difficult to quit smoking.

Increasingly powerful incentives for existing smokers to try to quit smoking, and strong support to help them succeed, are therefore urgently required. Further application and extension of the conventional policy options summarised in Chapter 3 might be expected, at best, to sustain the decline in smoking prevalence of close to 0.7 percentage point per year achieved over the past decade in the UK (see Fig 2.1, Chapter 2), the consequence of which will be that most of the current smokers in the UK, and particularly the most heavily addicted smokers, will continue to smoke for several decades. The public health imperative in relation to smoking is, however, to reduce prevalence as much and as quickly as possible, for example, to achieve the widely agreed objective of a ‘tobacco-free’ society (comprising smoking rates of 5% or less in all socio-economic groups) by 2035,\(^3\) and this requires the addition of new strategies. Harm reduction offers the potential to add significantly to the current rate of decline in smoking prevalence among all population groups. The availability of alternatives to tobacco, as a source of nicotine for the most heavily addicted smokers, also allows the application of much higher levels of taxation on tobacco without necessarily exacerbating poverty in those smokers who find themselves unable to quit in response to increases in tobacco prices. In Sweden,
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the availability of snus has been estimated to have added around 0.4 percentage point per year to the rate of decline in smoking prevalence. E-cigarettes, and other non-tobacco nicotine products, surely have the potential to achieve at least the same in the UK.

Harm-reduction approaches, by promoting substitution of tobacco with less hazardous sources of nicotine, thus represent a potentially powerful complement to existing prevention policy, particularly among the relatively highly addicted and typically disadvantaged smokers who are likely to find it most difficult to quit. However, pursuing a harm-reduction strategy also carries risks of unwanted effects in society. This chapter explores some of the harms caused by tobacco smoking in different periods of life, and the probable balance of risks and benefits of harm-reduction approaches based on substitution with NRT or other non-tobacco nicotine products, particularly e-cigarettes.

8.2 Potential hazards of harm reduction

Although harm-reduction approaches have the potential to reduce the hazard of nicotine use among the current smoking population, they also bring potential hazards to wider public health. For example, a product that is half as damaging to health as tobacco smoking has the potential to halve the harm caused by smoking in society, if used exclusively and completely as a substitute for tobacco by current smokers, and young people who would otherwise have become smokers. That benefit would be reduced or even reversed, however, if the new product came to be sufficiently widely used among non-smokers that the benefits to smokers were eclipsed by harm sustained by non-smokers. The benefit of harm reduction to smokers would also be offset at population level if use of harm-reduction products increased the risk of smoking uptake (known as gateway progression, see below), undermined existing tobacco control measures by making the act of smoking socially acceptable again (renormalisation) or discouraged quitting by being used as a partial substitute for tobacco smoking (‘dual use’), without progression to complete substitution among smokers who would otherwise have quit. These processes are discussed in more detail below.

8.2.1 Renormalisation

In relation to tobacco smoking, renormalisation refers to processes that undermine or reverse a progressively increasing perception in society that smoking is not a normal or desirable behaviour. For much of the 20th century smoking was part of the fabric of British life, and children grew up perceiving
smoking to be something that many, if not most, adults did. In recent years, however, the acceptability of smoking has changed, particularly as a consequence of prohibition of tobacco advertising, smoking in enclosed public places and point-of-sale displays, and other measures. Although smoking remains relatively common, and hence relatively normal, in some communities or social groups, this is no longer the case in general. Examples of renormalisation might include: the use of e-cigarettes in areas where smoking is prohibited, thus creating an impression that smoking is acceptable; advertising or other imagery that evokes tobacco smoking through e-cigarette use; behavioural modelling from use of e-cigarettes by parents, siblings, peers, friends, celebrities or others; or other processes that in some way make smoking more appealing.6,7

8.2.2 Gateway progression

Gateway progression is a process by which, in relation to tobacco smoking, use of non-tobacco nicotine is proposed to cause uptake of smoking that would not otherwise have occurred. Gateway theory has its origins as a descriptive model for progression from use of soft drugs to use of hard drugs, and a recent review of evidence from animal models concluded that nicotine exposure may indeed increase susceptibility to other drug use, independent of other determinants of common liability.8 In nicotine use, however, the gateway theory has also been applied as a predictive model proposing that use of non-tobacco nicotine is likely to cause progression to use of nicotine through tobacco smoking,9 and therefore that use of e-cigarettes by non-smokers, and particularly by children, could cause smoking uptake independent of other determinants of smoking initiation. Similar concerns have in the past been expressed in relation to nicotine replacement therapy (NRT) and smokeless tobacco.9

8.2.3 Dual use

Dual use refers to the concomitant use of non-tobacco nicotine by smokers who continue to smoke tobacco. As outlined in Chapter 5, reasons for dual use include relief of nicotine withdrawal symptoms at times when smoking is not allowed, or a desire to cut down on smoking without necessarily a commitment to quit. However, concerns have been expressed that dual use may inadvertently sustain smoking by making it easier to abstain when smoking is prohibited and the smoker might otherwise have quit, and that smokers who could otherwise have quit elect for dual use instead, in the mistaken belief that this generates significant health gains. There are particular concerns that the tobacco industry will promote dual use of e-cigarettes as a means of sustaining, rather than cutting down or quitting, tobacco smoking in their customers10 (see Chapter 9).
8.3 Harm to health and wellbeing of self and others from smoking at different stages of life

Smoking directly damages the health of all who smoke (see Chapter 1), increasing the risk of a wide range of fatal and non-fatal illnesses\(^\text{11}\) and causing over 120,000 deaths in the UK in 2010.\(^\text{12}\) However, the adverse effects of smoking extend well beyond this direct harm to the individual smoker, and are not limited to the later period of life when the increased mortality in smokers becomes more acute. Through the life course of any individual from the point of conception, maternal smoking (and hence fetal exposure \textit{in utero}) impairs fetal growth and development, and increases rates of fetal and neonatal death, low birth weight, preterm birth and developmental anomalies.\(^\text{13}\) Passive maternal smoking during pregnancy increases the risk of stillbirth and developmental anomalies\(^\text{14,15}\) and reduces birth weight.\(^\text{16}\) In childhood, passive exposure to tobacco smoke causes sudden infant death, respiratory infections, middle-ear disease and exacerbation of asthma.\(^\text{13}\) Passive exposure to others’ smoke during adulthood causes transient symptoms such as eye and throat irritation at all ages, and in later life contributes to higher mortality from lung cancer, cardiovascular disease and chronic obstructive pulmonary disease (COPD).\(^\text{17}\)

Harm from smoking is not limited to that arising from inhaling tobacco smoke. Probably through behavioural modelling and opportunities for experimentation, children whose parents or other household members smoke are more likely to take up smoking themselves,\(^\text{18}\) thus perpetuating smoking and its consequent harm in successive generations. Smoking rates in the wider communities and environments that children grow up in also influence smoking uptake, because children whose peers smoke, and those exposed to smoking imagery in the media, are more likely to become regular smokers.\(^\text{19}\) Smoking is a significant drain on family budgets, exacerbating poverty,\(^\text{20}\) and a drain on wider society, which suffers the opportunity cost of funding over £3.3 billion in direct healthcare and social care costs in the UK, and over £10 billion in lost productivity and other societal costs.\(^\text{21}\) Thus, although smoking has little direct effect on the personal health of individual smokers during early adult life,\(^\text{22,23}\) the risks to others, especially children, are substantial.

As outlined above, all or almost all of these harms could be prevented or else much reduced by substitution of smoked tobacco with a less hazardous source of nicotine. The potential benefits and risks to individual and societal health of doing so are now considered in relation to the two main options currently available in the UK: conventional NRT products and unlicensed non-tobacco nicotine products, including e-cigarettes.
8.4 Harm reduction with conventional NRT products

8.4.1 Health harms

As use of nicotine alone in the doses used by smokers represents little if any hazard to the user, complete substitution of smoking with conventional NRT products is, for practical purposes, the equivalent of complete cessation in almost all areas of harm to the user. NRT products do not emit vapour and so are not a source of passive exposure for adults or children. Packaging and dose restrictions render accidental poisoning in children highly unlikely. Questions remain about the safety of nicotine in pregnancy and potential effects on fetal development and mortality, although one recent study has reported a lower occurrence of developmental abnormality among children whose mothers used NRT in pregnancy than in those whose mothers did not.

8.4.2 Renormalisation of and gateway to smoking

Only the Nicorette inhalator bears any resemblance to a cigarette, so users of most NRT products provide no behavioural modelling that could encourage primary uptake of, or sustain, tobacco smoking by others. Use of NRT among never-smokers is rare at all ages and, despite early concerns to the contrary, there is no reported evidence that use of the inhalator or any other NRT product in young people has ever acted as a gateway to smoking.

8.4.3 Dual use and gateway from smoking

NRT was developed as a smoking cessation therapy for use after an abrupt and complete cessation of tobacco smoking. The efficacy of NRT used in this way is well established. More recently, however, NRT has been licensed in the UK for use together with continued smoking, to relieve withdrawal symptoms during temporary abstinence from smoking, or to cut down on smoking, i.e. for dual use. Before the advent of e-cigarettes, up to 15% of current smokers in England used NRT in this way, although the proportion is now closer to 5% (Fig 8.1). Although cutting down on smoking achieves relatively little in terms of health benefits, use of NRT together with tobacco smoking does appear to reduce compensatory smoking to a modest extent and, among smokers with no intention to quit, to increase, by as much as twofold, the likelihood of a subsequent quit attempt. It also protects those around the smoker from the harmful effects of passive smoking. For this and other reasons, dual use of NRT and tobacco smoking is licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) and recommended by the National Institute for Health and Care Excellence.
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Fig 8.1 Self-reported use of NRT or e-cigarettes to aid cutting down on smoking, England, 2009–15.29 (Adapted from the Smoking Toolkit Study29 with permission.)

(NICE) as a tobacco harm-reduction strategy.3,24 As use of NRT in this way increases the likelihood of quitting, in these circumstances NRT acts as a gateway from smoking.

8.4.4 Population health effects of substitution of smoking by NRT

With the possible exception of use during pregnancy, complete substitution of smoking by NRT achieves much the same in health terms as quitting both smoking and all nicotine completely. Widespread uptake of NRT by non-smokers would therefore result in little harm to public health, but is in any case rare. Gateway progression from NRT to smoking among those who have never smoked does not, for practical purposes, occur. Dual use results in a modest reduction in tobacco smoking of little or no significance to health, but promotes quitting. Promotion of NRT as a reduced harm substitute for smoking is therefore unequivocally good for health. Economic analysis of the use of NRT in a harm-reduction strategy, including a range of scenarios in which opting to cut down rather than quit detracted to different degrees for those who would otherwise have quit, found that all options were cost-effective in relation to preventing major disease costs to the NHS,33 and hence were acting in favour of population health.
8.5 Substitution with e-cigarettes

8.5.1 Health harm

As e-cigarettes have been in widespread use in the UK and most other countries for less than a decade, the health effects of long-term use are as yet unknown. As outlined in Chapter 5, there is very little evidence that short-term use of e-cigarettes causes any appreciable harm to users or to others, but information on long-term health effects of repeated and sustained inhalation of e-cigarette vapour is of necessity limited to inference, based on knowledge of the vapour’s constituents. The oxidant, particulate, carcinogen and other toxin contents summarised in Chapter 5 would be expected, from first principles, to increase the risk of lung cancer, COPD, cardiovascular disease and other diseases caused by smoking, but at much lower levels of risk. For the less common health sequelae of smoking, levels of increased risk are likely to be negligible. The risks attributable to long-term inhalation of nicotine in isolation from tobacco smoke, and of the propylene glycol, glycerine and other components unique to e-cigarettes, are also uncertain but likely to be low. The health harm to long-term users of e-cigarettes is therefore likely to be marginally greater than for those who use conventional NRT.

Harm to others from vapour exposure is negligible (see Chapter 5). The effects of maternal use on the fetus are unknown but, on the grounds of the very low levels of toxins in vapour, are probably close to those of NRT. Accidental poisoning in children from ingestion of e-cigarette solutions, which has been reported and typically results in nausea and vomiting, are preventable through the use of childproof fasteners.

8.5.2 Renormalisation and gateway to smoking

First-generation e-cigarettes were designed to resemble tobacco cigarettes in approximate shape and size, and hence their use provides a behavioural model similar to smoking, which could appeal to young people or smokers trying to quit smoking, appear to undermine smoke-free policy, and be used by the tobacco industry to cross-promote smoking imagery and hence tobacco products through e-cigarette advertising (see Chapter 9). However, even first-generation products are visually distinct from cigarettes, and exhaled vapour easily distinguishable from tobacco smoke in terms of appearance, smell and irritancy, making confusion unlikely between e-cigarettes and tobacco cigarettes in areas covered by smoke-free legislation. Later-generation e-cigarettes have less or no physical resemblance to tobacco cigarettes. Use of e-cigarettes to generate smoking imagery in advertisements is prevented under UK advertising codes of practice.
Data from Wales indicate that children whose parents or peers use e-cigarettes are more likely to experiment with e-cigarettes themselves,\(^38\) and to intend to smoke in the future, than children without this exposure.\(^38\) However, as parental e-cigarette use occurs almost exclusively among current or former smokers, children in these households would be expected to have higher smoking intentions,\(^19\) and it is unclear whether this risk is either increased or decreased by the availability of e-cigarettes as opposed to tobacco cigarettes.

The prevalence data on the use of e-cigarettes by both adults and children presented in Chapter 7 demonstrate that e-cigarette use in Britain is, to date, almost entirely restricted to current, past or experimental smokers. As with NRT, there is no evidence thus far that e-cigarette use has resulted, to any appreciable extent, in the initiation of smoking in either adults or children; the extremely low prevalence of use of e-cigarettes among never-smoking adults\(^39\) and children\(^40\)–\(^42\) indicates that, even if such gateway progression does occur, it is likely to be inconsequential in population terms. Although it remains important to monitor the use of e-cigarettes in young people, to ensure the quick identification of evidence of any increase in uptake of smoking arising from e-cigarette use, it appears that, to date, concerns over gateway progression into smoking are unfounded. The association between e-cigarette and tobacco cigarette use is therefore more likely to arise from common liability to use of these products, and to use of e-cigarettes as a gateway from, rather than to, smoking.

### 8.5.3 Dual use and gateway from smoking

Office for National Statistics data indicate that, in the first quarter of 2014, 11.8% of smokers, 4.8% of ex-smokers and 0.14% of never-smokers in Britain used e-cigarettes; smoking prevalence data from the same source indicate that these proportions represented approximately 2.2%, 2.6% and 0.08% of the total adult population, respectively.\(^43\) On these figures, therefore, about 45% of e-cigarette users in Britain are using them together with smoking, which is about twice as many as do so with NRT.\(^44\) As dual use of NRT is recommended as a means of increasing the likelihood that smokers will attempt to quit smoking,\(^3\) and early-generation e-cigarettes appear to be approximately as effective as NRT as a cessation aid,\(^45\) it follows that the same is likely to apply to e-cigarettes. Observational data from England confirm that smokers who use e-cigarettes at least daily are indeed twice as likely to make a quit attempt, or else to reduce their smoking, than those who do not, although in this study the likelihood of success among those attempting to quit was not increased by e-cigarette use.\(^46\) Independent clinical trials\(^45\) and observational data from the Smoking Toolkit Study\(^47\) indicate that e-cigarette use is associated with an increased chance of quitting successfully, but further longitudinal and trial data would be helpful to define any such effect more precisely.
These findings suggest, however, that, among smokers, e-cigarette use is likely to lead to quit attempts that would not otherwise have happened, and in a proportion of these to successful cessation. In this circumstance, e-cigarettes act as a gateway from smoking. However, it is not yet known whether, or by how much, e-cigarettes are being dually used by smokers who would otherwise have quit completely, and hence act as a barrier or delay to cessation. It is also not known whether or by how much a preference to try to quit using e-cigarettes is displacing uptake of the more effective conventional NHS Stop Smoking Services (SSSs)\textsuperscript{48} or other services combining pharmacotherapy with behavioural support, and hence reducing overall quit numbers, or whether this effect is counteracted by the much broader reach and uptake of e-cigarettes relative to NHS SSSs.

It seems likely that the chance of successful quitting with e-cigarettes would be increased if smokers who chose to use them, whether for cutting down or quitting, could also receive additional behavioural support,\textsuperscript{49} and perhaps, given the evidence that the combination of two nicotine products is more effective than one alone, were encouraged to combine e-cigarette use with a nicotine transdermal patch.\textsuperscript{50} Research and development of methods are clearly needed to engage and support smokers who start to use e-cigarettes, for whatever reason, to increase the likelihood of successfully quitting.

8.5.4 Population health effects of substitution of smoking with e-cigarettes

Thus far, the availability of e-cigarettes appears to have been positive for UK public health. Uptake has been rapid among adults and limited almost entirely to smokers, and has contributed to a continued downward trend in UK smoking prevalence. Use by children who would not otherwise smoke appears to be minimal. In many ways, therefore, their availability and adoption as a consumer alternative to smoking share many parallels with the use of snus as a consumer harm-reduction product in Sweden.\textsuperscript{51} Although long-term safety remains a concern, it appears likely that the combined influences of impending regulatory controls (see Chapter 10) and technological advances will lead to significant improvements in the probable long-term hazard profile of these products in the near future. These developments mean that unlicensed e-cigarettes are likely, in the near future, to approximate to NRT in terms of long-term hazard. The arrival on the market of licensed products, whether e-cigarettes or other novel designs, will make that prospect even more of a reality. In that case, e-cigarettes are likely to share the efficacy of NRT as a harm-reduction option under most circumstances.\textsuperscript{33}

However, the creation of models of these beneficial effects for products available today, and also those of potentially adverse influences such as widespread uptake
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by non-smokers, gateway effects into smoking and sustaining dual use rather than quitting among established smokers, is difficult and inevitably dependent on assumptions about the probable magnitude of these influences. At the time of writing, we are aware of only two published attempts to do so. A proof-of-concept study applying Markov modelling to a cohort of adults aged 18–24 in the USA developed two models of smoking and e-cigarette use, the more conservative of which predicted that the prevalence of adult cigarette smoking within the cohort would increase from 15% at baseline to 21% after 10 years.52 These figures do not therefore appear applicable to the UK, where a 6 percentage point increase in smoking prevalence after the age of 25 has not happened in over 40 years (see Fig 2.11). A Monte Carlo analysis approach, modelling various scenarios of relative uptake by smokers and non-smokers, and at levels of harm relative to smoking ranging from 1% to 50%, predicted population benefits as long as use of e-cigarettes is concentrated among those who already smoke, or would otherwise have become smokers.53 As the true magnitude of e-cigarette harm is likely to lie at the low end of that modelled range, and experience to date indicates that use of e-cigarettes is almost entirely confined to smokers, these predictions support the notion that e-cigarettes, within the context of a regulatory environment designed to discourage use among youth and never-smokers, are likely to benefit public health.

8.6 Summary

> Uptake of smoking is falling in the UK, but most current smokers are likely to continue smoking for many years.
> Most of the morbidity and mortality caused by smoking in the short- and near-term future will occur in people who are smoking now.
> More effective measures to help existing smokers to quit smoking, as soon as possible, are therefore urgently needed.
> Harm reduction has the potential to complement conventional tobacco control policy by offering an alternative means for smokers to stop smoking tobacco.
> Substituting medicinal nicotine (NRT) for tobacco almost completely prevents any further damage to self or others from nicotine use.
> Although the long-term hazards of e-cigarette use are not yet clearly defined, e-cigarettes are probably close to NRT in the harm that their use confers on the user and others.
> The long-term hazard associated with e-cigarette use is likely to fall, as a result of regulatory and technological developments.
> There is no evidence that either NRT or e-cigarette use has resulted in renormalisation of smoking.
> None of these products has to date attracted significant use among adult never-smokers, or demonstrated evidence of significant gateway progression into smoking among young people.
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- NICE guidance recommends dual use of NRT for harm reduction, largely because dual users are more likely eventually to quit smoking.
- Evidence on the natural history of smoking among dual users of e-cigarettes is less well established, but a similar effect is likely.
- Promotion of the use of non-tobacco nicotine, including e-cigarettes, as widely as possible as a substitute for smoking, in the context of a regulatory framework designed to discourage use among youth and never-smokers, is therefore likely to generate significant health gains in the UK.

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9 E-cigarettes, harm reduction and the tobacco industry

9.1 Introduction

In 2013, the investment bank Goldman Sachs identified e-cigarettes as one of eight emergent themes in the global economy capable of 'creative destruction', representing a new technology that could offer consumers a significantly superior proposition and potentially ‘forcing established companies and business models to either adapt or die’. In the same year, The Economist newspaper similarly asked whether the rise of e-cigarettes represented the tobacco industry’s ‘Kodak moment’ – ‘its version of the point at which the world’s leading maker of camera film realised that consumers had gone digital, and it was too late to chase them’. The continuing profitability of the tobacco industry, which arises overwhelmingly from sales of tobacco cigarettes, suggests that such reports of the industry’s demise are at best premature. However, these claims do highlight the substantial degree of uncertainty about the commercial implications of e-cigarettes for the future of the tobacco industry and therefore for the strategic development of tobacco control.

The disruptive effect of e-cigarettes is not confined to the tobacco industry. The chairman of the pharmaceutical giant GlaxoSmithKline, for example, has acknowledged that, in response to the declining performance of their nicotine replacement therapies (NRTs), the company considered manufacturing e-cigarettes before concluding that such a step would be ‘just too controversial’. Leading tobacco companies have, perhaps predictably, made a different decision, implementing a rapid programme of investment in and acquisition of vapour devices. The public health implications of such developments remain uncertain and contested, and reflect broader debates about the role of harm reduction in general. At one end of the spectrum, harm-reduction advocates and researchers see advantages in engaging an industry skilled in marketing nicotine in the promotion of products that could offer a potential exit strategy from selling cigarettes: identifying, for example, the ‘need to create a situation in which there are incentives for tobacco companies to gradually become nicotine companies … [such] that their long-term profits are going to be in other products than cigarettes’. At the other end of the spectrum are those who see no such prospect,
claiming, for example, that ‘only the most naive or captured advocates for vaping could fail to acknowledge that the tobacco industry wants people who vape to smoke and vape, not vape instead of smoking’. This chapter explores the motives for and potential consequences of the tobacco industry’s engagement in harm reduction and, in particular, the emerging e-cigarette market.

9.2 The tobacco industry and e-cigarettes

E-cigarettes have emerged as a significant component of the market in nicotine products with astonishing rapidity, both in the UK and globally. The market research company Nielsen identified e-cigarettes as the fastest-growing product in British supermarkets during 2014, with sales across large grocers increasing by almost 50%. A report on the UK market in nicotine vapour devices by the industry analysts Euromonitor suggested even greater growth, with a category that was worth only £25 million as recently as 2011 having reached overall sales of £459 million in 2014. This growth also reflected changing consumer preferences, with first-generation (‘cigalike’) devices (see Chapter 5) being displaced in the UK by the rapid expansion of tank systems and of e-liquids, which experienced value growth of 110% and 145% respectively in 2014. This shift is also strongly evident in other leading western European markets, although ‘cigalikes’ retain majority shares in both Russia and the USA. The UK e-cigarette market is now estimated to be the world’s second largest, being exceeded only by the USA, whereas global sales of an estimated $US6.5 billion now dramatically outstrip the declining international market for NRT ($US2.4 billion), and are equivalent in value to cigarette sales in the world’s 20th-largest cigarette market.

Having perhaps been taken by surprise by the rise of e-cigarettes, the transnational tobacco companies have all now committed to major initiatives in this emergent industry. A key moment was the April 2012 acquisition of the e-cigarette brand blu™ by the US-based cigarette manufacturer Lorillard for $US135 million, marking the tobacco industry’s first major foray into the e-cigarette market. In December 2012, British American Tobacco (BAT) became the first leading tobacco company to buy a British e-cigarette manufacturer through its purchase of CN Creative, the maker of Intellicig. This complemented BAT’s earlier formation of what was billed as a stand-alone start-up company, Nicoventures, to ‘focus exclusively on the development and commercialisation of innovative regulatory approved nicotine products’. All of the leading international cigarette manufacturers have now made substantial acquisitions or launched strategic initiatives in nicotine products, principally in e-cigarettes. Altria and Philip Morris International (PMI) manage vapour brands including Mark Ten, Nicotiles and the heat-not-burn product iQOS; BAT brands include Vype, Intellicig and an inhaled nicotine device called Voke; Japan...
Tobacco International have purchased E-Lites and launched Ploom; RJ Reynolds have developed Vuse and Revo, whereas Imperial Tobacco launched Puritane through its Fontem Ventures subsidiary and, in July 2014, obtained the blu™ brand that was sold as part of Reynolds’ takeover of Lorillard. These investments have, to date, been weighted heavily towards first-generation ‘cigalikes’, which mimic tobacco cigarettes more closely, but tend to deliver lower doses of nicotine than, later-generation devices (see Chapter 5), and it has been suggested that this is a deliberate strategy to avoid promoting products likely to be effective in aiding cessation. Recent developments suggest diversification, with tobacco companies looking beyond ‘cigalikes’: the Vivid Vapours e-liquid brand has become increasingly prominent in the UK after its acquisition by PMI, and the blu™ product range is expanding via its e-liquid portfolio. Investments in heat-not-burn technology (positioned as reducing risks associated with combustion by electronically heating tobacco rather than burning it), as well as in non-tobacco nicotine products (see Chapter 5), further increase the diversity of tobacco company initiatives in reduced risk products, and PMI’s launch of its iQOS Heatsticks, under its flagship Marlboro brand in test markets in Japan and Italy, suggests that this development is of major strategic importance to PMI. It does appear that tobacco industry efforts to build a market for reduced-risk products are now centred on vapour devices, as epitomised in July 2015 by PMI announcing the dissolution of its snus joint venture with Swedish Match while extending its international strategic collaboration with Altria in vaping products.

The engagement of the tobacco industry in the reduced-risk product sector is thus changing rapidly, and in relation to e-cigarette products is likely to continue to do so, given, among other things, the expected changes in regulatory context, new patterns of ownership and investment, the currently fragmented market, absence to date of dominant brands, and continuing technological innovation and shifting consumer preferences. Such uncertainties notwithstanding, however, rapid growth in the e-cigarette market is predicted to continue over the next few years, with Euromonitor suggesting that the global market for vaping products could reach US$50 billion by 2030. This is clearly a substantial and enticing prospect from a commercial perspective, although it needs to be interpreted alongside an expectation that it will remain a fraction of the market in tobacco products, with cigarettes remaining the dominant product category.

### 9.3 E-cigarette marketing

The first television advertisement for an e-cigarette, promoting the then independently owned E-Lites brand, was broadcast in the UK in January 2013. This was followed a year later by advertisements for Vype, an e-cigarette
marketed by BAT and representing the first overt paid-for television advertisement by a tobacco company in over two decades, and then, later in 2014, by advertisements showing the act of vaping for the VIP e-cigarette brand. Such developments occurred amid considerable ambiguity about how and whether existing regulatory frameworks applied to reduced-risk nicotine products. This led to a public consultation by the Committees of Advertising Practice, followed by the issuance of specific guidance intended to govern the period until the implementation of more stringent regulation of advertising, sponsorship and promotion under the 2014 revision of the EU Tobacco Products Directive 2014/40/EU.

The development of television advertising campaigns forms one strand of an extensive array of marketing, sponsorship and promotional efforts that have contributed to the rapid growth of the e-cigarette market. Sports sponsorship deals, for example, have included Nicolites partnering with Birmingham City Football Club, whereas E-Lites secured distribution deals and designated vaping areas in Celtic and Rangers football stadiums in Glasgow, and invoked the strong association between tobacco and motorsport in announcing its sponsorship of the British Superbike Championship. E-Lites secured the first product placement for e-cigarettes in a music video by the artist Lily Allen. Packaging innovations have included ‘smart packs’ produced by blu e-cigarettes that vibrate and flash a blue light when within 50 feet of other users, and which can transmit to Facebook and Twitter profiles, whereas Vapestick has created a retro-style computer game named Electronic cigarette wars. PMI also offered retailers free retail display shutter cases heavily branded with its Vivid e-liquid and Nicolites e-cigarettes, in preparation for the second stage of UK point-of-sale display legislation, which prohibited point-of-sale display of any tobacco product from April 2015.

Such high-profile activity is indicative of the recent rise of e-cigarette promotions across multiple fields, driven by rapidly escalating expenditure. During 2013, around £8.4 million was spent in the UK promoting five leading brands (E-Lites, Vype, SkyCig, NJOY King and Gamucci) across press, television, radio, the internet and outdoor media, figures that were to be dwarfed in 2014 with BAT’s television advertising for Vype as part of a £3.6 million marketing campaign and Skycig announcing investment in a £20 million marketing campaign. A similar surge in marketing spending has occurred in the USA, where a study of advertising spending across television, print, radio and the internet found that expenditure in the second quarter of 2013 amounted to $US28 million, some eight times more than that for the equivalent period in 2012.

This escalation of marketing expenditure reflects the increased resources available following the wave of investments in e-cigarettes by the tobacco industry, with the latter’s engagement in marketing raising distinct concerns.
Looking at the future development of the market in vapour devices from a commercial perspective, this represents both opportunity and risk, because leading tobacco companies 'have the capital to turn e-liquid brands into household names but also the reputational impairment to attract draconian regulation to the category'. In this context, discussions about how to regulate the marketing of e-cigarettes are inevitably coloured by the tobacco industry's long-standing global reliance on advertising and marketing to promote and maintain cigarette consumption, particularly by targeting young people. Health campaigners have raised concerns about the extent to which some e-cigarette advertising has sought to replicate imagery and themes that have long been central to marketing cigarettes. Magazine adverts for e-cigarettes in the USA have, for example, been seen as depicting equivalents to the rugged masculinity of the Marlboro Man or the glamorous independence of the Virginia Slims woman, sponsorship of sports and music events, and the development of sweet flavours are seen as enhancing appeal among youth, and blu™ e-cigarettes' use of a cartoon 'Mr Cool' evoked the notorious Joe Camel cartoons. In the UK, rules on advertising limit such opportunities and the Advertising Standards Authority recently upheld complaints about an advert for VIP e-cigarettes that showed a woman vaping 'in a sultry and glamorous way', creating a strong association with traditional smoking and thereby 'indirectly promoting the use of tobacco products'. Complaints about a UK advert for Vape Nation were upheld as encouraging use of e-cigarettes among ex-smokers.

Maintenance of extensive marketing freedom and potentially controversial promotional strategies for e-cigarettes has been defended as likely to appeal to smokers, and it has been argued that excessive regulation is likely to protect the market monopoly of tobacco cigarettes by inhibiting competition from e-cigarettes. Analyses from a social marketing perspective, however, have emphasised risks associated with e-cigarette marketing in general, and the role of tobacco companies within such activities in particular. In presenting the promotion of e-cigarettes as a reinvention of tobacco marketing, de Andrade et al highlight the active promotion of dual use, in which marketing activities are identified to have been 'promoting long term use as a permanent alternative to tobacco, and a temporary one in public places where smoking is banned'. An analysis of the marketing strategy of tobacco company-owned e-cigarettes for Cancer Research UK was organised around a distinction between marketing targeted at potential consumers and those activities oriented towards 'stakeholders', such as policymakers and public health agencies (Table 9.1).

Although debate about the potential for such campaigns to renormalise or inadvertently promote smoking continues, attention is increasingly focused on the tobacco industry's use of e-cigarettes and the wider harm-reduction agenda to rebuild its links with policymakers, and public health and other key stakeholders.
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Table 9.1 Tobacco-owned e-cigarettes – the marketing strategy

<table>
<thead>
<tr>
<th>Marketing challenge</th>
<th>Marketing strategy</th>
<th>Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who</td>
<td>Consumers</td>
<td>Stakeholders</td>
</tr>
<tr>
<td>Objective</td>
<td>Long-term sales of tobacco through ‘next-generation’ product (especially in developed countries), profit maximisation</td>
<td>Responsibility, legitimacy, credibility, access to policymakers/regulatory processes, public–private partnership, scientific proof</td>
</tr>
<tr>
<td>What</td>
<td>Reduced-harm product, safer alternative to cigarettes, used for pleasure, lifestyle products</td>
<td>Harm reduction</td>
</tr>
<tr>
<td>How</td>
<td><strong>Product</strong>: safe nicotine, used anywhere, flavoured lifestyle products</td>
<td><strong>Product</strong>: harm reduction</td>
</tr>
<tr>
<td></td>
<td><strong>Price</strong>: financial – affordable; psychological – safer and glamorous</td>
<td><strong>Price</strong>: financial – priceless, saving lives; psychological – it would be negligent to ignore this offering</td>
</tr>
<tr>
<td></td>
<td><strong>Promotion</strong>: where tobacco products cannot be advertised, lifestyle and celebrity</td>
<td><strong>Promotion</strong>: health bodies/experts, charities, politicians, regulators</td>
</tr>
<tr>
<td></td>
<td><strong>Place</strong>: everywhere tobacco is available, company websites, point-of-sale displays</td>
<td><strong>Place</strong>: regulated space</td>
</tr>
<tr>
<td></td>
<td><strong>Positioning</strong>: safer smoking alternative, necessity, capitalise on consumer’s preference</td>
<td><strong>Positioning</strong>: differentiation from NRT products, reframe perceptions of nicotine use, alternative for those who cannot or will not quit</td>
</tr>
</tbody>
</table>

9.4 Undermining tobacco control

The recognition of a fundamental conflict between public health objectives and tobacco industry interests has become a central tenet of tobacco control, epitomised by Article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), which requires countries to protect the setting and implementation of tobacco control policies from the industry’s commercial and other vested interests. The emergence of a distinctive model of
health governance, centred on minimising engagement with the industry, has led to tobacco companies experiencing increasing political marginalisation and difficulty obtaining access to policy elites. In this context, investments in harm reduction and e-cigarettes offer potential opportunities to claim legitimacy in re-engaging with policymakers, and even to rehabilitate what has become a pariah industry. If realised, these opportunities may therefore undermine tobacco control.

Tobacco companies have long sought to redress the challenge of a toxic reputation by seeking to establish partnerships or common ground with public health researchers and advocates. A key element of PMI’s ‘Project Sunrise’ in the mid-1990s, for example, was to ‘enhance our credibility’ by linking with ‘moderate’ tobacco control organisations on issues such as youth access legislation. Tobacco companies’ interest in the concept of harm reduction increased markedly following a 2001 Institute of Medicine report, driven by recognition of a dual opportunity to both ‘(re-)establish dialogue with and access to policymakers, scientists and public health groups and to secure reputational benefits via an emerging corporate social responsibility agenda’. The emergence of pure nicotine alternatives to traditional forms of tobacco consumption has thus created increased opportunities for both interaction with policymakers and the depiction of common ground with public health. In the context of a public consultation on the future of the NHS, for example, Imperial Tobacco met with the then minister for public health, and subsequently made a submission in which the company invoked its interests in harm reduction to argue against exclusion from policymaking and to position itself as a potential partner for the government. Several tobacco industry submissions to a Department of Health consultation on the future of tobacco control similarly used interests in harm reduction as a basis for suggesting that it could positively contribute to the challenge of reducing health inequalities.

Exploiting such opportunities was a key part of the remit of Nicoventures following its establishment by BAT. In 2012, Nicoventures initiated a medical education plan named the Smoking Harm Reduction Education Programme (SHARE), holding a series of meetings with healthcare professionals, including a round table at the Royal Society of Medicine, and publishing proceedings in GP and Pharmacy Magazine. In June 2013, Nicoventures approached public health officials across various regions in the UK to discuss harm reduction and regulation, with a sales representative describing the company as complying with the regulatory standards required of a pharmaceutical company. BAT also appointed Dr Richard Tubb to their board of directors in January 2013, describing this former physician to the president of the USA and ex-director of the White House Medical Unit as ‘a prominent and well respected expert in the field of tobacco harm reduction’ whose appointment ‘further demonstrates our commitment to putting science at the heart of our business’. The company
devoted its 2013 sustainability focus report to the issue of harm reduction, depicting BAT as a potential partner in a public health revolution; this included an endorsement of the group’s strategy by Dr Delon Human, a global health consultant and former head of the International Food and Beverage Alliance, as having the expertise and public commitment to harm reduction to suggest that ‘BAT could become part of the solution to addressing the epidemic of tobacco-related disease’. The report claims that ‘(m)ore collaboration between the tobacco industry, academia and tobacco research centres is … key to establishing an evidence-based regulatory framework to assess new products’.

Alongside such examples of formal endorsements, tobacco companies have also opportunistically cherry-picked statements from leading public health organisations and researchers so as to imply common ground and a shared perspective. The harm-reduction section of the PMI website cites a 2014 report from Public Health England (PHE) as recognising a need for ‘appropriate regulation, careful monitoring, and risk management’ for harm-reduction products; the citation is presented under a headline claim that the ‘public and private sectors are starting to embrace the public health opportunity new products provide’, but does so without noting that the PHE report highlights the involvement of the tobacco industry among ‘potential hazards, unintended consequences, (and) harms to public health’.

A key element of the strategic value of harm-reduction discourse to tobacco companies is its ability to polarise opinions held by those involved in tobacco control policy, fracturing the remarkable degree of political consensus that has characterised the tobacco control movement and been central to its success. PMI’s ‘Project Sunrise’ centred on the recognition of unity as a key strength of tobacco control, and promoting division was seen as critical to combating the movement’s success. The company’s strategy sought to exploit latent tensions between groups that it labelled ‘moderates’ and ‘prohibitionists’, and this finds strong contemporary echoes in the depiction of competing wings of tobacco control comprising ‘pragmatists’ who favour harm-reduction approaches being opposed by ‘idealists’ or ‘zealots’.

In this context, the very public dispute in 2014 between competing perspectives on harm reduction via ‘duelling letters’ from public health researchers and practitioners to the director-general of WHO, Dr Margaret Chan, appears very welcome from a tobacco industry perspective. The initial open letter of 24 May 2014 with 53 prominent signatories was prompted by a concern that harm reduction was being ‘overlooked or even purposefully marginalised’ in preparing for the forthcoming sixth Conference of Parties of the WHO FCTC. The letter began to receive significant media coverage on 29 May 2014 and on the same day BAT issued a press release calling for tobacco harm reduction to be adopted as a progressive public health policy.
Although neither the reputational management nor policy engagement opportunities afforded by harm reduction have yet been exploited with success that can be considered transformational, a number of strategically valuable ‘wins’ for the tobacco industry can be identified. Notable here is the success of BAT’s Nicoventures in securing marketing authority from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for its nicotine inhaler Voke, a success has been described as ‘an important waypoint on the industry’s journey to self-rehabilitation’.56 Vype, also owned by BAT’s Nicoventures, is marketed as a ‘pharmaceutical-grade product’ and sold via Lloyds Pharmacy, whereas Puritane e-cigarettes, owned by the Imperial Tobacco subsidiary Fontem, are exclusively available in Boots. Such distribution deals are inconsistent with advice from the Royal Pharmaceutical Society,27 and both bring reputational benefits of association with prominent high-street chemists and create strategic opportunities. Puritane’s deal with Boots is seen as leaving it well placed to benefit from any reclassification of e-cigarettes to ‘directly rival smoking cessation aids’.11

9.5 E-cigarettes and the future of the tobacco industry

Tobacco companies’ investments in e-cigarettes, as with earlier incarnations of the harm-reduction debate, have been characterised by considerable uncertainty, false starts and fluctuations, and there is nothing to suggest that the recent developments outlined above constitute a fixed and settled strategic direction, whether for specific companies or for the industry as a whole. There is, however, now a sufficient basis to draw some preliminary conclusions informed by marketing campaigns, investor presentations and stated strategic priorities. Such conclusions need to be informed by the historical experience of how and why tobacco companies viewed earlier reduced-risk products, with which striking similarities are becoming evident. One potential parallel has recently been drawn
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in light of the history of NRT, via tension between two competing conceptions of NRT as a therapeutic device to aid cessation and as a cigarette alternative capable of delivering nicotine in the ‘right way’. This analysis highlights the dangers of the potential of e-cigarettes being ‘easily compromised in the hands of tobacco companies, reflected by their tendency for imagining nicotine replacements … as creatively complementing rather than creatively destroying the market for combustible tobacco products’.

More broadly, the tobacco industry’s recent involvement with e-cigarettes carries echoes of its earlier rise to dominance of the Swedish snus market via acquisitions and joint ventures between 2001 and 2009, eg an analysis of BAT corporate documents from this period yielded no substantive evidence of the company encouraging smokers to switch permanently to smokeless tobacco, but indicated instead that these were essentially defensive investments that protected the status quo and the dominance of the cigarette by shifting ‘snus from a threat (a product that may have competed with cigarettes) to a major opportunity’ that presented common interests with public health and an alternative future amid long-term decline in cigarette sales.

One significant difference that emerges from comparison with the snus experience is the prominence afforded e-cigarettes and reduced-risk products in contemporary investor presentations. This contrasts with a near absence of snus from earlier BAT and PMI presentations, which suggest that snus was not central to business strategy. The reformulation of BAT’s vision statement to become ‘the world’s best at satisfying consumer moments in tobacco and beyond’ indicates newfound strategic centrality for nicotine projects, mirrored in PMI’s designation of reduced-risk products as ‘our greatest growth opportunity’. Although the reputational and stakeholder engagement advantages of e-cigarettes for tobacco companies are clearly considerable, this does seem also to represent a consumer market in which growth prospects are being taken seriously.

The extent to which this constitutes a transformation of the strategic landscape for tobacco companies should not, however, be overstated. To return to the image of creative destruction, the emphasis seems to be very much on e-cigarettes creatively complementing conventional products within an expanded portfolio, not on displacing the industry’s ongoing reliance on the conventional cigarette. Hence BAT has been unequivocal that their ‘ambition remains to lead the global tobacco industry’, retaining confidence in the growth of the global tobacco business and developing their portfolio of ‘beyond tobacco products’ within a single integrated view of the consumer. New products are therefore positioned alongside traditional cigarettes, combustible innovations and non-combustible offers in creating multiple satisfying ‘consumer moments’. Similarly, PMI chairman Louis Camilleri’s speech to the company’s 2015 annual meeting emphasised that ‘we expect our combustible products to be the core of our
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profitability growth for many years to come’, notwithstanding the significance attached to investing in and developing reduced-risk products. The decision to launch the company’s heat-not-burn iQOS system under the Marlboro brand is also consistent with ongoing concerns that tobacco companies are using e-cigarette marketing to promote dual use, thereby complementing and sustaining rather than challenging the future dominance of the cigarette.

Any suggestion that tobacco companies are using investments in e-cigarettes as a vehicle to secure their long-term exit from the cigarette market therefore looks like misplaced optimism. Their engagement in harm reduction is likely to be better understood in terms of exploring an emerging opportunity that can buttress their core business, and promise the maintenance of both their licence to operate and the prospect of rehabilitation. Appraising the implications of this perspective for the broader role of harm reduction within the future of tobacco control remains contentious, but it does serve to highlight the ongoing importance of protecting health policy from tobacco industry interference and of maximising compliance with guidelines for the effective implementation of WHO FCTC Article 5.3. Although the most optimistic interpretations of increased tobacco industry interests in reduced-risk products might suggest the prospect of some degree of shared interest with public health, the economic and political contexts within which such products are being promoted suggests that any such appraisal is dangerously naive and holds the potential significantly to undermine tobacco control policy and practice internationally. Interests in e-cigarettes and other reduced-risk products create important strategic opportunities for the tobacco industry, and therefore compound the complexities confronting public health in dealing with the harm-reduction agenda. The appropriate response is therefore to strengthen and broaden protections against conflicts of interest, protecting ‘tobacco control activities from all commercial and other vested interests related to [e-cigarettes], including interests of the tobacco industry’.

9.6 Summary

> The e-cigarette market has demonstrated massive growth in value and, until relatively recently, has been driven by independent e-cigarette companies.
> This success represents a potential challenge to the traditional business model of the tobacco industry, but also creates important commercial and political opportunities.
> After some delay the tobacco industry is now engaging in the e-cigarette market, and the possible reasons for doing so include:
  - promotion of low-efficacy products that are likely to fail and hence minimise the threat to tobacco sales
  - use of intellectual property rights to bring legal challenges against competitors
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- ensuring a share in the emerging e-cigarette market to harness a new, disruptive technology
- using these products to sustain tobacco smoking by promoting them as a complement rather than an alternative to tobacco
- using the products also to promote smoking through advertising and promotion to adults and children
- attracting customers who currently use competitors’ tobacco products
- creating justification to re-engage with policymakers, hence undermining the WHO FCTC (Article 5.3)
- exploiting harm reduction to build credibility in corporate social responsibility initiatives
- using harm reduction as a pretext to engage with and disrupt the activities of scientists and advocates in tobacco control.

The engagement of the tobacco industry in the e-cigarette market thus represents a significant potential threat to UK national and global tobacco control.

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10 Regulating nicotine products in the UK

10.1 What does nicotine product regulation need to achieve?

Products are regulated to ensure that they are safe and fit for purpose; the general product regulations that apply to all consumer products sold in the UK, and their equivalents in other countries, are intended to achieve this for general consumer goods. In the case of products for which safety is particularly important, these general product regulations are often supplemented or superseded by higher levels of specific safety regulation, with medicines, for example, being required to meet especially high standards of manufacturing, safety, product information and efficacy. The overall purpose of all of this regulation is, however, to ensure that consumers can access products that serve their purpose within reasonable bounds of safety, quality and efficacy.

The rationale for regulating nicotine products is the same as for any other, but is complicated by the fact that the market leader in nicotine products in the 20th and 21st centuries, the cigarette, is so intrinsically hazardous that it is beyond the scope of conventional general product regulations, and as an addictive product is too entrenched in society to be amenable to prohibition. It is therefore important that the approach to regulating non-tobacco nicotine products recognises the need not only to meet the general requirements of safety and fitness for purpose, but also to encourage the development and uptake of competitive alternatives to the fatally toxic product currently chosen by most habitual nicotine users.

Therefore, although regulation of all products should be proportionate to their potential hazard, proportionality in nicotine regulation must also incorporate the consideration that regulation that discourages or delays the development and use of non-tobacco nicotine is likely, in effect, to sustain tobacco smoking and hence perpetuate harm to smokers and wider society.

This report has argued that nicotine use, of itself, presents relatively little risk to users or wider society, and that most of the harm that arises from nicotine use is attributable to the vehicle of delivery, with tobacco smoke being by far the most hazardous. It therefore follows that, although the ideal course of action for any smoker is to quit smoking and all nicotine use, quitting smoking by long-term
substitution with a less hazardous nicotine source is the next best option. Nicotine regulation should therefore be designed to make non-tobacco nicotine a more attractive, available and affordable option for smokers than cigarettes, to prevent, as far as possible, uptake of nicotine use by never-smokers, particularly children, and to make smoked tobacco products as unappealing as possible.

When the RCP last reported on nicotine regulation in 2007,1 the range of available nicotine products fell into three classes: smoked tobacco, smokeless tobacco and nicotine replacement therapy (NRT). We argued then that the prevailing regulatory structure intrinsically favoured smoked tobacco over both NRT, which was regulated as a medicine, and smokeless tobacco, of which the lowest-hazard product, Swedish snus, is prohibited in the UK. The emergence of e-cigarettes has added a whole new product class to this range, and this spectrum of choice is likely to be increased still further by new technologies in development (see Chapter 5). The nicotine regulatory framework has also undergone substantial change since 2007.

This chapter describes recent developments and impending changes in UK nicotine regulation, identifies key areas of concern, and discusses alternative approaches that might increase the public health benefit accrued from the emergence of e-cigarettes and other non-tobacco nicotine. The discussion is based in the UK setting and pertains to the three broad types of nicotine product available on the UK market: tobacco, unlicensed nicotine products (predominantly e-cigarettes) and nicotine products that are licensed as medicines.

10.2 Current regulation of tobacco, and licensed and unlicensed nicotine products

10.2.1 Tobacco products

Since 1998, a comprehensive tobacco control strategy has been introduced in the UK, the component measures of which are discussed in more detail in Chapter 3. Regulatory approaches have included: reducing affordability by increasing taxation and reducing the size of the cheap and illicit market; imposing packaging and labelling requirements (including the implementation of standardised packaging legislation from May 2016); prohibiting all advertising, promotion and sponsorship; restrictions on where, how and to whom tobacco products can be sold; and smoke-free policies determining where tobacco can be used. After unsuccessful attempts to regulate the cigarette itself by restricting tar levels, regulation of product contents and emissions has not been extensively pursued, other than to prevent fires by reducing ignition propensity. The overall package of tobacco control policies in place in the UK is one of the most
advanced in the world, with the UK currently highest in the European tobacco control league table.\textsuperscript{2} The new EU Tobacco Products Directive (TPD)\textsuperscript{3} will, from May 2016, impose a range of new restrictions on tobacco products, which include a minimum pack size of 20 cigarettes (and 50 g hand-rolling tobacco), restrictions on the shape of packs, combined pictorial and text health warnings that cover 65\% of the front and back of the pack, and prohibition of flavourings including, after a delay, menthol.

10.2.2 Unlicensed nicotine products

E-cigarettes (most of which contain nicotine) and other unlicensed nicotine products are currently regulated in the UK by the EU General Product Safety Directive. This has recently been supplemented by legislation in England imposing a minimum purchase age of 18 years, which is currently in the process of being introduced elsewhere in the UK.\textsuperscript{4} General product regulations do not require products to be tested before being put on the market, but do allow retrospective action to remove products found to be faulty or harmful. In July 2015, the British Standards Institute (BSI) published a fast-track voluntary standard for e-cigarettes (PAS 54115), which was sponsored by the Electronic Cigarette Industry Trade Association (ECITA (EU) Ltd) and facilitated by the BSI.\textsuperscript{5,6} This standard gives guidance on the manufacture, import, labelling, marketing and sale of vaping products, including e-cigarettes, e-shishas and e-liquid mixing kits. However, at the time of writing it is not clear how widely this standard is being adopted by manufacturers and importers.

E-cigarette marketing in the UK has to comply with compulsory advertising codes administered by the Advertising Standards Authority (ASA). Although those codes contain general rules that apply to all advertising, concerns about the promotion of e-cigarettes led the ASA to introduce sector-specific rules in November 2014.\textsuperscript{7} These require the following of e-cigarette advertising: to be socially responsible; not to promote any design, imagery or logo that might be associated with a tobacco brand or show the use of a tobacco product in a positive light; to make clear that the advertised product is an e-cigarette and not a tobacco product; not to undermine quit smoking messages; and not to contain health or medicinal claims unless the product holds a medicines licence. There is a commitment to review progress with these rules after 12 months.

Although not subject to the smoke-free legislation that prohibits tobacco smoking in enclosed public places and workplaces, some businesses and organisations prohibit e-cigarette use in places where this legislation already prohibits smoking. Given the lack of evidence on the harmfulness of e-cigarette vapour to others (see Chapter 5), it would be inappropriate for national legislation to prohibit their use in public places and workplaces. At the time of
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going to press, an attempt by the Welsh government to legislate to ban the use of e-cigarettes in some enclosed places and workplaces had failed and was considered unlikely to be reintroduced in the next parliament after the elections in May.\(^8\)

There are some circumstances, such as prisons and mental health settings, where tobacco smoking is particularly prevalent. The option to use e-cigarettes where tobacco smoking is banned could help to introduce and sustain fully smoke-free policies, e.g. the South London and Maudsley NHS Foundation Trust implemented a policy that allows some types of e-cigarette to be used, as part of a care treatment pathway, in private spaces or grounds where smoking is prohibited.\(^9\)

Prisons in England and Wales have made single-use e-cigarettes available for sale to prisoners as a smoking substitute, in preparation for implementing fully smoke-free policies across the prison estate which started in late 2015.\(^10\)

10.2.3 Licensed nicotine products

Nicotine products licensed as medicines, generally known as nicotine replacement therapy (NRT), have been available in the UK since 1980. They were initially licensed by the Medicines Control Agency (MCA) for use to relieve nicotine withdrawal symptoms during attempts to quit smoking, and were subject to an extensive range of cautions and contraindications that arose from the use of comparison of adverse effects with those of placebo, rather than continued smoking.

The MCA was replaced in 2003 by the UK Medicines and Healthcare products Regulatory Agency (MHRA), which was established with a wider remit, including a new objective to make ‘an effective contribution to public health’. In 2005 the MHRA made some substantial changes to their regulation of NRT products in response to a review and recommendations by the Committee on Safety of Medicines, an advisory committee to the MHRA.\(^11\) These included the adoption of smoking rather than placebo as the comparator for NRT, which allowed some contraindications (e.g. stable cardiovascular disease) that inhibited use of NRT by smokers to be removed, extending the licence for NRT to include pregnant smokers, and smokers aged 12 and over, and allowing some NRT products to be used for cutting down in order to quit, as well as for abrupt quitting. There has also been a progressive relaxation of restrictions on the availability of NRT over recent years, starting in 2001 when prescriptions of NRT products became reimbursable through the NHS, and subsequently through extensions to retail availability by allowing NRT products to be sold by general retailers as well as pharmacies. Direct advertising of NRT to the public is permitted subject to regulations\(^12\) requiring the following from promotions: they are not misleading and do not imply that products are ‘safe’; they are compliant with the details listed in the summary of product characteristics; they are presented objectively to encourage rational use of
the product; and they are not directed exclusively or principally at people aged under 16. Provision of free samples of NRT for promotional purposes remains prohibited. Since 2007, NRT sold over the counter has been subject to VAT at a reduced rate of 5% to help make products more affordable.13

In 2010, the MHRA expanded the indication for NRT to allow long-term use as a harm-reduction alternative to smoking for those who were unwilling or unable to quit.14 The question of whether e-cigarettes should be regulated as medicines was considered by the MHRA at this time, which proposed that nicotine be deemed a medicine by function, thereby requiring that e-cigarettes should either be licensed as medicines or removed from the market. However, as immediate classification as medicines would have caused all e-cigarettes on the market at the time to be withdrawn, and hence potentially cause the many smokers who had already switched from using tobacco cigarettes to e-cigarettes to go back to tobacco smoking, the MHRA consulted on options15 that included implementing medicines regulation immediately, or after a delay allowing e-cigarette manufacturers and importers to comply, or else imposing no additional regulation. The proposed licensing option was described by the MHRA as ‘light touch’ and presented as a simplified, and hence quicker and less costly, route to medicines licensing. In particular, the proposed ‘light touch’ approach assumed that any product that delivered nicotine to a degree comparable with existing licensed nicotine products was clinically effective, thus removing the requirement for manufacturers or importers of e-cigarettes or other nicotine-containing products to carry out clinical trials to demonstrate efficacy.

The consultation received over 1,000 responses, most of which came from e-cigarette users opposed to any regulation, or else supporting regulation introduced in a way that allowed e-cigarettes to remain available to them. Responses from public health organisations, including the RCP, were generally supportive of ‘light touch’ regulation, but most recommended a delay to allow time for manufacturers to comply. Support for immediate regulation, with removal of unlicensed products from the market within 21 days, came from organisations including pharmaceutical companies, pharmacist and trading standards groups, and Imperial Tobacco.15 The MHRA responded by allowing e-cigarettes to remain on the market pending further consideration, and in 2013 announced that it would require all nicotine products to be licensed as medicines from the date of implementation of a revision of the TPD (see Section 10.3 below). The TPD version under consideration at that time required medicines regulation for all but very-low-dose products. The MHRA later rebadged the medicines licensing process for nicotine products as ‘right touch’ regulation.

In 2014, a revised version of the TPD, which superseded the MHRA proposal by providing an alternative route to market for e-cigarettes without a medicines licence, was negotiated and agreed.3,16 Medicines regulation remained an option
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for manufacturers and importers of e-cigarettes, and the MHRA continues to encourage companies to apply voluntarily for licences. However, licensing is no longer mandatory and, at the time of going to press in early 2016, only one e-cigarette, owned by British American Tobacco (BAT), had been awarded a medicines licence by the MHRA and was not yet commercially available. It is not known whether medicines licence applications have been made for other e-cigarette products. A medicines licence has, however, been awarded to a nicotine inhaler (not an e-cigarette) called Voke, developed by Kind Consumer and licensed to BAT, but at the time of going to press this product had not been marketed.

10.3 The 2014 EU TPD

The 2014 revision of the EU TPD, which comes into effect from May 2016, imposes significant new regulations on nicotine products, including e-cigarettes and refill containers that do not have a medicines licence. Although limited areas of flexibility in implementation for member states remain, the main provisions of the TPD in relation to e-cigarettes are as follows:

1 Manufacturers and importers of e-cigarettes must provide a detailed notification to the government-appointed ‘competent authority’ of a range of details relating to each product, and make this information publicly available. Non-compliant products can be manufactured until 20 November 2016 and sold until 20 May 2017. Products already on the market by 20 May 2016 must be notified by 20 November 2016. New products or substantial modifications introduced into the market between 20 May and 19 November 2016 must be notified at least 1 day in advance of going on sale. From 20 November 2016 all new products or substantial modifications must be notified 6 months in advance of going on sale.

2 Required details include: quantification and toxicological data for all ingredients and emissions, including when heated, and their potential health and addictive effects; nicotine delivery and uptake; a description of the product components and production process; and a declaration of responsibility for the quality and safety of the product when used under normal or reasonable foreseeable conditions.

3 There will be a limit on total nicotine content in e-cigarettes, which will be allowed to contain a maximum of 2 mL nicotine solution at a maximum nicotine concentration of 20 mg/mL. Refill containers will be subject to a maximum volume of 10 mL. Nicotine and all other ingredients used in manufacture must be of high purity and not pose a risk before or after heating, and substances other than those declared should be present only in trace quantities, which are unavoidable during manufacture. Products must be child and tamper proof, and protected against breakage and leakage.
4 Nicotine doses are required to be delivered at consistent levels under normal conditions of use.

5 Products should include a leaflet, which, among other things, contains instructions, warnings, and information on contraindications, possible adverse effects, addictiveness and toxicity. Outside packaging must list ingredients, nicotine content and delivery per dose, carry a batch number, and a health warning stating ‘This product contains nicotine which is a highly addictive substance’. Outside packaging must not include any promotional element or feature to suggest that the product is less harmful or has other health or lifestyle benefits.

6 Cross-border advertising, sponsorship and promotion in the press and broadcast and internet media are prohibited, as are cross-border sales unless subject to a registration scheme. Domestic advertising through billboards, at point of sale, on public transport or other local media is permitted unless prohibited by domestic legislation, as is under consideration in Scotland. Provision of information about products online is still legal.

7 Manufacturers and importers must deliver an annual submission on their products to governments, which should include comprehensive data on sales volumes, consumer preferences, mode of sale and market developments. These submissions should be made publicly available unless classified as trade secrets.

8 Manufacturers, importers and distributors of products are required to establish and maintain a system for collecting information about all the suspected adverse effects on human health. Corrective action is required if there are reasons to believe that products are not safe or of good quality, or not conforming to the directive.

9 Regulation of flavours, and age of sale, remains the responsibility of member states.

At the time of going to press, the UK government’s intention to transpose the TPD into UK law was still the subject of a legal challenge by an e-cigarette company, Totally Wicked. However, in December 2015 the advocate general dismissed this and other challenges to the TPD and, although a final court ruling is not due until 4 May, it now seems likely that the TPD will be implemented as originally proposed on 20 May 2016. The UK competent authority for e-cigarettes under the EU TPD will be the MHRA. From 20 May 2016, therefore, all e-cigarettes sold in the UK will be regulated by the MHRA either under the provisions of the TPD or as medicines, or both.
10.4 Advantages and disadvantages of medicines and TPD regulation of non-tobacco nicotine

The impending need for e-cigarettes and other non-tobacco nicotine products, either currently on the market or in development, to comply with one of the above regulatory options has significant implications for suppliers of these devices, and for wider public health. Both approaches have significant advantages and disadvantages, which suppliers will have to balance in their decision on which route or routes to pursue. These are as follows.

10.4.1 Medicines licensing

Key advantages to manufacturers who pursue medicines licensing include:

- higher consumer confidence in product quality and safety
- relief from TPD limits on nicotine solution concentration and volume
- freedom to advertise on TV, radio and in printed media, in line with MHRA rules
- freedom to make justified health claims in relation to quitting and harm reduction
- no obligation to carry health warnings informing consumers that nicotine is addictive
- eligibility for use in, and for subsidised prescription through, the NHS
- potentially subject to 5% rather than 20% VAT in the UK.

The main disadvantage of medicines licensing is the cost in time and money of the application process itself, and of the much higher manufacturing standards required of medicines. It is understood that the MHRA estimates first application costs at between £252,000 and £390,000, and annual recurring costs at between £65,000 and £249,000 for each product. In practice, however, it is likely that application costs incurred by companies inexperienced in negotiating this regulatory system may be significantly higher, whereas the additional cost of manufacturing to the medicines standard is estimated at several million pounds. These financial and related opportunity costs inevitably represent a significant barrier to innovation and market entry for new licensed nicotine products, and favour larger, better resourced entities such as pharmaceutical and transnational tobacco companies. Licensing and presentation of products as medicines may also undermine the perception of e-cigarettes as a consumer rather than a medical product, and hence inhibit experimentation and use.

That only one licence has been awarded to an e-cigarette product in the 5 years since the MHRA announced its ‘light touch’ licensing option, despite the rapid growth and hence evident value of the e-cigarette market and verbal reports from
the MHRA that ‘several’ e-cigarette companies had enquired about licensing, indicates that mandatory medicines regulation, had it been imposed as originally intended by the MHRA, would indeed have resulted in a period of several years in which no e-cigarettes were available for sale in the UK. Mandatory medicines licensing, as originally proposed, would therefore have been counterproductive to public health. Given the high product quality and safety standards that medicines licensing guarantees, as well as the option of providing products on prescription to those on low incomes, it is clearly desirable that the range of e-cigarette products available to consumers and health professionals includes some that are licensed as medicines. As recommended elsewhere, a review of the MHRA licensing process for e-cigarettes, to minimise the extent to which licensing procedures and demands unnecessarily obstruct the progress of new medicinal products to market, is clearly needed.

10.4.2 TPD regulation

At the time of writing, the exact detail of how the proposed TPD regulation will operate has not been published. It appears likely, however, that regulation under the TPD will offer e-cigarettes and other non-tobacco nicotine products a route to market that is less onerous, and hence quicker and less expensive, than medicines regulation.

The principal benefits of TPD regulation to consumers are that they will ensure that products that claim to deliver nicotine actually do so, and therefore that consumers are likely to find them effective, and provide reassurance that toxins and other by-products in vapour are at known and pragmatically low levels, thus protecting consumers from easily avoidable harm. Although it is inevitable that these reporting and performance requirements will impose costs on manufacturers and importers, these TPD measures appear to be congruent with the basic regulatory objective of ensuring that products are fit for purpose, and reasonably safe.

Other measures imposed by the TPD on e-cigarettes are less overtly constructive, however. The cap on nicotine concentrations may limit the effectiveness of e-cigarettes as a smoking substitute, particularly for heavier smokers. The derogation to member states of limits on the use of flavours, which may be a significant source of oxidant activity in e-cigarette vapour (see Chapter 5), may result in marked differences in relative potential harm of e-cigarettes available in different member states. Restrictions may also result in non-compliance. The restrictions on e-cigarette marketing, in effect limiting these to the point of sale, billboards, bus stops and other advertising that does not cross borders, limits opportunities for inappropriate promotion of e-cigarettes to non-smokers, including children, but also inevitably inhibits promotion to smokers. However,
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as most smokers are aware of e-cigarettes, and word of mouth and social media appear to have been the main drivers of use to date, it remains to be seen whether these advertising restrictions will reduce uptake by smokers. The Scottish Parliament is currently considering going further than the TPD to prohibit all advertising of e-cigarettes in Scotland other than at the point of sale.24

The requirement for nicotine products covered by the TPD to carry a health warning emphasising the risks of nicotine, when licensed nicotine products do not, appears illogical, as does the restriction on statements comparing the relative risks of e-cigarettes and tobacco cigarettes. The health warning required under the TPD provisions may also reinforce misperceptions about nicotine (see Section 10.7 below).

A further concern about TPD regulation is that, although a facility to recall products from the market is written into the legislation, there are no powers to relax regulations if usage and innovation are unnecessarily or inappropriately constrained by them. Despite requiring a review 3.5 years after implementation and at 2-yearly intervals thereafter, the previous EU TPD was not revised for 13 years, which is of great concern because much quicker mechanisms of feedback and revision will be required to maximise the benefits as well as minimise the risks of e-cigarettes. For these reasons, it is clearly important that TPD implementation be closely monitored to assess the extent of unintended, as well as intended, effects on the availability and use of non-tobacco nicotine products and, in particular, the consequences of these effects on tobacco smoking rates; it should also ensure that prompt action be taken if TPD regulation proves to work against, rather than for, the benefit of public health. We therefore recommend annual review in the UK.

10.5 The future of nicotine regulation

The UK is currently ahead of most countries in having an agreed set of principles on what nicotine regulation should be designed to achieve, which, as stated in our last report, is that ‘The current nicotine regulatory framework needs to be changed so that it encourages as many smokers as possible to quit smoking and all nicotine use completely, and encourages those who cannot quit to switch to a safer source of nicotine, while minimising use by people who would not otherwise have used nicotine products’. The UK government has reinforced the need for harm reduction alongside abrupt cessation and preventive approaches to tobacco control by introducing ‘new routes to quitting’,25,26 which involve encouraging smokers to reduce their cigarette consumption as a precursor to complete quitting, manage their nicotine addiction by using a safer alternative product when unable to smoke, and dramatically reduce harm to themselves and
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others by using a safer alternative to smoking whenever possible at other times. The UK government also encouraged innovation in the design and marketing of nicotine delivery medicines. The MHRA, by relaxing its regulation of nicotine-containing products, is following the same path. In 2013, the National Institute for Health and Care Excellence (NICE) produced public health guidance on harm-reduction approaches to smoking, recommending the integration of harm reduction into NHS and other care pathways. Public Health England has also recently endorsed the principles of the approach set out in the RCP’s 2007 report, as has civil society, through the more than 120 health-related organisations that endorsed the recent Smoking still kills policy document published by Action on Smoking and Health in 2015.

However, there is still some disagreement about the appropriate level of regulation to meet these principles. Some argue that medicines regulation is the best guarantee of safety, although experience to date suggests that it is too restrictive; some argue that the TPD regulatory framework about to be introduced is too stringent and will undermine the growing market for less harmful alternative nicotine products and restrict innovation; some believe that proposed TPD regulation does not sufficiently address the potential short- and long-term hazards of e-cigarette use which, although likely to be far less than those of smoking (see Chapter 5), could be minimised by medicinal quality and safety standards.

In 2007, the RCP argued for the creation of a regulatory authority specifically designed to cover all nicotine products, and to rationalise regulatory controls by making them proportionate to product hazards. However, experience elsewhere of giving powers to regulatory bodies to cover all nicotine products, e.g. in the USA and Canada, has not been encouraging (see Chapter 11), although in any case the current aversion to new regulation in the UK does not make a new regulatory body a feasible option at present. Some countries have regulated e-cigarettes in the same way as tobacco products, which we believe to be entirely inappropriate because e-cigarettes do not contain tobacco, and have a very different profile of risk. The political reality is therefore that, for the coming years, unless the legal challenge to the TPD is successful (see below), non-tobacco nicotine products in the UK will be regulated either by the TPD or as a medicine, whereas tobacco products will continue to be limited by the TPD and other national restrictions on use and presentation. It remains to be seen whether this approach will benefit public health by encouraging widespread substitution of smoked tobacco by non-tobacco nicotine in current and future smokers, or will in effect sustain smoked tobacco as the most widely used nicotine product. Much will depend on the approach taken by the MHRA in its role as the competent authority for TPD implementation. It is, however, crucial that the UK takes care to implement the revised TPD in such a way as to minimise, as far as is consistent with the regulations, the burden to manufacturers and importers in
meeting the TPD requirements. It is also important to look again at the medicinal licensing route to market, to try to make compliance more attractive to producers.

10.6 If e-cigarettes are removed from the TPD, what are the alternatives?

Following the December advocate general’s legal opinion, it seems likely that regulation under the TPD will go ahead. However, starting from the counterfactual\(^3\) allows options for a more appropriate regulatory structure to be set out within a European context. If the legal challenge to e-cigarette regulation under the revised TPD succeeds, then the previous status will prevail, unless and until the EU develops a new regulatory framework. This could be in the form of a new revision to the TPD, but past experience indicates that this would be likely to take years to materialise. An alternative is the earlier MHRA proposal to regulate all nicotine products as medicines, which to date has proved to operate against public health interest and has, in any case, been subject to successful legal challenges in other EU member states.\(^3\) Another option is to develop harmonised EU-wide standards under the General Products Safety Directive process, which could be less costly for manufacturers and importers to comply with than if each member state developed its own.\(^5\) Such standards could build on those being developed under the European CEN/TC 437 process, \(^3\) which is one of the three European standardisation organisations officially recognised by the EU and the European Free Trade Association (EFTA) as responsible for developing and defining voluntary standards at the European level.

A balance is needed to make products attractive, palatable, satisfying and effective substitutes for tobacco smoking, but also as safe as is reasonably possible, and avoiding use by adolescents and never-smokers. A pragmatic approach would retain the reporting requirements on nicotine delivery and toxins in e-cigarette vapour proposed under the TPD (see Section 10.3 above), adhere to industry and product standards, incorporate obvious safety measures such as childproof and tamper-proof seals and design, and simple advice on how to charge e-cigarettes safely. Advertising should be permitted as per current codes of practice administered by the ASA (with regular reviews to ensure that they remain fit for purpose), with the facility to promote claims of reduced risk in relation to tobacco smoking. Limits on nicotine dose and the requirement for health warnings are probably not appropriate. Any voluntary approach would have to build on the current BSI PAS 54115 standard for product regulation and the compulsory advertising codes, which are currently under review. Alternatives to the above approaches have been suggested, such as regulation as food or cosmetics, but neither regulatory structure seems appropriate to a product that is...
inhaled. Whatever approach is taken, it will remain essential to monitor sales and uptake of non-tobacco nicotine products, so that early action can be taken to deal with any trends or patterns of use likely to be detrimental to public health interest.

### 10.7 Providing consistency in messages to smokers

Recent evidence indicates that smokers are confused about the relative risks of tobacco and e-cigarettes, with many coming to believe that the health hazards of e-cigarettes and tobacco cigarettes are similar. Health professionals are also uncertain about the role of unlicensed nicotine products in healthcare provision, with many feeling reluctant to recommend or endorse a product or product class that is relatively unregulated and has unknown long-term health effects. The introduction of a regulatory structure for unlicensed products, as, for example, proposed under the TPD, may help to overcome these reservations, but there is a need for clear guidance on the role of unlicensed nicotine products in clinical services. The National Centre for Smoking Cessation and Training has produced new guidance on integrating e-cigarette use into the provision of smoking cessation services*, but to date NICE, which has issued extensive guidance on smoking cessation and harm reduction to organisations responsible for public health and tackling tobacco use, health professionals and the general public, has not addressed this issue. Some stop smoking services are providing advice and behavioural support to smokers interested in using e-cigarettes with encouraging results (see Chapter 6), but health professionals have a wider role to play in providing support and reassurance to e-cigarette users in routine contacts. NICE guidance should, therefore, be updated to include pragmatic recommendations on the role of e-cigarettes in tobacco harm reduction.

### 10.8 Taxation and price

Price is a key driver of consumer behaviour and, if the potential for e-cigarettes and other non-tobacco nicotine products to act as a widespread substitute for smoked tobacco is to be fully realised, it is crucial that they are priced as advantageously as possible in relation to tobacco. It is for this reason that the VAT applied to NRT products in the UK was reduced from 20% to 5% in 2007. Adding to the tax burden of e-cigarettes by including them in the remit of the EU Tobacco Tax Directive, and hence requiring them to be taxed as tobacco products in addition to the current taxation through VAT, would therefore be counterproductive. A rational approach to nicotine taxation would be to apply

*www.ncsct.co.uk/usr/pub/Electronic_cigarettes_A_briefing_for_stop_smoking_services.pdf*
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tax in proportion to their hazard, in which case the tax on e-cigarettes and other non-tobacco nicotine products should be held stable or even reduced. The availability of these products as a viable alternative for people addicted to nicotine does, however, provide justification for further tax increases on tobacco.

10.9 Summary

> The ideal regulatory framework for nicotine products is one that minimises harm to society arising from nicotine use.
> At present, nicotine is in widespread use in UK society and the most popular source of nicotine, the cigarette, is by far the most hazardous of those available.
> Nicotine regulatory approaches should therefore be designed to encourage as many smokers as possible to either quit all nicotine use, or switch completely from smoking to an alternative source of nicotine.
> Products are regulated to ensure that they are safe and fit for purpose. Regulation of e-cigarettes and other similar products should therefore aim to minimise potential exposure to harmful vapour constituents, ensure that those that deliver nicotine do so in doses that smokers find satisfying, and encourage substitution for smoked tobacco.
> Regulatory restrictions should therefore be designed to safeguard against unnecessary hazard but should also be proportionate, so as not unnecessarily to inhibit the development, availability and use of viable alternatives to smoking.
> Attempts by the MHRA over the past 5 years to adapt medicines licensing to the rapidly developing e-cigarette market has resulted in the award of only two medicines licences for alternative nicotine products, and no licensed e-cigarette has come to market.
> Regulations for e-cigarettes proposed in the new revision of the EU TPD include quality controls that are more permissive and, in our view, more proportionate than medicines regulation, but include some measures that may inappropriately constrain the e-cigarette market and hence inhibit e-cigarette use.
> At the time of going to press, the TPD regulations for e-cigarettes are still the subject of a legal challenge, but are expected to come into effect from 20 May 2016.
> In the event that the legal challenge succeeds, then a replacement regulatory approach should retain the requirements on reporting of nicotine delivery and toxins in e-cigarette vapour proposed under the TPD, and adhere to industry and product standards.
> To encourage smokers to switch from tobacco to less hazardous sources of nicotine, it is vital that non-tobacco nicotine products be excluded from tobacco taxes.
It is essential that NICE and other health organisations give clear guidance on the role of e-cigarettes, licensed or unlicensed, in smoking cessation and tobacco harm reduction. Effective regular surveillance, which we recommend should be annual, will be required to monitor intended and unintended impacts of regulation, and a rapid feedback mechanism to allow changes to be made to ensure that the potential benefits of e-cigarettes are maximised, while minimising the risks.

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Regulating nicotine products in the UK


11.1 Harm reduction and tobacco control policy implementation in the UK

Since the publication of the white paper *Smoking kills* in 1998, the UK has introduced an extensive and comprehensive range of tobacco control measures (see Chapter 3) and, having been at the forefront of the global smoking epidemic of the 20th century, is now a world leader in smoking prevention. As a result, UK smoking prevalence has declined substantially and at a rate similar to that observed in other countries that have also implemented comprehensive tobacco control programmes such as Australia, Canada, the USA (in California) and Uruguay. As discussed in Chapter 10, in addition to this comprehensive package of conventional tobacco control policies, England has also adopted a complementary harm-reduction policy strand that is embedded in national policy through government health and tobacco control strategies, guidance by the National Institute for Health and Care Excellence (NICE) and medicines regulation. To our knowledge the UK is the only country in the world to have developed, and to be in the process of implementing, a proactive tobacco harm-reduction approach to smoking prevention. This chapter describes the regulation of e-cigarettes and their use in other countries.

11.2 Approaches to regulation of e-cigarettes in other countries

There is a wide variation in approaches taken in different countries to the regulation of e-cigarettes and other unlicensed, non-tobacco nicotine products. The Institute for Global Tobacco Control (IGTC) summarises policy approaches in a total of 123 countries, including 90 from a World Health Organization (WHO) report on e-cigarette policies. Regulations are evolving rapidly, so the discussion here and in the following sections is based on data reported on the IGTC website* unless otherwise stated, and was accurate at the time of going to press. A discussion of whether published regulations have actually been enforced is beyond the scope of this chapter.

*http://globaltobaccocontrol.org
Also at the time of going to press, the use of e-cigarettes had been completely prohibited in three countries (Cambodia, Jordan and the United Arab Emirates), prohibited in enclosed public places in 15 countries and restricted in a further eight, prohibited on public transportation in 19 countries and restricted (or limited to non-nicotine-containing products) on certain public transportation vehicles in three. Restrictions on purchase or sale comprise: a minimum age for e-cigarette purchase which is usually the same as that for traditional cigarettes, and ranges from 18 to 21 years in 16 countries; prohibition (26 countries) or restrictions (21 countries) on the sale of all types of e-cigarette, including restriction or prohibition of sale or requirement for marketing authorisation for products that have nicotine. Of the 47 countries banning or restricting sale, 33 also prohibited or restricted advertising, promotion or sponsorship of e-cigarettes in their policies. Twelve other countries had explicit promotion bans/restrictions. Two countries (Togo and the Republic of Korea) impose taxes on e-cigarettes in addition to general sales taxes. Similar to the UK, some countries, including the USA, allow e-cigarettes to be sold under general consumer product regulations.

The experience of regulating e-cigarettes along with other nicotine products in a single regulatory structure, as proposed by the RCP in 2007, has since proved less encouraging than hoped. The US Food and Drug Administration (FDA), already responsible for regulating medicinal nicotine, was given responsibility for regulating tobacco products in 2009 and, after a legal decision, announced in 2011 that e-cigarettes would be brought within the remit of tobacco product regulation. At the time of writing the FDA still has more stringent regulations on the sale of medicinal nicotine than the UK, and has not yet put a regulatory process for e-cigarettes in place. Similar to the US experience with FDA regulation, Health Canada’s jurisdiction over all tobacco and nicotine products, which regulates nicotine under the Food and Drug Act, requires a marketing authorisation for e-cigarettes containing nicotine, and none has yet been awarded. The effect of this is therefore an actual prohibition of sale. In practice, however, this is not being observed, because a recent Canadian House of Commons’ report concluded that e-cigarettes with nicotine were still available in Canada. The report put forward recommendations to develop a new legislative framework for e-cigarettes that would probably allow their sale with nicotine, but with strict controls on marketing in line with those for tobacco. In the absence of a clear regulatory approach by Health Canada at the federal level, a number of provinces have already moved to impose strict regulations on e-cigarettes, including prohibition of use in public places, and of advertising and display.*

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Thus, the experience of a single regulatory authority in both the USA and Canada is that, in both cases, the authority has been unable to use its powers effectively to regulate nicotine products in relation to their hazard. Indeed, in both cases, single-body regulation of all nicotine products has probably hindered, rather than enabled, access to reduced-hazard nicotine products.

11.3 Awareness and use of e-cigarettes in different countries

Although there is a rapidly growing body of research on the prevalence of e-cigarette use in adults and adolescents internationally, methodological differences in the definition and measurement of ever, past or current use, particularly in adolescent research, make direct comparisons between studies difficult. This section therefore describes trends internationally drawing predominantly on between-country surveys; Section 11.4 analyses the relationship between regulatory frameworks and use where the evidence enables such comparisons to be made.

11.3.1 Awareness and use of e-cigarettes in adults

Significant variability in the prevalence of use of e-cigarettes has been observed between countries over time, but international surveys demonstrate rapid global increases in e-cigarette use across high-, middle- and low-income countries. The earliest between-country study assessed e-cigarette awareness and use among nationally representative samples of smokers and recent ex-smokers based on 2010–11 data from the International Tobacco Control policy evaluation project (ITC) in the UK, the USA, Australia and Canada. In the UK and the USA, e-cigarettes are regulated as consumer products; in Canada, e-cigarettes containing nicotine require authorisation, but none has been authorised; in Australia there is a ban on the sale and importation of e-cigarettes with nicotine, although there is a mechanism for legal import as an unapproved medicine with a doctor’s prescription. Awareness and current use were higher in the two countries where there were fewer restrictions (the USA and the UK).

The Canadian Tobacco, Alcohol and Drugs Survey (CTADS) also found, in 2013, much lower levels of e-cigarette use among adults in Canada than in the UK. Another ITC study compared trends in awareness, trial and use of e-cigarettes among nationally representative samples of smokers and ex-smokers in the UK and Australia. Use (defined as less than monthly or more often) of e-cigarettes was 18.8% in the UK and 6.6% in Australia in 2013; however, use increased at the same rate in both countries between 2010 and 2013. It therefore appears that prohibition may have delayed the uptake of e-cigarettes in Australia, but has not prevented a subsequent rapid increase in use.
A further ITC study\textsuperscript{21} presented data from 10 countries (the USA, the UK, Australia, Canada, the Netherlands, South Korea, Malaysia, Brazil, Mexico and China) surveyed at different time points between 2009 and 2013. Again, there was considerable variation in e-cigarette awareness and use among them: awareness varied from 88\% in the Netherlands (where e-cigarettes are regulated as a consumer product with some restrictions\textsuperscript{13}) to 31\% in China (where sale and purchase are legal at the national level, although may be restricted in some regions\textsuperscript{22}); self-reported trials varied from 20\% in Australia to 2\% in China; and current use from 14\% in Malaysia (where sale, distribution or importation of unlicensed nicotine-containing e-cigarettes is prohibited; nicotine-containing e-cigarettes can be sold only by licensed pharmacies or registered medical practitioners\textsuperscript{13}) to 0.05\% in China. These differences are likely to be due in part to differences in survey dates, but also to differences in regulations, market forces and enforcement. However, Malaysia had the highest prevalence of e-cigarette use despite tight restrictions on their sale.

The Global Adult Tobacco Survey\textsuperscript{23} has also published data on e-cigarette use among smokers and non-smokers from four middle- and low-income countries: Indonesia (in 2011), Malaysia (2011), Qatar (2013) and Greece (2013). At the time of the surveys, all these countries prohibited the sale of e-cigarettes apart from Malaysia, where only nicotine-containing e-cigarettes were restricted.\textsuperscript{13} E-cigarette awareness was highest in Greece (88.5\%), followed by Qatar (49\%), Malaysia (21\%) and Indonesia (10.9\%). Current use (daily and non-daily) of e-cigarettes among smokers was again highest in Malaysia (in this survey prevalence of use was 10.4\%), followed by Qatar (7.6\%), Indonesia (4.2\%) and Greece (3.4\%). Use of e-cigarettes among non-smokers was highest in Greece (1.3\%), followed by 0.4\% in each of the other three countries. Again, these data demonstrate little evidence that more restrictive national policies on e-cigarettes result in lower levels of use.

The most recent Eurobarometer 429 survey,\textsuperscript{24} carried out in November and December 2014, enabled an assessment of use of both tobacco cigarettes and e-cigarettes (defined as e-cigarettes or other similar electronic device) among people aged 15 years and over in the 28 European Union (EU) member states. France, Cyprus and Estonia (where e-cigarettes are regulated as either consumer or medicinal products according to nicotine content)\textsuperscript{13,25} had the highest proportions of respondents stating that they had ever tried e-cigarettes (17\% or higher); France and the UK had the highest prevalence of current e-cigarette use (both 4\%) and the UK had the highest proportion of current smokers who also used e-cigarettes (11\%). Fewer than 1\% of never-smokers currently used e-cigarettes in every country surveyed. The most common reason given for using e-cigarettes was to stop or reduce smoking. Across the EU, 14\% of smokers or ex-smokers who had tried e-cigarettes reported that they had helped them to stop smoking completely, 13\% that they had helped them to stop for a while before
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relapsing, 45% that they had not reduced their tobacco smoking and 21% that they helped them to reduce, but not stop, tobacco use. Ireland (24%) and the UK (21%) had the highest proportions of respondents who reported successfully stopping smoking with the help of e-cigarettes. The proportion of smokers using e-cigarettes in their quit attempts was highest in countries regulating them as consumer products: the UK and Ireland (19%), France (18%) and Cyprus (16%). The Eurobarometer noted that there were continuing declines in smoking across the EU at a time when e-cigarette use was increasing, as has been observed in UK surveys (see Chapters 2 and 7) and in the USA.26

11.3.2 Awareness and use of e-cigarettes by adolescents

We have been unable to find any survey using a consistent methodology to compare awareness and use of e-cigarettes among adolescents in different countries. Data on people aged 15 and over are included in the 2014 Eurobarometer study referred to above,24 which reported the prevalence of current use of e-cigarettes among people who had never smoked at 0%, suggesting that there were few such users among young or older people.

Survey data on the prevalence of e-cigarette use in young people at the country level are more extensive, but methodological differences, including the use of different definitions or terms to describe the different stages of e-cigarette use (ever, trial, current use), and differences in age ranges studied, limit the comparability of these findings. A recent review concluded that the common pattern emerging in countries where data were available was of very high awareness and increasing trial of e-cigarettes among young people, but very low levels (3% or less) of regular use.27 However, there were two countries where current use was substantially higher: Poland (where e-cigarettes are classified as consumer products, but with cartridges subject to regulations on chemical mixtures) at around 30%,28 and Hawaii (where e-cigarettes are classified as consumer products), where 29% of the sample of young people had tried e-cigarettes and 18% had used them in the past month.29

Serial surveys of young people in the USA have documented a rising prevalence of ever use of e-cigarettes30–32 and demonstrated that, as in the UK (see Chapter 7), those who use e-cigarettes are more likely also to smoke tobacco.31 A cohort study from California35 found that secondary school pupils who had not smoked, but reported having ever tried an e-cigarette, were more likely at 6- or 12-month follow-up to have ever tried a tobacco cigarette. A cohort study of a national US sample of 694 never-smokers who were classified as non-susceptible to tobacco smoking at baseline in 2013–14, and restudied in 2015,34 found that the 16 participants who reported ever
having used an e-cigarette at baseline were significantly more likely, after controlling for other covariates, to have become susceptible to cigarette smoking or have smoked at least one puff of a cigarette at follow-up. However, claims that these findings indicate that e-cigarette use may cause uptake of tobacco smoking have been challenged on the grounds of common liability (see Chapter 8), lack of measures of more regular use of either e-cigarettes or tobacco cigarettes, and that, during the time that these studies have been carried out, the prevalence of tobacco smoking among young people in the USA fell to a 22-year low.\textsuperscript{35–37} There is evidence from the USA that adolescent smokers using e-cigarettes are also more likely to use products such as tobacco hookahs or shisha and blunts (marijuana and tobacco).\textsuperscript{38}

11.4 Patterns of use across countries with different regulatory regimens

Although standardised between-country data on e-cigarette use over time are generally lacking, it is clear from the evidence presented above that, whereas countries with more liberal policies (which typically involve regulating e-cigarettes as consumer products) have higher levels of adult e-cigarette use, prohibition and tight restrictions have not prevented increasing uptake of e-cigarette use among adults in other countries. For adolescents the data are less clear but, as an example, the 2013 CTADS of Canadians aged 15 years and older found that 9% had ever tried an e-cigarette, with trials being higher among young people aged 15–19 years at 20%.\textsuperscript{19} This latter percentage is not dissimilar from the percentage who had tried e-cigarettes in the UK in 2015 (12.7% of 11- to 18-year-olds). Again, therefore, it appears that prohibition of sale has had little effect on experimentation with e-cigarettes in Canada, at least not in the younger age groups in these studies. A recent US study assessed the impact of state bans on sales of e-cigarettes on smoking rates among 12- to 17-year-olds across the USA,\textsuperscript{39} and found that reducing access through age-of-sale laws increased smoking among 12- to 17-year-olds, suggesting that restrictive regulations on e-cigarettes may be counterproductive.

In the EU, as set out in Chapter 10, the introduction of the Tobacco Products Directive\textsuperscript{40} will lead to a common regulatory platform from May 2016, although individual member states will be able to go further in prohibiting all advertising (as is under consideration in Scotland), restricting or prohibiting their use in public places (recently under consideration in Wales), legislating for an age of sale (set at 18 in England), restricting or prohibiting flavours, and implementing additional taxation. Monitoring the impact of these regulatory changes, and of their variations across the EU, will provide a useful indicator of the impact of different regulatory approaches.
11.5 Harm reduction and the WHO Framework Convention on Tobacco Control

E-cigarettes were not available when the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) was first negotiated. However, the FCTC alludes to harm reduction in Article 1, where tobacco control is defined as including ‘harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke’. This is further considered in Article 5.2(b), which states that ‘each Party shall, in accordance with its capabilities … adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke’. The FCTC does not have a remit for the regulation of medicinal nicotine, although it has produced guidelines on tobacco dependence and cessation (Article 14 of the FCTC).

The growing popularity of e-cigarettes led to discussions on their role at the biennial FCTC Conference of the Parties (COP), the governing body of the treaty, in 2010 and 2012. At the 2012 COP5, the WHO was asked to produce a report on ‘options for prevention and control’ of e-cigarettes (referred to as electronic nicotine delivery systems or ENDSs) for consideration at the next COP. The WHO report to COP6 focused on three areas of concern: health risks to users and non-users; efficacy in helping smokers to quit smoking and (ultimately) nicotine use; and interference with existing tobacco control efforts and implementation of the FCTC. The main focus of the report was on the latter issues, but, in terms of health risks, the report concluded that ‘well-regulated ENDS’ would be likely to be less toxic than tobacco cigarette smoking for established adult smokers. In relation to smoking and nicotine cessation, the report concluded that e-cigarettes might have a role in supporting attempts to quit for individuals who had failed treatment, or who were intolerant of or refused conventional treatments. The report discussed and recommended parties to regulate e-cigarettes as either medicines or tobacco products, in accordance with the FCTC.

In response, the Framework Convention Alliance (FCA, a coalition of over 350 non-governmental organisations from over 100 countries) developed a consensus position. The FCA concluded that, because of differences in regulatory systems and national circumstances, it would be difficult to reach consensus at COP6 on specific regulatory approaches to ENDSs. Instead, the FCA position paper set out the following principles as a starting point for reaching agreement on the role and regulation of e-cigarettes, for consideration by the COP:
1 The global burden of death and disease from tobacco is primarily caused by smoking.

2 Although quitting tobacco use is paramount, quitting nicotine use altogether is the best option.

3 For those unable to quit, switching to alternative sources of nicotine that are less harmful than tobacco can reduce, often very substantially, the harm that smoking causes to the individual.

4 The benefits of such an approach would be maximised if uptake were limited to existing smokers who are unable to quit.

5 The risks of such an approach would be minimised by limiting uptake by never-smokers, in particular among young people, and by taking measures to protect non-users and discourage long-term dual use.

6 There could be negative unintended consequences from over-regulation, just as there could be from under-regulation.

7 The involvement of tobacco companies in the production and marketing of e-cigarettes is a matter of particular concern, because there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

After discussion by the COP, a decision was taken to ask parties to the FCTC to take note of the WHO report, and the WHO was asked to produce a further report with updated intelligence for consideration in time for COP7, which will be held in the last quarter of 2016. The decision also asked parties to the FCTC to consider ‘prohibiting or regulating’ e-cigarettes, suggesting that this could be as tobacco, or medicinal or consumer products, and to comprehensively monitor their use. E-cigarettes will therefore be discussed again at the next WHO FCTC COP in November 2016 in India.

In the case of tobacco, a range of comprehensive tobacco control measures has been found to be effective and been codified in the FCTC. E-cigarette regulation does not sit appropriately within the context of the FCTC, the explicit objective of which is control of the supply of and demand for a lethal product, tobacco, through the introduction of increasingly restrictive and prohibitive regulatory measures. Furthermore, there is as yet an insufficient evidence base or range of national experience that would enable the development of a detailed set of recommendations for the specific approaches to many of the complicated regulatory issues that these products raise at the global level.
11.6 Summary

> A variety of different approaches to tobacco harm reduction and regulation of e-cigarettes, including extension of regulations for alternative products to e-cigarettes and including complete prohibition, have been adopted in different countries around the world.
> The prevalence of use of e-cigarettes is rising or already significant in some countries that have attempted to prohibit use, suggesting that prohibition is not an effective approach to regulation.
> Surveillance data are limited in most countries, as are the use of consistent terminology and standardised measures of e-cigarette use, so between-country differences are difficult to assess.
> There is general recognition that comprehensive monitoring and surveillance of the evidence and national regulatory experience of e-cigarettes are essential.
> The WHO recognises a role for e-cigarettes as part of a harm-reduction strategy for smokers, but in the context of a recommendation by the FCTC COP that they be regulated to minimise any potential risks.
> However, currently there is no consensus about what this regulatory framework should be, and as yet an insufficient evidence base, or range of national experience, that would justify the development of a regulatory structure at a global level.

References


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12.1 Moral and ethical considerations of harm-reduction strategies

This report has made the case for applying harm-reduction principles to tobacco smoking, principally to prevent avoidable harm to smokers. There is, however, a strong ethical dimension to the use of harm-reduction strategies in tobacco control that were discussed in some detail in our earlier report; these strategies include a duty to ensure that options to reduce harm are made available to smokers, and provision of a substitute for tobacco to smokers, particularly those on low incomes, to protect them from the hardship that might otherwise arise from applying tax increases to provide a stronger fiscal disincentive to smoke. There are, however, wider considerations arising from concerns over the broader effects of applying harm-reduction strategies in society.

The central ethical concern is with harm, and whether the harm-reduction strategies identified and adopted will, in practice, reduce it. However, there are also wider questions relating to the ethos of harm reduction itself, over and above any examination of the effectiveness of particular strategies. In some areas of public health (particularly in drug control, alcohol control and sex work control, for example), there is a societal concern that the behaviour being targeted is inherently wrong. Drug addiction, prostitution and drunkenness, it is sometimes thought, are inherently bad, and the proper focus of public health should not be on making the use of drugs, or sex work, or excess alcohol consumption safer; it should be on eradicating these behaviours. In tobacco control, however, this argument is rarely made: few people acknowledge smoking as a behaviour that is immoral. Its harms are real and serious, and inflicting these on unwilling third parties is wrong, but these concerns fit quite naturally within the harm-reduction model.

A second concern is with the distribution of harm. A harm-reduction strategy could be considered to have failed if the net harm were reduced, but the distribution of harm changed in a way that was unjust, eg if, as a result of the harm-reduction strategy, some socially or economically vulnerable group
became more at risk of harm, or systematically less able to benefit from smoking cessation and prevention strategies. The benefit to existing smokers of switching to e-cigarettes is clear, but, if large numbers of never-smokers were to take up e-cigarette use, they would be exposing themselves to health risks that would otherwise be avoided, and financial costs, which are of particular detriment to poorer smokers, that they would not otherwise incur. At present this does not appear to be happening, but it could occur, for example, if the addictive potential of e-cigarettes and other non-tobacco nicotine products increases over time.

A third concern relates to social responsibility: if engaging in harm reduction involves working with corporate actors with a track record of deceit or other socially irresponsible business practices, and particularly of undermining public health, then there is a concern that doing so may have wider ramifications than the harm-reduction strategy itself. Such engagement might, for example, discredit other public health interventions or institutions that are focused on ending these bad practices. We can think of this as ‘reputational harm’. Conversely, it may be that such corporate actors acquire some perverse benefit from such engagement: by appearing to be responsible in one area (the provision of reduced-harm products) they might be able to reclaim a good reputation in other areas, however undeservedly. From a ‘harm-reduction’ point of view, these factors must be considered, but these harms may be inchoate and hard to measure, certainly compared with the real benefits accruing to harm-reduction products in terms of reductions in mortality and morbidity.

Setting aside these objections to harm reduction in principle, we turn instead to the objections that might be raised against particular harm-reduction strategies from within a focus on harm. Obviously, the most important consideration is whether the harm-reduction intervention actually does reduce harm, in terms of reduction of lives (and life years) lost, increase in numbers of smokers who successfully quit smoking tobacco, reductions in the numbers of new smokers, etc. However, as for any other medical or public health intervention, we need to consider any particular strategy in the light of available alternatives: in particular, if we focus on regulation of a tobacco harm-reduction product, we need to ask whether the regulatory mechanism is the most effective in reducing harm, or whether some other approach would be more effective. We need to ask whether adoption of a particular regulatory approach makes the production of some products more likely than others, and whether the products favoured by this approach are, in fact, better from a harm-reduction and public health point of view than those disfavoured. As within the harm-reduction model, the least harmful intervention is the most ethical intervention, we need always to keep in mind that choice of regulatory approach must be seen in ethical terms. The evidence summarised in this report goes some way towards addressing these questions.
12.2 Smoking and public health

Tobacco smoking is the biggest avoidable cause of death and disability in the UK. In 2014, 21% of men and 16% of women were smokers, which in absolute terms represents almost 9 million people. Half these smokers, or 4.5 million people, alive in the UK today will have their lives cut short by smoking and, if their smoking continues unabated, their total loss of life will amount to nearly 90 million years. Their smoking will also cause thousands of fetal deaths and cases of childhood illness, and deaths in non-smoking adults, and cost our health services and wider society billions of pounds. This massive burden of death, disability and lost opportunity has been entirely avoidable, and much of it can still be prevented by measures that encourage as many smokers as possible, as soon as possible, to stop smoking. As the biggest beneficiaries of preventing smoking are individuals who are disadvantaged, marginalised or have mental health problems, prevention of smoking will make society both healthier and more equal. Smoking may be less prevalent today than when the RCP published its first report on smoking and health in 1962, but it is still our biggest health problem. All measures that can be deployed to prevent smoking should therefore be applied, as quickly as possible, and to their maximum effect.

12.3 The effect of conventional tobacco control approaches

The UK is a world leader in tobacco control policy. Since the late 1990s, a comprehensive package of policies, including an advertising ban, smoke-free legislation, high taxes, minimum purchase age, mass media campaigns, a point-of-sale display ban and clinical services to help smokers to quit, has been introduced, and will be enhanced in 2016 by standardised packaging legislation. The result in the UK has been the same as in other countries that have followed this approach: smoking prevalence has fallen steadily, but slowly. However, the decline in smoking prevalence that has occurred over recent decades appears to owe more to success in preventing the uptake of smoking: quit rates among established smokers have changed relatively little. However, it is the adults smoking today, particularly those in middle and older age, who will generate most of the burden of death and disability caused by smoking in the short- and near-term future, and it is these adults whom tobacco control policies need to target in particular if this burden of harm is to be reduced. All existing and new policies with the potential to promote smoking cessation, particularly among disadvantaged groups, should therefore be applied to their fullest extent.
12.4 Priorities for conventional tobacco control policy implementation

Of the range of policies available, the UK has already achieved a relatively high level of prohibition of tobacco advertising and smoke-free policy. Opportunities to promote tobacco brands will be further reduced by the introduction of mandatory standardised packaging in May 2016, although a great deal more could be done to reduce exposure of children and young people to the normalising effect of smoking imagery in the media, including films, television programmes, music videos and computer games. Children may also be less likely to grow up thinking that smoking is a normal or aspirational adult behaviour if they were exposed less to smoking behaviour among adults in their everyday lives, which could be achieved by extending smoke-free policies to outdoor areas, eg at school gates, play areas, town centres and other areas where smokers congregate in view of children. Making hospital premises completely smoke free generates an opportunity to initiate and support cessation among the many smokers, and their visitors, who use hospital services. Similarly, making prisons smoke free will provide an opportunity to reduce the very high prevalence of smoking among prisoners. More could also be done to reduce retail availability of tobacco to children, particularly in areas close to schools, and the requirement that tobacco retailers be licensed would be a useful step towards making enforcement of regulations easier. Mass media campaigns are effective in motivating smokers to try to quit, but require funding to achieve and sustain the necessary intensity and salience for success. Cessation services also need to be adequately funded, and in clinical settings integrated much more systematically into routine health service delivery. Large increases in tobacco prices, particularly in the lower cost range of products preferred by low-income smokers, have a particular potential to reduce smoking among disadvantaged groups. Proper funding of enforcement measures against illicit tobacco and measures to curtail the tobacco industries’ own involvement in this trade are crucial. All these measures would be likely to help to achieve further reductions in smoking prevalence. However, almost all would be complemented by promoting harm-reduction approaches that encourage smokers, who otherwise prove unwilling or unable to quit smoking, to switch to an alternative, low-hazard source of nicotine.

12.5 Nicotine addiction and its effects

Nicotine is the main addictive component of tobacco smoke. Although other tobacco smoke components probably contribute to the development of nicotine addiction, it is the capacity to achieve rapid increases in systemic arterial levels through pulmonary absorption that makes tobacco smoking particularly addictive, as well as lethal, although factors such as the taste and smell of
cigarette smoke, and the behavioural action of smoking, can reinforce nicotine use and hence themselves become important drivers of continued smoking. At low doses, nicotine is a stimulant, which in the short term increases heart rate and may improve attention, memory and fine motor skills. Although potentially lethal at very high doses, at the blood levels typically achieved by smoking nicotine does not result in clinically significant short- or long-term harms. Nicotine is not a carcinogen; there is no evidence that sustained human use of nicotine alone increases the risk of cancer. It is possible that nicotine exposure during the fetal and/or adolescent periods causes cognitive impairment, but in all other respects, and certainly in relation to tobacco smoke, the real and potential hazards of sustained nicotine use are negligible. The harm of smoking is therefore caused not by nicotine, but by other constituents of tobacco smoke. Non-tobacco nicotine products that reproduce the nicotine delivery and behavioural characteristics of smoking, without the many other toxins in tobacco smoke, therefore have the potential to allow smokers to continue to use nicotine and avoid the significant harm to themselves and others that smoking causes.

12.6 Non-tobacco nicotine products

A wide range of nicotine replacement therapy (NRT) products, licensed as medicines to reduce symptoms of nicotine withdrawal among people trying to quit smoking, is available. In clinical trials, NRT has been shown consistently to be effective in helping smokers to quit smoking. Although initially developed to help people give up all smoking and nicotine use, NRT licences have been extended to include short-term use to relieve withdrawal symptoms during temporary abstinence from smoking, and long-term use as a partial or complete substitute for smoking (harm reduction). These licensed applications of NRT, which are endorsed by the National Institute for Health and Care Excellence (NICE), promote dual use of NRT and tobacco on the grounds that smokers who learn to use NRT in this way are more likely to quit smoking completely. NRT products have to date been produced by pharmaceutical companies and offer high levels of purity and hence safety, such that a smoker who switches from tobacco to NRT use, but continues to use NRT in the long term, probably achieves much the same in health terms as a smoker who quits all tobacco and nicotine use.

The choice of non-tobacco nicotine products in the UK has been substantially extended by the emergence of e-cigarettes, which have to date been marketed as consumer alternatives to smoking. E-cigarettes offer a behavioural experience that is much closer to smoking than is the case with NRT products, and later-generation e-cigarettes appear able to achieve venous nicotine levels similar to those of tobacco smoking. The extent to which inhalation of e-cigarette vapour results in rapid pulmonary absorption remains uncertain, but it seems likely that,
as the technology improves, the degree of pulmonary absorption will increase, making the products more effective as smoking substitutes, but also increasing addictiveness, and hence posing the new ethical problems highlighted above. E-cigarettes generate vapour from a solution that typically contains nicotine, propylene glycol and glycerine, but, in addition to these constituents, e-cigarette vapour contains a variable range of compounds arising from impurities in the solutions or generated by the heating process that produces vapour. There appear to be few, if any, significant short-term adverse effects of e-cigarette use, but adverse health effects from long-term exposure to constituents of vapour cannot be ruled out. Although unknown, the hazard to health arising from long-term vapour inhalation is unlikely to exceed 5% of the harm from tobacco smoke. Switching from tobacco to e-cigarettes is therefore likely to be almost as effective in preventing harm as switching to NRT. However, the recent award of a medicines licence to an e-cigarette product raises the prospect of e-cigarettes with safety profiles similar to NRT becoming available in the near future.

12.7 How smokers in the UK try to quit, and their chances of success

Around one in three smokers in the UK tries to quit each year, but only around one in every six of those who try to quit is successful. Those who try are slightly more likely to be younger and female, and to be in non-manual occupations; those in non-manual occupations are also more likely to succeed. Most of those who try to quit do so without help, or until recently by using NRT bought over the counter. Over the past 3 years, however, e-cigarettes have become the most widely used aid to quitting.

The observational data on quitting used in this report suggest that those who use prescribed medication and behavioural support from a qualified stop smoking adviser (typically through NHS Stop Smoking Services (SSSs)) are two to three times more likely to succeed than those using no help. However, the use of NHS SSSs has declined significantly in recent years, such that they are now accessed by only a small minority of smokers. For reasons that are not clear, those who use over-the-counter NRT appear to be no more likely to succeed in quitting smoking than those using no help, whereas those who use e-cigarettes, or NRT or other pharmacotherapy provided by a healthcare professional, are around 50% more likely to succeed than those using no help at all.

The popularity of e-cigarettes has thus resulted in a substantial increase in the proportion of smokers using effective help to quit. It is probable that adding behavioural support would increase the likelihood of quitting with e-cigarettes still further, and this is an important area for new research. Possible explanations for the popularity of e-cigarettes, and their effectiveness relative to NRT, include
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their ability to replace some of the behavioural components of smoking, their relatively high nicotine delivery, the fact that smokers tend to try them for longer and with more frequent dosing than NRT, and their cultural acceptability.

Smokers are motivated to make a quit attempt in particular by cost and health concerns. Price rises, media campaigns and health professional advice are therefore likely to increase the numbers of smokers trying to quit.

12.8 Use of e-cigarettes by smokers and non-smokers

E-cigarettes are used almost exclusively by smokers who are trying to cut down or quit smoking, or who have quit smoking. Among adults, use by non-smokers is extremely rare. A higher proportion of non-smoking children than adults have experimented with e-cigarettes, but most of those who do have smoked in the past, or are current smokers. More than experimental use among children who are not also experimenting with tobacco is rare. Among regular users, whether children or adults, second- and third-generation devices are now much more widely used than first-generation ‘cigalike’ devices. Fruit flavours are popular among e-cigarette users, whether adults or children.

12.9 Harm reduction and population health

The emergence and consumer success of e-cigarettes, as a partial or complete substitute for smoking, reflects significant potential to reduce the harm caused by smoking to society by encouraging as many smokers as possible to use e-cigarettes, or indeed other non-tobacco nicotine products, rather than tobacco cigarettes. There are many, however, who retain significant concerns over the potential risks and adverse effects of this approach, for both individuals and wider society.

Concerns that e-cigarettes are not hazard free are justified, but this hazard could be minimised by a combination of technological development and appropriate regulation. Concerns that e-cigarettes will be used dually by smokers are inconsistent with current guidance and licence indications for NRT, which encourage dual use as a step towards quitting smoking and of protecting those around the smoker from the harmful effects of second-hand smoke. All the UK evidence, and almost all the international evidence, on the use of e-cigarettes by children and young people to date indicates that concerns about e-cigarettes helping to recruit a new generation of tobacco smokers through a gateway effect are, at least to date, unfounded, although vigilant surveillance is required to ensure that the emergence of any such effect is detected and reversed promptly. Renormalisation concerns, based on the premise that e-cigarette use encourages
tobacco smoking among others, also have no basis in experience to date. Exploitation of e-cigarette advertising as a means of promoting tobacco smoking by tobacco companies is perhaps a more real concern, but will largely be prevented by impending controls on advertising in the EU Tobacco Products Directive (TPD).8

12.10 Regulation and harm reduction

It is difficult to determine, and more difficult still to apply, the right level of regulation for reduced-harm products. The wide range of different regulatory approaches adopted in different countries in relation to e-cigarettes, which spans a spectrum from freedom to market as a consumer product to complete prohibition, reflects a desire, on the one hand, to encourage as many smokers as possible to switch from tobacco to e-cigarettes and, on the other, to prevent harm to users or others from e-cigarette use. A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

In the UK, consumer product regulation supported by advertising codes of practice has worked well to date, but does not guarantee that products actually deliver nicotine to a degree that smokers will find satisfying or, more importantly, that vapour is as toxin free as is reasonably possible. Medicines regulation guarantees efficacy and safety, but imposes high manufacturing, compliance and opportunity costs. That even the streamlined Medicines and Healthcare products Regulatory Agency (MHRA) ‘right touch’ medicines regulation has to date awarded a licence to only one e-cigarette, and none that has come to market, indicates that mandatory medicines regulation of e-cigarettes, although valuable as a complement to other regulatory approaches, is not ideal as a single regulatory approach. EU TPD regulation, if implemented as planned, offers a compromise between these two approaches by requiring emission reporting that will enable consumers to identify the best and cleanest nicotine delivery systems, but includes much, such as health warnings and nicotine content limits (see Chapter 10), that is potentially counterproductive. None of these approaches is therefore ideal, and experience in other countries does not offer better alternatives. The UK needs a nicotine regulatory system that applies controls on products in proportion to their potential harm, to promote innovation and diversity, ensure reasonable levels of protection for consumers and, above all, discourage tobacco use.
The use of reduced-harm products, and hence the health gains that they generate, is also influenced by other regulatory policies. Applying low levels of tax to non-tobacco nicotine products, as, for example, the 5% VAT rate levied on NRT, helps to make reduced-harm products attractive to smokers and offset the potentially regressive effect of tobacco tax increases. Allowing messages on harm relative to smoking in commercial and government media campaigns could help to reverse the growing misconception that e-cigarettes and tobacco cigarettes are similarly harmful (see Chapter 10). Prohibition of use of e-cigarettes where smoking is also prohibited may discourage smokers from trying e-cigarettes, and may also contribute to a false impression that they are similarly harmful. The inclusion of recommendations on use of unlicensed (and, in due course, licensed) e-cigarettes in NICE guidance is another example of an area where policies can change to encourage more smokers to switch from smoking to a non-tobacco nicotine product.

12.11 The tobacco industry and e-cigarettes

Tobacco companies make their money by selling tobacco, and the industry’s recent programme of investment and acquisitions in e-cigarettes perhaps indicates recognition that these products represent a disruptive technology that should be harnessed to protect the core business of selling tobacco, exploited to expand tobacco markets or developed as an opportunity to make nicotine products attractive to non-smokers. There is little likelihood that the industry sees e-cigarettes as a route out of the tobacco business, but it is highly likely that e-cigarettes will be exploited to enhance claims of corporate social responsibility, and to undermine implementation of Article 5.3 of the World Health Organization Framework Convention on Tobacco Control.’ There is no firewall between a ‘good’ tobacco industry that is marketing harm-reduction products in the UK and a ‘bad’ one that promotes smoking, or undermines tobacco control activities, in low- and middle-income countries.

12.12 Conclusions

Harm reduction was proposed by the RCP in 2007 as a means of reducing still further the vast burden of death and disability that tobacco smoking causes in our society. The evidence summarised in this report demonstrates that the emergence of e-cigarettes has generated a massive opportunity for a consumer-as well as a healthcare-led revolution in the way that nicotine is used in society. As the technology of these and other non-tobacco nicotine products improves, so the vision of a society that is free from tobacco smoking, and the harm that smoking causes, becomes more realistic. Experience to date suggests that, as predicted in principle in the 2007 report, the availability of e-cigarettes has been beneficial to UK public health. There is, however, no room for complacency and
it is particularly important that patterns of use of tobacco and non-tobacco nicotine continue to be monitored closely, and prompt remedial measures applied to deal with changes that are counterproductive to health. The potential for the tobacco industry to exploit and appropriate harm reduction, to undermine public health and bolster sales of tobacco, is a real problem that is likely to become more acute as tobacco companies move into the licensed, as well as unlicensed, nicotine market, but that problem can be managed with vigilance and care. **Large-scale substitution of e-cigarettes, or other non-tobacco nicotine products, for tobacco smoking has the potential to prevent almost all the harm from smoking in society. Promoting e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible, as a substitute for smoking, is therefore likely to generate significant health gains in the UK.**

### 12.13 Summary

- Smoking is the biggest avoidable cause of death and disability, and social inequality in health, in the UK.
- Most of the harm to society and to individuals caused by smoking in the near-term future will occur in people who are smoking today.
- Vigorous pursuit of conventional tobacco control policies encourages more smokers to quit smoking.
- Quitting smoking is very difficult and most adults who smoke today will continue to smoke for many years.
- People smoke because they are addicted to nicotine, but are harmed by other constituents of tobacco smoke.
- Provision of the nicotine that smokers are addicted to without the harmful components of tobacco smoke can prevent most of the harm from smoking.
- Until recently, nicotine products have been marketed as medicines to help people to quit.
- NRT is most effective in helping people to stop smoking when used together with health professional input and support, but much less so when used on its own.
- E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes.
- E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.
- E-cigarettes are not currently made to medicines standards and are probably more hazardous than NRT.
- However, the hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco.
- Technological developments and improved production standards could reduce the long-term hazard of e-cigarettes.
Tobacco harm reduction

- There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking.
- To date, there is no evidence that any of these processes is occurring to any significant degree in the UK.
- Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.
- There is a need for regulation to reduce direct and indirect adverse effects of e-cigarette use, but this regulation should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers.
- A regulatory strategy should, therefore, take a balanced approach in seeking to ensure product safety, enable and encourage smokers to use the product instead of tobacco, and detect and prevent effects that counter the overall goals of tobacco control policy.
- The tobacco industry has become involved in the e-cigarette market and can be expected to try to exploit these products to market tobacco cigarettes, and to undermine wider tobacco control work.
- However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK.

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Nicotine without smoke
Tobacco harm reduction

A report by the Tobacco Advisory Group
of the Royal College of Physicians

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Royal College of Physicians
11 St Andrews Place
Regent's Park
London NW1 4LE
www.rcplondon.ac.uk
How to define e-cigarette prevalence? Finding clues in the use frequency distribution

Michael S Amato,1 Raymond G Boyle,1 and David Levy2

1Research Department, ClearWay Minnesota, Minneapolis, Minnesota, USA
2Department of Oncology, Georgetown University, Lombardi Comprehensive Cancer Centre, Washington DC, USA

Correspondence to Dr Michael S Amato, Research Department, ClearWay Minnesota Minneapolis, MN 55425, USA;
mamato@clearwaymn.org

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Abstract

Objective

E-cigarette use has rapidly increased. Recent studies define prevalence using a variety of measures; competing definitions challenge cross-study comparison. We sought to understand patterns of use by investigating the number of days out of the past 30 days when adults had used e-cigarettes.

Design

We used the 2014 Minnesota Adult Tobacco Survey, a random digit dial population survey (n=9304 adults). Questions included ever using e-cigarettes, number of days used in the past 30 days and reasons for use. Smoking status was determined by combustible cigarette use. Histograms of e-cigarette use were visually inspected for current, former and never smokers with any 30-day e-cigarette use. Different definitions of current use were compared.

Results

Use ≤5 days in the past 30 days demarcated a cluster of infrequent users at the low end of the distribution. Among those with use in the past 30 days, infrequent users were the majorities of current (59%) and never smokers (89.5%), but fewer than half of former smokers (43.2%). Infrequent users were more likely to cite curiosity and less likely to cite quitting/cutting down other tobacco use as reasons for use.

Conclusions

Defining adult prevalence as any use in the past 30 days may include experimenters unlikely to continue use, and is of questionable utility for population surveillance of public health trends over time. Defining prevalence as >5 days excludes those infrequent users.
INTRODUCTION

The use of electronic cigarettes (e-cigarettes) has increased rapidly in the past several years.1–6 Sales in 2014 are estimated to be nearly $2 billion and one recent business analysis predicted they could ultimately surpass combusted cigarette sales.7–7 Although helpful, sales data provide no information about how individuals use the product. For e-cigarette users, surveillance or other surveys are necessary. The extent of an individual’s e-cigarette use may be an important factor related to transition of smokers away from cigarette use (ie, cessation), as well as potential initiation of non-smokers and relapse of former smokers into cigarette use. Understanding the population effects of e-cigarette use on these transitions will be crucial in determining definitions of use that are most useful in gauging the public health impact of that use. In particular, it will be important to distinguish more established patterns of use from short-term (eg, experimental use) in gauging the effects of e-cigarettes on population health, since relative risks are likely to be dependent on long-term use.

One of the challenges for survey research is the importance of asking questions to reliably measure meaningful use of a tobacco product. A 2009 review of major tobacco surveillance surveys identified inconsistent methodology as an area for improvement, particularly with regard to tobacco products other than cigarettes.8 A standard measure of adult cigarette smoking, based on a lifetime minimum threshold of 100 cigarettes smoked and reporting currently smoking ‘every day or some days’, is widely used and allows straightforward comparison across studies. The measure’s wide adoption has been attributed in part to its efficiency for reducing the survey burden on both researchers and respondents; however, it has also faced criticism for being arbitrarily chosen and inadequately sensitive, particularly, but not exclusively for youth samples.9 In light of these concerns, the 2014 US Surgeon General’s report on smoking estimated current cigarette smoking prevalence for youth and young adults based on having smoked all or part of at least one cigarette in the past 30 days.10 Nonetheless, surveys such as the National Survey on Drug Use and Health, which have adopted the 30-day measure, have also retained the historically more common measure in recognition of the importance of maintaining comparability with previous studies that used the historically more common measure.

In contrast, a historically common definition of e-cigarette current use prevalence does not exist; a variety of definitions can be found in the literature. Reflecting the shift in measurement of cigarette smoking prevalence, many recent studies have adopted a measure of adult e-cigarette current use based on any use in the past 30 days.5,11–13 Alternatively, some researchers have adopted language from the conventional cigarette current use definition of use on every day or some days, but without the lifetime threshold question.4,6,14–16 Other studies have reported current use from questions that included multiple choice options for self-reported frequency.17–19

In addition to reporting prevalence of current use, several studies have investigated the distribution of use frequency by also reporting the prevalence of daily use;4,11,13 or some other measure designed to exclude non-established users; however, their operationalisations of ‘daily use’ and ‘established use’ were not uniform.4,11,14,20 Excluding non-established users is important in some instances because evidence suggests they differ from established users not only in extent of participation, but also in their reasons for initially trying e-cigarettes. Specifically, individuals from a US sample who had ever used e-cigarettes were roughly twice as likely to continue their e-cigarette use if they had tried them for a goal-oriented reason, such as quitting or cutting down other tobacco use or using them in places where smoking was not allowed, compared to individuals who had tried e-cigarettes for a non-goal reason such as curiosity.16 The authors of that study argued that measures of current use which distinguish types of users in terms of their goals for e-cigarette use would be most useful to public health researchers and practitioners.
More broadly, competing definitions of prevalence based on different frequencies of use present a challenge to cross-study comparison. It is not immediately clear which definition provides the most useful information about how the introduction of e-cigarettes is or is not changing the overall environment of tobacco use, especially combusted cigarettes. The tobacco control community has been confronted with similar challenges of measurement with regards to changing patterns of use among young adults\(^1\) and less-than-daily cigarette smoking.\(^2\) While it is likely that no single question or set of questions will be able to fully satisfy all research needs, particularly with regard to the psychological mechanisms of behaviour change, large scale population surveillance efforts for public health may benefit from increased consistency in definitions of e-cigarette current use prevalence across studies.\(^9\)

We had an opportunity to examine frequency of e-cigarette use, measured as a continuous variable, in a recent population-based study. We focused on the shapes of the e-cigarette use frequency distributions among current smokers, former smokers and never smokers. To keep the study limited in scope, we restricted our definition of ‘smoker’ to use of cigarettes only; we did not investigate other forms of combustible tobacco. By examining the shapes of the distributions, we hoped to take advantage of information that is lost when focusing on measures of central tendency such as the mean or median. We then investigated the relationship between those distributions and respondents’ reasons for using e-cigarettes. Our goal was to conduct a data-driven investigation in order to contribute evidence towards an eventual consensus regarding a standard definition of e-cigarette current use prevalence for the purpose of population surveillance.

**METHODS**

Data were collected as part of the 2014 Minnesota Adult Tobacco Survey, which uses a random digit dialing (RDD) methodology to obtain a cross-sectional sample of Minnesotan adults aged 18 years or older. Two sampling frames were used, one that included landline numbers and another that included cell phone numbers. Prescreening calls identified households and selected individuals within households; the main survey instrument was subsequently administered. A rigorous calling protocol was used, and letters were mailed to refusers and non-responders when addresses were available. Attempts were made to convert refusers. RDD response rates calculated by American Association for Public Opinion Research methodology were 25.2% for the landline sampling frame and 18.2% for the cell phone frame.\(^23\) Sampling weights were calculated based on sampling frame response rates and demographic characteristics known to be correlated with tobacco use behaviours, to obtain unbiased population level estimates. More methodological detail is available at [http://www.mnadulttobaccosurvey.org](http://www.mnadulttobaccosurvey.org). The final sample in 2014 included 9304 participants; 9301 of the participants provided valid responses for the items considered in this analysis.

Smoking status was established according to the historically common Behavioural Risk Factor Surveillance System (BRFSS) methodology. *Current smokers* had smoked ≥100 cigarettes in their lifetime and now smoked ‘every day’ or ‘some days’; *former smokers* had smoked ≥100 cigarettes in their lifetime, but now smoked ‘not at all’; and *never smokers* had not smoked ≥100 cigarettes in their lifetime. E-cigarette use was measured by two items. Participants were first asked, “Have you ever used an electronic cigarette, even just one time in your entire life?” Affirmative answers were followed by the question, “During the past 30 days, on how many days did you use e-cigarettes?” Responses were entered as integers by the data collector; respondents offering non-integer responses were prompted to provide an integer. Respondents who had ever used e-cigarettes were asked whether each of the following was a reason for use: to quit other tobacco products; to cut down on other tobacco products because they are affordable; because they are available in menthol flavour; because they are available in flavours other than menthol; to use them in places where other tobacco products are not allowed; curiosity about e-cigarettes; and because you believe these might be less harmful than other ways of smoking.
tobacco products. Based on the findings of Pepper et al, reasons were classified as goal oriented or non-goal oriented.

All analyses were conducted with the R software package, V.3.1.1, using the survey package V.3.30-3. All population estimates are presented with 95% CIs. Where direct comparisons of CIs are insufficient to establish significance at the α=0.05 level (ie, where CIs overlapped), we report p values for pairwise comparisons that were calculated using linear regression.

RESULTS

In 2014, 17.7% (16.6% to 18.8%) of Minnesota adults had tried e-cigarettes. Most current smokers (70% (66.7% to 73.4%)) had tried e-cigarettes at least once in their life, compared to smaller percentages of former smokers (15.9% (14% to 17.9%)) and never smokers (5.6% (4.7% to 6.5%); table 1). Across all cigarette smoking statuses, fewer than half of those who had ever tried e-cigarettes in their lifetime reported having used them in the past 30 days: current smokers 38.9% (34.4% to 43.5%); former smokers 30.3% (23.9% to 36.7%); never smokers 21.5% (15.3% to 27.7%).

Table 1

Percentage of Minnesota adults using e-cigarettes, by increasingly restrictive definitions of prevalence based on reported frequency of use

Histograms showing frequency of e-cigarette use for all individuals reporting any use in the past 30 days, separated by smoking status, are presented in figure 1. Based on the histograms, use less than or equal to 5 days in the past 30 days appeared to be a meaningful cut-off point to demarcate a cluster of respondents at the low end of each distribution whom we subsequently refer to as ‘infrequent’ users. Respondents who reported using an e-cigarette on 30 out of the past 30 days were categorised as ‘daily’ users. Respondents reporting use between 6 and 29 days (inclusive) were categorised as ‘intermediate’ users. Respondents who had used e-cigarettes in their lifetime, but not within the past 30 days, were categorised as ‘past users’.

Figure 1

Histograms of number of days respondents reported using an e-cigarette, for respondents with some 30-day use.

Current smokers were more likely to use e-cigarettes than former smokers or never smokers, across all frequency categories (table 1). Among current smokers who had used an e-cigarette in the past 30 days, the most common category was infrequent user (59% (51.5% to 66.5%)), followed by intermediate users (28.7% (21.8% to 35.6%)) and daily users (12.3% (7.2% to 17.4%)).

In contrast with current smokers, the proportions of former smokers reporting e-cigarette use in the past 30 days who were categorised as infrequent users (43.2% (30.2% to 56.1%)) versus daily users (40.9% (28.7% to 53%)) did not statistically differ (p=0.8). Comparatively fewer former smokers were categorised as intermediate users (16% (6.1% to 25.8%)).

The majority of never smokers who reported some use of e-cigarettes in the past 30 days were infrequent users (89.5% (81.5% to 97.4%)). Smaller proportions reported intermediate (5.4% (0.4% to 10.5%)) or daily (5.1% (0.0% to 11.4%)) e-cigarette use.
The reasons respondents cited for current or past use of e-cigarettes are presented in Table 2. Significantly fewer infrequent users endorsed the goal-oriented reasons for using e-cigarettes compared to daily users, p<0.05 for all goal-oriented reasons. The proportions of infrequent users endorsing the goal-oriented reasons of quitting other tobacco products, cutting down on other tobacco products and affordability were all similarly significantly lower than the corresponding proportions of intermediate users. In contrast, a greater proportion of infrequent users cited curiosity as a reason for their e-cigarette use. The proportions of current, former and never smokers within each use frequency category that endorsed each reason were numerically similar, but are not reported because small sample sizes prevented reliable inference.

### Table 2

Reasons cited by all adults who ever used e-cigarettes for why they use/have used them

Overall estimates of e-cigarette current use prevalence among Minnesota adults varied considerably depending on which types of users were included in the count: 6% (5.2% to 6.6%) if all user types were included; 2.4% (2% to 2.9%) if intermediate and daily users were included; 1.1% (0.8% to 1.4%) if only daily users were included (Table 1).

### DISCUSSION

Defining e-cigarette current use prevalence as any use in the past 30 days failed to differentiate a cluster of infrequent users at the low end of the distribution from other users. In addition to having a distinctly different behavioural profile in terms of use frequency, infrequent users were more likely to report curiosity as a reason for using e-cigarettes and less likely to report goal-oriented reasons, compared to intermediate or daily users. These results suggest that many infrequent users are experimenters, unlikely to continue their e-cigarette use over time. If that is the case, then measuring e-cigarette current use prevalence based on any use in the past 30 days may lead to an over-estimate of regular users. That conclusion is reinforced by the finding that most individuals who had ever used e-cigarettes reported no use in the past 30 days.

The importance of considering the distribution of days used has also been previously documented. Zhu et al examined a nationally representative sample of e-cigarette users and similarly found the proportion of daily users was lower among current smokers (11.5%) than recent former smokers (45.7%). Other studies that have separated users at the top of the distribution from others have used the terms ‘established users’ and ‘intensive users’. Clinically, a strict measure of use on 30 out of 30 days may have less utility than a broader category, because it may inadvertently exclude daily users who were temporarily abstinent for artificial reasons such as a broken device or serious illness.

A limitation of the current study is that we measured frequency of use in only a single, 30-day time window. We did not measure lifetime use of e-cigarettes; however, measures related to the quantity of use are problematic with e-cigarettes in light of the variety of types of cigarettes with varying quantities of nicotine and different associated use patterns. A more appropriate measure of use relevant to population health may be duration of use, measured by time since the individual first started e-cigarette use. Information on duration of use may be used in conjunction with numbers of days used in the past 30 days. Longitudinal data, such as the Population Assessment of Tobacco and Health study currently being conducted in the USA, will be particularly valuable for better understanding how e-cigarette use changes over time, how that use affects cigarette smoking, and how factors such as device type moderate these relationships. Another limitation is that we did not investigate demographic differences in this study, in order to keep this article focused on the primary methodological research question of operationalising prevalence. However, specific subpopulations may differ not only in overall...
prevalence, but also in the shape of their distributions, and more fine-grained questions about their cigarette and e-cigarette use may be necessary to accurately understand their behaviour. Finally, this study did not consider alternative measures of e-cigarette use such as number of times used per day or concentration of nicotine.

The 2012–2013 National Adult Tobacco Survey asked respondents, “Do you now use e-cigarettes every day, some days, rarely, or not at all?” The researchers included ‘rarely’ in the set of response options based on cognitive testing that suggested some participants felt neither ‘some days’ nor ‘not at all’ accurately described their use. Agaku et al. report two separate estimates of e-cigarette current use prevalence: an estimate of 1.9% based only on responses of ‘everyday’ and ‘some days’, and another estimate of 4.2% that also included responses of ‘rarely’. Our study investigated a different population (Minnesota vs USA) at a different time period (2014 vs 2012–2013). However, it is notable that the more restrictive definition in our study (use on more than 5 days; 2.4%) yielded an estimate 60.0% smaller than the less restrictive definition (any use in the past 30 days; 6.0%); the more restrictive definition reported by Agaku et al. yielded an estimate that was similarly 54.8% smaller than their less restrictive definition. While further research allowing more direct comparison is needed, the similarity in magnitude between our study and Agaku et al. is at least suggestive that providing respondents with the ‘rarely’ option may be an important and effective method for differentiating experimenters from other users.

These results are consistent with an interpretation that many people are trying e-cigarettes, but few continue use. Furthermore, based on the sparsity in the centre of the distributions, the transition from infrequent to daily user appears to be fairly rapid for those who make it. If the transition were gradual, we would expect to see more individuals along the continuum at the level of intermediate users, which is not the case. There is evidence that some respondents’ answers to the number of days question were influenced by a preference for round numbers, for example, local peaks are observed at 5, 10, 15, 20 and 25 days. While the number of respondents at these local peaks in the centre of the distribution is too small to have substantially affected our conclusions, the preference for 5 may suggest that the distinct cluster of infrequent users observed in this self-report data may be less distinct in actual practice.

Previous research suggests that learning to obtain a ‘satisfying’ nicotine hit from current e-cigarette devices takes practice, as well as knowledge of nicotine concentrations and devices. One possibility is that regular users who are trying to quit cigarettes persist as infrequent users until they either learn to use e-cigarettes to effectively manage their nicotine addiction, at which point they quickly make the transition to daily users, or until they decide e-cigarettes are not for them and abandon the effort. If the current generation of e-cigarettes were a more perfect substitute for nicotine delivery we would expect more daily use, a prediction supported by findings that established users tend to use different devices than the broader population of ever users. Frequency of use profiles may differ considerably based on device type; for example, daily users have a strong preference for refillable ‘tank’ devices. Survey items specific to particular device types and products will be useful for advancing research regarding how each tends to used, and for further differentiating types of users. At the same time, a consistent measure of use frequency across studies and devices will further our understanding of the relationship between device type and behaviour, and provide an efficient measure for public health surveillance.

**CONCLUSIONS**

These results suggest that defining e-cigarette current use as any reported use in the past 30 days captures a heterogeneous group of users at best and risks substantially overestimating its prevalence. Defining current use as ‘more than 5 days out of the past 30’ may be a more accurate measure if the research goal is to estimate the proportion of a population that will persist in using e-cigarettes, but
further research is necessary. Regardless of whether that definition or some other is adopted as a standard, greater consistency across studies is needed to better understand how the advent of e-cigarettes is (or is not) changing the landscape of tobacco use.

What this paper adds

- Electronic cigarette use has rapidly increased in recent years.
- Many tobacco control researchers are working to understand the extent of use and the implications.
- Unlike combustible cigarette smoking, a uniform definition for ‘current use’ of electronic cigarettes does not exist.
- That lack of standardisation presents a challenge to cross-study comparison, slowing progress.
- We found that defining prevalence as ‘any 30-day use’ included many users who were motivated by curiosity and were unlikely to continue use.
- This study identifies a methodological barrier to effective tobacco control policy regarding electronic cigarettes and uses a data-driven approach to propose a solution.

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Footnotes

Twitter Follow Raymond Boyle at @Raymond_Boyle

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A report commissioned by Public Health England

Authors:

Ann McNeill\textsuperscript{1,2}, Leonie S Brose\textsuperscript{1,2}, Robert Calder\textsuperscript{1}, Linda Bauld\textsuperscript{2,3,4}, Debbie Robson\textsuperscript{1,2}

\textsuperscript{1} King’s College London
\textsuperscript{2} UK Centre for Tobacco & Alcohol Studies
\textsuperscript{3} University of Stirling
\textsuperscript{4} Cancer Research UK
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Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

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Evidence review of e-cigarettes and heated tobacco products 2018:
A report commissioned by Public Health England

Authors

Ann McNeill 1,2, Leonie S Brose 1,2, Robert Calder 1, Linda Bauld 2,3,4, Debbie Robson 1,2

Additional contributors to individual chapters

Ilze Bogdanovica (Ch 11) 2,5, John Britton (Ch 11) 2,5, Jamie Brown (Ch 7) 2,6, Peter Hajek (Ch 4,9) 2,7, Hyun Seok Lee (Ch 12) 1, Magdalena Opazo Breton (Ch 11) 2,5, Lion Shahab (Ch 7,9) 2,6, Erikas Simonavicius (Ch 12) 1, Robert West (Ch 7) 2,6

1 King’s College London
2 UK Centre for Tobacco & Alcohol Studies
3 University of Stirling
4 Cancer Research UK
5 University of Nottingham
6 University College London
7 Queen Mary, University of London

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Authors

Professor Linda Bauld is Professor of Health Policy and Director of the Institute for Social Marketing and Dean of Research (Impact) at the University of Stirling. She is a Deputy Director of the UK Centre for Tobacco and Alcohol Studies (UKCTAS) and Chair in Behavioural Research for Cancer Prevention at Cancer Research UK (CRUK). She has no links with any tobacco or e-cigarette manufacturers.

Dr Leonie Brose is a Senior Lecturer in the Nicotine Research Group at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King’s College London and a member of the UKCTAS. She is a CRUK/BUPA Foundation Cancer Prevention Fellow. She has no links with any tobacco or e-cigarette manufacturers.

Mr Robert Calder is a Research Assistant and PhD student at the Addictions Department, IoPPN, King’s College London, and has no links with any tobacco or e-cigarette manufacturers.

Professor Ann McNeill is a Professor of Tobacco Addiction and leads the Nicotine Research Group at the IoPPN, King’s College London. She is a Deputy Director of the UKCTAS. She receives funding for projects from a variety of funders such as CRUK and the National Institute for Health Research (NIHR) and has no links with any tobacco or e-cigarette manufacturers.

Dr Debbie Robson is a Senior Post-Doctoral Researcher in the Nicotine Research Group at the IoPPN, King’s College London. She is funded by the NIHR Collaboration for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care. She has no links with any tobacco or e-cigarette manufacturers.

Contributors

Dr Ilze Bogdanovica is a Senior Research Fellow and a CRUK Career Development Fellow in the Division of Epidemiology and Public Health, University of Nottingham. She has no links with any tobacco or e-cigarette manufacturers.

Professor John Britton is Professor of Epidemiology at the Faculty of Medicine & Health Sciences, University of Nottingham, Director of the UKCTAS and Honorary
Consultant in Respiratory Medicine, Nottingham University Hospital Trust. He has no links with any tobacco or e-cigarette manufacturers.

Dr Jamie Brown is a CRUK Principal Research Associate and Deputy Director of the Tobacco and Alcohol Research Group, University College London. He has received unrestricted research funding to study smoking cessation from Pfizer outside the submitted work. He has no links with any tobacco or e-cigarette manufacturers.

Professor Peter Hajek is Director of the Health and Lifestyle Research Unit at Wolfson Institute of Preventive Medicine, Queen Mary University of London (QMUL). He has provided consultancy to and received research funding from manufacturers of stop-smoking medications including Pfizer, GSK and Johnston and Johnston. His research into safety and effects of e-cigarettes was funded by MHRA and NIHR. He has no links with any tobacco or e-cigarette manufacturers.

Mr Hyun Seok Lee is a medical student at the Faculty of Life Sciences and Medicine, King’s College London and has no links with any tobacco or e-cigarette manufacturers.

Dr Magdalena Opazo Breton is a Research Fellow in Epidemiology & Public Health at the University of Nottingham with funding from CRUK. She has no links with any tobacco or e-cigarette manufacturers.

Dr Lion Shahab is Senior Lecturer (Associate Professor) in Health Psychology at the Department of Behavioural Science and Health, University College London. He has received grants, personal fees, and nonfinancial support (that is, research grants, consultancy, travel, and hospitality) from Pfizer, Johnson & Johnson, the National Centre for Smoking Cessation and Training and Atlantis Health Care outside the submitted work. He has no links with any tobacco or e-cigarette manufacturers.

Mr Erikas Simonavicius is a NIHR Maudsley Biomedical Research Centre PhD student in the Nicotine Research Group at the IoPPN, King’s College London. He has no links with any tobacco or e-cigarette manufacturers.

Professor Robert West is Professor of Health Psychology and Director of Tobacco Studies at the Department of Behavioural Science and Health, University College London. He has received grants, personal fees, and nonfinancial support (that is, research grants, consultancy, travel, and hospitality) from Pfizer, Johnson & Johnson, and GlaxoSmithKline outside the submitted work. He has no links with any tobacco or e-cigarette manufacturers.
Executive summary

1  Introduction

- In England, adult smoking prevalence in 2016 was 15.5% and while it has fallen considerably over the last few decades, smoking remains the leading preventable cause of illness and premature death and one of the largest causes of health inequalities.
- This report has been commissioned to summarise evidence to underpin policy and regulation of e-cigarettes/vaping devices.
- It is the fourth in a series of reports commissioned by Public Health England (PHE) on e-cigarettes. In particular, this report updates the 2015 PHE report on e-cigarettes.
- Since the previous report, heated tobacco products, so-called ‘heat-not-burn’ tobacco products, have come onto the market in the UK and the report will provide evidence on this new product type as well as on e-cigarettes.

2  Methods

- The methods and sources of data used in the remaining chapters of the report focus on evidence produced since the previous report in 2015.
- The evidence falls into three main categories: 1) peer-reviewed literature and 2) surveys and 3) other reports and database sourced by and made available to PHE, King’s College London and other partner organisations since the publication of the 2015 report:

  1) Peer-reviewed literature
     - Searches of the published, peer reviewed literature on e-cigarette published between 1 January 2015 and 18 August 2017.
     - A separate literature search was conducted for heat-not-burn products. This was not included in the 2015 report so literature was searched from 1 January 2010 to 13 July 2017.

  2) The use of survey data
     - For youth, these included: ASH Smoke-free Great Britain – Youth survey; Wales Schools Health Research Network; Scottish Schools Adolescent Lifestyle and Substance Use Survey; Smoking, Drinking and Drugs Survey; Youth Tobacco Policy Survey.
     - For adults, these included: ASH Smoke-free Great Britain - Adult survey; Eurobarometer; International Tobacco Control Policy Evaluation Survey; Internet cohort Great Britain survey; Opinions and lifestyle survey; Smoking Toolkit Study.
3) Other reports and databases

- Data from NHS Digital (derived from local authorities) were assessed for Stop Smoking Service information.
- Publicly available data from the National Poison Information Service were used for information on poisonings.
- UK Fire and Rescue Incident Recording System (as reported by the Home Office) data was used for information on fires due to e-cigarettes.
- Freedom of information requests were also sent to the UK regional fire and rescue services for information on fires caused by e-cigarettes and mobile phones.
- A freedom of information request was sent to burns units, but for many, the cost of accessing the data would have been excessive. No data was included in this report.
- The Medicines and Healthcare products Regulatory Agency provided us with details for spontaneous suspected adverse reaction reports for e-cigarettes along with details of suspected adverse drug reactions for nicotine replacement therapy products.
- The ECig Intelligence Global Database was used to explore average price of various categories of e-cigarette.

3 Policy

Key findings

- As with tobacco products, in most parts of the UK, there is a minimum age of sale of 18 for e-cigarettes and e-cigarettes cannot be purchased on behalf of someone under the age of 18.
- The revised European Union Tobacco Products Directive is now fully operational in England, transposed into UK law through the UK Tobacco and Related Products Regulations 2016, and covers e-cigarettes and nicotine-containing e-liquids that do not have a medicinal licence. These regulations include a notification process to the Medicines Healthcare products Regulatory Agency (MHRA), minimum standards for safety and quality of e-cigarette products, standards for information provision (including a nicotine health warning) and advertising restrictions and updated standards. The Advertising Standards Authority has carried out a consultation on health claims; the results are awaited. A system to report side-effects and safety concerns related to e-cigarettes has been implemented.
- Over 32,000 e-cigarette and nicotine containing e-liquid products have been notified which suggests a level of compliance with the regulations, and that the notification process is not too onerous.
- There are some signs that ways are being found to avoid the law, for example particularly on size of bottles, but evidence is limited.
Alongside products regulated in line with the EU Tobacco Products Directive, manufacturers can also apply for medicinal licensing from the Medicines Healthcare products Regulatory Agency. However, no licensed e-cigarette has yet been marketed.

Other e-cigarette related developments include consensus statements from a number of organisations and guidance on the use of e-cigarettes in public places and on their use in research.

Non-nicotine e-cigarettes are governed by general product safety regulations (unlike combustible tobacco products).

There is a separate notification process for heated tobacco products (to PHE) and results from a consultation on the tax treatment of these products are forthcoming. At the time of writing, two products had been notified.


Implications

Research

There is a need for continued research on the impact of regulations on smoking rates and patterns, use of e-cigarettes by adults and young people, product design and quality, and adverse effects of e-cigarettes.

Research should specifically assess the impact of the EU Tobacco Products Directive on production (with a specific focus on independent manufacturers who were the first to enter this field), innovation of products, and e-cigarette users and smokers.

Policy

Regulations need to balance the risks of e-cigarettes with their potential benefits – and achieve key aims of reducing smoking and continuing to avoid uptake of e-cigarettes by non-smokers. This requires keeping them under regular review and evaluating their impact.

Regulations for heated tobacco products should be made as least a stringent as for e-cigarettes.

It remains a viable and important goal to facilitate regulation of some e-cigarettes as medicines via the Medicines Healthcare products Regulatory Agency. A review is needed of how to achieve this, possibly including more focus on post marketing surveillance and the provision of licences for short-term rather than extended use.

Restrictions on communicating relative risks of e-cigarettes in comparison with combustible tobacco should be reconsidered. In any future review of the EU Tobacco Products Directive, consideration should be given to the wording of the health warning on nicotine per se given public misperceptions of its harmfulness.
There appears to be no evidence justifying an urgent change regarding non-nicotine e-cigarettes or e-liquids which are currently outwith the scope of the EU Tobacco Products Directive.

4 Nicotine

Key findings

- The addictiveness of nicotine depends on the delivery system.
- It is possible that the addictiveness of tobacco cigarettes may be enhanced by compounds in the smoke other than nicotine.
- As e-cigarettes have evolved, their nicotine delivery has improved. This could mean that their addiction potential has increased, but this may also make them more attractive to smokers as a replacement for smoking. It is not yet clear how addictive e-cigarettes are, or could be, relative to tobacco cigarettes.
- While nicotine has effects on physiological systems that could theoretically lead to health harms, at systemic concentrations experienced by smokers and e-cigarette users, long-term use of nicotine by ‘snus’ (a low nitrosamine form of smokeless tobacco) users has not been found to increase the risk of serious health problems in adults, and use of nicotine replacement therapy by pregnant smokers has not been found to increase risk to the foetus.
- Adolescent nicotine use (separate from smoking) needs more research.
- The long-term impact of nicotine from e-cigarettes on lung tissue is not yet known and may be different from its impact systemically.

Implications

Research

- More research on nicotine in comparison to tobacco cigarette smoking is needed, and the popularity of e-cigarettes enables such research, albeit in the context of the other components in e-cigarette and e-cigarette aerosol.
- Further research is needed on the similarities and differences in addictiveness of e-cigarettes and tobacco cigarettes and the potential harms associated with inhaled nicotine.

Policy and practice

- Widespread misperceptions about the relative risks of nicotine and tobacco (see Chapter 10) need to be addressed and corrected.
• Clear messages, based on current evidence about nicotine, its relationship with harms, and its addictiveness, compared with smoking, are necessary and could have a marked impact on public health.
• Policies on tobacco and e-cigarettes should have at their core the recognition that nicotine use per se presents minimal risk of serious harm to physical health and that its addictiveness depends on how it is administered.

5 Use of e-cigarettes among young people

Key findings

• E-cigarettes cannot be legally sold to young people under the age of 18 in most parts of the UK. Purchasing does occur including from sources rarely used for tobacco, such as online suppliers.
• Despite some experimentation with these devices among never smokers, e-cigarettes are attracting very few young people who have never smoked into regular use.
• E-cigarettes do not appear to be undermining the long-term decline in cigarette smoking in the UK among young people.
• Never smokers in the UK who try e-cigarettes are more likely to have tried smoking subsequently than those who have not tried e-cigarettes. A causal link has not been established and neither has progression to regular smoking. The ‘common liability’ hypothesis seems a plausible explanation for the relationship between e-cigarettes and smoking implementation.

Implications

• Trends in e-cigarette use and smoking among youth should continue to be monitored using standardised definitions of use. This should include the use of nicotine in e-cigarettes and checks on the understanding of survey questions.
• Patterns of e-cigarette purchasing by young people should be closely monitored, particularly internet sales. Age of sale regulations are in place for e-cigarettes and cigarettes and should be strongly enforced.
• Research is needed on trajectories of use – not just from e-cigarette experimentation to smoking, but also from smoking to e-cigarette use among young people.
6 Use of e-cigarettes in adults

Key findings

Prevalence

- In GB, prevalence of e-cigarette use in adults has plateaued at approximately 6% of the adult population.
- E-cigarette use among never smokers in GB remains very rare at less than 1%, similar to the level of use of nicotine replacement therapy. Among never smokers who have ever used e-cigarettes, a minority have used nicotine-containing liquids and the vast majority not progressed to regular use.
- Prevalence of e-cigarette use and trial among smokers has plateaued while use and trial among ex-smokers continue to increase.
- Socioeconomic differences in e-cigarette use by smokers and recent ex-smokers have become smaller with no clear gradient in prevalence by occupational grade.
- Prevalence of dual use (use and smoking) is similar for e-cigarette users and users of nicotine replacement therapy.

Characteristics of use

- Most e-cigarette trial does not become regular use.
- Most current e-cigarette users use daily and have used e-cigarettes for more than six months.
- Models with refillable tanks for liquids are the most widely used type.
- Since May 2017, nicotine concentration in liquids has been limited to a maximum of 20mg/mL. In March 2017, around 6% of e-cigarette users reported using higher nicotine concentrations; substantial proportions had difficulties reporting these figures so more may have been affected by the limit.
- The most popular groups of flavours among current e-cigarette users are fruit (29%), tobacco (27%) and menthol/mint (25%).
- Specialist vape shops (physical premises rather than online) are the most popular place of purchase (>40%).
- The most common reason for e-cigarette use continues to be in order to stop smoking, and smokers who use e-cigarettes on average have higher motivation to stop smoking than other smokers.
International

- Data can be outdated by the time of publication.
- Prevalence of current use in GB is at the higher end for countries in the EU where the average is 2% for current e-cigarette use. Prevalence estimates for current e-cigarette use in the US are around 4% to 6%, which is similar to GB.
- Across international surveys, a consistently low prevalence (<1%) of e-cigarette use has been reported among never-smokers; one exception is one Spanish survey at 1.2%.
- Prevalence figures found for smokers and ex-smokers vary more widely across surveys in different countries (4% to 22% among smokers and 0.1% to 5% among ex-smokers).

Implications

Research

- As recommended in the 2015 PHE report, trends in e-cigarette use among adults should continue to be monitored using standardised definitions of use. Measures should include frequency and type of device used including different types of tank models.
- E-cigarette use among ex-smokers needs monitoring and further evidence to understand when and why they take up e-cigarette use and whether this is associated with an increase or decrease of relapse to smoking.
- More research is needed into different patterns of e-cigarette use while smoking and their effect on subsequent smoking behaviour to understand how best to move dual users to stop smoking.
- More research is needed on the impact of e-cigarettes on health and economic inequalities associated with smoking; in particular on use of e-cigarettes in disadvantaged groups with high smoking prevalence and smoking-related morbidity and mortality, such as those with mental health problems or offenders. Data that have been gathered from the Adult Psychiatric Morbidity Survey should be released for analysis.

Policy

- As recommended in 2015 and as per existing NICE guidance, all smokers should be supported to stop smoking completely, including ‘dual users’ who smoke and use e-cigarettes.
- Access to e-cigarettes should be improved for smokers in disadvantaged groups.
7 The effect of e-cigarette use on smoking cessation and reduction

Key findings

- In the first half of 2017, quit success rates in England were at their highest rates so far observed and for the first time, parity across different socioeconomic groups was observed. It is plausible that e-cigarettes have contributed to this.
- Recent estimates of additional quitters resulting annually from the availability of e-cigarettes, using the same dataset but two different methods, resulted in similar figures within the range of 16,000-22,000. Varying the assumptions, and updating these estimates for 2016, resulted in an upper bound estimate of around 57,000 additional quitters annually resulting from e-cigarettes (lower bound around 22,000). While caution is needed with these figures, the evidence suggests that e-cigarettes have contributed tens of thousands of additional quitters in England.
- E-cigarette use, alone or in combination with licensed medication and behavioural support from a Stop Smoking Service, appear to be helpful in the short term. However, fewer smokers use an e-cigarette as part of a quit attempt with a Stop Smoking Service compared with licensed medication.
- We identified 14 systematic reviews of e-cigarettes for smoking cessation and/or reduction published since our last report, seven of which included a meta-analysis. The authors of the systematic reviews arrived at the same conclusion that further randomised controlled trials of e-cigarettes are needed. However, the reviews that included a meta-analysis produced different results; two found a positive effect on cessation for e-cigarette use, four found an inconclusive effect for cessation and one found a negative effect.

Implications

Research

- An important focus of future research is longer-term relapse trajectories of people who use e-cigarettes for quitting compared with other stop smoking treatments and also assess whether the uptake of e-cigarettes after quitting can prevent relapse back to smoking.
- Funders should consider that although randomised controlled trials (RCTs) may yield higher internal validity this is at the cost of lower generalisability. Future robust observational studies and RCTs should consider allowing for user experimentation (eg trial and error of different types of e-cigarette products), as well as the inclusion of study outcomes that are relevant and meaningful for e-cigarette users.
- Funders should commission research about the effect of e-cigarettes on smoking cessation in vulnerable populations (eg people who smoke who have a mental illness, substance misuse disorder, homeless or prison populations).
Policy and practice

- Stop smoking practitioners and health professionals should provide behavioural support to smokers who want to use an e-cigarette to help them quit smoking.
- Stop smoking service practitioners and health professionals supporting smokers to quit should receive education and training in use of e-cigarettes in quit attempts.
- Local authorities should continue to fund and provide Stop Smoking Services in accordance with the evidence base.

8 Poisonings, fires and explosions

Key findings

Poisonings

- There are recorded cases of poisoning from e-liquid in the UK. These have predominantly involved accidental ingestion with fewer incidences of other routes (e.g., ocular or dermal) of exposure.
- Intentional poisoning using e-liquids has been reported in self-harm and suicide attempts.
- Toxic effects from e-cigarette poisoning are usually short in duration and of minimal severity; severe cases and fatalities, while very rare, have been recorded.
- E-cigarette poisonings reported to medical centres most commonly occur in children under five years old. Toxic effects for this age group are usually short in duration and non-severe. Fatalities, while very rare, have also been recorded in this age group.
- Incidents of poisoning in children are often preventable and have involved liquids stored non-securely, in unmarked containers or in containers without safety caps.

Fires

- E-cigarette fires are recorded at the discretion of individual fire rescue services in the UK. Information provided to us through a Freedom of Information request suggest that, where recorded, they occur in low numbers and are vastly outweighed by fires caused by smokers’ materials. There were no fatalities from fires caused by e-cigarettes in the reporting period.
- E-cigarettes and/or their batteries are recorded as the cause of fires by UK fire rescue services. The root cause of e-cigarette fires is likely to be through a malfunctioning lithium-ion battery.

Explosions

- Exploding e-cigarettes can cause severe burns and injuries that require intensive and prolonged medical treatment especially when they explode in users’ hands, pockets or mouths.
- Incidents are very rare. The cause is uncertain but appears to be related to malfunctioning lithium-ion batteries.

Implications

Research

- Research is required on the prevalence of e-liquid poisoning, fires and explosions caused by e-cigarettes in England. This will require some synthesis of existing datasets.
- Research on presence and effectiveness of safety features and instructions should be part of a future review of the EU Tobacco Products Directive.

Policy and practice

- Monitoring of fires caused by e-cigarettes should be recorded by Fire Rescue Services in a mandatory way (similar to “cooking appliances”, “smokers’ materials” and “other electrical appliances”) and should not continue to rely on free text entry.
- E-cigarettes can trigger fire/smoke detectors and therefore consumers should be advised to move away from detectors when using them.
- It is too early to assess the impact of the EU Tobacco Products Directive in reducing poisonings, fires or explosions, or whether further regulations are needed. Therefore, continued monitoring is required to assess effectiveness of EU Tobacco Product Directive regulations (such as childproof containers), in reducing accidental ingestion of e-liquid.
- Regulations should require that labelling on e-liquid bottles advises customers to store products away from similar looking medicines such as eye drops, ear drops and children’s medicine.
- Regulations should require that labelling reinforces advice on the safe storage and transportation of batteries used by e-cigarettes. For example, advice should be given that e-cigarettes should not be carried in pockets with coins, keys or other metallic objects, and that the correct charger should always be used.
9 Health risks of e-cigarettes

Key findings

- One assessment of the published data on emissions from cigarettes and e-cigarettes calculated the lifetime cancer risks. It concluded that the cancer potencies of e-cigarettes were largely under 0.5% of the risk of smoking.
- Comparative risks of cardiovascular disease and lung disease have not been quantified but are likely to be also substantially below the risks of smoking. Among e-cigarette users, two studies of biomarker data for acrolein, a potent respiratory irritant, found levels consistent with non-smoking levels.
- There have been some studies with adolescents suggesting respiratory symptoms among e-cigarette experimenters. However, small scale or uncontrolled switching studies from smoking to vaping have demonstrated some respiratory improvements.
- E-cigarettes can release aldehydes if e-liquids are overheated, but the overheating generates an aversive taste.
- To date, there is no clear evidence that specific flavourings pose health risks but there are suggestions that inhalation of some could be a source of preventable risks.
- To date, the levels of metals identified in e-cigarette aerosol do not give rise to any significant safety concerns, but metal emissions, however small, are unnecessary.
- Biomarkers of exposure assessed to date are consistent with significant reductions in harmful constituents and for a few biomarkers assessed in this chapter, similar levels to smokers abstaining from smoking or non-smokers were observed.
- One study showed no reductions across a range of biomarkers for dual users (either for nicotine replacement therapy or e-cigarette dual users).
- To date, there have been no identified health risks of passive vaping to bystanders.
- Reporting of some academic studies has been misleading.

Implications

Research

- More research is needed with human users about biomarkers of exposure, risk and harm and health effects over time.
- More research with biomarkers across the range of different combinations of dual use is needed.
- Adverse effects of passive vaping should be monitored.
Policy

- Policy makers and regulators should ensure that e-cigarettes are manufactured in a way that minimises harm. An advantage of e-cigarettes is that particular constituents can be removed or minimised in a way that is not feasible with tobacco cigarettes.
- Regulations should therefore be flexible to ensure any emerging evidence of constituent harmfulness can be acted upon, such that products are modified to remove any components shown to pose avoidable risks.
- Consumers and health professionals should be encouraged to use the Yellow Card Scheme for reporting adverse reactions to e-cigarette use.
- Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe.
- The lack of difference in biomarkers between dual users and smokers found so far underlines the need to encourage and support dual users to stop smoking altogether.

10 Perceptions of relative harms of nicotine, e-cigarettes and smoking

Key findings

- Perceived relative harm of e-cigarettes compared with cigarettes has continued to increase; less than half of adults in Great Britain think e-cigarettes are less harmful than smoking.
- Nicotine replacement therapy is subject to similar misperceptions and only just over half of adults in GB think that nicotine replacement therapy is any less harmful than smoking.
- Adult smokers are poorly informed about relative risks of different products.
  - Only half of smokers believe that e-cigarettes are less harmful than smoking and this decreases to one third among smokers who have never tried e-cigarettes.
  - In contrast to evidence to date, it appears that a majority of smokers and ex-smokers does not think that complete replacement of cigarettes with e-cigarettes would lead to major health benefits.
  - Only half of all adult smokers believe that nicotine replacement therapy is any less harmful than smoking.
• As the common factor for cigarettes, nicotine replacement therapy and (most) e-cigarettes is nicotine, these misperceptions may be linked to the perception of nicotine.
  o When adults in GB are asked what proportion of the health harms of smoking is due to nicotine, the accurate response (most health harms are not caused by nicotine) is the least common response consistently chosen by 8-9%. Smokers’ knowledge around nicotine is similarly poor.
  o Four in ten smokers and ex-smokers incorrectly think nicotine in cigarettes is the cause of most of the smoking-related cancer.
  o Misperceptions around nicotine and cancer are greater in more disadvantaged groups.
• It is unclear to what extent the perception of addictiveness underpins the perception of harm.
• Among youth in GB, perceived harm of e-cigarettes relative to cigarettes has also increased over time and nicotine knowledge is similarly poor (7% correctly responded that none or a small portion of the harms of smoking is due to nicotine).
• Where available, international data show similar misperceptions around nicotine and relative harmfulness of e-cigarettes and smoking as in England. International data also support the trends of increased harm perception of e-cigarettes with the exception of one survey in youth in the US.

Implications

Research

• Future research should aim to assess causes and effects of misperceptions of the relative harmfulness of e-cigarettes and nicotine replacement therapy compared with cigarettes, including to what extent the perception of addictiveness contributes to these misperceptions.

Policy

• Misperceptions of nicotine and different nicotine-containing products need to be addressed. These have deteriorated further since the PHE report in 2015 which called for clear and accurate information on relative harms.
  o Misperceptions of the relative harms of nicotine replacement therapy and e-cigarettes compared with cigarettes need to be addressed, particularly among smokers who would benefit from switching to nicotine replacement therapy or e-cigarettes.
  o Knowledge about the role of nicotine in the development of cancers and other diseases caused by smoking needs improvement.
11 Pricing

Key findings

- Price varies considerably between products, and there appear to be differences between online and bricks and mortar shop prices, with closed system products tending to be cheaper online, and open system kits cheaper in bricks and mortar shops.
- Generally, average maximum and minimum prices seem to have remained relatively stable from August 2015 to July 2017 for all product categories.
- There appear to have been no major and consistent changes in price over the first year since implementation of the EU Tobacco Products Directive.

Implications

- Current available data provide minimum, maximum and average prices, but do not provide detail on nicotine levels, brands and flavours that would be helpful to our understanding of market developments.
- Currently e-cigarette products are available in a wide range of prices and therefore affordable to various types of e-cigarette users. Any changes in pricing need to ensure that e-cigarettes are affordable to smokers to avoid discouraging smokers from switching away from smoked tobacco which would be counter-productive in public health terms. There should therefore be a competitive advantage for the prices of e-cigarettes compared to combustible tobacco products.

12 Heated tobacco products

Key findings

- In mid 2017 heated tobacco products were commercially available in 27 countries and further country launches were planned. Three tobacco manufacturers were promoting heated tobacco products: ‘IQOS’ was promoted by Philip Morris International, ‘glo’ by British American Tobacco, and ‘Ploom TECH’ by Japan Tobacco International.
- Out of 20 studies that were included in this review, 12 were funded by manufacturing companies so there is a lack of independent research.
- There is a variety of heated tobacco products, including some that deliver via both vapour and combustion.
- Most studies published at the time of the search for this review evaluated IQOS, none evaluated glo or Ploom TECH. An updated version of the review including later publications is in preparation to be published separately.
Evidence review of e-cigarettes and heated tobacco products 2018: 
A report commissioned by Public Health England

- In Great Britain, in 2017, awareness and ever use of heated tobacco products were very rare.
- Nicotine in mainstream aerosol from heated tobacco products reached 70%–84% of the nicotine detected in smoke from reference cigarettes.
- The tested heated tobacco products delivered more nicotine in aerosol than a cigalike e-cigarette and less nicotine than a tank style e-cigarette.
- Pharmacokinetics and delivery of nicotine after single use of a heated tobacco product were generally comparable with smoking a cigarette. However, studies that compared ad libitum use of heated tobacco products with smoking cigarettes consistently reported lower nicotine levels in heated tobacco product users compared with smokers.
  - Probably to compensate, smokers who were switched to using heated tobacco products adjusted their puffing behaviour.
- Heated tobacco product use reduced urges to smoke, but smokers consistently reported heated tobacco product use to be less rewarding compared with smoking a cigarette.
- Compared with cigarette smoke, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds. The extent of the reduction found varies between studies.
- The limited evidence on environmental emissions from use of heated tobacco products suggests that harmful exposure from heated tobacco products is higher than from e-cigarettes, but further evidence is needed to be able to compare products.
- Japan, where e-cigarettes are not available, has the most diverse heated tobacco product market with three tobacco manufacturers participating. Past 30 day use for the most frequently used product increased from 0.3% in 2015 to 3.7% in 2017, suggesting rapid penetration of heated tobacco products.

**Implications**

**Research**

- There is a need for more research that is independent of commercial interests.
- Different types of heated tobacco products will have different characteristics and effects, presenting a challenge for research.
- Research is needed on relative risks of heated tobacco products to users and those around them compared with cigarettes and e-cigarettes.
- Evidence is needed on appeal of heated tobacco products to smokers and non-smokers, particularly among youth.
- Effects on smoking need to be researched, this includes whether they replace or complement cigarettes. Due to co-branding of some products with cigarettes and the more similar sensory profile, findings may be different than for e-cigarettes.
Future studies, whether funded by manufacturers or independently, should ensure conduct of studies in line with established guidelines such as definitions of abstinence from smoking, using intention-to-treat analysis and registering trial protocols prior to the start of participant recruitment.

The appropriateness of different methods for measuring emissions and their translation from cigarettes to heated tobacco products should be evaluated to be able to recommend a gold standard.

Prevalence and market share should be monitored, particularly in markets targeted by manufacturers.

- In line with recommendations for e-cigarette use, measures should go beyond lifetime use or past 30 day use to assess current use; uptake and use should be assessed by smoking status.
- Monitoring should include transitions between smoking, e-cigarette use and heated tobacco product use.

Policy

- The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes.
- With a diverse and mature e-cigarette market in the UK, it is currently not clear whether heated tobacco products provide any advantage as an additional potential harm reduction product.
- Depending on emerging evidence on their relative risk compared to combustible tobacco and e-cigarettes, regulatory levers such as taxation and accessibility restrictions should be applied to favour the least harmful options alongside continued efforts to encourage and support complete cessation of tobacco use.
1 Introduction

In England, smoking prevalence has fallen considerably over the last few decades, but smoking remains the leading preventable cause of illness and premature death and one of the largest causes of health inequalities. The decline has continued in the last few years: adult smoking prevalence in England declined from 19.9% in 2010 to 15.5% in 2016 (1). In 2017, the Department of Health and Social Care for England has published a new Tobacco Control Plan aiming to achieve a ‘smokefree generation’ with smoking prevalence eventually at 5% or below (2). Four ambitions were outlined, which highlighted the importance of reducing smoking in young people, in more disadvantaged groups including those with mental health problems and reducing smoking in pregnancy; the fourth ambition recognised the role that less harmful alternatives could play. The Tobacco Control Plan indicated that PHE would update their evidence report on e-cigarettes (EC) and other novel nicotine delivery systems annually until the end of Parliament in 2022. This report is the first of those updates.

EC comprise a battery-powered heating element that is designed to vaporise a solution made of propylene glycol and/or glycerine, water and frequently flavouring and nicotine. This vapour (or rather aerosol) is then inhaled. There are many different types of EC; they can be classified into three basic types: (1) one-time, disposable products (often referred to as cigalikes); (2) reusable, rechargeable kits that are designed to be refilled with liquid by the user (often referred to as tanks) and (3) reusable, rechargeable kits that allow users to customise their product such as by regulating the power delivery from the batteries to the heating element (sometimes these are included with other tank models). In contrast to EC, heated tobacco products in general apply heat to tobacco instead of liquids (although there are hybrid products). Typically, heated tobacco products are rechargeable and include a holder, and tobacco sticks, plugs or capsules to be heated with an electronically controlled heating element.

Objective of the report

This report has been commissioned to summarise evidence to underpin policy and regulation of EC and novel nicotine delivery systems. It is the fourth in a series of reports commissioned by PHE on EC (3, 4). In particular, this report updates the 2015 PHE report on EC (5). Since the previous report, heated tobacco products, so-called ‘heat-not-burn’ tobacco products have come onto the market in the UK and the report will summarise evidence on this new product type as well as on EC.

Structure of the report

Following this introduction, Chapter 2 describes the methods used for the chapters presenting the most recent evidence on EC and heated tobacco products. Chapter 3
provides a summary of the current regulations for EC and heated tobacco products in the UK and Chapter 4 summarises evidence on the role of nicotine in tobacco and EC use, its addictiveness and safety profile. Chapter 5 summarises evidence on use among young people and Chapter 6 summarises evidence on use among adults. Chapter 7 considers the evidence for EC in smoking cessation. Chapter 8 summarises the available evidence on the risks of fires, poisonings and explosions related to EC and Chapter 9 discusses health risks to users and bystanders. Chapter 10 provides evidence on the relative harm perceptions of different nicotine-containing products. Chapter 11 describes trends in indicative pricing of EC. Finally, Chapter 12 assesses the evidence on heated tobacco products. This report is focused on England, and draws on surveys from England, Great Britain and the United Kingdom. A brief overview is also given, where appropriate, of the international situation.

Acronyms and abbreviations used in this report

A&E = Accident and Emergency
ASA = Advertising Standards Authority
ASH = Action on Smoking and Health
ASH-A = ASH Smoke-free Great Britain-Adult survey
ASH-Y = ASH Smoke-free Great Britain-Youth survey
AOR = Adjusted Odds Ratio
BAT = British American Tobacco
CHTP = Carbon Heated Tobacco Product
CI = Confidence Interval
CO = Carbon Monoxide
CPD = Cigarettes Per Day
CVD = Cardiovascular Disease
EC = E-cigarette/E-cigarettes
ENDS = Electronic Nicotine Devices/Electronic Nicotine Delivery Systems
EU TPD = The Revised European Union Tobacco Products Directive
EU = European Union
FDA = Food and Drug Administration (US)
FOI = Freedom of Information
FOI-B = Freedom of information request made to UK burns treatment centres
FOI-F = Freedom of information request made to UK fire rescue services
GB = Great Britain
GBP = Pounds Sterling
GPs = General Practitioners
HCI = Health Canada Intense
HPHC = Harmful and Potentially Harmful Compounds
ICGBS = Internet cohort Great Britain survey
ISO = International Organization for Standardization
ITC = International Tobacco Control
IV = Intra Venous
KCL = King’s College London
MHRA = Medicines and Healthcare products Regulatory Agency
NYTS = National Youth Tobacco Survey (US)
NHS = National Health Service (UK)
NICE = National Institute for Health and Care Excellence
NPIS = National Poisons Information Service
NRT = Nicotine Replacement Therapy
ONS = Office for National Statistics
OR = Odds Ratio
OTC = Over the Counter
PATH = Population Assessment of Tobacco and Health (US)
PG = Propylene Glycol
PHE = Public Health England
PMI = Philip Morris International
RCP = Royal College of Physicians
RCTs = Randomised Controlled Trials
SALSUS = Scottish Schools Adolescent Lifestyle and Substance Use Survey
SD = Standard Deviation
SDD = Smoking, Drinking and Drugs Survey
SHRN = Wales Schools Health Research Network survey
STS = Smoking Toolkit Study
WHO = World Health Organization
YTPS = Youth Tobacco Policy Survey
Evidence review of e-cigarettes and heated tobacco products 2018:
A report commissioned by Public Health England

2 Methods

Introduction

This chapter describes the methods and sources of data used in the report and focuses on evidence produced since the previous report in 2015. The evidence falls into three main categories:

- peer-reviewed literature reviews: Searches of the published, peer reviewed literature on EC produced between 1 January 2015 and 18 August 2017. A separate literature search was conducted for heated tobacco products (often referred to as heat-not-burn). This was not included in the 2015 report so literature was searched from 1 January 2010 to 13 July 2017.
- survey data
- other reports and databases sourced by and made available to PHE, King’s College London (KCL) and other partner organisations since the publication of the 2015 report

A summary of methods for each topic is given at the beginning of each chapter, but details of the literature reviews and sources of surveys and other data are given here.

Literature reviews

A full systematic review was not possible given the timeframe within which the report was commissioned and needed to be delivered, and the wide scope of the topics covered. However, a systematic review was carried out for heated tobacco products – see below for the search strategies and methods used, and chapter 12. For the remainder of the report topics covering EC, we carried out one literature search using systematic review methods, and we included key material on EC relevant to the topics studied, such as new syntheses of evidence, new evidence or data from research studies or detailed case studies. In addition, studies published since the search were included where they were pertinent to the topics we were studying and provided new relevant information.

EC literature

The literature search was based on the search developed and used in the 2015 PHE report (5) to ensure consistency between the two reports. However two terms within the search were updated. The terms “ENDS” and “Vap*” were both combined with the term “nicotine” because of their use in non-nicotine fields. The final search term was:

(("2015/01/01"[Date - Publication]: "3000"[Date -Publication])) AND (((((e-cigarette) OR Electronic cigarettes) OR e-cig*) OR electronic cig*) OR (ENDS AND Nicotine)) OR electronic nicotine delivery systems) OR electronic nicotine delivery system) OR ((Nicotine) AND (Vaping* OR Vape* OR Vaporiz* OR Vaporis* OR Vapouris*)). The term ",(2015/01/01"[Date - Publication]: "3000"[Date -Publication])” limits the search to all literature published after 1 January 2015 to the day of the search.

The final search was completed on 18 August 2017 and covered the following databases: Pubmed, Embase, PsychInfo, MEDLINE, Web of Science and CINAHL. This search yielded 10,810 results which were screened initially by title and abstract and then by full text. The full screening process is shown in Figure 1. Literature was included where it reported on EC, published new evidence or data from research studies, presented a new synthesis of existing evidence, detailed case studies relevant to EC, analysed policy and was published in English. Literature was excluded where they did not present new data, were editorial or opinion based in nature (ie did not contain new data), syntheses or research findings, were not peer-reviewed or were published before 1 January 2015. Additional literature known to the authors was included where it was able to provide context.

In addition to literature identified by this screening process, high profile studies that were published since the search were included where they provided new relevant information or generated particular media interest. Some studies published before 2015 were also included where they provided relevant background or context.
Heated tobacco products literature review

A separate literature search was conducted for evidence on heated tobacco products.

Search strategy and selection of studies

MEDLINE, EMBASE, PsychInfo, ProQuest, Scopus, and Web of Science databases were searched on 13 July 2017. The search included terms relating to general heated tobacco product names (‘heat not burn’, ‘tobacco heating system’) and brand names (‘IQOS’, ‘Ploom’, ‘Heets’), and were limited to studies published from 2010. Endnote X7 was used to record publications at all stages of the review.

The final search term was as follows:

("2010/01/01"[Date - Publication]: "3000"[Date -Publication]) AND ((Heat not burn) OR (tobacco heating system) OR (heat* adj3 tobacco) OR (IQOS) OR (Ploom) OR (Heets))

One reviewer (ES) screened all titles and abstracts of initially included studies, and two reviewers (ES and LBr) independently screened full text papers; Cohen’s kappa was calculated as a measure of agreement. Articles were screened in if they were studies of...
heated tobacco products, studies of emissions or human studies, studies that presented new data or evidence and were research papers. Articles were excluded if the subject was not heated tobacco, not peer reviewed (e.g., conference abstracts, commentaries, editorials), published before 1 January 2010, were animal or in vitro studies, if focused on products that are no longer available such as Premier or Eclipse. The full screening process is shown in Chapter 12.

Data extraction

Data was extracted to a pre-defined table by one reviewer (ES) and checked by a second reviewer (LBr).

Data synthesis

Data from studies on heated tobacco product emissions and on use of heated tobacco products by humans were synthesised separately. Key findings were summarised in a narrative synthesis, and quantitative results were compared between studies where comparison was possible.

Surveys

In the introduction of each chapter in this report we detail the specific datasets used in that chapter. Data from several surveys were used, their details are listed in Table 1. Where possible, references are made to peer-reviewed publications that have used the data.

Table 1: Surveys used in this report

<table>
<thead>
<tr>
<th>Name and acronym</th>
<th>Commissioned &amp; conducted by</th>
<th>Geographic coverage, sample</th>
<th>Representativeness</th>
<th>Design</th>
<th>Time-frame included</th>
<th>Example publications</th>
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</thead>
<tbody>
<tr>
<td><strong>Youth surveys</strong></td>
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<tr>
<td>ASH Smoke-free Great Britain-Youth survey (ASH-Y)</td>
<td>ASH, YouGov plc</td>
<td>GB, aged 11-18, annual n&gt;2,000</td>
<td>Recruited via a panel, weighted to be representative of all GB 11-18 year olds</td>
<td>Online, repeated cross-sectional</td>
<td>2016 and 2017</td>
<td>(6, 7) (8)</td>
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<td>Wales Schools Health Research Network survey (SHRN)</td>
<td>Partnership led by Cardiff University; with Welsh Government, Public Health Wales, Cancer Research UK and 113 secondary schools</td>
<td>Wales secondary school pupils, n=32,479</td>
<td>Network schools represent about half of all secondary schools, representation in all local authority areas. 87 participating schools; where full participation was not possible two randomly selected mixed ability classes</td>
<td>Online, school-based, repeated cross-sectional</td>
<td>2015</td>
<td>(6) (9) (10)</td>
</tr>
<tr>
<td>Scottish Schools Adolescent Lifestyle and Substance Use Survey (SALSUS)</td>
<td>Scottish Government, Ipsos MORI Scotland</td>
<td>Scotland, second-year (n=13,607) and fourth-year (n=11,697) secondary school pupils</td>
<td>Sample weighted to be in line with the pupil census at national level</td>
<td>School-based, online and on paper in exam conditions, repeated cross-sectional</td>
<td>2015/16</td>
<td>(6) (10)</td>
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<tr>
<td>Smoking, Drinking and Drugs Survey (SDD)</td>
<td>NHS Digital, Ipsos MORI</td>
<td>England, school pupils aged 11-15, 2016 n=12,051</td>
<td>Sample weighted to be in line with the pupil census at national level</td>
<td>Completed on paper in exam conditions, repeated cross-sectional</td>
<td>2016</td>
<td>(11)</td>
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<tr>
<td>Youth Tobacco Policy Survey (YTPS)</td>
<td>Stirling University, FACTS International (Ashford, UK),</td>
<td>UK, aged 11-16, n=1,213</td>
<td>Random location sampling in 92 electoral wards, stratified to cover geographic areas and socio-demographic backgrounds</td>
<td>Face-to-face household interviews, repeated cross-sectional</td>
<td>2016</td>
<td>(6)</td>
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<tr>
<td>Name and acronym</td>
<td>Commissioned &amp; conducted by</td>
<td>Geographic coverage, sample</td>
<td>Representativeness</td>
<td>Design</td>
<td>Time-frame included</td>
<td>Example publications</td>
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<tr>
<td><strong>Adult surveys</strong></td>
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<tr>
<td>ASH Smoke-free Great Britain-Adult survey (ASH-A)</td>
<td>ASH, YouGov plc</td>
<td>GB, aged 18+, annual n&gt;12,000</td>
<td>Recruited from a panel according to quotas; responses weighted to be representative</td>
<td>Online, repeated cross-sectional</td>
<td>Annually 2010 to 2017</td>
<td>(12-14)</td>
</tr>
<tr>
<td>Eurobarometer</td>
<td>European Commission, TNS</td>
<td>EU, aged 15+, n=27,901</td>
<td>Multi-stage random probability sampling in each country, responses weighted</td>
<td>Face-to-face interviews, repeated cross-sectional</td>
<td>2017</td>
<td>(15)</td>
</tr>
<tr>
<td>ITC Policy Evaluation Survey (ITC)</td>
<td>A variety of funders, see <a href="http://www.itcproject.org/sponsors">http://www.itcproject.org/sponsors</a></td>
<td>29 country cohorts typically smokers and ex-smokers aged 18 years and over. N~ 2000 per country per survey.</td>
<td>Typically random sampling within stratified population quota. Weighted data</td>
<td>Telephone, online, longitudinal</td>
<td>Surveys 2002-2016</td>
<td>(16)</td>
</tr>
<tr>
<td>Name and acronym</td>
<td>Commissioned &amp; conducted by</td>
<td>Geographic coverage, sample</td>
<td>Representativeness</td>
<td>Design</td>
<td>Time-frame included</td>
<td>Example publications</td>
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<tr>
<td>Opinion and lifestyle survey (ONS)</td>
<td>ONS</td>
<td>GB, aged 16+, n=7,713</td>
<td>Two stage, stratified random probability sample, responses weighted</td>
<td>Household face-to-face interviews, repeated cross-sectional</td>
<td>2016</td>
<td>(22) For more detail about the methods of this survey see <a href="https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifecircumstances/bulletins/adultsmokinghabitsinengland/2016">https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifecircumstances/bulletins/adultsmokinghabitsinengland/2016</a>,</td>
</tr>
<tr>
<td>Smoking Toolkit Study (STS)</td>
<td>University College London, Ipsos MORI</td>
<td>England, aged 16+, n~1800 per month</td>
<td>Recruited to be nationally representative to the population of England according to census data</td>
<td>Household face-to-face interviews, repeated cross-sectional</td>
<td>Monthly 2011-2017</td>
<td>(23)</td>
</tr>
</tbody>
</table>

For more detail about the methods of this survey see https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifecircumstances/bulletins/adultsmokinghabitsinengland/2016,
Other reports and databases

The following section details sources of data used in the present report. These include data sources that were available, or otherwise sought by PHE, KCL and other partners. The methods used to create each individual dataset are summarised here as well as methods used to source the data where relevant.

NHS Digital; formerly Health and Social Care Information Centre (HSCIC)

PHE monitors the delivery of Stop Smoking Services in England. Data are collected from local authorities by NHS Digital (formerly the HSCIC), an internal NHS Information technology provider. The data include information on the number of patients setting a quit date; the number who successfully quit and key measures of the service including intervention type, intervention setting and type of pharmacotherapy received. Since 2014, Stop Smoking Services have been asked to record if an EC was used in a quit attempt. A successful quitter is defined as a person who reports they have not smoked in the past two weeks, when assessed 4 weeks after their designated quit date. Clients who self-report as having quit at the 4-week follow up are required to have their CO levels monitored as a validation of their quit attempt; self-reported quit rates and CO validated rates are reported separately by NHS Digital. We report data from April 2015 to March 2017.

National Poisons Information Service (NPIS)

Data from publicly available reports by NPIS were used. The NPIS advises hospitals, emergency services and members of the public on the treatment of poisoned patients by providing up-to-date advice and information by telephone and online. NPIS records the numbers of enquiries, treatments and outcomes for different types of poisoning and publishes annual activity reports. Activity between 2015 and 2017 were used here.

For more detail about the methods of this survey see (24)

Fire Service data

Fire statistics are published by the UK government Home Office (25) using data collected from the UK Fire and Rescue Incident Recording System. An entry on to the system is made after each incident attended and covers the causes of fires (or other incidents), contributing factors, injuries and fatalities, locations and outcomes. The Incident Recording System uses pre-determined categories which includes the category "smokers’ materials" but does not specify EC materials. There is however a free text box in which extra data can be entered where the cause of fire is not adequately represented by existing categories. Data from April 2015 to March 2017 was used here.
Freedom of Information data – Fire services (FOI-F)

Fifty-two regional UK fire services were identified and a Freedom of Information (FOI) request was sent to each asking for data on fires caused by EC (including their batteries and chargers) as well as fires caused by mobile phones (including their batteries and chargers) for context. It was not possible to send an FOI to one service because their regulations specified that you must be a local resident to do so. The data was requested for each year from 2015 to 2017. Data for 2017 were requested during August 2017 and the data available up to that point were provided, accordingly the cut off dates for 2017 data varied between services. Data was collected and analysed specifically for the current report. Responses came from fire services who were able to search the free text box in the incident recording system described above (see “Fire Service Data”).

All Fire and Rescue Services were asked for the following information:

The number of recorded fires and false alarms related to ECs and mobile phones for 2015, 2016 and 2017. (False Alarms are incidents where the Fire Rescue Service attends a location believing there to be an incident, but on arrival, discovers that no such incident exists or existed.)

The number of injuries and fatalities related fires caused by EC or mobile phones for 2015, 2016 and 2017.

FOI Burns units (FOI-B)

Twenty-five adult, and four children’s UK burns services were identified and a FOI request was sent to each asking for data on burns caused by EC as well as burns caused by mobile phones for each year from 2015 to 2017. Data was collected and analysed specifically for the current report. For many burns services the data was only recorded in case notes and therefore the cost of accessing these data exceeded the limit set by the FOI Act.

MHRA Yellow Card Scheme

The Yellow Card Scheme, run by the MHRA, is the system for recording suspected adverse reactions to medicines and medical devices in the UK. On 20 May 2016 the Yellow Card Scheme launched an online reporting form tailored to collecting cases of suspected adverse reactions and physical safety concerns associated with EC. The Yellow Card Scheme was established in 1964 and is an important way in which the MHRA collects information to monitor the safety of medicines in the UK; medicines safety information from other UK and international data sources supplements data
collected by the Yellow Card Scheme. Any suspected adverse drug reaction to a medicine can be reported by a health professional, or member of the public and manufacturers have a legal obligation to report reactions. Inclusion of a report in the Yellow Card Scheme database does not necessarily mean that the reactions reported were caused by a medicine or an EC, only that the person reporting the event had a suspicion it may have, or it had a close temporal relationship to the administration of the medicine or EC. The MHRA provided us with anonymised details for spontaneous suspected adverse reaction reports for EC along with details of suspected adverse drug reactions for NRT products. We report spontaneous adverse drug reactions for the period 1 January 2015 to 20 October 2017.

**ECigIntelligence data**

ECigIntelligence is an independent resource that tracks market intelligence for the EC sector. The available data from the ECigIntelligence Global Database from August 2015 to July 2017 describe average prices of various categories of EC. Since the number of products available is substantial, ECigIntelligence data typically present average lowest prices, thus reflecting the floor price of the products involved though towards the end of study period offers prices for some of the most expensive clearomiser/tank. The categories are:

- **Closed system products**: EC with pre-filled clearomisers or cartomisers
  - Cheapest closed system kit- products with varying content but include at least one of the following- a USB charger, one cartomiser/capsule/ clearomiser (prefilled and containing nicotine) or one battery (non-reusable kit);
  - Cheapest pre-filled clearomiser- the refillables of the closed system kit are pre-filled cartridges, capsules or clearomisers;
  - Cheapest disposable EC - must contain nicotine, generally come in a cigalike form

- **Open system products**: EC that allows a user to choose their preferred e-liquid to refill their hardware device
  - Cheapest basic open system kit- products with varying content but include at least one of the following- a USB charger, one cartomiser/capsule/ clearomiser (prefilled and containing nicotine) or one battery. This kit should allow user to use any e-liquid without any modifications.
  - Cheapest clearomiser- the clearomiser is ready to use and include outer casing, an atomiser and a mouthpiece.
  - Cheapest e-liquid- lowest prices e-liquid bottle containing at least 10mL, and the price per mL is calculated
  - Variable wattage/ voltage kits
  - Most expensive clearomiser
Price data was provided in US dollars and converted to British pounds using monthly exchange rates obtained from Bank of England website (26). For most categories, the majority of data was derived from online sales, though towards the end of the study period data from retailers such as vape shops were included in the analysis. Average, minimum, maximum and median prices were provided; we used average price to explore the trends and maximum and minimum values to illustrate the price range.
3 Policy

Introduction

Since the 2015 PHE report (5), several new regulations for EC have been implemented. These include age of sale regulations and the Revised European Union Tobacco Products Directive (EU TPD) (27) translated into UK law through the UK Tobacco and Related Products Regulations 2016 (see below). The national competent authority for these regulations is the MHRA acting for the Secretary of State for Health. The MHRA has implemented a notification scheme for EC and e-liquids (EC refill containers) and a system for notification of side-effects and safety concerns from EC under the TPD. Other TPD regulations cover minimum standards for safety and quality, advertising, labelling and packaging. E-liquid products that do not contain nicotine when sold (eg disposable EC and 0% nicotine e-liquids) are not deemed to fall within the scope of the TPD in the UK regulations and therefore do not have to meet its requirements, but are regulated under General Product Safety Regulations (28). The General Product Safety Regulations impose requirements concerning the safety of products intended for consumer use, and require producers only to place safe products on the market (it is worth noting that combustible tobacco products are exempt from this). Another regulatory option for EC is for manufacturers to apply for a medicines licence through the MHRA. Additionally, the Department of Health and Social Care in England has published a new Tobacco Control for England plan (2) and heated tobacco products (a new type of product often called heat-not-burn) have appeared on the market. Although we heralded some of these in our previous report, we describe relevant new regulations in detail in this chapter, roughly in order of date of implementation.

Age of sale of EC

New legislation came into force in England and Wales on 1 October 2015 and in Scotland on 1 April 2017 (29), introducing a minimum age of sale of 18 for EC and prohibiting the purchase of these products on behalf of someone under the age of 18. This mirrors the law for the age of sale for tobacco cigarettes.

The data in Chapter 5 suggest that among those who use these products, similar proportions (approximately one third) of 11-15 year olds purchase EC as do purchase cigarettes. A smaller proportion of young people purchase EC than purchase cigarettes, from newsagents, but this may reflect the lower prevalence of EC available for purchase in newsagents. Around a quarter of 11-15 year olds reported buying EC from EC shops, and large proportions reported being given or buying their EC or
cigarettes from other people. Clearly there is scope to improve enforcement of age of sale laws for EC and cigarettes.

**European Union Tobacco Products Directive (EU TPD)**

Article 20 of the revised EU TPD (27) introduced new regulations for nicotine-containing EC. The EU TPD was adopted in 2014 and translated into UK law through the UK Tobacco and Related Products Regulations 2016 (30) (Parts 6 and 7) which came into force on 20 May 2016, although some provisions were phased in during the period leading up to 20 May 2017¹. The advertising component of the EU TPD was implemented in May 2016 and superseded the previous voluntary agreement on advertising which was revised and a further consultation closed in October 2017 (see below).

Under the TPD, the Secretary of State can require EC producers to withdraw their products from the market if they believe that they could present a serious risk to human health. The Secretary of State is obliged to review the regulations and publish a report within five years of coming into force and within every five years afterwards.

In our last report we described the challenge by Totally Wicked, a privately-owned business selling EC devices and e-liquids, against one Article of the EU TPD, on the basis that it represented disproportionate and inappropriate regulation. The challenge was supported by nearly 100,000 EC users from across the European Union (EU) who signed a petition that was delivered to the Department of Health and Social Care in England. On 4 May 2016 the European Court (31) rejected the challenge ruling in agreement with the European Commission and upholding the EU TPD.

**Notification process**

Producers of EC and nicotine containing e-liquids are required to notify the MHRA and submit relevant information (a producer is defined as anyone who manufactures or imports these products or who re-brands any product as their own). Producers of all EC and e-liquids that were on the market before 20 May 2016 had until 20 November 2016 to submit a notification to the MHRA. Producers of new EC and/or e-liquid products must submit a notification six months before they intend to put their product on the UK market. Submissions must be updated when products are modified or withdrawn. Relevant information required must be submitted electronically (by type of submission required); Table 2 summarises the key components.

¹ For an overview of consumer product regulations for EC please see [https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products](https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products), updated 29 November 2017
Table 2: Details of notification requirements for EC

<table>
<thead>
<tr>
<th>Information required</th>
<th>Guidance and notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and contact details of manufacturer, importer or a responsible person within an EU Member State</td>
<td>EC guidance Chapter 2 (32)</td>
</tr>
<tr>
<td>Product type</td>
<td></td>
</tr>
<tr>
<td>A list of all ingredients contained in, and emissions resulting from the use of the product by brand and variant name including quantities</td>
<td>EC guidance Chapter 3 for emissions (33)</td>
</tr>
<tr>
<td></td>
<td>EC guidance Chapter 6 for ingredients (34)</td>
</tr>
<tr>
<td>Toxicological data regarding the product’s ingredients (including in heated form) and emissions, referring in particular to their effects on the health of consumers when inhaled and taking into account, among other things, any addictive effect (see also prohibited additives below)</td>
<td>EC guidance Chapter 6 for ingredients (34)</td>
</tr>
<tr>
<td>Nicotine dose and consistency of dose uptake</td>
<td>EC guidance Chapter 4 (35)</td>
</tr>
<tr>
<td>Uptake when consumed under normal or reasonably foreseeable conditions</td>
<td></td>
</tr>
<tr>
<td>A description of the components of the product including, where applicable, the opening and refill mechanism of the EC or refill container</td>
<td></td>
</tr>
<tr>
<td>A description of the production process and a declaration that the production process ensures conformity with the requirements</td>
<td></td>
</tr>
<tr>
<td>A declaration that the producer bears full responsibility for the quality and safety of the product when supplied and used under normal or reasonable foreseeable conditions</td>
<td></td>
</tr>
<tr>
<td>Annual submissions (on or before 20 May) including sales volume by brand/type in the UK, preferences of consumer groups (published or unpublished data), mode of sale of products, executive summaries of market surveys</td>
<td>EC guidance chapter 1 (36)</td>
</tr>
<tr>
<td></td>
<td>Annual reporting guide (37)</td>
</tr>
<tr>
<td></td>
<td>The Secretary of State is required to monitor this information particularly in relation to their use acting as a “gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers”</td>
</tr>
</tbody>
</table>

The fee (38) for notifying each product is £150. A fee of £60 is also payable on 1 April annually for each product remaining on the market. These fees are to cover the MHRA’s costs of administering the notification scheme and also the requirement to oversee the publication of the notification information on a website (although trade secrets are treated in a confidential manner). The MHRA has given a commitment to review the level of fees in the light of the number of notifications received in the first year, so it is likely these will be reduced.
Notifications registered with the MHRA

As of 31/10/2017, almost 400 different producers had submitted information about 32,407 different e-liquids (90% of notifications) or devices (10% of notifications). A recent rise in the number of nicotine shots notified has been observed (39). Nicotine shots are 10mL bottles of high strength nicotine e-liquid which are flavourless, and which comply with the EU TPD regulations. Nicotine shots can then be added to much larger bottles of flavoured nicotine free e-liquids (which are not covered by the EU TPD, but would be prohibited if they contained nicotine) to make the desired nicotine content. These larger bottles are deliberately made to leave space for the nicotine shots to be added (referred to as “short-fills”). This practice is sometimes referred to as ‘Shake and Vape’. A survey carried out by ECigIntelligence of industry associations and New Nicotine Alliance members estimated that approximately 20% of the total EC product market was outside of the EU TPD and notification process (the percentage of EC user respondents claiming to use non-EU TPD products was multiplied by the percentage of the market estimated to be represented by enthusiast advanced tank users; ECigIntelligence consumer survey 2017 (39) and personal correspondence). This survey also estimated that the reduction in price between a 10mL EU compliant bottle and a 60mL short fill and 10mL shot was on average 30% (ECigIntelligence consumer survey 2017 (39)).

Minimum standards for safety and quality

Minimum standards for the safety and quality of all nicotine containing EC and e-liquids came into effect 20 May 2016, with a transition period until 20 May 2017. These included:

- child-resistant and tamper evident packaging
- protection against breakage and leakage
- a mechanism for ensuring re-filling without leakage
- prohibition of certain additives such as colourings, caffeine and taurine (these are listed under Article 16 of the Tobacco and Related Products Regulations, 2016 and pertain to tobacco products but are extended to EC)

Additional restrictions have been placed on the size of the tank and strength of nicotine in e-liquid, summarised in Table 3.
Table 3: Restrictions on tanks and nicotine strength

<table>
<thead>
<tr>
<th>Component</th>
<th>Maximum allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tank capacity</td>
<td>2mL</td>
</tr>
<tr>
<td>E-liquid refill container capacity</td>
<td>10mL</td>
</tr>
<tr>
<td>Nicotine strength of e-liquid</td>
<td>20mg/mL</td>
</tr>
</tbody>
</table>

Information provision

From 20 May 2017, all EC/liquids had to comply with requirements to have a health warning and provision of other information on the pack or on the device/bottle if there was no outer packaging (40, 41).

Health warning

This must be prominent in black text on a white background covering 30% of the area on the front and back of the unit packet and any container pack:

“This product contains nicotine which is a highly addictive substance”

Other labelling requirements

On the pack:

- list of ingredients in liquid where they are used in quantities of 0.1% or more
- nicotine content and delivery per dose
- batch number
- recommendation to keep the product out of reach of children

Unless included on the pack, the following information was required on an accompanying leaflet:

- instructions for use and storage, including instructions for refilling where appropriate and the MHRA advise the information should include appropriate advice on product storage, particularly on how to ensure the battery does not malfunction
- contra-indications, warnings for specific risk groups and possible adverse effects, addictiveness and toxicity
- contact details of producer including a contact within the EU

There are requirements on product presentation such as not to encourage consumption. Offers and discounts and product safety/health claims are prohibited (see below).
Advertising

The EU TPD prohibited cross-border advertising of nicotine-containing EC which covered broadcast television and radio, newspapers, magazines, periodicals, online media and some other forms of electronic media. This superseded a voluntary code which had been in place prior to EU TPD implementation. In 2017, the Committee of Advertising Practice (CAP) introduced a new rule in its Code, to reflect the prohibitions in the revised EU TPD and Tobacco and Related Products Regulations 2016. These outlined the channels that are and are not allowed, Table 4 (42). The guidance indicates that indirect effects are also prohibited (such as non-nicotine EC should not have the indirect effect of cross-promoting a nicotine-containing EC).

Table 4: Advertising regulations (other than broadcast media which is all prohibited)

<table>
<thead>
<tr>
<th>Prohibited</th>
<th>Allowed*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newspapers</td>
<td>Outdoor advertising, including digital outdoor advertising</td>
</tr>
<tr>
<td>Magazines</td>
<td>Posters on public transport (not leaving the UK)</td>
</tr>
<tr>
<td>Periodicals</td>
<td>Cinema</td>
</tr>
<tr>
<td>Commercial email</td>
<td>Direct copy hard mail</td>
</tr>
<tr>
<td>Commercial text messaging (for this and the prior item, unless specifically opted in, should be given to opt-out with every communication)</td>
<td>Leaflets</td>
</tr>
<tr>
<td>Marketers online activities eg website/social media (except factual information, see guidance as this is a complex area)</td>
<td>Private, bespoke correspondence between a marketer and a consumer</td>
</tr>
<tr>
<td>Online (display) ads in paid-for space</td>
<td>Media which are targeted exclusively to the trade</td>
</tr>
<tr>
<td>Paid-for search listings; preferential listings on price comparison sites; viral advertisements</td>
<td>Advertisements for businesses in non-broadcast media</td>
</tr>
<tr>
<td>Paid social media placements, advertisement features and contextually targeted branded content</td>
<td>Sponsorship of events which isn’t across borders</td>
</tr>
<tr>
<td>In-game advertisements</td>
<td></td>
</tr>
<tr>
<td>Commercial classified ads</td>
<td></td>
</tr>
<tr>
<td>Advertisements which are pushed electronically to devices</td>
<td></td>
</tr>
<tr>
<td>Advertisements distributed through web widgets</td>
<td></td>
</tr>
<tr>
<td>Promotional marketing online</td>
<td></td>
</tr>
<tr>
<td>Affiliate links</td>
<td></td>
</tr>
<tr>
<td>In-app advertising</td>
<td></td>
</tr>
<tr>
<td>Product placement</td>
<td></td>
</tr>
</tbody>
</table>

* must still comply with relevant CAP rules about content and placement
A further CAP Code 22 (43) indicates restrictions to protect those under 18 from EC, such as ensuring marketing communications for EC are socially responsible, clear they are for EC rather than tobacco cigarettes, etc.

In autumn 2017, CAP and BCAP (the UK Code of Broadcast Advertising) carried out a consultation on changes to their Codes to remove the current prohibition on health claims being made for EC and to guide advertisements for health campaigns which refer to EC (44). The outcome might mean that advertisers could make claims about the health benefits of EC in comparison to tobacco, although the likelihood is that such claims would need to be linked to evidence for the exact product under consideration, rather than to the generic category (eg EC).

Retailers

Retailers of EC had until 20 May 2017 to sell existing stock of products that did not comply with EU TPD labelling and product composition requirements. Guidance for retailers on EC is available (45). The Independent British Vape Trade Association (IBVTA)(46) reported that there were around 2,000 independent vape stores on the high streets in the UK, compared with over 50,000 convenience stores and around 10,000 supermarkets in the UK, the vast majority of which are likely to sell tobacco. While tobacco outlets may also sell EC, it’s likely that the independent vape stores sell a greater variety of EC models (including those thought to be more effective, the tank models) than the tobacco outlets.

Reporting of side-effects and safety concerns

In May 2016, the MHRA extended its Yellow Card reporting system to include reporting on EC and e-liquids. Consumers and healthcare professionals can report both side-effects and product safety concerns to the MHRA. Report received are summarised in Chapter 9. Alternatively, issues about defective/non-compliant EC can be raised with local Trading Standards offices. However, a recent report from the National Audit Office (47) indicated concern about capacity of local Trading Standard offices which had lost 56% of full time equivalent staff since 2009, with 20% of services having had reduced funding by over 60% since 2011 (47). Trading Standards therefore may not have the capacity to deal with EC issues, or enforce relevant regulations.

Medicines licensing process through the MHRA

As indicated above, EC producers can also apply for a medicines licence for their products from the MHRA (48). Nicotine–containing products that make claims for cutting down, quitting or reducing the harms of smoking are considered to be medicinal products and regulated by the MHRA. Licences can be for the General Sales List, Pharmacy Medicines or Prescription Only Medicines. Licensed EC are exempt from the
EU TPD and Classification, Labelling and Packaging regulations, and subject to the requirements of medicinal regulation instead. Licensing is important as this may allow health professionals to prescribe EC which could make them more accessible to more disadvantaged smokers, and also enable them to be supplied with advice and support about their use (see Chapter 7).

In the 2015 PHE report (5), we described how Voke (a non-EC nicotine inhaler product) had been granted a medicines licence and that a British American Tobacco (BAT) electronic product (e-Voke) was going through the medical licensing process. In November 2015, general sales list marketing authorisations were indeed given for 10mg and 15mg e-Voke to Nicovations (formerly Nicoventures, both fully-owned BAT subsidiaries) for marketing as an aid to help people to stop smoking (49). E-Voke uses cartridges containing pharmaceutical grade nicotine. Medicines licensing meant that the product could be prescribed by medical practitioners. However, neither Voke nor e-Voke have been brought to market so far. In January 2017, BAT and the original developer of Voke, Kind Consumer Ltd, announced a new approach to its commercialisation, with Kind Consumer taking back ownership. There is no EC product that has received a medical licence currently available on the market or on prescription.

In February 2017 the MHRA updated its guidance on the licensing process. This indicated that manufacturers would be expected to comply with relevant standards. The British Standards Institute had published a British Standards Institute-endorsed Publicly Available Specification (PAS) (50) for EC produced by key stakeholders. The standard covers, inter alia: purity of e-liquid ingredients, potential contaminants from device materials and potential emissions from device operation; a test solution-liquid, and an outline for the toxicological and chemical analysis of emissions; safety of batteries and chargers. The French national standards authority AFNOR has also produced a standard (51). European and international standards are in the process of being developed by the European Committee for Standardisation (CEN) and the International Organization for Standardization (ISO) respectively. For medicinal EC and nicotine containing products, the MHRA stated that additional requirements, additional to published standards, might also be needed to meet safety, quality and efficacy criteria under medicines regulations. It is likely that efficacy standards are clear, as manufacturers need to be able to demonstrate that nicotine delivery is comparable with licensed nicotine replacement therapies. However, demonstrating long-term safety may be more difficult for newer products. This might suggest that, in the first instance, licences could be granted for short-term use as was the case with NRT licences initially, before the harm reduction licence was added in 2010 (52).
Other policy-related developments

General product safety regulations

These regulations exist for all consumer products and non-nicotine EC are required to comply with these regulations (28). As noted above, combustible tobacco products are exempt from these regulations.

Classification, labelling and packaging regulations

EC must comply with the EU TPD but also with classification, labelling and packaging regulations (53) which are European regulations based on a United Nations system. Classification, labelling and packaging regulations apply to chemicals in EC as it does to other chemicals placed on the market, irrespective of whether they contain nicotine or not. Labelling and packaging requirements therefore pertain to any chemicals in EC.

Consensus statements

Following the publication of the 2015 PHE report, an emerging public health consensus was published on EC between PHE and 12 other organisations (54). This consensus statement emphasized the opportunity that EC provide by helping smokers to quit, but that combining EC (the most popular method) with most effective (stop smoking services) would optimise that opportunity. A recent publication by the British Medical Association on EC (55) is in line with this consensus.

In September 2017, NHS Scotland published a consensus statement on EC (56) created in collaboration with, NHS and public health bodies, Royal Colleges, charities and universities. One of its two key messages addressed smokers, urging them to try stopping smoking whether or not they use EC and advising them of the help available. The other key message urged health professionals to advise smokers about the different ways they can quit and the evidence base and not to turn anyone away because they choose to use EC.

Guidance on the use of EC in public places

In 2015, Action on Smoking and Health (ASH) and the Chartered Institute of Environmental Health published a briefing on ‘five questions’ concerning the implementation of controls on vaping in work and public places (57). Following on from this, PHE carried out a consultation and survey on five principles for policy and practice (58). In July 2016, PHE published advice for organisations to support policy making in relation to the use of EC in public places and workplaces (59). The advice is based around the five principles, covering the need to make a clear distinction between
vaping and tobacco cigarette smoking, ensuring policies are informed by the evidence on risks to bystanders, identifying and managing risks of uptake by children and young people, supporting smokers to stop smoking and stay stopped, and supporting compliance with the smokefree law and policies. The advice, published together with a brief five-point guide, is non-prescriptive in recognition of the fact that settings differ and there is no ‘one-size-fits-all solution’.

MHRA guidance on EC in research

The MHRA has produced an algorithm, guidance and examples on the use of EC in clinical trials (60). As EC are not medicinal they are not considered as investigational medicinal product (IMP) in health or clinical research. A clinical trial authorisation (CTA) would only be required in most circumstances if the research uses a licensed nicotine product as a comparator. Accessing this guidance should be made easier for researchers.

Heated tobacco product (heat-not-burn) regulations

In heated tobacco products, processed tobacco is heated instead of being combusted. Part 4 and Part 5 of the UK Tobacco and Related Products Regulations 2016 detail the notification process for novel tobacco products such as heated tobacco products (30). Notification must be done electronically to PHE which is an executive agency sponsored by the Department of Health and Social Care and the UK’s competent authority for overseeing and publishing the notifications for tobacco products as well as herbal products for smoking. Notification of novel tobacco products must be done at least six months before the producer intends to supply the product. Fees apply for the notification process, for the annual reports and testing, and for any modifications.

Notification should include the following information:

a) detailed description (including components, mechanisms by which any emission/vapour is generated, and means by which nicotine is absorbed by the consumer)
b) instructions for use
c) ingredients (by weight and quantity and including reasons for inclusion, status of each ingredient, classification, any available toxicological data in burnt or unburnt form as appropriate, referring in particular to the effect of the ingredient on health including addictive effects)
d) emissions (including information about the product’s tar, nicotine and CO and other emissions by brand and variant name)
e) available studies on the toxicity, addictiveness and attractiveness of the product in particular with regard to ingredients and emissions

f) any available studies, executive summaries or market research, in relation to the product on the preferences of consumer groups, including young people and current smokers

g) any other available information (including risks and benefits, expected effects on cessation of tobacco consumption, expected effects on tobacco consumption initiation, and the predicted perception of the product by consumers and potential consumers).

A recent HM Treasury consultation (61) on the tax treatment of heated tobacco products in the UK classified heated tobacco products into three main types:

- Type 1 - processed tobacco heated directly to produce vapour
- Type 2 - tobacco designed to be heated in a vapouriser
- Type 3 - devices that produce vapour from non-tobacco sources, where the vapour is then passed over processed tobacco in order to flavour the vapour

Type 2 products include vaporisers often used for cannabis which have been sold for some time in the UK but we are not aware of any such products being marketed by the tobacco industry in the UK or elsewhere. The Treasury are currently analysing the responses to their consultation.

It should be noted that the Treasury made clear that this category of tobacco product did not include EC, stating that EC do not contain tobacco and are therefore not liable for tobacco duty.

Two products have been notified to PHE, one Type 1 (IQOS, produced by Philip Morris International) and one Type 3 product (iFuse, produced by British American Tobacco) and are currently available on the market in the UK (see Chapter 12).

Towards a Smokefree Generation. A Tobacco Control Plan for England

The new Tobacco Control Plan for England (2) sets out the commitments of the Department of Health and Social Care, PHE and MHRA (Table 5) to support smokers to quit and adopt the use of less harmful nicotine products.

Over the next five years the ambition is to:

- reduce the prevalence in:
  - 15 year olds who regularly smoke to 3% or less
  - adults in England from 15.5% to 12% or less
  - pregnancy to 6% or less
- reduce the inequality gap in smoking prevalence between those in routine and manual occupations and the general population
Evidence review of e-cigarettes and heated tobacco products 2018:
A report commissioned by Public Health England

- improve data collected on smoking and mental health to help support people with mental health conditions to quit smoking and make all mental health inpatient services sites smokefree by 2018
- help people to quit smoking by permitting innovative technologies that minimise the risk of harm and maximise the availability of safer alternatives to smoking

Table 5: Organisational commitment to support smokers to quit and adopt the use of less harmful nicotine products

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHE</td>
<td>• Update their evidence report on EC and other novel nicotine delivery systems annually until the end of the Parliament in 2022.</td>
</tr>
<tr>
<td></td>
<td>• Include within quit smoking campaigns messages about the relative safety of EC.</td>
</tr>
<tr>
<td></td>
<td>• Continue to provide smokers and the public with evidence based information on the relative harm of nicotine, EC, other nicotine delivery systems and smoked tobacco, to enable informed decision-making. This will include the publication of an assessment of the risks of nicotine addiction.</td>
</tr>
<tr>
<td></td>
<td>• Provide evidence based guidance for health professionals to support them in advising smokers who want to use EC or other nicotine delivery systems to quit.</td>
</tr>
<tr>
<td>Department of Health and Social Care</td>
<td>• Monitor the impact of regulation and policy on EC and novel tobacco products in England, including evidence on safety, uptake, health impact and effectiveness of these products as smoking cessation aids to inform our actions on regulating their use.</td>
</tr>
<tr>
<td></td>
<td>• Based on the evidence reviews undertaken by PHE, review policy and regulation of nicotine delivery systems to provide an environment that facilitates smokers taking action to improve their health and the health of those around them, while minimising any risk of new nicotine addiction in children.</td>
</tr>
<tr>
<td>The MHRA</td>
<td>• Ensure that the route to medicinal regulation for EC products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription.</td>
</tr>
</tbody>
</table>
International policy overview

World Health Organization position statement

In August 2016, a report was published by the World Health Organization (WHO) on Electronic Nicotine Devices and electronic non-nicotine delivery systems (ENDS) for discussion at the November 2016 Conference of the Parties to the WHO Framework Convention on Tobacco Control (62). The paper concluded with a list of regulatory options that Parties might consider to: 1) prevent initiation by non-smoker and youth; 2) minimise potential health risks to users and protect non-users from exposure to emissions; 3) prevent unproven health claims being made about the products; and 4) protect tobacco control activities from all commercial and other vested interests relating to the products including interests of the tobacco industry. The vast majority of these options have been implemented in England.

Global situation

At the time of writing, 27 countries ban sales of all types of EC, nine countries prohibit the sale of nicotine-containing EC (63).

Within the EU, there were some changes due to the EU TPD with some European countries now having fewer restrictions (eg Croatia, Sweden, Switzerland) but others, like the UK having greater restrictions (eg Netherlands, Cyprus, France).

Conclusions

Key findings

- As with tobacco products, in most parts of the UK, there is a minimum age of sale of 18 for EC and EC must not be purchased on behalf of someone under the age of 18.
- The revised European Union Tobacco Products Directive is now fully operational in England, transposed into UK law through the UK Tobacco and Related Products Regulations 2016, and covers e-cigarettes and nicotine-containing e-liquids that do not have a medicinal licence. These regulations include a notification process (to the MHRA), minimum standards for safety and quality of EC products, standards for information provision (including a nicotine health warning) and advertising restrictions and updated standards. The Advertising Standards Authority (ASA) has carried out a consultation on health claims; the results are awaited. A system to report side-effects and safety concerns related to EC has been implemented.
- Over 32,000 EC products have been notified which suggests a level of compliance with the regulations and that the notification process is not too onerous.
• There are some signs that ways are being found to avoid the law, for example particularly on size of bottles, but evidence is limited.
• Alongside products regulated in line with the EU TPD, manufacturers can also apply for medicinal licensing from the MHRA. However, no licensed EC has yet been marketed.
• Other EC-related developments include consensus statements from a number of organisations and guidance on the use of EC in public places and on their use in research.
• Non-nicotine EC are governed by general product safety regulations (unlike combustible tobacco products).
• There is a separate notification process for heated tobacco products (to PHE) and results from a consultation on the tax treatment of these products are forthcoming. At the time of writing, two products had been notified.
• A new Tobacco Control Plan for England was published in July 2017.

Implications

Research

• There is a need for continued research on the impact of regulations on smoking rates and patterns, use of EC by adults and young people, product design and quality and adverse effects of EC.
• Research should specifically assess the impact of the EU TPD on production (with a specific focus on independent manufacturers who were the first to enter this field), innovation of products, and EC users and smokers.

Policy and practice

• Regulations need to balance the risks of EC with their potential benefits – and achieve key aims of reducing smoking and continuing to avoid uptake of EC by non-smokers. This requires keeping them under regular review and evaluating their impact.
• Regulations for heated tobacco products should be made as least as stringent as for EC.
• It remains a viable and important goal to facilitate regulation of some EC as medicines via the MHRA. A review is needed of how to achieve this, possibly including more focus on post marketing surveillance and the provision of licences for short-term rather than extended use.
• Restrictions on communicating relative risks of EC in comparison with combustible tobacco should be reconsidered. In any future review of the EU TPD, consideration should be given to the wording of the health warning on nicotine per se given the public misperceptions of its harmfulness (Chapters 4 and 10).
• There appears to be no evidence justifying an urgent change regarding non-nicotine EC or e-liquids which are currently outwith the scope of the EU TPD.
4 Nicotine

Introduction

Professor Michael Russell was one of the pioneers of nicotine research (64). In 1971 Professor Russell (65) explained that over recent centuries ‘no population has dispensed with one form of tobacco use without replacing it by another’ and ‘once experienced, nicotine use has continued in populations as it does in individuals.’ He subsequently commented that ‘people smoke for the nicotine, but die from the tar’ (66), and in a later paper (67) discussed the potential for recreational use of cleaner nicotine delivery devices to be a solution to the tobacco epidemic. NRTs, while cleaner forms of nicotine delivery, have simply not been taken up by significant proportions of the smoking population in the way that EC have. In the light of the advent of EC, therefore, Russell’s prophecy has now become a realistic possibility, but their widespread use will depend on their relative safety and addictiveness compared to smoking tobacco cigarettes.

A systematic review of nicotine was not carried out for this report because it was agreed by the commissioners that nicotine would have a stronger focus in a forthcoming PHE review. This chapter, therefore, briefly summarises and updates evidence in the Royal College of Physicians (RCP) report (68), focusing on nicotine addictiveness, nicotine delivery in relation to EC, and any recent evidence which suggested nicotine use could cause significant harm. Chapters 8 and 9 discuss safety and health risks pertaining to EC.

By acknowledging the centrality of nicotine to smoking and other tobacco use, we do not wish to diminish the role of other social and environmental factors (69). However, because most EC use in England involves nicotine (see Chapter 5 and 6), studying nicotine itself is an important focus in improving our understanding of EC use.

Nicotine addictiveness

It is well established that nicotine is the primary addictive component of tobacco smoke (70). In this section we explore the addictiveness of nicotine, as well as the extent to which it varies across different forms of nicotine delivery.

Nicotine delivery and dose

The dose and rate at which a drug reaches the brain influences its addictive potential. In one of the earliest studies to assess nicotine delivery, Russell and Feyerabend (71) concluded that, for smokers, it was the puff-by-puff high-nicotine bolus, which reached...
the brain within seconds of inhalation, that made cigarette smoking so addictive. Nicotine is inhaled into the lungs in the form of tobacco smoke reaching the brain within 15-20 seconds; the rate of increase in arterial nicotine concentrations is much faster than those achieved by intravenous (IV) injection (68, 72).

All forms of NRT deliver nicotine much more slowly and at lower doses than smoking, but the speed and amount vary according to the delivery system (oral, dermal or nasal) and the dose. The faster acting NRT products (nasal and mouth spray) deliver peak plasma nicotine levels within about 10 minutes. Use of NRT therefore results in much slower nicotine delivery than smoking. Absorption of nicotine is also affected by other factors such as pH. Overall, the addictiveness of NRT is much lower than that of cigarettes, with only a very small proportion of those who use these products persevering with use for a year or longer. Around 10% of nasal nicotine spray users will use for a year or longer, 5% of those using oral nicotine products, and fewer for the patch (68).

It is useful to compare the dependence potential of smokeless tobacco with smoking and NRT. Smokeless tobacco covers a heterogeneous array of very different products. One product, snus, which is a low nitrosamine smokeless tobacco product with a long history of use in Sweden, has been studied as a proxy for the long-term health effects of nicotine (see below). We will therefore discuss snus in relation to dependence here. Similar to oral nicotine products, nicotine absorption with snus also occurs through the buccal route, aided by the alkaline pH of snus. As such, nicotine absorption is slower when using snus, than from cigarette smoking, as there are no arterial boli of nicotine delivered to the brain. Nevertheless, nicotine exposure overall can be very similar between snus users and cigarette smokers. There is strong evidence that using snus induces dependence, since snus users exhibit a withdrawal syndrome when attempting to quit, with some similarity to that observed in cigarette smokers abstaining. This indicates that factors other than speed of delivery are important in the dependence potential of nicotine delivery products. It is possible that the higher addictiveness of snus relates to the tobacco and other factors such as the pH, compared with oral nicotine products. This may be relevant to heated tobacco products (see Chapter 12).

We discussed nicotine delivery of EC in our last report, commenting that no studies had allowed an appraisal of the comparison between EC and cigarettes in terms of giving a rapid increase in arterial blood nicotine levels after puffing, but that it was likely some EC products were providing a degree of lung absorption. Since our last report, nicotine delivery has been shown to vary considerably across the variety of EC products, (eg(73, 74)). However, experienced users can achieve greater increases in blood nicotine levels than naïve users under the same puffing regime, albeit slower than from cigarette smoking (75-77). Studies with experienced users found comparable or, in some cases, higher venous blood nicotine levels than with cigarette smokers. A study with 16 experienced users and high nicotine concentrations (36mg/mL) found a higher

pre-post nicotine boost following a standardised puffing regimen than that typically seen with tobacco cigarettes (78). A further study (77) with 30 participants (10 smokers and 20 experienced EC users) found similar doses and speed of nicotine delivery to tobacco cigarettes among those using third generation devices (mods). An additional study, with 13 experienced users again during a standardised puffing session demonstrated that venous nicotine blood levels of experienced EC users from later generation devices were comparable to, and in some cases higher than those of smokers (79). Most of the participants had peak nicotine levels within two to five minutes after puffing an EC, suggestive of pulmonary delivery and likely to lead to dependence, although not all the nicotine retained was absorbed through the lungs (79). The same study also included a subsequent ad libitum phase (80). Here the authors found that vaping behaviour differed from smoking behaviour in that EC users took longer puffs and grouped their puffs in shorter clusters (two to five puffs). The intermittent puffing patterns led to a more gradual rise in plasma nicotine levels across the session, in contrast to the bolus dosing from cigarette smoking. Nicotine intake was related to puff topography only for the tank users but not across the whole sample (which included cigalikes and other devices).

In summary, nicotine dose and rate of delivery are important factors in the dependence potential of nicotine delivery devices, but other factors such as pH and what comes along with the nicotine (also see below) are involved. Experienced EC users can have nicotine levels similar to those of cigarette smokers, although the speed of delivery is slower. Nicotine delivery varies across the different designed EC products. As yet, it is unclear how addictive EC are, or could be, compared to tobacco cigarettes.

Self-reported dependence

Several studies have found that self-reported dependence is lower in daily vaping ex-smokers compared with daily smokers (e.g. (81, 82). In a comparison between EC dependence and dependence on nicotine gum, Etter and Eissenberg (83) reported that EC were either as addictive or less addictive than the nicotine gum, but more likely to be reported as being used to avoid relapse to smoking. Liu and colleagues (82) found that self-reported dependence in EC users was lower than among smokers but reported that over three-quarters considered themselves addicted to EC.

A recent analysis of US tobacco and nicotine (EC) users, (84) included an instrument to assess tobacco dependence across different tobacco and nicotine group users. Using this measure, cigarette smokers had the highest mean level of tobacco dependence, with similar levels among multiple products users, and slightly lower mean levels in smokeless tobacco users; EC only users were among the lowest levels (with cigar only users and waterpipe only users).
The findings of these studies need to be viewed with caution pending validation of the measures.

**Uptake among non-smokers**

Concerns have also been raised about the propensity for adolescent non-smokers to become dependent on cleaner nicotine products. This propensity is likely to be affected by addictiveness (alongside other variables such as marketing and accessibility). Consistent with the above, the RCP report concluded that there was no substantial evidence of non-smokers becoming dependent on NRT (68). In comparison, the dependence of tobacco smoking is much greater with a recent meta-analysis finding that around two-thirds of non-smokers who experiment with smoking becoming regular daily smokers (85). As we will see later, there is evidence of EC experimentation among non-smokers, but little regular use, consistent with these observations for NRT (Chapters 5 and 6).

**Nicotine effects**

Although the metabolism of nicotine varies considerably between individuals, nicotine has a short-half life, approximately two hours which, together with the repeat high boli of nicotine resulting from puffing on tobacco cigarettes, enables users to self-titrate. Self-titration is also seen in EC users (86). The speed at which nicotine is metabolised is affected by a number of factors, and plays a role over and above the rate at which it is absorbed and delivered to the brain and the dose received.

At low doses, nicotine is a stimulant. However, tolerance develops quickly and chronic exposure results in neuroadaptations, causing withdrawal effects. Addictiveness may be related to the severity of these negative withdrawal symptoms. Nicotine has complex effects, caused by its binding to and desensitizing nicotine acetylcholine receptors, and facilitating the release of a variety of neurotransmitters, including dopamine. Dopamine acts as a positive reinforcer, is involved in other addictive drug use, and is likely to underpin the pleasure that smokers report from smoking. Addictiveness and pleasure are likely to be intertwined. Pleasure is rarely reported from NRT users, but has been reported by EC users (87). It can be hard, however, to distinguish positive reward and relief from incipient withdrawal.

**Other influences on addictiveness of nicotine products**

Other aspects of nicotine products may potentiate addictiveness (68). These include the monoamine oxidase (MAO) inhibitors in tobacco smoke, substances added to tobacco such as sugars and polysaccharides, flavourings such as menthol or alkaline additives, as well as design characteristics. Secondary reinforcers, such as the
behavioural aspects, smell or taste, may also be acting to enhance the addictiveness of cigarette smoking.

The PHE and the RCP reports detailed how nicotine concentration and other constituents of e-liquid, such as the presence of propylene glycol (PG) (probably due to its lower boiling point than glycerine), and vaping topography affect nicotine delivery. Thus, similar to tobacco cigarettes, various factors influence the nicotine delivery of EC. One study suggested that a floor level of nicotine, rather than a ceiling (as in the EU, see Chapter 3) would prevent excessive puffing of EC in order to achieve desired nicotine levels. Flavours may also affect the rate of nicotine absorption and affect satisfaction from EC (88).

Typologies of nicotine users

Russell (89) also argued that there were three types of smokers: non-inhalers, peak-seekers (~ one cigarette per hour gives a blood nicotine profile of repeated high blood nicotine peaks), who smoke predominantly for positive pleasure, and trough-maintainers (~ one cigarette every 30 minutes), motivated by the need to maintain a high blood nicotine level to avoid unpleasant withdrawal effects. A recent study (90) identified three different accounts of vaping: ‘Vaping as pleasure’ in which ex-smoking EC users reported vaping as enjoyable and likely to be sustained over time, held a strong vaping identity and rejected a medical model of vaping; ‘Vaping as medical treatment’ in which ex-smoking EC users reported vaping as a pragmatic choice to medicate one’s smoking addiction, with the aim of treating and reducing their nicotine dependence; and ‘Ambivalent e-cigarette use’ in which dual users reported fewer benefits and more negative beliefs about EC, rejecting an EC user (or vaper) identity. While these typologies have not been shown to be related to duration of use of either tobacco cigarettes or EC, they are included to illustrate the heterogeneity of nicotine users.

Summary

In summary, nicotine addictiveness depends on a number of factors including presence of other chemicals, speed of delivery, pH, rate of absorption, the dose, and other aspects of the nicotine delivery system, environment and behaviour. Tobacco smoking with rapid delivery of nicotine to the lungs and absorption, has been demonstrated to be highly addictive, compared with the NRT patch, for example, which has much lower dependence potential and long term use. Addictiveness is related to pleasure as well as severity of withdrawal discomfort, which are hard to tease apart. The addictive potential of other nicotine products is likely to be within the two extremes set by the cigarette and NRT patch, with some products, eg snus, also being addictive. It is thus inaccurate to say that nicotine per se is highly addictive, such statements need to be more nuanced, as addictiveness is dependent on the delivery system.
Nicotine safety

Nicotine toxicity

As we detailed in our last report, the source of the oft-repeated claim about ingestion of 30-60mg of nicotine being fatal, was hard to locate. A recent study (91) concluded that the lower dose limit for fatal nicotine is thought to be considerably higher, in the region of 500-1,000 mg ingested nicotine.

Health effects of nicotine use

The health effects of cleaner nicotine products per se is important, but the key comparison should be with smoking as, to our knowledge, no-one in public health is recommending nicotine to never smokers. For smokers, cleaner nicotine delivery systems will be orders of magnitude safer. Risk benefit assessments are carried out for medications routinely and many medications used to treat serious diseases bear some risks (92).

The RCP report indicated that short-term nicotine use does not result in ‘clinically significant harm’ and concluded that there was no evidence of any increase in the risk of heart attack, stroke or death from use of NRT in quit attempts. The best study of long-term NRT use, dates from 2009, the Lung Health study (93), a randomised controlled trial of five years duration, in which all subjects were offered NRT and subjects were followed up for up to seven and a half years. There was no evidence of a relationship between NRT and cancers, whereas continued smoking was associated with developing cancer.

For harms of longer term use of nicotine, the best evidence stems from snus, described earlier. The Global Burden of Disease Study (94), did not find sufficient evidence of a detrimental effect of snus on any outcome. This includes oral and pharyngeal cancer which had both been linked with smokeless tobacco use in general, and the latter with snus.

These studies suggest that, for smokers, the risks of nicotine use are likely to be very low or negligible. The risks of long-term inhaled nicotine separate from inhaling smoke have not been studied in humans, and it is possible that inhaled nicotine could have adverse effects that nicotine taken in through other routes does not have.

The health risks of EC are discussed in more detail in Chapter 9 and below we highlight recent studies reported as finding risks of nicotine use which were of concern.
Recent studies assessing nicotine safety

A recent animal study suggested that nicotine can have adverse effects on the lung (95). The study used very large doses of nicotine administered intermittently for four months. The organ damage could have been due to systemic poisoning and may not be relevant to exposure in smokers and EC users (96). Nevertheless, the effects of inhaled nicotine on lung function in humans require further investigation.

A reference made at a conference to a research letter (97) reported that nicotine in EC causes transient stiffening of arteries and the author claimed in a media release that this shows risks of vaping and that he would ‘not encourage the use of the devices’. This generated several headlines, such as the front page headline ‘Vaping as bad as fags: E-cigs seriously damage heart’ (McDermott, the Sun 2016, available at: https://www.thesun.co.uk/living/1693653/e-cigs-are-just-as-bad-for-your-heart-as-smoking-fags-as-they-damage-key-blood-vessels-say-experts/) and other similar headlines ‘E-cigarettes are as bad for the heart as tobacco: Nicotine vapour damages blood vessels and raises risk of disease’; and ‘Vaping as bad for your heart as smoking cigarettes’ (http://www.telegraph.co.uk/news/2016/08/29/vaping-as-bad-for-your-heart-as-smoking-cigarettes-study-finds/). It seems likely that this effect is due to the acute sympathetic activation induced by nicotine through the release of norepinephrine. However, the same author (98) had previously found that the same effect, but stronger and longer lasting, follows drinking coffee, and also after chronic consumption (99). Similar effects have also been observed among students who are sitting an exam or engage in other common activities that can result in mental stress (100).

A study using the UK Clinical Practice Research Datalink detected a shorter survival time in patients with pre-existing CVD who were prescribed NRT compared to those receiving stop-smoking advice only (16). The raw data, however, did not control for potential selection biases: for example, General Practitioners (GPs) may have a greater propensity to prescribe NRT to heavier smokers about whom they are concerned; similarly, smokers with more severe symptoms may be more willing to accept the prescription. The study also did not control for or assess the duration of NRT use – any past use was sufficient to categorise the patient as an NRT user. Further studies controlling for relevant covariates would be useful to clarify the above issues.

A new review of possible effects of nicotine in EC on cardiovascular function concluded that short-term use of EC appeared to pose low cardiovascular risk in healthy users (72). The authors commented that some adverse effects may exist in people with pre-existing CVD, though these would be lower than risks of smoking. The concern is based on a finding that although snus use does not increase CVD risks, among people who suffer a myocardial infarction, those who continue using snus have lower survival rates compared to those who quit snus. This could be due to post-myocardial infarction nicotine use. However, it is also possible that people unable to stop tobacco use...

despite suffering a myocardial infarction are typically highly dependent and this is associated with lower socioeconomic status, less access to health care and a possibility that they seek help later than non-tobacco users, have higher levels of stress, and a range of lifestyle behaviours detrimental to health. Studies controlling for such factors are needed to clarify this issue.

**Foetal nicotine exposure**

There has been much concern about the use of EC by pregnant women and the role that nicotine may play in harming foetal development. Animal research has suggested foetal exposure to very high doses of nicotine has adverse consequences which are maintained through to adolescence, but the relevance for humans is unclear (101, 102).

In humans, it has been difficult to separate the impact of nicotine from smoking in pregnancy, given the low use of cleaner nicotine products among pregnant women. Thus assumptions about harms from nicotine in human pregnancies, have until recently, emerged either as a result of studies of tobacco use in pregnancy or are extrapolated from animal research. More recently, however, it has been reported that infants born to pregnant smokers, who used NRT for smoking cessation during pregnancy, were less likely to have developmental impairments compared with those who used placebo two years after birth (103). The reason for this requires more research but the authors argued it could be due to reduced smoking early in pregnancy as a consequence of NRT use. The licence for prescribing NRT was extended in the UK in 2005 to include use in pregnancy and NRT is currently widely prescribed in the UK to pregnant women who smoke (104).

Limited research has been conducted with pregnant smokers or ex-smokers who use EC (105). Further research is needed and a large trial of EC for smoking cessation in pregnant women is now underway in the UK (https://www.journalslibrary.nihr.ac.uk/programmes/hta/155785/#/).

**Adolescent nicotine exposure**

As discussed in the RCP report, smoking in adolescence has been associated with cognitive and attentional deficits and suggested to impact mental health, although confounding factors (such as self-selection) have not been taken into account thus far. The recent US Surgeon General’s report (106) gave a comprehensive review of the potential impact of nicotine on adolescent brains using human studies with smokers and animal studies. It concluded that the use EC by youth should be avoided and actively discouraged. We concur with that recommendation. However, we do not see this as a major issue when discussing adolescent smokers, who are already getting nicotine from tobacco cigarette smoking; and providing smoking and nicotine use
among adolescents overall continues to decline (Chapter 5). Nevertheless, careful monitoring of these trends is needed and more research of the impact of nicotine, as opposed to cigarette smoke, on cognitive functioning and attention would be welcomed.

Summary

Overall, there is evidence that nicotine plays a very minor role in the harmfulness of tobacco smoking. The risk profile may be different with inhaled nicotine but this would appear unlikely. As we will see in Chapter 10, this evidence is at odds with public perceptions of the harm caused by nicotine in tobacco smoking, and these perceptions need addressing.

International developments

One of the most recent developments internationally, has been the re-emergence of policy discussions and initiatives on the role of nicotine-reduced cigarettes for tobacco product regulation. In the US, the US Food and Drug Administration (FDA) (107) has commissioned research into nicotine reduced cigarettes and released a consultation on this. Recently, the need for, and role of, less harmful nicotine delivery devices, alongside such a strategy has been given more prominence. Similarly, the WHO has discussed the role of nicotine-reduced cigarettes for tobacco product regulation, producing an advisory note (108). There is currently no appetite for a nicotine reduction strategy in cigarettes in England. Greater discussion of this will follow in a subsequent report.

Niaura (109) and Abrams (110) on behalf of the Truth Initiative and Schroeder Institute for Tobacco Research and Policy Studies in the US, re-examined the role nicotine plays in society and presents a view that nicotine products may contribute to an overall tobacco harm reduction and control strategy. In line with the thrust of this chapter, Niaura and Abrams assert that most of the physiological harm attributable to cigarette smoking derives from the toxicants in tobacco and combustion and that, separated from combustion or other toxic modes of delivery, nicotine, by itself, is much less harmful.
Conclusions

Key findings

- The addictiveness of nicotine depends on the delivery system.
- It is possible that the addictiveness of tobacco cigarettes may be enhanced by compounds in the smoke other than nicotine.
- As EC have evolved, their nicotine delivery has improved. This could mean that their addiction potential has increased, but this may also make them more attractive to smokers as a replacement for smoking. It is not yet clear how addictive EC are, or could be, relative to tobacco cigarettes.
- While nicotine has effects on physiological systems that could theoretically lead to health harms, at systemic concentrations experienced by smokers and EC users, long-term use of nicotine by ‘snus’ (a low nitrosamine smokeless tobacco) users has not been found to increase the risk of serious health problems in adults, and use of NRT by pregnant smokers has not been found to increase risk to the foetus.
- Adolescent nicotine use (separate from smoking) needs more research.
- The long-term impact of nicotine from EC on lung tissue is not yet known and may be different from its impact systemically.

Implications

Research

- More research on nicotine, compared to tobacco cigarette smoking is needed, and the popularity of EC enables such research, albeit in the context of the other components in EC and EC aerosol.
- Further research is needed on the similarities and differences in addictiveness of EC and tobacco cigarettes and the potential harms associated with inhaled nicotine.

Policy and practice

- Widespread misperceptions about relative risks of nicotine and tobacco (see Chapter 10) need to be addressed and corrected.
- Clear messages, based on current evidence about nicotine, its relationship with harms, and its addictiveness, compared with smoking, are necessary and could have a marked impact on public health.
- Policies on tobacco and EC should have at their core the recognition that nicotine use per se represents minimal risk of serious harm to physical health and that its addictiveness depends on how it is administered.
5 Use of EC among young people

Introduction

Our literature search identified studies examining EC use by children and young people described in articles published between 1 January 2015 and 18 August 2017, updating searches conducted for the 2015 PHE report (5). Twenty-four articles from the UK that included data from adolescents were identified and an additional 223 articles were identified that included data from countries other than the UK.

The focus of this section is on current patterns of EC use by young people in the UK. In this section, therefore, we focus on the existing literature that examines the prevalence of EC use in young people rather than the wider literature from the UK which includes studies of issues such as EC marketing and young people, qualitative accounts of young people’s perceptions of EC, studies reporting on intentions to use EC, or perceptions of product characteristics, for example. In addition, the extensive international literature identified could not be thoroughly reviewed because of time and resource limitations but key points are highlighted below, to put the UK data in context.

The literature on EC marketing in particular is now well-developed, but has recently been reviewed in a report for Cancer Research UK (111). This literature largely relates to the impact of EC marketing on young people in countries other than the UK. Since May 2016, cross-border advertising of EC was prohibited in the UK as discussed in Chapter 3.. Thus with the exception of billboard and point of sale promotion, almost all forms of EC marketing are no longer permitted in the UK, measures largely designed to protect non-smokers and children from marketing. These new changes limit the relevance of the available marketing literature on EC to the UK context.

Since the literature search was conducted, the authors of this report, along with other colleagues, have published a detailed analysis of the most up to date survey data on smoking and vaping among young people in the UK. This paper was in press at the time of the cut off for the literature search and published just ten days later. Its findings are outlined in detail here, supplemented by more recent data as appropriate.

This section of the report outlines existing data on four key themes:

- use of EC among young people
- trajectories of smoking and EC use
- where young people obtain EC
- the international context
Use of EC among 11 to 16 year olds

Each of the four countries that make up the UK conduct representative surveys of young people which now include questions on EC use. Some of these are not conducted annually and thus availability of the most recent data varies by year. In the 2015 PHE report, findings from one survey that covers all of Great Britain, a regional survey in the North West of England, two surveys in Wales and one in Scotland were included.

The most recent data are from surveys conducted between 2015 and 2017, recently published in an article outlining finding from these surveys that include just over 60,000 11 to 16 year olds from across all of the UK (6).

Five surveys are available for this latest period (also see Chapter 2 for details). These include:

- The Youth Tobacco Policy Survey (YTPS) which includes a representative sample of young people from the UK including Wales, Scotland, England and Northern Ireland (n=1,213 11-16 year olds)
- The ASH Smokefree Great Britain (GB) -Youth (two surveys) (ASH-Y). This includes a sample of 1,205 11-16 year olds in 2016 and 1,361 in 2017
- The Schools Health Research Network (SHRN) Wales which includes 32,479 young people aged 11-16
- The Scottish Schools Adolescent Lifestyle and Substance Use Survey (SALSUS) which surveys a representative sample of pupils in their second year of secondary school in Scotland (average age 13, n=13,607) and a representative sample of pupils in the fourth year of secondary school in Scotland (average age 15, n=11,697).

Questions about EC use were comparable in each survey but employed slightly different wording to describe the products. Details on question wording and the data collection methods are outlined in the original article (6). Results from these surveys for 2015 to 2016 are included in Figure 2.
Figure 2: Prevalence of EC use in teenagers by smoking status, UK surveys 2015/16

Notes: YTPS, N=1,213 (2016); ASH -Y, N=1,205 (2016); SHRN, N=32,479 (11 to 16 year olds in 2015); SALSUS, N=13,607 (13 year olds in 2015), N=11,697 (15 year olds in 2015). Base for regular smokers in YTPS and ASH-Y is less than 50.

As Figure 2 illustrates, data was available on: ever use of EC among all respondents; regular (defined as at least weekly) use of EC among all respondents; never smokers’ use of EC (ever and regular use); and regular smokers’ use of EC (ever and regular use).

For 11-16 year olds overall, ever use of an EC ranged from 7-18% among the surveys that included this age range. In the SALSUS survey, ever use was 15% among 13 year olds and 32% among 15 year olds. This rate of ever use represents an increase compared with surveys from previous years. For example, in the single survey that covers the UK as a whole, the YTPS, the rate of ever use for 11-16 year olds was 12% in 2014 compared with 17% in 2016 (112).

Rates of regular (at least weekly) use among all 11-16 year olds are much lower, ranging from 1-3% in all the surveys, including among the sample of 15 year olds in Scotland. Rates of regular use have not increased in recent years in the surveys where comparisons are possible - for example between the YTPS in 2014 and 2016.

Among young people who have never smoked, some experimentation – or ‘ever use’ – of EC is occurring in the UK. This ranges from 4-10% among 11-16 year olds, and up
to 14% among 15 year olds in the SALSUS survey in Scotland. Never smokers’ ever use has increased slightly compared with previous years - for example from 3% in 2014 in the UK wide survey (YTPS) to 5% in 2016.

However, rates of regular use of EC in young people who have never smoked remain very low in all surveys, ranging from 0.1% to 0.5%.

EC use is concentrated in young people who already smoke. As Figure 2 shows, up to 91% of regular smoking youth in UK surveys have tried an EC and up to 38% of them use an EC at least weekly.

The ASH-Y survey is also available for 2017, representing the most recent data available. Figure 3 provides data comparing 2016 with 2017 for 11-16 year olds in this particular survey. Ever use increased between the two years when all young people were included (from 7% in 2016 to 11% in 2017) but this is largely accounted for by a rise in use among young people who are regular smokers. Both ever and regular use among never smokers did not increase between the two years.

Figure 3: Prevalence of EC use in 11-16 year olds 2016-2017, ASH-Y

Notes: ASH-Y N=1,205 (2016), N=1,361 (2017). Base for regular smokers in 2016 survey is only 14 and for 2017 is only 28.

The ASH-Y survey is also the only UK survey that asked whether EC used by young people contain nicotine. Among 11 to 16 year olds who had used EC in the past or were currently using (those who had tried EC once or twice were not asked), 22% said that the device had always contained nicotine, 39% that it had sometimes contained
nicotine, 27% that it had never contained nicotine, and 12% didn’t know. However, it is unclear how accurate recall or understanding of this issue is among participants in youth surveys. Future research should examine this in more detail.

Use of EC among 17 to 18 year olds

Comparable data to the above for 17 to 18 year olds are only available from the ASH-Y surveys and these are presented here (Table 6).

Table 6: EC use among all 17 to 18 year olds in Great Britain, and by smoking status

<table>
<thead>
<tr>
<th></th>
<th>2015 (n=728)</th>
<th>2016 (n=814)</th>
<th>2017 (n=790)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All: Ever Use</td>
<td>22.2%</td>
<td>25.2%</td>
<td>28.0%</td>
</tr>
<tr>
<td>All: At least weekly</td>
<td>1.0%</td>
<td>1.3%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Never smokers: Ever use</td>
<td>5.7%</td>
<td>8.8%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Never smokers: Weekly use</td>
<td>0.3%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Regular Smokers: Ever use</td>
<td>81.8%</td>
<td>74.2%</td>
<td>75.8%</td>
</tr>
<tr>
<td>Regular Smoker: Weekly use</td>
<td>3.9%</td>
<td>9.6%</td>
<td>8.2%</td>
</tr>
</tbody>
</table>

Notes: Source ASH-Y

These data are consistent with the data for 11 to 16 year olds, with never-smokers’ weekly EC use being negligible and never smokers’ EC experimentation being around 9% since 2016.

Trajectories of smoking and EC use

A key question for policy-makers and others is whether EC use contributes to the uptake of tobacco smoking in young people. In the period covered by our review, two new UK studies were published that provide relevant data. Both were longitudinal studies originally designed to focus on other tobacco control topics, with questions on EC use added after the studies commenced.

The first study added questions on EC to a project designed to assess the impact of the point of sale tobacco display ban in Scotland (113). This particular project has produced other papers on EC identified in our review from cross-sectional survey results. However, the 2017 paper was distinctive in that it included both baseline and follow up data collected from 11-18 year old never smokers who were originally surveyed in 2015 and followed up one year later in 2016.

At baseline, 8.6% of never smokers who completed the initial survey and follow-up had tried an EC. Of those that had tried EC at baseline, 40.4% had tried smoking by the
follow-up stage. This compares to 12.8% of baseline never EC users who had tried smoking at follow-up. A total of 22.9% of those that tried cigarettes at follow up had previously tried an EC, compared to 77.1% who had never used an EC at baseline. The fully adjusted model showed that having tried an EC at baseline was significantly associated with trying cigarettes in the following year (OR = 6.64, 95% CI: 3.60-12.26).

The second study took place in England with 13-14 year olds who were originally surveyed towards the end of 2014 and followed up one year later. At baseline, 61.5% of these school pupils hadn’t tried either EC or cigarettes, 16.0% had tried EC but not cigarettes, 4.4% had tried cigarettes but not EC, and 18.2% had tried both. After controlling for covariates, having tried EC at baseline was significantly associated with having tried smoking at follow up (OR = 4.06, 95% CI: 2.94-5.60). In those that had tried smoking at baseline, there was no significant relationship between having tried EC at baseline and subsequent increased smoking (OR = 1.89, 95% CI: 0.82-4.33).

Both these studies conducted statistical modelling which attempted to account for other factors that might explain the fact that young never smokers who had tried an EC had gone on to try smoking by follow up. This included factors such as having friends or family who smoked or other measures of susceptibility to smoking. However even after controlling for these, EC use emerged as a predictor of subsequent tobacco use. These findings are similar to those identified in a number of longitudinal studies in the US whose results have been summarised in a recent systematic review identified in our literature search (114). They are also similar to a recent study from Canada published after the systematic review but employing similar methods. This was a longitudinal cohort study of secondary school pupils (115). It identified an association between recent (past 30 day) EC use among never smokers at baseline and both ever smoking and daily smoking at follow up.

These studies suggest that EC use is associated with subsequent smoking in young people. However, all of them face similar limitations which need to be understood before assuming that this relationship is causal. One of the most significant relates to the measurement of both vaping and smoking. In both the UK studies, for example, EC use was classified as ever use meaning that many of the young people included could have tried a device just once or twice. Likewise the measure of tobacco use at follow up was ever use, which includes experimentation. Some of the American studies and also the Canadian study assessed recent use of EC (past 30 day) but not regular use of EC. This does not mean that the findings of the US or Canadian studies are incorrect, just that the measures are different from those in the UK.

Secondly, smoking uptake is determined by a wide range of factors. Despite the statistical analysis techniques employed, the studies can’t control for all relevant confounders. There may well be other factors not measured in the studies (such as sensation seeking, curiosity, expectancies, genetic vulnerabilities) that explain why some young people had tried smoking by follow up. It is also possible that there are groups of teenagers who are more susceptible to trying new things in general, or participating in risk-taking behaviour, and this is the group that may try both vaping and smoking.

Some support for this explanation, known as a ‘common liability’ theory, comes from a study in the UK (and one in the US see below). This study used a cohort of over 1,000 11-18 year olds surveyed in April 2016 and followed up four-six months later. The study used logistic regression models and causal mediation analysis to assess the relationships between 1) ever EC use and escalation among baseline never smokers and its association with smoking initiation at follow up and 2) ever smoking and escalation among baseline never EC users and EC initiation at follow up. As well as finding support for relationship 1) between ever EC use and smoking initiation (as found in the other studies above), this study also found support for the opposite relationship identified in 2) ie that ever smokers at baseline were more likely to initiate EC use at follow up³.

However, the main factor which challenges the ‘vaping leads to smoking’ hypothesis is what is happening with rates of youth tobacco cigarette use in the UK (and indeed in North America where the other studies were conducted). During the period when surveys show that young people are experimenting with EC, including some non-smokers, tobacco cigarette smoking rates have continued to decline.

To expand on this, we include the latest data on the prevalence of smoking in teenagers from UK surveys conducted between 2015 and 2017. As Figure 4 shows, rates of ever having tried a tobacco cigarette range from 11-20% in surveys of 11-16 year olds overall, but were higher (31%) in the sample of 15 year olds in the SALSUS survey in Scotland. Rates of regular smoking are much lower - between 1-4% for 11-16 year olds as a whole and 7% for 15 year olds in Scotland.

These smoking prevalence figures represent much lower rates than in the past. For example in Scotland, regular smoking has dropped from 30% in 15 year olds and 10% in 13 year olds at the turn of the century to these current low rates of 7% (15 year olds) and 2% (13 year olds) in 2015 (117). In England, 10% of 11-15 year olds were weekly smokers in 2002, but by 2014 this had dropped to 3% (118). In fact this same survey in England found that 18% of youth in 2014 reported ever trying smoking at all, even once, which was the lowest level identified since the survey began in 1982 (118).

The ASH-Y survey also gives smoking prevalence among 17-18 year olds which are also consistent with the above trends in younger age groups (Table 7).

### Table 7: Smoking prevalence in Great Britain among 17 to 18 year olds

<table>
<thead>
<tr>
<th></th>
<th>2015 (n=728)</th>
<th>2016 (n=814)</th>
<th>2017 (n=790)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking prevalence (ever)</td>
<td>40.3%</td>
<td>38.4%</td>
<td>45.2%</td>
</tr>
<tr>
<td>Smoking prevalence (regular)</td>
<td>8.7%</td>
<td>6.5%</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

Notes: Source ASH-Y
Since the Bauld and colleagues article (6) was released, a further official survey of Smoking Drinking and Drug Use (SDD) in young people (aged 11-15 years) in England has been published. Consistent with the trends above, it also identified a continued decline in youth smoking in England. For example, in 2006, 20% of 15 year olds in England were regular cigarette smokers but in the latest results, for 2016, this had dropped to 7% (11). Similar declines have been noted in the US including during the period when US studies (such as those outlined in Soneji and colleagues, 2017 (114)) were reporting a relationship between EC and tobacco experimentation (119, 120).

If EC use was causing smoking at the population level, these reductions in youth cigarette smoking would have significantly slowed or indeed reversed in the UK. This is not happening, and suggests that EC are not currently undermining what decades of efforts to prevent youth smoking uptake have achieved.

**Where young people obtain EC**

The SDD survey also included questions on how young people obtain EC, with data from 2016 in England (11). Respondents could give more than one answer (Figure 5). The most common source was being given them by other people (48%). This compares to 63% of current smokers in the same survey who reported being given cigarettes by other people. Thirty-nine per cent of regular EC users reported buying (rather than being given) EC from other people (mostly friends or relatives) compared to 32% of current smokers. Thirty-seven per cent of EC users reported buying an EC from a shop compared to 33% of current smokers.
The most popular place to purchase EC among regular users was a vape shop with 24% reporting purchasing from these specialist stores. Slightly fewer (23%) reported buying online, making the two most common purchase points for EC different ones than for tobacco – with no sales of tobacco reported from vape shops, and just 0.6% of smokers buying online. Newsagents were the most popular place to purchase cigarettes by young smokers, accounting for 22% of purchases, whereas just 9% of EC purchases by young people were from newsagents.

Fifty-six percent of regular EC users reported asking someone else to buy a device or refills from a shop compared to 79% of current smokers. Seventy-two percent of those who asked someone else to purchase an EC on their behalf reported success compared to 85% of those asking someone else to purchase cigarettes.
These findings have a number of implications. First, it is concerning that young people can continue to access tobacco cigarettes, including purchasing them from newsagents despite age of sale laws that have been in place for many years in England and throughout the UK. Similar age of sale laws (age 18) now exist for EC in England (and also in Wales and Scotland – age of sale is not yet in place in Northern Ireland but should be enacted soon) but this legislation does not appear to be deterring around one third of young EC users in England from purchasing them in retail outlets. In addition, almost one in four young people in England who use EC are purchasing them online – while online purchase of tobacco by young people is negligible. Online purchases of EC by young people should be monitored.

That said, the most common source of young people obtaining either EC or tobacco was from friends and relatives and this proxy purchasing needs further attention. This is particularly concerning for the much more harmful product - cigarettes - and provides the basis for Scotland’s legislation which includes powers to fine adults convicted of proxy sales of tobacco – legislation not in place in other parts of the UK.

**The international context**

An additional issue of interest is how EC use by young people in the UK compares to that in other countries. Direct comparisons are challenging for at least three reasons:

- the ages of adolescents included in surveys varies between jurisdictions
- many surveys are not representative of young people in the relevant jurisdictions but instead include convenience samples or those from particular schools or communities
- surveys do not use identical or even similar questions to assess use of EC

The issue of survey questions is particularly challenging. In the UK, a clear distinction is made between ever or occasional use and regular (at least weekly) use. This is rarely attempted in other countries where the vast majority of surveys include (or only report) measures of ever or recent use, with recent use defined as in the past 30 days, a measure not used in the UK.

However, it is possible to describe general trends in countries that report data from youth surveys. These are almost all high income countries where EC are available for sale. Our literature search identified one systematic review of the international literature on youth use of EC (121). This included 22 relevant studies on EC awareness and use in under 18s from January 2014 to January 2016. Seventeen of these reported prevalence figures on: ever use; recent use (past 30 days); and, in three articles, regular use. Given the review was conducted to include articles published up to 2016 many of these data are now some years old. For example, articles published in 2016 commonly included data from 2013/14, meaning that this overview may now be five
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A report commissioned by Public Health England

years out of date. In addition, as the authors point out, the surveys vary in terms of the age groups involved.

Despite these considerable limitations, Greenhill and colleagues’ paper (14) provides a snap shot of youth prevalence figures from a few years ago. Ever use, for example, varied from 4.4% in Germany to 38.5% in Romania.

Recent (past 30 day) use of EC in the various youth surveys identified in the systematic review (121) ranged between 2 and 14% in the US, 7.2% in Canada and 1.1% in Hong Kong. Regular use in the review was defined as at least once per month and only reported in one study from the UK (again 2014 figures, at 1.5%), 3.2% in Ireland and 0.5% in Greece.

These international comparisons paint a rather confusing picture, and as Greenhill and colleagues point out, the measurement challenges we identify above make direct comparisons very difficult if not impossible.

However, considerable attention has been paid to comparisons between the UK and North America and here it may be instructive to look at more recent surveys in an attempt to describe whether what is observed in the UK is unusual or not.

One recent large, nationally representative survey of young people in grades 6-12 (aged 11 to 18) in Canada has recently been published (122). This includes data from the Canadian Student Tobacco, Alcohol and Drugs Survey across 336 schools, capturing results from 42,094 students between October 2014 and May 2015. The Canadian findings for ever use are broadly similar with those in the UK from the subsequent year, as outlined above. They found that 17.7% of young people reported ever using EC. Overall 5.7% reported use in the past 30 days, but this rate was just 1.8% in never smokers - illustrating, like UK data, that these products are used primarily by young people who also smoke tobacco cigarettes.

Likewise in the US, an analysis of the 2015 National Youth Tobacco Survey (NYTS) has recently been published (123). As with the Canadian survey and our UK data, this is a representative survey of young people across the US and included 17,711 young people in middle school (aged 11-14) and high school (aged 14-19). This is a slightly broader age group than in the UK datasets above. The NYTS focuses on ‘current use’ of tobacco products and EC which is use in the past 30 days. Overall 11.3% of all young people in the survey reported current EC use (124).

Collins and colleague examined the NYTS data in more detail and identified similar patterns to an earlier study of the 2014 data from the same survey (125). They found that almost all EC users were either currently using another tobacco products (such as cigarettes) or had used tobacco at some point in the past. Only 1.6% of never tobacco
users ('tobacco naïve' youth) were current EC users. Although 'frequent' use is not reported in the NTYS reports, Collins and colleagues analysed the raw data and found that less than 0.1% of tobacco naïve youth reported using EC on 10 days or more in the past month.

At least one survey in the US asked questions about whether youth had vaped nicotine and found that the vast majority of youth (65-66%) who report trying or currently using an EC used one that did not contain nicotine (126).

Although these surveys in Canada and the US cannot be directly compared with data from the UK, they suggest similar patterns. First, that ever or recently using an EC is not unusual among young people overall. However, both ever and recent use is far more common among young people who smoke than young people who have never smoked. The very recent analysis by Collins and colleagues also shows that regular use of EC is extremely rare among never smoking young people in the US, as the UK data also shows. A future priority for research should be to harmonise measures and questions across youth surveys to allow reliable and accurate international comparisons to be made.

As mentioned above, a recent systematic review of studies on trajectories of use (114) has identified in the international literature a link between EC ever use at baseline and smoking initiation at follow up. In addition, one of these studies (127) also found a relationship between smoking at baseline and recent use of EC at follow up, similar to the UK study identified above.

Conclusions

Key findings

- E-cigarettes cannot be legally sold to young people under the age of 18 in most parts of the UK with the exception of Northern Ireland. Purchasing does occur including from sources rarely used for tobacco such as online suppliers.
- Despite some experimentation with these devices among never smokers, EC are attracting very few young people who have never smoked into regular use.
- EC do not appear to be undermining the long-term decline in cigarette smoking in the UK among young people.
- Never smokers in the UK who try EC are more likely to have tried smoking subsequently than those who have not tried EC.
- A causal link has not been established and neither has progression to regular smoking. The ‘common liability’ hypothesis seems a plausible explanation for the relationship between EC and smoking experimentation.
Implications for research, policy and practice

- Trends in EC use and smoking among youth should continue to be monitored using standardised definitions of use. This should include the use of nicotine in EC and checks on the understanding of survey questions.
- Patterns of EC purchasing by young people should be closely monitored, particularly internet sales. Age of sale regulations are in place for EC and cigarettes and should be strongly enforced.
- Research is needed on trajectories of use – not just from EC experimentation to smoking, but also from smoking to EC use among young people.
6 Use of EC in adults

Introduction

The objective of this chapter is to provide an overview of available data on prevalence of trial and use of vaping devices/EC in adults in Great Britain and information on characteristics of EC use. This information will be followed by a brief overview of international evidence on prevalence of trial and use.

Surveys used to describe the situation in Great Britain are the 2016 Office for National Statistics (ONS) ‘Adult smoking habits in Great Britain’ (respondents aged 16 and over), the Smoking Toolkit Study from England (STS, respondents aged 16 and over) and the ASH Smokefree Great Britain surveys of adults (ASH-A, respondents aged 18 and over). In this chapter, EC use will be presented over time alongside smoking prevalence, followed by a breakdown of trial and use by smoking status and socio-demographic characteristics as available. Characteristics of EC use will be presented for all current EC users as well as broken down by vaping and smoking status, mainly relying on the ASH-A. International information will be summarised based on the literature review described in Chapter 2.

The surveys use different questions to determine EC trial and use. In the ASH-A, two questions determine EC use status. First “Which of the following statements BEST applies to you? a) I have never heard of e-cigarettes and have never tried them; b) I have heard of e-cigarettes but have never tried them; c) I have tried e-cigarettes but do not use them (anymore); d) I have tried e-cigarettes and still use them; e) Don’t know”. Options c) and d) combined are classed as ‘ever tried’ and those responding c) or d) are asked a follow-up question about how often they had used or currently used e-cigarettes which includes the option “Not applicable – I have only tried e-cigarettes once or twice” as well as five options ranging from “Everyday” to “Less than once a month” and an additional “Don’t know”. Those responding c) to the first question and “Not applicable – I have only tried e-cigarettes once or twice” are treated as past triers, those responding c) and any frequency of use in the follow-up question as past users. Those responding d) to the first question are treated as current users which includes a small percentage who have at the point of the survey only tried once or twice.

In the ONS, respondents were asked to select one response out of a) No, I have never used one and I will not use one in the future; b) No, I have never used one but I might use one in the future; c) Yes, I have used one in the past but no longer use one; d) Yes, I currently use one; e) I tried one, but did not go on to use it; f) I don't know what an e-cigarette is (spontaneous only). Little information is provided in publications, so the question wording is not available. Those responding c), d) or e) are combined as
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having ever tried an EC; those responding c) or d) as ever users, and those responding
d) as current users.

The STS uses a different approach and does not assess whether respondents have
ever tried or used EC. Depending on smoking status, variations on the question “Are
you using any of the following?” are asked, followed by a list of products including
‘Electronic cigarette’. Those who smoked cigarettes in the past year and have made
any attempts to quit smoking are also asked about aids used, these also include EC as
an option.

Evidence from recent GB surveys

Trial and use of EC in adults in GB

For 2016/17, the estimates for prevalence of current use were very similar across the
three different surveys and ranged from 5.6% to 5.8%, regardless of different
geographical coverage and slightly different minimum age of respondents (Figure 6 and
Table 8). This prevalence translates to about 2.9 million current adult EC users in Great
Britain.

Figure 6 shows prevalence of EC use and smoking prevalence in adults from the three
surveys over the last few years. This indicates that EC use prevalence has plateaued
while smoking prevalence continues to decrease.

Table 8: Current prevalence of EC use and trial in adults

<table>
<thead>
<tr>
<th></th>
<th>ONS, 2016, %</th>
<th>ASH-A 2017, %</th>
<th>STS 2017, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever tried EC</td>
<td>18.6</td>
<td>16.7</td>
<td>-</td>
</tr>
<tr>
<td>Current EC user</td>
<td>5.6</td>
<td>5.8</td>
<td>5.6</td>
</tr>
</tbody>
</table>

Notes: Unweighted ns: ONS 7,713; STS 20,395; ASH-A 12,696. Ages 16+ for ONS and STS, 18+ for ASH-A
Figure 6: Prevalence of smoking and EC use in the adult population in three national surveys

![Graph showing prevalence of smoking and EC use from 2010 to 2017](image)

Notes: STS measured EC use from Quarter 4 in 2013, ASH-A is conducted in March. Ages 16+ for ONS and STS, 18+ for ASH-A

EC use and smoking status

Figures for EC use by smoking status vary a little across surveys (Table 9). This may at least partly be due to different questions and categorisations used to define smoking status. Additionally, the STS reports figures for past-year smokers (combining current smokers and those who stopped within the last 12 months) and long-term ex-smokers (those who stopped smoking more than 12 months ago) separately, whereas other surveys report data for current smokers and ex-smokers of any length of time. However, all recent surveys find the highest level of EC use among smokers (often referred to as ‘dual use’) and very low levels of EC use among never-smokers.

‘Dual users’ are not a homogenous group. This label includes a wide range of smoking and EC use patterns, from those who smoke many cigarettes a day and use EC only very occasionally to those who use EC many times a day and smoke only very occasionally, and every combination of behaviours in between. There has been little
research into different patterns of using EC while smoking and their effects on health or changes in smoking and EC use behaviour over time.

Table 9: Current EC use by smoking status, adults

<table>
<thead>
<tr>
<th>Smoking status</th>
<th>ONS, 2016</th>
<th>ASH-A, 2017</th>
<th>STS, 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current smokers/ past-year smokers in STS</td>
<td>13.7</td>
<td>18.0</td>
<td>20.1</td>
</tr>
<tr>
<td>Ex-smokers/ long-term (&gt;1 year) ex-smokers for STS</td>
<td>12.1</td>
<td>9.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Never-smokers</td>
<td>0.6</td>
<td>0.3</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Notes: Unweighted ns: ONS 7,713; STS 20,395; ASH-A 12,696. Ages 16+ for ONS and STS, 18+ for ASH-A

The smoking status of those who use EC has changed over time; the proportion of smokers has been decreasing and the proportion of ex-smokers increasing so that the majority of EC users are now ex-smokers (Figure 7).

Figure 7: Smoking status of current EC users

Notes: ASH-A, reproduced (128). Unweighted bases in the appendix Age 18+
Figure 8 shows ever EC trial and current EC use by smoking status over time as recorded in the ASH-A survey. EC trial and use in current smokers seem to have levelled off with little change in use between 2014 and 2017; 40% of all current smokers have never tried EC. For comparison, in the 2016 survey, 59% of smokers had never tried NRT and 3% reported currently using NRT (19% for EC). In ex-smokers, use continues to increase. In never-smokers, EC use has remained very low since surveillance began in 2012 with the highest prevalence of 0.3% recorded in 2017. A similar picture emerges from the STS, where EC use among smokers and recent ex-smokers has plateaued (Figure 9) while use among long-term ex-smokers continues to increase (Figure 10). Similar to the ASH-A, the STS has recorded EC use among never smokers around 0.5%; interestingly, EC use has been at the same level as use of NRT in this group (Figure 10).

**Figure 8: Ever trial and current use of EC in adults by smoking status over time**

*Notes: ASH-A. Unweighted bases in the appendix Ages 18+*
Figure 9: Prevalence of EC use among smokers and recent ex-smokers

Notes: STS, N=27,389 adults (16+) who smoke or who stopped smoking in the past year
Figure 10: Use of NRT and EC by never smokers and long-term (>1 year) ex-smokers over time

Notes: STS. N=67,513 never and long-term ex-smokers aged 16+ from November 2013

STS data show a decline in the use of NRT alongside smoking and an increase in EC use alongside smoking (Figure 11). The extent to which EC use is cannibalising NRT is discussed in Chapter 7.
Dual use of EC while smoking is unlikely to be associated with substantial reductions in harm, particularly when there is no substantial reduction in the number of cigarettes smoked (129). However, a comparison between dual users and smokers also indicated that dual use is not associated with an increase in harm. It is also worth noting that dual use is not specific to EC; very similar proportions of EC and NRT users also smoke or have smoked within the last year (Figure 12).
**EC use and socio-demographics**

Prevalence of current use in different socio-demographic groups is shown in Table 10. There does not appear to be a clear association with gender or a strong association with age, although all surveys report lower prevalence in the oldest and youngest age groups.

In terms of socioeconomic status, the association found depends on the population analysed (Table 11). In all adults in the general population (ONS and ASH-A), prevalence of EC use is higher in groups with lower socioeconomic status. This is expected due to a higher smoking prevalence in lower socioeconomic groups and the higher prevalence of EC use among smokers (ie groups with higher smoking prevalence are likely to have a higher EC use prevalence). In past-year smokers, the STS shows no clear gradient in prevalence of EC use, meaning that the socioeconomic differences seen in earlier years (5) have shrunk. This suggests that smokers from different socioeconomic status groups have a similar likelihood of using EC for quitting smoking although this remains to be tested empirically.
There are some regional variations; the proportion of adults using EC ranges from 3.0% in Wales to 11.5% in Yorkshire and the Humber and the proportion of smokers who have never tried EC ranges from 34.8% in Wales to 50.0% in the South West and in the West Midlands (Table 12).

Table 10: Current EC use by socio-demographics and smoking

<table>
<thead>
<tr>
<th>Gender</th>
<th>ONS, 2016, adults</th>
<th>ASH-A, 2017, adults</th>
<th>STS 2017, adult past-year smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>6.3</td>
<td>6.4</td>
<td>20.2</td>
</tr>
<tr>
<td>Women</td>
<td>4.9</td>
<td>5.3</td>
<td>19.9</td>
</tr>
</tbody>
</table>

Notes: Unweighted ns: ONS 7,713; STS 20,395; ASH-A 12,696. Ages 16+ for ONS and STS, 18+ for ASH-A
<table>
<thead>
<tr>
<th>Age</th>
<th>ONS, 2016 adults</th>
<th>ASH-A, 2017 adults</th>
<th>STS 2017 adult past-year smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 25</td>
<td>5.8</td>
<td>5.2</td>
<td>19.8</td>
</tr>
<tr>
<td>25 to 34</td>
<td>6.9</td>
<td>6.3</td>
<td>20.3</td>
</tr>
<tr>
<td>35 to 49</td>
<td>7.1</td>
<td>6.9</td>
<td>22.0</td>
</tr>
<tr>
<td>50 to 59</td>
<td>6.5</td>
<td>6.9</td>
<td>21.4</td>
</tr>
<tr>
<td>60 and over</td>
<td>2.9</td>
<td>4.6</td>
<td>20.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Socioeconomics</th>
<th>Socioeconomics</th>
<th>Socioeconomics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree</td>
<td>3.6</td>
<td>AB</td>
</tr>
<tr>
<td>Higher education</td>
<td>5.9</td>
<td>C1</td>
</tr>
<tr>
<td>A-Level or Highers</td>
<td>6.5</td>
<td>C2</td>
</tr>
<tr>
<td>ONC or National Level BTEC</td>
<td>8.2</td>
<td>D</td>
</tr>
<tr>
<td>O-Level, GCSE, CSE, Standard Grade*</td>
<td>6.4</td>
<td>E</td>
</tr>
<tr>
<td>Other qualifications</td>
<td>5.9</td>
<td></td>
</tr>
<tr>
<td>No formal qualifications</td>
<td>5.3</td>
<td></td>
</tr>
</tbody>
</table>

Notes: Unweighted ns: ONS 7,713; STS 20,395; ASH-A 12,696. Ages 16+ for ONS and STS, 18+ for ASH-A

AB: Higher & intermediate managerial, administrative, professional occupations; C1: Supervisory, clerical & junior managerial, administrative, professional occupations; C2: Skilled manual occupations; DE: Semi-skilled & unskilled manual occupations, Unemployed and lowest grade occupations.

*Calculated from O-Level or GCSE equivalent (grade A-C), GCSE (grade D-G), CSE (grade 2-5) or Standard Grade (level 4-6)
Table 12: Regional prevalence of current EC use in adults in the general population and proportion of smokers who have never tried EC, ASH-A 2017

<table>
<thead>
<tr>
<th>Region</th>
<th>Adult prevalence of EC use, %</th>
<th>Smokers who have never tried EC* , %</th>
</tr>
</thead>
<tbody>
<tr>
<td>North East</td>
<td>3.8</td>
<td>45.2</td>
</tr>
<tr>
<td>North West</td>
<td>9.9</td>
<td>37.9</td>
</tr>
<tr>
<td>Yorkshire and the Humber</td>
<td>11.5</td>
<td>41.7</td>
</tr>
<tr>
<td>East Midlands</td>
<td>10.3</td>
<td>39.6</td>
</tr>
<tr>
<td>West Midlands</td>
<td>7.6</td>
<td>50.0</td>
</tr>
<tr>
<td>East of England</td>
<td>7.3</td>
<td>36.7</td>
</tr>
<tr>
<td>London</td>
<td>4.9</td>
<td>36.0</td>
</tr>
<tr>
<td>South East</td>
<td>6.1</td>
<td>38.2</td>
</tr>
<tr>
<td>South West</td>
<td>7.2</td>
<td>50.0</td>
</tr>
<tr>
<td>Wales</td>
<td>3.0</td>
<td>34.8</td>
</tr>
<tr>
<td>Scotland</td>
<td>5.5</td>
<td>35.4</td>
</tr>
</tbody>
</table>

* Including those who had never heard of EC and those who didn’t know. Unweighted bases in the appendix. Age 18+

Characteristics of EC use

This section mostly presents data from the ASH-A 2017; characteristics will be shown for current and past EC users by smoking status. Where the unweighted sample size is less than 50, percentages will not be reported because reliability of these figures would be low. This means that characteristics of use are not shown for never-smokers who currently use (n=15) or never-smokers who used more than once or twice in the past (n=45) in the ASH-A.

Frequency of use

Across different surveys, most respondents who say they currently use EC report daily EC use; 75% and 67% of current EC users reported daily use in the ONS 2016 and the ASH-A 2017 respectively. In the STS from 2013 to 2017, 62% of smokers who reported current EC use and 87% of ex-smokers who reported current EC use were daily users.

Among those who used or tried EC in the past, frequency of use looks very different (Figure 13); the most common response, regardless of smoking status, is that they only tried EC once or twice.

Among never-smokers who said they had ever used or tried an EC, experience with EC was mostly limited to trial. While 2.3% of never-smokers reported ever having tried or used EC, around half of those (50.7%) had only used EC once or twice. Among those who had used EC more often, the majority had used less than monthly (22.4% of all...
never-smokers who had ever tried); 10.5% of never smokers who had ever tried EC reported they had used or were using every day (this equates to 0.2% of all never smokers or an unweighted n of 12 out of 6626 never smokers).

These data are in line with findings that frequent users are more likely to continue use from a longitudinal study in the US (130) which assessed frequency of EC use at baseline and again after a year. About 27% (95% CI: 18 to 40) of those who at baseline used on 1 to 5 days in the past month reported any use at follow-up, while 89% (95% CI: 78 to 100) of those who reported daily use at baseline also reported use at follow-up. To date, there is no evidence as to how EC use changes in the long-term, such as more than one year.

Figure 13: Frequency of EC use among past users or triers and current EC users by smoking status

Notes: ASH-A 2017. Unweighted bases in the appendix. Age 18+
Duration of use

Current EC users appear to be mostly long-term users. About three quarters of current users (76.0%) have used for more than 6 months (83.0% among ex-smokers, 68.9% among smokers), including one third (33.7%) who have used EC for more than two years (Figure 14). Among those who used (not only tried once or twice) EC in the past, the majority (71.7%) used for less than 6 months, with half of those (36.6%) having used for a month or less.

Figure 14: Duration of EC use among past and current EC users by smoking status

Notes: ASH-A 2017. Unweighted bases in the appendix. Age 18+
Device type

Devices with tanks that can be refilled with liquid continue to be the most popular type of devices among current EC users. In 2014, 40.8% of current EC users responded that they most often used a tank type; this increased to two thirds of current EC users in 2015 (66.2%) and remained at over two thirds in 2016 (71.0%) and 2017 (69.4%). Devices that use replaceable cartridges were used by 21.5% of EC users in 2017, similar to the previous two years (2015: 26.3%, 2016: 22.7%) and lower than in 2014 (46.7%). Past EC users (who had used EC more than once or twice) were less likely to have mostly used tank models (44.2%, Figure 15), potentially partly because their use occurred when these models were less popular or because continuing EC users move on to tank models.

The STS uses slightly different categories and also finds tank devices to be the most popular among EC users surveyed since August 2016. Split by smoking status, 57.6% of ex-smokers who used EC and 51.1% of smokers who used EC used this type of device, followed by modular systems [described as “A modular system that you refill with liquids (you use your own combination of separate devices: batteries, atomisers, etc.)”] that were used by 28.0% of ex-smokers and 22.8% of smokers who used EC. Eleven per cent of ex-smokers and 16.6% of smokers who used EC used cartridges.

The ONS used a simpler measure for type of device; here, 20.0% of EC users reported using one that resembles a cigarette, 73.9% one that does not resemble a cigarette and 6.1% some other kind.
Figure 15: Device types used by past and current EC users by smoking status

Notes: ASH-A 2017. Unweighted bases in the appendix. Age 18+

Amount of liquid

Only daily EC users were asked about the amount of liquid used. The majority (62.2%) of them reported using less than 4 mL per day and only a small percentage (1.5%) used more than 10 mL a day, the maximum amount allowed under the EU TPD to be sold in one refill bottle. Almost a fifth (18.1%) of daily EC users did not know how much liquid they use, indicating difficulty with self-report measures for consumption (Figure 16).
Nicotine

In the ASH-A, among current EC users, 69.3% always and 18.9% sometimes used nicotine (leaving 6.0% who never used nicotine and 5.8% who were unsure). Among past EC users who had used more than once or twice, 49.1% had always and 21.4% sometimes used nicotine. Notably, among never-smokers who had used EC, less than a third had used nicotine (29.5%) and most of those only sometimes. However, the same proportion of never-smokers who had used EC did not know whether they had used nicotine (Figure 17).

In the STS from August 2016 to July 2017, 84.5% of smokers and 88.1% of recent ex-smokers who use EC say that the EC or vaping device they mainly use contains nicotine.
Figure 17: Use of nicotine-containing liquid used by past and current EC users by smoking status

In the ASH-A 2017 survey, those responding “always” or “sometimes” to using nicotine were asked about the concentration of nicotine in the liquid they used usually (strength). Among current EC users using nicotine, 6.0% used strengths over 20mg/mL which were still allowed in March 2017 when the survey was run, but not after 20 May 2017 under the EU TPD (Figure 18). The STS reports a similar figure for the time from August 2016 to June 2017 when 4.3% of smokers and 6.7% of ex-smokers who also used EC used strengths of 20mg/mL or more (note that this includes 20mg/mL, the upper threshold of legal concentrations). While among current EC users, 9.4% did not know or remember the strength, this was common among past EC users (39.6%).
Flavour

Overall, the most popular group of flavours among current EC users was fruit flavours (28.5%), followed by tobacco (26.9%, including 2.4% who used tobacco menthol flavour) and menthol or mint flavours (25.3%). The same order was found among current smokers who currently use EC (fruit 31.5%, tobacco 30.3% and menthol/mint 20.9%), while among ex-smokers, menthol/mint flavours were slightly more popular (30.2%) than fruit and tobacco (both 25.5%, all figures from the ASH-A 2017). Very few current EC users use no flavours (2.6%) or do not know the flavour (2.2%). Data on flavours were not collected for past EC users.

Place of purchase

In 2016/17, specialist vape shops were the most popular source for purchase of EC among past-year smokers; 49.2% of current smokers who used EC and 42.8% of ex-
smokers who used EC had purchased their device there, followed by 16.7% and 15.3% respectively who had purchased from a supermarket, 12.8% and 11.9% respectively from a newsagent and 9.9% and 11.9% from an online specialist vape shop (STS).

Main reasons for use

Surveys use different lists of reasons from which respondents can choose, but consistently find that the desire to stop smoking is an important reason. In the ASH-A 2017, across all adults (regardless of smoking status) who had ever tried EC, the most common reason was ‘just to give it a try’ (36.0%), followed closely by ‘to help me stop smoking entirely’ (35.6%) and ‘Because I had made an attempt to quit smoking already and I wanted an aid to help me keep off tobacco’ (24.5%). When excluding those who had tried once or twice, ‘to help me stop smoking entirely’ was the most common reason (42.0%), endorsed by 35.1% of current smokers, 54.5% of ex-smokers and 7.2% of never smokers who had used or were using EC. The ONS found similar percentages when asking EC users to select their main reason; ‘aid to stop smoking’ was the most frequently endorsed (46.6% overall, 50.1% among current smokers, 48.2% among ex-smokers, unweighted n for never smokers <50), followed by ‘less harmful than cigarettes’ (26.6%). Chapter 10 provides further information on harm perceptions.

Among smokers, trial, past use and current use of EC appears to be driven by different reasons. In one recent analysis of ASH-A 2016 data, among smokers who had ever tried or used EC, the most frequent reasons overall were ‘to give it a try’, ‘to help stop smoking’ and ‘to help reduce smoking’. However, reasons differed between groups with different EC use experience. Current users’ most frequent reason was ‘to reduce smoking’ (45.3%) followed closely by ‘to help stop smoking (37.4%). Current users were more likely to endorse smoking reduction compared with past users (24.2, adjusted odds ratio (AOR) = 2.40, 95% CI: 1.59–3.64) and to endorse overcoming smoking restrictions (26.0% versus 13.4%, AOR = 2.03, 95% CI: 1.22–3.38) For those who had tried EC but not gone on to use them, the most frequent reason was ‘to give it a try’ (50.8%), and compared with past users, they were more likely to endorse this reason (20.8%, AOR = 2.99, 95% CI: 1.99–4.50) and less likely to endorse ‘to help stop smoking’ (18.9%) which was the most popular reason among past users (36.8%, AOR = 0.46, 95% CI: 0.33–0.73)(14).

Motivation to stop smoking

Among all smokers in the ASH-A 2017, 18.3% were motivated to stop smoking with the intention to do so either in the next month or the next three months (131). Broken down by EC use status, 23.2% of smokers who were currently using EC gave these responses, compared with 13.2% of smokers who had never tried EC. Using 2016 data, a recent publication has analysed this association in more detail (14). Adjusting
for socio-demographics and dependence, current dual users were significantly more likely to be motivated to stop smoking in the next three months than those who had used EC in the past whose motivation was similar to those who had never tried EC suggesting that dual use may be a transient phase of heightened motivation to stop smoking.

Gaps in the available data

There are a few notable gaps in the available data. More information is needed to tease out whether ex-smokers are initiating EC use after a period of abstinence, their reasons for any uptake and whether this is associated with an increase or decrease of relapse to smoking.

Information on the impact of EC on health and economic inequalities associated with smoking are scarce.

Notably, no data are currently available to assess prevalence of trial and use of EC in disadvantaged groups with high smoking prevalence and smoking-related morbidity and mortality, such as those with mental health problems or offenders. In 2014, the Adult Psychiatric Morbidity Survey (132) included some questions on EC use as advised by Leonie Brose and Ann McNeill; however, the data have not yet been made available for analysis. Funding awarded to Leonie Brose has for the first time enabled the Smoking Toolkit Study to be extended with a mental health module; data are currently accruing.

International overview of EC use

A large number of surveys has been conducted, but often these are restricted to specific regions or populations for example college students in a particular US state. For this section, the focus was on national surveys with representative samples, surveys with other samples are however included in meta-analyses identified in the literature review. A limitation is that data on EC use prevalence can become outdated quickly; by the time survey data have been published in peer-reviewed publications, they may already be out of date.

Two meta-analyses have reviewed evidence from existing surveys on awareness, ever EC use and current EC use. One meta-analysis included all surveys of adults with a sample size of at least 200 (133) which provided information on awareness, ever use, current use (last 30 day use) or relative harm perceptions. In 28 studies published between 2009 and 2014, they found a pooled awareness of EC of 61.2%, ever use of 16.8% and past 30-day use of 11.1%. In line with findings from GB, figures differed by smoking status; ever use was 27.2% among current smokers and 2.5% among never smokers; past 30 day use was 16.8% for current smokers and 1.2% for never smokers.
A similar meta-analysis of data from 26 surveys published between 2011 and 2015 also found that current smokers were far more likely to use EC than non-smokers (adults: OR=14.7, 95% CI: 11.0 to 19.5) (134). These findings need to be interpreted in the light of some limitations. The included studies often did not survey a representative sample of the population, some restricted sampling to those with a specific smoking status (excluding never smokers which increases prevalence estimates) or even exclusively EC users. Although studies were from a range of countries, the majority was conducted in the US and as detailed elsewhere, past 30 day use overestimates actual use (for a discussion on this measure see Amato, Boyle and colleagues 2016, and Pearson, Hitchman and colleagues 2017 (135, 136)).

Other data from European countries

Peer-reviewed publications using the Eurobarometer survey (see Chapter 2 for details) published recently used 2012 and 2014 survey data (137-140). Data from the most recent Eurobarometer 2017 are available in a report (141). Across the 28 EU countries, 15% of those aged 15 and over have ever tried EC, including 2% who reported current EC use (decimal places not reported), which is unchanged since the previous survey in 2014. Current EC use ranges from 0% in Bulgaria, Croatia, Italy, Romania, Slovakia and Sweden to 5% in the UK. Similar to the UK, EC use remains concentrated among current and former smokers; overall, 4% of current smokers are current users, ranging from 0% (Bulgaria, Croatia, Hungary, Italy and Sweden) to 8% in the UK. Also, 4% of ex-smokers are current EC users with a range from 0% (Latvia, Lithuania, Luxembourg, Slovakia and Spain) to 14% in the UK. Among never-smokers, EC use is very rare. Across the EU, EC use is 0% among never-smokers and only in 5 countries is any use among never-smokers reported (all 1%, Austria, Belgium, Cyprus, Estonia and UK). In the EU, among those who use EC (base n=565), 67% use them daily, which translates to 1% of the EU population being daily EC users. The most popular flavours among current users were fruit flavours (47%), followed by tobacco (36%) and menthol/mint (22%). The most frequently mentioned reason for taking up EC was to stop or reduce tobacco consumption (61%). All other reasons were cited only by a minority; 31% said that they started using EC because they saw them as less harmful, and 25% cited the lower cost of EC (141).

A very small number of other representative surveys assessing EC use in European countries has been published; their findings are presented alongside the figures from the Eurobarometer for the country where applicable. A survey of people over the age of 14 living in Germany in 2016 reported weighted percentages of 11.8% for ever EC use and 1.4% for current EC use (142), broadly in line with the 14% and 2% reported by the Eurobarometer. EC had ever been used by 32.7% of ever smokers and 2.3% of never smokers; 4.3% and 0.1% respectively reported current EC use (compared with Eurobarometer 6% and 0%). A 2014 survey of a representative sample of 1,016 respondents aged 16 and over in Spain (143) found 10.3% ever use, including 2.0%
current use (compared with Eurobarometer 12% and 1%). Current EC use was 1.2% for never smokers, 1.1% among ex-smokers and 4.8% among current smokers (compared with Eurobarometer 0%, 0% and 2%). In Serbian adults aged 18 and over in 2014, ever EC use was reported as 9.5% and current use at 2.0%. As usual, the majority of current EC users were current or past cigarette smokers; there were no current EC users among never smokers in Serbia (0.0%, (144).

North America

US population information on current EC use in the recent peer-reviewed literature have been collected by the Population Assessment of Tobacco and Health (PATH) in 2013/14 and the National Health Interview Survey in 2014. Current EC use among adults was 5.5% in the PATH (n=32320) (145, 146), 3.7% in the National Health Interview Survey 2014 (n=36697) (147) and 3.5% in the National Health Interview Survey 2015 (148). Daily EC use was reported by 1.2% in the PATH and 1.1% in the National Health Interview Survey 2014. Some surveys also report the less accurate measure of past 30 day use (see above and (130, 135, 136)). A consumer-based survey in 2014 (n=4269) reported past 30 day EC use of 4.8% (149), PATH found 6.7% (146) and another 2014 survey found 4.9% (150).

Delnevo and colleagues broke down EC use in the National Health Interview Survey data by smoking status, separating current daily smokers (16.2% EC use), non-daily smokers (14.9% EC use), recent quitters who had quit in the last year (18.0% EC use), ex-smokers who had quit smoking 2 or 3 years ago (10.3% EC use), ex-smokers who had quit at least 4 years ago (0.8% EC use) and never smokers (0.4% EC use), demonstrating that use was extremely low among never smokers as well as long-term ex-smokers (147).

Among Canadians aged 15 and over, in 2013, 1.8% had used EC in the past 30 days; among current smokers, this was 9.6%, compared with 0.9% among ex-smokers and 0.3% among never-smokers (151).

Other countries

A handful of surveys for countries outside Europe and North America was identified. In a representative sample of 26021 respondents aged 15 and over in Taiwan in 2015, 2.7% reported ever EC use; this was 14.2% among smokers, 3.2% among ex-smokers and 0.8% among never smokers. Current EC use was not assessed (152). A small survey of respondents aged 15 to 65 in Hong Kong 2014 reported a weighted prevalence of 2.3% for ever EC use (11.8% among smokers, 4.3% among ex-smokers and 1.0% among never smokers; n=809). Again, current EC use was not assessed (153). Among adults in the Republic of Korea, the 2013 weighted prevalence of ever and current EC use were 6.6% and 1.1 %, respectively (n=5338). Current EC use was
reported by 21.8% of current smokers, 4.8% of ex-smokers and 0.7% of never smokers (154). One survey conducted among those aged 15 and over in Japan in 2015 has been published (155). It collapses use of EC and heated tobacco products and reports 6.6% ever use and 1.3% past 30 day use (weighted) which was 4.4% among smokers, 1.7% among ex-smokers and 0.3% among never smokers.

In New Zealand in 2014, a survey of 2594 respondents aged 15 and over reported weighted prevalence of 13.1% for ever EC use and 0.8% for current EC use. At 4%, current smokers reported the highest rate of current EC use (0.1% for ex-smokers and never-smokers) (156).

The International Tobacco Control (ITC) project measures current EC use among smokers and recent quitters in a large number of countries, however, published data date from 2009 to 2013 (157, 158); these data are currently being updated and will be published in Spring 2018. This will, for the first time, provide population-level information on EC use in lower or middle income countries.

Conclusions

Key findings

Prevalence

- In GB, prevalence of EC use in adults has plateaued at approximately 6% of the adult population.
- EC use among never smokers in GB remains very rare at less than 1%, similar to the level of use of NRT. Among never smokers who have ever used EC, a minority have used nicotine-containing liquids and the vast majority have not progressed to regular use.
- Prevalence of EC use and trial among smokers has plateaued while use and trial among ex-smokers continue to increase.
- Socioeconomic differences in EC use by smokers and recent ex-smokers have become smaller with no clear gradient in prevalence by occupational grade.
- Prevalence of dual use (use and smoking) is similar for EC users and NRT users.

Characteristics of use

- Most EC trial does not become regular use.
- Most current EC users use daily and have used EC for more than six months.
- Models with refillable tanks for liquids are the most widely used type.
- Since May 2017, nicotine concentration in liquids has been limited to a maximum of 20mg/mL. In March 2017, around 6% of EC users reported using higher nicotine
concentrations; substantial proportions had difficulties reporting these figures so more may have been affected by the limit.

- The most popular groups of flavours among current EC users are fruit (29%), tobacco (27%) and menthol/mint (25%).
- Specialist vape shops (physical premises rather than online) are the most popular place of purchase (>40%).
- The most common reason for EC use continues to be in order to stop smoking, and smokers who use EC on average have higher motivation to stop smoking than other smokers.

International

- Data can be outdated by the time of publication.
- Prevalence of current use in GB is at the higher end for countries in the EU where the average is 2% for current EC use. Prevalence estimates for current EC use in the US are around 4% to 6%, which is similar to GB.
- Across international surveys, a consistently low prevalence (<1%) of EC use has been reported among never-smokers; one exception is one Spanish survey at 1.2%.
- Prevalence figures found for smokers and ex-smokers vary more widely across surveys in different countries (4% to 22% among smokers and 0.1% to 5% among ex-smokers).

Implications

Research

- As recommended in the 2015 PHE report, trends in EC use among adults should continue to be monitored using standardised definitions of use. Measures should include frequency and type of device used including different types of tank models.
- EC use among ex-smokers needs monitoring and further evidence to understand when and why they take up EC use and whether this is associated with an increase or decrease of relapse to smoking.
- More research is needed into different patterns of EC use while smoking and their effect on subsequent smoking behaviour to understand how best to move dual users to stop smoking.
- More research is needed on the impact of EC on health and economic inequalities associated with smoking, in particular on use of EC in disadvantaged groups with high smoking prevalence and smoking-related morbidity and mortality, such as those with mental health problems or offenders. Data that have been gathered from the Adult Psychiatric Morbidity Survey in England should be released for analysis.
Policy and practice

- As recommended in 2015 and as per existing National Institute for Health and Care Excellence (NICE) guidance, all smokers should be supported to stop smoking completely, including ‘dual users’ who smoke and use EC.
- Access to EC should be improved for smokers in disadvantaged groups.
7 The effect of EC use on smoking cessation and reduction

Introduction

The objective of this chapter is to provide an overview of available data about the effect of EC on smoking cessation and reduction in England. First, we provide smoking cessation data from the Smoking Toolkit Study (a repeated monthly series of national household surveys of representative samples of approximately 1800 adults aged 16 and above on smoking) followed by details of EC use for smoking cessation and estimates of long-term quitters resulting from EC use. This is followed by an examination of the use of EC in treatment settings using data from English Stop Smoking Services. We then examine the use of EC on smoking cessation and reduction from systematic reviews of Randomised Controlled Trials (RCTs) and observational studies. We comment on comparable data in vulnerable groups where this exists.

Smoking cessation rates in England

The effect of EC on smoking cessation needs to be viewed within the context of overall smoking prevalence and cessation rates. As identified in the introduction, the official estimate of smoking prevalence has declined to 15.5% in 2016.

Figure 19 and Figure 20 present the proportion of people who tried to quit and were successful (defined as those who tried to stop in the preceding 12 months and reporting still not-smoking at time of the survey) between January 2007 and December 2017, using data from the Smoking Toolkit Study (STS). The proportion of people who reported trying to quit smoking declined annually between 2007 and 2011 and has been variable for the past six years.
Figure 19: Proportion of people who tried to stop smoking in past year

Base: Adults (age 16+) who smoked in the past year. Graph shows prevalence estimate, upper and lower 95% confidence intervals. From: http://www.smokinginengland.info/latest-statistics/ accessed 12/01/2018
In a report which examined quit success rates from 2007 to 2017, Brown and West (159) analysed data from 18,356 participants included in the STS. Using the definition of quit success above, they compared quit success rates for the first six months of 2017 with those in the previous 10 years and also assessed whether any trends in quit smoking success rates extended across different social groups. They found that quit success rates varied over time; the lowest rate (13.1%) was in 2010 and the highest (19.8%) in the first half of 2017; the quit rate in the first half of 2017 was significantly higher than the average for the previous 10 years (OR=1.33, 95% CI 1.09-1.62). Age, sex or the region the smoker lived in made no difference, whereas an increase in success rates was greater in people with lower socioeconomic status (OR=1.66, 95% CI 1.11-2.51). This is an important finding as it shows parity between the groups in quit success rates for the first time in over 10 years (and possibly ever). The authors commented that many factors may have contributed to these improvements in success rates, including an environment more conducive to quitting and the availability of a range of support for quitting including EC.
Use of EC for smoking cessation in England

The 2015 PHE report on EC (5) stated that since 2013, EC had been the most common quitting aid for smokers in England. The most recent data from the STS suggest this is still the case (Figure 21) although overall, the use of EC for quitting has plateaued since 2015. The popularity of EC as a quitting aid appeared to peak in the last quarter of 2016 when 40.6% of participants in the STS samples reported using an EC to quit smoking compared to 14.7% who used NRT bought over the counter from a shop (OTC) or on prescription (2.8%) and 4.7% who used varenicline. In the most recent STS findings (the last quarter of 2017), 38.2% of people reported they used an EC in their recent quit attempt compared with 18% who reporting using NRT OTC, or on prescription (1.6%) and 2.8% who used varenicline (Figure 21). From a visual inspection of the graph in Figure 21 the changes in use of EC and NRT OTC appear to be almost a mirror image of each other in that as EC use changes it is accompanied by a commensurate change in the use of NRT OTC. We discuss the issue of EC cannibalising the licensed NRT market later in the chapter.

Figure 21: Support used in most recent quit attempts

N=13,456 adults (age 16+) who smoke and tried to stop or who stopped in the past year; method is coded as any (not exclusive) use From: http://www.smokinginengland.info/latest-statistics/ accessed 12/01/2018
How EC might help smokers stop smoking

Figure 22 below shows how EC use might in theory help a smoker to stop smoking. The most obvious way is through use of an EC in a gradual or abrupt quit attempt. A second possibility is that a smoker who is not currently planning to stop tries an EC, perhaps out of curiosity or as an alternative to smoking in smoke-free settings and goes on to stop smoking without making a conscious decision to do so. Such smokers might not classify themselves as having made a ‘quit attempt’. A third route is by preventing relapse to smoking in someone who has already stopped. In this scenario, a smoker who stopped smoking with or without the use of EC, may subsequently use an EC in a way that prevents relapse to smoking.

There are also ways that EC might also hinder quitting, such as if the dual use of tobacco cigarettes and EC prevents people from quitting because they feel reassured they are reducing tobacco related harm and are less motivated to quit. However, as discussed in chapter 6, a recent study found that current dual users were significantly more likely to be motivated to stop smoking in the next three months than those who had used EC in the past, whose motivation was similar to those who had never tried EC (14). Quitting may also be hindered if smokers who also use an EC find quitting harder.

Finally, successful quitters may try vaping and then, as a result, relapse to smoking. These routes are also included in Figure 22. Note that these are all theoretical impacts of using EC on quitting; what happens in practice needs to be examined empirically to establish a better of understanding about causal pathways. As there are no data yet on EC hindering quitting in England, they are not considered further here, but included in Figure 22. The assumptions underpinning estimates of additional quitters due to EC are discussed later in this chapter.
Figure 22: How EC might impact on stopping smoking

- **IN A QUIT ATTEMPT**
  - Smoker uses an EC to quit smoking
    - Stops smoking abruptly
    - Stops smoking gradually
    - Continues to vape & smoke
    - Continues to smoke

- **NOT IN A QUIT ATTEMPT**
  - Smoker uses an EC to quit smoking
    - Stops smoking abruptly
    - Stops smoking gradually
    - Continues to vape & smoke
    - Continues to smoke

- **RELAPSE PREVENTION**
  - Stopped smoking without an EC, tries an EC to prevent returning to smoking
    - Remains a non-smoker
    - Continues to vape & remains a non-smoker
    - Continues to vape & returns to smoking
    - Quits vaping & returns to smoking

- **RELAPSE PREVENTION**
  - Stopped smoking with an EC, continues to use an EC
    - Remains a non-smoker
    - Continues to vape & remains a non-smoker
    - Continues to vape & returns to smoking
    - Quits vaping & returns to smoking
Estimates of the impact of EC use on the number of long-term quitters

West and colleagues (160) and Beard and colleagues (161) have estimated the number of long-term additional quitters in England resulting from the use of EC in quit attempts, using Smoking Toolkit Study (STS) data and two different methods. Although their estimates are for 2014 and 2015, we include these studies here as they were published after the 2015 PHE report. Beard and colleagues (161) also assessed the temporal association between prevalence of current use of EC in smokers and recent ex-smokers (ie not necessarily within a quit attempt) on prevalence of quit attempts and success.

2014 estimate

West and colleagues (160) used an indirect method to estimate the number of additional long-term quitters generated by EC in 2014. In summary, using their STS data for 2014, they estimated:

1) A total of 891,000 smokers had used an EC to stop smoking (37.3% of all last year smokers had tried to stop at least once, 28.2% of whom used an EC without other support).

2) The one year (long-term) success rate of such quit attempts was 7.5% (50% more than the 5% estimated success rates for those without help or using a licensed nicotine product purchased OTC) (162) which would result in ~67,000 smokers successfully stopping.

3) As STS has identified no consistent changes in the proportion of smokers trying to quit that could be confidently attributable to EC use, they assumed that all these smokers would have made quit attempts even in the absence of EC. If these ~67,000 smokers had used no support/licensed nicotine OTC then 5% (ie two-thirds) would have stopped smoking leaving a residual 2.5% (~22,000) who additionally stopped because of EC. This gives their upper estimate of ~22,000 additional long-term quitters in 2014 caused by EC.

4) For the lower bound estimate, they further assumed that EC was contributing to the decline in the use of prescription medications over time (which they estimated to be a decline of approximately 10% since EC started to become popular). They estimated that the decline in use of prescription medicines was approximately 10% of quit attempts (3.7% smokers in 2014, 313,000 smokers) and that an upper estimate for the contribution of EC to that decline was 80%, thus representing 250,000 smokers.

5) Thus they estimated that if EC had detracted from these methods of stopping, then of the initial 891k smokers using EC to quit, this would have resulted only in 641,000
additional smokers making quit attempts using EC, with an estimated success rate of 2.5% over and above had smokers used no support/licensed nicotine OTC, giving ~16,000 additional long-term quits in 2014, their lower estimate.

**Contribution of EC to stopping smoking using time series analysis and 2015 estimate**

The second study (161) used time series analyses of population trends to estimate more directly how population-level EC use had been associated with changes in quit attempts, quit success, and use of other support in quit attempts between 2006 and 2015 using STS data and data from people setting a quit date with English Stop Smoking Services.

In the discussion section of the paper, the authors estimated the number of additional long term quitters due to EC use in 2015. This study also allowed an assessment of the assumptions made in West and colleagues (160) described above. To control for possible changes in use of stop smoking support, a range of potential confounders were included in their analysis such as advertising expenditure and the introduction of several tobacco control policies. The prevalence of quit attempts and quit success was predicted from current smokers’ prevalence of EC use and prevalence of EC use during a quit attempt.

Between 2006 and 2015, data was collected on 170,490 participants aged 16 years in the Smoking Toolkit Study. Of these, 41,301 were past year smokers and 37,765 were current smokers. The proportion who reported a quit attempt increased and then decreased overall changing from 45.4% at the start of the study to 31.2% in the last quarter of the study. There was an overall increase in the success rate of those who reported a quit attempt (from 10.6% in the last quarter of 2006 to 18.6% in the first quarter of 2015). Over the same period, current use of EC among smokers increased from negligible use in the last quarter of 2006 to 21.3% at the end of the study, and EC use in a quit attempt also rose from negligible use in the last quarter of 2006 to 35.0% in the first quarter of 2015.

The data did not show clear evidence of an association between prevalence of use of EC by smokers and attempts to quit smoking (supporting the assumption 3 discussed above (160)). However, the increase in prevalence of EC use by smokers was positively associated with the success rates of quit attempts and the association remained after adjustment for a range of confounding variables (161); for every percentage point increase in prevalence of EC use by smokers, the success rate of quit attempts increased by 0.098 percentage points. EC use in quit attempts was also positively associated with quit success, with every percentage point rise in prevalence of EC use in quit attempts associated with a 0.058 percentage point increase in the success of attempts.
The authors focused on the latter finding (that a one percentage point increase in EC use in quit attempts was associated with a 0.058 percentage point increase in quit successes) as this was likely to reflect a causal link and be a fairer point estimate. Using this finding, they estimated the impact on long-term quits as follows: 32.5% of 8m smokers (2.6m) made a quit attempt in 2015 and prevalence of EC use in quit attempts was 36%; this leads to 54,288 additional short to medium term (<1 year) quitters in 2015 compared with no use of EC in quit attempts. Assuming a 66% subsequent relapse rate, they estimated that EC may have contributed about 18,000 additional long-term ex-smokers in 2015 (a figure similar to the 2014 estimates).

Assumptions in quit estimates

The similarity in the estimates from West and colleagues (160) and Beard and colleagues (161) using different methods is reassuring. However, they both still rely on certain assumptions. Below, we discuss how the estimate might vary if key parameters were changed and then recalculated the estimates varying two parameters for 2014 and 2016 STS data.

Cannibalisation of other quit methods

An earlier study using Smoking Toolkit Study data suggested EC were not cannibalising the licensed NRT market (for smoking reduction, not quitting) (163). The more recent study described above (161) found no significant associations between EC use in quit attempts and the use of stop smoking services, NRT, OTC and prescription treatment overall. However, a significant association between EC use in quit attempts and the use of NRT on prescription was observed (for every percentage point increase in EC use in quit attempts, there would be a 0.098 percentage point decline in NRT use on prescription). During the study the mean proportion of quit attempts including NRT on prescription was 8.9 (Standard Deviation (SD) 2.45). This suggests that the lower bound 2014 estimate of 16,000 (160) is probably too conservative as they had allowed for a higher level of cannibalisation of other support methods than observed in Beard and colleagues (161). In our estimates below (Table 13) we have therefore varied this assumption, from 80% to 20% of the 10% decline in use of other methods.

Impact on relapse

As noted above, it is possible that using an EC in a quit attempt might result in a different relapse trajectory from the use of the other stop smoking support. This would affect the above estimates of long-term quitting, which would be larger if there is less relapse with EC, or smaller if there is more relapse with EC. Additionally, if some ex-smokers became EC users in order to prevent relapse (and this had worked), this would have resulted in the estimate for additional long-term quitters due to EC, being
an underestimate. As we are not aware of any data on this issue (and there is a need for research here), we have not altered this assumption below.

Success rates of quit attempts involving EC

This may now be higher than the 50% increase from 5% cited by West and colleagues, (160). The estimated 50% increase in success rates over and above no support/licensed nicotine OTC due to EC in quit attempts, derives from a previous study by the authors using the Smoking Toolkit Study data (162) when the type of products on the market were somewhat different, with fewer tank models being used (see Chapter 6 and ASH data and see below). We have recently replicated this study using a different dataset (ICGBS) which was presented at a conference, and therefore not yet peer reviewed (164). We aggregated data from the 2013, 2014 and 2016 waves to study the impact of using two different types of EC in quit attempts: non-tank (disposable or rechargeable model refillable with pre-filled cartridges) vs tank (rechargeable device with a tank that can be refilled with liquids or modular EC). The outcome was participant’s self-reported smoking status at time of survey, regardless of length of abstinence. Participants stating that they had stopped smoking completely in the last year/since the last survey were classified as quit. A range of covariates (strength and frequency of urges to smoke, number of recent quit attempts, time since last quit attempt started, abrupt of reduction quit method, sex, age, social grade, survey year) were controlled for. Quit success rates were 31.2% for self-help/no help, 19.9% for non-tank EC, 38.0% for tank EC and 21.7% for licensed nicotine products OTC. In the fully adjusted analyses, using tank models increased the odds of quitting 2.19 times (OR 2.19 (1.50,3.19) compared with self-help/no help. The overall impact when tank and non-tank EC were combined was also significantly higher (OR 1.59, (1.19,2.13)) than self-help/no help.

The findings are in line with an earlier study using the ICGBS (20) which suggested that tank models were more effective than other EC as quit smoking aids. As approximately 70% of EC use involves tank models in 2017 (see Chapter 6), it is likely that the estimates of quitters generated by EC in more recent years would now be higher than the West and colleagues (160), and Beard and colleagues (161), estimates.

In our estimates below (Table 13) we have therefore varied the success rate over and above no help/licensed nicotine product from 50% to 100%, to estimate what impact that would have on the estimated number of smokers who have quit as a result of EC.

Updated quit rates based on STS 2016 data and varied parameters

As discussed above, we have recalculated the West and colleagues (160) indirect analysis varying two parameters: the success rate over and above no help/licensed nicotine product use (from 50% to 100%) and the percentage contribution of EC to the
Evidence review of e-cigarettes and heated tobacco products 2018: 
A report commissioned by Public Health England

decline in use of existing therapies (from 80% to 20%); we have then replicated the original and adjusted estimates using the 2016 STS data. The resulting figures are shown in Table 13 below, with the original estimates shaded grey.

Table 13 shows that varying the two parameters for 2014 gave the lowest estimate as ~21,000, and the highest estimate ~44,000). Using the same parameters as West and colleagues, 2014, for the 2016 year gave a lower estimate of ~22,000 and higher estimate ~29,000). Varying the two parameters for 2016, gave the lowest estimate as ~27,000 and the highest estimate ~57,000.

Table 13: Estimates for the additional contribution of EC to long term quitters for 2014 and 2016 using STS data (original estimates highlighted)

<table>
<thead>
<tr>
<th>% contribution of EC to 10% decline in use of existing therapies</th>
<th>2014 Upper estimate</th>
<th>2016 Upper estimate</th>
<th>2014 Lower estimate</th>
<th>2016 Lower estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated success rate for EC above that of no help/licensed nicotine product</td>
<td>50%</td>
<td>100%</td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>Upper estimate</td>
<td>0</td>
<td>22,245</td>
<td>44,489</td>
<td>28,662</td>
</tr>
<tr>
<td>Lower estimate</td>
<td>80</td>
<td>15,934</td>
<td>31,868</td>
<td>22,275</td>
</tr>
</tbody>
</table>

It should be noted that we have not changed the assumption that in the absence of EC, the smokers trying to quit using EC would have tried to quit anyway. This is because there is no evidence of a consistent change in quit attempts due to the advent of EC and therefore it is not possible to attribute, with any confidence, a proportion of quit attempts that would not have happened in the absence of EC. Finally, as noted above, there are other routes to quitting smoking other than through traditional quit attempts, which have not been modelled.

Summary

Quit success rates in England are at the highest rates so far observed and for the first time, parity across different socioeconomic groups is observed. It is plausible that EC are contributing to this. Recent estimates of additional quitters resulting from the availability of EC, using the same dataset but two different methods, resulted in similar figures within the range of 18,000-22,000. Varying the assumptions, and updating these estimates for 2016, resulted in an upper bound estimate of around 57,000 additional quitters annually resulting from EC. While caution is needed with these figures, the evidence suggests that EC have contributed tens of thousands of additional

quitters in England annually. Insofar that success rates with EC have increased, then an updated time-series analysis including data from 2016 and 2017 may find a larger association between the use of EC and quit attempts, which may lead to larger estimates in the time since 2015.

**EC use in English Stop Smoking Services**

Local authorities were given responsibility for public health by the Health and Social Care Act 2012. This transfer of functions was funded through a ring-fenced grant. The grant is used to commission a variety of services, including Stop Smoking Services. Stop Smoking Services offer smoking cessation support which involves the use of pharmacotherapies (NRT, varenicline, EC, bupropion, in combination or alone) and/or behavioural support. Data are collected from local authorities every three months about the number of treated smokers in each service, the number who successfully quit at 4 weeks (self-reported and carbon-monoxide (CO) verified) and key measures of the service including intervention type, intervention setting and type of pharmacotherapy received. A treated smoker is defined according to the Russell Clinical Standard (a clinical version of the Russell Standard for outcomes assessment in smoking cessation clinical trials) (165); a smoker who has at least one treatment session and sets a quit date is counted as a treated smoker, whereas a smoker who attends one treatment session but fails to attend future session is not counted in the data. A smoker is counted as a 'self-reported four-week quitter if they are assessed (face to face or by telephone) four weeks after the designated quit date (minus three days or plus 14 days) and declares that they have not smoked even a single puff on a cigarette in the past two weeks. A smoker is counted as a CO-verified four-week quitter if they are a self-reported four-week quitter and his/her expired-air CO is assessed four weeks after the designated quit date (minus three days or plus 14 days) and found to be less than 10ppm. Treated smokers lost to follow up (cannot be contacted for the four week follow up assessment) are counted as non-quitters. Since 2014, Stop Smoking Services have been asked to record if an EC was used in a quit attempt, either alone or in combination with a licensed medication. These data are naturalistic and do not allow us to control for things like the severity of tobacco dependence known to influence success rates or if the Stop Smoking Service was supportive of EC use. It is also possible that that the people using EC alone or in combination with licensed stop smoking medicines may differ from the rest of the smokers quitting with these services. However, these data provide valuable information about the use of EC within Stop Smoking Services and their contribution to quit success.

Between April 2015 and March 2017, 690,007 set a quit date and 51% were self-reported quitters at four-week follow up (37% were CO validated quitters). In 2016/17, the number of people setting a quit date with a Stop Smoking Service and the number of successful self-reported quitters fell for the fifth consecutive year (though the self-reported quit rate has remained relatively stable at 51-52% in recent years).
In both 2015-16 and 2016-17, the highest number of quit attempts involved combination NRT, though the highest quit rate was in people who used a licensed medicine and an EC consecutively. The number of treated smokers using each type of support and the quit rates between April 2015 and March 2017 are presented in Figure 23. These data suggest that smokers who are treated by a Stop Smoking service with behavioural support and use EC with or without additional licensed medication, have comparable quit success to smokers using a licenced medication.

**Figure 23: Self-reported four-week successful quitters by pharmacotherapy type (2015-2017)**

![Graph showing self-reported four-week successful quitters by pharmacotherapy type](image)

*Notes: Data for all age groups*

**EC use by region**

EC use as part of quit attempt varies by region (Figure 24). In 2015-16, Yorkshire and the Humber reported that 1.6% of the people who set a quit date with their services used an EC as part of their quit attempt compared to 5.4% in the East Midlands. In 2016-17, the North East region reported that 2.4% of the people who set a quit date with their services used an EC as part of their quit attempt compared to 6.8% in the East Midlands.
Similarly, quit rates vary between regions (Figure 25). For context, Figure 26 gives overall success rates by region for the same time period, although a range of factors will be influencing these success rates. In 2015-16, 45% of people in the North East region who used an EC as part of their quit attempt successfully quit (self-reported) compared to 70% in the East of England. In 2016-17, 49% of people in the South West region who used an EC as part of their quit attempt successfully quit (self-reported) compared to 68% in London.
Figure 25: Self-reported four-week successful quitters using an EC by region

Self-reported 4-week quit rates

Number who used EC as part of a quit attempt

<table>
<thead>
<tr>
<th>Region</th>
<th>2015-2016</th>
<th>2016-2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>North East</td>
<td>n=1,256</td>
<td></td>
</tr>
<tr>
<td>North West</td>
<td>n=4,394</td>
<td></td>
</tr>
<tr>
<td>Yorkshire and the Humber</td>
<td>n=1,226</td>
<td></td>
</tr>
<tr>
<td>East Midlands</td>
<td>n=3,497</td>
<td></td>
</tr>
<tr>
<td>West Midlands</td>
<td>n=2,166</td>
<td></td>
</tr>
<tr>
<td>East of England</td>
<td>n=2,497</td>
<td></td>
</tr>
<tr>
<td>London</td>
<td>n=4,421</td>
<td></td>
</tr>
<tr>
<td>South East</td>
<td>n=2,973</td>
<td></td>
</tr>
<tr>
<td>South West</td>
<td>n=3,213</td>
<td></td>
</tr>
</tbody>
</table>
In recent years there has been a reduction in the availability and use of Stop Smoking Services. In an annual Survey of Tobacco Control Leads in English local authorities conducted in June 2016, ASH reported that 59% of local authorities have cut their smoking cessation budgets, largely in response to the cut in the national public health grant and the wider cost pressures on local authority budgets (166). One in twenty local authorities no longer have a Stop Smoking Service beyond that offered by GPs and pharmacists and in 20% of Authorities, the Specialist Stop Smoking Service has been replaced by an integrated ‘lifestyle’ service of some kind. Without a specialist component, these services can be expected to be less effective in helping smokers quit.

Stop Smoking Services increase the chances of a successful quit attempt up to four-fold (167) and should be available to all smokers. As discussed above, the combination of EC with support from Stop Smoking Services is likely to optimise chances of stopping smoking when using an EC. Hence, all services should offer support to smokers wishing to use an EC to stop smoking. However, not all Stop Smoking Service practitioners are supportive of providing help to smokers wishing to use EC. In an online survey of 1,801 Stop Smoking Service practitioners and managers, (168) reported that less than 5% would recommend EC to all their clients.
It seems reasonable to propose that combining the most popular source of support (EC) used by smokers in the general population (identified from the STS data), with the most effective (Stop Smoking Service support), should be a recommended option available to all smokers.

Summary

EC use alone or in combination with licensed medication and behavioural support from a Stop Smoking Service, appear to be helpful in the short term. However, fewer smokers use an EC as part of a quit attempt with a Stop Smoking Service compared with licensed medication. If ECs are contributing to higher success rates, Stop Smoking Services in England may be missing an opportunity to maximise cessation outcomes for smokers who use their service.

Randomised controlled trials of EC use for smoking cessation or reduction (published since the last report)

Our literature search identified one RCT published since our previous report. Tseng and colleagues (169) compared the efficacy of a nicotine containing EC with a placebo EC on smoking reduction. Participants were daily smokers aged 21-35 who were not ready to quit smoking. They were randomised to receive either a disposable 4.5% nicotine EC (n=50) or a placebo EC (n=49) for three weeks. Participants in both groups were also given brief behavioural support about how to reduce their cigarette intake but minimal instructions on EC use. The main outcome was self-reported smoking reduction of at least 50% in the number of cigarettes smoked per day (CPD), three weeks after the start of the intervention. Both groups achieved significant reductions in overall number of cigarettes smoked per day. Compared with baseline, a significant reduction in CPD was observed at both study time periods (1 and 3 weeks) for the group who received the nicotine EC (from an average of 14 CPD to 6 CPD, p< .001) and the placebo EC (from an average of 15 CPD to 8 CPD, p< .001). The participants in the nicotine EC group were more likely to reduce by 50% or more at end of treatment, only after adjusting for EC consumption and baseline readiness to quit. The authors acknowledge that the study sample size was small and was underpowered to detect the small-moderate effect size observed in smoking reduction at the end-of-intervention, the intervention was brief and follow up period modest.

Overview of systematic reviews of EC use for smoking cessation or reduction

We identified 14 systematic reviews of EC for smoking cessation and/or reduction published since our last report; seven included a meta-analysis (170-176) and seven provided only a narrative synthesis (73, 177-181). The characteristics of the systematic reviews which included a meta-analysis are described in Table 14 and their primary studies in the Appendix.
**Table 14: Characteristics of systematic reviews including a meta-analysis**

<table>
<thead>
<tr>
<th>Authors &amp; funder</th>
<th>Date searched up to</th>
<th>Participants</th>
<th>1] Interventions</th>
<th>2] Comparators</th>
<th>Outcomes and length of follow up</th>
<th>No of studies included in each review</th>
<th>Method of synthesis</th>
<th>Tools used for 1] Risk of bias</th>
<th>2] Certainty of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rahman, 2015(175) Funder: No external funding</td>
<td>5/2014</td>
<td>Current smokers who had used an EC for 6 months or more</td>
<td>1] Nicotine EC 2] Placebo EC 2] NRT 2] No intervention</td>
<td>Self-reported or CO validated cessation at any follow up</td>
<td>RCT: 2 Uncontrolled intervention: 1 Observational (longitudinal or cross sectional):3</td>
<td>Pooled RR for 2 RCTs using a Mantel-Haenszel fixed effects model. Pooled ES for all included studies.</td>
<td>1] van Tulder Scale (182) 2] Downs and Black Scale (183)</td>
<td></td>
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<tr>
<td>Hartmann - Boyce, 2016(171) Funder: Cochrane Collaboration</td>
<td>31/1/16</td>
<td>Current cigarette smokers at enrolment into studies, motivated or unmotivated to quit</td>
<td>1] Nicotine EC. 2] Placebo EC. 2] Alternative smoking cessation aids, including NRT 2] No intervention. 1] EC added to standard treatment (behavioural or pharmacological or both) 2] Standard treatment alone</td>
<td>CO validated cessation at the longest follow-up point, (at least 6 months from the start of intervention)</td>
<td>RCT: 3 Uncontrolled intervention: 6 Observational (longitudinal or cross sectional):8</td>
<td>Pooled RR for 2 RCTs using a fixed-effect Mantel-Haenszel model. Other designs: narrative synthesis</td>
<td>1] Cochrane Risk of Bias tool (184) 2] GRADE (185)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Khoudigian, 2016(173) Funder: No external funding reported</td>
<td>26/5/14</td>
<td>Current cigarette smokers intending/not intending to quit</td>
<td>1] Nicotine EC 2] Placebo EC 2] NRT</td>
<td>Self-reported or CO validated cessation and reduction in number of cigarettes smoked per day at least 6 months follow up</td>
<td>RCT: 2 Various other designs: 3</td>
<td>Pooled RR or 2 RCTs using a random-effects Mantel-Haenszel model</td>
<td>1] Cochrane Collaboration's Risk of Bias Tool (184)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Authors</td>
<td>Date</td>
<td>Study Design</td>
<td>Intervention</td>
<td>Outcome Measure</td>
<td>Study Type</td>
<td>Analysis Method</td>
<td>Funder</td>
<td>Bias Assessment Tool(s)</td>
<td></td>
</tr>
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<td>------------------------</td>
<td></td>
</tr>
<tr>
<td>Vanderkam, 2016(176)</td>
<td>14/6/15</td>
<td>Current smokers</td>
<td>1] Nicotine EC 2] Placebo EC</td>
<td>Self-report or CO verified cessation and reduction on cigarette intake of at least 50% at 3 months or longer follow-up</td>
<td>RCT: 2 Uncontrolled intervention:3 Observation (longitudinal/cross sectional): 9</td>
<td>Pooled RR for 2 RCTs using a random-effects Mantel-Haenszel model. Other designs: narrative synthesis</td>
<td>Funder: No external funding reported</td>
<td>1] Cochrane Risk of Bias Tool (184)</td>
<td></td>
</tr>
<tr>
<td>Kalkhoran and Glantz, 2016(172)</td>
<td>17/6/15</td>
<td>Current or past cigarette smokers intending/not intending to quit</td>
<td>1] EC use. including any past 30-day use, ever use 2] People who have not used an EC</td>
<td>Self-reported and/or biochemically-validated cessation at any duration of follow-up</td>
<td>RCT: 1 Various other designs: 37</td>
<td>Pooled OR for 20 studies (various study designs)</td>
<td>Funders: National Institutes of Health, National Cancer Institute, FDA Center for Tobacco Products</td>
<td>1] Modified ACROBAT-NRSI Tool (186)</td>
<td></td>
</tr>
<tr>
<td>Malas, 2016(174)</td>
<td>1/2/16</td>
<td>Not reported</td>
<td>1] Nicotine EC 2] Placebo EC 2] NRT 2] No intervention</td>
<td>Self-reported and/or CO-validated cessation or reduction at any duration of follow-up</td>
<td>RCT: 2 Observation (longitudinal/cross sectional): 9</td>
<td>Pooled AORs by synthesising results of studies based on methodological quality using QualSyst tool</td>
<td>Funder: Ministry of Health and Long-Term Care (Health System Research Fund, Canada)</td>
<td>1] QualSyst 2] GRADE (185)</td>
<td></td>
</tr>
<tr>
<td>El Dib, 2017(170)</td>
<td>29/12/15</td>
<td>“Cigarette smokers, regardless of whether the users were using them as part of a quit attempt”</td>
<td>1] EC with or without nicotine 2] No intervention 2] Stop smoking medication and/or behavioural support 2] Alternative EC with or without nicotine</td>
<td>Self-report or CO verified cessation and reduction on cigarette intake of at least 50% at 6 months or longer follow-up</td>
<td>RCT:3 Observation (longitudinal/cross sectional): 9</td>
<td>Pooled RR for 2 RCTs and pooled OR for observational studies using a random-effect Mantel-Haenszel model</td>
<td>Funder: WHO</td>
<td>1] Modified version of the Cochrane Risk of Bias tool (187) 1] Modified Newcastle - Ottawa Scale (188) 2] GRADE (185)</td>
<td></td>
</tr>
</tbody>
</table>
The authors of the systematic reviews arrived at the same conclusion that further RCTs of EC are needed. However the reviews that included a meta-analysis produced different results; two found a positive effect (171, 175), four found an inconclusive effect (170, 173, 174, 176) and one found a negative effect (172) (Table 15). There appear to be several possible explanations for the discrepancies:

**Types of studies included in a meta-analysis:** Four reviews conducted a meta-analysis and/or sensitivity analysis that only included RCTs designed to evaluate the efficacy or effectiveness of an EC on cessation or reduction (171, 173, 175, 176); these studies are Bullen and colleagues, (189) and Caponnetto and colleagues (190) and were included in our previous report. The remainder of the reviews included studies within a meta-analysis (cross sectional and longitudinal studies) most of which were not specifically designed to test if EC resulted in cessation or reduction. Therefore one reason for the difference in findings across reviews is due to the inclusion of observational study designs, not specifically designed to test if EC resulted in cessation.

**Types of participants included in a meta-analysis:** Some reviews synthesised results from primary studies that enrolled only current smokers to their studies (171, 173, 175, 176); whereas other reviews included studies from a diverse range of participants, including current and ex-smokers, smokers who had ‘tried an EC’ but who continued to smoke. Studies which analyse results of smokers based on EC use at baseline by virtue of their design have already excluded people who have successfully stopped smoking using an EC. Such studies only keep patients in their study who are classed as treatment failures or who are in the middle of a quitting attempt where they may be cutting down to quit. Combining such diverse groups (with differing degrees of exposure to an EC) is likely to underestimate the effect of EC for cessation. Participants’ motive, frequency and duration of EC use is also likely to influence findings, and combining studies of infrequent, brief EC use with more intensive long term EC use may influence review results.

**Types of outcomes included in a meta-analysis:** One of the main reasons for the differences between the results of the reviews relates to the length of follow up (whether review authors combined participants quit rates at 6 month or 12 month follow up) and how missing data was handled (on an intention to treat basis or complete case analysis). Two reviews reported cessation at the longest follow-up point from the start of the intervention (ie 6 months follow up for the Bullen and colleagues study and 12 month follow up for Caponnetto and colleagues (190), measured on an intention- to-treat basis (171, 175), two reviews reported consistent follow up points (at six months), also on an intention to treat basis (173, 176). The reason for the difference in the effect estimates between these four reviews related to the length of follow up: one participant in the Caponnetto control group (placebo EC) changed from being a non-quitter at six months follow up to a quitter at 12 months follow up (Table 16).
Table 15: Length of follow up of RCTs included in a meta-analysis

<table>
<thead>
<tr>
<th>Study and length of follow up</th>
<th>Number who quit with a nicotine EC</th>
<th>Total participants</th>
<th>Number who quit with placebo EC</th>
<th>Total participants in study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bullen, 2013(189): 6 months</td>
<td>21</td>
<td>289</td>
<td>3</td>
<td>73</td>
</tr>
<tr>
<td>Caponnetto 2013(190): 6 months</td>
<td>22</td>
<td>200</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>Caponnetto 2013(190): 12 months</td>
<td>22</td>
<td>200</td>
<td>4</td>
<td>100</td>
</tr>
</tbody>
</table>

The difference between the findings of El-Dib and colleagues and the two reviews by Rahman and colleagues and Hartmann-Boyce and colleagues relates to how missing data was handled. El-Dib’s (170) complete cases analysis excluded 181 participants from the two RCTs whereas Rahman and colleagues (175) and Hartmann-Boyce and colleagues (171) included all randomised participants in an intention to treat analysis. In smoking cessation trials, it has been standard practice for several years that participants who do not complete follow up assessments or drop out of the trial early are counted as smokers. Therefore leaving them out of the analysis or filling in their missing data based on their last assessment (if they had quit), would lead to greater bias in efficacy comparisons (165).
Table 16: Results of systematic reviews that included a meta-analysis of cessation

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Method for participants lost to follow up</strong></td>
<td>Included participants with missing data and counted them as still smoking</td>
<td>Included participants with missing data and counted them as still smoking</td>
<td>Included participants with missing data and counted them as still smoking</td>
<td>Included participants with missing data and counted them as still smoking</td>
<td>Unclear</td>
<td>Not reported</td>
<td>Excluded participants with missing data and counted complete cases</td>
</tr>
<tr>
<td><strong>Effect Estimate</strong></td>
<td>RR 2.29, (95%CI 1.05-4.96) p=0.04</td>
<td>RR 2.29, (95%CI 1.05-4.96) p=0.04</td>
<td>RR 2.02, (95%CI 0.97-4.22) p=0.06</td>
<td>RR 1.91, (95%CI 0.93-3.89) p=0.08</td>
<td>OR 0.72, (95% CI 0·57-0·91)</td>
<td>AOR 0.10, (95% CI: 0.05, 0.22) - 6.07 (95% CI: 1.11, 33.18)</td>
<td>RR 2.03, (95% CI 0.94-4.38) p=0.07</td>
</tr>
<tr>
<td><strong>Authors’ conclusion</strong></td>
<td>EC use is associated with smoking cessation &amp; reduction</td>
<td>EC with nicotine, compared with placebo EC, helped smokers to stop smoking long-term</td>
<td>Non-statistically significant trend toward smoking cessation in adults using nicotine EC exists compared with other therapies or placebo.</td>
<td>The use of EC with nicotine decreases tobacco consumption among regular smokers</td>
<td>EC are associated with significantly less quitting among smokers</td>
<td>While the majority of studies demonstrate a positive relationship between EC use and smoking cessation, the evidence remains inconclusive</td>
<td>It is impossible to make strong inferences regarding whether EC use promotes, has no effect or hinders smoking cessation</td>
</tr>
</tbody>
</table>
Summary of systematic reviews

We identified 14 systematic reviews of EC for smoking cessation and/or reduction published since our last report, seven of which included a meta-analysis. The authors of the systematic reviews all concluded that further RCTs of EC are needed. However, the reviews that included a meta-analysis produced different results because of methodological differences. Two found a positive effect, four found an inconclusive effect and one found a negative effect for EC use on cessation.

The standardisation of the reporting of smoking cessation trials has been greatly improved since the publication of the Russell Standard (165). Researchers continue to add other outcome measures in the context of their own trials and this is to be encouraged. However, when reporting trial outcomes, a core set of outcomes, as per the Russell Standard should be encouraged. Similarly, the standardisation of systematic reviews and meta-analytical methods have been improved since the development of the Cochrane Collaboration of Researchers, and we encourage reviewers to report a core set of outcomes using similar methods to the Cochrane Collaboration, in addition to their own outcomes.

Improving the methodological quality of EC research

Villanti and colleagues (181) provide the most recent narrative systematic review to be published and while a narrative synthesis was employed, we include it because the authors propose a set of standards for research on EC use and cessation. To improve the scientific rigor of EC research, Villanti and colleagues (181) have proposed a hierarchy of methodological criteria for considering whether a study provides sufficient evidence to assess if EC use leads to smoking cessation or reduction (box 1) and tested their proposed hierarchy in a systematic review. They searched relevant literature up to the beginning of February 2017 and included any type of research design from studies that claimed to have evaluated the impact of EC use on abstinence from tobacco cigarettes or the reduction in number of tobacco cigarettes consumed. Their search identified 91 identified papers; after assessing if studies assessed the outcome of interest, EC use as the exposure and study design (criterion 1-3), seven studies remained, though only four articles from three RCTs were considered to have met all six of their proposed criteria (169, 189).
Box 1: Hierarchy of methodological criteria for assessing EC use for smoking cessation/reduction (181)

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion 1</td>
<td>Does the study examine and adequately measure the outcome of interest (cigarette smoking abstinence or reduction)?</td>
</tr>
<tr>
<td>Criterion 2</td>
<td>Does the study examine EC use specifically for smoking cessation or reduction as the exposure of interest (were EC specifically used with the intention to quit or reduce smoking?)</td>
</tr>
<tr>
<td>Criterion 3</td>
<td>Does the study use an appropriate design with control or comparison groups to address the potential impact of EC use on smoking cessation or reduction?</td>
</tr>
<tr>
<td>Criterion 4</td>
<td>Does the study measure EC use (exposure) before measuring smoking cessation or reduction (the final outcome)?</td>
</tr>
<tr>
<td>Criterion 5</td>
<td>Does the study evaluate the dose and duration of exposure, to determine adherence and adequate delivery of active ingredients for a sufficient time period?</td>
</tr>
<tr>
<td>Criterion 6</td>
<td>Does the study evaluate the type and quality of the EC product used?</td>
</tr>
</tbody>
</table>

Villanti and colleagues (191) reach a similar conclusion to the most recent Cochrane Review (171) even though Villanti and colleagues arrived at their conclusion using a slightly different process. The Villanti paper may be expected to contribute to improved rigour in EC research; although no observational studies met all their criteria (192). The strict inclusion and exclusion criteria of RCTs often have limited applicability to patients in real-world clinical settings or people in the general population who smoke or use EC. Therefore, the conclusion drawn from Villanti and colleagues’ systematic review using their new hierarchy may be conservative. Likewise, the requirement of maintaining fidelity to an intervention, such as using EC, within certain parameters (eg type, dose, duration and frequency) is also discordant with what happens in real life. As EC technology has become more sophisticated and varied, and the people who use EC more heterogeneous, new and flexible ways of conducting observational studies and RCTs to allow for user experimentation (eg trial and error of different types of EC products), as well as the inclusion of patient/user reported outcome measures that are relevant and meaningful to EC users are necessary (192).

EC use for smoking cessation or reduction in vulnerable groups

Smoking prevalence in vulnerable groups such as those with a mental illness, substance misuse disorder, people who are homeless or prisoners remain considerably higher than in the general population (193-196). Similar treatments to those that are effective for general population smokers are also effective for people who smoke who have a severe mental illness (197, 198) or substance misuse disorder (199). Historically, smokers from vulnerable groups have been offered fewer opportunities to stop smoking compared to smokers in the general population, although there is now a concentrated focus on reducing harm from smoking in this population following recent
policy initiatives (200). As the evidence base rapidly grows for EC use in the general population, it is important that researchers include vulnerable populations when testing EC for smoking cessation or harm reduction. It is also important that practitioners and policy makers ensure equal opportunities to all potential cessation aids for these populations.

Since the previous PHE report (5), we have found no published RCTs of EC for smoking cessation or reduction in the above mentioned vulnerable groups. There has been one uncontrolled study of EC use in smokers with severe mental illness and one in people who smoke who are maintained on methadone. Pratt and colleagues (201) provided EC for four weeks and instructions on how to use them, to 21 people with schizophrenia or bipolar disorder and assessed participants weekly for four weeks. Nineteen participants completed weekly assessments. Thirteen (68%) of participants were female, their mean age was 42 and they had been smoking for an average of 24 years. Between baseline and four weeks, two participants quit and 17 reduced their mean tobacco cigarette intake from 192 to 67 cigarettes/week (p = 0.005), confirmed by reduction in breath CO levels from 27 ppm to 15 ppm (p=0.004). Temporary and mild side-effects were reported by 58% of participants and included dry/sore throat, nausea, dizziness, and cough. Pratt and colleagues (201) also captured subjective experiences of using an EC and reported participants commented that they perceived that EC were healthier and helped them feel more accepted by non-smokers. However, some participants felt that the EC did not provide the same “hit” they were used to and some participants reported that they tended to use their regular tobacco instead of the EC when they were experiencing emotional distress.

Stein and colleagues (202) provided EC for six weeks and instructions how to use them to 12 smokers who were maintained on methadone. Participants were all male, and their mean age was 46 years. Participant's reduced their CPD by an average of 13.4 at nine weeks follow up and one participant quit. Temporary and mild side-effects were reported by the minority of clients and included headache, cough and sore throat. Both studies had high adherence rates to EC and low attrition rates.

A similar uncontrolled pilot study of EC (203) with smokers with serious mental illness not intending to stop smoking soon and who were accessing community services, currently under peer review, found similar reductions in tobacco use and measures of smoke intake while using the EC.

**International overview of EC use for smoking cessation or reduction**

The previous section on systematic reviews is largely international literature; here we provide a brief summary on national surveys with representative samples and finish with a framework for considering the potential deaths that could be averted by hypothetically replacing cigarettes with EC.
In Chapters 6 and 10 we report data from the Eurobarometer 2017 study (EC special Eurobarometer 458 (141)) about EC use in 28 Member States of the European Union. Of 3,612 respondents who reported they currently smoked or used to smoke and have at least tried EC, 14% indicated that using EC enabled them to stop smoking tobacco entirely and 17% reported they had reduced their tobacco consumption due to the use of EC, but did not stop using tobacco entirely. Men (43%) were slightly more likely than women (37%) to say that using EC helped them reduce their tobacco consumption: nearly half (46%) of those aged 55 or over said that using EC helped them cut their use of tobacco, compared with less than a third (32%) of those aged between 15 and 24. The longer someone spent smoking, the more likely they were to say that EC helped them stop or reduce their tobacco consumption. More than two-thirds of former daily smokers (67%) found EC helpful, compared to 58% of former occasional smokers (58%).

In the US, Zhu and colleagues (204) used the US Current Population Survey-Tobacco Use Supplement included data from five surveys, (2001-02, 2003, 2006-07, 2010-11, and 2014-15) to assess the relationship between EC use and smoking cessation in a representative sample of the US population. Of 161,054 respondents to the 2014-15 survey, 22,548 were current smokers, and 2136 recent quitters. EC users were more likely than non-users to make a quit attempt (65.1% v 40.1%), and more likely to succeed in quitting (8.2% v 4.8%). The overall quit attempt rate in 2014-15 (45.9%) was significantly higher compared with the previous surveys. The overall population smoking cessation rate increased between 2010-2011 (4.5%) and 2014-15 (5.6%) representing approximately 350 000 additional US smokers who quit in 2014-15. Zhu and colleagues (204) explain the limitations of their study design and data collection methods and suggest there may be many reasons other than the use of EC that contributed to an increase in quit attempts and quit success (eg an increase in federal tobacco tax and national media campaigns). However, their findings are consistent with Beard and colleagues (161) discussed earlier in this chapter.

Modelling the overall impact of EC

Mathematical and computational modelling play an increasingly important role in guiding public health policy, though are not without their limitations; in this section we report two studies about the potential population impact of EC use in the US. Cherng and colleagues (205) used an agent-based modelling approach to examine hypothetical scenarios of EC use by smoking status and the effects of EC on the initiation and cessation of tobacco smoking). Using multiple sources of data from national surveys, census and epidemiological studies, the model simulated a population of U.S. adults, aged 18 to 85, and their smoking and EC use status. The model included four nicotine-use states: 1) exclusive EC user, 2) exclusive cigarette smoker, 3) dual user of both EC and cigarettes and 4) never user of either product. Cherng and colleagues (205) found larger reductions in smoking prevalence than
potential impact on smoking initiation. They reported if EC increased individual-level smoking cessation probabilities by 20%, the model estimated a 6% reduction in smoking prevalence by 2060 compared to baseline model (no effects) outcomes. In contrast, prevalence of EC use among never smokers would have to rise dramatically from current estimates, with EC increasing smoking initiation by more than 200% relative to baseline model estimates in order to achieve a corresponding 6% increase in smoking prevalence by 2060.

In the second modelling study, Levy and colleagues (206) present a framework for considering all the potential contributions that EC might make to population health. They modelled the potential deaths that could be averted in the US by hypothetically replacing cigarettes with EC using a model that took account of potential cohort effects. They compared projected smoking rates and health outcomes over a 10 year period (2016-2026) using a Status Quo Scenario (essentially a world where EC do not exist) with two Substitution scenarios (a world where cigarettes are replaced with EC, taking an optimistic and pessimistic view) (Box 2). The Status Quo Scenario focused on cigarette use only with the population classified as never, current and former cigarette smokers. Smoking rates were projected forward using age and sex-specific initiation and cessation rates. The number of smoking related deaths of current smokers was calculated by age, sex and year as the product of their excess mortality risks (ie current smoker mortality rate minus never smoker mortality rate) multiplied by the number of smokers. A parallel process was used to calculate estimates for former smokers. Their findings are in Box 2.
Box 2: Assumptions for substitution scenarios (207)

<table>
<thead>
<tr>
<th>OPTIMISTIC SCENARIO</th>
<th>PESSIMISTIC SCENARIO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replacing 10% of cigarette by EC users over 10 years, so that a residual of 5% cigarette smoking prevalence remains in 2026</td>
<td>Replacing 10% of cigarette by EC users over 10 years, so that a residual of 10% cigarette smoking prevalence remains in 2026</td>
</tr>
<tr>
<td>Never smokers who would have smoked cigarettes instead become EC users at the same rates as initiation of cigarette use in the Status Quo Scenario after the 5% smoking prevalence is reached</td>
<td>EC initiation is assumed to occur at 150% of the Status Quo smoking initiation rate to reflect some renormalisation of nicotine</td>
</tr>
<tr>
<td>EC users each year quit at the same age-specific and sex-specific cessation rate as smokers in the Status Quo Scenario</td>
<td>EC users each year quit at half the rate of cigarette smokers in the Status Quo Scenario</td>
</tr>
<tr>
<td>An excess risk of EC use at 5% of cigarette excess risk is applied to current EC users</td>
<td>An excess risk of EC use at 40% of cigarette excess risk is applied to current EC users</td>
</tr>
<tr>
<td>Predicted potential 6.6 million fewer premature deaths and an estimated 86.7 million fewer life years lost</td>
<td>Predicted potential 1.6 million fewer premature deaths and an estimated 20.8 million fewer life years lost.</td>
</tr>
</tbody>
</table>

Conclusions

Key findings

- In the first half of 2017, quit success rates in England were at their highest rates so far observed and for the first time, parity across different socioeconomic groups was observed. It is plausible that EC have contributed to this.
- Recent estimates of additional quitters resulting annually from the availability of EC, using the same dataset (STS) but two different methods, resulted in similar figures within the range of 16,000-22,000. Varying the assumptions, and updating these estimates for 2016, resulted in an upper bound estimate of around 57,000 additional quitters annually resulting from EC (lower bound around 22,000). While caution is needed with these figures, the evidence suggests that EC have contributed tens of thousands of additional quitters in England.
- EC use alone or in combination with licensed medication and behavioural support from a Stop Smoking Service, appear to be helpful in the short term. However, fewer smokers use an EC as part of a quit attempt with a Stop Smoking Service compared with licensed medication.
• We identified 14 systematic reviews of EC for smoking cessation and/or reduction published since our last report, seven of which included a meta-analysis. The authors of the systematic reviews arrived at the same conclusion that further randomised controlled trials of EC are needed. However, the reviews that included a meta-analysis produced different results; two found a positive effect on cessation for EC use, four found an inconclusive effect for cessation and one found a negative effect.

Implications

Research

• An important focus of future research is longer-term relapse trajectories of people who use EC for quitting compared with other stop smoking treatments and also assess whether the uptake of EC after quitting can prevent relapse back to smoking.
• Funders should consider that although RCTs may yield higher internal validity this is at the cost of lower generalisability. Future robust observational and RCTs should consider allowing for user experimentation (eg trial and error of different types of EC products), as well as the inclusion of study outcomes that are relevant and meaningful for EC users.
• Funders should commission research about the effect of EC on smoking cessation in vulnerable populations (eg people who smoke who have a mental illness, substance misuse disorder, homeless or prison populations).

Policy and practice

• Stop smoking practitioners and health professionals should provide behavioural support to smokers who want to use an EC to help them quit smoking.
• Stop smoking practitioners and health professionals supporting smokers to quit should receive education and training in use of EC in quit attempts.
• Local authorities should continue to fund and provide Stop Smoking Services in accordance with the evidence base.
8 Poisonings, fires and explosions

Introduction

The objective of this chapter is to summarise the evidence on poisonings, fires and explosions attributed to EC and their component parts. These incidents are examined in two categories: harm caused by exposure to e-liquids (poisoning) and harm caused by malfunctioning EC (injuries from fires and exploding EC or EC batteries). Incidents of this nature often gain media attention (208-211), yet little is known about their prevalence and context. This chapter will summarise the evidence available and, where possible, will provide context by reporting risks from other commercially available products. The health implications of inhaling vapour during regular EC use are discussed in Chapter 9 and are not covered here. This chapter presents data from peer reviewed literature published since January 2015, a FOI request sent to Fire Rescue Services (FOI-F) and a FOI request sent to burn treatment centres (FOI-B); these data sources are described in Chapter 2. Of the 29 FOI requests issued to burn treatment centres, data was returned from nine. We are very grateful to those centres that did provide data, however the total response was insufficient to draw either inference or conclusions, therefore the data are not presented in this report.

EC Poisoning

E-liquids typically consist of a solution containing PG, VG, nicotine and flavourings. This section reviews the evidence on cases of poisoning resulting from exposure to e-liquids that far exceeds that from routine EC use but which nevertheless provide valuable background and context to poisoning from e-liquids.

The data here are presented in four sections: National Poison Information Service (NPIS) data for the UK, UK case reports, non-UK case reports and activity reports from international poison treatment centres.

National Poisons Information Service Data (NPIS)

The NPIS collates and summarises UK wide data from its telephone and online (TOXBASE) poison enquiry services as described in Chapter 2 (in 2015 a TOXBASE app was introduced for iOS and Android mobile devices which is not discussed further here as it only accounts for less than 2% of all queries received). The NPIS records enquiries made by clinicians and the public about the assessment and treatment of poisoning cases. Unlike hospital records it can capture incidents that involve accident and emergency services (A&E) attendance but that do not require a hospital admission.
In 2016/17 the NPIS recorded 662,105 TOXBASE user sessions. The most commonly accessed pages were those for Paracetamol (99,584) Ibuprofen (27,675), Sertraline (25,524), Diazepam (23,913) and Codeine phosphate (23,322). The NPIS reported a total of 43,611 patient-related telephone enquiries for all causes of poisoning in 2016/17, a reduction from 48,000 the previous year. These included 1,210 for enquiries for drugs of misuse, 694 for iron poisoning, 498 for dishwashing tablets, 419 for carbon monoxide, and 295 enquiries for automotive screenwashes.

For EC poisoning, the NPIS reported 230 patient-related telephone enquiries in 2016/17 compared to 272 such enquiries in 2015/16. Of the 230 enquiries in 2016/17, 185 were recorded as accidental poisoning, 32 intentional poisoning and 13 “all other” or “unknown” (Figure 27). The vast majority (95%) of EC telephone poisoning enquiries recorded by NPIS between 2015 and 2017 were recorded as minor, or no toxicity; 2% resulted in moderate toxicity; 1% (n=2) in severe toxicity and 2% of unknown toxicity (Figure 28). Both incidences of severe toxicity in 2016/17 involved a cardiac arrest. There were 608,868 user sessions of the online NPIS service TOXBASE concerning all poisoning causes in 2015/16, and 602,012 user sessions in 2016/17. Online enquiries for EC were down from 3,724 in 2015 to 2,664 for the 10 months of 2017 (the number from the equivalent 10 months in 2015 were 3,044).

**Figure 27: Telephone enquiries of EC poisoning by cause 2015 - 2017: NPIS data (all ages)**
Review of UK case reports from the literature

There were no peer-reviewed case reports from the UK identified by our literature search. We did identify a letter to an academic journal and a conference abstract that described poisoning by EC. Despite the limitations of these articles they can provide some detail and context to poisoning events and are often used to highlight emerging issues. The research letter reported accidental application of e-liquid to a person’s eye after confusing the e-liquid for eye-drops (212). The letter reported that the liquids were stored adjacently in the same cabinet. The person was treated for eye irritation but suffered no long-term damage. The conference abstract reported a man who presented at A&E having ingested two bottles of e-liquid (213). He was treated with benzodiazepines to control and prevent seizures and was discharged after 36 hours and suffered no long-term effects.

Review of case reports from outside the UK

We identified ten papers detailing 11 case reports of EC poisoning outside the UK (Table 17).
Accidental exposure

Five cases described accidental exposure to e-liquid. In two of these cases the e-liquid was mistaken for a medication. In one case report a parent gave 5mL of e-liquid to their 15-month old child mistaking it for cold medicine (214). A second case was of a parent who had prepared and stored e-liquid in an old liquid ibuprofen bottle. They then mistakenly gave 10mL of e-liquid to their six-year-old child believing it to be ibuprofen (215). In other cases, children were reported to have ingested e-liquid from bottles that had no safety cap or child resistant lid (216, 217) one of these incidents resulted in death (216) (Table 17).

Intentional exposure to e-liquid and exposures of uncertain intent

Three cases involved intentional use of e-liquid in a suicide attempt. One reported IV injection of 4mL of 32mg/mL liquid. The patient survived following medical intervention (218). Another case involved subcutaneous injection of between 100 and 400mL e-liquid of uncertain strength resulting in a fatality (219). The third case involved oral ingestion of e-liquid of unknown quantity or strength also, resulting in a fatality (220). An additional three case reports, two of which were fatal, were uncertain about whether the ingestion was intentional or accidental (218, 221, 222) (Table 17).
Table 17: Non–UK e-liquid poisoning case studies from the peer reviewed literature

<table>
<thead>
<tr>
<th>Author, Publication year, country</th>
<th>Number of cases</th>
<th>Gender</th>
<th>Age</th>
<th>Type of liquid/container</th>
<th>Storage</th>
<th>Intent</th>
<th>Route</th>
<th>Outcome/symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bartschat, 2015(222) Germany</td>
<td>1</td>
<td>Male</td>
<td>34</td>
<td>Three empty 50mL vials of e-liquid were found. Bottles marked as 72mg/mL</td>
<td>In bedroom; liquids ordered online</td>
<td>Inconclusive.</td>
<td>Oral</td>
<td>Fatal</td>
</tr>
<tr>
<td>Chen, 2015(220) US</td>
<td>1</td>
<td>Female</td>
<td>24</td>
<td>Two empty 15mL vials of concentrated liquid nicotine (100mg/mL) were found</td>
<td>Not stated</td>
<td>Intentional suicide attempt</td>
<td>Oral</td>
<td>Fatal</td>
</tr>
<tr>
<td>Eggleston, 2016(216) US</td>
<td>1</td>
<td>Male</td>
<td>18 months</td>
<td>100mg/mL nicotine bottle size not stated. In an uncapped, non-child-resistant container</td>
<td>Not stated</td>
<td>Accidental</td>
<td>Oral</td>
<td>Fatal</td>
</tr>
<tr>
<td>Gill, 2015(217) Canada</td>
<td>1</td>
<td>Female</td>
<td>2</td>
<td>One 60mL bottle over 3/4s full was found containing 24 mg/mL nicotine. Liquid was grape flavoured; the bottle was similar to an eye dropper, had no safety cap and had cartoon monkeys on it</td>
<td>Not stated - but the toddler was found with the bottle in her hand</td>
<td>Accidental</td>
<td>Oral</td>
<td>Patient vomited for 30 minutes</td>
</tr>
<tr>
<td>Lam, 2017(223) China</td>
<td>1</td>
<td>Male</td>
<td>24</td>
<td>A nicotine free flavoured mix, with liquid from an unmarked bottle purchased online as &quot;liquid cannabis&quot;. The patient reported to have ingested two drops.</td>
<td>Not stated</td>
<td>Accidental</td>
<td>Oral</td>
<td>Acute confusion, agitation, visual hallucinations, rapid irregular heart rhythm</td>
</tr>
<tr>
<td>Noble, 2017(215) US</td>
<td>1</td>
<td>Female</td>
<td>6</td>
<td>E-liquid was stored in an ibuprofen container. The patient was given 10mL of e-liquid which was analysed and found to be 70.3mg/mL nicotine - pH 8.97.</td>
<td>In the fridge (in a liquid ibuprofen bottle having been mixed at home)</td>
<td>Accidental</td>
<td>Oral</td>
<td>Vomiting, sweating, visual disturbance, muscle twitching, incontinence and brief loss of consciousness</td>
</tr>
<tr>
<td>Author, Publication year, country</td>
<td>Number of cases</td>
<td>Gender</td>
<td>Age</td>
<td>Type of liquid/container</td>
<td>Storage</td>
<td>Intent</td>
<td>Route</td>
<td>Outcome/symptoms</td>
</tr>
<tr>
<td>----------------------------------</td>
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<td>-----------------</td>
</tr>
<tr>
<td>Rasanen, 2017(219) Finland</td>
<td>1</td>
<td>Female</td>
<td>29</td>
<td>Patient injected between 100 and 400 mg of e-liquid of undisclosed strength. This was combined with an undisclosed intake of diazepam and alcohol.</td>
<td>Not stated</td>
<td>Intentional suicide attempt</td>
<td>Subcutaneous injection</td>
<td>Fatal</td>
</tr>
<tr>
<td>Seo, 2016(214) South Korea</td>
<td>1</td>
<td>Female</td>
<td>15 months</td>
<td>5mL of liquid nicotine, (10mg/mL); the e-liquid was mistaken for cold medicine.</td>
<td>Not stated</td>
<td>Accidental</td>
<td>Oral</td>
<td>Fatal</td>
</tr>
<tr>
<td>Sommerfeld, 2016(218) Poland</td>
<td>2</td>
<td>Female</td>
<td>21</td>
<td>The patient drank 30mL e-liquid with a concentration of 12mg/mL (12.4mg/mL on analysis)</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Oral</td>
<td>Vomited profusely 15 minutes after ingestion. Abdominal pain, motor agitation, anxiety and difficulty breathing. Low pulse and blood pressure. The patient returned to normal after 12 hours and was discharged after 40 hours.</td>
</tr>
<tr>
<td>Sommerfeld, 2016 Poland</td>
<td></td>
<td>Male</td>
<td>32</td>
<td>32mg/mL nicotine (32.2mg/mL on analysis). Injected approx. 4mL.</td>
<td>Not stated</td>
<td>Intentional suicide attempt</td>
<td>IV Injection</td>
<td>Abnormal slow breathing and loss of consciousness after approx. 1hr</td>
</tr>
<tr>
<td>You, 2016(221) South Korea</td>
<td>1</td>
<td>Male</td>
<td>39</td>
<td>EC with liquid bottle was found. 7.2mg/mL</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Oral</td>
<td>Fatal</td>
</tr>
</tbody>
</table>
Review of data from poison centres outside the UK

The literature review identified six articles of EC incidents from poison treatment centres, all based outside the UK (Table 18). Five articles were from the US and one was from the EU (this study did not analyse any data from UK poison centres). Four articles reported EC poisoning for all age groups and two focused on EC poisoning events in children. Three articles from the US reported activity at a regional level, and two provided national statistics (224, 225). Accordingly, some poisoning incidences may contribute to both regional and national reports and so caution must be used when comparing or combining these data.

In reports that included all age groups, there were 3,609 incidences reported in children aged five or under compared to 2,755 in all other age ranges. These reports covered all of the US, as well as ten EU member states; each report included data from between 3 and 5 years. Most of these poisoning events were accidental; however intentional overdose and self-harm incidents were also reported. Intentional incidents accounted for 5 to 18% of the total number of EC poisonings where reported. The most common route of exposure was ingestion followed by inhalation, with these making up over three quarters of events in all reports. Dermal, ocular and “other” routes of exposure were also reported. The most commonly reported side-effect was vomiting, with the following adverse health effects also reported: drowsiness, tachycardia, agitation, dizziness, headache, eye pain, red eye, conjunctivitis, blurred vision, corneal abrasion, lethargy, throat conditions, abdominal conditions, diarrhoea, breathing conditions and tremor. There were two fatalities (224), one accidental ingestion of e-liquid by a child aged under five, and one suicide attempt involving injection of e-liquid.

In the two studies that focused specifically on children, over half of the events reported by Forrester (226) and Kamboj and colleagues (225) involved children under two years old, with marginally more incidents attributed to males in both studies. Here ingestion was again the most common route of administration accounting for 93% (Forrester) and 82% (Kamboj and colleagues) of cases, with low levels (<5%) reported for dermal, inhalation and ocular routes. Vomiting was the most common side-effect, with other adverse health effects including coughing and choking, eye pain, respiratory arrest, seizures, and tachycardia. Forrester and colleagues reported one “major effect”; Kamboj and colleagues reported five “major effects” and one fatality where a one year old accessed an open refill container. Kamboj compared this to two “major effects” and no deaths from tobacco cigarette poisonings during the same period, noting that overall the number of EC poisonings in children was less than a quarter of the number of poisonings from cigarettes during the same period.
<table>
<thead>
<tr>
<th>Article</th>
<th>Location and date range</th>
<th>Proportion by age (n)¹</th>
<th>EC n</th>
<th>Cigarettes n</th>
<th>Gender</th>
<th>Intent²</th>
<th>Data source</th>
<th>Route of administration %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chatham Stephens et al., 2016 (224)</td>
<td>US 2010-2014</td>
<td>0-5 = 58% (3,341)</td>
<td>5,807</td>
<td>20,372</td>
<td>54% male</td>
<td>Not reported</td>
<td>Calls to the US national repository and surveillance system</td>
<td>Ingestion = 65.8% Inhalation/nasal = 11.0% Eye = 8.6% Multiple routes = 8% Skin = 6.5% Ear = 0.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6-10 = 1.9% (108)</td>
<td></td>
<td></td>
<td>46% female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>11-19 = 5.5% (314)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20+ = 34.7% (2,001)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ordonez et al., 2015 (227)</td>
<td>Texas, US 2009-2014</td>
<td>0 – 5 = 53% (119)</td>
<td>225</td>
<td>1,893</td>
<td>49% male</td>
<td>87% unintentional 5% intentional</td>
<td>Exposures reported to the Texas Poison Center network</td>
<td>Ingestion = 78% Multiple routes = 10% Inhalation = 9% Dermal = 8% Ocular = 4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6-19 – 6% (13)</td>
<td></td>
<td></td>
<td>51% female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20+ = 41% (93)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Weiss et al., 2016 (228)</td>
<td>Wisconsin, US 2010-2015</td>
<td>0 – 5 = 58.2% (57)</td>
<td>98</td>
<td>671</td>
<td>Not provided</td>
<td>86.7% unintentional 8.1% intentional</td>
<td>Calls to Wisconsin Poison Centre</td>
<td>Ingestion = 66.3% Inhalation = 14.3% Ocular = 6.1% Dermal = 2.0% Other = 9.3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 – 19 = 11.2% (11)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20+ = 30.6% (30)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vardavas et al., 2017 (229)</td>
<td>Ten EU Member states 2012-2015</td>
<td>0 – 5 = 33.2% (92)</td>
<td>277</td>
<td>N/A</td>
<td>51% male</td>
<td>71.3% unintentional 17.8% intentional</td>
<td>Data from poison information centres from ten EU States</td>
<td>Ingestion = 67.5% Respiratory = 16.6% Dermal = 9.0% Ocular = 7.6% Other = 2.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 – 18 = 9.8% (27)</td>
<td></td>
<td></td>
<td>49% female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>19+ = 57.0% (158)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Article</td>
<td>Location and date range</td>
<td>Age range~</td>
<td>EC n</td>
<td>Cigarettes n</td>
<td>Gender</td>
<td>Intent*</td>
<td>Data source</td>
<td>Route of administration</td>
</tr>
<tr>
<td>----------------------</td>
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<td>------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Forrester, 2015</td>
<td>Texas, US 2010-2014</td>
<td>0 = 8.9%  (18) 1 = 35.2%  (64) 2 = 38.5%  (85) 3 = 11.8%  (28) 4 = 3.9%  (6) 5 = 1.6%  (3)</td>
<td>203</td>
<td>N/A</td>
<td>51.2% male 48.8% females</td>
<td>All accidental</td>
<td>Exposures reported to the Texas Poison Center network concerning children under five years old</td>
<td>All alone or in combination</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ingestion = 93.1%</td>
<td>Ingestion = 93.1%</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Dermal = 11.3%</td>
<td>Dermal = 11.3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ocular = 3.0%</td>
<td>Ocular = 3.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inhalation = 2.0%</td>
<td>Inhalation = 2.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Multiple routes = 9.9%</td>
<td>Multiple routes = 9.9%</td>
</tr>
<tr>
<td>Kamboj et al., 2016</td>
<td>US 2012-2015</td>
<td>0 = 8.9%  (267) 1 = 35.2%  (1,452) 2 = 38.5%  (1,591) 3 = 11.8%  (487) 4 = 3.9%  (161) 5 = 1.6%  (67)</td>
<td>4,128</td>
<td>17,512</td>
<td>55.2% Male 44.6% Female 0.2% Unknown</td>
<td>All accidental</td>
<td>NPDS The National Poison Data System holds data on calls to all US poison control centres</td>
<td>Ingestion = 81.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dermal = 9.7%</td>
<td>Dermal = 9.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inhalation/nasal = 3.3%</td>
<td>Inhalation/nasal = 3.3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ocular = 1.6%</td>
<td>Ocular = 1.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Other = 0.5%</td>
<td>Other = 0.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Unknown = 0.1%</td>
<td>Unknown = 0.1%</td>
</tr>
</tbody>
</table>

1 Total calls may differ from sum of ages as age was not always recorded. 2 Intent of all events not known so percentages do not always combine to make 100
EC fires and explosions

EC along with many other personal and portable electrical appliances use rechargeable lithium-ion batteries. In common with all types of batteries, lithium-ion batteries can fail; this is usually typified by a slow decline in performance to the point where the battery needs replacing. On rare occasions, a battery may fail by discharging all its stored energy at once. This can be triggered by mechanical damage, exposure to extreme heat, unsafe charging, short-circuiting or by design and manufacturing faults within the battery. This type of immediate failure is known as “thermal runaway” and can occur in all battery types (230). When thermal runaway occurs, the pressure and temperature of the battery increases and can cause the battery to vent flammable gasses at high pressure (231). This can cause the battery and device in which it is stored to be propelled at high velocity. This has the potential to be more extreme in lithium-ion batteries than in other types of batteries because of the large amount of energy they can store. The immediate and dramatic nature of such events means that they are often given a high media profile (208-210). Lithium-ion batteries are commonly used in consumer electronics and although their instability and potential for fire is rare, it has been documented in other products such as mobile phones (232). It is because of the use of lithium-ion batteries that we sought to compare EC fires/explosions with those attributed to mobile phones.

This section of the chapter summarises data from FOI requests made by the authors to UK fire rescue services and burn treatment centres as described in Chapter 2. We will also summarise the peer reviewed literature published since January 2015 on EC fires, burns and explosions.

Data from individual UK Fire Rescue Services

Forty-nine fire rescue services responded to the FOI request described in Chapter 2. Six were unable to provide any data, citing high costs or that the data requested were not available. Data on fires and false alarms attributed to EC were available for 41 fire rescue services (Figure 29); and data on both EC and mobile phone incidents from 2015 to 2017 were available for 38 fire rescue services (Figure 30). For 2017 data, fire rescue services reported data that was available at the time of the FOI request (August 2017).

Call outs for EC related fires increased from 2015 to 2016, with 93% of this increase attributed to false alarms. In 2016 (the most recent full year data) fire services included in this analysis recorded a total of 269 call outs comprising 202 false alarms and 67 fires. There were nine casualties reported in 2015, 11 in 2016 and four in the data available for 2017. No fatalities were recorded in the data available between 2015 and 2017.
Figure 29: EC fires and false alarms recorded by 41 fire rescue services 2015-2017

Figure 30: Fire attributable to EC and mobile phones for 38 fire services 2015-2017

Data on EC and mobile phones from 2015 to 2017 were provided by 38 fire rescue services (Figure 30). False alarms were excluded from this analysis because EC can trigger false alarms by either observers mistaking the vapour for smoke, or by the vapour triggering fire detection mechanisms (correspondence to the authors from Tyne and Wear, Royal Berkshire, and East Sussex Fire and Rescue Services). Mobile phones do not cause false alarms in these ways and so comparisons of false alarms between devices are not appropriate in this context. There were 151 fires related to EC
and 84 related to mobile phones between 2015 and 2017, and no fatalities recorded for either EC or mobile phones in this analysis.

**National fire statistics**

National data on fires attributed to smokers’ materials are available from official Home Office statistics (25). These are drawn from all 52 fire rescue services and from mandatory recording procedures which do not apply to EC, so are not directly comparable with the FOI-F data presented above but provide useful context.

In the UK in 2015/16 there were 3,608 fires caused by smokers’ materials causing 584 non-fatal casualties and 77 fatalities. In 2016/17 there were 3,156 fires caused by smokers’ materials causing 479 non-fatal casualties and 68 fatalities.

**London fire brigade**

In their response to the FOI request, London Fire Rescue Service volunteered additional data on both EC and cigarettes enabling a direct comparison of EC and cigarette data from a single service. It is important to note that these data was used in the FOI analyses above and will have also fed into the national data in the same time period for EC.

Table 19 compares fires attributed to EC and to smokers’ materials in London between 2015 and August 2017. London Fire Rescue Service reported 3,527 fires attributed to smokers’ materials compared to 13 attributed to EC. Cigarettes were associated with 395 injuries and 44 fatalities compared to no injuries or fatalities recorded in the same time period for EC.

**Table 19: Fires recorded in London**

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>2015</th>
<th>2016</th>
<th>2017 (Available data)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC</td>
<td>Smoking related</td>
<td>EC</td>
<td>Smoking related</td>
</tr>
<tr>
<td>Total Fires</td>
<td>13</td>
<td>3,527</td>
<td>4</td>
<td>1,346</td>
</tr>
<tr>
<td>Injuries</td>
<td>0</td>
<td>395</td>
<td>0</td>
<td>130</td>
</tr>
<tr>
<td>Fatalities</td>
<td>0</td>
<td>44</td>
<td>0</td>
<td>14</td>
</tr>
</tbody>
</table>

**Limitations**

The FOI-F data has considerable limitations. Recording of EC as the cause of fire is not mandatory, and requires use of a free-text box. The reliance on searching a free text box for EC events means that events may be excluded if they are misspelled or
abbreviated. The numbers reported from different services were varied. For example, one service reported a nil return against our criteria, where another reported 79 call outs indicating the potential for a wide range in recording practices across fire services in the UK. This is also reflected in the discrepancies between Figure 29 and Figure 30 which include data from different numbers of fire services.

There are no data sources that are sufficient to determine the prevalence of EC poisonings fires or explosions in the UK given that such questions are not included in population wide surveys. Individual cases within the data presented here are confidential and cannot be identified. It is therefore possible for single incidents to be reported to the NPIS and to be written up as a case study and hence be included more than once in this summary. Similarly, there may be potential overlap between regional and national poison centre reports in the US. It is also likely that these data underestimate incidences of poisonings, fires and explosions attributable to EC. Not all incidences are reported to health, fire or medical services, and incidences that are reported may not always be recorded as related to EC.

Case reports concerning injury from fires and explosions

We reviewed the literature on injuries from EC fires and explosions following the protocol outlined in Chapter 2. The search identified 25 articles, three of which are case reports or case series from the UK and 21 of which were non-UK case reports or case series. There were three additional articles from the international literature, one was a review of EC fires and explosions in the US using information reported to federal agencies, and two were retrospective audits of referrals to burn centres.

Case reports originating from the UK

We identified three articles describing six case studies of EC related burns in the UK (233-235) (Table 20). All patients were male and their average age was 33 years. In five cases, patients sustained burn injuries as a result of an EC exploding in their trouser pocket. One of these reported having coins in the same pocket as the EC. One case occurred while the EC was charging.

Injuries included superficial partial thickness and mixed depth thermal burns covering 1-7% of the total body surface area; injuries occurred to the lower extremities (foot, thigh, genitals) and hands, one case included alkali chemical burns from the lithium battery. Treatment included wound management with one person needing a skin graft. In addition to describing three cases, Arnoult and colleagues (233) included information about a further nine male patients aged 24-63 who sustained superficial partial thickness and mixed depth thigh burn injuries from EC batteries, although information about the context and cause of these injuries was not included.
Case reports originating outside the UK

We identified 21 papers describing 43 cases from outside the UK (18 in the US, one each from Canada, Germany and Malaysia) (see table in appendix). Forty-one patients were male and two were female and their average age was 29 years. Twenty-three cases described patients who had sustained injuries as a result of an EC (and/or EC battery) exploding while being carried in a trouser pocket; four of which reported they were carrying keys and/or coins in their pocket at the time of the explosion. There were 13 explosions that occurred when the EC device was in the patient’s mouth, four while holding it, one while modifying their device and one during a motorcycle accident.

Injuries included thermal and chemical burns to the face, hands, thighs, buttocks and genitals; puncture wounds, fractures, loss of teeth and eye injuries. Thirty-six cases resulted in burn injury; the mean total surface area of the burn was 6% (range 0.5% to 27.5%) in 27 cases. Treatment included wound management, dental and maxillofacial surgery; 13 patients required a skin graft.
### Table 20: UK case reports concerning injuries caused by EC explosion

<table>
<thead>
<tr>
<th>Author, year and setting</th>
<th>Number of cases</th>
<th>Gender</th>
<th>Age</th>
<th>Circumstance of EC explosion</th>
<th>Nature of injury</th>
<th>Treatment</th>
<th>Details of EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arnaout et al., 2017 (233), UK</td>
<td>3</td>
<td>Male</td>
<td>22</td>
<td>While charging</td>
<td>1% TSBA superficial partial thickness burns to hands and sole of right foot</td>
<td>Wound management</td>
<td>Rechargeable device</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>22</td>
<td>While in right trouser pocket</td>
<td>1% TSBA mixed depth burn to right thigh and scrotum, superficial, partial thickness burns to left hand</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>49</td>
<td>While in trouser pocket with coins (lithium battery only)</td>
<td>7% TBSA, superficial partial thickness burns to right thigh</td>
<td>Wound management</td>
<td>Rechargeable device</td>
</tr>
<tr>
<td>Nicoll et al., 2016 (234), UK</td>
<td>2</td>
<td>Male</td>
<td>39</td>
<td>While in trouser pocket (lithium battery only)</td>
<td>4% TSBA, superficial partial thickness burns to his right thigh, minor superficial burns to the right hand</td>
<td>Skin graft</td>
<td>EC showed no sign of damage before explosion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>30</td>
<td>While in trouser pocket (lithium battery only)</td>
<td>3% superficial partial thickness burns to his right thigh. Superficial burns were also sustained to the right hand.</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td>Walsh et al., 2016 (235), UK</td>
<td>1</td>
<td>Male</td>
<td>35</td>
<td>While in right trouser pocket (with keys)</td>
<td>1.5% Total Body Surface Area, mixed depth burn to right thigh</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
</tbody>
</table>
Additional international literature

Rudy and Durmowitz (236) reviewed EC fires and explosions in the US. They searched media outlets, five US federal agencies and the scientific literature, identifying 92 events related to EC overheating, catching fire or exploding. There were 45 incidents involving injury to 47 people, and 67 incidents involved property damage. The majority of injuries sustained were burns (thermal = 33, chemical = 4) and the remainder were blast injuries (fractures and lacerations to the upper extremities). Most incidents happened during charging (n=44) with fewer occurring while inhaling or between puffs (n=20); the remainder occurred during transportation or storage. It was suggested in some occurrences that EC user actions may have contributed to the malfunction, for example when using a substitution charger, charging a non-rechargeable battery, using a recalled or incorrect battery or using an EC near oxygen containers. This review was limited by inconsistent and incomplete primary reports, lack of device identifiers and device damage, reliance of voluntary reporting to agencies and the possibility of undetected duplicate cases reported to Federal agencies and the media.

A retrospective case note audit of referrals to three burn centres in California, US, (237) identified 29 patients who had sustained injuries caused by EC explosions between February 2015 and July 2016 as well as one patient in 2014. Twenty-four of the 30 patients (80%) were male and their average age was 30 years. Explosion of a fully assembled EC was described in 16 cases and an isolated battery in 10 cases; with the EC status unclear in the remaining four cases. Patients sustained injuries to the lower part of the body (legs and genitalia) and upper part (hands, torso and face). The burn size ranged from less than 1 to 8% of the total body surface area, with a mean total body surface area of 4%. Nine patients (30%) received surgical intervention.

In a retrospective case note audit of referrals to one burn centre in California (a different burn centre to the one reported by Ramirez and colleagues (237)), US, Toy and colleagues (238) identified 24 male patients and one female patient who sustained a burn injury from an EC. Their average age was 34 years. The majority (72%) of burn injuries occurred when the EC (and/or EC battery) exploded in the patient's pocket, the remainder while in use. Thigh and genital areas were the most commonly affected areas of the body. The area of burns averaged 4.1% total body surface area with a range of 1% to 9% and five patients required a skin graft.

Limitations of case reports

Case reports and case series have long been accepted as a way to present unusual, uncontrolled observations regarding symptoms, clinical findings and novel treatments and are often written to educate other clinicians. However, as a methodology, they are limited; they are not chosen from representative population samples and cannot be generalised, they rely on the patients’ recall of events and the observer’s subjectivity.
can bias the quality and interpretation of the observation (ie information bias). Case reports often deal with rare and atypical events and can be easily over-interpreted or misinterpreted, as they often have an emotional appeal on readers. In the case of EC the above information cannot therefore provide information on incidence or prevalence of explosions and cannot be generalised to the current 2.9 million EC users in the UK. Although explosion events are very rare, the case reports can alert us to precautions that can be taken to minimise further events and guide clinical treatment decisions.

Conclusions

Key findings

Poisonings

- There are recorded cases of poisoning from e-liquid in the UK. These have predominantly involved accidental ingestion with fewer incidences of other routes (eg ocular or dermal) of exposure.
- Intentional poisoning using e-liquids has been reported in self-harm and suicide attempts.
- Toxic effects from EC poisoning are usually short in duration and of minimal severity; severe cases and fatalities, while very rare, have been recorded.
- EC poisonings reported to medical centres most commonly occur in children under five years old. Toxic effects for this age group are usually short in duration and non-severe. Fatalities, while very rare, have also been recorded in this age group.
- Incidents of poisoning in children are often preventable and have involved liquids stored non-securely, in unmarked containers or in containers without safety caps.

Fires

- EC fires are recorded at the discretion of individual fire rescue services in the UK. Information provided to us through a FOI request suggest that, where recorded, they occur in low numbers and are vastly outweighed by fires caused by smokers’ materials. There were no fatalities from fires caused by EC in the reporting period.
- EC and/or their batteries are recorded as the cause of fires by UK fire rescue services. The root cause of EC fires is likely to be through a malfunctioning lithium-ion battery.
Explosions

- Exploding EC can cause severe burns and injuries that require intensive and prolonged medical treatment especially when they explode in users’ hands, pockets or mouths.
- Incidents are very rare. The cause is uncertain but appears to be related to malfunctioning lithium-ion batteries.

Implications

Research

- Research is required on the prevalence of e-liquid poisoning, fires and explosions caused by EC in England. This will require some synthesis of existing datasets.
- Research on presence and effectiveness of safety features and instructions should be part of a future review of the EU TPD.

Policy and practice

- Monitoring of fires caused by EC should be recorded by Fire Rescue Services in a mandatory way (similar to “cooking appliances”, “smokers’ materials” and “other electrical appliances”) and should not continue to rely on free text entry.
- EC can trigger fire/smoke detectors and therefore consumers should be advised to move away from detectors when using them.
- It is too early to assess the impact of the EU TPD in reducing poisonings, fires or explosions, or whether further regulations are needed. Therefore, continued monitoring is required to assess effectiveness of EU TPD regulations (such as childproof containers), in reducing accidental ingestion of e-liquid.
- Regulations should require that labelling on e-liquid bottles advises customers to store products away from similar looking medicines such as eye drops, ear drops and children’s medicine.
- Regulations should require that labelling reinforces advice on the safe storage and transportation of batteries used by EC. For example, advice should be given that EC should not be carried in pockets with coins, keys or other metallic objects, and that the correct charger should always be used.
9 Health risks of EC

Introduction

The 2015 PHE report (5) reviewed studies that had raised concerns about potential health risks resulting from using EC. It identified that most toxins responsible for health damage from smoking are absent in EC aerosol and that those that are present are there at much lower levels (below 5% and mostly below 1%) than in tobacco cigarettes. Regarding ingredients specific to EC, no significant health risks had been identified at the time. We therefore concluded that the new studies did not demonstrate substantial new risks and thus did not change the conclusions of previous reviews that EC were substantially less harmful than smoking (4). We considered a 5% residual risk to be a cautious estimate allowing for uncertainty over risks in the longer term. Since the 2015 PHE report, the Royal College of Physicians (RCP) has also reviewed evidence on the safety of EC and concluded that they were “unlikely to exceed 5% of the harm from smoking tobacco”. Over the past two years, many new studies were published of which several raised concerns regarding EC safety.

This chapter reviews the new evidence to update conclusions on potential health risks from using EC. In this chapter, we focus on studies that provide new relevant information, EC adverse events from the MHRA Yellow Card reporting system, reviews and high profile studies. We start with a brief consideration of approaches to assess health risks of vaping and a summary of the adverse reactions data. Following this, the Chapter organises the new findings into thematic sections according to the safety concerns they cover, beginning with overall effects and followed by studies concerning propylene glycol and glycerine, aldehydes, flavours, metals and passive vaping. Nicotine was discussed in Chapter 4, therefore the discussion below focuses on other EC constituents. Within each section, where appropriate, we report the different categories of studies including: animal and cell studies; studies of the chemical composition of EC aerosol; and, studies of toxin intake and vaping effects in EC users. As EC are a product that is competing with tobacco cigarettes, the focus of the review is mainly on risks of vaping compared to risks of smoking. In addition, given we believe that biomarkers of exposure might be particularly informative at this time, we include a more detailed analysis of four candidate biomarkers of exposure, an analysis not yet peer reviewed but which brings together different study findings and is therefore relevant. Finally, we have an additional section at the end in which we explore the misreporting of some studies and possible reasons why this may be happening.
Considerations for assessing the health risks of EC

There are different approaches to assessing risks of vaping, with each posing certain methodological challenges. The weakest evidence comes from animal and cell studies, because their relevance for estimating effects of vaping for human exposure is unclear. In addition, it can be difficult to emulate realistic vaping conditions and generate realistic dosing of EC aerosol. However, such studies can provide indications of which constituents of EC aerosol human research should focus on. Another approach is to look at the chemical composition of EC aerosol. Such studies are essential and can obviously generate important information, but they too can suffer from using EC settings that generate unrealistic exposure.

The strongest evidence for relative risks of EC and tobacco cigarettes will eventually come from actual health outcomes in cohorts of EC users compared to cohorts of smokers and non-smokers. However, this will take time. EC prevalence has only been at a measurable level since about 2011/12, not long enough to measure long term impacts of vaping on health. There is also the issue that most EC users are former or current smokers and smoking-related health risks can persist for a long time, therefore assessment of harm/risk from EC has to account for the possible damage related to current or past smoking. Cohort studies will need to include ex-smokers quitting with different methods as well as those who switched to vaping, those who carry on smoking, and those who never smoked.

An additional approach is to study switching to EC versus quitting smoking among smokers with established smoking-related disease – these studies might expose any benefits or risks sooner than in studies largely of healthy smokers. Reported adverse reactions to EC can also be assessed from research studies of EC users, and any mandatory reporting schemes.

An alternative option is to assess biomarkers of potential or actual harm, such as lung function, premalignant lesions or chromosomal aberrations. Here, changes might occur more quickly and before health outcomes can be measured, thereby ameliorating problems with time lags. It does not, however, necessarily help to discriminate between the effects of smoking and the effects of EC use among people who have used both. Special attention needs to be given to the extent to which any acute effects indicated by biomarkers translate into chronic effects and relevant health outcomes.

A further option is to look at biomarkers of exposure such as measuring internal exposure to eg constituents of tobacco smoke or EC aerosol which can be measured in bodily fluids – one such example are tobacco specific nitrosamines which can be measured in urine samples. This has the benefit of accumulating evidence quickly about short term and reversible harms. Such biomarkers must be reasonably specific to the exposure and related to a disease to provide evidence of harm. Advantages of
using biomarkers of exposure include that they are less affected by prior exposure to smoking and they can be observed in users of the products.

Adverse reactions

MHRA Yellow Card Scheme

No population-based studies on adverse outcomes of EC use were identified in the search. Instead, we report data from the Yellow Card Scheme. Run by the MHRA, is a reporting system to record suspected adverse reactions to medicines from health professionals, manufacturers or members of the public. To coincide with implementation of the EU TPD 2014/14/EU (see Chapter 3), on 20 May 2016 the MHRA extended its Yellow Card reporting system to include EC and e-liquids, although some reports had been received prior to this date. Consumers and healthcare professionals can report both side-effects and product safety concerns. A report can be made when a medicine (or EC) is suspected to have led to an adverse reaction. The person making the report does not need proof that the medicine/EC caused the symptoms, only to suspect that it may have, or that there was a close temporal relationship to the administration of the medicine/EC. The MHRA provided us with anonymised reports for spontaneous suspected adverse reactions for EC along with details of spontaneous suspected adverse drug reactions for Nicotine Replacement Therapy (NRT) products for context. Due to differences in adverse reaction reporting requirements between marketing authorisation holders of nicotine containing licensed medicines and EC producers it is not possible to directly compare the number of reports, therefore we have included this information for context only. Adverse reaction reporting rates are influenced by the seriousness of adverse reactions, their ease of recognition, the extent of use of a particular product, and may be stimulated by promotion and publicity about a product. There is a requirement for all medicinal products to have details of reporting to the Yellow Card Scheme in their product information; however this does not extend to EC.

A total of 37 reports were received with a suspected adverse reaction to EC between 1 January 2015 and 20 October 2017, 263 reports were received associated with a suspected adverse drug reaction to NRT during the same reporting period (Figure 31). EC reports listed 23 EC or e-liquid brands (two brands were indicated twice and it was unreported in 12 cases). The dose of e-liquid content was reported in 14 cases and ranged from 3-24mg (mean= 12.5mg). As reported in Chapter 6, there are approximately 2.9 million adult EC users in GB in 2017. In the same survey (ASH-A) in 2016 1.18% of participants responded that they had “tried NRT products and still use them” from which we can estimate that approximately 600,000 people were using NRT in GB.
It is not possible to determine from this data source if an EC or NRT caused or contributed to a suspected adverse reaction or if it was coincidental. We also do not have information if the EC user was also a smoker or if the NRT user was a smoker and/or used an EC. There may also be differences between propensity to report EC and NRT suspected adverse reactions, for example if consumers are more likely to perceive EC as a consumer product than medicinal, compared to NRT. As ECs are not subject to the same regulations around safety reporting as licensed medication there is no legal obligation for manufacturers to provide the MHRA with reports; therefore it is not possible to directly compare two different products.

Between 2015 and 2017, the 37 reports included 99 suspected adverse reactions (with many individuals reporting multiple adverse reactions such as nausea and headache). The most commonly reported adverse reaction related to gastrointestinal disturbance (n=19, eg nausea) and respiratory problems (n=17, eg cough). One report was of a non-fatal cardiac arrest. Additional data from the Yellow Card Scheme noted that this patient had a relevant cardiac history. In the same reporting period, the 263 NRT reports included 649 suspected adverse drug reactions including one report of suicide where NRT was recorded.

**Adverse reaction reports from research studies**

In the most recent Cochrane systematic review of the effect of EC on cessation (see chapter 7 for details about primary studies), Hartmann-Boyce and colleagues (171) concluded that none of the studies included in the review found that smokers who used
Evidence review of e-cigarettes and heated tobacco products 2018:
A report commissioned by Public Health England

EC for up to two years had an increased health risk compared to smokers who did not use EC. Ten studies included in the review assessed adverse effects; the findings are described narratively in the review and were not subject to a meta-analysis. In an RCT by Bullen and colleagues (189) the event rate was 0·8 events per person month in the nicotine EC group and NRT patch group, and 0·9 in placebo EC group and the difference was not significant (incidence rate ratio 1·05, 95% CI 0·82–1·34, p=0·7). In an RCT by Caponnetto (190) there was no difference in the frequency of adverse events at three or 12-month follow-up between the three groups receiving 1) an EC containing a 7.2mg nicotine cartridge for 12 weeks; 2) an EC containing a 7.2mg nicotine cartridge for six weeks and 3) a nicotine free EC for 12 weeks. The frequency of adverse events decreased significantly over time, with the exception of throat irritation. Eight cohort studies reported they assessed adverse effects though only five provided numbers and/or proportions of adverse events (189, 190, 239-243). Duration of EC use for these five studies was between one week and 6 months and the most common adverse effects reported were dry cough, mouth and throat irritation.

Overall effects of EC vapour exposure in users

In the absence of long-term use data, the RCP discussed the likely effects of EC use, in relation to the main constituents of concern. The RCP report (68) commented that most reviews raising concerns about constituents, related to their presence, rather than absolute levels which are “generally the more important determinant of toxicity”. They commented that all of the constituents identified were at lower levels than in cigarette smoke, but that long-term use of even these low levels could be problematic although “the magnitude of these risks relative to those of sustained tobacco smoking is likely to be small”.

Recent studies

Animal and cell studies

A recent study (244) exposed laboratory rats weighing around 250 grams to a variable voltage EC with a setting that is avoided by human users when using the particular device used in the study (15 Watts). The volume of exposure to the animals (6-second puffs with 5-second inter-puff interval delivered for 5 days a week for 4 weeks) was also discordant with the puffing regime observed in people who use EC. In comparison, EC users typically take puffs of under 3 seconds with 18 second inter-puff intervals (245). Also, there was no comparison with rats exposed to tobacco smoke. The authors detected a range of effects. The title of the paper (‘E-cigarettes induce toxicological effects that can raise the cancer risk’) did not mention that the study focused on animals forced to vape in these conditions, rather than human EC users. The abstract concluded ‘Our results demonstrate that exposure to e-cigs could endanger human
health, particularly among younger more vulnerable consumers’ (244), which did not appear to be borne out by the study.

Another study exposed cells to EC vapour or cigarette smoke (246) and found that EC vapour generated some damage after several weeks of exposure, while smoke killed the cells within 24 hours. The abstract did not mention the cigarette smoke results and the press release claimed that the study showed the dangers of vaping.

### Composition of EC and EC aerosol

A recent study (247) was accompanied by a press release claiming that ‘cancer-causing benzene was found in EC vapours operated at high power’. The authors did not find any benzene in vapour from cartridge-based EC that used benzoic acid (this can be transformed to benzene, but this does not seem to happen at normal vaping temperatures). They then created their own benzoic acid-containing e-liquid and submitted it to high ‘dry puff’ temperatures and this did generate benzene - albeit in levels lower than those in ambient air (248).

In a separate study (249), published data on emissions from cigarettes and EC and their cancer potencies were used to calculate lifetime cancer risk using daily consumption estimates. EC cancer potencies were largely found to be only a small fraction of those of smoking (0.4%). Where findings exceeded 1% of the risks of smoking, the relationship between formaldehyde levels and user aversion (248) suggests that they were associated with dry puffs.

### Studies with EC users

#### Biomarker data

A presentation at a meeting of American Urological Association in 2017 reported finding two out of five putative carcinogens in the urine of 12 of 13 EC users. It is not clear what the levels of the carcinogens were – only the abstract of the conference presentation was published (250) - but both chemicals (o-toluidine and 2-naphthylamine) are normally found in urine of non-smokers as well (251). Neither has been reported in EC liquid or aerosol so far, so their presence or absence remains to be verified.

A comparison was recently published of biomarkers of nicotine and a range of carcinogens and toxins - three TSNAs and 14 Volatile Organic Compounds (VOCs, including aldehydes and acrolein, a major contributor to the respiratory effects of smoking)- in the body fluids of smokers, EC users who stopped smoking, NRT users who stopped smoking, and dual users of EC or NRT and cigarettes (129). There were no differences in nicotine intake. NRT-only and EC-only users had significantly lower
levels of all biomarkers than groups that continued to smoke. The messages from this study were that: i) EC only users were comparable to NRT users in terms of exposure to the toxins and carcinogens studied; ii) dual users did not differ in toxin intake from smokers and should be encouraged to stop smoking altogether. For the latter finding, it is not known whether the dual users were heavier smokers prior to taking up EC and further research is needed to explore toxin intake across the range of dual use (eg predominantly smokers or predominantly EC users).

A recent study of smokers who switched to vaping for two weeks, supported these findings. There was no change in nicotine intake, but a substantial reduction in exposure to a range of carcinogens and toxicants (252).

Other data from switching/cessation studies

Several small sample or uncontrolled studies have suggested some benefits in smokers switching to vaping on some respiratory and other measures. Smokers who switched to vaping during the ECLAT study in Italy (Chapter 7) and who had elevated blood pressure initially lowered their systolic blood pressure compared to baseline (253). A tobacco – industry funded study randomised smokers to switch partially or completely to vaping or stop using nicotine products altogether for a period of five days (15 smokers per study condition). The study findings suggested little difference between vapers and abstainers in terms of blood pressure, heart rate, lung function (one-second forced expiratory volume and forced vital capacity), exhaled CO and nitrous oxide (254).

An uncontrolled longitudinal study of 16 smokers with asthma who switched to vaping found improvements in lung function and respiratory symptoms which were maintained up to 24 months after switching (255). This was also observed in dual users.

An on-line survey asked established EC users about any changes in the incidence of respiratory infections following their switch to vaping (256): 29% reported no change, 5% reported worsening, and 66% reported an improvement.

Other data from adolescent studies

Adolescents who tried EC were reported to have increased rates of ‘chronic bronchitic symptoms’ (257). Participants were asked about wheezing, cough, phlegm and ‘bronchitis’ (definition not provided). The unadjusted analysis suggested an association between trying an EC in the past three months and bronchitis, but this association disappeared when smoking status was controlled for. EC experimentation in the past remained associated with ‘bronchitis’ in the current year, but also with a significant decrease in wheezing.
Self-reported asthma symptoms among adolescents were associated with current EC use even after controlling for smoking within the past 30 days in one study(258). Past asthma was significantly associated with current EC use which suggests confounding. Further studies are needed in this area.

Summary

In summary, a study of cancer potencies of EC emissions suggested that these are largely less than 0.4% of smoking. There are no similar data-based estimates available for cardiovascular and lung risks. There are chemicals whose presence or absence in EC vapour remains to be assessed, but the main carcinogens and toxins that are inhaled by smokers have been detected in smokers who switched to EC use at levels that are much lower and similar to those in NRT users. Adolescents who tried vaping reported more respiratory symptoms than those who did not. Some small scale or uncontrolled studies have noted improvements in asthma and in respiratory infections in smokers who switched to vaping, but more research is needed in this area.

Propylene glycol (PG) and glycerine

Propylene glycol and glycerine, both organic compounds, are used in varying proportions to make the e-liquids for EC. The RCP report (3) summarised that in relation to both PG and glycerine, studies with animals have been generally reassuring in relation to health consequences. There was some evidence, from one study in humans, that PG was an airways irritant and a further one of a relationship between exposure in the home and asthma and rhinitis in children. Glasser (73) reported that PG and vegetable glycerine in EC liquids were not cytotoxic for any human and animal cell types. Indeed, a recent case study reported a resolution of recurrent tonsillitis in a non-smoker who started to use EC, proposing that such effects could be due to bactericidal properties of PG. It has been suggested that a controlled trial with nicotine free EC in non-smoking patients (so they are not given nicotine) with recurrent throat infections could provide more definitive answers (259).

Aldehydes

Heating PG or glycerine can release aldehydes such as formaldehyde, acrolein and acetaldehyde, which are also produced during smoking. The 2015 PHE report discussed the phenomenon of ‘dry puff’ when the e-liquid is overheated which creates an aversive taste that EC users avoid. A study published at the end of 2015 (260) which used these conditions reported that, at a maximum power setting of a variable voltage EC, the EC emitted up to 15 times more formaldehyde than tobacco cigarettes. EC users however do not vape under these conditions. The phenomenon has been compared to toasters that can burn toasts so severely that the resulting char contains a range of carcinogens, but the taste would be so aversive that people would be very
unlikely to eat it. In a recent replication of the above study, using the same apparatus and conditions, experienced EC users reported dry puffs well below the power setting at which high aldehyde levels were detected (248).

Recent studies

Composition of EC and EC aerosol

A recent study also reported very high aldehyde emissions, from an EC using a top-coil device and silica wick, operated at 3.8 and 4.8V (261). The results were unprecedented and an attempt at replication using even higher settings failed to replicate the phenomenon (262). The same settings in newer devices which do not overheat the e-liquid, generate aldehyde emissions that are much below regulatory limits and much lower than in cigarette smoke (262). This tallies with a study showing that newer EC devices that use bottom coils produce less aldehydes than earlier EC devices (263).

Another study (264) found that aldehydes in EC aerosol generated at normal settings were either absent or present at low levels, well below safety limits for cumulative exposure that is normally used for assessing exposure hazards. However, levels of one of these aldehydes, formaldehyde, exceeded a threshold (the American Conference of Governmental Industrial Hygienists acute (one inhalation) exposure) ceiling limit of 0.3 ppm (0.38mg/m3) in over 50% of the samples and the median was nearly twice as high as the ceiling limit. This appeared of concern but no comparison with smoking was provided. Smokers are commonly exposed to acute concentrations of 60-130 mg/m3, ie at least a hundred times higher (265). In addition to this, the acute exposure presented as if it was exceeding the exposure limit was in fact far below the ceiling limit. The authors’ calculation assumed that the full inhalation consists of the EC puff. In reality, 45-80mL puffs from EC get mixed with air so that the resulting 500mL inhalation dilutes the puff contents at least six-fold.

Another recent study compared tobacco smoke and six e-liquid refills and their resultant aerosol emissions (using a realistic setting and puffing regime) on a range of chemical constituents (266). The e-liquids were accurately labelled and contained none or only a very small fraction of potentially harmful chemicals including trace elements, metals, pesticides and polycyclic aromatic hydrocarbons (PAHs) compared to tobacco smoke. Compared to tobacco smoke, levels of carbonyls were <1 vs 1,540 ng/mL for acetaldehyde; none to 2.2 vs 171 ng/mL for acrolein and 0.4 to 1.5 vs 82ng/mL for formaldehyde.

Studies with EC users

One of the aldehydes, acrolein, that is considered to present a particularly strong health risk as a potent respiratory irritant, produces a specific and stable primary metabolite

(3-HPMA) and this allows estimates of its actual intake in EC users. The 2015 PHE report included studies which demonstrated lower aldehyde including acrolein levels in switchers (smoking to vaping) and dual users (267, 268). These findings have now been confirmed by further studies which have found levels in EC users that are much lower than those in smokers and similar to those in non-smokers ((252) and (129) described above).

Summary

In summary, although EC can release aldehydes and the levels can be high if the e-liquid is overheated, the overheating generates an aversive taste and this ensures that such emissions are avoided. At normal vaping temperatures, aldehyde content in EC aerosol is only a small fraction of levels inhaled by smokers.

Flavours

The RCP report summarised that flavours used in e-liquids are generally recognised as safe (GRAS) but this is in relation to eating or drinking, rather than inhalation following being heated.

One of the most commonly heard safety concerns about flavourings used in e-liquids is that flavours that contain diacetyl might cause bronchiolitis obliterans (also referred to as 'popcorn lung'), a serious disease that has been linked to the exposure to high levels of this chemical in popcorn plant workers. Diacetyl has been detected in some EC flavourings, but at hundreds of times lower levels than observed in cigarette smoke (269). Given that even at these levels, smoking is not a major risk factor for this rare disease, the diacetyl content in EC flavourings is unlikely to pose much risk. In any case though, manufacturers are now avoiding flavourings that use this. The Glasser review (73) reported that in cytotoxicity studies, cinnamon flavour was found to be the most cytotoxic when comparing different flavours. Concerns about tobacco flavoured e-liquids having potentially higher tobacco specific nitrosamine (TSNA) levels do not appear to be founded; one study found that tobacco flavoured e-liquids (sometimes made through using natural extracts of tobacco), did not have higher TSNAs but possible higher nitrate content than other e-liquids; nevertheless they were all consistently (orders of magnitude) lower than levels in tobacco smoke (270).

Recent studies

Animal and cell studies

Several in-vitro studies have examined flavourings. For example, cells which were exposed to direct contact with flavouring chemicals (not EC aerosol) for 24 hours
showed signs of damage (271). Similar results were reported with directly exposed human umbilical vein endothelial cells. Some flavourings showed some negative impact, but less than tobacco smoke, even at high EC extract concentrations (272).

In another study, bronchial epithelial cells were exposed to EC aerosol with various flavourings, tobacco smoke or air. Some flavourings in EC aerosol generated adverse effects on the cells, but again this was less than tobacco smoke (273). The actual levels of chemical constituents responsible for the effect were not established. It is not known whether EC release higher levels of relevant compounds than occupational safety limits, and this issue warrants further attention.

The exact relevance of these cell studies for human vaping is unclear. However, these types of studies can help to provide information on the relative risks of different flavourings overall, which could be used by EC users for guidance and provides information for quality standards.

Composition of EC and EC aerosol

A new concern was raised by a study that reported that e-liquid flavourings released high levels of aldehydes (274). Such levels were previously only found with dry puffs as discussed above in the section on aldehydes. In this instance, the authors reported that while flavoured e-liquids produced aldehydes, unflavoured e-liquids used with the same device settings released no aldehydes at all, suggesting that it was the flavours which were causing the aldehyde production. The report is in contrast to other studies that detected no such phenomenon (275, 276). Indeed, the Klager and colleagues (264) study reported above, looked specifically at correlations between a range of flavourings and aldehydes and detected no significant relationship.

We are aware of a recent replication of the original study using the same EC device and e-liquids. The manuscript has been submitted for publication (277). One of the flavoured liquids generated aldehydes at levels statistically higher than the unflavoured sample, but at very low levels, much below environmental safety limits and several-fold lower than in the replicated study. The replication results tally with previous studies and suggest that the earlier finding was likely to be an artefact of problems with laboratory procedures, equipment or data analysis. Further studies of effects of flavouring on aldehydes will provide definitive answers.

Summary

In summary, while no clear evidence that specific flavourings pose health risks has been identified so far, there are suggestions that inhaled chemicals in some flavourings could be a source of preventable risks. Further research on the presence and effects of inhaled flavourings is warranted.
Metals

Previous studies found several metals in EC liquid and aerosol, but at very low levels, comparable to those in nicotine inhaler, and considerably below the levels found in cigarette smoke. A comparison of the levels detected in these studies with several safety norms confirmed this (278). The RCP report (68) concluded that this was probably not a major concern because of the low levels and that they could be reduced further by manufacturing improvements. These were perceived to be unlikely to pose any risks to health.

Recent studies

Composition of EC and EC aerosol

A recent study (279) analysed metals in e-liquids removed from cartridges of five ‘cigalike’ EC brands. (The pre-filled cartridges in which e-liquid is exposed to metal continuously for weeks to months can be expected to have higher metal content than refillable tank systems). The authors presented a list of dangers associated with various metals when ingested or inhaled in large doses, but the study provided no indication of whether the levels actually detected could pose any risks. The levels were expressed in different metrics than in previous studies. Using conservative assumptions, they are concordant with previous findings and so signal very low risk. The study, however, identified one issue that is of relevance. EC products differed in metal emissions. This could be related to the age of different cartridges, but also to materials used in atomisers and coils, and requires further study.

A later study (280) confirmed that EC products differ in nickel and chromium levels released in the aerosol from the heating coil and that this is reflected in salivary and, to a lesser extent, also in urinary levels of these metals in EC users using these products. This does not necessarily signal a health risk as the metal levels were very low, with urine nickel concentrations lower than population norms. Levels of chromium (which is non-toxic apart from chromium IV that is unlikely to be generated by EC) were higher, but still in the range that could be influenced by environment and diet. As with the previous study though, the finding is informative as it suggests that manufacturing practices can and should be adopted that keep metal emissions to a minimum, and users should avoid nickel or nichrome coils.

Summary

In summary, the levels of metals identified in EC aerosol do not give rise to any significant safety concerns. However, product differences show that metal emissions,
however small, are unnecessary. EC that generate minimal metal emissions should become an industry standard.

**Passive vaping**

There is no side-stream vapour emitted from the end of EC, just the exhaled aerosol entering the atmosphere. In the 2015 PHE report, we discussed a particular concern about nicotine being deposited on surfaces raised from one study, but this did not reflect levels of vaping and had indicated very low levels; we concluded that there were no identified health risks to bystanders. Particle exposure was another concern that we discussed in the 2015 PHE report in which we concluded that it was the content of the particles, rather than their presence or size which had health implications. Given the low levels of toxins we report above in the EC aerosol, there are unlikely to be health implications. The Glasser review (73) found that second-hand vapour studies showed that non-users may be exposed to nicotine vapour but the level of exposure was low, and exposure to other compounds were also very low, or at trace or non-detectable levels when compared with second-hand smoke. Glasser and colleagues (73) however reported that it was unclear if any levels were sufficient to be of biological concern to humans and that more definitive studies were needed before conclusions about harm can be made. We discuss several new studies below.

**Recent studies**

**Composition of EC and EC aerosol**

A recent modelling of passive exposure suggested that bystanders could be exposed to aldehydes (281), but the modelling was based on the study discussed above that used a laboratory set-up generating dry puffs (261).

**Studies with EC users**

A recent study (tobacco industry funded) examined air in an experimental chamber with air exchange rate typical for office buildings where 10-11 EC users used different EC devices for four hours (282). A wide range of potential toxicants was evaluated. Negligible levels of chemicals were detected, which were much below permissible exposure limits. In addition, with regards to concerns about metals in EC aerosol reviewed above, no emissions of nickel or chromium were detected. There was also no significant increase in nicotine deposits on surfaces.

A study analysing the exhaled breath of EC users reported that of chemicals inhaled, only 6% of nicotine, 8% of PG and 16% of glycerine was exhaled (79). This therefore suggests that 94% of nicotine is retained by EC users. Indeed, a study that examined
surface samples from homes of EC users found no difference in nicotine levels compared to homes of non-tobacco users (283).

In relation to particles, an extensive study measured indoor air quality in 193 households with children under 14 to assess the impact of a range of occupant activities and home characteristics (284). The study included week-long airborne particle measurements. Cigarette and marijuana smoking as well as other activities such as burning candles and variables such as home type affected mean weekly particle counts, but vaping (present in 43 out of 193 homes) had no discernible effect.

Concentrations of vaping-related chemicals in the air of a vape shop were well below occupational exposure limits and nicotine was undetectable (285). Other unpublished reports on the results of checking air quality in vape shops by California Department of Public Health and by the National Institute for Occupational Safety and Health in Cincinnati reported that even in a shop with relatively poor ventilation where 13 customers used EC during the shift, creating a visible cloud, a range of flavouring compounds and formaldehyde were all below the lowest occupational exposure limit and nicotine was virtually undetectable (285).

Summary

In summary, to date there have been no identified health risks of passive vaping to bystanders.

Comparison of studies assessing biomarkers for exposure

In this section we summarise evidence from twelve, mostly new, studies, with different methodologies and designs (Table 21), that evaluated differences in four candidate biomarkers for exposure between smokers and EC users (286). The participants varied across the studies, in some cases smokers who used EC for just a few hours, in others, smokers who had switched to EC for a year or more. Unadjusted raw data was used and the amount for EC users was divided by the amount observed for smokers, to give a percentage reduction compared with smoking. Levels observed in people not smoking (either smokers abstaining or never-smokers) are taken into account only in the final section. Four of the studies were funded by the manufacturer of ECs tested, presenting a conflict of interest which may bias findings. It should be emphasised that this assessment has not been peer reviewed but a version of it was presented at a recent conference (286).
Table 21. Study characteristics

<table>
<thead>
<tr>
<th>Authors</th>
<th>Design</th>
<th>Duration</th>
<th>Population</th>
<th>Groups/comparisons</th>
<th>Funding</th>
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<td>RCT</td>
<td>12 weeks</td>
<td>Smokers, n=387</td>
<td>Switched to EC use, n=286</td>
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<td>Continued cigarette smoking, n=101</td>
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<td>(Part in confinement&lt;sup&gt;1&lt;/sup&gt;)</td>
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<td>D’Ruiz et al, 2016 (288)</td>
<td>RCT</td>
<td>5 days</td>
<td>Smokers, n=105</td>
<td>Switched to EC use, n=45</td>
<td>Fontem Ventures B.V., subsidiary of Imperial Brands plc</td>
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<td>Goniewicz et al, 2017 (252)</td>
<td>Longitudinal cohort</td>
<td>2 weeks</td>
<td>Smokers, n=20</td>
<td>Before (baseline) and after encouragement to switch to using EC (provided)</td>
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<td>Hecht et al, 2015&lt;sup&gt;H&lt;/sup&gt; (267)</td>
<td>Historical comparison</td>
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<td>n=28&lt;sup&gt;H&lt;/sup&gt; +27&lt;sup&gt;K&lt;/sup&gt; Smokers, n=224&lt;sup&gt;H&lt;/sup&gt; +38&lt;sup&gt;K&lt;/sup&gt;</td>
<td>National Cancer Institute at the National Institutes of Health, US</td>
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<td>EC users (regularly for ≥6 months and ≤5 cigarettes per week), smokers, non-smokers, n=39</td>
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<td>National Institutes of Health, US; Foods and Drug Administration, Center for Tobacco Products, US</td>
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<td>McRobbie et al, 2015 (268)</td>
<td>Longitudinal cohort</td>
<td>4 weeks</td>
<td>Smokers, n=33, supported to quit</td>
<td>Baseline before quit date compared with follow-up 4 weeks post quit date, EC provided from quit date. At follow-up: Not smoking, using EC, n=16; smoking, using EC, n=17</td>
<td>UK Medicines and Healthcare Products Regulatory Agency</td>
</tr>
<tr>
<td>Pulvers et al, 2016 (292)</td>
<td>Longitudinal cohort</td>
<td>4 weeks</td>
<td>Smokers willing to switch to EC, n=40</td>
<td>Before (baseline) and after encouragement to switch to EC (provided). Throughout follow-up 6 exclusive EC users.</td>
<td>University of Minnesota, US; California State University San Marcos, US</td>
</tr>
<tr>
<td>Shahab et al, 2017 (129)</td>
<td>Cross-sectional</td>
<td>N/A</td>
<td>EC users (≥6 months use), NRT users (≥6 months use), smokers, ex-smokers (≥6 months quit), n=181/n=144</td>
<td>EC-only users (ex-smokers), n=36&lt;br&gt;EC users and smokers, n=36&lt;br&gt;NRT users and smokers, n=36&lt;br&gt;NRT-only users (ex-smoker), n=36&lt;br&gt;Smokers, no NRT or EC, n=37 (only in Shahab et al)</td>
<td>Cancer Research UK; Society for the Study of Addiction, UK; National Institute on Drug Abuse and National Cancer Institute, National Institutes of Health, US; Roswell Park Alliance Foundation, US</td>
</tr>
<tr>
<td>Nelson et al, 2015 (293)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authors</td>
<td>Design</td>
<td>Duration</td>
<td>Population</td>
<td>Groups/comparisons</td>
<td>Funding</td>
</tr>
<tr>
<td>---------------------------------</td>
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<td>-----------------------------------------------</td>
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<td>--------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Vansickel et al, 2010 (295)</td>
<td>Cross-over</td>
<td>For each product 12h abstinence followed by 2.5h use session</td>
<td>Smokers, n=32</td>
<td>EC use, Cigarette, Unlit cigarette</td>
<td>National Cancer Institute, US Public Health Service</td>
</tr>
<tr>
<td>Walele et al, 2016 (296)</td>
<td>Cross-over</td>
<td>For each product overnight abstinence followed by 3h use session</td>
<td>Smokers, n=12</td>
<td>EC, NRT inhalator, Cigarette (All in confinement)</td>
<td>Fontem Ventures, Imperial Tobacco Group [Imperial Brands]</td>
</tr>
<tr>
<td>Yan &amp; D’Ruiz, 2015 (297)</td>
<td>Cross-over</td>
<td>For each product: 36h abstinence followed by 1.5h use session</td>
<td>Smokers, n=23</td>
<td>EC, Cigarette</td>
<td>LOEC Inc, subsidiary of Lorillard [BAT]</td>
</tr>
</tbody>
</table>

1 Confinement means that participant stayed in a controlled environment and were not given access to other products.
2 Available on request.
4-(methylNitrosamino)-1-(3-pyridyl)-1-butanol (NNAL)

NNAL is a marker for exposure to nitrosamines (nicotine-derived nitrosamine ketone (NNK)) which are potent lung carcinogens. It is specific to tobacco use and linked to subsequent cancer risk (298) and its urinary half-life is about 10 days (299). There were 10 published papers reporting on eight studies between 2015 and 2017 that evaluated tank-type EC (total n=658). Figure 32 shows NNAL levels in EC users as a percentage of NNAL levels in those who smoked cigarettes. Overall, there was a 91.4% average difference in NNAL levels (weighted by sample size in each study); this increased to 96.4% when restricting only to those who had been abstinent from smoking for at least four weeks (129, 267, 290, 292, 293).

Figure 32: Level of NNAL in EC use relative to smoking

1-hydroxypyrene (1-HOP)

1-HOP is a urinary metabolite of the non-carcinogen pyrene, and is a biomarker for polycyclic aromatic hydrocarbons which include carcinogens such as benzo[a]pyrene (300). Its urinary half-life is about 20 hours (301). There were four papers covering three studies between 2015 and 2017 with a total of 271 participants; mostly evaluating
tank-type EC. The studies showed an average difference in 1-HOP of 57.6% in EC users relative to smokers. However, one of the studies (252) found only a 4.1% difference, although it is important to note that this study did not require abstinence from smoking or substantial reduction in cigarettes smoked (Table 21; Figure 33). Excluding this study resulted in an average difference in 1-HOP of 61.9% in EC users relative to smokers.

**Figure 33: Level of 1-HOP in EC use relative to smoking**

3-hydroxypropylmercapturic acid (3-HPMA)

This is a marker of the volatile organic compound acrolein, a potent respiratory irritant (302). It is relatively specific to tobacco use, toxic and is a short-chain aldehyde; several short-chain aldehydes have been linked to cancer (303). Its urinary half-life is about one day (304). There were eight papers covering seven studies published between 2015 and 2017 with 658 participants in total; again mostly evaluating tank-type EC. They found an average difference in 3-HPMA levels of 59.6% in EC users compared to cigarette smokers (Figure 34).
Carbon Monoxide (CO)

CO is a highly toxic gas (265) that is the product of incomplete combustion, produced when smoking tobacco and linked to CVD (305). In exhaled breath it has a half-life of about 5 hours (306).

Between 2010 and 2017, there were nine papers reporting on eight studies (total n=245) measuring exhaled CO levels among EC users; these studies included earlier cigalike and tank-type EC. Across the studies there was an average difference of 77.9% in CO levels (Figure 35).
Comparison with smokers abstaining or non-smoker levels

Importantly, five of the studies also compared the levels of some or all of these biomarkers in smokers who had switched to EC with the levels in non-smokers or smokers abstaining/using NRT, and found those levels comparable (Figure 36). While some comparisons were with smokers only abstaining for a short period (Table 21), overall this suggests how some of these biomarkers have other endogenous and exogenous sources which can result in exposure. Hence there cannot be a reduction of 100% when comparing the risk of EC with smoking.
**Figure 36: Levels of biomarkers of exposure in EC use and never-smokers or smokers abstaining relative to smokers.**

Notes: Full bars are levels observed in EC use; striped bars are levels observed in non-smoking groups (D’Ruiz/O’Connell nicotine abstinence condition; Martin non-smokers; Shahab/Nelson never smokers; Vansickel unlit cigarette condition; Walele NRT inhalator condition; see Table 21 for length and details of studies).

**Limitations**

There are limitations with these data as only a few specific biomarkers are included in these analyses, and it is unclear whether there are linear or threshold effects (ie would a 95% reduction in exposure represent a 95% reduction in harm). Most of the non-smoker comparisons were with smokers abstaining for short periods. It should also be noted that some of the studies were tobacco industry funded. Additionally, the mode of delivery may affect risks of harm, and harm may change with changing patterns of use and products.

**Summary**

The biomarker data assessed in this section are consistent with significant reductions in harmful constituents and in EC users some biomarkers show similar levels to non-smokers or smokers abstaining from smoking.
Misreporting of scientific studies

Over the past few years, a number of research findings have been presented as documenting serious risks of vaping and received widespread coverage. Of course all studies have strengths and weaknesses in their research designs, and that includes those that demonstrate that EC use is much less harmful than smoking. However, the way the results of some studies with particular limitations have been designed and reported, and then subsequently presented in the media, may have caused serious concerns about EC use as shown by growing misperceptions of the health risks of EC in Chapter 10.

We believe that there are a number of contributory reasons for this:

1. Studies that compare EC and tobacco cigarette exposures and show the latter as much more toxic are not viewed as newsworthy (eg Husari and colleagues (307))
2. Understandably, journals, authors and research organisation press offices are keen to seek publicity for articles in order to gain impact, resulting in press releases. Sometimes, these do not accurately represent the article on which they are based.
3. Study findings can be further exaggerated when discussed in the media.
4. Posters or presentations at conferences, when there is not yet a peer-reviewed article to accompany them, are sometimes reported as if they have been through peer review and taken as definitive findings.

These are some recent headings in the media generated from some of the studies previously described in this chapter:

- **E-cigarettes are no better than regular smoking**
  (http://www.dailymail.co.uk/health/article-3377730/E-cigarettes-NO-better-regular-smoking-Toxins-devices-cause-cancer-nicotine-FREE.html)

None of these headlines would be justifiable from the research studies they refer to. However, it is understandable how some of these headlines were generated from press materials accompanying the papers or, in one case, conference presentation.

As we have seen, the most frequent source of concerns is from animal and in-vitro studies which have unclear relevance for human exposure. They also typically avoided
comparisons with smoking. Often the studies suffer from one or both of two major methodological problems.

The first is that EC exposure was much greater than the level of exposure to which human EC users would be exposed. For example, in in-vitro studies, cells are bathed in e-liquid or exposed directly to EC aerosol. In animal studies, laboratory animals that are a fraction of the size of humans and much more sensitive to nicotine and other chemicals, including strong smells, are exposed to emissions that are of much higher magnitude than those to which human EC users are exposed relative to body weight. The animals are also sometimes severely distressed over extended periods of time. Systemic poisoning and an aftermath of chronic distress are then interpreted as a sign of the toxicity of vaping.

The second problem, as discussed in detail above, is that when the e-liquid is overheated it releases toxic aldehydes, but this is not applicable to human EC users because overheated e-liquid generates acrid aversive tasting emissions which EC users avoid. When the toxic products from overheated e-liquid are detected in the bodies of animals, or affect tissues and cells, this is again claimed to show risks of vaping, despite the fact that EC users do not generate, or absorb, these chemicals.

The consequences of this inaccurate or inadequate reporting are that the general public is misled. This could induce smokers to carry on smoking rather than switching and EC users to relapse to smoking. While such inaccurate reporting is not confined to the tobacco harm reduction and EC field, the impact is rarely as large. Smoking is uniquely dangerous and each year in England around 80,000 smokers die because of tobacco use (2). There are few other scientific areas where the gains and losses to public health are so high. It is very likely that these reports and headlines are playing a key role in the persistent misperceptions that the public have about the relative risks of EC and tobacco cigarettes as explored in Chapter 10 of this report.
Conclusions

Key findings

- One assessment of the published data on emissions from cigarettes and EC calculated the lifetime cancer risks. It concluded that the cancer potencies of EC were largely under 0.5% of the risk of smoking.
- Comparative risks of cardiovascular disease and lung disease have not been quantified but are likely to be also substantially below the risks of smoking. Among EC users, two studies of biomarker data for acrolein, a potent respiratory irritant, found levels consistent with non-smoking levels.
- There have been some studies with adolescents suggesting respiratory symptoms among EC experimenters. However, small scale or uncontrolled switching studies from smoking to vaping have demonstrated some respiratory improvements.
- EC can release aldehydes if e-liquids are overheated, but the overheating generates an aversive taste.
- To date, there is no clear evidence that specific flavourings pose health risks but there are suggestions that inhalation of some could be a source of preventable risks.
- To date, the levels of metals identified in EC aerosol do not give rise to any significant safety concerns, but metal emissions, however small, are unnecessary.
- Biomarkers of exposure assessed to date are consistent with significant reductions in harmful constituents and for a few biomarkers assessed in this chapter, similar levels to smokers abstaining from smoking or non-smokers were observed.
- One study showed no reductions across a range of biomarkers for dual users (either for nicotine replacement therapy or EC dual users).
- To date, there have been no identified health risks of passive vaping to bystanders.
- Reporting of some academic studies has been misleading.

Implications

Research

- More research is needed with human users about biomarkers of exposure, risk and harm and health effects over time.
- More research with biomarkers across the range of different combinations of dual use is needed.
- Any adverse effects of passive vaping should be monitored.
Policy

- Policy makers and regulators should ensure that EC are manufactured in a way that minimises harm. An advantage of EC is that particular constituents can be removed or minimised in a way that is not feasible with tobacco cigarettes.
- Regulations should therefore be flexible to ensure any emerging evidence of constituent harmfulness can be acted upon, such that products are modified to remove any components shown to pose avoidable risks.
- Consumers and health professionals should be encouraged to use the Yellow Card Scheme for reporting adverse reactions to EC use.
- Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. The previous estimate that, based on current knowledge, vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean EC are safe.
- The lack of difference in biomarkers between dual users and smokers found so far underlines the need to encourage and support dual users to stop smoking altogether.
10 Perceptions of relative harms of nicotine, EC and smoking

Introduction

The 2015 PHE report (5) described an increase over time in the proportion of the population believing EC to be at least as harmful as cigarettes. The objective of this chapter is to update the previous findings with the latest data available for Great Britain for adults and youth and to provide a brief overview of recent findings from other countries.

Evidence from recent GB surveys

ASH-A, ASH-Y, ONS, STS and the ICGBS all include questions about (relative) harm perceptions of different products.

Adults’ perception of harm of EC relative to cigarettes

Among adults in Great Britain, the ASH-A shows that the previously observed trend of increased perceived relative harm of EC has continued (5, 21). In 2017, 44.2% perceived EC as less harmful than cigarettes, the lowest percentage since tracking started in 2013, and 25.8% perceived them to be equally (22.7%) or more harmful (3.1%), which is the highest percentage recorded (28.7% don’t know, Figure 37).

The ONS also asked about relative perceived harm among all adults, without providing a ‘don’t know’ option. Here, about 74% responded that EC were less harmful than cigarettes (21.1% about as harmful, 5.1% more harmful). The difference between the two surveys could suggest that if forced to choose a response, respondents are likely to pick less harmful but possibly without particular confidence in this response.
A downward trend in accurate understanding of the relative risks of cigarette smoking and EC use has also been observed among current smokers in the STS, where a declining minority believe EC are less harmful than cigarettes (Figure 38). Smokers who also use EC are more likely to perceive EC to be less harmful than smokers not using them.
Figure 38: Perception that EC are less harmful than cigarettes in smokers over time

Although accurate perception seems to be a little higher among smokers in the ASH-A 2017 than in the STS, breaking down the ASH-A 2017 data by smoking and EC use status, it becomes apparent that relative harm perceptions of EC are particularly poor among groups who could benefit from EC use. It is lowest among current smokers who have never tried EC, where only one third (33.1%) think that EC are less harmful than cigarettes. Among smokers who tried or used EC in the past and stopped EC use but still smoke, only half (51.5%) think that EC are less harmful than smoking (Table 22). In comparison, 90% of ex-smokers who use EC accurately perceived EC as less harmful than cigarettes.
Table 22: Proportion selecting accurate response by smoking and EC use status. ASH-A 2017

<table>
<thead>
<tr>
<th>Smoking status</th>
<th>EC use status</th>
<th>EC less harmful than cigarettes, %</th>
<th>NRT less harmful than cigarettes, %</th>
<th>Portion of health risk of smoking due to nicotine – none or very small, %1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never smokers</td>
<td>Any/all</td>
<td>42.4</td>
<td>57.9</td>
<td>4.6</td>
</tr>
<tr>
<td></td>
<td>Never used EC</td>
<td>42.0</td>
<td>59.2</td>
<td>9.2</td>
</tr>
<tr>
<td></td>
<td>Ever tried/used2</td>
<td>55.8</td>
<td>56.5</td>
<td>4.6</td>
</tr>
<tr>
<td>Ex-smokers</td>
<td>Any/all</td>
<td>45.2</td>
<td>61.6</td>
<td>9.7</td>
</tr>
<tr>
<td></td>
<td>Never used EC</td>
<td>37.5</td>
<td>61.6</td>
<td>5.9</td>
</tr>
<tr>
<td></td>
<td>Used /tried in the past</td>
<td>58.3</td>
<td>63.0</td>
<td>18.9</td>
</tr>
<tr>
<td></td>
<td>Current EC use</td>
<td>89.8</td>
<td>65.7</td>
<td>30.4</td>
</tr>
<tr>
<td>Smokers</td>
<td>Any/all</td>
<td>48.9</td>
<td>52.9</td>
<td>13.5</td>
</tr>
<tr>
<td></td>
<td>Never used EC</td>
<td>33.1</td>
<td>53.4</td>
<td>10.6</td>
</tr>
<tr>
<td></td>
<td>Used/tried in the past</td>
<td>51.5</td>
<td>53.7</td>
<td>14.8</td>
</tr>
<tr>
<td></td>
<td>Current EC use</td>
<td>73.9</td>
<td>56.7</td>
<td>18.4</td>
</tr>
</tbody>
</table>

1 The figures for any/all are in some instances lower than the figures for all subgroups shown; this is because the additional subgroup consisting of those who did not know or provide their vaping status (1.9%) mostly also responded ‘don’t know’ to these questions, thereby lowering the overall average.

2 Tried or used in the past or currently, combined for never smokers due to small ns, combined unweighted n=110. Unweighted ns for EC question: Never smokers n=6,256, ex-smokers n=4,276, smokers n=1,569.

Notes: Adults aged 18+. Unweighted ns for NRT and nicotine questions: Never smokers n=6,626, ex-smokers n=4,438, smokers n=1,632

To further assess perception of relative harm and the effect of replacing tobacco cigarettes with vaping, the ICGBS asked respondents to estimate the change in health harms including perception of harm reduction achieved by replacement. Responses differentiated complete replacement (10/10 CPD replaced by EC) and partial replacement (5/10 cigarettes). Very small proportions believed that replacement would increase health harms a little or a lot (3.5% for complete, 3.8% for partial replacement). Considerable minorities thought that complete (12.2%) or partial replacement (18.4%) of cigarettes would not have any effect on health harms; 29.4% and 45.4% respectively responded that health harms would be a little reduced. Only 38% of the sample of smokers and ex-smokers thought that complete replacement would reduce health harms a lot, compared with 15% for partial replacement. While it may be desirable that fewer smokers think that partial replacement will be beneficial, it is striking that only a minority think that their health would benefit from what would in effect be smoking cessation.
Addictiveness

Little evidence has been collected on perceptions of addictiveness of EC. In the ICGBS, 6.3% thought that EC/vaping devices are more addictive than tobacco cigarettes, 47.2% that they are equally addictive, 29.0% that EC are less addictive and 17.5% didn’t know. There was some variation across groups with different levels of EC use experience (Figure 39).

Future research should aim to assess to what extent the perception of addictiveness contributes to the misperceptions of relative harmfulness of EC compared with cigarettes.

Figure 39: Perceived addictiveness of EC relative to tobacco cigarettes

Notes: ICGBS 2016. N=3,431 adult smokers, ex-smokers and EC users aged 18+

Don’t know  
Equally addictive  
EC more addictive than cigarettes  
EC less addictive than tobacco
Perceived health impact of EC on others

Only the ONS asked about perceptions of health impact of EC on individuals who are exposed to them but do not use them directly. Responses were presented separately for current and ex EC users and those who had never been a user (but may have tried) EC. The latter group was further divided into those who were current or ex-smokers and those who had never smoked. Among ever EC users, 72.9% believed that EC would have no health impact on those exposed second-hand and 23.9% that they would have a damaging impact. Among never EC users who were current or ex-smokers, 53.9% believed EC would have no impact and 42.1% believed they would have a damaging impact. Among never EC users who had never smoked, this was 49.6% and 46.1% respectively. Raw data for this survey were not available, so the data could not be split primarily by smoking status. It would be useful to be able to specifically assess smokers’ thoughts on the health impact on others of EC relative to smoking, eg do they think those around them would benefit from not being exposed to smoke but to EC emissions instead?

Perceived relative harm for NRT, EC and cigarettes

Perceived harm for NRT relative to cigarettes is inaccurate in large proportions of the general adult population. In the ASH-A 2017, just over half (58.4%) responded that NRT is any less harmful than smoking cigarettes and there is less variation by smoking and vaping status than for EC harm perception (Table 22). This means that the lack of knowledge extends to smokers and ex-smokers with only small majorities thinking that NRT is less harmful than cigarettes (Figure 40). Particularly among smokers, there is little difference between relative harm perception for NRT (52.9% less harmful than cigarettes) and EC (48.9% less harmful than cigarettes) (Figure 40).

The ICGBS also included questions about perceived harm of EC and NRT relative to cigarettes. Proportions responding more, equally, and less harmful were almost identical for both types of products relative to cigarette smoking (Figure 41). In this survey, these questions were followed by a direct comparison of EC and NRT; respondent’s views were fairly evenly distributed across response options and the modal response was ‘don’t know’ (30.0%), suggesting smokers and ex-smokers may find the difference in harm between EC and NRT difficult to judge (Figure 41).
Figure 40: Perceived harm of NRT and EC relative to cigarettes among smokers and ex-smokers

Notes: ASH-A 2017. Unweighted base sizes in the appendix. Adults aged 18+
Perceived harms of nicotine

The common factor for cigarettes, NRT and (most) EC is nicotine, and misperceptions of relative harm may be linked to the perception of nicotine (see also eg (308) for an association between perceived nicotine content and perceived harm of cigarettes).

Knowledge about the portion of harm of smoking attributable to nicotine in the general adult population is poor and not improving. In 2017, only 7.5% thought that none or a very small part of the risk of smoking comes from nicotine (the correct response) whereas 14.0% thought that it was nearly all the risk; almost a quarter (24.2) of the population chose ‘don’t know’ (Figure 42). Smokers overall may be slightly better informed with 13.5% thinking it is none or a very small part of the risk and 6.0% that it is nearly all the risk, although again 24.6% did not know. However, among smokers who have never tried EC, only 10.6% give the correct response (Table 22), repeating the pattern seen for relative harm perception of EC use vs smoking among smokers with different EC use status. It is interesting that the highest accurate response to this question was given by ex-smokers who were current EC users (30.4%). Responses from the ICGBS which surveys smokers and ex-smokers, are in line with the population
data for these groups with 12.9% thinking that only a very small portion of the risk of smoking is due to nicotine.

The ICGBS also asked whether respondents believed that nicotine is the chemical in cigarettes that causes most of the cancer and a considerably proportion of respondents (39.5%) erroneously believed this to be true. This question was not included in any of the other recent surveys, but these results are in line with older data from the ITC study for smokers and ex-smokers in the UK, US, Canada and Australia (309); for more detail see Figure 44 and Figure 45.

**Figure 42: Perceived portion of the harms of smoking due to nicotine, ASH-A, 2017**

![Bar chart showing perceived portion of the harms of smoking due to nicotine by year.](image)

*Notes: Unweighted base sizes in the appendix. Adults aged 18+*

**Harm perceptions among youth**

For youth, a recent publication reports harm perception in the ASH-Y over time among those aware of EC (8) and shows a similar trend to adults. In 2013, 73.4% of youth aware of EC thought that EC were less harmful than cigarettes and this dropped significantly to 62.3% in 2016 (8). In 2017, this perception was held by only 61.9% of youth (Eastwood, personal communication).

An analysis using the 2016 ASH-Y found that accurate perception was more likely among youth 14 years and older, those who had tried or used EC sometimes (compared with those who had never used EC), those who had at least one family member who used EC and those who thought that the public either approve or neither
approve nor disapprove of EC use. Respondents’ own smoking status was not associated with perception (116).

Nicotine knowledge among youth is also poor; in 2017, 6.5% thought that none or a very small part of the risk of smoking comes from nicotine and about a fifth thought it was nearly all the risk (Figure 43). In the 2016 ASH-Y data, accurate nicotine knowledge was higher among those who were 16 years and older and those who had at least one family member smoking. Again, respondents’ own smoking status was not associated with nicotine knowledge (116).

**Figure 43: Perceived harm of EC relative to cigarettes in youth. ASH-Y, 2017**

![Perceived harm of EC relative to cigarettes in youth. ASH-Y, 2017](image)

Notes: Unweighted base n=1977, aged 11-18.

**International overview**

Many surveys, mostly from the US, have included questions about perceived harmfulness. This section will focus on reviews and surveys reporting on national samples of adults or youth.

**ITC project**

The ITC Project has collected data on nicotine perceptions over time among smokers in four industrialised countries, Australia, Canada, UK and US. Given these are cohort data with replenishment, binary generalised estimating equation models were used to estimate the adjusted percentage of smokers correctly responding that nicotine in cigarettes does not cause cancer, for each country. The adjusted estimates controlled for sex, age group, income, education, daily vs. non-daily smoking status, Heaviness of Smoking Index, use of NRT, survey mode and time in sample. The general pattern in the UK is similar compared with the other three countries although more recently, the level of misperceptions seems to be slightly lower in the UK than in the other countries.
(Figure 44). Misperceptions vary consistently by indicators of socioeconomic status across the four countries, with more disadvantaged smokers and recent ex-smokers having higher rates of misperceptions (Figure 45).

**Figure 44:** Proportion correctly responding that nicotine in cigarettes does not cause cancer in the ITC 4 country study over time

![Graph showing proportion of nicotine in cigarettes does not cause cancer over time by country](image)

*Notes: Adult smokers and ex-smokers aged 18+*
Figure 45: Proportion correctly responding that nicotine in cigarettes does not cause cancer in the ITC 4 country study over time by educational level

Notes: Adult smokers and ex-smokers aged 18+

The ITC Project has also collected data on perceived harmfulness of EC relative to tobacco cigarettes among smokers across a variety of countries (Table 23). These data show that misperceptions of relative harm abound in other countries too, with smokers in England being better informed than in most other countries.
Table 23: Percentage of adult smokers across different countries thinking EC are equally as harmful or more harmful than cigarettes (ITC data)

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>‘EC equally or more harmful than cigarettes’, % ¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>High income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>2016</td>
<td>66</td>
</tr>
<tr>
<td>United States</td>
<td>2016</td>
<td>37</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2015</td>
<td>32</td>
</tr>
<tr>
<td>Canada</td>
<td>2016</td>
<td>30</td>
</tr>
<tr>
<td>England ²</td>
<td>2016</td>
<td>24</td>
</tr>
<tr>
<td>Australia ²</td>
<td>2016</td>
<td>22</td>
</tr>
<tr>
<td>Uruguay</td>
<td>2014</td>
<td>19</td>
</tr>
<tr>
<td>Middle income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaysia</td>
<td>2013</td>
<td>70</td>
</tr>
<tr>
<td>Zambia</td>
<td>2014</td>
<td>57</td>
</tr>
<tr>
<td>Thailand</td>
<td>2012</td>
<td>54</td>
</tr>
<tr>
<td>Mexico</td>
<td>2014-15</td>
<td>38</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>2014-15</td>
<td>37</td>
</tr>
<tr>
<td>Brazil</td>
<td>2012-13</td>
<td>22</td>
</tr>
<tr>
<td>China</td>
<td>2013-15</td>
<td>15</td>
</tr>
</tbody>
</table>

¹ Among smokers who have heard of EC.

² Figure from ITC, amended from presentation by Professor Geoffrey T Fong at European Network for Smoking and Tobacco Prevention (ENSP) conference, Athens, 2017.

The data for Australia and England are preliminary and unweighted. The data for England are adjusted for oversampling of 18-24 year olds; there was no such oversampling in Australia.

Two reviews of studies from any country have included perceived harm of EC relative to cigarettes. Reviewing 50 samples from 23 studies, Czoli and colleagues found that in 70% of samples a majority perceived EC to be less harmful than cigarettes (310). The comprehensive review of studies by Glasser and colleagues (73) concluded that generally, EC are perceived to be less harmful and less addictive than cigarettes regardless of the respondent’s tobacco use status. They also concluded that evidence from the US and GB shows that the belief that EC are less harmful has eroded over time, with more individuals mistakenly believing EC are as harmful or more harmful than cigarettes (73).

Other data from European countries

As far as we are aware, peer-reviewed publications using Eurobarometer data and reporting on harm perception (139) have not yet used the latest wave, but 2017 Eurobarometer data are available in a report (141). In contrast to most other surveys, the Eurobarometer asks about absolute perceived harm to the health of users, rather than relative risks. In 2017, just over half (55%) of EU citizens thought that EC are harmful to the health of their users, an increase of three percentage points since the
last survey in 2014. In 22 out of 28 countries, at least half of respondents agreed that EC are harmful and in seven of these countries, over three quarters gave this answer (Estonia 75%, Luxembourg and Cyprus 76%, Denmark 79%, Latvia 80%, Lithuania 80%, Finland 81% and the Netherlands 85%). The lowest proportion agreeing with this statement was found in Italy (34%). The proportion of respondents who think that EC are harmful has increased in almost all countries since the previous survey. For the UK, the Eurobarometer reports that 50% thought EC were harmful. The meaning of an absolute harm question without any option of grading the response or a comparator is somewhat difficult to interpret.

One representative survey of those aged 14 and over conducted in Germany in 2016 (142) found that 20.7% of respondents believed EC to be less dangerous than cigarettes, 46.3% equally dangerous, and 16.1% believed they were even more dangerous (17.0% no response). This was similar among current smokers, where only 25.5% believed that EC are less dangerous and 15.9% believed EC to be more dangerous than cigarettes.

**United States**

For US adults, data on relative perceived harm from the Health Information National Trends Surveys (HINTS) 2012 to 2014 have been published. Among those who were aware of EC (77% in 2012 to 94% in 2014), perception that EC were less harmful than cigarettes declined from 50.7% in 2012 to 43.1% in 2014 (311). In a separate publication, data from the Health Information National Trends Survey (HINTS-FDA) 2015 show absolute harm perception of different products; 90.5% perceived cigarettes and 48.7% EC to be very harmful; cigarettes were perceived to be moderately harmful by another 8.9% while 41.9% perceived EC to be moderately harmful (312). Another representative survey of US adults, the Tobacco Products and Risk Perception Survey waves 2012, 2014 and 2015 also show a decline in the proportion believing EC to be less harmful than cigarettes (39.4% in 2012, 35.2% in 2014 and 30.7% in 2015) and steep increases in the proportions believing EC to be equally (11.5% to 35.7%) or more harmful (1.3% to 4.1%) than cigarettes (313).

The HINTS-FDA and the Tobacco Products and Risk Perception Survey each also included a question on addictiveness. Under a third (28.7%) of adults believed that using EC was very addictive and 21.1% that it was moderately addictive, compared with 76.8% and 10.5% for cigarettes (314). The proportion of adults agreeing that people can become addicted to EC increased from 32.0% in 2012 to 67.6% in 2015 (313).

One review summarised US studies examining perceptions of EC during pregnancy and found that mostly, these were perceived to be less harmful than cigarettes but this was accompanied by considerable uncertainty (315). This lack of information is further
supported by findings from one national survey of US adults where 11.1% believed using EC during pregnancy was less harmful than smoking, 51.0% believed it was equally harmful, 11.6% believed it was more harmful, and 26.2% did not know (316).

Among US youth, data are available from the PATH and the NYTS. In the first wave of the PATH in 2013-14, perceived relative harm was measured using both a direct measure asking respondents to compare EC with cigarettes and an indirect measure that asked about the harm to the user separately for each product. In the direct measure, 50.2% of the 12 to 17-year old respondents perceived EC to be less harmful than cigarettes; this was true for 67.3% when using an indirect measure (317). Data from the 2012 and 2014 NYTS (318) are unusual compared with other youth and adult surveys in that they show an increase in the proportion of respondents perceiving EC to be less harmful than cigarettes. In 2012, 30.6% responded that they perceived EC to be less harmful which increased to 50.7% in 2014, a figure which is comparable with the PATH direct measure. This increase is mirrored by a decrease in the proportion who were unaware of EC or who didn’t know enough to respond to the question (50.9% in 2012 to 30.6% in 2014). The NYTS also asked about addictiveness compared with cigarettes; 31.3% thought EC were less addictive, 29.7% equally addictive, 5.4% more addictive and 33.8% were unaware of the product or didn’t know enough to answer the question (318).

Conclusions

Key findings

- Perceived relative harm of EC compared with cigarettes has continued to increase; less than half of adults in GB think EC are less harmful than smoking.
- NRT is subject to similar misperceptions and only just over half of adults in GB think that NRT is any less harmful than smoking.
- Adult smokers are poorly informed about relative risks of different products.
  - Only half of smokers believe that EC are less harmful than smoking and this decreases to one third among smokers who have never tried EC.
  - In contrast to evidence to date, it appears that a majority of smokers and ex-smokers does not think that complete replacement of cigarettes with EC would lead to major health benefits.
  - Only half of all adult smokers believe that NRT is any less harmful than smoking
- As the common factor for cigarettes, NRT and (most) EC is nicotine, these misperceptions may be linked to the perception of nicotine.
  - When adults in GB are asked what proportion of the health harms of smoking is due to nicotine, the accurate response (most health harms are not caused by nicotine) is the least common response consistently chosen by 8-9%. Smokers’ knowledge around nicotine is similarly poor.
Four in ten smokers and ex-smokers incorrectly think nicotine in cigarettes is the cause of most of the smoking-related cancer.

Misperceptions around nicotine and cancer are greater in more disadvantaged groups.

- It is unclear to what extent the perception of addictiveness underpins the perception of harm.
- Among youth in GB, perceived harm of EC relative to cigarettes has also increased over time and nicotine knowledge is similarly poor (7% correctly responded that none or a small portion of the harms of smoking is due to nicotine).
- Where available, international data show similar misperceptions around nicotine and relative harmfulness of EC and smoking as in England. International data also support the trends of increased harm perception of EC with the exception of one survey in youth in the US.

Implications

Research

- Future research should aim to assess causes and effects of misperceptions of the relative harmfulness of EC and NRT compared with cigarettes, including to what extent the perception of addictiveness contributes to these misperceptions.

Policy and practice

- Misperceptions of nicotine and different nicotine-containing products need to be addressed. These have deteriorated further since the 2015 PHE report in 2015 which called for clear and accurate information on relative harms (5).
  - Misperceptions of the relative harms of NRT and EC compared with cigarettes need to be addressed, particularly among smokers who would benefit from switching to NRT or EC.
  - Knowledge about the role of nicotine in the development of cancers and other diseases caused by smoking needs improvement.
11 Indicative EC pricing

Introduction

To illustrate the price range of EC, the ECigIntelligence Global Database was used.

Price of different products

Cheapest disposable EC

The price of the cheapest disposable EC has fluctuated from less than 4 GBP to 6 GBP over the time period from August 2015 to July 2017 (Figure 46). For cheapest disposable EC, online prices were generally lower than those of specialised vape shops. Other brick and mortar shop prices appeared to be the highest.

Figure 46: Average monthly price of cheapest disposable EC

![Average monthly price of cheapest disposable EC](image-url)
Cheapest closed system kit

The average price of the cheapest closed system kit remained between 10 and 20 GBP between August 2015 and June 2017, with an increasing trend observed towards the end of the study period which was probably due to a considerable increase in the maximum price of cheapest closed system kit. Although average price data for EC sold in vape shops were available only for a few months at the end of study period, they suggest that prices were slightly higher in vape shops than online (Figure 47).

Figure 47: Average monthly price of the cheapest closed system kit

Cheapest pre-filled clearomiser/cartomiser

The price of the cheapest pre-filled clearomiser/cartomiser has remained relatively stable, at around 2 GBP throughout the study period. It appears that in May/June 2017 the average price increased, but this is likely to be explained by a steep increase in the maximum price of the cheapest pre-filled clearomiser on some websites (Figure 48).
It is possible that the increase in minimum price after April 2017 is related to implementation of the TPD, but in order to explore causality long term trends are required. As with other products, the average price of pre-filled clearomisers/cartomisers was considerably lower when purchased online.

**Figure 48: Average monthly price of cheapest pre-filled clearomiser/cartomiser**

![Graph showing average monthly price of cheapest pre-filled clearomiser/cartomiser](image)

**Cheapest basic open system kit**

The price of the cheapest basic open system kit has remained relatively constant, but decreased towards the end of the study period, and unlike other products was slightly higher from online suppliers towards the end of the study period (Figure 49).
Figure 49: Average monthly price of the cheapest basic open system kit

Cheapest clearomiser

As with the average monthly price of a basic open system kit, the average price of the cheapest clearomiser has remained relatively stable during the study period. However, an increase towards the end of the study period has been observed, possibly due to an increase in the maximum prices of the cheapest clearomisers (Figure 50). Prices from vape shops, available only in the last few months of the study period, appeared lower than from online retailers.
Figure 50: Average monthly price of the cheapest clearomiser
Most expensive clearomiser/tank

Prices of the most expensive clearomiser/ tank have been available in the dataset since December 2016. The prices have remained almost unchanged, and only minor fluctuations in minimum and maximum prices have been observed (Figure 51).

Figure 51: Average monthly price of the most expensive clearomiser/ tank

- **Average price most expensive clearomiser/ tank (online, GBP)**
- **Min price most expensive clearomiser/ tank (online, GBP)**
- **Max price most expensive clearomiser/ tank (online, GBP)**
Variable wattage/variable voltage kits

The average monthly price of variable wattage/variable voltage kits has been available only since March 2016 and has remained stable over time with a slight decrease towards the end of the study period (Figure 52). However, in this category, the range of prices available from various online sources is wide, from about 20 GBP to 130 GBP. As with other open system kits described above, average prices of these products in vape shops appear to be below those observed in online retailers.

Figure 52: Average monthly price of variable wattage/variable voltage kit
Cheapest e-liquid

The average price of the cheapest e-liquid has decreased over time, and appears to have been higher in vape shops than online (Figure 53). It appears that despite restrictions on e-liquid bottle size included in the EU TPD price of e-liquid per mL has not increased.

Figure 53: Average monthly price per 1mL of the cheapest e-liquid

Limitations

These data are descriptive and most of the data presented refer to the cheapest EC product online. It is difficult to investigate trends particularly in relation the implementation of the TPD given the relatively short period of time since full implementation; in addition some data points are missing.
Conclusions

Key Findings

- Price varies considerably between products, and there appear to be differences between online and bricks and mortar shop prices, with closed system products tending to be cheaper online, and open system kits cheaper in bricks and mortar shops.
- Generally, average maximum and minimum prices seem to have remained relatively stable from August 2015 to July 2017 for all product categories.
- There appear to have been no major and consistent changes in price over the first year since implementation of the EU TPD.

Implications

- Current available data provide minimum, maximum and average prices, but do not provide detail on nicotine levels, brands and flavours that would be helpful to our understanding of market developments.
- Currently EC products are available in a wide range of prices and therefore affordable to various types of EC users. Any changes in pricing need to ensure that EC are affordable to smokers to avoid discouraging smokers from switching away from smoked tobacco which would be counter-productive in public health terms. There should therefore be a competitive advantage for the prices of EC compared to combustible tobacco products.
12 Heated tobacco products

Introduction

Heated tobacco products are products that do not combust tobacco like cigarettes but heat it to a lower temperature with the aim of avoiding the harmful products of combustion; they are often referred to as ‘heat-not-burn’ tobacco products. In contrast to EC, heated tobacco products in general apply heat to tobacco, instead of liquids. There is however a range of different types of heated tobacco products, and some classifications include products where vapour is produced from non-tobacco sources and then passed over processed tobacco to be flavoured (319). Typically, heated tobacco products are rechargeable and include a holder, and tobacco sticks, plugs or capsules to be heated with an electronically controlled heating element.

Heated tobacco products have been launched by tobacco companies since the 1980s (320, 321) but failed to attract consumers. The heated tobacco products described in the current literature are also manufactured by tobacco companies. Philip Morris International’s (PMI’s) heated tobacco product IQOS was launched initially in test markets in cities in Japan, Italy and Switzerland in 2014 before expanding into all of Japan and other countries. As of July 2017, it was available in 27 countries worldwide including Great Britain (322). In some countries IQOS is branded as Marlboro, representing co-branding with cigarettes. PMI is preparing city tests for further products such as TEEPS (https://www.pmi.com/smoke-free-products). Other heated tobacco products currently include glo by BAT which was first available in Japan in late 2016, followed by a small number of other countries (Canada, Switzerland, Korea), and Ploom TECH by Japan Tobacco International which was launched in Japan and Switzerland in summer 2017.

In Great Britain, IQOS has been available from a dedicated shop in London since December 2016 and more recently also online and a couple of other outlets in London. Other heated tobacco products are expected to be launched in the UK soon, therefore the UK government is seeking to develop a specific taxation category for heated tobacco products (319). Before being put on the market, heated tobacco products need to be notified to PHE (see chapter 3). In the US, PMI has submitted an application equivalent to millions of pages to the FDA to be able to market its heated tobacco products as a modified risk tobacco product (323).

The objective for this chapter was to review the existing peer-reviewed evidence on emissions and use of current heated tobacco products and to supplement this with recent evidence from UK surveys.
Systematic review of existing literature

Description of studies

From 843 records identified after the initial search, 19 studies were included in the review (Figure 54). Of these, seven studies were funded independently of the tobacco industry, eleven were funded by the manufacturer of IQOS and one study was funded by a competitor tobacco company (Table 24).

Manufacturers researching their own products or competitor products experience a conflict of interest which may bias findings and interpretations, so results need to be interpreted with caution (324). A further study we became aware of through contact with the study authors was also included, making a total of 20 studies.

Figure 54: Heated tobacco products review flowchart

Original search: 13 July 2017
N = 843

Scopus = 492
Web of Science = 138
Embase = 104
Medline = 77
ProQuest = 20
PsycInfo = 12

Duplicates identified and removed
N = 222

Excluded after titles & abstracts screening (n=547)
Not heated tobacco (n=5)
Conference abstracts (n=15)
Obsolete product (n=3)
Not in English language (n=2)
Animal studies (n=15)
In vitro studies (n=15)
Duplicates published findings (n=2)
Studies on methodology (n=2)

Remaining following duplicate removal
N = 621

Excluded after titles & abstracts screening or due to specific exclusion criteria
N = 602

Additional unpublished evidence, obtained as personal communication (n = 1)

Remaining for data synthesis
n = 20
1. Emissions (n = 8)
2. Human use (n = 11+1)
Different types of products assessed in these studies were categorised as:

1. **Loose-leaf tobacco vaporiser:** One study focused on Pax by Ploom.
2. **Carbon heated tobacco product:** This predecessor of TEEPS by PMI was the focus of one study. A specifically designed electric lighter lights the carbon heating source which then heats a tobacco plug. Twelve puffs of the Carbon Heated Tobacco Product (CHTP) are reported to yield 3 mg tar, 2 mg glycerol, 0.4 mg nicotine, and 1 mg of CO (325).
3. **Tobacco heating system 2.1 (THS 2.1):** Developed by PMI, a predecessor of IQOS, was assessed in two studies.
4. **Tobacco heating system 2.2 (THS 2.2), available commercially as IQOS:** THS2.2/IQOS was assessed in 16 studies. According to the manufacturer, compared with THS 2.1, THS 2.2 has a slightly lower operating heating temperature of <350°C (326) compared with <400°C (327), higher ISO nicotine yield per tobacco stick (0.5 mg (326) compared with 0.3 mg (328, 329)) and ‘improved puff by puff consistency and improved sensory satisfaction’ (330).
5. **Other commercially available heated tobacco products:** glo and Ploom/Ploom TECH were included alongside IQOS in two studies from Japan.

Eight of the included studies were laboratory studies on heated tobacco product emissions (331-338). These compared IQOS emissions with emissions from factory-made (331-333, 335-338) or hand-rolled (335) tobacco cigarettes, EC (332, 334-336) and a nicotine inhalator (334). Four were independently funded.

Nine publications reported on six RCTs using a few different products (Table 24), one of them published in two parts, and two cross-over design experimental trials in human participants (total \( n = 796 \)) (325, 326, 328, 329, 339-343). One of these studies was independently funded (339), the other eight were funded by the manufacturer and all published by the same set of authors.

One publication was a case report (\( n = 1 \), (344)), one reported findings from a national cross-sectional survey from Japan (\( n = 8240 \), (155)); both independently funded. In addition to the studies identified from the literature, we included an independently funded update to the survey in Japan (345) that was not yet published at the time of the literature search but which the authors shared with us.
### Table 24: Summary of included heated tobacco product studies

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<tr>
<th>Authors, year of publication</th>
<th>Funder, country</th>
<th>Study design</th>
<th>Heated tobacco product and reference products</th>
<th>Main aim</th>
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<td><strong>Mainstream emissions</strong></td>
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<tr>
<td>Auer, Concha-Lozano et al. 2017(331)</td>
<td>Not reported, Switzerland</td>
<td>Laboratory comparison study using smoking machines</td>
<td>IQOS Cigarette</td>
<td>To compare levels of HPHC in mainstream IQOS emissions with those in mainstream cigarette smoke</td>
</tr>
<tr>
<td>Farsalinos, Yannovits et al. 2017(332)</td>
<td>No funding, Greece</td>
<td>Laboratory comparison study using smoking machines</td>
<td>IQOS Cigarette EC: (i) Cigalike (ii) eGo-style, 2nd generation (pen-style tank) (iii) variable wattage (tank)</td>
<td>To compare levels of nicotine in mainstream IQOS emissions with nicotine in different type of EC aerosol and in mainstream cigarette smoke</td>
</tr>
<tr>
<td>Schaller, Keller et al. 2016(337)</td>
<td>PMI, Switzerland</td>
<td>Laboratory comparison study using smoking machines</td>
<td>THS 2.2 Cigarette</td>
<td>To compare levels of HPHC in mainstream emissions and smoke</td>
</tr>
<tr>
<td>Schaller, Pijnenburg et al. 2016(338)</td>
<td>PMI, Switzerland</td>
<td>Laboratory comparison study using smoking machines</td>
<td>THS 2.2 Cigarette</td>
<td>To compare levels of HPHC in mainstream IQOS emissions from regular and menthol tobacco sticks with those in mainstream cigarette smoke</td>
</tr>
<tr>
<td><strong>Sidestream &amp; environmental emissions</strong></td>
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<tr>
<td>Mitova, Campelos et al. 2016(333)</td>
<td>PMI, Switzerland</td>
<td>Laboratory comparison study using smoking volunteers</td>
<td>THS 2.2 Cigarette</td>
<td>To compare levels of environmental smoke/emissions</td>
</tr>
<tr>
<td>O'Connell, Wilkinson et al. 2015(334)</td>
<td>IT, United Kingdom</td>
<td>Laboratory comparison study using smoking volunteers</td>
<td>THS 2.2 Cigarette Nicorette inhalator EC (cigalike)</td>
<td>To compare levels of sidestream emissions</td>
</tr>
<tr>
<td>Protano, Manigrasso et al. 2016(335)</td>
<td>Non-sponsored, Italy</td>
<td>Laboratory comparison study using smoking volunteers</td>
<td>THS 2.2 Cigarette Hand-rolled cigarette EC (pen-style tank)</td>
<td>To compare levels of environmental smoke/emissions</td>
</tr>
<tr>
<td>Ruprecht, De Marco et al. 2017(336)</td>
<td>National Cancer Institute Italy &amp; University of Southern California, not reported</td>
<td>Laboratory comparison study using smoking volunteers</td>
<td>THS 2.2 Cigarette EC (cartridge)</td>
<td>To compare levels of environmental smoke/emissions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Authors, year of publication</th>
<th>Funder, country</th>
<th>Study design</th>
<th>Heated tobacco product and reference products</th>
<th>Main aim</th>
</tr>
</thead>
<tbody>
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<td><strong>Effects of use by humans</strong></td>
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<tr>
<td>Brossard, Weitkunat et al. 2017 (341)</td>
<td>PMI, Japan</td>
<td>Randomised crossover experimental trial</td>
<td>THS 2.2 Cigarette Nicotine gum</td>
<td>To compare nicotine delivery and effects on urge to smoke</td>
</tr>
<tr>
<td>Haziza, de La Bourdonnaye, Merlet et al. 2016 (328)</td>
<td>PMI, Japan</td>
<td>RCT</td>
<td>THS 2.2 Cigarette</td>
<td>To compare exposure to HPHC during 5 days of use</td>
</tr>
<tr>
<td>Haziza, de La Bourdonnaye, Skiada, et al. 2016 (329)</td>
<td>PMI, Poland</td>
<td>RCT</td>
<td>THS 2.2 Cigarette</td>
<td>To compare exposure to HPHC during 5 days of use</td>
</tr>
<tr>
<td>Kamada, Yamashita et al. 2016 (344)</td>
<td>None reported, Japan</td>
<td>Case report</td>
<td>IQOS</td>
<td>To report a case of acute eosinophilic pneumonia following use</td>
</tr>
<tr>
<td>Lopez, Hiler et al. 2016 (339)</td>
<td>National Institutes of Health &amp; FDA, United States</td>
<td>Randomised crossover experimental trial</td>
<td>Pax LLTV Cigarette eGo EC (pen-style tank)</td>
<td>To compare nicotine delivery, expired air CO and abstinence symptom suppression</td>
</tr>
<tr>
<td>Ludicke, Baker et al. 2017 (326)</td>
<td>PMI, Poland</td>
<td>RCT</td>
<td>THS 2.1 Cigarette</td>
<td>To compare exposure to HPHC during 5 days of use in confinement</td>
</tr>
<tr>
<td>Ludicke, Haziza et al. 2016 (325)</td>
<td>PMI, Poland</td>
<td>RCT</td>
<td>CHTP Cigarettes</td>
<td>To compare exposure to HPHC during 5 days of use in confinement</td>
</tr>
<tr>
<td>Ludicke, Picavet et al. 2017c (343)</td>
<td>PMI, Japan</td>
<td>RCT</td>
<td>THS 2.2 Cigarette</td>
<td>To compare exposure to HPHC during 5 days of use in confinement and further 85 days of use in an ambulatory setting</td>
</tr>
<tr>
<td>Ludicke, Picavet et al. 2017b (342)</td>
<td>PMI, Japan</td>
<td>RCT</td>
<td>THS 2.2 Cigarette</td>
<td>To compare effect on biologically and clinically relevant risk markers during 90 days of use</td>
</tr>
<tr>
<td>Picavet, Haziza et al. 2016 (340)</td>
<td>PMI, United Kingdom</td>
<td>RCT</td>
<td>THS 2.1 Cigarette</td>
<td>To compare nicotine delivery and effects on urge to smoke</td>
</tr>
<tr>
<td><strong>Epidemiology</strong></td>
<td></td>
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</tr>
<tr>
<td>Tabuchi, Gallus et al. 2017 (345)</td>
<td>Ministry of Health, Labour and Welfare &amp; Society for the Promotion of Science, Japan</td>
<td>Follow-up survey of participants in Tabuchi et al, 2016 (155)</td>
<td>IQOS, Ploom/Ploom TECH, glo</td>
<td>To assess population interest, rate of use, predictors of use, and perceived effects of second-hand aerosol</td>
</tr>
</tbody>
</table>
Evidence review of e-cigarettes and heated tobacco products 2018:
A report commissioned by Public Health England

1 Labels as provided by study authors, additional EC categories in brackets

2 Confinement means that participant stayed in a controlled environment and were not given access to other products. Ambulatory refers to a period of use outside of that controlled environment.

Abbreviations: CHTP: carbon heated tobacco product; Cigarette: Factory-made cigarette; HPHC: harmful and potentially harmful compounds; IT: Imperial Tobacco (now Imperial Brands); LLTV: loose-leaf tobacco vaporiser; PMI: Philip Morris International; THS 2.1: tobacco heating system 2.1.; THS 2.2: tobacco heating system 2.2 (commercially available as IQOS)
Heated tobacco product nicotine and emissions

Nicotine levels in tobacco sticks

An independent study (332) reported that a regular IQOS tobacco stick contained 15.2 ± 1.1 mg of nicotine per gram of tobacco and a menthol tobacco stick contained 15.6 ± 1.7 mg of nicotine per gram of tobacco. Based on the reported average weight of a tobacco stick of 320 mg (327), this equates to 4.9–5 mg of nicotine in each IQOS tobacco stick. For comparison, commercially available cigarettes have around 10–14 mg nicotine per gram of tobacco (346) and the mean amount per cigarette has been reported as 8.7 mg (347) or 10–15 mg (348). However, the content of products before use is less relevant than what is inhaled by the user and those around them. Smokers usually take in about 1-2 mg nicotine per cigarette (348).

Emissions

For cigarettes, emissions can be categorised into mainstream, sidestream and environmental (or second-hand) tobacco smoke. Mainstream tobacco smoke is usually defined as the smoke that the user draws in (349). Laboratory studies use machines to measure the mainstream that would be inhaled by a smoker. Sidestream smoke is smoke that is emitted from the burning end of a cigarette or other tobacco product (349). Environmental tobacco smoke or second-hand smoke is the combination of exhaled mainstream smoke and sidestream smoke and ambient air (349). To categorise the studies in this section, we transfer this categorisation to heated tobacco products as mainstream, sidestream and environmental emissions. All eight studies that focused on heated tobacco product emissions (Table 24) assessed IQOS products; we present the results based on the studies’ key focus on i) mainstream emissions, ii) sidestream and environmental heated tobacco product emissions.

Mainstream emissions

Nicotine levels

The available evidence suggests that nicotine levels in mainstream heated tobacco product aerosol are lower than those in cigarette smoke. Two independent (331, 332) and two manufacturer-funded studies (337, 338) reported on nicotine levels in heated tobacco product aerosol. The studies used different reference cigarettes and different machine smoking regimes, either the ISO regime (ISO; 35 mL puff volume, 30 s intervals between puffs, 14 puffs on average during 5–6 minutes) or the Health Canada Intense regime (HCl; 55 mL puff volume, 2 s puff duration, 30 s intervals between puffs, 14 puffs on average during 5–6 minutes). Generally, for cigarettes, the HCl regime yields higher levels of Harmful and Potentially Harmful Compounds (HPHC) (350) than
the ISO regime but neither are representative of human smoking behaviour and exposure (351). These regimes were also used for the heated tobacco products and EC, sometimes with adaptations.

One independent study (331) followed the ISO puffing regime and used BAT’s Lucky Strike Blue Lights (7 mg tar, 0.6 mg nicotine) as a reference cigarette, another independent study (332) used the HCI regime and PMI’s Marlboro Regular reference cigarette (10 mg tar, 0.8 mg nicotine). The two studies funded by the manufacturer (337, 338) used the HCI regime and University of Kentucky 3R4F reference cigarette (9.4 mg tar, 0.7 mg nicotine). The independent study that used the ISO regime (331) reported an average yield of 0.3 mg of nicotine in the aerosol from a single tobacco stick. The other three studies (332, 337, 338) used the HCI puffing regime and reported nicotine levels in the aerosol which were similar across studies. For regular tobacco sticks, they found a mean and SD of 1.40 ± 0.16 mg (332), 1.38 ± 0.2 mg (338) and 1.32 ± 0.16 mg nicotine (337) and for menthol sticks they reported 1.38 ± 0.11 mg (332) and 1.21 ± 0.09 mg (337) nicotine. Across the four studies, the relative level of nicotine in the heated tobacco product aerosol compared with nicotine in cigarette smoke was reported at 84% (331), 73% (338), 72% (332) and 70% (337).

One study (332) compared nicotine levels in heated tobacco product aerosol with nicotine in aerosol from EC using the HCI puffing regime with increased 4 seconds puffing duration. The heated tobacco product delivered more nicotine than a cigalike EC (0.86 ±0.08 mg, p<0.001), but less than an ‘eGo-style’ (pen-style tank) EC (1.73 ± 0.09 mg, p<0.001) or a variable wattage tank style EC (1.84 ± 0.11 mg, p<0.001).

Harmful and potentially harmful compounds

One independent (331) and two manufacturer-funded studies (337, 338) reported levels of HPHC in mainstream heated tobacco product aerosol compared with cigarette smoke. Different machine puffing regimes and reference cigarettes were used across studies, so results cannot be directly compared. The three studies reported proportions of HPHC in aerosol from regular tobacco sticks for the heated tobacco product compared with HPHC levels in smoke from reference cigarettes; for some, they found similar proportions, others differ widely (Table 25).

When comparing levels of polycyclic aromatic hydrocarbons in heated tobacco product aerosol and cigarette smoke, the independent study (331) used reference data from 50 US cigarette brands (350). However, as a critique from PMI noted (352), Auer and colleagues (331) had inadvertently used incorrect reference values for these constituents (data obtained under HCI instead of ISO regimes). Therefore, for the purposes of this chapter, we recalculated the ratios and provide both the originally published and the recalculated ratios in the comparison of relative levels of three polycyclic aromatic hydrocarbons across the three studies (Table 25).
Auer and colleagues also assessed further constituents and reported a much higher concentration of the polycyclic aromatic hydrocarbon acenaphthene for the heated tobacco product relative to cigarettes (295% reported in the publication; 580% if using ISO reference values). Acenaphthene was not included in the manufacturer studies; the manufacturer commented that the compound is not included in any regulatory lists and that Auer’s method may have been faulty, and that they ‘could not detect it [acenaphthene] in the IQOS aerosol’ (352).

Table 25: Level of constituents in mainstream heated tobacco product (IQOS) aerosol relative to mainstream cigarette smoke (only showing constituents measured in all three studies)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference cigarette</td>
<td>Regular</td>
<td>Regular</td>
<td>Menthol</td>
</tr>
<tr>
<td>Puffing regimen</td>
<td>HCl</td>
<td>HCl</td>
<td>ISO</td>
</tr>
<tr>
<td>Levels relative to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cigarette</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicotine (mg/stick)</td>
<td>73%</td>
<td>70%</td>
<td>64%</td>
</tr>
<tr>
<td>Gases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitric oxide (µg/stick)</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Carbonyls</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetaldehyde</td>
<td>12%</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>Propionaldehyde</td>
<td>12%</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>11%</td>
<td>10%</td>
<td>8%</td>
</tr>
<tr>
<td>Acrolein</td>
<td>7%</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Crotonaldehyde</td>
<td>&lt;6%</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>Acetone</td>
<td>5%</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>Polycyclic aromatic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hydrocarbons</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzo[a]pyrene (ng/stick)</td>
<td>7%</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>Benz [a]anthracene</td>
<td>10%</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>Pyrene (ng/stick)</td>
<td>10%</td>
<td>&lt;6%</td>
<td>10%</td>
</tr>
</tbody>
</table>

* Originally reported proportions

** We calculated these proportions based on mean values of polycyclic aromatic hydrocarbons in mainstream smoke of 50 commercial US cigarettes measured by the ISO smoking regimen as reported by (Vu, Taylor et al. 2015)

Sidestream and environmental emissions

Published evidence disagrees on the extent to which heated tobacco products produce environmental emissions and the composition of these emissions.
Four studies, two independent (335, 336), one manufacturer-funded (333) and one funded by a competing tobacco company (334), compared environmental heated tobacco product emissions with environmental tobacco smoke from factory-made (333, 335, 336) or hand-rolled (335) tobacco cigarettes, or aerosol from a nicotine inhalator (334) and different EC (334-336). The studies were heterogeneous in the methods used and in the reporting of results, therefore only key findings are summarised here.

Two studies (334, 335) reported few measurements of individual compounds and only provided some general conclusions about environmental heated tobacco product emissions. The independent study (335) reported that the tested EC and heated tobacco product generated four times lower levels of submicronic particles, an indicator of second-hand smoking, compared with environmental tobacco smoke from regular or hand-rolled cigarettes. Despite low levels of emissions, the study authors concluded that the tested EC and heated tobacco products still posed health risks to users and bystanders (335). The study funded by the competing tobacco company (334) reported that IQOS produced a significantly greater level of sidestream emissions than a nicotine inhalator or an EC: the heated tobacco product emissions were detectable when the device was activated but not used, which contradict the manufacturer's claims that IQOS 'does not emit a true sidestream aerosol' (333).

The second independent study (336) reported levels of particulate matter of different sizes (>1.0 µm, >0.3 µm, and 10-1000 nm) and HPHC in environmental heated tobacco product emissions. In simulated indoors conditions with 1.54 air changes per hour levels of nano-sized (10-1000 nm) particulate matter in environmental heated tobacco product emissions reached up to 23.8% of the levels detected in environmental tobacco cigarette smoke; levels for other size particulate matter in environmental heated tobacco product emissions ranged from 0.7% to 7.3%. Regarding HPHC in environmental heated tobacco product emissions, acrolein concentration reached 1.8%-2.3% of levels detected in environmental cigarette smoke, acetaldehyde reached 5.0%-5.9%, and formaldehyde 6.9%-7.1%. For EC, these were not detectable, with the exception of nano-sized particles (5.7%-7.0% of cigarettes), acetaldehyde (0.2%-0.3%) and formaldehyde (3.1%-3.7%). The study concluded that environmental emissions from heated tobacco products were substantially higher than from EC but significantly lower than those detected in environmental tobacco smoke from a cigarette. The study authors also noted the presence of carbonyls in environmental heated tobacco product emissions as a concern that heated tobacco product use might affect bystanders (336).

In contrast to other three studies, the manufacturer-funded study (333) concluded that the tested heated tobacco product did not produce particulate matter and also reported lower levels of environmental heated tobacco product emissions compared with environmental tobacco smoke from a cigarette. In simulated indoors condition with 1.2 air changes per hour, no change in particulate matter markers was detected and levels
of HPHC in air after heated tobacco product use ranged from 5.8% for benzene to 40.5% for formaldehyde compared with cigarette smoke.

Heated tobacco product use by human participants and effects of use

We summarise nine articles that compared levels of exposure to biomarkers of HPHC, nicotine delivery characteristics, human puffing topography, effect on urges to smoke and subjective satisfaction with heated tobacco products. The six RCTs (one of them reported in two papers) and two studies with a crossover design are presented by the type of heated tobacco product they assessed.

Loose-leaf tobacco vaporiser

One independent study (339) used a crossover design (so that each of the 15 participants went through all three conditions) to compare the loose-leaf tobacco heated tobacco product Pax, cigarettes and pen-style EC. The study compared nicotine delivery, levels of expired air CO concentration and suppression of nicotine abstinence symptoms after short periods of use. The short period of use consisted of 10 puffs separated by 30 seconds and each period was separated by 60 minutes. The highest plasma nicotine levels were reported after cigarette use (24.4 ng/mL), lower levels were found after heated tobacco product use (14.3 ng/mL) and the lowest after EC use (9.5 ng/mL). Baseline expired air CO was around 5 parts per million for all conditions. After two periods of smoking a cigarette, this increased significantly (up to 16.9 parts per million, p<0.001), which contrasted with small but significant decreases after single periods of heated tobacco product and EC use (ps<0.05); no differences between the latter two were observed. Nicotine delivery was associated with suppression of nicotine abstinence symptoms; smoking a cigarette suppressed them most, use of the heated tobacco product was less effective, and use of the EC was least effective. Based on participants’ responses to a specifically modified version of Direct Effects of Product Scale questionnaire, the study authors concluded that the heated tobacco product and the EC were less satisfying than cigarettes.

Carbon heated tobacco product

One manufacturer-funded RCT (325) compared levels of exposure to HPHC between smokers who were randomised to using a CHTP (predecessor to TEEPS), to continue smoking, or to abstain from smoking, for five days in ‘confinement’, ie in a controlled environment without access to other products (n=112). After switching, smokers in the CHTP group were reported to demonstrate less exposure to HPHC than participants who continued smoking (Table 26). Smokers in the CHTP group altered their behaviour: they took more frequent and longer puffs, showed higher average and total puff volumes. On day five, product consumption by those randomised to the CHTP was reported to be 19.7 compared with 18.8 cigarettes among smokers randomised to
continued cigarette smoking. At the end of the five-day confinement period, nicotine equivalents measured in urine in the CHTP group was reported at 19.1 ng/mL compared with 17.2 ng/mL in the cigarette smoking group, plasma cotinine for the past 24 hours was 319.8 mg versus 289.8 mg; these differences were not statistically significant.

**Tobacco heating system 2.1 (THS 2.1)**

Two manufacturer-funded RCTs (326, 340) reported findings on THS 2.1. One trial (340) compared the pharmacokinetic nicotine delivery profile of THS 2.1 with non-menthol and smokers’ preferred cigarettes (n=28). After single use, THS 2.1 and cigarettes were reported to be similar in how fast plasma nicotine levels reached peak (median for both: 8 minutes), reduction of urges to smoke, and in the nicotine half-life length (2.6 hours for THS 2.1 and 2.5 hours for a cigarette). However, compared with cigarettes, THS 2.1 delivered lower peak levels of nicotine after single and a day’s *ad libitum* use (70% and 62%, respectively) and participants consumed fewer tobacco sticks than smokers smoked cigarettes during an *ad libitum* use day (10.9 tobacco sticks versus 16.7 CPD). THS 2.1 was perceived less rewarding in sensory and physical effects when used *ad libitum*; on the modified cigarette evaluation scores (353), THS 2.1 was rated significantly lower on four out of five subscales (Smoking satisfaction, Psychological rewards, Enjoyment of respiratory tract sensation and Craving reduction). The other trial (326) compared exposure levels to HPHC in smokers randomised to using THS 2.1 with smokers randomised to continued smoking; both groups were in confinement for five days (n=40). The exposure to HPHC was reported to be lower in the THS 2.1 group (Table 26). In contrast to the previous study findings that showed less use during one day, in this five-day study smokers in the THS 2.1 group used up to 35% more tobacco sticks than the other group cigarettes (27.2 and 20.1 respectively). Despite compensatory puffing (increased frequency, duration and volume), THS 2.1 users achieved only 85% and 88% of nicotine and cotinine of the cigarette group on the last confinement day. Modified cigarette evaluation scores were again significantly lower for THS 2.1 on the same four subscales.

**Tobacco heating system 2.2 (THS 2.2)**

The review identified a single case report related to use (344), one publication on a manufacturer randomised cross-over study and four publications reporting on three manufacturer-funded RCTs (328, 329, 341-343) using THS 2.2 which is equivalent to the commercially available IQOS.

The case report (344) described a case of acute eosinophilic pneumonia in a 20-year-old man from Japan who used 20 IQOS tobacco sticks per day for six months and 40 IQOS tobacco sticks a day for two weeks before hospitalisation. Based on the relationship between cigarette smoking and this type of pneumonia, the case report
authors presumed that the rapid increase in the daily use of tobacco sticks had caused the onset of the acute eosinophilic pneumonia.

The randomised cross-over study (341) was conducted in Japan and assessed pharmacokinetic nicotine delivery properties of regular and menthol THS 2.2 compared with cigarettes (n=44) and nicotine gum (n=18). The study authors concluded that the use of regular and menthol THS 2.2 delivered nicotine in a similar way as smoking regular and menthol cigarettes. In detail, compared with cigarettes, nicotine pharmacokinetics for regular and menthol tobacco sticks were similar to each other and similar to cigarettes: peak plasma concentrations for regular and menthol tobacco sticks and cigarettes were reached in six minutes, actual exposure to nicotine was comparable (ratio THS 2.2 : cigarettes: 96.3% for regular, 98.1% for menthol), as was nicotine half-life (93.1% and 102.3%). Peak nicotine concentration ratio for regular tobacco sticks versus cigarettes was 103.5% and 88.5% for menthol tobacco sticks versus cigarettes. Relative to nicotine gum, the results are less clear, probably due to the small sample. Regular tobacco sticks appeared to outperform menthol sticks for actual exposure to nicotine (127.2% and 55.9%) and peak nicotine concentration (240.2% and 101.6%); however, with only 18 participants, this may be due to chance. Relative to gum, nicotine half-life was 87.3% for regular and 92.1% for menthol tobacco sticks.

Four papers reported on the three RCTs. Two manufacturer-funded RCTs, one conducted in Japan (328) and the other in Poland (329), compared the exposure to HPHC in smokers who were in confinement randomised to using regular THS 2.2 for five days, to continued smoking of their preferred non-menthol cigarette, or to smoking abstinence (both RCTs n=160). Two papers (342, 343) reported findings from one manufacturer-funded RCT comparing menthol THS 2.2 with menthol cigarettes conducted in Japan where exposure to HPHC and change in health risk markers were assessed after five days in confinement and a further 85 days in ambulatory setting. This RCT also had a third group of participants randomised to abstain from smoking.

The three RCTs reported daily product use at the end of five days in confinement and provided contrasting results; in the trial in Japan (328), the THS 2.2 group used significantly fewer (on average 20%) tobacco sticks than the smoking group smoked cigarettes, while in the trial in Poland (329), the THS 2.2 group used significantly more (on average 25%) tobacco sticks than the other group cigarettes. In the menthol study (343), daily use of tobacco sticks and cigarettes did not differ.

Publications on all three RCTs reported lower levels of exposure to biomarkers of HPHC in smokers who switched to using THS 2.2 compared with smokers who continued smoking (Table 26), (328, 329, 342). Across the three studies, the reduction in exposure to HPHC in the THS 2.2 groups approached that reported in the groups randomised to smoking abstinence.
The three RCTs also reported similar findings on puffing topography, the ability of THS 2.2 to suppress urges to smoke and modified cigarette evaluation scores. THS 2.2 users throughout all three studies demonstrated different puffing behaviours that may indicate compensatory puffing (increased puffing frequency, duration and number of puffs compared with the smoking group). THS 2.2 was reported to suppress urges to smoke similarly to smoking cigarettes and was in all three studies rated lower on sensory and psychological satisfaction than cigarettes (significantly lower scores for THS 2.2 on four out of five modified Cigarette Evaluation Questionnaire (mCEQ) subscales in two studies (329, 343) and on one subscale in the other study (328).

The RCT with a 90-day follow-up (342) additionally measured changes in a set of risk markers associated with CVD (eg endothelial functions, cholesterol metabolism, platelet functions, inflammation and oxidative stress). When compared with smokers who continued to smoke menthol cigarettes, smokers who had been randomised to using menthol THS 2.2 were reported to show improvements in risk markers associated with endothelial dysfunction, oxidative stress, inflammation, and high-density lipoprotein cholesterol counts, with the changes reportedly approaching those in the group randomised to complete abstinence. However, participants may have been non-compliant with study conditions. Reportedly, 92.5% participants randomised to smoking abstinence and 89.7% randomised to exclusive heated tobacco product use were compliant throughout the 85 days of ambulatory use. However, compliance was defined as not having used more than two menthol CPD since the last visit and not more than half a cigarette per day on average. Consumption was assessed by self-reported electronic diary entries, and while expired CO was measured, results were not reported, thereby not following standard practice (165) (354). This suggests that both 'abstinent' participants and heated tobacco product participants may have been smoking. If heated tobacco product users had also smoked, any reduction in biomarkers relative to smokers would be conservative; however, comparison with the abstinence group should be treated with particular caution as the extent of abstinence is unclear. Study validity is further undermined because the study used a per-protocol approach instead of intention to treat analysis which compromises the validity of randomisation (355) and is in contravention to trial standards outlined eg in the CONSORT statement (356).
### Table 26: Product use and level of exposure to HPHC in heated tobacco product users relative to cigarette smokers

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Carbon heated tobacco product</td>
<td>THS 2.1, 0.3mg nicotine, 5.0mg* glycerol</td>
<td>Non-menthol THS 2.2, 0.5mg nicotine, 4.9mg glycerol</td>
<td>Non-menthol cigarette, preferred brand</td>
<td>Non-menthol cigarette, preferred brand</td>
<td>Menthol THS 2.2, 1.2mg nicotine, 3.9mg glycerol</td>
</tr>
<tr>
<td>Reference product</td>
<td>Non-menthol cigarette, preferred brand</td>
<td>Non-menthol cigarette, preferred brand</td>
<td>Non-menthol cigarette, preferred brand</td>
<td>Non-menthol cigarette, preferred brand</td>
<td>Menthol cigarette, preferred brand</td>
</tr>
<tr>
<td>Mean (SD) product use (heated tobacco vs reference)</td>
<td>19.7 (7.8) vs 18.8 (4.4)</td>
<td>27.2 (9.1) vs 20.1 (3.2)</td>
<td>9.9 (3.9) vs 12.5 (3.5)</td>
<td>20.7 (8.1) vs 16.6 (3.8)</td>
<td>13.9 (4.3) vs 13.6 (4.7)</td>
</tr>
<tr>
<td>Biomarkers for HPHC, Mean (95% CI if available)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbon monoxide (CO)</td>
<td>39% (21%–26%)</td>
<td>23% (44%–50%)</td>
<td>24% (22%–25%)</td>
<td>45%</td>
<td></td>
</tr>
<tr>
<td>Acrolein</td>
<td>26% (23%–33%)</td>
<td>28% (46%–61%)</td>
<td>42% (38%–46%)</td>
<td>52%</td>
<td></td>
</tr>
<tr>
<td>1,3-butadiene</td>
<td>12% (9%–16%)</td>
<td>12% (18%–29%)</td>
<td>8% (7%–10%)</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>Benzene</td>
<td>7% (5%–10%)</td>
<td>16% (13%–19%)</td>
<td>6% (5%–7%)</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Nicotine-derived nitrosamine ketone (NNK)</td>
<td>52% (25%–44%)</td>
<td>49% (42%–57%)</td>
<td>44% (39%–48%)</td>
<td>44%</td>
<td></td>
</tr>
<tr>
<td>Pyrene</td>
<td>57% (36%–51%)</td>
<td>43% (41%–52%)</td>
<td>44% (40%–49%)</td>
<td>38%</td>
<td></td>
</tr>
<tr>
<td>N-nitrosonornicotine (NNN)</td>
<td>not reported</td>
<td>12% (24%–38%)</td>
<td>24% (18%–33%)</td>
<td>29%</td>
<td></td>
</tr>
<tr>
<td>4-Aminobiphenyl</td>
<td>16% (31%–53%)</td>
<td>18% (15%–22%)</td>
<td>15% (13%–17%)</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>1-aminonaphthalene</td>
<td>not reported</td>
<td>not reported</td>
<td>4% (3%–5%)</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>2-aminonaphthalene</td>
<td>19% (8%–14%)</td>
<td>11% (15%–21%)</td>
<td>12% (10%–13%)</td>
<td>14%</td>
<td></td>
</tr>
<tr>
<td>o-toluidine</td>
<td>49% (48%–71%)</td>
<td>58% (42%–60%)</td>
<td>42% (36%–48%)</td>
<td>41%</td>
<td></td>
</tr>
<tr>
<td>Acrylonitrile</td>
<td>not reported</td>
<td>15% (18%–25%)</td>
<td>13% (12%–15%)</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td>Ethylene oxide</td>
<td>not reported</td>
<td>not reported</td>
<td>38% (32%–45%)</td>
<td>32% (20%–38%)</td>
<td>51%</td>
</tr>
<tr>
<td>Crotonaldehyde</td>
<td>not reported</td>
<td>not reported</td>
<td>38% (32%–45%)</td>
<td>32% (20%–38%)</td>
<td>43%</td>
</tr>
<tr>
<td>Benzo(a)pyrene</td>
<td>not reported</td>
<td>not reported</td>
<td>30% (25%–36%)</td>
<td>28% (23%–33%)</td>
<td>28%</td>
</tr>
<tr>
<td>Nicotine equivalents</td>
<td>111% (76%–100%)</td>
<td>87% (92%–120%)</td>
<td>113% (91%–140%)</td>
<td>113% (91%–140%)</td>
<td>118%</td>
</tr>
<tr>
<td>Nicotine</td>
<td>not reported</td>
<td>85% (91%–140%)</td>
<td>113% (91%–140%)</td>
<td>not reported</td>
<td></td>
</tr>
<tr>
<td>Cotinine</td>
<td>110% (75%–103%)</td>
<td>88% (71%–131%)</td>
<td>96% (71%–131%)</td>
<td>111% (91%–136%)</td>
<td>not reported</td>
</tr>
</tbody>
</table>

All figures from fifth day of confinement (including only studies that used at least 5 days of confinement)

* Reported as 50mg in publication, authors confirmed this was a typo and should be 5.0mg

1 Originally reported proportions

2 Proportions we calculated based on raw study figures

Epidemiological studies on heated tobacco product use

The literature search identified one independently-funded survey on awareness and use of heated tobacco products in Japan in 2015 (155), which was conducted about three months after the launch of IQOS and about a year after the launch of Ploom. EC are not generally available in Japan. Additionally, we report unpublished findings from a follow-up to that survey (357).

The 2015 survey (155) provided evidence from a nationally representative sample of 8,240 respondents aged 15 to 69 years. Survey questions did not distinguish between EC and heated tobacco products; almost half of Japan’s population (48%) were aware of EC and/or heated tobacco products, 6.6% had ever used these products, and 1.3% used them in the last 30 days. Data by product type were only reported for ever use which showed that 0.5% of the population had ever used Ploom and 0.6% had ever used IQOS. The as yet unpublished data on heated tobacco use in Japan in 2017 (357) are based on annual surveys following up the 2015 sample (follow-up rate 65.6% in 2016 and 52.2% in 2017) and suggest growth in IQOS use. These data include past 30 day use for different products for 2015 allowing comparisons over time; in 2015, 0.3% reported using IQOS in the last 30 days, this increased to 0.6% in 2016 and 3.6% in 2017 (never smokers 1.3%, ex-smokers 2.1%, current smokers with intention to quit 18.8%, current smokers without intention to quit 10.3%). Last 30-day use of other commercially available heated tobacco products in 2017 was reported at 1.2% for Ploom/ploom TECH and 0.8% for glo (the same respondent may have used more than one product). Smoking rates remained unchanged across survey waves (22.1% in 2015, 22.0% in 2017). It is also reported that among the 7% of never-smokers who had been exposed to second-hand heated tobacco aerosol, nearly half reported at least one acute symptom, although these symptoms were not serious (357).

Data and trends from Japan are not easily transferrable to the UK because in contrast to the UK, EC are not legal in Japan giving heated tobacco products a very different starting position. Nevertheless, data from Japan show rapid penetration of a non-combustible tobacco product into the market.
Additional survey data from GB

These data are unpublished and therefore not included in the preceding systematic review. The STS and ASH-A have introduced questions on heated tobacco products. In the ASH-A 2017, 9.3% reported awareness of heated tobacco products and 1.7% had tried or were using the products. Among those who had ever tried heated tobacco products, 38.7% had tried it once or twice and 12.7% had been using it daily. However, survey participants were asked about heated tobacco products prior to answering about EC, which is likely to have led to overestimations of awareness and use of heated tobacco products (see Brose and colleagues (358) for more details). The hypothesis that the ASH-A represents an overestimation is strongly supported by data from the STS. Between January and July 2017, nearly 12,000 respondents were surveyed. The STS did not ask about awareness of the product, only about use. Last-year smokers (n=2,185) were asked about use of heated tobacco products in recent quit attempts (n=4 reported use), to help cut down the amount smoked (n=6), in situations where not allowed to smoke (n=1) or for any other reason (n=0). Among never and long-term ex-smokers (n=9,777), n=5 said they were using heated tobacco products.

Conclusions

Key findings

- In mid 2017 heated tobacco products were commercially available in 27 countries and further country launches were planned. Three tobacco manufacturers were promoting heated tobacco products: ‘IQOS’ was promoted by PMI, ‘glo’ by BAT, and ‘Ploom TECH’ by Japan Tobacco International.
- Out of 20 studies that were included in this review, 12 were funded by manufacturing companies so there is a lack of independent research.
- There is a variety of heated tobacco products, including some that deliver via both vapour and combustion.
- Most studies published at the time of the search for this review evaluated IQOS, none evaluated glo or Ploom TECH. An updated version of the review including later publications is in preparation to be published separately.
- In Great Britain, in 2017, awareness and ever use of heated tobacco products were very rare.
- Nicotine in mainstream aerosol from heated tobacco products reached 70%–84% of the nicotine detected in smoke from reference cigarettes.
- The tested heated tobacco products delivered more nicotine in aerosol than a cigalike EC and less nicotine than tank style EC.
- Pharmacokinetics and delivery of nicotine after single use of a heated tobacco product were generally comparable with smoking a cigarette. However, studies that compared ad libitum use of heated tobacco products with smoking cigarettes

- Consistently reported lower nicotine levels in heated tobacco product users compared with smokers.
  - Probably to compensate, smokers who were switched to using heated tobacco products adjusted their puffing behaviour.
- Heated tobacco product use reduced urges to smoke, but smokers consistently reported heated tobacco product use to be less rewarding compared with smoking a cigarette.
- Compared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC). The extent of the reduction found varies between studies.
- The limited evidence on environmental emissions from use of heated tobacco products suggests that harmful exposure from heated tobacco products is higher than from EC, but further evidence is needed to be able to compare products.
- Japan, where EC are not available, has the most diverse heated tobacco product market with three tobacco manufacturers participating. Past 30 day use for the most frequently used product increased from 0.3% in 2015 to 3.7% in 2017, suggesting rapid penetration of heated tobacco products.

Implications

Research

- There is a need for more research that is independent of commercial interests.
- Different types of heated tobacco products will have different characteristics and effects, presenting a challenge for research.
- Research is needed on relative risk of heated tobacco products to users and those around them compared with cigarettes and EC.
- Evidence is needed on appeal of heated tobacco products to smokers and non-smokers, particularly among youth.
- Effects on smoking need to be researched, this includes whether they replace or complement cigarettes. Due to co-branding of some products with cigarettes and the more similar sensory profile, findings may be different than for EC.
- Future studies, whether funded by manufacturers or independently should ensure conduct of studies in line with established guidelines such as definitions of abstinence from smoking, using intention-to-treat analysis and registering trial protocols prior to the start of participant recruitment.
- The appropriateness of different methods for measuring emissions and their translation from cigarettes to heated tobacco products should be evaluated to be able to recommend a gold standard.
- Prevalence and market share should be monitored, particularly in markets targeted by manufacturers.
o In line with recommendations for EC use (135), measures should go beyond lifetime use or past 30 day use to assess current use; uptake and use should be assessed by smoking status.
o Monitoring should include transitions between smoking, EC use and heated tobacco product use.

Policy and practice

- The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than EC.
- With a diverse and mature EC market in the UK, it is currently not clear whether heated tobacco products provide any advantage as an additional potential harm reduction product.
- Depending on emerging evidence on their relative risk to combustible tobacco and EC, regulatory levers such as taxation and accessibility restrictions should be applied to favour the least harmful options alongside continued efforts to encourage and support complete cessation of tobacco use.
Bibliography

Evidence review of e-cigarettes and heated tobacco products 2018:
A report commissioned by Public Health England


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167. West R. Stop smoking services: increased chances of quitting. London: National Centre for Smoking Cessation and Training (NCSTC); 2012.


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289. O’Connell G, Graff DW, D’Ruiz CD. Reductions in biomarkers of exposure (BoE) to harmful or potentially harmful constituents (HPHCs) following partial or complete substitution of cigarettes in adult smokers. Toxicol Mech Method. 2016;26(6):453-64.


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Appendices

1. ASH-A unweighted base sizes

1. By smoking status over time (age 18+)

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2. By EC use and smoking status, 2017 (age 18+)

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3. By EC use and smoking status for those who have used EC more than once or twice, 2017 (age 18+)

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## Table of primary studies included in systematic reviews of EC for cessation or reduction (chapter 7)

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† Conference abstract *same study
### 3 Non–UK case reports concerning injuries caused by EC explosion (Chapter 8)

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<th>Gender</th>
<th>Age</th>
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<th>Nature of injury</th>
<th>Treatment</th>
<th>Details of EC</th>
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<td>Archambeau et al., 2016 (395) US</td>
<td>1</td>
<td>Male</td>
<td>59</td>
<td>In mouth while vaping</td>
<td>Fractures to skull and nose, black eye, laceration to lips. Pneumocephalus.</td>
<td>Oral and maxillofacial surgery</td>
<td>Bought it online 2 days previously, no modifications made</td>
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<td>Bauman et al., 2017 (396) US</td>
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<td>Male</td>
<td>58</td>
<td>While in right trouser pocket</td>
<td>7% TBSA combination of deep partial-thickness and full-thickness burns to the back and side of left thigh</td>
<td>Wound management. Skin graft</td>
<td>Reported as unclear</td>
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<td></td>
<td>Male</td>
<td>20</td>
<td>While in right trouser pocket (with coins and keys)</td>
<td>4% TBSA superficial, partial-thickness burn to the right thigh</td>
<td>Wound management</td>
<td>Immediately prior to the injury, the patient had changed the used battery</td>
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<tr>
<td></td>
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<td>Male</td>
<td>37</td>
<td>While in right trouser pocket</td>
<td>11% TBSA deep partial-thickness to full-thickness burn to left thigh and buttock</td>
<td>Wound management and skin graft</td>
<td>The lithium battery in his EC was over 1-year old</td>
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<tr>
<td>Bohr et al., 2016 (397) Germany</td>
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<td>Male</td>
<td>24</td>
<td>While in right trouser pocket</td>
<td>8% TBSA superficial and deep burn and soot-particle contamination to right leg</td>
<td>Wound management</td>
<td>Tank style EC</td>
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<td>Brooks et al., 2017 (398) US</td>
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<td>18</td>
<td>In mouth while vaping</td>
<td>Loss of three teeth and damaged a further three. External/intra oral lacerations. Fracture to nose.</td>
<td>Wound management and four teeth extracted</td>
<td>Had been vaping for approx. an hour and occurred after refilling EC with e-liquid.</td>
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<td>Male</td>
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<td>In mouth while vaping</td>
<td>Loss and fracture of several teeth. External/intra oral lacerations. Third-degree burn injuries to legs and second-degree burn injuries to genitalia and/or hands</td>
<td>Sutures and dental care</td>
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<td></td>
<td>Male</td>
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<td>While in right trouser pocket</td>
<td>1% TBSA superficial and deep burn and soot-particle contamination to right leg</td>
<td>Skin graft</td>
<td>Not reported</td>
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<td>While in right trouser pocket</td>
<td>11% TBSA deep partial-thickness to full-thickness burn to left thigh and buttock</td>
<td>Skin graft</td>
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<td>Cason et al., 2016 (400) US</td>
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<td>23</td>
<td>In mouth while vaping</td>
<td>Multiple fractures to hard palate (roof of mouth) and nose. Loss of teeth. Fractured finger. Corneal abrasion.</td>
<td>Surgical repair of his hard palate</td>
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<td>30</td>
<td>While holding the EC</td>
<td>First and second-degree burns to left hand. Material from EC device embedded deep in tissue from high pressure injection</td>
<td>Wound management and surgery to finger immediately and 5 months later</td>
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<td>While in trouser pocket along with coins (EC battery)</td>
<td>10% TBSA mixed partial thickness and full-thickness burns to his right thigh, buttock and leg, and left inner thigh</td>
<td>Wound management and skin graft</td>
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<td>Male</td>
<td>36</td>
<td>While in trouser pocket along with coins and keys (EC battery)</td>
<td>3% TBSA deep partial and full thickness burns to his right thigh and superficial partial thickness burns to right hand</td>
<td>Wound management and skin graft</td>
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<td>Gender</td>
<td>Age</td>
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<td>Nature of injury</td>
<td>Treatment</td>
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<td>28</td>
<td>In mouth while vaping</td>
<td>Tooth loss and damage, burns to tongue, lips and gum</td>
<td>Teeth extraction, gum surgery and teeth implants</td>
<td>EC had just been charged (with a charger purchased separately to EC)</td>
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<td>While in trouser pocket (lithium battery only)</td>
<td>8% TBSA superficial partial-thickness burn to right leg</td>
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<td>26</td>
<td>While in trouser pocket</td>
<td>5.5% Mixed partial and full thickness <em>burn to</em> left thigh and lower leg, groin and scrotal area</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>46</td>
<td>While in his lap</td>
<td>4.4% TBSA partial thickness burn to left thigh</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>19</td>
<td>Battery explosion (circumstance not reported)</td>
<td>3.5% TBSA mixed partial and full thickness Left hand and forearm, left thigh</td>
<td>Skin graft</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>29</td>
<td>While in trouser pocket</td>
<td>4.5% TBSA full-thickness burn to left thigh</td>
<td>Skin graft</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>19</td>
<td>Motorcycle crash inducing ignition of EC in trouser pocket</td>
<td>2% TBSA mixed partial and full thickness burn to right thigh</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>18</td>
<td>In mouth while vaping</td>
<td>1% TBSA partial thickness burn to right hand, dental and face trauma</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>38</td>
<td>While in trouser pocket</td>
<td>5% TBSA mixed partial and full thickness to right thigh</td>
<td>Skin graft</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>22</td>
<td>While in trouser pocket (with keys)</td>
<td>3% TBSA burn to left thumb left thigh</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>29</td>
<td>Vaporiser explosion (circumstances not reported)</td>
<td>27.25% TBSA mixed deep partial and full thickness burns to Bilateral upper extremities, face, ear, anterior chest, abdomen</td>
<td>Skin graft and elective contracture releases of his axillary region and both hands at later date</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>22</td>
<td>While in trouser pocket</td>
<td>3.25 TBSA mixed partial thickness burn to right thigh and right hand</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td>Khairudin et al., 2016 (406)</td>
<td>1</td>
<td>Male</td>
<td>18</td>
<td>While modifying the EC</td>
<td>Laceration to right eyelid and conjunctival. Traumatic mydriasis, anterior uveitis. Cataract.</td>
<td>Irrigation and suturing of the eyelid and conjunctival laceration wounds</td>
<td>Modifying the tank of the mechanical EC, changing the original coil to a homemade copper coil</td>
</tr>
<tr>
<td>Kite et al., 2016 (407)</td>
<td>2</td>
<td>Male</td>
<td>19</td>
<td>In mouth while vaping</td>
<td>External/intra oral lacerations. Loss of three teeth, fractures to four teeth 3% TBSA deep partial thickness, second-degree burns to chest and left forearm. Full thickness skin and soft tissue loss to right palm and fingers. Metal and chemical deposits in soft tissue of the hand</td>
<td>Oral and maxillofacial surgery and eventually amputation of finger</td>
<td>Homemade vaporizer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>24</td>
<td>While holding EC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author, publication year and location</td>
<td>n of cases</td>
<td>Gender</td>
<td>Age</td>
<td>Circumstance of EC explosion</td>
<td>Nature of injury</td>
<td>Treatment</td>
<td>Details of EC</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>------------</td>
<td>--------</td>
<td>-----</td>
<td>--------------------------------</td>
<td>-----------------</td>
<td>-----------</td>
<td>--------------</td>
</tr>
<tr>
<td>Kumetz et al., 2016 (408) US</td>
<td>2</td>
<td>Male</td>
<td>29</td>
<td>In mouth while vaping</td>
<td>External/intra oral burns, lip lacerations and superficial burns. Loss and fracture of several teeth. Post-traumatic stress disorder. 4% TBSA partial and full thickness burn to the right thigh. Partial-thickness burns to palm and 3 fingers on right hand</td>
<td>Oral and maxillofacial surgery</td>
<td>Refillable rechargeable device</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>23</td>
<td>While in trouser pocket</td>
<td>Fractures of two vertebrae. Fractures to two teeth. Partial thickness burns to lips. Abrasion on tongue.</td>
<td>Surgery to remove EC component from spine</td>
<td>Not reported</td>
</tr>
<tr>
<td>Norii and Plate, 2017 (409) US</td>
<td>1</td>
<td>Male</td>
<td>27</td>
<td>In mouth while vaping</td>
<td>4% TBSA partial and full thickness burn to the right thigh. Partial-thickness burns to lips. Abrasion on tongue.</td>
<td>Eye surgery</td>
<td>Occurred after replacement of a new battery</td>
</tr>
<tr>
<td>Paley et al., 2016 (410) US</td>
<td>2</td>
<td>Male</td>
<td>45</td>
<td>In mouth while vaping</td>
<td>First-degree burns to face and right hand. Loss of two teeth. Lacerations to both corneas and irises. Damage to eyesight. Burns to face, neck, and hands and both corneas</td>
<td>Treatment for burns unspecified; irrigation and topical treatment to eyes.</td>
<td>Vape pen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>16</td>
<td>While holding EC at chest level</td>
<td>0.5% TBSA burn to face, lip laceration, corneal abrasion</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td>Patterson et al., 2016 (411) US</td>
<td>2</td>
<td>Male</td>
<td>46</td>
<td>While in trouser pocket</td>
<td>1% TBSA partial thickness burns to left thigh, penis and two fingers of left hand</td>
<td>An ‘operative intervention’</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>41</td>
<td>In mouth while vaping</td>
<td>0.5% TBSA burn to face, lip laceration, corneal abrasion</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td>Roger et al., 2016 (412) US</td>
<td>1</td>
<td>Male</td>
<td>18</td>
<td>In mouth while vaping</td>
<td>Oral and abdominal burns (severity not specified), oral lacerations, tooth loss and fracture</td>
<td>Reconstructive surgery and dental implants</td>
<td>Not reported</td>
</tr>
<tr>
<td>Shastry and Langdorf, 2016 (413) US</td>
<td>1</td>
<td>Male</td>
<td>26</td>
<td>In mouth while vaping</td>
<td>Small area of second-degree burns. Foreign body penetration in abdomen and chest; small penetrating foreign bodies in thumb</td>
<td>Wound care</td>
<td>Patient was a paid tester for an EC company. Was using an experimental customizable, device with a lithium-ion battery</td>
</tr>
<tr>
<td>Sheckter et al., 2016 (414) US</td>
<td>3</td>
<td>Male</td>
<td>34</td>
<td>While in trouser pocket</td>
<td>15 % TBSA; deep partial-thickness and full-thickness burn of the right leg</td>
<td>Skin graft</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>19</td>
<td>While in trouser pocket</td>
<td>7 % TBSA mixed partial- and full-thickness burn to the thigh and calf</td>
<td>Skin graft</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>35</td>
<td>While in trouser pocket</td>
<td>2 % TBSA partial- and full-thickness burn to right thigh</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td>Treitl et al., 2017 (415) US</td>
<td>3</td>
<td>Male</td>
<td>25</td>
<td>While in trouser pocket (lithium battery only)</td>
<td>6% TBSA partial thickness burns to the left thigh and knee</td>
<td>Wound management</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>43</td>
<td>While in trouser pocket (battery only)</td>
<td>3–4% TBSA partial and full thickness burns to his right thigh, scrotum, and penis. &lt; 1% TBSA partial thickness burns to hands. Neuropathic pain 4 months post event. 10% TBSA, partial thickness burns, as well as 2–3% TBSA full-thickness burns to his left calf</td>
<td>Wound management and transferred to burn centre</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>30</td>
<td>While in trouser pocket (battery only)</td>
<td></td>
<td>Wound management and transferred to a burn centre for skin graft</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

1 TBSA = total body surface area
Press release

E-cigarettes: an emerging public health consensus

From: Public Health England
First published: 15 September 2015
Part of: Smoking

Joint statement on e-cigarettes by Public Health England and other UK public health organisations.

We all agree that e-cigarettes are significantly less harmful than smoking. One in 2 lifelong smokers dies from their addiction. All of the evidence suggests that the health risks posed by e-cigarettes are relatively small by comparison but we must continue to study the long term effects.

And yet, millions of smokers have the impression that e-cigarettes are at least as harmful as tobacco and we have a responsibility to provide clear information on the facts as we know them to be. It is our duty to provide reassurance for the 1.1 million e-cigarette users who have completely stopped smoking to prevent their relapse.

To be clear, the public health opportunity is in helping smokers to quit, so we may encourage smokers to try vaping but we certainly encourage vapers to stop smoking tobacco completely.

We know that e-cigarettes are the most popular quitting tool in the country with more than 10 times as many people using them than using local stop smoking services. But, we also know that using local stop smoking services is by far the most effective way to quit.

What we need to do is combine the most popular method with the most effective and that is why we are encouraging those who want to use e-cigarettes to quit smoking to seek the help of their local stop smoking service.

The current national evidence is that in the UK regular e-cigarette use is almost exclusively confined to those young people who smoke, and youth smoking prevalence is continuing to fall. This is an area that we will continue to research and keep under closest surveillance. In October this year, regulations to protect children will make it an offence to sell e-cigarettes to anyone under 18 or to buy e-cigarettes for them and within a year the EU Tobacco Products Directive proposes a ban on all print and broadcast advertising of e-cigarettes as part of a full range of regulations.

The concerns on Public Health England’s evidence review, raised by McKee and Capewell in the BMJ today, are not new and have been covered and fully responded to before.
We should not forget what is important here. We know that smoking is the number one killer in England and we have a public health responsibility to provide smokers with the information and the tools to help them quit smoking completely and forever.

PHE has always been very clear on its commitment to providing up to date information on the emerging evidence on e-cigarettes, as shown in the recent review which is the third in this area in the last 2 years. This commitment drove PHE and Cancer Research UK to set up the UK E-cigarette Research Forum. PHE is honouring its longstanding promise to monitor and share the evidence, providing clear messages to the public.

There is no circumstance in which it is better for a smoker to continue smoking – a habit that kills 1 in every 2 and harms many others, costing the NHS and society billions every year. We will continue to share what we know and address what we don’t yet know, to ensure clear, consistent messages for the public and health professionals.

Public Health England

Action on Smoking and Health

Association of Directors of Public Health

British Lung Foundation

Cancer Research UK

Faculty of Public Health

Fresh North East

Public Health Action (PHA)

Royal College of Physicians

Royal Society for Public Health

Tobacco Free Futures

UK Centre for Tobacco and Alcohol Studies

UK Health Forum
Press release

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The concerns on Public Health England’s evidence review, raised by McKee and Capewell in the BMJ today, are not new and have been covered and fully responded to before.
How to define e-cigarette prevalence? Finding clues in the use frequency distribution

Michael S Amato, Raymond G Boyle, and David Levy

1Research Department, ClearWay Minnesota, Minneapolis, Minnesota, USA
2Department of Oncology, Georgetown University, Lombardi Comprehensive Cancer Centre, Washington DC, USA

Correspondence to Dr Michael S Amato, Research Department, ClearWay Minnesota Minneapolis, MN 55425, USA; mamato@clearwaymn.org

Abstract

Objective

E-cigarette use has rapidly increased. Recent studies define prevalence using a variety of measures; competing definitions challenge cross-study comparison. We sought to understand patterns of use by investigating the number of days out of the past 30 days when adults had used e-cigarettes.

Design

We used the 2014 Minnesota Adult Tobacco Survey, a random digit dial population survey (n=9304 adults). Questions included ever using e-cigarettes, number of days used in the past 30 days and reasons for use. Smoking status was determined by combustible cigarette use. Histograms of e-cigarette use were visually inspected for current, former and never smokers with any 30-day e-cigarette use. Different definitions of current use were compared.

Results

Use ≤5 days in the past 30 days demarcated a cluster of infrequent users at the low end of the distribution. Among those with use in the past 30 days, infrequent users were the majorities of current (59%) and never smokers (89.5%), but fewer than half of former smokers (43.2%). Infrequent users were more likely to cite curiosity and less likely to cite quitting/cutting down other tobacco use as reasons for use.

Conclusions

Defining adult prevalence as any use in the past 30 days may include experimenters unlikely to continue use, and is of questionable utility for population surveillance of public health trends over time. Defining prevalence as >5 days excludes those infrequent users.
INTRODUCTION

The use of electronic cigarettes (e-cigarettes) has increased rapidly in the past several years.\textsuperscript{1–6} Sales in 2014 are estimated to be nearly $2 billion and one recent business analysis predicted they could ultimately surpass combusted cigarette sales.\textsuperscript{2,7} Although helpful, sales data provide no information about how individuals use the product. For e-cigarette users, surveillance or other surveys are necessary. The extent of an individual’s e-cigarette use may be an important factor related to transition of smokers away from cigarette use (ie, cessation), as well as potential initiation of non-smokers and relapse of former smokers into cigarette use. Understanding the population effects of e-cigarette use on these transitions will be crucial in determining definitions of use that are most useful in gauging the public health impact of that use. In particular, it will be important to distinguish more established patterns of use from short-term (eg, experimental use) in gauging the effects of e-cigarettes on population health, since relative risks are likely to be dependent on long-term use.

One of the challenges for survey research is the importance of asking questions to reliably measure meaningful use of a tobacco product. A 2009 review of major tobacco surveillance surveys identified inconsistent methodology as an area for improvement, particularly with regard to tobacco products other than cigarettes.\textsuperscript{8} A standard measure of adult cigarette smoking, based on a lifetime minimum threshold of 100 cigarettes smoked and reporting currently smoking ‘every day or some days’, is widely used and allows straightforward comparison across studies. The measure’s wide adoption has been attributed in part to its efficiency for reducing the survey burden on both researchers and respondents; however, it has also faced criticism for being arbitrarily chosen and inadequately sensitive, particularly, but not exclusively for youth samples.\textsuperscript{9} In light of these concerns, the 2014 US Surgeon General’s report on smoking estimated current cigarette smoking prevalence for youth and young adults based on having smoked all or part of at least one cigarette in the past 30 days.\textsuperscript{10} Nonetheless, surveys such as the National Survey on Drug Use and Health, which have adopted the 30-day measure, have also retained the historically more common measure in recognition of the importance of maintaining comparability with previous studies that used the historically more common measure.

In contrast, a historically common definition of e-cigarette current use prevalence does not exist; a variety of definitions can be found in the literature. Reflecting the shift in measurement of cigarette smoking prevalence, many recent studies have adopted a measure of adult e-cigarette current use based on any use in the past 30 days.\textsuperscript{5,11–13} Alternatively, some researchers have adopted language from the conventional cigarette current use definition of use on every day or some days, but without the lifetime threshold question.\textsuperscript{4,6,14–16} Other studies have reported current use from questions that included multiple choice options for self-reported frequency.\textsuperscript{17–19}

In addition to reporting prevalence of current use, several studies have investigated the distribution of use frequency by also reporting the prevalence of daily use,\textsuperscript{4,11,13} or some other measure designed to exclude non-established users; however, their operationalisations of ‘daily use’ and ‘established use’ were not uniform.\textsuperscript{4,11,14,20} Excluding non-established users is important in some instances because evidence suggests they differ from established users not only in extent of participation, but also in their reasons for initially trying e-cigarettes. Specifically, individuals from a US sample who had ever used e-cigarettes were roughly twice as likely to continue their e-cigarette use if they had tried them for a goal-oriented reason, such as quitting or cutting down other tobacco use or using them in places where smoking was not allowed, compared to individuals who had tried e-cigarettes for a non-goal reason such as curiosity.\textsuperscript{16} The authors of that study argued that measures of current use which distinguish types of users in terms of their goals for e-cigarette use would be most useful to public health researchers and practitioners.
More broadly, competing definitions of prevalence based on different frequencies of use present a challenge to cross-study comparison. It is not immediately clear which definition provides the most useful information about how the introduction of e-cigarettes is or is not changing the overall environment of tobacco use, especially combusted cigarettes. The tobacco control community has been confronted with similar challenges of measurement with regards to changing patterns of use among young adults \(^\text{21}\) and less-than-daily cigarette smoking.\(^\text{22}\) While it is likely that no single question or set of questions will be able to fully satisfy all research needs, particularly with regard to the psychological mechanisms of behaviour change, large scale population surveillance efforts for public health may benefit from increased consistency in definitions of e-cigarette current use prevalence across studies.\(^\text{9}\)

We had an opportunity to examine frequency of e-cigarette use, measured as a continuous variable, in a recent population-based study. We focused on the shapes of the e-cigarette use frequency distributions among current smokers, former smokers and never smokers. To keep the study limited in scope, we restricted our definition of ‘smoker’ to use of cigarettes only; we did not investigate other forms of combustible tobacco. By examining the shapes of the distributions, we hoped to take advantage of information that is lost when focusing on measures of central tendency such as the mean or median. We then investigated the relationship between those distributions and respondents’ reasons for using e-cigarettes. Our goal was to conduct a data-driven investigation in order to contribute evidence towards an eventual consensus regarding a standard definition of e-cigarette current use prevalence for the purpose of population surveillance.

**METHODS**

Data were collected as part of the 2014 Minnesota Adult Tobacco Survey, which uses a random digit dialing (RDD) methodology to obtain a cross-sectional sample of Minnesotan adults aged 18 years or older. Two sampling frames were used, one that included landline numbers and another that included cell phone numbers. Prescreening calls identified households and selected individuals within households; the main survey instrument was subsequently administered. A rigorous calling protocol was used, and letters were mailed to refusers and non-responders when addresses were available. Attempts were made to convert refusers. RDD response rates calculated by American Association for Public Opinion Research methodology were 25.2% for the landline sampling frame and 18.2% for the cell phone frame.\(^\text{23}\) Sampling weights were calculated based on sampling frame response rates and demographic characteristics known to be correlated with tobacco use behaviours, to obtain unbiased population level estimates. More methodological detail is available at [http://www.mnadulttobaccosurvey.org](http://www.mnadulttobaccosurvey.org). The final sample in 2014 included 9304 participants; 9301 of the participants provided valid responses for the items considered in this analysis.

Smoking status was established according to the historically common Behavioural Risk Factor Surveillance System (BRFSS) methodology. Current smokers had smoked ≥100 cigarettes in their lifetime and now smoked ‘every day’ or ‘some days’; former smokers had smoked ≥100 cigarettes in their lifetime, but now smoked ‘not at all’; and never smokers had not smoked ≥100 cigarettes in their lifetime. E-cigarette use was measured by two items. Participants were first asked, “Have you ever used an electronic cigarette, even just one time in your entire life?” Affirmative answers were followed by the question, “During the past 30 days, on how many days did you use e-cigarettes?” Responses were entered as integers by the data collector; respondents offering non-integer responses were prompted to provide an integer. Respondents who had ever used e-cigarettes were asked whether each of the following was a reason for use: to quit other tobacco products; to cut down on other tobacco products because they are affordable; because they are available in menthol flavour; because they are available in flavours other than menthol; to use them in places where other tobacco products are not allowed; curiosity about e-cigarettes; and because you believe these might be less harmful than other
tobacco products. Based on the findings of Pepper et al, reasons were classified as goal oriented or non-goal oriented.

All analyses were conducted with the R software package, V.3.1.1, using the survey package V.3.30-3. All population estimates are presented with 95% CIs. Where direct comparisons of CIs are insufficient to establish significance at the α=0.05 level (ie, where CIs overlapped), we report p values for pairwise comparisons that were calculated using linear regression.

RESULTS

In 2014, 17.7% (16.6% to 18.8%) of Minnesota adults had tried e-cigarettes. Most current smokers (70% (66.7% to 73.4%)) had tried e-cigarettes at least once in their life, compared to smaller percentages of former smokers (15.9% (14% to 17.9%)) and never smokers (5.6% (4.7% to 6.5%); table 1). Across all cigarette smoking statuses, fewer than half of those who had ever tried e-cigarettes in their lifetime reported having used them in the past 30 days: current smokers 38.9% (34.4% to 43.5%); former smokers 30.3% (23.9% to 36.7%); never smokers 21.5% (15.3% to 27.7%).

Table 1
Percentage of Minnesota adults using e-cigarettes, by increasingly restrictive definitions of prevalence based on reported frequency of use

Histograms showing frequency of e-cigarette use for all individuals reporting any use in the past 30 days, separated by smoking status, are presented in figure 1. Based on the histograms, use less than or equal to 5 days in the past 30 days appeared to be a meaningful cut-off point to demarcate a cluster of respondents at the low end of each distribution whom we subsequently refer to as ‘infrequent’ users. Respondents who reported using an e-cigarette on 30 out of the past 30 days were categorised as ‘daily’ users. Respondents reporting use between 6 and 29 days (inclusive) were categorised as ‘intermediate’ users. Respondents who had used e-cigarettes in their lifetime, but not within the past 30 days, were categorised as ‘past users’.

Figure 1
Histograms of number of days respondents reported using an e-cigarette, for respondents with some 30-day use.

Current smokers were more likely to use e-cigarettes than former smokers or never smokers, across all frequency categories (table 1). Among current smokers who had used an e-cigarette in the past 30 days, the most common category was infrequent user (59% (51.5% to 66.5%)), followed by intermediate users (28.7% (21.8% to 35.6%)) and daily users (12.3% (7.2% to 17.4%)).

In contrast with current smokers, the proportions of former smokers reporting e-cigarette use in the past 30 days who were categorised as infrequent users (43.2% (30.2% to 56.1%)) versus daily users (40.9% (28.7% to 53%)) did not statistically differ (p=0.8). Comparatively fewer former smokers were categorised as intermediate users (16% (6.1% to 25.8%)).

The majority of never smokers who reported some use of e-cigarettes in the past 30 days were infrequent users (89.5% (81.5% to 97.4%)). Smaller proportions reported intermediate (5.4% (0.4% to 10.5%)) or daily (5.1% (0.0% to 11.4%)) e-cigarette use.
The reasons respondents cited for current or past use of e-cigarettes are presented in Table 2. Significantly fewer infrequent users endorsed the goal-oriented reasons for using e-cigarettes compared to daily users, p<0.05 for all goal-oriented reasons. The proportions of infrequent users endorsing the goal-oriented reasons of quitting other tobacco products, cutting down on other tobacco products and affordability were all similarly significantly lower than the corresponding proportions of intermediate users. In contrast, a greater proportion of infrequent users cited curiosity as a reason for their e-cigarette use. The proportions of current, former and never smokers within each use frequency category that endorsed each reason were numerically similar, but are not reported because small sample sizes prevented reliable inference.

Table 2
Reasons cited by all adults who ever used e-cigarettes for why they use/have used them

Overall estimates of e-cigarette current use prevalence among Minnesota adults varied considerably depending on which types of users were included in the count: 6% (5.2% to 6.6%) if all user types were included; 2.4% (2% to 2.9%) if intermediate and daily users were included; 1.1% (0.8% to 1.4%) if only daily users were included (Table 1).

DISCUSSION

Defining e-cigarette current use prevalence as any use in the past 30 days failed to differentiate a cluster of infrequent users at the low end of the distribution from other users. In addition to having a distinctly different behavioural profile in terms of use frequency, infrequent users were more likely to report curiosity as a reason for using e-cigarettes and less likely to report goal-oriented reasons, compared to intermediate or daily users. These results suggest that many infrequent users are experimenters, unlikely to continue their e-cigarette use over time. If that is the case, then measuring e-cigarette current use prevalence based on any use in the past 30 days may lead to an over-estimate of regular users. That conclusion is reinforced by the finding that most individuals who had ever used e-cigarettes reported no use in the past 30 days.

The importance of considering the distribution of days used has also been previously documented. Zhu et al examined a nationally representative sample of e-cigarette users and similarly found the proportion of daily users was lower among current smokers (11.5%) than recent former smokers (45.7%). Other studies that have separated users at the top of the distribution from others have used the terms ‘established users’ and ‘intensive users’. Clinically, a strict measure of use on 30 out of 30 days may have less utility than a broader category, because it may inadvertently exclude daily users who were temporarily abstinent for artificial reasons such as a broken device or serious illness.

A limitation of the current study is that we measured frequency of use in only a single, 30-day time window. We did not measure lifetime use of e-cigarettes; however, measures related to the quantity of use are problematic with e-cigarettes in light of the variety of types of cigarettes with varying quantities of nicotine and different associated use patterns. A more appropriate measure of use relevant to population health may be duration of use, measured by time since the individual first started e-cigarette use. Information on duration of use may be used in conjunction with numbers of days used in the past 30 days. Longitudinal data, such as the Population Assessment of Tobacco and Health study currently being conducted in the USA, will be particularly valuable for better understanding how e-cigarette use changes over time, how that use affects cigarette smoking, and how factors such as device type moderate these relationships. Another limitation is that we did not investigate demographic differences in this study, in order to keep this article focused on the primary methodological research question of operationalising prevalence. However, specific subpopulations may differ not only in overall...
prevalence, but also in the shape of their distributions, and more fine-grained questions about their cigarette and e-cigarette use may be necessary to accurately understand their behaviour. Finally, this study did not consider alternative measures of e-cigarette use such as number of times used per day or concentration of nicotine.

The 2012–2013 National Adult Tobacco Survey asked respondents, “Do you now use e-cigarettes every day, some days, rarely, or not at all?”. The researchers included ‘rarely’ in the set of response options based on cognitive testing that suggested some participants felt neither ‘some days’ nor ‘not at all’ accurately described their use. Agaku et al report two separate estimates of e-cigarette current use prevalence: an estimate of 1.9% based only on responses of ‘everyday’ and ‘some days’, and another estimate of 4.2% that also included responses of ‘rarely’. Our study investigated a different population (Minnesota vs USA) at a different time period (2014 vs 2012–2013). However, it is notable that the more restrictive definition in our study (use on more than 5 days; 2.4%) yielded an estimate 60.0% smaller than the less restrictive definition (any use in the past 30 days; 6.0%); the more restrictive definition reported by Agaku et al yielded an estimate that was similarly 54.8% smaller than their less restrictive definition. While further research allowing more direct comparison is needed, the similarity in magnitude between our study and Agaku et al. is at least suggestive that providing respondents with the ‘rarely’ option may be an important and effective method for differentiating experimenters from other users.

These results are consistent with an interpretation that many people are trying e-cigarettes, but few continue use. Furthermore, based on the sparsity in the centre of the distributions, the transition from infrequent to daily user appears to be fairly rapid for those who make it. If the transition were gradual, we would expect to see more individuals along the continuum at the level of intermediate users, which is not the case. There is evidence that some respondents’ answers to the number of days question were influenced by a preference for round numbers, for example, local peaks are observed at 5, 10, 15, 20 and 25 days. While the number of respondents at these local peaks in the centre of the distribution is too small to have substantially affected our conclusions, the preference for 5 may suggest that the distinct cluster of infrequent users observed in this self-report data may be less distinct in actual practice.

Previous research suggests that learning to obtain a ‘satisfying’ nicotine hit from current e-cigarette devices takes practice, as well as knowledge of nicotine concentrations and devices. One possibility is that regular users who are trying to quit cigarettes persist as infrequent users until they either learn to use e-cigarettes to effectively manage their nicotine addiction, at which point they quickly make the transition to daily users, or until they decide e-cigarettes are not for them and abandon the effort. If the current generation of e-cigarettes were a more perfect substitute for nicotine delivery we would expect more daily use, a prediction supported by findings that established users tend to use different devices than the broader population of ever users. Frequency of use profiles may differ considerably based on device type; for example, daily users have a strong preference for refillable ‘tank’ devices. Survey items specific to particular device types and products will be useful for advancing research regarding how each tends to used, and for further differentiating types of users. At the same time, a consistent measure of use frequency across studies and devices will further our understanding of the relationship between device type and behaviour, and provide an efficient measure for public health surveillance.

**CONCLUSIONS**

These results suggest that defining e-cigarette current use as any reported use in the past 30 days captures a heterogeneous group of users at best and risks substantially overestimating its prevalence. Defining current use as ‘more than 5 days out of the past 30’ may be a more accurate measure if the research goal is to estimate the proportion of a population that will persist in using e-cigarettes, but
How to define e-cigarette prevalence? Finding clues in the use frequency distribution

further research is necessary. Regardless of whether that definition or some other is adopted as a standard, greater consistency across studies is needed to better understand how the advent of e-cigarettes is (or is not) changing the landscape of tobacco use.

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**What this paper adds**

- Electronic cigarette use has rapidly increased in recent years.
- Many tobacco control researchers are working to understand the extent of use and the implications.
- Unlike combustible cigarette smoking, a uniform definition for ‘current use’ of electronic cigarettes does not exist.
- That lack of standardisation presents a challenge to cross-study comparison, slowing progress.
- We found that defining prevalence as ‘any 30-day use’ included many users who were motivated by curiosity and were unlikely to continue use.
- This study identifies a methodological barrier to effective tobacco control policy regarding electronic cigarettes and uses a data-driven approach to propose a solution.

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**Acknowledgements**

The authors are grateful to Ann St Claire, Ann Kinney, Pete Rode and the Westat team for collection of MATS. The authors wish to thank Mike Fiore, Bruce Christiansen, and Andrea Mowery for feedback on the manuscript.

**Funding** This research was funded by ClearWay Minnesota, an independent non-profit organisation.

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**Footnotes**

Twitter Follow Raymond Boyle at @Raymond_Boyle

Contributors RGB led design of the population survey and data collection. Discussions among all three authors shaped the conception of this article. MSA and RGB led the analysis and wrote the initial drafts. All three authors contributed to refinement of the final article language.

Competing interests None declared.

Ethics approval Minnesota Department of Health Institutional Review Board.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement This manuscript draws on the 2014 Minnesota Adult Tobacco Survey (MATS). After planned analyses have been conducted and written up for submission, all data will be made publicly available to researchers on request through the ClearWay Minnesota website. Previous versions of MATS are currently available through the ClearWay Minnesota website.

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**REFERENCES**


2. Esterl M. ‘Vaporizers’ are the new draw in e-cigarettes. Wall Street Journal. 2014


We should not forget what is important here. We know that smoking is the number one killer in England and we have a public health responsibility to provide smokers with the information and the tools to help them quit smoking completely and forever.

PHE has always been very clear on its commitment to providing up to date information on the emerging evidence on e-cigarettes, as shown in the recent review which is the third in this area in the last 2 years. This commitment drove PHE and Cancer Research UK to set up the UK E-cigarette Research Forum. PHE is honouring its longstanding promise to monitor and share the evidence, providing clear messages to the public.

There is no circumstance in which it is better for a smoker to continue smoking – a habit that kills 1 in every 2 and harms many others, costing the NHS and society billions every year. We will continue to share what we know and address what we don’t yet know, to ensure clear, consistent messages for the public and health professionals.

Public Health England

Action on Smoking and Health

Association of Directors of Public Health

British Lung Foundation

Cancer Research UK

Faculty of Public Health

Fresh North East

Public Health Action (PHA)

Royal College of Physicians

Royal Society for Public Health

Tobacco Free Futures

UK Centre for Tobacco and Alcohol Studies

UK Health Forum
Subject: FW: Public Hearing September 17 Re Tobacco
To: Karen Telega
From: Julie Wischnack
Date: Monday, September 10, 2018 3:48:01 PM
Attachments: image001.png

Subject: Public Hearing September 17 Re Tobacco

Dear Mayor Wiersum and Members of the Minnetonka City Council-

I represent Holiday Stationstores, LLC (Holiday), a 90 year convenience store company based in Minnesota. Holiday has one store in the City of Minnetonka, located at 2801 Hopkins Cross Roads (which we have operated for over 40 years). We understand that the City will be taking up a number of tobacco restrictions at the September 17 city council meeting such as raising the age to purchase tobacco products to 21, prohibiting the sale of flavored tobacco and pricing/packaging regulations. I am sending you this email to explain why Holiday and other retailers believe local regulation of the products we sell is ill-advised public policy.

Local retailers are not the source of tobacco products to those under lawful age to purchase. Holiday has a rigorous training program for age restricted sales and an ID is requested of any person who appears to be 40 or under (the FDA only requires requesting an ID for someone who appears to be 27 or younger). In the decades Holiday has been doing business in the City, we have never failed a compliance check.

Local regulations of any lawful product are problematic, including tobacco. Patchwork regulation around the metro/state presents significant compliance challenges for retailers otherwise working hard in a competitive world to operate a profitable business.

Convenience stores need the ability to sell lawful products as defined by state law. In this case, the lawful age to purchase tobacco under state law is 18. When a city raises the age to purchase an age restricted product, the consumers under age 21 simply go to a nearby city. At the same time those customers will buy other products such as gas, pop, sandwiches, chips and so forth that we really need to need to keep in the City. We have seen that happen in cities that impose restrictions on tobacco products such as flavor bans.

We also understand that there will be no penalty for an adult between 18-20 who possesses or uses tobacco. Under state law, a minor who possess or uses tobacco can be found guilty of a petty
misdemeanor under Minn. Stat. Section 609.685, Subd. 3, which can result in a fine of up to $300 under Section 609.02, Subd 4a. It makes no sense to refuse to punish an adult who violates the law and yet allow a minor to be subject to a petty misdemeanor if the goal is to deter smoking. The only party being punished under the ordinance is the retailer.

A ban on the sale of flavored products would be devastating. Both Minneapolis and St. Paul have complete flavor bans, including menthol, wintergreen and mint tobacco products. Neither city conducted an economic study on a flavor ban impact to the retail community. Between the lost sales of flavored tobacco and ancillary sales of gasoline and inside products, retailers in both cities are suffering and some stores have already closed.

Minimum pricing and packaging restrictions also do not prevent access to less expensive tobacco. When these restrictions essentially ban these products since they can be purchased in another city at a lower price, customer traffic just migrates to a different jurisdiction.

Finally, if the legal age to purchase is raised to 21, the other restrictions are not necessary as legal youth of high school age will not have access to tobacco to sell to youth who are under age.

I appreciate this opportunity to give you feedback on behalf of Holiday. Thank you.

Steven G. Rush  
Attorney  
Rush Law & Advocacy, PLLC  
7037 Connelly Court  
Savage, MN 55378

Rush Law & Advocacy, PLLC
September 10, 2018

The Honorable Brad Wiersum and Members of the Minnetonka City Council
14600 Minnetonka Boulevard
Minnetonka, MN 55345

Dear Mayor Wiersum and Members of the City Council,

As Minnetonka’s former police chief and proud supporter for this wonderful community, I am writing once again to urge you to strengthen the City of Minnetonka’s tobacco ordinance by raising the tobacco sales age to 21. I appreciate that the ordinance you are considering on September 17th removes penalties for possession, use and purchase, as these penalties are not effective at preventing youth tobacco use.

Strengthening Minnetonka’s tobacco prevention policy is a great way to send a message that we care about health and wellness. That being said, it is paramount that the ordinance to raise the tobacco age to 21 includes e-cigarettes and vaping devices. These products are addicting the community’s youth at alarming rates.

According to the 2016 Minnesota Student Survey, 21.7% of Minnetonka 11th graders reported using e-cigarettes in the past 30-days; this is higher than the state average of 17.1%. These sleek devices resemble Apple products, come in a variety of flavors and are almost impossible to detect. It seems like everyday there is a news article about these dangerous products and how rampant they are in our middle and high schools.

It is important to work together to keep our kids and families healthy and thriving by addressing this problem. I urge you to join other cities across the state that are taking a stand for health by raising the tobacco sales age to 21 and including e-cigarettes in the restriction.

Sincerely,

[Signature]

JOY M. RIKALA
Retired Minnetonka Chief of Police

C: Geralyn Barone, City Manager
One more

Corrine A. Heine | City Attorney
City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8262

Dear Mayor and City Council Members,

I begin by assuring you that I am absolutely convinced that cigarette smoking or the use of tobacco in any fashion poses a serious risk to the health of the user. Also, I have absolutely nothing to gain or lose should you approve—or amend, or disapprove—the proposed ordinance banning sales of tobacco products to people under the age of 21.

Before you vote, however, I hope you consider the following: A Minnetonka under the age of 21 may

A. Vote. Thus he or she is entrusted the same duty and privilege those over 21 have in selecting the people who run governments at all levels.

B. Operate motorized vehicles of various types on land and waters. Thus he or she could pose serious dangers to many other people as well as to himself/herself.

C. Purchase and use firearms, including assault weapons. Need I say more?
D. Join the US military and, if unlucky, serve our country in several foreign countries where US military personnel are at risk every second they serve.

I ask that you consider the following admittedly hypothetical situation: a young man or woman graduates from Minnetonka High School and then enlists in the US military. He or she undergoes basic training and then is assigned to his/her unit. If our Minnetonkan is really unlucky, he or she could spend two tours (a total of 18 to 24 months) in Afghanistan, or Iraq, or some other place where he or she would basically be a potential target every second. Our Minnetonkan is lucky, however, and returns unscathed. He or she is on leave at home and wants to buy a pack of cigarettes. He or she is not yet 21 years of age and therefore is not allowed to make the purchase here and must drive elsewhere. Is there a “disconnect” somewhere?

I realize the City Council has good intentions, but I consider the proposed ordinance to be a bad example of trying to legislate behavior. I also do not know how the City would enforce the ordinance or pay for that enforcement.

If you have read this far, I thank you.

Thomas M. Troy
This can be added to the packet. Anything that is after 9 a.m. tomorrow; add to the change memo to Monday.

From: Molly Moilanen <mollymoilanen@gmail.com>
Sent: Wednesday, September 12, 2018 3:57 PM
To: Brad Wiersum <bwiersum@eminnetonka.com>; Deborah Calvert <dcalvert@eminnetonka.com>; Patty Acomb <pacomb@eminnetonka.com>; Bob Ellingson <bellingson@eminnetonka.com>; Tony Wagner <twagner@eminnetonka.com>; Mike Happe <mhappe@eminnetonka.com>; Tim Bergstedt <tbergstedt@eminnetonka.com>; Rebecca Schack <rschack@eminnetonka.com>
Cc: Julie Wischnack <jwischnack@eminnetonka.com>; ruth.tripp@hennepin.us; Kathy Leervig <kleervig@eminnetonka.com>; mollymoilanen@gmail.com
Subject: New resources on youth nicotine addiction - please vote YES on Tobacco 21

Dear Mayor Wiersum and Council Members:

As you prepare for Monday’s council meeting and consider strengthening our city’s tobacco ordinance, I wanted to make sure you had these new national and state resources.

The Minnesota Department of Health today issued a new advisory on youth nicotine addiction, calling it a “major health concern” – available on their website: health.state.mn.us/ecigarettes. The advisory describes the dangers of nicotine addiction to young brains, and details the steps that parents, educators and school staff, health care providers and policymakers can take to reduce nicotine addiction. MDH also issued a press release highlighting the advisory and their response to youth e-cigarette use (aka “vaping”).

WCCO did a thorough news story on this issue featuring interviews with adults and young people at the State Fair (spoiler alert: the adults had no idea what JUUL and Suorin devices were, but the 13 year-olds did). Here is the link: "Officials Warn E-Cigarettes Are More Dangerous Than They Appear."

In our effort to warn parents about this growing problem, Minnesotans for a Smoke-Free Generation also issued a press release and graphic, available here, titled Is Big Tobacco in Your Kid’s Backpack?

Separately, the FDA today announced new efforts to address what they are calling the “epidemic of youth e-cigarette use,” including new enforcement actions and a 60-day timeline for e-cigarette companies to prove they aren’t targeting youth. View the FDA release here.

There has been a lot of national coverage of this issue, including this New York Times story posted to the front page of the Star Tribune: “FDA cracks down on Juul and e-cigarette makers over teen sales.”
Please let me know if you would like additional information. As a new Minnetonka resident myself, I’m counting on you to make Minnetonka the next Tobacco 21 city in Minnesota.

Thank you,
Molly

Molly Moilanen, M.P.P.
Director of Public Affairs
ClearWay Minnesota
952-767-1421 (o) / [REDACTED]

From: Molly Moilanen
Sent: Thursday, August 9, 2018 2:53 PM
To: bwiersum@eminnetonka.com; dcalvert@eminnetonka.com; pacomb@eminnetonka.com; bellingson@eminnetonka.com; twagner@eminnetonka.com; mhappe@eminnetonka.com; tbergstedt@eminnetonka.com; RSchack@eminnetonka.com
Cc: Julie Wischnack <jwischnack@eminnetonka.com>
Subject: New federal warning labels on e-cigarettes

Dear Mayor Wiersum and Council Members:

Thank you for the opportunity last month to testify in support of the proposed changes to Minnetonka’s tobacco ordinance, including e-cigarettes. I wanted to let you know that e-cigarettes, which have surged in popularity among Minnesota youth, will soon carry a federal warning. Beginning August 10, 2018, the U.S. Food and Drug Administration (FDA) will require warning labels on e-cigarettes and certain other tobacco products. I will be on TPT’s Almanac on Friday night to talk about this topic. The warning label is a needed and overdue step but it’s not sufficient. States and localities need to do more to prevent youth addiction. That is why I’m proud that my city, Minnetonka, is considering increasing the tobacco age to 21 and restricting the sale of flavored tobacco products to adult-only stores. Together, these two policies will reduce the visibility of and access to tobacco products that are addicting young people in our community and across the state. Please let me know if you would like more information on these new warnings or the proposed policies.

Thank you,
Molly

Molly Moilanen, M.P.P.
Director of Public Affairs
ClearWay Minnesota
952-767-1421 (o) / [REDACTED]
Ordinance No. 2018-

An Ordinance amending sections 625.040 and 625.045 of the Minnetonka City Code, relating to the minimum age for sales of tobacco-related products

The City of Minnetonka Ordains:

Section 1. The Minnetonka City Code is amended by adding a new section 625.000 as follows:

625.000. Purpose. The city finds that: smoking causes premature death, disability and chronic diseases, including cancer, heart disease and lung disease; smoking-related diseases result in excess medical care costs; and smoking initiation occurs primarily in adolescence. The city desires to prevent young people from starting to smoke, to encourage and assist smokers to quit, and to promote clean indoor air through the adoption of tobacco licensing regulations.

Section 2. Section 625.040 of the Minnetonka City Code is amended to read as follows:

625.040. Prohibited Sales Acts. A person must not sell, offer to sell, or give away any tobacco-related product to any person below the age of 2118 years. A person must not sell, dispense, or give away any tobacco related product through the use of a vending machine or similar automated dispensing device. A person must not sell, dispense or give away any tobacco-related product through self-service merchandising, except in facilities where the retailer ensures that no person younger than 2118 years of age is present, or permitted to enter, at any time. A person must not sell tobacco-related products outside the location or area covered by a license.

Section 3. Section 625.045 of the Minnetonka City Code is amended to read as follows:

625.045. Other Illegal Acts. Unless otherwise provided, the following acts are a violation of this section.

1. Illegal Possession. A person under 18 years of age must not have in his or her possession, or use any tobacco-related product. A person under 18 years of age must not sell a tobacco-related product or otherwise come in contact with a tobacco-related product during the course of employment. This subdivision does not apply to minor lawfully involved in a compliance check. [repealed]
2. Illegal Procurement. A person **under 18 years of age** must not purchase or attempt to purchase or otherwise obtain any tobacco related product, and a person must not purchase, **attempt to purchase**, or otherwise obtain such items **any tobacco-related product** on behalf of a **person under the age of 21 years** minor. A person must not coerce or attempt to coerce a **minor person under the age of 21 years** to illegally purchase or otherwise obtain or use any tobacco related product. **This subdivision does not apply to minors lawfully involved in a compliance check.**

3. False Identification. A person **under 18 years of age** must not attempt to disguise his or her true age by the use of a false form of identification, nor possess a false form of identification, whether the identification is that of another person or one on which the age of the person has been modified or tampered with to represent an age older than the actual age of the person.

Section 4. A violation of this ordinance is subject to the penalties and provisions of Chapter XIII of the city code.

Section 5. This ordinance is effective Jan. 1, 2019.

Adopted by the city council of the City of Minnetonka, Minnesota, on Sept. 17, 2018.

Brad Wiersum, Mayor

Attest:

__________________________
David E. Maeda, City Clerk

**Action on this Ordinance:**

Date of introduction: July 23, 2018
Date of adoption:  
Motion for adoption:  
Seconded by:  
Voted in favor of:  
Voted against:  
Abstained:  
Absent:  
Ordinance adopted.

__________________________
The stricken language is deleted; the underlined language is inserted.
Date of publication:

I certify that the foregoing is a true and correct copy of an ordinance adopted by the city council of the City of Minnetonka, Minnesota, at a meeting held on Sept. 17, 2018.

David E. Maeda, City Clerk
Ordinance No. 2018-

An Ordinance amending sections 625.005 and 625.040 of the Minnetonka City Code, relating to tobacco-related products

The City of Minnetonka Ordains:

Section 1. Section 625.005 of the Minnetonka City Code, relating to definitions, is amended by adding a new subdivision 2 to read as follows and by renumbering subsequent subdivisions accordingly:

2. “Flavored tobacco-related product” means any tobacco-related product that contains a taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, that is distinguishable by an ordinary consumer either prior to or during consumption of the licensed product, including, but not limited to, any taste or aroma of chocolate, vanilla, honey, cocoa, or any candy, dessert, alcoholic beverage, fruit, herb, or any spice. A public statement or claim, whether expressed or implied, made or disseminated by the manufacturer of a tobacco product, or by any person authorized or permitted by the manufacturer to make or disseminate such statements or claims, that a tobacco product has or produces taste or aroma other than tobacco, menthol, mint or wintergreen, may be one of the methods used to determine that the tobacco product is a flavored tobacco product, and shall to the extent permitted by law, create a rebuttable presumption that the tobacco product is a flavored tobacco product.

Section 2. Section 625.040 of the Minnetonka City Code is amended to read as follows:


1. A person must not sell or give away any tobacco-related product to any person below the age of 18 years.

2. A person must not sell, dispense, or give away any tobacco-related product through the use of a vending machine or similar automated dispensing device.

3. A person must not sell, dispense or give away any tobacco-related product through self-service merchandising, except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

4. A person must not sell tobacco-related products outside the location or area covered by a license.

4.5. A person must not sell, offer for sale, give away, or otherwise deal in flavored tobacco-related products or samples of such products. This restriction does not
apply to facilities where the retailer ensures that no person younger than 21 years of age is present, or permitted to enter, at any time.

Section 3. A violation of this ordinance is subject to the penalties and provisions of Chapter XIII of the city code.

Section 3. This ordinance is effective Jan. 1, 2019.

Adopted by the city council of the City of Minnetonka, Minnesota, on Sept. 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

Action on this Ordinance:

Date of introduction: July 23, 2018
Date of adoption: 
Motion for adoption: 
Seconded by: 
Voted in favor of: 
Voted against: 
Abstained: 
Absent: 
Ordinance adopted.

Date of publication:

I certify that the foregoing is a true and correct copy of an ordinance adopted by the city council of the City of Minnetonka, Minnesota, at a meeting held on Sept. 17, 2018.

David E. Maeda, City Clerk

The stricken language is deleted; the underlined language is inserted.
Ordinance No. 2018-
An Ordinance amending sections 625.010, 625.015, 625.025, and 625.040 of the Minnetonka City Code, relating to tobacco-related products

The City of Minnetonka Ordains:

Section 1. Section 625.010 of the Minnetonka City Code is amended to read as follows:

625.010. License Required.

No person shall must not directly or indirectly keep for retail sale, sell or offer to sell at retail, dispense, or give away in a retail setting any tobacco related product at any place in the city, without first obtaining a license from the city.

Section 2. Section 625.015 of the Minnetonka City Code is amended to read as follows:

625.015. Application and Issuance.

Application for a new license or license renewal must be made to the community development director on a form supplied by the city. The application must state the full name of the applicant, the location of the building and the part intended to be used by the applicant under the license, the kind of business conducted at the location, and the other information as required by the application form. The community development director has the authority to determine whether or not a license will be issued or renewed. An applicant may appeal the director’s decision to the city council by submitting a written request to the city clerk within 10 days after the decision. A license may be denied or, if the license is mistakenly issued or renewed to a person, it shall be revoked upon the discovery that the person was ineligible for the license, for the following reasons:

1. the applicant is under the ages of 18 years;

2. the applicant has been convicted within the past five years of any violation of a federal, state, or local law, ordinance provision, or other regulation relating to tobacco-related products;

3. the applicant has had a license to sell tobacco-related products revoked within the preceding twelve months of the date of application;

4. the applicant fails to provide any information required on the application, or provides false or misleading information; or

5. The applicant is prohibited by federal, state, or other local law, ordinance, or other regulation, from holding such a license.

The strucken language is deleted; the underlined language is inserted.
Section 3. Section 625.025 of the Minnetonka City Code is amended to read as follows:

625.025. License Display and Signage.

1. Every license must be kept conspicuously posted at the place for which the license is issued and must be exhibited to any person upon request.

2. Notice of the legal sales age must be posted at each location where tobacco-related products are offered for sale. The required signage must be posted in a manner that is clearly visible to anyone who is or is considering making a purchase.

Section 4. Section 625.040 of the Minnetonka City Code is amended to read as follows:


1. A person must not sell or give away any tobacco-related product to any person below the age of 18 years.

2. A person must not sell, dispense, or give away any tobacco related product through the use of a vending machine or similar automated dispensing device.

3. A person must not sell, dispense or give away any tobacco-related product through self-service merchandising, except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

4. A person must not sell tobacco-related products outside the location or area covered by a license.

5. A person must not sell, offer for sale, give away, or otherwise deal in flavored tobacco-related products or samples of such products. This restriction does not apply to facilities where the retailer ensures that no person younger than 21 years of age is present, or permitted to enter, at any time.

6. A person must not sell, offer to sell or distribute liquid, whether or not such liquid contains nicotine that is intended for human consumption and use, in an electronic delivery device that is not contained in child-resistant packaging as that term is defined in Code of Federal Regulations, title 16, section 1700.15(b)(1) as in effect on January 1, 2015.

7. A person must not sell, offer to sell, give away, distribute or display tobacco-related products in a manner prohibited by federal or state law.

Section 5. A violation of this ordinance is subject to the penalties and provisions of Chapter...
XIII of the city code.

Section 6. This ordinance is effective Jan. 1, 2019.

Adopted by the city council of the City of Minnetonka, Minnesota, on Sept. 17, 2018.

Brad Wiersum, Mayor
Attest:

David E. Maeda, City Clerk

**Action on this Ordinance:**

Date of introduction:
Date of adoption:
Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Ordinance adopted.

Date of publication:

I certify that the foregoing is a true and correct copy of an ordinance adopted by the city council of the City of Minnetonka, Minnesota, at a meeting held on Sept. 17, 2018.

David E. Maeda, City Clerk

The stricken language is deleted; the underlined language is inserted.
Brief Description
Concept Plan for redevelopment of the property at 1809 Plymouth Road

Action Requested
Provide comments and feedback. No formal action is required.

Background
The property at 1809 Plymouth Road is roughly two-acres in size and is improved with a 35,350 square-foot, three-story bank/office building and associated parking lot. The property is zoned PID, planned I-394 district, and holds a mixed-use designation in the 2030 Comprehensive Guide Plan.

Concept Plan
Oppidan Development has submitted a concept plan for the property. The plan contemplates construction of a one-story, freestanding bank building south of the existing bank/office building. The plan further suggests remodeling of the existing building.

A formal proposal based on the concept plan would likely require approval of the following items: (1) major amendment to the existing master development plan; (2) final site and building plans.

Review Process
Staff has outlined the following review process for the proposal. At this time, a formal application has not been submitted.

- **Neighborhood Meeting.** Oppidan hosted a neighborhood meeting on Sept. 5, 2018. Two residents attended the meeting. One resident expressed concern that the proposal was not consistent with the redevelopment vision of the area and the subdivision of land, as proposed, would complicate future redevelopment. The other resident asked a series of questions pertaining to site design and bank operations.

- **Planning Commission Concept Plan Review.** The planning commission reviewed the concept plan on Sept. 6, 2018. One area property owner addressed the commission and generally expressed support for an office use with a request that details related to landscaping and building design be thoughtfully considered. Planning commissioners generally commented the concept would be an appropriate short term use, but that higher density/intensity use would be better for the long term.

- **City Council Concept Plan Review.** The city council Concept Plan Review is intended as a follow-up to the planning commission meeting and would follow the same format as the planning commission Concept Plan Review. No staff recommendations are provided, the public is invited to offer comments, and council members are afforded the opportunity to ask questions and provide feedback without any formal motions or votes.
Key Issues

Staff requests council comment/feedback on the following key issues and any other issues the council deems appropriate. The comments/feedback provided are intended to assist Oppidan Development should the company chose to put together a formal application package. However, the council decisions on any formal redevelopment application are not suggested or restricted by concept plan review comments/feedbacks.

- **Land Use.** The Ridgedale Village Center study suggests greater land use intensity within the Ridgedale Village Center, particularly adjacent to the regional mall. This intensity consideration was also raised as the city reviewed multiple redevelopment concepts for the TCF property, which is immediately north of the subject property. Feedback related to intensity of land use is requested.

- **Building and Site Design.** The concept plans suggests a one-story building generally located within an existing parking lot. Feedback on building and site design is requested.

Staff Recommendation

Staff recommends the city council provide comment and feedback on the identified key issues and any others the city council deems appropriate.

Through: Geralyn Barone, City Manager
Julie Wischnack, AICP, Community Development Director
Loren Gordon, AICP, City Planner

Originator: Susan Thomas, AICP, Assistant City Planner
ADDITIONAL INFORMATION

Next Steps

- **Formal Application.** If the developer chooses to file a formal application, notification of the application would be mailed to area property owners. Property owners are encouraged to view plans and provide feedback via the city’s website. Through recent website updates: (1) staff can provide residents with ongoing project updates, (2) residents can “follow” projects they are particularly interested in by signing up for automatic notification of project updates; (3) residents may provide project feedback on project; and (4) and staff can review resident comments.

- **Council Introduction.** The proposal would be introduced at a city council meeting. At that time, the council would be provided another opportunity to review the issues identified during the initial Concept Plan Review meeting, and to provide direction about any refinements or additional issues they wish to be researched, and for which staff recommendations should be prepared.

- **Planning Commission Review.** The planning commission would hold an official public hearing for the development review and would subsequently recommend action to the city council.

- **City Council Action.** Based on input from the planning commission, professional staff and general public, the city council would take final action.

City Roles and Responsibilities

- **City Council.** As the ultimate decision maker, the city council must be in a position to equitably and consistently weigh all input from their staff, the general public, planning commissioners, applicants and other advisors. Accordingly, council members traditionally keep an open mind until all the facts are received. The council ensures that residents have an opportunity to effectively participate in the process.

- **Planning Commission.** The planning commission hosts the primary forum for public input and provides clear and definitive recommendations to the city council. To serve in that role, the commission identifies and attempts to resolve development issues and concerns prior to the council’s consideration by carefully balancing the interests of applicants, neighbors, and the general public.

- **City Staff.** City staff is neither an advocate for the public nor the applicant. Rather, staff provides professional advice and recommendations to all interested parties, including the city council, planning commission, applicant and residents. Staff advocates for its professional position, not a project. Staff recommendations consider neighborhood concerns, but necessarily reflect professional standards, legal requirements and broader community interests.
Location Map

Project: Wells Fargo
Address: 1809 Plymouth Rd
Ridgedale: A Vision for 2035
City of Minnetonka
September 2012

LMN Architects
Damon Farber Landscape Architects
Leland Consulting Group
Studio Cascade
2035 Concept Plan
2035 Concept Plan: Potential New Development
Appropriate Elements for Ridgedale

- Housing, low & mid-rise
- Office, mid-rise
- Hotel, mid-rise
- Conference center
- Restaurants

- Multiplex cinema
- Additional retail
- Outdoor park/plaza/multi-use
- Expanded YMCA
# Total Potential Development

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
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<tr>
<td>Total Capital Estimate</td>
<td>$400,000,000 or greater</td>
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<tr>
<td>New Housing</td>
<td>800 dwelling units</td>
</tr>
<tr>
<td>Office Space</td>
<td>180,000 square feet</td>
</tr>
<tr>
<td>New Hotel</td>
<td>250 rooms</td>
</tr>
<tr>
<td>New Conference Center</td>
<td>20,000 square feet or larger</td>
</tr>
<tr>
<td>Restaurants (6)</td>
<td>45,000 square feet</td>
</tr>
<tr>
<td>Structured / Surface Parking</td>
<td>2,800 spaces (may not all be required)</td>
</tr>
</tbody>
</table>
Public Realm Concept

- PARK SPACE NEAR LIBRARY
- PEDESTRIAN/BIKE CONNECTION
- FREEWAY GATEWAY MARKERS
- NORTH FRONTAGE ROAD
- INTERSTATE 394
- GREEN WALL
- TRAIL CONNECTION
- TRAIL CONNECTION
- FRONT DOOR DINING PLAZA
- COMMONS
- CONNECTION TO OPEN SPACE/TRAILS
- PEDESTRIAN/GATEWAY MARKER
- ROUNDABOUT
- ENTRY FEATURE PEDESTRIAN LINK
- PEDESTRIAN/BIKE CONNECTION
- NORTH
Vignettes

East Side of Mall: Expansion

South Side of Mall: Expansion and Renovation
Vignettes

Potential Hotel at
Ridgedale Parkway &
Plymouth Rd.
Vignettes
Cow was required to secure a parking agreement prior to obtaining the certificate of occupancy.

Sewall thought there would be an opportunity for additional parking agreements to be made. He thought the parking situation would be worse in five years. He saw it more as a problem for the property owner to address.

Sewall confirmed with Cauley that none of the businesses on the site have a condition of approval requiring the business to have a cross parking agreement. If a parking problem would occur, the property owner could obtain additional parking agreements and if the city received parking complaints, then a parking study could be done and require the insufficient number of parking stalls be obtained elsewhere with a parking agreement.

Powers likes that the city has methods to deal with a parking issue.

**Powers moved, second by Henry, to recommend that the city council adopt the resolution approving a conditional use permit with variances for a restaurant with on-sale liquor at 14725 Excelsior Blvd.**

**Henry, Powers, Sewell, Hanson, and Kirk voted yes. Knight was absent. Motion carried.**

**C. Concept plan for redevelopment of the property at 1809 Plymouth Road.**

Chair Kirk introduced the proposal and called for the staff report.

Gordon reported. Staff recommends the planning commission provide comments and feedback on the identified key issues and any others the planning commission deems appropriate.

Drew Johnson, of Oppidan, representing the applicant, stated that:

- He looked forward to hearing the feedback.
- Wells Fargo currently occupies the first floor with the rest of the building vacant. Wells Fargo would continue operation throughout redevelopment. A branch would be built on the site and the existing building would be reused and reinvigorated.
- The process would not impede the 2030 plan.
- The applicant would purchase the property if the proposal would move forward.
- The proposal would include trail connections to adjacent uses, better landscaping, and achieve office goals.
- The ring road is controlled by an OEA made up of TCF, Wells Fargo, and U.S. Bank. All three parties would have to agree.
- The proposal would not complicate future redevelopment of the area.
• The drive-through design would consist of one window with one vacuum tube and an ATM bypass.
• Setbacks would conform to ordinance requirements.
• The amount of parking would increase on the site.
• The existing drive through would be converted to parking.
• He was available for questions.

Powers asked if the exterior or roof would be changed. Mr. Johnson answered affirmatively. The exterior of the building would be refreshed and landscaping would be added.

Chair Kirk understood the need for banks to downsize. He appreciated the intent to reface and remodel the building.

Gordon provided results from a study by Marquette Advisors that found that the Twin Cities vacancy rate for office buildings is 14.2 percent. Minnetonka’s vacancy rate for office buildings is 13 percent. Buildings in the I-394 corridor have 15.5 percent vacancy.

Chair Kirk invited those present to comment.

Annette Bertelsen, 13513 Larkin Drive, stated that:

• She attended the neighborhood meeting. The developer was generous with his time. She contacted a couple dozen of her neighbors to get their comments.
• The proposal seems like a good use.
• Some businesses were lost with the Highland Bank redevelopment. It would be nice to have a dental office or insurance agent, for example.
• No one she talked to objected to an office use.
• Walkability and safety is always a priority. She assumed that the sidewalks would be connected.
• Staff has done a great job in requesting that new and remodeled buildings have consistent elements.
• The landscaping of the TCF area is pretty sparse and has lots of concrete. The concrete benches are streaked, have chunks missing, and they are less than one year old.
• The proposed new building would be boring and underwhelming. She would like the building to look more beautiful.
• She wants appropriate transitions from the single-family houses to the Ridgedale Village area. What happens here impacts her neighborhood.
• The proposed landscaping could be more exciting.

No one else chose to speak.
Chair Kirk thought the proposed building would look small compared to the neighboring building. Walkability to the site would be very important. It is important to recognize sidewalks and how to handle snow removal. The dedicated cueing for the drive lane takes room from the parking lot that could be used to provide walkability. He would rather see space for several really mature trees rather than a thin boulevard of 200 bushes to soften the look. The building is uninspiring and could use some dressing up. He wants to understand the potential of the building.

Sewall thought the land use would be appropriate for the next five years. He thought the best scenario would be for the whole block to be bought up and redeveloped in one, large, cohesive development. That would provide an opportunity for better design and flow. In terms of immediate land use, the use would be appropriate. He agreed with Chair Kirk’s comments regarding walkability and landscaping. He supports making the site and entire area more visually appealing.

Powers was more concerned with getting tenants in the office building than the idea for the proposed one-story Wells Fargo building. This is not 300 years ago when the area was all trees. He does not want the building to be ugly or boring, but it has to remain affordable. He wants the site to speak visually that it is Minnetonka and the Ridgedale area.

Henry would like the area to have higher density.

This item is scheduled to be reviewed by the city council on September 17, 2018.

9. Adjournment

_Sewall moved, second by Powers, to adjourn the meeting at 9 p.m. Motion carried unanimously._

By: ____________________________
Lois T. Mason
Planning Secretary
City Council Agenda Item #14C
Meeting of Sept. 17, 2018

**Brief Description**  
Concept plan review for Hennepin County Medical Examiner’s Office at 14300 Co. Rd. 62

**Action Requested**  
Discuss concept plan with the applicant. No formal action required.

**Background**

Hennepin County is proposing to build a new Medical Examiner’s Office on the County Home School property located at 14300 Co. Rd 62. The current office is located in downtown Minneapolis. All operations from the downtown location would be moved to the Minnetonka site. The Medical Examiner’s Office also serves Dakota and Scott Counties.

As proposed, the 68,510 square-foot building would be sited on the eastern portion of the 161-acre Home School site. The building, parking and access road would occupy approximately 10 acres of the property. A new roadway would be constructed at the southwestern site access at County Road 62, but separated from the access to the Home School.

The building would include office, autopsy and conference spaces. The county anticipates the facility would also serve as a teaching and training facility for students, university faculty and practitioners. There would not be a crematorium in the building.

The site is guided as institutional in the 2030 Comprehensive Guide Plan and zoned Planned Unit Development. The immediate area has a mix of existing land uses. Glen Lake Golf Course, also owned by Hennepin County, is located to the west. Single family neighborhoods and Glen Lake are located to the north. To the east and south are industrial uses. Major transportation corridors also define the eastern and southern borders - County Road 62, the Minnesota River Bluffs LRT Regional trail and the Soo Line railroad.

In 2016, the city completed the Glen Lake Neighborhood Study, a part of which evaluated the possibilities for development of the Home School site if the county were to move current services. Since that time, the county has made a further commitment to continue to utilize the site for county related services and the potential development scenarios identified are not part of the considerations for the site at this time. Regardless, the study provides good information about the site features, access considerations, important woodland and wetland resources and future park opportunities. The study can help guide county and city decisions as services and facilities evolve to meet changing needs.

**Key Issues**

City staff has identified the following considerations for any development of the property:

- **Site Plan**: The proposed building location on the undeveloped eastern portion of the site would require construction of a number of roadway, utility and building pad area improvements. These improvements will likely result in tree removals, large amounts of grading and large retaining walls for the roadway.
• **Impact to Site Character:** The eastern upland area of the site contains valued woodland and prairie natural resources. A tamarack wetland is also located east of this upland area along the regional trail. The proposed facility would introduce development of this natural area. Minimizing site impacts should be a goal of the project. Additional plan perspectives of the proposed office will be needed to evaluate building siting and character.

• **Planned Unit Development:** The zoning of the site is planned unit development. Further site development will need to demonstrate public purpose.

**Review Process**

Staff has outlined the following review process for the proposal. At this time, a formal application has not been submitted.

• **Neighborhood Meeting.** The developer held a neighborhood meeting on June 7, 2018. Five people attended the meeting raising a few questions about the project schedule, uses within the building and if future housing development was planned for the site.
• **Planning Commission Concept Plan Review.** The planning commission reviewed the concept plan at the June 14, 2018 meeting. The objective of this meeting was to identify major issues and challenges in order to inform the subsequent review and discussion. The meeting included a presentation by the developer of conceptual sketches and ideas, but not detailed engineering or architectural drawings. No staff recommendations were provided, the public was invited to offer comments, and planning commissioners were afforded the opportunity to ask questions and provide feedback without any formal motions or votes.

The planning commission provided the following input during its review:

  o The facility would be a good use of county property.
  o Questioned the facility location on the eastern portion of the property.
  o Concerns about piecemeal development of the property.
  o Liked the treatment of parking lots into smaller meandering pieces.
  o The planning commission would like to tour the site.

One resident asked about the city’s review authority and number of attendees at possible conferences within the proposed building.

• **City Council Concept Plan Review.** The city council Concept Plan Review is intended as a follow-up to the planning commission meeting and follows the same format as the planning commission Concept Plan Review. No staff recommendations are provided, the public is invited to offer comments, and council members are afforded the opportunity to ask questions and provide feedback without any formal motions or votes.

**Staff Recommendation**

Staff recommends the city council provide comment and feedback on the identified key issues and others the council deems appropriate. The discussion is intended to assist the applicant with future direction that may lead to the preparation of more detailed development plans.

Through:  Geralyn Barone, City Manager
          Julie Wischnack, AICP, Community Development Director

Originator:  Loren Gordon, AICP, City Planner
ADDITIONAL INFORMATION

Next Steps

- **Formal Application.** If the developer chooses to file a formal application, notification of the application would be mailed to area property owners. Property owners are encouraged to view plans and provide feedback via the city’s website. Through recent website updates: (1) staff can provide residents with ongoing project updates, (2) residents can “follow” projects they are particularly interested in by signing up for automatic notification of project updates; (3) residents may provide project feedback on project; and (4) and staff can review resident comments.

- **Neighborhood Meeting.** Prior to the planning commission meeting and official public hearing, an additional public meeting could be held with neighbors to discuss specific engineering, architectural and other details of the project, and to solicit feedback. This extends the timing that has historically been provided in advance of the planning commission review to allow more public consideration of the project specifics.

- **Council Introduction.** The proposal would be introduced at a city council meeting. At that time, the council would be provided another opportunity to review the issues identified during the initial concept plan review meeting, and to provide direction about any refinements or additional issues they wish to be researched, and for which staff recommendations should be prepared.

- **Planning Commission Review.** The planning commission would hold an official public hearing for the development review and would subsequently recommend action to the city council.

- **City Council Action.** Based on input from the planning commission, professional staff and general public, the city council would take final action.

Roles and Responsibilities

- **Applicants.** Applicants are responsible for providing clear, complete and timely information throughout the review process. They are expected to be accessible to both the city and to the public, and to respect the integrity of the public process.

- **Public.** Neighbors and the general public will be encouraged and enabled to participate in the review process to the extent they are interested. However, effective public participation involves shared responsibilities. While the city has an obligation to provide information and feedback opportunities, interested residents are expected to accept the responsibility to educate themselves about the project and review process, to provide constructive, timely and germane feedback, and to stay informed and involved throughout the entire process.

- **Planning Commission.** The planning commission hosts the primary forum for public input and provides clear and definitive recommendations to the city council. To serve in that role, the commission identifies and attempts to resolve development issues and
concerns prior to the council's consideration by carefully balancing the interests of applicants, neighbors, and the general public.

- **City Council.** As the ultimate decision maker, the city council must be in a position to equitably and consistently weigh all input from their staff, the general public, planning commissioners, applicants and other advisors. Accordingly, council members traditionally keep an open mind until all the facts are received. The council ensures that residents have an opportunity to effectively participate in the process.

- **City Staff.** City staff is neither an advocate for the public nor the applicant. Rather, staff provides professional advice and recommendations to all interested parties, including the city council, planning commission, applicant and residents. Staff advocates for its professional position, not a project. Staff recommendations consider neighborhood concerns, but necessarily reflect professional standards, legal requirements and broader community interests.
Location Map

Project: Hennepin County Medical Examiner's Office
Address: 14300 Co Rd 62
NEW REGIONAL MEDICAL EXAMINER'S

SITE HISTORY

1937

1916 - GLEN LAKE SANATORIUM BUILT

1947 - SITE ACQUIRED BY HENNEPIN COUNTY
1961 - Oak Terrace Nursing Home Joins Glen Lake Sanatorium

1968 - Pine Tree Stand Planted

1976 - Glen Lake Sanatorium Closes
1991 - Oak Terrace Nursing Home closes
1993 - Sanatorium and Nursing Home demolished
1997 - Glen Lake Golf Course built
NEW REGIONAL MEDICAL EXAMINER'S

VIEW ONE TO SITE

SITE IS BEHIND TREES
### BUILDING SIZE:

<table>
<thead>
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<th>Building Type</th>
<th>Area (GSF)</th>
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<tr>
<td>Autopsy Wing Including Sally Port</td>
<td>35,570</td>
</tr>
<tr>
<td>Administration Wing/Conference Center</td>
<td>25,600</td>
</tr>
<tr>
<td>Second Level</td>
<td>7,340</td>
</tr>
<tr>
<td><strong>Total Area</strong></td>
<td><strong>68,510</strong></td>
</tr>
</tbody>
</table>

**Building Includes:**

- Autopsy Tables: 10
- Isolation/BSL-3 Autopsy Tables: 2
- Offices: 21
- Open Workstations: 37

### BUILDING SITE:

<table>
<thead>
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<tbody>
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<td>CHS Campus</td>
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<tr>
<td>Medical Examiner Building Site</td>
<td>8</td>
</tr>
<tr>
<td>Medical Examiner Site Access</td>
<td>2</td>
</tr>
<tr>
<td><strong>Medical Examiner Site Total</strong></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

**Site Includes:**

- Staff Parking: 55 Stalls
- Visitor/Conference Parking: 29 Stalls
- Conference Overflow Parking: 13 Stalls
- **Total Parking**: 94 Stalls
QUESTIONS
FIGURE 4.3 DEVELOPMENT SITES MAP
FIGURE 3.2 AREA ANALYSIS MAP
Situated on the southern boundary of Glen Lake and north of Country Road 62 is the current Hennepin County Home School. Comprising nearly 146 acres of contiguous land, the site features a mix of wetlands, woodlands, open grassland with the primary campus on the western portion of the site adjacent to Glen Lake Golf and Practice Center.

On August 13, 2015 County Commissioner Jan Callison provided an update to the community on the Hennepin County site including reviewing the history of the Home School, the current services at the facility, and then discussed the possibility of partnering with Ramsey County to consolidate the two entities and locations closer to where services are more needed, rendering this site obsolete. The County may be looking to sell the property in the future, thus the reason for the City of Minnetonka to explore potential development scenarios on the property, however no formal time table or commitments by Hennepin County have been established.

The eastern portion of the site has a large wetland, woodland area and pine stand as significant natural features. A central wetland bisects the site with the main campus on the western side and open grassland on the remaining eastern portion. There are two access points to the facility on the western edge near the golf course. During the review process with the community, comments on this site included:

» Try to find a balance between development, and preserving park, open space and wildlife habitat
» Ensure that development is designed sustainably to protect Glen Lake, too much density is a concern
» Create trail connections to and from the site
» Explore a broader park or small commercial use as well
FIGURE 5.12 HENNEPIN COUNTY SITE - SITE ANALYSIS
BUILDABLE AREAS ANALYSIS

After removing larger wetlands, steep slopes as well as desired landscape features to preserve such as the pine woodland on the eastern edge of the property and the lakeside areas, two distinct development areas exist. The West and East sides are separated by a large wetland complex. The West side is home to the existing Home School facility and comprises approximately 41 acres of buildable land. The East side is currently undeveloped and is similar in size at 38 buildable acres, for a total of 79 +/- buildable acres.

Access to the site is an important future consideration for development. Existing access points should remain. A third access point should be explored with the Hennepin County Transportation Department to provide direct access to the eastern half of the property. At the narrowest point between the east and west sides, a roadway connection could be established to link the two areas and provide better internal site circulation and emergency service access. The location is a great opportunity for a signature bridge feature for the development.

Connection between buildable areas presents a unique opportunity for an identity bridge feature

The roadway connection between the east and west sides of the property creates a unique opportunity for a signature development feature
FIGURE 5.13 HENNEPIN COUNTY SITE - BUILDABLE AREAS

NOTE: Realign existing access to improve traffic flow and entry sequence into existing golf course and potential redevelopment area.
GUIDING PRINCIPLES - PARKS, TRAILS & OPEN SPACE

» Allow the existing natural features (wetlands, woodlands, pine groves, topography) to dictate development areas

» Preserve a continuous open space network along the southern shore of Glen Lake, extending to the east and capturing the wetland network and woodland hillside

» Preserve the existing woodland and dense pine stand on the east side of the site as a buffer and wildlife corridor

» Preserve and enhance the surrounding wetlands

» Preserve and enhance the central wetland as an amenity and wildlife corridor

» Target approximately 40% of the land area to be open space, preserve or park

» Create a common, shared dock and beach near existing Home School water access location

» Provide a network of trails linking a singular lake access point, smaller internal, neighborhood scale parks and connecting more broadly to the surrounding neighborhoods and the Minnesota River Bluffs LRT Regional Trail to the east

» Create wetland overlook and habitat viewing areas

» Provide an expanded trail network linking new park features, preserved open spaces, and existing trails and neighborhoods surrounding Glen Lake

» Develop a central open space amenity with wetland restoration, stormwater treatment, and central bridge feature

Develop a singular shared or common dock and beach area for the entire development, preserving the natural shoreline of Glen Lake

Develop an integrated trail network, linking internal amenities with surrounding trails and adjacent neighborhoods

An enhanced centralized wetland can be an attractive amenity for future development
FIGURE 5.14 HENNEPIN COUNTY SITE - PARKS, TRAILS & OPEN SPACE CONCEPT
GUIDING PRINCIPLES - LAND USE & DEVELOPMENT

» Focus on residential land use on the site ranging from low density detached to high density attached

» Provide a mix of housing types on the site, including single family home sites, villas, townhomes, apartments and condominiums

» Transition from higher density in the southwest portion of the site to lower density in the northern and eastern portions of the site

» Explore options for preserving and reusing portions of the existing campus buildings

» Explore the opportunity for a new southerly access point to Highway 62

» Provide an identifiable loop street network throughout the development

SUGGESTED LAND USES

The size of the overall site, and the configuration (East and West sides) allows for a range of residential development on the site. The reuse of portions of the Home School Facility is a possibility as well.
NOTE: Concepts do not represent actual development proposals and are for discussion purposes only. They do not imply that development is or will be supported by property owners.
A. Concept plan review for Hennepin County Medical Examiner's Office at 14300 County Road 62.

Chair Kirk introduced the proposal and called for the staff report.

Gordon reported. Staff recommends that planning commissioners provide comments and feedback on the identified key issues and other issues commissioners deem appropriate. The discussion is intended to assist the applicant with future direction that may lead to the preparation of more detailed development plans.

John Rode, senior facility planner with Hennepin County Facility Services Planning and Project Development, representing the applicant, stated that the site has 160 acres. He provided a history of the site.

Zach Essig, engineer with Leo A. Daly, stated that:

- He pointed out what wetland area and trees would be protected. The Tamarack bog would be protected and preserved up to the slope.
- There would be 24.5 acres of buildable space.
- He compared possible building locations considering access, impact to trees, wetlands, and slopes.
- The proposed building location would provide a nice approach through the south side of the wetland between the woodland preserve and wetland area using retaining walls to reach the road. The road would have a typical width with retaining walls that would not have any permanent impact on the wetland or woodland preserve.
- As many coniferous trees would be preserved as possible.

Mr. Rode stated that:

- The autopsy wing would be 3,500 square feet. There is a second level that would house mechanical equipment and building services. There would be 10 autopsy tables and two isolation autopsy tables.
- There would be 21 offices and 37 work stations.
- The site pad would be located on eight acres. Access uses another two acres. There would be 55 secure parking stalls for staff. There would be 29 visitor stalls and 13 additional overflow stalls to accommodate the conference center.

Melissa Lallak, department administrator for the medical examiner’s office, stated that:

- The medical examiner’s office investigates deaths that meet statutory requirements in a forensic manner.
• The facility would operate 24 hours a day, seven days a week.
• The facility is a collaboration of Hennepin, Dakota, and Scott Counties. There are a number of highly educated staff in the field of forensic science.
• They are an accredited site to train forensic scientists.

Sewall asked if there would be an environmental impact. Ms. Lallak said that the environmental impact would be minimal. There would be no crematorium. Specimens would be collected in containers that would be sent to outside testing labs. The ventilation in the building would be set up to be respectful to the outside.

Sewall asked how many vehicle trips the site would generate. Ms. Lallak stated that 16 employees would travel to and from the site. The investigative staff operate 24/7, but that would create a minimal number of trips. Funeral homes and the transport agency typically use white vans. The facility has two rigs that investigators drive to scenes that are silver and have the Hennepin County Medical Examiner’s Office logo on the outside.

Powers asked if other sites are being considered. Mr. Rode stated that three other sites were considered in Bloomington, but they did not work out. The applicant will receive state bonding for the project and is looking for help from Dakota and Scott Counties for funding.

Chair Kirk thought it looked like the north part of the site is less wooded. Mr. Rode said that having the building further south minimizes the access road length.

Gordon noted that city requirements would allow for a larger buildable area on the site than the applicant’s determination.

Chair Kirk asked about the type of planted trees on the site. Gordon answered that the trees are mostly red pines and some scotch pines.

Chair Kirk recommended requesting permission for commissioners to visit the site. Gordon agreed. Mr. Rode stated that a minimal background check would have to be done for each visitor, but that would be possible.

Powers asked for the size of the current operating site. Mr. Rode stated that the facility takes up half of a city block. The existing building is 62,000 square feet in size. It also has a functional crime lab. The medical examiner utilizes 40,000 square feet with the crime lab using 22,000 square feet. The proposed building would have approximately 68,500 square feet. That would provide the anticipated capacity requirements for the next 30 years. The proposed parking is projected to be adequate until 2047.

Chair Kirk asked if anyone in the audience wanted to provide comments.

Anne Hossfeld, 14616 Glendale Street, asked for the level of approval the city has over the site and questioned the number of attendees at the conferences.
Gordon explained that the city’s land use ordinances apply to a publically-owned property the same as a privately-owned property. Schack provided the example of a restroom facility that was approved for the Hopkins High School site. An application submitted by a school district is treated the same as an application submitted by a private-property owner.

Ms. Lallak explained that Hennepin County currently sponsors a MN Coroners and Medical Examiners three-day conference which is held at a hotel in St. Louis Park. A two-day conference may be held at the proposed facility. Transportation and lodging options would need to be researched.

Schack thought the proposal would be a good use of county-owned property. She wished more trees could be saved. She understood there would be a trade-off to move the building further north. She is less concerned with the pines than if it was an oak forest. The county figures the buildable area as 24 acres, but the city’s parameters would allow a lot more development on the site.

Sewall liked the idea of visiting the site as a group. He would like to see how far north the building could be moved and compare the increase in hard surface coverage to the number of trees that could be saved. He would like to see a rendering of the proposed building. The building would be relatively central. It is a very large site. It would be an appropriate land use.

Chair Kirk struggled with the land use. He understood that it may seem like an appropriate use to be adjacent to the county home school. The property is beautiful and has so much potential.

Powers thought something special could be built on the 161 acres. He was worried that it would be developed in pieces.

Schack appreciate the value of the property. She saw it evolving into a county campus. The public use is of value. It would be a loss to provide an opportunity for housing, but the site is not zoned residential.

Sewall stated that individual property owners have rights. He agreed this would be a great spot for housing and the county may decide to split up the property, but the use would be appropriate for the current situation.

Powers saw it as an educational facility.

Schack made a correlation to Carlson Companies proposing to add a building to its campus on McGinty Road West. There is a lot of land that would make great residential housing, but she did not think that would happen in her lifetime. She would be hard pressed to deny Carlson the ability to develop their land within the city’s ordinance requirements.
Sewall asked commissioners to consider if the proposal would limit the ability of the property to be subdivided and used for housing in the future.

Wischnack said that commissioners could request a possible build-out scenario from the applicant.

Powers would not want a 10-acre development to define the entire 161-acre parcel.

Knight was concerned with locating the building in the middle of the property to site area to the north. The building could be moved further north without adding too much more driveway.

Chair Kirk likes how the parking areas meander through the site to break-up the parking instead of having one massive parking lot. The site would be respectful of the tree canopy.

The city council is tentatively scheduled to review this item at its meeting on July 9, 2018.
City Council Agenda Item #14D  
Meeting of Sept. 17, 2018

Brief Description:  Ordnances related to franchise fees

Recommended Action:  Adopt the ordinances

Background

On Aug. 27, the city council introduced two ordinances. The first would increase the franchise fees currently imposed on electric utility accounts. The second would impose a new franchise fee on gas utility accounts. The franchise fee revenues would be used to expand the city’s trail and sidewalk system, making it safer for pedestrians, cyclists and motorists alike. This evening, council is requested to adopt the ordinances.

Franchise fee authority and history

State law authorizes cities to require gas and electric utility companies to obtain a franchise in order to place their facilities within city streets and public property. Franchises are granted by ordinance. Minnetonka first required that Northern States Power Company obtain a franchise in 1975. The franchise was renewed in 1998 and again in 2018. The city first granted a franchise to a gas utility in 1963, which was renewed in 1983, and 2002.

The city’s franchise ordinances and state law authorize the city to impose franchise fees on utility franchisees, and the fees serve as a kind of “rent” for use of city assets, the publicly owned rights of way. The gas and electric franchise ordinances both require that, if a franchise fee is adopted, it must be adopted by a separate ordinance. The city has not previously adopted a franchise fee on gas accounts. The city first adopted an electric franchise fee in 2005 and increased the fee in 2007. There has been no increase in the electric franchise fee since 2007.

### Electric franchise monthly fee history and proposed

<table>
<thead>
<tr>
<th>Customer Classification</th>
<th>2005 Ordinance</th>
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<td>Municipal Pumping - Demand</td>
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Proposed monthly gas franchise fee

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<tr>
<td>Large Volume, Dual Fuel (LVDF)</td>
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</tbody>
</table>

Use of franchise fee revenue

Under state law, cities may use franchise fees to raise revenue or to defray the increased municipal costs that result from the utility’s operations, or both. However, the use of franchise fees may be restricted by the franchise ordinance.

The city’s gas franchise ordinance does not restrict the use of franchise fees. The current electric franchise ordinance does not restrict the use of franchise fees, provided that the city imposes equivalent franchise fees on both gas and electric utilities. If, however, the city does not impose equivalent fees on both utilities, the electric franchise ordinance requires that the electric franchise fees be used only for betterment of electric facilities, such as undergrounding electric lines or installing decorative lighting. That restriction has been in place since 1998, and all electric franchise fees collected since 2005 have been used for that purpose.

The new franchise fee revenue generated by the gas franchise fee and around 60 percent of the increase in the electric franchise fee are proposed to be designated for improvements to the city’s trail system. The remainder will continue to fund the current base capital program for electric burials and decorative street lights.

City trail system: needs, demands and benefits

The most repeated request from residents through the city’s recent community engagement process, Imagine Minnetonka, was for expansion of the city’s trail system and making sidewalks and streets safer for pedestrians. The community survey shows that trails are clearly the most popular park amenity used by our residents. City council and park board discussions have also identified expansion of the trail system and street and sidewalk safety improvements as a priority.

Trails are an integral part of the city’s parks, open space and pedestrian system as well as the comprehensive guide plan. The construction of an integrated and connected trail system is expected to provide significant benefits – not only for health and recreation, but also for safety, air quality, economic development, environmental sustainability, and traffic. A summary of benefits is included in the August 27 council report; a link to it is provided at the end of this report. Trails are becoming a fundamental component of transportation infrastructure for many cities seeking to encourage and provide for these benefits in their communities.
Anually, the city commissions a random sample community survey conducted by an experienced professional survey firm. (The results are projectable to the entire city within +/- five percent in 95 out of 100 cases.) The 2018 results indicated that 82 percent of Minnetonka residents surveyed supported the use of municipal dollars for the expansion and improvement of trails and sidewalks in the city, and 52 percent of all respondents were willing to increase their monthly municipal costs by at least $4 for those purposes.

In 2016, the city's internal trails team updated the feasibility score and reprioritized unscheduled and unfunded segments. The vision for trail segments uses a score based on: Community Access (40%), Nature of Use (40%), Cost Effectiveness (10%), and Degree of Construction Difficulty (10%). At the same time, the trails team also estimated approximate costs to construct the remaining priority trail network at a projected total of $58.9 million. Staff used these planning level estimates to develop an approximate idea of funding needed to build out these segments, with the intent to complete feasibility reports as segments are scheduled or get closer to construction to refine the detailed costs. A link to the 2019 Trail Improvement Plan is at the end of this report.

Alternative funding options

In years past, the city’s philosophy was to consider adding trails or sidewalks at the time of city or county road reconstruction projects to economize the expenditures for what would otherwise be very expensive improvements. However, a number of the high priority segments are located on roads that are not scheduled at this time and would not be reconstructed for many years. This was confirmed by Hennepin County’s August 30 list of requested road projects for consideration in their 2019-2023 Capital Improvement Program, which lists all of Minnetonka’s county roads as “Request Not Recommended” (attached). Although the city will continue to pursue grant funding from partners such as Hennepin County, Three Rivers Park District and the Metropolitan Council, to name a few, there is a clear desire to accelerate construction of a number of segments in the next ten years.

There is currently no dedicated funding source for construction of priority trail segments, and in previous years the city has used a “pay-as-you-go” strategy. On a very inconsistent basis, the city may receive some park dedication fees that might be used for trails or other similar public betterment. Also, when other capital project priorities do not take precedence, the city may realize a significant enough improvement to the general fund balance to afford some portion of an expensive trail segment. In 2019 for example, both the current and recommended CIP includes a transfer from the general fund balance to accommodate the more expensive segment of the Plymouth Road trail. Because the year-end general fund balance varies annually and the first priority is to preserve an adequate fund balance per council policy, this is not a consistently reliable funding source.

Staff considered a number of options for creating a dedicated funding source. One option, bonding, would require a voter referendum and would generate one-time revenues that would have only a limited impact in meeting the significant and expensive needs and would not be able to support ongoing maintenance requirements. And despite the continued relatively low interest environment, the high cost of the projects list would necessitate long payback periods and significantly add to the expense.
Alternatively, to generate enough revenue to afford and make any headway on the list of unfunded segments equivalent to the franchise fee revenue proposed here, the city would require a property tax levy increase of at least 4.8 percent. Staff estimates that if an additional levy increase was added to the preliminary levy increase proposed for other primary costs of the city to be discussed later this evening, the total impact to the median-value homeowner in Minnetonka ($359,800 for payable 2019) would be an almost 9.5 percent increase in their city property tax bill.

Staff believes franchise fees are an appropriate source for trails due to the clear nexus between rights of way and trail locations. In addition, franchise fees are paid by all gas and electric customers, including entities that would be exempt from an increase in the property tax levy, such as schools and churches. Schools and churches would typically be large users of trails and have approached the city on many occasions to request trail segments near their properties. Recently, Minnetonka High School and advocates around the area worked with the city on safety improvements near the school; however, current financial demands throughout the city did not allow for construction of a trail/sidewalk in the identified area. Staff recently learned an online petition supporting this request has already garnered nearly 500 signatures and may be submitted to the city in the near future.

Revenue projections and projects

As noted in the 2019-2023 Capital Improvement Program, approved in June of this year, the new fees would generate approximately $1.8 million per year and allow for the completion of approximately eight new priority segments over the next ten years. This includes the addition of the following segments in the 2019-2023 CIP:

- Excelsior Boulevard (Baker Road to Shady Oak Road),
- Excelsior Boulevard (Glenview Drive to Caribou Drive),
- Ridgedale Drive (White Birch Road to Target),
- Minnetonka Boulevard (The Marsh to Fairchild Lane), and
- Hopkins Crossroads (Cedar Lake Road to Wayzata Boulevard).

Relevant tables from the CIP are attached to the August 27 council report, a link for which is at the end of this report. For further information on planned trail improvements, reference is made to the CIP approved on June 4, 2018.

Comparison with other cities

Around 75 percent of the cities in the 7-county metro area charge franchise fees and the revenue garnered as a result serves to buy down what otherwise might be levy requirements of those cities. A table of fees charged by other metro cities and information on franchise fees collected by nearby cities and those throughout the state were attached to the previous council report of August 27 (see link provided at the end of this report). Six out of our ten comparable cities in the metro similarly charge both electric and natural gas franchise fees for use of public right of way. Those cities use this ongoing source of revenue for a range of purposes including trails, pavement management, street reconstruction, sustainability efforts, and general city facility upgrades.
Public outreach

The staff identified the franchise fee funding proposal for the city council during the process for adoption of the 2019-2023 CIP. At the April 23 study session, staff presented a plan to fund additional trail segments through use of franchise fees as compared to an additional levy increase with the understanding additional approvals would be necessary in the future. The council approved the 2019-2023 CIP on June 4, 2018 without comments about the proposed use of franchise fees.

Since the adoption of the CIP, the city published prominent articles about the proposal to increase franchise fees to pay for trail improvements. The articles appeared in the July, August and September issues of the Minnetonka Memo and invited public comment. A direct mailing about the proposal was sent to approximately 1,000 businesses. Around 45 property owners and/or ratepayers (representing 0.2 percent of property parcels in the city) have called or written to provide feedback. All of the new written feedback and staff’s answers since the August 27 council meeting where it was possible are provided as an attachment to this report.

Of all the communications, just over half did not support the proposal, around 15 percent supported the proposal and for almost one-third, the individual’s position was unclear. Only one of the persons represented a known business located in the city. Many sought more information on the proposal and a number of the individuals expressed specific concerns related to the funding mechanism, i.e. using franchise fees as the method of financing. Only one person clearly stated their objections to building any additional trails.

Other comments included: a preference for property taxes because it is more transparent; a concern that the fees were too regressive (those with lesser incomes paid the same fees as those with greater incomes); a desire that only those who used the trails should pay for the trails; and a request for a voting referendum on the issue. Two individuals suggested “wheel taxes” or bicycle licensing for use of the trails, which would be extremely challenging to administer, and one person suggested corporate sponsorships for each trail.

When the ordinances were introduced at the August 27 city council meeting, six people provided public comment. While most were supportive of additional trails and sidewalks, five opposed use of the franchise fee and one spoke in favor of them.

Process and effective date

Both the gas and the electric franchise ordinances require the city to provide notice to the franchisee prior to imposing or increasing the franchise fee. The city notified the franchisees in June. Representatives of both companies have communicated with the finance director, expressing their acceptance of the proposed fees.

If adopted, the city is required to provide notice of the adoption of the ordinances to the franchisees. Both of the proposed ordinances expressly provide that the companies are not required to start collecting the fee until the first billing period in January 2019. If the notice is given immediately after adoption of the ordinance this evening, both companies will have more than 100 days to prepare for implementation of the ordinance.
Summary

The residents of Minnetonka and the city council have clearly indicated support for a more aggressive build out of trails and sidewalks. This is especially true for segments to be located along busy roads, where safety is an immediate concern for pedestrians, cyclists, and motorists alike. Although construction of all the unfunded routes will still take some time, designating legally permitted franchise fees as a dedicated funding source would improve safety in thoughtfully prioritized areas more quickly.

Recommendation

Adopt the following ordinances:

- Ordinance increasing the electric franchise fee on Northern States Power Company for providing electric energy service within the City of Minnetonka
- Ordinance implementing a gas franchise fee on Centerpoint Energy Minnesota Gas for providing gas energy service within the City of Minnetonka

Submitted through:
  Geralyn Barone, City Manager
  Will Manchester, Director of Engineering
  Kelly O’Dea, Director of Recreation Services

Originated by:
  Corrine Heine, City Attorney
  Merrill King, Finance Director
  Carol Hejl, Park and Trail Planner

Supplemental Information

City Council Agenda Packet of August 27, 2018, Item 12A, “Items related to franchise fees”
2019 Trail Improvement Plan

Attachments

“Hennepin County Capital Project Needs Request Results” as submitted by county staff for consideration in the Hennepin County 2019-2023 Transportation Capital Improvement Program (CIP) in August 2018
Proposed ordinance increasing the electric franchise fee
Proposed ordinance implementing a gas energy franchise fee
Citizen input
## Capital Project Needs Request Results

*project needs submitted in 2017 - results listed in alphabetical order by municipality / agency*

8/30/2018

<table>
<thead>
<tr>
<th>Municipality / Agency</th>
<th>Project</th>
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<tbody>
<tr>
<td><strong>Programmed in 2018-2022 CIP</strong></td>
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<tr>
<td>1 Bloomington</td>
<td>CSAH 17 (France Ave) safety improvements from American Blvd to Minnesota Dr</td>
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<tr>
<td>2 Minneapolis</td>
<td>CSAH 3 (Excelsior Blvd) intersection reconstruction at CSAH 25 (Lake St)</td>
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<tr>
<td>3 Minneapolis</td>
<td>CSAH 152 (Webber Pkwy) reconstruction from CSAH 2 (Penn Ave) to 41st Ave</td>
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<td>4 Plymouth</td>
<td>CSAH 6 retaining wall replacement from Dunkirk Ln to Vicksburg Ln</td>
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<td>5 Richfield</td>
<td>77th St underpass at TH 77</td>
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<td>6 St. Louis Park</td>
<td>CSAH 5 (Minnetonka Blvd) reconstruction from TH 100 to France Ave</td>
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<td><strong>Recommended for 2019-2023 CIP</strong></td>
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<td>1 Brooklyn Center</td>
<td>CSAH 152 (Brooklyn Blvd) reconstruction from CSAH 10 (Bass Lake Rd) to 65th Ave</td>
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<td>2 Brooklyn Center</td>
<td>CSAH 57 (Humboldt Ave) reconstruction from 53rd Ave to 57th Ave</td>
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<tr>
<td>3 Excelsior</td>
<td>CSAH 82 (Mill St) off-road facility from Apple Rd to County Line</td>
</tr>
<tr>
<td>4 Golden Valley</td>
<td>CSAH 70 (Medicine Lake Rd) drainage improvements at CSAH 156 (Winnetka Ave)</td>
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<td>5 Independence</td>
<td>CSAH 90 intersection improvements at Hwy 12</td>
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<td>6 Independence</td>
<td>CSAH 92 intersection improvements at Hwy 12</td>
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<td>7 Mound/Minnetrista</td>
<td>CSAH 44 (Westedge Blvd) reconstruction from TH 7 to CSAH 110 (Bartlett Blvd)</td>
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<td>8 Shorewood</td>
<td>CSAH 82 (Mill St) off-road facility from 2nd St to County Line</td>
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<tr>
<td>9 Spring Park</td>
<td>CSAH 51 (Sunset Dr) reconstruction from Northern Ave to CSAH 19 (Shadywood Rd)</td>
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<td><strong>Designated 2019-2023 Provisional Project</strong></td>
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<td>1 Brooklyn Park/Three Rivers Park District</td>
<td>CSAH 81 (Bottineau Blvd) off-road facility from CSAH 109 (85th Ave) to 1st Ave NW</td>
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<td>2 Dayton</td>
<td>CSAH 121 (Fernbrook Ln) safety improvements at Pineview Ln</td>
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<td>3 Dayton</td>
<td>Dayton Pkwy interchange at I-94 (from CSAH 101 to CSAH 81)</td>
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<td>4 Golden Valley/Three Rivers Park District</td>
<td>CSAH 66 (Golden Valley Rd) off-road facility from Regent Ave to Bonnie Ln</td>
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<td>5 Maple Grove</td>
<td>CSAH 130 (Elm Creek Blvd) interchange improvements at TH 169</td>
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<td>6 Minneapolis</td>
<td>CSAH 153 (Lowry Ave) reconstruction from CSAH 23 (Marshall St) to CSAH 27 (Stinson Blvd)</td>
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<td>7 Minneapolis</td>
<td>CSAH 23 (Marshall St NE) reconstruction from 10th Ave NE to 27th Ave NE</td>
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<td>CSAH 3 (Lake St) interchange improvements at TH 55 (Hiawatha Ave)</td>
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<td>CSAH 36 (University Ave) and CSAH 37 (4th St) enhanced bikeway from I-35W to Oak St</td>
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<td>10 Plymouth</td>
<td>CSAH 9 (Rockford Rd) interchange improvements at I-494</td>
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<td>11 Robbinsdale</td>
<td>CSAH 9 (42nd Ave) reconstruction from BNSF RR to CSAH 8 (W Broadway)</td>
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<td>12 Shorewood/Excelsior</td>
<td>CSAH 19 (Manitou Rd) off-road facility from Smithtown Rd/Manitou Rd to Excelsior-Studer Park</td>
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## Capital Project Needs Request Results

*project needs submitted in 2017 - results listed in alphabetical order by municipality / agency*

8/30/2018

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<td>1 Crystal</td>
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<tr>
<td>7 Excelsior</td>
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<td>8 Hanover/Rogers/Three Rivers Park District</td>
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<tr>
<td>26 Rogers</td>
</tr>
<tr>
<td>27 Shorewood</td>
</tr>
<tr>
<td>28 St. Louis Park</td>
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</table>
Ordinance No. 2018-

An Ordinance increasing the electric franchise fee on
Northern States Power Company for providing electric
energy service within the City of Minnetonka

The City of Minnetonka Ordains:

Section 1. Background. On August 10, 1998, the Minnetonka City Council adopted Ordinance No. 1998-15 ("Franchise Ordinance"), granting an electric franchise to Northern States Power Company ("Company"). The Franchise Ordinance allows the City of Minnetonka to impose a franchise fee in the form of a fee per metered service.

Section 2. Existing Franchise Fee. By Ordinance No. 2005-04, the City of Minnetonka established a franchise fee for the electric franchise. The city council increased the fee by Ordinance No. 2007-29.

Section 3. Change to Franchise Fee. The city council has determined that an increase in the franchise fee is appropriate, commencing with the Company’s January 1, 2019 billing month. The amount of the fee will be in accordance with the following schedule:

<table>
<thead>
<tr>
<th>Customer Classification</th>
<th>Amount per Month</th>
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<tbody>
<tr>
<td>Residential</td>
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<td>Municipal Pumping – Demand</td>
<td>$ 4.50</td>
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</tbody>
</table>

Section 4. Account Fee. This fee is an account based fee and not a meter-based fee. In the event that an entity covered by this ordinance has more than one meter, but only one account, only one fee shall be assessed to that account. In the event any entities covered by this ordinance have more than one account, each account shall be subject to the appropriate fee. In the event a question arises as to the proper fee amount for any account, the highest possible fee amount shall apply.

Section 5. Payment and Modification. The franchise fee shall be payable quarterly in accordance with Section 9.4 of the Franchise Ordinance. The franchise fee may be increased or decreased by ordinance from time to time, in accordance with Section 9.2 of the Franchise Ordinance.

Section 6. Disputes. Any dispute, including enforcement of a default regarding this ordinance will be resolved in accordance with Section 2.5 of the Franchise Agreement.

The strike over line is deleted; the underlined language is inserted.
Section 7. Effective Date of Franchise Fee. The effective date of fee collection shall be January 1, 2019 or ninety (90) days after the City sends written notice enclosing a copy of this adopted Ordinance to the Company by certified mail, whichever date is later.

Section 8. Effective Date of Ordinance. This ordinance becomes effective from and after its passage and publication, in accordance with Section 3.06 of the Minnetonka City Charter.

Adopted by the city council of the City of Minnetonka, Minnesota, on _________, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

Action on this Ordinance:

Date of introduction:
Date of adoption:
Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Ordinance adopted.

Date of publication:

The stricken language is deleted; the underlined language is inserted.
I certify that the foregoing is a true and correct copy of an ordinance adopted by the city council of the City of Minnetonka, Minnesota, at a meeting held on

David E. Maeda, City Clerk
ORDINANCE NO. __________________

An Ordinance implementing a gas energy franchise fee on Centerpoint Energy Minnesota Gas for providing gas energy service within the City of Minnetonka

The City of Minnetonka Ordains:

Section 1. Definitions. For the purposes of this Ordinance, the following terms shall have the following meanings:

(1) City. The City of Minnetonka, County of Hennepin, State of Minnesota.


(3) Franchise Agreement. The franchise agreement between the City and Company’s predecessor in interest, Reliant Energy Minnegasco, a division of Reliant Energy Resources Corporation, a Delaware corporation, pursuant to Ordinance No. 2002-01, adopted by the Minnetonka City Council.

(4) Notice. “Notice” means a writing served by any party or parties on any other party or parties. Notice to Company shall be mailed to CenterPoint Energy, Vice President Regional Operations, 505 Nicollet Mall, Minneapolis, MN 55402. Notice to City shall be mailed to City Clerk at City of Minnetonka, 14600 Minnetonka, MN 55435.

Section 2. Franchise Fee Authorized; Finding. The Minnetonka City Council has determined that it is in the best interest of the City to impose a franchise fee on those public utility companies that provide natural gas services within the City. Pursuant to the Franchise Agreement the City has the right to impose a franchise fee on Company.

Section 3. Franchise Fee Statement and Schedule. A franchise fee is hereby imposed on Company commencing with the January 2019 billing month, and in accordance with the following fee schedule:
Customer Classification | Amount per Account per Month ($)
--- | ---
Residential | $4.50 per month
Firm A | $4.50 per month
Firm B | $13.50 per month
Firm C | $45.00 per month
Small Volume, Dual Fuel A ("SVDF A") | $45.00 per month
Small Volume, Dual Fuel B ("SVDF B") | $45.00 per month
Large Volume, Dual Fuel ("LVDF") | $45.00 per month

Section 4. **Account Fee.** This fee is an account based fee and not a meter-based fee. In the event that an entity covered by this ordinance has more than one meter, but only one account, only one fee shall be assessed to that account. In the event any entities covered by this ordinance have more than one account, each account shall be subject to the appropriate fee. In the event a question arises as to the proper fee amount for any account, the highest possible fee amount shall apply.

Section 5. **Payment.** Franchise fees are to be collected by the Company, consistent with the Minnesota Public Utility Commission’s March 23, 2011 Order establishing franchise fee filing requirements in Docket No. E,G999/CI-09-970, and submitted to the City as follows:

- January – March collections due by April 30.
- April – June collections due by July 31.
- July – September collections due by October 31.
- October – December collections due by January 31.

Section 6. **Record Support for Payment.** The Company shall make each payment when due and, if requested by the City, shall provide a statement summarizing how the franchise fee payment was determined, including information showing any adjustments to the total made to account for any non-collectible accounts, refunds or error corrections. The Company shall permit the City, and its representatives, access to the Company’s records for the purpose of verifying such statements.

Section 7. **Payment Adjustments.** Payment to the City will be adjusted where the Company is unable to collect the franchise fee. This includes non-collectible accounts.

Section 8. **Surcharge.** The City recognizes that the Minnesota Public Utilities Commission may allow the Company to add a surcharge to customer rates of city residents to reimburse the Company for the cost of the fee, consistent with the Minnesota Public Utility Commission’s March 23, 2011 Order establishing franchise fee filing requirements in Docket No. E,G999/CI-09-970.

Section 9. **Effective Date of Franchise Fee.** The effective date of this Ordinance shall be January 1, 2019 or sixty (60) days after the City sends written notice enclosing a copy of this adopted Ordinance to Company by certified mail. Collection of the fee shall commence as provided above.
Section 10. **Relation to Franchise Agreement.** This ordinance is enacted in compliance with the Franchise Agreement and shall be interpreted as such.

Section 11. **Permit Fees.** The Company will administer the collection and payment of franchise fees to the City in lieu of permit fees, or other fees that may otherwise be imposed on the Company in relation to its operations as a public utility in the City so long as the following requirements are met:

a) The Company applies for any and all permits, licenses and similar documentation as though this provision did not exist.

b) The Company requests the fee to be waived at the time of application.

This section only relates to waiver of fees and does not otherwise restrict or limit the City’s rights under Minn. Stat. § 237.163 or other law.

Section 12. **Effective Date of Ordinance.** This ordinance becomes effective from and after its passage and publication, in accordance with Section 3.06 of the Minnetonka City Charter.

Adopted by the city council of the City of Minnetonka, Minnesota on ______________, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this Ordinance:**

Date of introduction:
Date of adoption:
Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Ordinance adopted.

The *stricken* language is deleted; the *underlined* language is inserted.
Date of publication:

I certify that the foregoing is a true and correct copy of an ordinance adopted by the city council of the City of Minnetonka, Minnesota, at a meeting held on

______________________________
David E. Maeda, City Clerk

The stricken language is deleted; the underlined language is inserted.
Hi, Mr. Anderson.

You are correct that “in the end,” like property taxes, all property owners in Minnetonka would pay these fees through their utility companies. Because the city is making a connection between using road right-of-ways for both trails and utility companies, the law requires us to use the technical term of franchise fee in labeling the method used for collection. I appreciate your perspective and am happy to pass it along to the city council as they deliberate on final authorization for financing the trail system improvements. Thanks for providing the input.

Sincerely,

Merrill King

Merrill King | Finance Director/Treasurer | City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8253

Director King,

I was reading the latest Minnetonka Memo and noted the article about the possible franchise fee increase to support the trail system. I support the additions to and maintenance of the trail system but I feel that the proposed franchise fee increase is VERY misleading. I feel that you should call it what it is, a TAX increase. Is this just a sneaky way to increase taxes?

Jerry Anderson
3724 Hilltop Road
Minnetonka
The resident cited an article that appears on the website of the Center for the American Experiment. The article purports to be testimony given by Peter Nelson, on behalf of the Center, to the Minnesota legislature. He makes the following assertions:

- When franchise fees are used to raise revenue, they are a tax, subject to the state constitutional limitations on taxes.
- State law expressly allows cities to use franchise fees to raise revenue or defray costs. But the law creates a confusing situation, because there are different legal standards for taxes than fees.
- Citing an Iowa Supreme Court case, he asserts there is a risk that the city could be forced to refund some or all of franchise fees if a court finds that the fees are being used for purposes other than regulation of the franchisee.

The focus of the resident’s email is the Iowa court case. The Iowa case is not applicable to our franchise fees, which are imposed under Minnesota law. Iowa state law expressly prohibits cities from levying any tax unless specifically authorized by state law. The Iowa Supreme Court held that state law did not authorize cities, including home rule charter cities, to use franchise fees to raise revenue. The Iowa court therefore remanded the case back to the trial court to determine what portion of the franchise fees that Des Moines had established were needed to offset the city’s administrative expenses in regulating the franchise.

Unlike Iowa, and as noted by Peter Nelson, Minnesota state law expressly authorizes cities to impose franchise fees “to raise revenue or defray increased municipal costs accruing as a result of utility operations, or both.”

That leaves Mr. Nelson’s argument that franchise fees are a tax, to the extent that the fees collected exceed the city’s costs in regulating its right of way. If a court determined the fees to be an exercise of taxing power, the following would apply:

- The city must have statutory authority to impose the tax. As noted, it does.
- The taxes must be uniform upon the same class of subjects. Uniformity doesn’t require mathematical precision. The city is imposing equivalent fees on the gas utility and the electric utility, and the companies have not disputed that the fees are equivalent.
Revenues from taxes must be used for public purposes. The franchise fees will be used for public purposes.

Certain entities must be exempt from taxes (generally, cemeteries, schools, hospitals, and charitable institutions). The franchise fee is imposed on the gas and electric companies, and they are not tax exempt. The city does not impose the fee on utility customers. The companies ask for the city to set the fee based on accounts, because the companies can then put that amount on customer bills. That’s the companies’ preference. We have the statutory ability to impose a franchise based on percentage of revenues, but the companies won’t agree to franchises on that basis, because they want to be able to identify it as a passed-through charge. That doesn’t change the fact that the fee is imposed on the company, not the customer.

Corrine A. Heine | City Attorney
City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8262

From: Geralyn Barone
Sent: Wednesday, August 29, 2018 1:03 PM
To: Corrine Heine <cheine@eminnetonka.com>
Subject: FW: Franchise fee discussions

Corrine,

Please advise. Thanks!

Geralyn

From: Deborah Calvert
Sent: Wednesday, August 29, 2018 12:30 PM
To: Geralyn Barone <gbarone@eminnetonka.com>
Subject: Fwd: Franchise fee discussions

Hi Geralyn,

My understanding from the packet and discussions on the matter is that Corrine is confident that we would be safely within the boundaries of the laws and ordinances around franchise fees should we choose to approve them. Again, I would like to answer this resident accurately, and of course I could only support it if that were the case.

Deb

Sent from my iPhone

Begin forwarded message:

From: Nancy Bresnahan
Date: August 28, 2018 at 1:11:43 PM CDT
To: "dcalvert@eminnetonka.com" <dcalvert@eminnetonka.com>
Subject: Franchise fee discussions

I found the discussion of a franchise fee increase to pay for trail development and maintenance extremely interesting. I was wondering if the council knew of the following and considered it
Finally, I want to note that cities are taking a risk in establishing these fees. If a Minnesota court later finds that these franchise fees did not fund the regulation of the franchise agreement, then any money spent on core services may need to be remitted. This is exactly what happened in Des Moines, Iowa. In 2012, the Iowa Supreme Court required Des Moines to refund around $40 million in excess fees paid. From 2016
For the next packet – please include only Mr. Bucaro’s comments.

Fernando,
Thank you for your e-mails. I take your concerns seriously and I will consider your input as this matter moves forward.

I would like to address a couple of the issues you raise in your e-mail:

1. I disagree that our side of Minnetonka is often “forgotten”. To the contrary, Ward 2 is one of the busiest and most vibrant areas in the city. As you may know, Ward 2 is growing quickly and is receiving some major attention from the city in regards to infrastructure over the next couple of years. The Ridgehaven (bridge project near Ridgedale) is nearing completion and within the next couple of years we will have a brand new park in our Ward.
2. No matter how it is funded, I believe many residents Sherwood Forest would benefit from the addition of a trail on Hopkins Crossroads. This is one of the projects on the calendar in the event the funding is available.
3. I disagree that the fact that the city does not spend every available cent each year is evidence that there are funds available in the budget. As I am sure you can imagine, there are certain variables that the city has little, if any, control over each year (i.e. snowfall amounts and timing, unfilled positions, etc.) that impact the amount of money that may be leftover at the end of each year. As you may know, funds that are not used in any give year are rolled into the next year and considered in the budgeting for that following year. In other words, the funds unspent in 2017, offset the amount needed to be generated in 2018.

All that said, I do understand your overlying concern regarding the franchise fee as a mechanism for funding the trails/sidewalks.

Please continue to stay engaged and to reach out to me with your input.

Sincerely,
Rebecca Schack

Sent from my iPad

On Aug 29, 2018, at 7:46 PM, Fernando Bucaro wrote:
Ms Schack,

Sorry for the additional email. I’ve spent part of my evening looking into the city’s finances a bit more and am concerned how the city cannot already afford to do this without this hidden tax increase. Below is what I recently posted on Nextdoor – it is a bit unprofessional but it was in response to another poster. I’d be happy to discuss in person or over the phone anytime. I thank you for your time.

Let’s peel back the onion shall we - on the city’s finances. The city has, in its general fund (please review fund based government accounting if interested), $22.9M at the end of 2017. This fund increased by $1.6M from end of year 2016. This was largely driven by savings to budgeted expenditures. Great job city managers!

However, looking at the 2016 financial results I see a savings of $1.4M to budget while the fund balance grew by $1.6M Great job city managers...

In 2015 the numbers were $1.4M and $2.3M respectively. Now I worry - because variances that high year over year are a sign of something simply called "sandbagging".

So - my point being - to the comment - "It is valid to say ‘can’t thy save money elsewhere?’ But that is t related to the question at hand ‘should we fund the trails’. They can work on cost savings independent of this plan. Totally separate issue and not related to the trail topic.” - I would agree and the city has proven it can save money (or sandbag) - yet we don’t see it.

Instead, we are being asked to pony up $1.8M / year for 10 years for more trails where clearly through better budgeting and fund management perhaps the money is already there without touching or asking to use any restricted funds.

Thank you,

Fernando Bucaro

From: Fernando Bucaro
Date: Wednesday, August 29, 2018 at 1:49 PM
To: <rschack@eminnetonka.com>
Subject: Franchise fees

Ms Schack,

I have just become aware of the utility franchise fees being proposed by our fine city. It is my understanding that is it two separate proposals - $1/month for electricity services and $4.50/month for natural services – to all Minnetonka residents (I’m unsure if that is by structure or unit – to account for multi housing units).

I am not in favor of these fees.

1. I already pay $2537.55 in property taxes to that go directly to the City of Minnetonka for General Revenue (naturally my total property taxes are much higher than that). This is directly off the Hennepin County Website.

2. As you are aware, as a Ward 2 resident – we are often forgotten as the less fancy side of Minnetonka. I personally live in Sherwood Forest and I will receive zero direct benefit from this initiative (parks and trails). If given a choice I would much rather have the funds be used to keep our neighborhood safe. Streets are so narrow (with no room for a sidewalk) that I often find myself fearing for my life as cars speed by at 40 MPH, instead of the posted 20 MPH speed limit yet seldom see any police cars patrolling our streets.
3. If this is a priority for the residents then I believe the city should find other places in which to reduce spending to meet this want/need.

4. I assume that the proposed and approved park near Ridgedale as well as the proposed and approved trail along Plymouth Road to Minnetonka Boulevard have already been approved and paid for so I am perplexed as to why yet another grab for money.

5. While many of us are fortunate in Minnetonka, there are still many people for whom a $66 annual increase is painful.

Ultimately I am completely opposed to this hidden tax increase upon our residents.

Regards,

Fernando Bucaro
Sherwood Forest Resident
Dear Ms. Furness:

Thank you for your note. I appreciate knowing how you feel about this important topic.

I will say that I was somewhat taken aback by the tone of your note. Whether I agree or disagree with someone, I always work to be respectful. I will take a pass on calling you. However, I will be happy to talk with you anytime. My phone number is on the city website, and I would welcome your call. Thank you again!

Sincerely,

Brad Wiersum
Mayor
City of Minnetonka

On Aug 29, 2018, at 1:08 PM, Diane Furness wrote:

Mayor Wiersum,
I have just watched the City Council meeting on TV and I am DISGUSTED you seem to be voting for the proposed franchise fee's to be added to our gas and electric bills. As i see it you are trying to hide your expenses by adding them to those bills!
It isn't at all clear on those bills where the money goes. You are NOT being honest at all with the citizens. These charges should be part of the property taxes!! So sick of feeding the beast on the backs of the people less able to pay and figure out what is exactly going on!!
I will be posting this disgusting consideration on Facebook and Nextdoor.
D Furness Resident of Minnetonka for 41 years
if you want to talk
From: Brad Wiersum  
Sent: Sunday, September 02, 2018 10:14 AM  
To: linda goecke  
Cc: Geralyn Barone <gbarone@eminnetonka.com>  
Subject: Re: sidewalks/ trails

Dear Ms. Goecke:

Thank you very much for your note. You are correct...words matter, and how we describe what we are proposing may have a significant impact on the public perception of what is being considered. It is clear that connections within Minnetonka, particularly north/south and to areas of commercial activity, need to be improved. "Walkability" and "bike-ability" are the issues. When we discuss this further, I will make a point of using those terms, rather than the more generic term "trails." Thank you for sharing your thoughts.

Sincerely,

Brad Wiersum  
Mayor  
City of Minnetonka

From: linda goecke  
Sent: Wednesday, August 29, 2018 10:13 AM  
To: Brad Wiersum  
Subject: sidewalks/ trails

To: Mayor Wiersum  
From: Mrs. Linda Goecke

I just watched on the eminnetonka website some of your very long meeting Monday, Aug 27. I was very interested in the whole discussion of funding for more sidewalks and trails. I thought your last comments were excellent. You seem to have a good vision. I liked your idea of demonstrating that Minnetonka has a commitment for trails/sidewalks. This commitment, you said, may attract $ from other sources -- in addition to the money sources discussed at the meeting. I definitely think Minnetonka needs to have more WALKABILITY and I guess you could use the word BIKEABILITY also. For the reasons you and others mentioned: safety, connection, health.

Here are suggestions I have on communicating about this issue:  
When writing/talking about sidewalks and trails -- use the words that are most correct. Sometimes when people hear the word "trail" - - they think only of bike trails OR woody walks. The August issue of the Minnetonka Memo used "Trails" in a headline about the franchise fee. The September issue of the Memo says "walking and biking paths" -- again the walkability, bikeability, safety -- which I believe is much better and conveys what is really being talked about.
Thank you, Linda Goecke
Should have copied you!

BJW

---

From: Brad Wiersum  
Sent: Sunday, September 2, 2018 8:16 AM  
To: Sheila Goldstein  
Subject: Re: Proposed Mtka Tax Fee an issue for Seniors & Low Income

Dear Ms. Goldstein:

Thank you for your note. I appreciate knowing your point of view on this proposal. I appreciate you taking the time to write to me.

Sincerely,

Brad Wiersum  
Mayor  
City of Minnetonka

---

From: Sheila Goldstein  
Sent: Friday, August 31, 2018 12:38 PM  
To: Ellen Silva  
Cc: Baubieshe Baubieshe; LuAnn Tolliver; Peggy Kvam; link.barb@Comcast.net; Sharon Borine; Sandy Brandt; Janet Kramer; Nancy Gooch; barb.westmoreland@yahoo.com; Arlene Nystuen; Dorothy Boen; Patty Acomb; Brad Wiersum  
Subject: Re: Proposed Mtka Tax Fee an issue for Seniors & Low Income

In my opinion, being on a fixed income and owning a home, I prefer to stay away from putting fees on property taxes. They remain fairly permanent with no sunset or options for such. Everything is getting expensive, but the income stays put.

Sheila Goldstein

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On Aug 31, 2018, at 11:13 AM, Ellen Silva wrote:

It is highly effective to email individual council members and the mayor. Use their council email addresses. Send your email to both your ward council member and the 2 at-large members
You’ll have to look up your ward using the Secretary of State site at [https://pollfinder.sos.state.mn.us/Default.aspx](https://pollfinder.sos.state.mn.us/Default.aspx)
The result will give you your ward in this format:
Precinct:
MINNETONKA W-2 P-C 2130
This number after the W is the ward; in this example, it would be ward 2.

Cheers,
Ellen (Action Chair, LWV-MEPH)

On Aug 29, 2018, at 3:10 PM, LuAnn Tolliver wrote:

Hi Peggy,
Thanks for your feedback.

I agree you should be neutral.

Some little voice is telling me I need to be an advocate on this. :-)

Searching the LWV websites the only 2 things I found is in the LWV-US tax position:

1) "the League lobbied in support of principles and programs that benefit low income Americans while opposing tax breaks for the wealthiest in the country."

2) "As part of its strong legislative campaign, the League opposed a value-added tax as regressive."
   * Note the city is calling the franchise fee 'regressive'.

I will carry on... as an individual. It will be an up-hill battle... such is life!

Thanks!!
LuAnn

-----Original Message-----
From: Peggy Kvam
To: LuAnn Tolliver
Subject: Re: Proposed Mtka Tax Fee an issue for Seniors & Low Income

Hi, LuAnn,

This proposal is way too local for LWV to have a position, I believe. Your best approach
to express your position is to contact the city as an individual. Our issues positions are posted on https://www.lwvmeph.org/ at the links at the bottom of the home page. If you find something you think relates, you could contact LWVMN to discuss further.

I'm serving on the Park Board still, and although the Board does not have any financial authority, I think it best that I take a no-comment neutral position here.

Peggy

On 8/29/2018 2:37 PM, LuAnn Tolliver wrote:

Dear MEPH Board,

Mtka City Council is seeking feedback on a proposed ordinance that will place a $5.50 per month electric and gas franchise fee on all Mtka residents. The proposed fee will produce approximately 1.8 million dollars a year to fund needed city trails and sidewalks.

NOTE: I am NOT opposed to the expansion and improvement of the Mtka city trails. I believe this is needed.

I am opposed to the funding mechanism - the franchise fee.

I feel the franchise fee will have an adverse affect on Seniors on fixed budgets and low income individuals. This funding is not proportionate - Seniors and low income residents will pay the same $5.50 per month as the $4 million mansion on Grey's bay.

I do not consider myself a senior (although some folks may disagree) and I do not consider myself low income. I did not want to get involved in this - but my conscience just couldn't let it go. I feel I must be an advocate for the low income home owners in Mtka.

The city has stated that 85% of residents indicate they would be in favor of a property tax increase to fund this. I believe a property tax increase would be the proper funding mechanism.

1) Tax increases are proportionate. Homeowners with a small 2 bedroom home will pay their fair share AND the $4 million home would also pay it's fair share - based on percentage of home value.
   * Also - low income residents can get property tax refunds - based on their property taxes vs. income, etc.
   * Residents can use property taxes as a deduction (I believe up to $10,000 under the new tax law).
2) A fee is not proportionate.
   * I feel a fee is discriminating against elderly and low income.
   * I feel a fee is promoting tax relief for the wealthy.

The same amount of money would be raised via a franchise fee or via increased property taxes.

Here are other reasons I feel that the property tax is the appropriate way to proceed to fund the trails:
   * This would be more transparent if it is part of property taxes - residents can easily see what the money is being spent on.
   * The Trails could be prioritized by city officials against other city wants/needs as part of the yearly tax planning process.

So my question to the MEPH Board is this: Does LWV (MEPH, State LWV or US LWV) have a position on Tax vs Fee... or proportionate taxes vs flat fee/tax.
I look forward to your response. The city will be making this important decision on September 17th.

Respectfully submitted,
LuAnn B. Tolliver
Hi, Mr. Hacker.

The franchise fee proposal under discussion incorporates alternative rates for non-residential gas and electric utility accounts, and the level of the fee depends upon the category of non-residential account as defined by each private utility. For purposes of simplicity, we are referring to non-residential as “commercial,” which would include tax exempt properties. In general, small-user commercial accounts (accounts that use approximately the same energy as residential) would pay the same level of fee as residential ($4.50 per month for each gas and electric); medium-user commercial accounts would be charged $13.50 per month for each gas and electric; and large-user commercial accounts would be charged $45.00 per month for each gas and electric. The most recent information the city has from the private utilities indicate that residential accounts make up just over 91 percent of the total number of accounts. Of the total estimated revenue to be garnered from the proposed franchise fees, residential accounts would contribute roughly 75 percent.

You asked about whether the city has taken into account future transportation technologies relative to trails and sidewalks. The city is currently engaged in developing its 2040 Comprehensive Plan, which takes a broad reaching look at all infrastructure as well as development that may be required into the future. The transportation portion of the work incorporates your question. You can find more about that process on the city’s website here: https://eminnetonka.com/planning/comprehensive-guide-plan/2040-comprehensive-guide-plan Because technologies are blurring classifications of different motors, the legality of using “motorized” vehicles on trails is already a matter of discussion with our legal and public safety staff. More to come.

Thank you for your questions. I’ll be sharing our email exchange with the city council as they continue to deliberate the franchise fee proposal.

Sincerely,

Merrill King

Merrill King | Finance Director/Treasurer | City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8253
At the last council meeting, one argument made on going with fees vs property taxes was that tax exempt organizations would be contributing via users fees. My question is how much? For example will a church, school, or non-profit group, with a single electric account pay just the extra $5.00 per month— the same as a resident? And for that matter will the same apply to a businesses? Will a Byerlys - Lunds, Best Buy, or Cargill Office building for examples, pay just $5.50 extra per location? I imagine, you’ve run the numbers so I think we need to see a breakdown starting with: How much of the $1.8 million per year will be borne just by the residents vs the total amount, as to gain a more accurate perspective of what groups will be paying these new fees.

The 2nd issue is the nature and scope of the use of these funds. Today, we are talking about people walking and riding bicycles but we are also talking about a 30-year project. **How will we be dealing with technological innovations that involve transporting people?** Let's start with electric bikes which are becoming increasingly popular with people of all ages. Will these new and existing trails allow for their use? The current signs I see say that no motorized vehicles are allowed. Now, let's add in: electric scooters, mopeds, golf carts, Segways, hover boards, and the the probability, that in 5-10 years, this list will include new devices that have not yet even been invented. The discussion point here is that if technology provides an affordable way for motorized assistance to move people, we have to expect that our residents will avail themselves to it. And since these motorized assistance vehicles will most likely **not be street legal**, are we prepared for the residents who expect to use them on these new sidewalks and trails, given that they have paid for them?

I just turned 65, my health is good, and I can ride my bike. But in all honesty, as I get older, I will be increasingly looking at units that can provide motorized assistance. I believe that this **motorized assistance** issue needs to be address as part of the fee increase, and I suspect that with the inclusion for adapting to motorized assistance, that more residents who currently do not walk or bike, will see that fee increase, will bring more than just a better and safer and way to walk and bike. Thanks
Merrill King

From: Geralyn Barone
Sent: Tuesday, July 17, 2018 4:10 PM
To: Merrill King
Subject: Citizen input - Chuck Humenik FW: I will be watching...

FYI.

From: Brad Wiersum
Sent: Tuesday, July 17, 2018 3:57 PM
To: Chuck Humenik
Cc: Geralyn Barone <gbarone@eminnetonka.com>; Kelly ODea <kodea@eminnetonka.com>; Kari Spreeman <kspreeman@eminnetonka.com>
Subject: Re: I will be watching...

Dear Mr. Humenik:

Thank you for resending your email. I understand your point. Any action on this form of funding (franchise fees) for trails will require a public process and city council action. That has not occurred. Right now, this is a proposal up for discussion...not a decision.

This is an example of the classic conundrum that city councils face. Community surveys and anecdotal conversations indicate that Minnetonka residents value trails, want more of them and are willing to pay for them. A straight up tax increase is the most intellectually honest way to pay for trails. Franchise fees are used by some cities to pay for city improvements, and state law allows that use, with some restrictions. There appears to be agreement among city council members that trails are desired and needed... particularly, connectivity between key parts of the city. The challenge will be how to pay and how much to pay. That is why the Minnetonka Memo carried the story you referenced. It is the start of a public conversation on this topic. I appreciate hearing what your thoughts are. Thank you again!

Sincerely,

Brad Wiersum
Mayor
City of Minnetonka

From: Chuck Humenik
Sent: Wednesday, July 4, 2018 3:24 AM
To: Brad Wiersum
Subject: Fw: I will be watching...

Mayor Brad Wiersum I'm resending you this e-mail to make sure the proper people see it and it's not lost in the shuffle.
Keep up your good work Thanks" Chuck
----- Original Message -----
P.S. I'm not even saying I don't agree with your project. But I don't agree with your method of funding it. What's next housing for immigrants on my phone bill ???

----- Original Message ----- 
From: Chuck Humenik
To: comments@eminnetonka.com
Sent: Sunday, July 01, 2018 7:05 PM
Subject: I will be watching...

I just happened to take a look at the Minnetonka Memo today and I can't believe what I'm seeing here !!! "The city council to consider franchise fee" I'm sorry but my power & gas bill's are just that for my power & gas not a dirty corrupt way for dirty corrupt socialist council members to steal my money from me for thier special projects. Do it the right way let the people vote on it not sneak it by in a city paper most residents don't even read... I will be watching and if this passes I will see you in court you people are out of control !!!
Hi
Thank you so much for your quick response and information on the trail plans. You have answered all my questions for now.

Appreciate it,
Carol Johnson

Mrs. Johnson,

I found a faster way to get directly to the city's trails plan on our website here:

Hope this is helpful. Thanks again.

Merrill King
Finance Director/Treasurer
City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8253

Hi, Mrs. Johnson.

I have answered below in red the questions you posed. I hope this information is helpful. I will pass along to the council your questions and my answers to them for their Sept. 17 deliberation on the franchise fee funding for the trails. Thank you for writing.

Sincerely,
Finance Director Merrill King,

Greetings, I am a resident of Minnetonka and have a couple of questions regarding the proposed electric and gas franchise fee introduced at the Minnetonka city council meeting recently.

- How are trails and sidewalks funded currently? Trails and sidewalks are currently financed using a combination of sources, but primarily through our Parks & Trails Fund. The Parks & Trails Fund is supported with a property tax levy and inconsistently with park dedication funds (paid by developers of new housing in the city) and with council transfers of budgeted general operating funds that remain unspent at the end of prior fiscal years when available. The city has also been successful in the past in getting other governments, especially Hennepin County, to financially partner to improve the city’s trails and sidewalks. The Parks & Trails Fund also supports costs of the capital upkeep and betterment of all of the city’s neighborhood and citywide parks, so not all of the revenue in the fund is available for the trail and sidewalk system.

- With the current system, how much funding is available for construction of sidewalks and trails compared with the proposed increase in funding if the franchise fee is approved? The prior five-year (2018-2022) capital program appropriated a total of around $6.4 million over the five years to trail improvements. The new five-year capital program (2019-2023), which includes use of the proposed new franchise fee revenue, appropriates almost $14.8 million over the five years to trail improvements.

- Many streets in Minnetonka do not have sidewalks. When deciding where to place new sidewalks, what criteria is used? Over the course of many years and most recently in April 2018, the city has developed a detailed trails plan that uses 15 criteria to evaluate and score all proposed trails and prioritize their future construction. In general, the score is based upon: community access (40%), nature of use (40%), cost effectiveness (10%), and degree of construction difficulty (10%). You can find the plan here on the city’s website within the appendix of the five-year capital plan: https://eminnetonka.com/images/finance/REVISED%202019-2023%20CIP.pdf (Note: You’ll want to use the bookmarks in the Adobe pdf file to get directly to the Trails Plan in the appendix.)

- I am concerned that an increase in monthly fees will place additional strain on residents on a fixed income. Has this been considered in discussions about adding the franchise fee? The city council has discussed in their meetings the regressive nature of the franchise fees, e.g. homeowners of more expensive homes will pay the same amount as those with less expensive homes, and every time the city council discusses any tax or fee increase, they talk about the fiscal impact to our community members, including homeowners and businesses.
• Does the proposed $5.50 per month apply to both gas and electric ($11) or does $5.50 cover both electric and gas? The $5.50 per month is the combined total increase for both electric and gas.

I appreciate your answers and comments. I understand the city council will vote on this proposal at the Sept. 17 meeting.

Thank you,
Carol Johnson
12611 Orchard Rd
Minnetonka, MN
Hi, Janet.

The Xcel franchise fee you see on your bill as a city fee was begun in 2005. It has been specifically directed to undergrounding electric lines along city streets and improvements to street lighting in Minnetonka. The fee revenue and expenses are specifically accounting for within a separate fund and specifically appropriated by the city council as part of the city’s Capital Improvement Program (CIP) budget.

Hope this information is helpful to you.

Sincerely,

Merrill King

Merrill King | Finance Director/Treasurer | City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8253

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Hello Merrill,

Could you please tell me when the current $2.50 City Fee my Xcel Energy electric bill was initiated and where it is directed in the city budget? Does this revenue go to a specific project or a general fund? Thank you for your help.

Janet Larson
3614 Westmark Drive
Minnetonka, MN 55345
Merrill King

From: Brad Wiersum  
Sent: Tuesday, September 11, 2018 4:40 PM  
To: Janet Larson  
Cc: Merrill King; Geralyn Barone  
Subject: Citizen input - Janet Larson 9/11/18 RE: Franchise Fee Increases

Dear Ms. Larson:

Thank you very much for your note. Your points are well taken, and they are exactly the issues that the City Council needs to consider. Your points are well made.

Surveys tell us that greater connection and walkability is what Minnetonka residents want. It is unfortunate that the word “trails” is being used. That suggests that we will get more of what we already have. The goal is greater connection and walkability. The need is there...but as you note, it is a pretty big ticket item. This will be a pretty robust discussion. It will be more about how to pay for an amenity that people say they want. Thank you for writing. I hope that you are doing well.

Sincerely,

Brad Wiersum
Mayor
City of Minnetonka

From: Janet Larson  
Sent: Tuesday, September 11, 2018 11:18 AM  
To: Brad Wiersum <bwiersum@eminnetonka.com>; Mike Happe <mhappe@eminnetonka.com>; pacomb@eminnetonka.com; Deborah Calvert <dcalvert@eminnetonka.com>; Geralyn Barone <gbarone@eminnetonka.com>  
Subject: Franchise Fee Increases

Mr. Mayor, Council Members, Ms. City Manager:

I am supportive of our city having trails and sidewalks for the safety and convenience of walkers and bikers. I am totally opposed to adding or using any utility franchise fee to fund them! I'm opposed on multiple levels. On principle, I'm opposed to any dedicated fee that does not directly apply or benefit the base on which it draws revenue. Sidewalks and trails have nothing to do with the delivery or use of gas or electric utilities by the consumers. Applying an impervious surface in the utility easement doesn't pass the 'so what', test. Transparency in taxation is critical. Sidewalks and trails are part of the infrastructure and should be financed out of general funding and forced to be recognized as a cost along with every thing else the city funds. If sidewalks and trails are such an important issue, then what can we do without?? This proposal is very aggressive. The $5.50 new franchise fee on gas is estimated to bring in $18M over ten years. The bond proposal for the new and improved fire and police facilities is $25M over thirty years. Fire and police facilities support critical city services, sidewalks and trails, don't compare! I was surprised to read that there is a $60M unfunded backlog of requests for sidewalks. In total we're looking at a huge amount of money!

I am most opposed to adding a $5.50 burden to already tight household budgets for many folks in our community. You may say, " $5.50 no big deal." But it is a very big deal for many households! I'll refer you to an article reprinted in the Wed. Aug. 29th Star Tribune from the Associated Press which details...
that 40 percent of U.S. families struggled to meet one or more of their basic needs last year, including paying for food, health care, housing or utilities. Of this 13% missed paying a utility bill payment, which was higher than the 10% who missed a mortgage or rent payment. Nationally that's one in three families and they live in Minnetonka too! Using my actual utility bills as a base, $5.50 will add 7% to my monthly budgeted gas bill for this next year. Looking at my actual gas bill, including all taxes and fees, for August 2018 $5.50 would add 23.5% to my bill! In total, adding $1.00 to the electric franchise fee of $2.50, and adding $5.50 to a gas franchise fee will be $9.00 a month or $108.00 per year. This will add 6% to my combined gas and electric bills for 2019! Go Figure!!

Sincerely and Respectfully,

Janet Larson

3614 Westmark Drive
Minnetonka, MN 55345
DEAR MERRILL KING,

I AM WRITING ABOUT THE PROPOSED $5.50 FRANCHISE FEES TO BE ADDED TO OUR UTILITY BILLS. I AM WONDERING WHY THE CITY OF MINNETONKA HAS THE RIGHT TO ADD FEES TO ELECTRIC AND GAS BILLS. THE SERVICES PROVIDED BY CENTER POINT ENERGY AND XCEL HAVE NOTHING TO DO WITH ADDING TRAILS IN MINNETONKA.

IF YOU WANT TO ADD TRAILS IN THE CITY, YOU SHOULD ASK THE VOTERS FIRST. IF APPROVED, BY THE VOTERS, THE FEES SHOULD BE ADDED TO HOMEOWNER’S TAX BILLS.

I HAVE BEEN UPSET, FOR A LONG TIME, ABOUT THE CITY FEE OF $2.50 ADDED TO OUR ELECTRIC BILL. DOES THE CITY PAY TO BURY LINES, OR DOES XCEL ENERGY? A PROPOSED $1.00 INCREASE IS BEING CONSIDERED. I LIVE IN AN AREA WHERE SOME LINES ARE BURIED AND SOME ARE NOT. MY LINES ARE BURIED. AND YET, I HAVE THREE UGLY LINES RUNNING THROUGH MY FRONT YARD. I HAVE ASKED, A FEW TIMES TO HAVE THE LINES REMOVED FROM MY FRONT YARD. TOLD I WOULD HAVE TO WAIT MY TURN.

I LIVE IN THE NORTHERN PART OF MINNETONKA. I USE THE DAKOTA TRAIL, STARTING IN WAYZATA, OR THE LUCE LINE IN PLYMOUTH. RARELY WOULD I USE OTHER TRAILS IN MINNETONKA.

MY HUSBAND IS HAVING A MEDICAL PROCEDURE ON MONDAY. OTHERWISE I WOULD ATTEND THE MEETING ON MONDAY.

PLEASE FEEL FREE TO DISCUSS MY LETTER AT THE CITY COUNCIL MEETING, ON AUGUST 27, 2018.

THANK YOU.

CAROL MOLAND
251 TOWNES ROAD
WAYZATA, MN 55391
Merrill King

From: Merrill King
Sent: Tuesday, September 11, 2018 12:36 PM
To: ‘Patricia O’Brien’
Subject: Citizen input - Patricia O’Brien RE: Utility franchise fees

Hi, Ms. O’Brien.

Thank you for your input on the franchise fee proposal to finance trails, which will be discussed again by the city council on Monday evening. I am happy to ensure that your comments are published and part of the council’s materials for that meeting.

Sincerely,

Merrill King

Merrill King | Finance Director/Treasurer | City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952‐939‐8253

From: Patricia O’Brien
Sent: Tuesday, September 11, 2018 12:21 PM
To: Merrill King <mking@eminnetonka.com>
Subject: Utility franchise fees

Ms. King,

I have pasted below a message I am sending to Ms. Barone and members of the Minnetonka City Council: I am writing to urge you to find an alternative to utility franchise fees to fund walking and bike paths. I regret I was unable to address this earlier this summer; I was dealing with a death in my family.

According to the article in the Sun Sailor, funding this through property taxes was not considered an option because "A 4.8 percent property tax levy increase would charge people with higher-value properties more for trails." But adding a flat franchise fee to utility bills would charge more percentage-wise to people such as renters, retirees, and low-to-middle income families. Where is the concern for them?

Geralyn Barone is quoted as referring to the franchise fees as "regressive" which the IRS defines as those that "take a larger percentage of income from low-income groups than from high-income groups."

This would be unjust. Why should one or two people living in an apartment or small home be charged the same as some in a more expensive home with more occupants?

For the record: I have lived in an apartment in Minnetonka for 26 years.

A $4.50 monthly fee will increase my gas bill by 26%.
A $2.00 monthly additional fee will increase my electric bill by 6.5%.

I believe people with higher-value properties would be more able to afford a property tax increase and would benefit the most because:
- their property values would likely be enhanced
- they are more likely to have higher incomes
- they are more likely to use the trails and paths

Please try to find another way to pay for this.
Thank you.
Pat O'Brien
2875 Jordan Ave. S. #406
Ms. Park,

Thank you very much for writing of your support of the franchise fee proposal for trails as well as your acknowledgement of the city’s effort to engage the community in the decision. I will be sharing your email with the city council as they finalize their deliberations on the issue.

Sincerely,

Merrill King

Merrill King | Finance Director/Treasurer | City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8253

Ms. King,

I attended the council meeting last week (8/27) and after listening to the discussion regarding the proposed franchise fees (and seeing another note in the Minnetonka Memo), feel compelled to reach out. I support the proposed franchise fees and believe that a majority of Minnetonka residents would find an increase of roughly $80/year a well-spent investment for the city and its residents. Most of us live incredibly busy lives juggling work and kids that make speaking up about this proposal low of our list of priorities. As mentioned during the meeting, there is already an existing franchise fee on our utility bill, but please know that I do not feel that there is any lack of transparency on the city’s end—a feeling that will not change if the fee is marginally increased. (Especially with the advanced notice that the city has given us all).

If Minnetonka is to remain a community that attracts young families, we need to consider a long-term plan to ensure we have the amenities they are looking for—which I guarantee walkability and connectivity are high on the list of priorities.

After seeing the discussion at the meeting, I feel it's important to make it known that there is support for the franchise fee proposal.

Thank you for your time.

Respectfully,
Megan Park
Sept. 5, 2018

City of Minnetonka
14600 Minnetonka Blvd.
Minnetonka, Mn. 55345

RE: Franchise fee increase
Bike paths and Mountain Bike trails

Dear Council:

I was told by a city of Minnetonka staff member that a survey was conducted by the city and that 85% of those surveyed wanted more bike paths in the city. I'm sure you are aware that you can get any result you want on a survey depending on how you ask the questions. I wonder if those surveyed were told that their utility bills would increase by $78.00 per year for those trails. My guess is probably not.

Many of us use our air conditioning sparingly, in the winter months we keep our thermostat set low and then set it even lower when we leave home. We turn off unnecessary lighting. But now the City of Minnetonka is considering increasing our annual utility bills by $78.00 for bike paths and mountain bike trails.

I try to spend my money carefully, and I expect the City of Minnetonka to also spend my money carefully. Let's not add to our already high utility bills to fund additional bike paths and mountain bike trails.

Sincerely,

[Signature]

Forrest Schmidt
700 Fairfield Cir.
Minnetonka, Mn. 55305
Hi Bruce:

Thanks very much for your note. Things are good north of the causeway, and I hope that you and Jane are doing well.

I appreciate your perspective on the trail proposal and your thoughts on franchise fees as a funding resource. I am hearing reasonably broad support for the notion of improving walkability in Minnetonka, and some pretty strong sentiment on why a number of people really dislike the franchise fee idea. The issue that the city council will grapple with is how to pay for an amenity that has quite broad (but not universal) support. Thanks for your input. Your suggestion to look for places where departmental cuts can be made is well taken. That question will be asked.

Thank you again, Bruce. Let's find a time to grab a cup of coffee at some point.

Sincerely,

BJW

Brad Wiersum
Mayor
City of Minnetonka
My best,

Bruce Schultz

Sent from my iPhone
Hi, Ms. Thomas.

I apologize for my tardiness in replying to your email. You asked about the rationale for raising revenue for city trails through electric and natural gas franchise fees.

Around three-quarters of the cities in the 7-county metro charge franchise fees to the private utilities as a sort of “rent” for those companies’ use of the cities’ rights-of-way assets. As with any private enterprise, it is part of the cost of those companies to do business. Like fishing licenses, the “users” in the case of franchise fees are the private utility companies. The utilities in turn choose to pass those costs on to their customers and label them specifically as a “city fee.” The use of the revenues garnered by the cities through the rent varies greatly from road maintenance, trails, public buildings to general government services. The franchise fee revenue reduces the property taxes that would otherwise needed to be raised in the communities for those costs.

Most, but not all, of the cities that charge the rent do so to both their electric and natural gas providers, in part because the utility companies request equal treatment with each other. For over ten years, the City of Minnetonka has only charged Xcel Energy a franchise fee, and the city has used those revenues explicitly for betterments of street lighting and burial of electric lines. The proposal being discussed by the council on Sept. 17 would increase the current franchise fee to Xcel and add a franchise fee to CenterPoint Energy to support the construction of additional trails along major city roadways. The nexus between the fees and trails is that the trails are along the same rights-of-way for which the utilities are paying rent.

While the council is aware that bonding is an alternative funding source, the high cost (currently estimated at a total of around $60 million) would require a very long payback period that, despite the lower interest rate environment, would result in a very high additional cost for interest over a very long period of time.

The city council may consider raising the property taxes for the purposes of constructing the currently unfunded trail plan as an alternative funding source. A 4.8 percent increase in the levy would be required to raise the same revenue as the proposed franchise fees. Staff analysis indicates that when added to the proposed tax levy increase of 3.8 percent for other city operating and service costs in 2019, the impact to the median-value home in Minnetonka would be a total increase of 9.5 percent. The burden of the city’s tax levy will shift slightly to residential real estate in 2019 due to the relatively greater increase in real estate value of the residential properties over commercial properties in Minnetonka.

Thank you for writing. I will be sharing your email and my answers to your questions with the city council for their deliberation on the franchise fees on Monday evening.

Sincerely,

Merrill King

Merrill King | Finance Director/Treasurer | City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8253
Hello, Director King -

I applaud when the City listens to the residents and takes action - improve sidewalks and trail.

I do have some questions that I am sure you'll be able to address or will know can at the City.

The Minnetonka Memo drew my attention to my X Cel residential electric bill - there is was a $2.50 city fee. So, the successful ordinance would increase it to $3.50/month?

Neither ordinance adds any fees to commercial/business gas and electricity bills?

While 85% of the residents recently agreed "to support the use of municipal funds" for these endeavors -

What is the rationale to raise these funds via G & E "Franchise Fees"?

> Not user fees akin to fishing licenses, car plates, etc

> MMemo also touts AAA bond rating. So, why not bonds? (Funds can be dedicated and more transparent than F Fees)

> How about part of City levy? ($1.8 million is a couple drops in the bucket and "dedicated" Council members would assure the funds were not diverted. Also more transparent)

So, kindly please explain why the Franchise Fees is the best method to generate "municipal funds" for these projects.

Have a nice weekend,

Kim Thomas
Minnetonka
Hi, Ms. Griffin.

Thank you for writing. I will make sure your email is shared with the city council for their deliberation at their meeting on Monday evening on the issue of how to fund the walkways and trails in the city.

Sincerely,

Merrill King

From: Sandra Griffin
Sent: Wednesday, September 12, 2018 3:35 PM
To: Merrill King <mking@eminnetonka.com>
Subject: Minnetonka Trail Project

Mr. King:

I am writing to provide feedback on the proposal to add franchise fees to pay for more trails. Supporting our community with walkways and trails is a worthy project that will enhance our ability to walk in the community with more safety and access to new commercial areas in the years to come. As a retired single adult female living in modest housing, I would like you to hear my concerns about the regressive and quite expensive addition to monthly utility bills. As you know, the recession we have just recovered from left those of us on social security or pensions with little ability to stay even with inflation over the past eight years. Indeed, health insurance and medical expenses, along with other living expenses have surged well ahead of the either no increase or a small percentage increase in cost of living adjustments. I am surprised that the proposal is so regressive and affects all of us living with modest means the hardest. Indeed even the use of the trails will support younger families much more than seniors. I would ask that a referendum, bond issuance or sliding scale fee structure be an option for strong consideration going forward. The proposed franchise structure for a project that is desirable and not essential places an unfair burden on those least able to afford this fee structure.

Thank you for hearing me on this concerning matter.

Sincerely,

Sandra Griffin
3612 Elmo Road
Minnetonka, MN 55305
City Council Agenda Item #14E
Meeting of Sept. 17, 2018

Brief Description: Items related to the 2019 preliminary tax levy

1) Resolution setting a preliminary 2018 tax levy and preliminary 2018 HRA levy, collectible in 2019, and a preliminary 2019 budget, and consenting to a special benefit tax levy of the Minnetonka Economic Development Authority

2) Resolution setting preliminary 2018 tax levy, collectible in 2019, for the Bassett Creek Watershed Management Tax District

Recommended Action: Adopt the resolutions

As discussed at the city council’s August 20 study session, the proposed 2019 levy and budget are consistent with our strategic goals and community values. Within that framework, the budget recommended is forward looking; aligns with long-term forecasts of service requirements associated with the city's strong development activity, operating costs for facilities currently being planned, adopted program enhancements and a conservative eye to future changes in the national economy.

As outlined in this report, staff recommends increasing the preliminary city levy for 2019 by 3.8 percent. Also the Economic Improvement Program (EIP) adopted by the city council in June and adopted recommendations of the Economic Development Advisory Commission (EDAC) indicate a 0.1 percent levy increase for HRA supported programs.

Staff estimates that the impact of this proposed property tax increase on a median-value home in the city would be approximately $53, a 4.4 percent increase. The city’s total proposed levy increase of 3.9 percent is likely to place Minnetonka at the lower end of our group of similar cities in the metro. While several of our comparable cities began to receive Local Government Aid in 2014, Minnetonka will continue to not receive this state financial support in 2019.

This is an exciting time for the city, with increasing vitality and vibrancy spurred on by redevelopment and expanding park and trail amenities. The 2019 budget proposal proactively and responsibly ensures quality city service levels keep pace with these dynamic community enhancements.

OUR PUBLIC PROCESS

State law requires cities, school districts and other government taxing jurisdictions to certify preliminary budgets and tax levies to the county by September 30, 2018. This is the maximum amount the city can levy for 2019. Counties then report these preliminary levies to all property owners in early November.

Guided by the council’s initial discussions in August, staff will develop detailed budget requests for council review in November and final adoption in December. At the November 19 study session, staff will have more complete information regarding revenues and expenses for the
current year, along with any additional information available to forecast 2019. The final 2019
levy may be less than the preliminary amount, but cannot be greater.

Minnetonka always encourages input on its budget from the public. In addition to the public
budget discussion scheduled and published on proposed tax notices by Hennepin County for
December 3, residents and businesses will again have the opportunity to provide feedback via
the city’s website, www.eminnetonka.com, opportunities that are publicized in the Minnetonka
Memo. Comments will be shared with council as budget options are considered, and updated
information will consistently be posted in the Memo and on the city’s website.

ENSURING MINNETONKA’S POSITION OF FISCAL RESPONSIBILITY

As detailed in the city’s adopted Strategic Profile, the city of Minnetonka takes a responsible,
long-term perspective with financial planning and management. Decisions are made with the
future in mind to ensure the city’s ongoing ability to provide quality services at a reasonable
price. The recent reaffirmation of the city’s Aaa bond rating by Moody’s reflects this responsible
approach.

General Fund (GF) Financial Projections

As a part of general best practices in budgeting, staff looks closely at both a forecast for the
remainder of this year’s revenues and expenses, those for 2019 as well as those projected for
the future five years through 2023. Staff aligns the General Fund (GF) revenues and costs
predictions along the adopted five years of the Capital Improvements Budget (CIP), which is
also heavily dependent upon property tax revenues. This long range perspective is instrumental
in developing recommendations and making decisions for the next year’s budget and property
tax levy.

Current revenues. 2018 GF revenues are presently estimated to come in approximate to the
adopted budget. While investment interest is improving, the city continues to realize lower public
safety fine revenue than had been forecasted based on recent historical averages. Recreational
receipts and community center rental revenue are expected to meet projections. Permit and
licensing revenues are currently trending to meet forecasts as well. However, as commonly
occurs, the timing of some significant construction projects currently underway (e.g. Ridgedale
Active Adult, Jordan Avenue apartments) may result in relatively large early proceeds that would
lead to a gain to the city’s General Fund bottom-line at the close of the 2018 fiscal year.

Current spending. GF operating costs in 2018 are currently estimated to be at a pace greater
than last year. If spending continues at the rate experienced up to the end of July, more of the
budget will be spent by the end of this year than last year, and departments will have spent 97.1
percent of their budgets, compared to 95.8 percent last year. At the current rate, almost
$990,000 of the GF budget would remain on the bottom-line at the end of 2018, compared to
$1.4 million at the end of 2017. Most importantly, there still remains 2018 costs that cannot be
known at this time, such as the number of snow plow events in early winter.

Fund balance. The city of Minnetonka adopts a balanced GF operating budget each year
whereby revenue is equal to expenditures. With adoption of the annual budget, the city council
also affirms and/or amends the first year of the adopted CIP, which may include a transfer from
the GF fund balance to capital funds for planned costs. After revenue and spending balances are known, net change to the GF fund balance for 2017 compared to 2018 are projected here:

<table>
<thead>
<tr>
<th>($ thousands)</th>
<th>2017 Actual</th>
<th>2018 Projected</th>
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</thead>
<tbody>
<tr>
<td>Excess revenues</td>
<td>$185</td>
<td>$0</td>
</tr>
<tr>
<td>Remaining expenditure budgets</td>
<td>1,465</td>
<td>990</td>
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<tr>
<td>Capital transfers (CIP)</td>
<td>(750)</td>
<td>(1,200)</td>
</tr>
<tr>
<td>Net change GF fund balance</td>
<td>$900</td>
<td>($210)</td>
</tr>
</tbody>
</table>

Despite some uncertainties, timing of the previously mentioned permit revenues may portend some funds available at the end of 2018. These “excess revenues” may be either transferred from the General Fund balance for one-time costs within the city’s 2020-2024 CIP, which will be discussed by the council next spring, or to ensure the fund balance can remain at sufficient levels over the next five years to meet council policy. As we approach the council’s second detailed budget study session in November, additional information may adjust these current forecasts.

Revenue projections. Because permit revenue is the city’s second greatest source of GF revenue after property taxes, it can significantly impact the city’s budget and levy needs. While generally using historical trends to forecast revenue over the next five-year period, staff analyzes current development projects planned and in progress as the basis for next-year’s revenue forecast of permit revenue. Therefore, the long term revenue forecast responsibly assumes the currently robust economy will not continue much beyond 2019, and staff uses a ten-year average of actual revenues prior to 2018 as the basis for permit revenues beginning 2020.

As a result of these projections, the city is likely to experience a significant increase in permit revenues in 2019 that will likely not be repeated in 2020 and the following few years. This will add pressure to the property tax levy to financially maintain the city’s current level services and any additionally projected costs after 2019.

Expenditure projections. With the remainder of this report focused upon the budget and levy recommendations for 2019, staff was careful also to project for over the following four years additional new ongoing operating costs that are anticipated due to projects and programs already approved and in the pipeline and future costs that are likely due to known service pressures. Some of these projected increased costs are rolled out over more than one year, and the most significant of these roughly estimated costs and their dates of rollout include:

- police body camera and squad camera administration/staffing and related technology service agreements (primarily 2021);
- energy costs and janitorial requirements for the potentially new and expanded public safety facilities (2020, 2021);
- public works maintenance of new trails, sidewalks and related landscaping in the adopted CIP (2020, 2021, 2023);
- communication staffing (2022);
- a second state-required increase by city for police and full-time firefighter pensions (2020); and
- an economic development marketing initiative (2021).
Staff assumes current staffing levels and makes very rough estimates on salary and inflationary pressures across the five years using current union contracts and the information known about contracts in other comparable cities in the metro. Added to these GF operating pressures, the property tax levy will also increase almost one percent in 2020 for property tax-supported debt service, if the bonding is approved for the new and expanded public safety facilities. And, although it is self-supporting, the city will be required to increase the levy for the Ridgedale tax abatement each year.

As a result of this analysis, staff currently projects that the property tax levy would require the following increases over the next five years, with the greatest pressures on years 2020 and 2021 at 5.7 percent and 5.9 percent, respectively.

These overall projected levy impacts have informed staff budget recommendations for 2019 and some recommendations for amending the currently adopted CIP.

Between now and the second council study session on the 2019 budget in November, any new data either unanticipated or not currently available will allow staff to further analyze 2018 and 2019 service cost projections and new or changed revenues. For example, additional grants may become available or, per regular procedures, the CIP budget may be amended with levy and budget adoption in December to reflect more accurate capital project cost projections and/or altered plans and priorities relative to new information. Also, as will be explained further in this report, recommendations of a consultant conducting a study of the city’s fire services will not be available until October.

2019 BUDGET

Staff proposes the 2019 General Fund city operating budget total $36.1 million, which is slightly higher than discussed at the council’s August budget study session. This total, financed with multiple sources of revenue, is 6.2 percent greater than the 2018 adopted budget. As a primarily service organization, the greatest of the additional costs are associated with market wage pressures and cost of living adjustments. The proposed increase is net a proposed budget
reduction of almost $300,000 associated with one-time costs that are no longer needed in 2019 and the final elimination of 9-1-1 dispatch costs.

General Fund Operating Budget ($ thousands)

<table>
<thead>
<tr>
<th></th>
<th>2018 Adopted</th>
<th>2019 Proposed</th>
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</thead>
<tbody>
<tr>
<td>Current services</td>
<td>1,288</td>
<td></td>
</tr>
<tr>
<td>Reductions &amp; savings</td>
<td>(296)</td>
<td></td>
</tr>
<tr>
<td>Add’l svc needs, programs</td>
<td>1,105</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$33,967</td>
<td>$36,064</td>
</tr>
</tbody>
</table>

6.2% increase

The proposed additional spending will be more fully outlined in the remainder of this report. The greatest of these is funding to efficiently and effectively accommodate both current and projected increasing demands of the city’s public safety services as the city has grown and is projected to grow, including a new patrol officer and significant changes in how police officer compensated hours are structured for training and patrol. Since, the council’s August budget study session, the additional spending includes funding to accommodate greater development and construction permit activity in the city. Also later in this report, staff will address an additional needed placeholder to prepare the city for recommendations of the fire services study due to be completed in October, which will address the ongoing challenges facing the city’s paid-on-call fire service structure.

Budget reductions and savings

The city of Minnetonka conservatively budgets revenues and expenses in a manner that balances the economic impact of taxes and fees upon property owners and tenants with ensuring that vital local government services are never interrupted. Therefore, good budgeting practices requires we strip the base budget of cyclical and one-time expenditures as well as reduce it for anticipated savings. As such, the proposed 2019 budget includes the following reductions:

- Final 9-1-1 dispatch technology fees $75,800
- Comprehensive Plan to be completed 85,000
- Fire services study to be completed 75,000
- Job description contract completed 30,000
- Cyclical statewide election costs 30,000

**Total Budget Reductions, Savings** $295,800

Current services, inflationary personnel cost pressures

Because city government is primarily a service industry, three-quarters of the General Fund operating budget is the cost of its greatest assets, its workers. Commensurately, much of the increase to maintain current level services for our community is to compensate our human resources. While our effective relationships with our bargaining units continue to reap both production and economic benefits for the community, the city faces continued market pressures to retain and recruit these high-valued assets.
While general inflation (CPI-U) for the Twin Cities area was 2.4 percent at the end of July, wages for the metropolitan statistical area are measuring annual increases of slightly over three percent for the same period. At the same time, the national Municipal Cost Index, which incorporates a basket of goods consumed by local governments, was 3.7 percent year-over-year as of July.

The city plans to continue to use a 1.5% base salary increase and review all positions according to its market philosophy structure to ensure that employees are fairly and competitively compensated compared with what other comparable cities pay their employees with similar responsibilities. Market wage pressures on the city of Minnetonka will require an average around three percent total increase in wages in 2019 (base plus market). Only one of the city’s three labor contracts will expire at the end of 2018 and will be up for negotiation.

As a member of the LOGIS Healthcare Consortium, a guaranteed rate cap for 2019 has been negotiated and is not to exceed a 10 percent increase for health insurance premiums. Since the city structures its benefits package using a cafeteria contribution system, the premium increase is largely borne by employees who enroll in the city’s benefit offerings. Using this information, an employer benefit contribution increase has been estimated based upon the insurance package selected. This approach reinforces the philosophy to move from an equitable to an affordable benefits package.

**Budget enhancements**

The proposed 2019 General Fund (GF) budget includes new funding of $1.1 million. The larger of these costs are:

- current and projected police service demands, including the addition of one sworn officer;
- heightened inspection and permitting services associated with enhanced development activity in the city, including one additional inspector position;
- sidewalk, trail and cul-de-sac service maintenance, including snow removal;
- technology applications for the city’s website and other operational programs;
- additional interns for legal services and administration;
- implementation of the EAB (Emerald Ash Borer) program with the hiring of an additional forestry technician (only partially funded with additional costs to the GF along with transfers from the Forestry Fund); and
- placeholder for recommendations from the fire service operations study.

Staff is also proposing additional staffing for the Williston Center, one additional evening maintenance position and one tennis program position, which are both to be fully funded by the center’s fee revenue. Including the new Williston center positions and not assuming any specific staffing recommendations from the fire services study, staffing at the city would increase by a little over four cumulative net positions.

**Police Services**

The police department protects human life and property by responding to emergency and non-emergency calls for service, enforcing laws and ordinances, investigating crimes, apprehending criminals, providing proactive policing and maintaining order. The Minnetonka Police Department, established in 1959, has a long standing history of embracing a community policing...
philosophy. In 2017, internal staffing changes were made to meet changing needs of the department and community. Two new positions, community engagement officer and crime analyst, were created using existing staffing levels.

Currently, the police department is staffed with 56 sworn officers, up from 54 in 2000. Between 2000 and today, staffing has fluctuated between 54 and 58 sworn officers. The difference is due to the elimination of four school resource officers (SROs) at Hopkins Middle Schools West and North, Minnetonka Middle School East, and West Education Center, along with the addition of a traffic officer and a detective. The SROs augment patrol in the summer months, increasing staffing during this time. With the elimination of four of the department's seven SROs, summer patrol staffing is not at previous levels.

Geographically, the city is approximately 28 square miles and divided into four distinct patrol districts, or beats, that are predetermined based on call volume. Each patrol district is staffed 24 hours a day, seven days a week by at least one uniformed officer—allowing a prompt response to calls for service. (Attached is current district map.) In addition to the four patrol districts patrolled by an officer, there is at least one supervisor, sergeant, on duty 24 hours a day, seven days a week. The current patrol districts were last updated in 2000 when police responded to 34,834 calls for service, compared to 43,504 in 2017. Calls for service continue to rise and are on pace to exceed 44,000 in 2018.

Employment in Minnetonka has increased from 44,100 jobs in 2010 to 46,200 in 2017. Population has increased from 49,734 in 2010 to 53,394 in 2017. Approved and proposed development, specifically in the Ridgedale and Opus areas, is anticipated to add approximately 2,712 housing units, increasing the city’s population by over 5,000 in the next three years. These areas are located in the northeast and southeast portions of the city, and increased residential units will impact patrol response.

Providing core police services can be challenging as each core service has its own characteristics, scope, and breadth of work; and as our population flourishes, service demands will expand and become more competitive. Calls for service that require a two officer response is on the rise, which also impacts capacity to respond to other calls. These incidents include mental health and medical related calls, and calls for service at facilities such as Nexus on the Hennepin County Home School property. Complex calls also require officers to remain on scene longer, making them unavailable to respond to additional calls for service, which can create a backlog of non-priority calls.

The primary concern is not if the police department can continue to provide acceptable responses to core service work demands despite these growing difficulties; but how well can police continue to do so given the competitive nature of current and future demands. Studies indicate that the majority of a police officer’s time is spent in non-arrest situations. Many of these calls involve residents who are dealing with common day-to-day, noncriminal problems. This trend is expected to continue.

With all calls for police assistance, residents expect the police will arrive promptly and address their concern(s). The volume of calls directly impacts the ability to respond quickly and with adequate resources. Call volume can also affect an officer’s ability to conduct traffic enforcement and proactively patrol neighborhoods, parks and other areas to deter criminal activity or to interact with residents in a non-enforcement encounter.
**Staffing proposal.** Staff continuously reviews its procedures and operational model looking for strategies to provide effective and efficient police services. In addition, technology continues to evolve, providing invaluable contributions. While these strategies are vital, staff believes current staffing levels should be increased. The four patrol districts have served the community well, providing appropriate coverage and response to all areas of the city. As calls for service increase and development continues, staff believes an additional patrol district is needed to meet this demand.

To adequately staff a fifth patrol district, additional resources are needed and staff has identified a combination of strategies to increase patrolling capacity. The first two strategies include hiring an additional police officer and making changes to our current model for compensating training hours. A third strategy is dependent on the outcome of on-going discussions with District 287, West Education Center, and if there is a change to its SRO position.

**Additional officer.** The preliminary 2019 budget includes the addition of one sworn police officer assigned to the patrol division. This is based on the growth in the city’s employment base, population, and calls for service in recent years, coupled with the anticipated addition of over 2,700 housing units in a relatively short period of time. The cost of this position would be $166,000, inclusive of personnel expenses and capital costs for an additional squad car. Often, the question is how many officers are needed based on a city’s population. Each city is unique, but a survey of seven comparable Hennepin County police agencies found the average is one officer per 780 residents. The Minnetonka Police Department is currently at one officer per 953 residents.

**Training compensation.** Officers are required to complete specific annual training as mandated by the Minnesota Board of Peace Officer Standards and Training (POST). In addition to POST training, the department mandates additional training each year. The police department’s current practice is to assign training to patrol officers in one of two ways. Either, 1) officers are allowed to train on their regular scheduled work day if minimum staffing levels are maintained. Typically, this allows one or two officers to train on-duty and is available by seniority. Or, 2) officers are assigned on their day off and subsequently flex off their regular scheduled patrol shift. Both have a direct impact on patrol coverage. Per the FLSA (federal Fair Labor Standards Act), flexing of time must occur during the two-week pay period. This requirement can make it difficult to manage shift minimums during certain department-wide training.

Staff reviewed the mandated training hours and found it requires approximately 47 hours each year, per officer. Because this has a direct impact on patrol staffing and minimum coverage, it does not apply to non-patrol positions, such as detectives, SROs, the community engagement officer and command staff. Staff believes that annually, approximately 1,833 hours is flexed off of patrol to accommodate the mandated training.

If mandated training for patrol was provided on the officer’s day off and officers were compensated at an overtime rate, staff believes the approximate 1,833 hours would be spread out among all patrol officers and more coverage would be available on patrol. This **would not** change the practice of flexing time off for non-mandated training. The 2019 preliminary budget includes $126,300 in funding to accommodate changing the training compensation practice.

**West Education Center.** West Education Center (WEC) is a District 287 school located at 11140 Bren Road West. The school opened in 2004 and is a highly structured environment serving six different programs. A condition of the school’s conditional use permit (CUP) approved by the city requires an agreement with the police department for the delivery of police
liaison services, a.k.a. SRO. Upon opening, an assigned SRO was funded by the school at a cost of approximately ten months' salary and benefits. A second SRO was added in 2009 due to SRO safety concerns and was also funded by the school.

During the 2016-2017 school year, district administration approached the city and requested that one of the positions be eliminated due to costs. The district stated changes to programming and response to behavioral problems was occurring, and that they did not believe a second officer was needed. The police department and city agreed to eliminate the second position, and in 2018 the second position was eliminated through attrition, reducing the sworn officer count from 57 to 56.

Recently, district administration informed the police department of their intent to request an amendment to their CUP eliminating the requirement for any police services. These discussions are on-going and currently no agreement has been made. Staff feels strongly that the SRO position is necessary based on the number and types of police responses at the school. However, should the CUP be amended to remove the requirement and no funding is received from the school, the impact to the 2019 budget is $41,000.

This SRO position is used to backfill patrol during the summer months and if the school eliminates funding, the 2019 proposed budget includes funding for the position within the police department’s annual operating budget. The police budget currently funds approximately two month’s salary and benefits for the position. To offset the cost, the police department would eliminate a vacant 0.6 FTE (full-time equivalent) community service officer position, and the equivalent of a second 0.6 FTE after a full-time records clerk position is eliminated and the part-time evidence technician position is changed to full-time. To ensure adequate city staffing is maintained, the current 2019 budget proposal includes an additional $41,000, which is the net cost of these changes along with the city assuming funding for the sworn officer position.

The current and anticipated rise in calls for service based on the city’s population and employment growth, along with the potential for elimination of the SRO at West Education Center, warrant improvements to the police staffing model. A combination of personnel adjustments and use of overtime is included in the recommended 2019 budget to address these impacts.

Construction inspection and permit services

Since the council met in August to discuss the 2019 budget, staff is proposing to amend the current 2018 operating budget and include in the 2019 preliminary budget funds for the hiring of one additional inspector. Although it was hoped that temporary and seasonal positions could continue to handle the heightened demand for inspection services associated with the city's increase in development activity, a very tight labor market has made that staffing structure difficult to meet customer expectations. In order to ensure the city can provide an appropriate level of service, the 2019 preliminary budget includes $110,500 in additional funding for one new inspector position. These additional costs would be incorporated using the already forecasted increase in permit revenue in 2019 and no additional levy increase above that already proposed. Hiring of the position this year can be supported with savings from temporary vacancies that the department has experienced in 2018.

Street, sidewalks, trails services

In response to citizen demand for greater and safer pedestrian and bicycle infrastructure, the adopted 2019-23 Capital Improvement Plan (CIP) includes significant planned expansion of the
city’s sidewalks and trails system over the five years and potentially into the future. Included in the adopted plan are substantial trail improvements surrounding Ridgedale Mall and along major roadways throughout the city. Public feedback continues to be sought through articles in the *Minnetonka Memo* and on the city’s website, along with a direct mailing seeking input from businesses. On August 27, the council introduced an ordinance to establish an ongoing funding source for constructing the plan and take public comment.

As the city has expanded and is expanding its trails and sidewalk systems, there are increasing demands by our community for greater city maintenance, especially during the winter. Therefore, the 2019 proposed budget for street maintenance includes an additional $60,000 to address a number of road and sidewalk/trail maintenance items. Quicker snow removal in cul-de-sacs and extended plowing hours are seen as ways that snowplowing can be improved in the city. Next year, the use of contract and/or seasonal plow operators will to be experimented with to determine if this is an appropriate solution to addressing increased demands. A variety of communities have tried limited contract snow removal; however, the quality of the work has to be monitored very closely. Also, as the importance and the size of the sidewalk/trail system expands, additional resources will also be directed to improve snow removal in this area.

**Technology**

At a total additional cost of over $82,000, the 2019 recommended budget also includes investments in technology within the organization to assist with customer service efforts and increased service delivery levels. In some cases, new software applications will replace existing systems that have become obsolete. Elsewhere, technology maintenance costs have increased, particularly for public safety mobile equipment. Examples of the investments include a new operating platform and more efficient content management system for the city’s website; election management database software for judge training, assignments and payroll for approximately 450 election judges; fire service scheduling and tracking module; and technology for police squad cars.

**LMC Internship Program**

Although most of the city’s departments have employed interns for many years, staff created a formalized internship program in 2017, for implementation in 2018. A total of $50,000 is proposed to be included in the 2019 budget to support participation by the Administrative Services and Legal Departments in separate internship programs. Both programs are being coordinated by the League of Minnesota Cities (LMC), in an effort to attract students to the fields of public administration and municipal law. The League will hire the interns, and participating cities or law firms will reimburse the League for salary costs. The initial year of the legal internship program is being coordinated with the League, Mitchell-Hamline School of Law, Minnetonka, and private law firms that represent cities. The initial year of the administrative fellowship program involves the League, Minnetonka, and the city of Delano.

**CIP Amendments**

In addition to operating cost increases, staff recommends two amendments to the 2019 capital budget, which will require an increase to the 2019 levy for the Capital Replacement Fund. The first, $40,000 for an additional squad car associated with the new sworn patrol officer in the police department, was mentioned earlier in this report. The second is an additional $100,000 related to the already scheduled City Hall and Community Center renovation projects.
Fire Services Operational Study

Beginning in April of 2018 the city engaged a fire service consultant to assist in planning future operational objectives and needs, especially in relation to the increase in turnover of paid-on-call (POC) personnel. The city’s primary intention is to remain proactive, identifying needs and solutions that will enable sustained, effective delivery of emergency services into the future. The consultant is expected to have completed recommendations by October 2018 that will include additional career staffing to support the POC fire service structure and enable the city to sustain the use of POC firefighters. Information on the positions and their functions are being incorporated into the study, and staff does not yet have specific details on costs.

It is noteworthy that many of our comparable cities are shifting from the POC fire service staffing model to a career department of full-time personnel (most recently, Plymouth and Eagan). Our calculations indicate operating a POC department is much less expensive, and maintaining this model as long as possible can result in significant savings for the community and ensure the ongoing qualitative advantages wrought by a POC fire force. The consultant’s study is expected to suggest ways to do so, at a cost yet to be determined.

Staff is projecting $370,000 in estimated costs for study recommendations, to be included in the 2019 budget and preliminary levy (a one percent levy increase). Current forecasts indicate it is likely that 2020 and 2021 will be much tighter and more difficult levy years for any such additional costs. Because state law requires that the maximum preliminary budget be adopted prior to September 30, including the estimated cost provides flexibility in making a final determination. Prior to adoption of the final 2019 levy in December, council will have the opportunity to review the results of the study, consider any staffing adjustments, and determine funding levels that may be the same or lower than the recommended amount, but may not be higher.

On a closely related note, the city has applied for a federal grant titled Staffing for Adequate Fire & Emergency Response (SAFER) that would fund a coordinator position, equipment, material and services for our recruitment and training activities, especially for new POC firefighters. The application is for a one-time $711,000 over a four-year period, and the project is an additional proactive effort to address sustaining our POC fire service structure and the related turnover. As of the drafting of this letter, notifications of awards have not been sent.

HRA LEVY

The city’s first levy for housing and redevelopment began in 2009. State law limits levies, and the maximum rate is 0.0185 percent of a city’s taxable market value. This equals approximately $1.55 million in Minnetonka. Beginning in 2010, the annual levy increased to $175,000 (0.00212 percent). The levy remained at that dollar level until 2017 to accommodate village center master planning, housing programs, marketing efforts, and more recently light rail. In 2018, it was increased to $250,000.

On June 4 the city council adopted the 2019–2023 Economic Improvement Program (EIP), which sets the 2019 HRA levy at $300,000 (up from its 2018 level of $250,000) and results in a 0.13 percent levy increase for HRA supported programs. The indicated uses of the funds are: SW Light Rail ($75,000); WHAHLT or Homes within Reach ($100,000); Housing Programs ($100,000) and Business Outreach ($25,000). The light rail funds are set aside for a ten-year
payback to the city’s Special Assessment Construction Fund for a portion of the city’s commitment to the project.

The Economic Development Advisory Commission (EDAC) reviewed the HRA budget at its Aug. 9 meeting and recommended adopting a preliminary HRA levy of $300,000 with the above described categories.

2019 PRELIMINARY LEVY

The 2019 proposed operating and adopted capital budgets would require an overall increase in the city property tax levy of 3.8 percent. The change is the net effect of budget reductions/savings and the one-time projected increase associated with development related revenue that would offset a 3.5 percent increase that would be required to maintain current services, a three percent increase for new operating needs, and a one percent increase associated with the adopted CIP. The HRA levy would be an additional 0.1 percent increase ($50,000).

<table>
<thead>
<tr>
<th>Levy (thousands)</th>
<th>2018</th>
<th>2019</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>City property taxes, current services</td>
<td>$36,963</td>
<td>$38,250</td>
<td>3.5%</td>
</tr>
<tr>
<td>Revenue increase</td>
<td>(1,106)</td>
<td>(3.0)%</td>
<td></td>
</tr>
<tr>
<td>Budget reductions, savings</td>
<td>(296)</td>
<td>(0.8)%</td>
<td></td>
</tr>
<tr>
<td>New needs, initiatives</td>
<td>1,105</td>
<td>3.0%</td>
<td></td>
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<tr>
<td>Capital program increase</td>
<td>373</td>
<td>1.0%</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>36,963</strong></td>
<td><strong>38,326</strong></td>
<td><strong>3.7%</strong></td>
</tr>
<tr>
<td>Voter-approved bond debt decrease</td>
<td>(11)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Ridgedale tax abatement increase</td>
<td>40</td>
<td>0.1%</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$36,663</strong></td>
<td><strong>$38,355</strong></td>
<td><strong>3.8%</strong></td>
</tr>
<tr>
<td>HRA</td>
<td>$250</td>
<td>$300</td>
<td></td>
</tr>
</tbody>
</table>

**Comparisons with Other Cities.** The proposed 2019 city levy increase is likely to place Minnetonka at the low end of comparable cities. The differences amongst these communities appears mostly to be related to whether cities are adding staff and whether those new costs may be offset with permit revenue increases or debt retirement.
Further, two of the comparable cities shown, St. Louis Park and Brooklyn Park, continue to receive an allocation of state Local Government Aid (LGA), which began in 2014. As has been the case for over a decade, Minnetonka does not and will not receive LGA in 2018. Equally important, unlike many of these other cities, the city does not rely upon special assessments to fund street reconstruction and maintenance.

**Homeowner Impacts.** New development and redevelopment in the city again increased the city’s property tax base last year as reported in March by the city assessor. Over the last five years, the city’s assessed market value has increased by 23 percent. A portion of that increase is the result of actual improved real estate as opposed to market forces alone. The commercial proportion of the city’s tax base increased at a relatively less robust pace as compared to residential and apartment properties. For taxes payable in 2019, the commercial property base experienced only a 2.9% growth increase compared to single family homes at 7.7 percent and apartment properties at 9.3 percent. Although there continue to be some very significant real estate improvements currently in the pipeline (e.g. Opus-area and Ridgedale-area developments), many of those will not add to the property tax base until after payable 2019.

This differential between the increase in the tax base due to residential versus commercial real estate will cause a shift in the property tax burden away from commercial (nearly one-third of
the city’s tax base) to residential (59 percent of the tax base) and apartments (nine percent of the tax base). As a result, staff estimates that that the impact of the proposed increase in the tax levy of 3.8 percent will result in a 4.4 increase in city property taxes to the median-value home in Minnetonka ($359,800 for taxes payable in 2019). That translates to an estimated increase in annual taxes of approximately $53.

RECOMMENDATION

As already noted, this is an exciting time for Minnetonka. Taking into account increasing vitality and vibrancy spurred on by redevelopment and expanding park and trail amenities, the budget proposal proactively and responsibly ensures that quality city service levels keep pace with these dynamic community enhancements.

Responsible long-term financial planning has continued to position the city of Minnetonka to provide highly rated services to city residents and businesses. The 2019 preliminary city tax levy will be limited to an increase of 3.8 percent to address increased demands on our public safety services, heightened demand for construction and permitting services, expanding maintenance costs of our transportation infrastructure, and increasing costs of appropriate technology. This eventual increase is near the lower end of comparable cities. It ensures our position of fiscal responsibility, preserves our standards of excellence, and encourages innovative and creative thinking. The HRA levy increase would add another 0.1 percent onto the total property taxes imposed by the city. Even if the council were to include an additional one percent levy for fire operations, the city would still be at the lower end of comparable cities.

As always, the city of Minnetonka will continue to provide the excellent services our residents and businesses have come to expect, and at a reasonable price, both in 2019 and well into the future.

Therefore, staff recommends the city council adopt the attached resolutions:

1) Setting a preliminary 2018 tax levy and preliminary 2018 HRA levy, collectible in 2019, and a preliminary 2019 budget, and consenting to a special benefit tax levy of the Minnetonka Economic Development Authority

2) Setting preliminary 2018 tax levy, collectible in 2019, for the Bassett Creek Watershed Management Tax District

Originated by:
Geralyn Barone, City Manager
Merrill King, Finance Director
Resolution No. 2018- 
Resolution setting a preliminary 2018 tax levy, collectible in 2019, and a preliminary 2019 budget, and consenting to a special benefit tax levy of the Minnetonka Economic Development Authority

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01. As required by state legislation under M.S. 275.065, municipalities are required to adopt a preliminary budget and tax levy by September 30, 2018.

1.02. The law also requires that the City Council hold a meeting to discuss the budget and property tax levy and, before a final determination, allows public input to its final adoption in December.

1.03. The law further requires the final levy be adopted on or before December 28, 2018, and the final tax levy may not exceed the preliminary tax levy.

Section 2. Findings.

2.01. The City Manager’s preliminary 2019 budget of $100,659,055 (the Preliminary Budget) appears reasonable and sufficient to fund the desired general fund municipal services, debt service supported by property taxes, and capital needs in 2019.

2.02. Preliminary general, capital and debt tax levies of $38,266,442 for levy in 2018, collectible in 2019, will fund the City Manager’s Preliminary Budget.

2.03. A preliminary tax abatement levy of $60,000 for levy in 2018, collectible in 2019, is estimated to equate to revenues associated with and will fund commitments under the Ridgedale Mall development agreement adopted by the city council on April 15, 2013.

Section 3. Authorization.

3.01. The preliminary budget and tax levy is hereby approved.

3.02. Pursuant to Minn. Stat. Section 469.033, subd. 6, the City Council consents to the Economic Development Authority in and for the City of Minnetonka (the “EDA”) levying a special benefit tax levy in the amount requested by the Board of Commissioners of the EDA by resolution adopted on the date hereof.

3.03. The City Clerk is hereby directed and ordered to transmit a certified copy of this resolution to the Hennepin County Director of Property Tax and Public Records.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

_________________________________
Brad Wiersum, Mayor
ATTEST:

_________________________________
David E. Maeda, City Clerk

ACTION ON THIS RESOLUTION:

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

_________________________________
David E. Maeda, City Clerk
Resolution No. 2018-

Resolution setting a preliminary 2018 tax levy, collectible for 2019, for the Bassett Creek Watershed Management Tax District

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01. Minnesota state law requires special taxing districts to adopt a preliminary budget and tax levy by September 30 of this year.

1.02. The law also requires that the City Council hold a meeting to discuss the budget and property tax levy and, before a final determination, allows public input to its final adoption in December.

1.03. The law requires a final levy be adopted after that public input and the final tax levy may not exceed the preliminary tax levy.

Section 2. Findings.

2.01. A preliminary tax levy of $28,989 for the Bassett Creek Watershed Management District for levy in 2018, collectible in 2019, will fund the City’s expenses for that tax district.

Section 3. Authorization.

3.01. The preliminary tax levy of $28,989 for the Bassett Creek Watershed Management District is hereby approved.

3.02. The City Clerk is hereby directed and ordered to transmit a certified copy of this resolution to the Hennepin County Director of Property Tax and Public Records.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

____________________________________
Brad Wiersum, Mayor

ATTEST:

____________________________________
David E. Maeda, City Clerk
ACTION ON THIS RESOLUTION:

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

_________________________________
David E. Maeda, City Clerk
CURRENT PATROL DISTRICTS
Brief Description
Items related to the Green Line Extension (Southwest LRT)

Recommendation
Approve the following agreements and adopt the resolutions related to Southwest LRT:

1) Resolution approving the reaffirmation of previous approvals for Southwest LRT
2) Subordinate Funding Agreement (SFA) 6 - Change Orders for Locally Requested Capital Improvements (LRCI’s)
3) Subordinate Funding Agreement (SFA) Amendments - SFA 4 and SFA 5
4) Resolution approving real estate conveyances

Background
In February 2015, the council approved the Master Funding Agreement with the Metropolitan (Met) Council related to the Green Line Extension (Southwest Light Rail Transit - SWLRT). Additionally, the city entered into two Subordinate Funding Agreements for locally requested capital improvements (LRCIs) related to the 17th Avenue street extension design and environmental work and the Smetana station design and environmental work. As the project progressed, the city identified three additional LRCIs that require the city to enter into a third Subordinate Funding Agreement with the Metropolitan Council to allow the project office to begin the design work on these projects. The Met Council’s Southwest Project Office is now requesting that the city reaffirm previous zoning approvals, amend the payment dates related to the LRCI’s, agree to a process for processing change orders, and approve documents related to easements on public and private parcels.

In August, the Met Council settled a lawsuit brought by Twin Cities & Western Railroad that allows the Met Council to acquire rights-of-way for freight using the line. The finalization of the agreements with BNSF Railroad and Twin Cities & Western was required prior to the Met Council’s application for federal funding in the amount of $929 million. Following this settlement the Met Council also submitted a letter of no prejudice to the Federal Transit Administration. If granted, the letter of no prejudice would allow the Met Council to award the civil construction contract by the end of September and issue a limited notice to proceed to begin construction this year.

Reaffirmation
In 2016, the city council adopted a series of resolutions related to natural resources.

- Resolution No. 2016-082. A resolution approving a wetland and floodplain alteration permit.
- Resolution No. 2016-083. A resolution approving a wetland replacement plan as regulated by the Wetland Conservation Act for the Southwest Light Rail Transit line.
• Resolution No. 2016-084. A resolution approving wetland, wetland buffer, and floodplain variances.

• Resolution No. 2016-085. A resolution approving a conditional use permit for impervious trails within wetland buffers.

• Resolution No. 2016-086. A resolution approving construction on a steep slope development and tree removal.

While acknowledging that the SWLRT line will impact natural resources within Minnetonka, the council noted that these impacts must be weighed against the public good provided. Regional and local policy makers have determined that the SWLRT line will ultimately provide the regional population with a transportation alternative and, as such, contribute toward the greater public good. Further, the project and its alignment have been approved at national, regional, and local levels.

The approvals expired on Dec. 31, 2017. Staff is recommending that the city council adopt a resolution reaffirming the previous approvals.

Subordinate Funding Agreement Change Orders (SFA 6)

On Jan. 9, 2017, the city council approved agreements and funding for LRCIs associated with the SWLRT project. The LRCIs approved are the 17th Avenue extension, storm water utility casings, railing/fencing, and retaining wall staining.

At this time, the Met Council is requiring that the city approve a change order agreement that will allow city staff to approve changes during construction, if needed. The agreement establishes a maximum value of changes to be $160,000, which is 10% of the cost of the LRCIs. Funding for this agreement is already included in the CIP approved by city council.

Subordinate Funding Amendments for Payment Dates (SFA 4 and 5)

On Jan. 9, 2017, the city council approved Subordinate Funding Agreements (SFAs) for the $2 million city commitment (SFA 5) and (SFA 4) related to the LRCIs, for the construction of stormwater utility casings, railing/fencing, and retaining walls. At the time, the payments were scheduled to commence in 2017, following the civil contract notice to proceed. The Met Council now anticipates that the civil contract notice to proceed will commence in the fall of 2018. The SFAs must now be amended to reflect the current project schedule and corresponding payments (equal to the original council action) as depicted below:
Payment schedule for city funding contribution (SFA 4)

<table>
<thead>
<tr>
<th>Payment #</th>
<th>Payable on or before:</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30 Days Following SWLRT Project Civil Contract Limited Notice to Proceed 1</td>
<td>$392,870</td>
</tr>
<tr>
<td>2</td>
<td>February 1, 2018</td>
<td>$785,738</td>
</tr>
<tr>
<td>3</td>
<td>February 1, 2019 154 Days Following SWLRT Project Civil Contract Limited Notice to Proceed 1</td>
<td>$392,870</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$1,571,478</strong></td>
</tr>
</tbody>
</table>

Payment schedule for locally requested capital improvements (SFA 5)

<table>
<thead>
<tr>
<th>Payment #</th>
<th>Payable on or before:</th>
<th>Contribution Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>March 1, 2018 30 Days Following SWLRT Project Civil Contract Limited Notice to Proceed 1</td>
<td>$666,666.67</td>
</tr>
<tr>
<td>2</td>
<td>March 1, 2019 182 Days Following SWLRT Project Civil Contract Limited Notice to Proceed 1</td>
<td>$666,666.67</td>
</tr>
<tr>
<td>3</td>
<td>March 1, 2020 548 Days Following SWLRT Project Civil Contract Limited Notice to Proceed 1</td>
<td>$666,666.67</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$2,000,000.01</strong></td>
</tr>
</tbody>
</table>

Staff is recommending that the city council approve the amendments to SFA 4 and SFA 5, authorizing the revised payment schedules.

**Real Estate Conveyances**

The alignment for the SWLRT crosses two parcels of land that are owned by the city. The Met Council wants to acquire fee title to most of one parcel and permanent and temporary easements over the other parcel. In addition, the city is benefited by a tree preservation easement over a private property, which the parties to the easement propose to amend in order to allow tree removal within the Met Council’s transit easement. Based on the earlier actions of the city council, these conveyances were anticipated.

By Resolution 2016-107, the city committed to transfer necessary real estate interests to the Met Council, upon terms and conditions to be addressed in “subsequent City resolutions, other required government actions, and appropriate agreement whereby the Metropolitan Council accepts transfer to it by the City and all obligations and encumbrances relating thereto.” The
proposed resolution authorizes the mayor and city manager to execute a contract that must contain specific terms, although the terms include flexibility for final adjustments in language by the city manager, city attorney and city engineer. Overall, the city and Met Council staffs have agreed upon most of the conditions for the land transfer. The major outstanding issues are: (1) whether the city will retain an easement for future construction of an elevated walkway over the train line, so that pedestrians could cross from the Dominium apartment parcel to the Minneapolis Mart parcel; and (2) obtaining assurance from the Met Council that it will provide the city with adequate easements for city facilities that are relocated as part of the SWLRT project. The city would not release the transfers until those items were satisfied.

Under state law, the city may contract with another political subdivision, like the Met Council, to transfer real estate without regard to charter provisions. For that reason, staff is not proposing that the council approve the transfers by ordinance.

Recommendation

Staff recommends the city council approve the following agreements and resolutions related to the Southwest LRT Green Line Extension and authorize the mayor and city manager to execute the agreements, including subsequent non-material changes, as approved by the city manager and community development director in a form acceptable to the city attorney.

1) Resolution approving the reaffirmation of previous approvals for Southwest LRT

2) Subordinate Funding Agreement (SFA) 6 - Change Orders for Locally Requested Capital Improvements (LRCI’s)

3) Subordinate Funding Agreement (SFA) Amendments - SFA 4 and SFA 5

4) Resolution approving real estate conveyances

Submitted through:
Geralyn Barone, City Manager
Corrine Heine, City Attorney
Julie Wischnack, AICP, Community Development Director
Susan Thomas, Assistant City Planner
Phil Olson, Assistant City Engineer
Will Manchester, Director of Engineering
Merrill King, Finance Director

Originated by:
Alisha Gray, EDFP, Economic Development and Housing Manager

Supplemental Information

January 9, 2017 City Council Meeting – SFA 4 and SFA 5 and CIP Amendment

October 24, 2016 City Council Meeting – LRCI Design SFA 3

August 22, 2016 City Council Meeting – Natural Resources Permitting for Southwest LRT
Resolution No. 2016-082

Resolution approving a wetland and floodplain alteration permit to accommodate construction of the Southwest Light Rail Transit line

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01 To accommodate construction of that part of the Southwest Light Rail Transit (SWLRT) line located within the City of Minnetonka, the following alteration will occur:

- Temporary alteration of 1.24 acres of wetland;
- 1,180 cubic yards of 100-year floodplain fill; and
- 1,582 cubic yards of 100-year floodplain excavation/creation.

1.02 The areas to be altered are depicted on Exhibit A of this resolution.

1.03 On August 4, 2016, the planning commission held a hearing on the proposed alteration. The commission considered all of the comments received and the staff report, which are incorporated by reference into this resolution. The commission recommended the city council approve the permit and wetland replacement plan.

Section 2. General Standards.

2.01 By City Code §300.23 Subd.10(c), alteration of land within a wetland overlay district will only be allowed if the wetland and its buffer are provided in an amount compensatory to that being altered and that, unless otherwise approved by the city council, compensatory wetland area and its buffer is provided within the same subwatershed district as the wetland being altered.

2.02 City Code §300.23 Subd.10(d), states that in determining the appropriateness of wetland alteration, the city will consider certain factors
including but not limited to the size of the total watershed district, the magnitude of the area proposed for alteration, the impact on the overall function and value of the wetland and such other factors that provide the maximum feasible protection to wetlands. These factors are incorporated by reference into this resolution.

2.03 City Code §300.24 Subd. 9(c), states that in reviewing floodplain alteration permits, the city will consider whether certain general standards are met. These standards are incorporated by reference into this resolution.

2.04 City Code §300.24 Subd. 9(d), states that an alteration permit will not be granted unless certain specific standards are met. These standards are incorporated by reference into this resolution.

Section 3. Findings.

3.01 The proposed wetland alteration would meet the intent of City Code §300.23 Subd. 10. Approximately 1.24 acres of wetland will be altered, and per the Minnesota Interagency Water Resource Application dated May 6, 2016, a detailed restoration and monitoring plan for each temporary impact location will be submitted for review and approval of the city prior to construction. This restoration and monitoring plan will ensure that the functions and values of the wetlands will be restored to the pre-project conditions.

3.02 The proposed floodplain alteration would meet the general standards outlined in City Code §300.24 Subd. 9(c):

1. The alteration area would be relatively small given the large floodplain area within the transit corridor.
2. The alteration would not increase buildable area of properties.
3. The alteration would not negatively impact the hydrology of the floodplain, given the small area of fill relative to the larger area.
4. The floodplain mitigation area would not negatively impact adjacent properties.
5. The alteration would meet the intent of the city's water resources management plan and the zoning ordinances.
6. The alteration would not adversely impact governmental facilities, utilities, services or existing or proposed public improvements.
7. The alteration would not have an undue adverse impact on the public health, safety or welfare.

3.03 The proposed floodplain alteration would meet the specific standards outlined in City Code §300.24 Subd. 9(d):

1. Adequate water storage would be maintained and provided in an amount at least equal to that filled.

2. No floodplain would be filled for the purpose of creating buildable area.

3.04 A Technical Evaluation Panel (TEP) has evaluated the proposed wetland alterations and the TEP found the temporary impacts and proposed restoration to be acceptable.

3.05 The Federal Transit Authority has issued a Record of Decision finding that as designed the SWLRT line complies with all relevant federal environmental requirements.

Section 4. City Council Action.

4.01 The above described wetland and floodplain alteration permit is hereby approved based on the findings outlined in section 3 of this resolution.

4.02 Approval is subject to the following conditions:

1. Subject to staff approval, the alteration must occur in substantial conformance with Exhibit A of this resolution and as described in the Minnesota Interagency Water Resource Application dated May 6, 2016.

2. Metro Transit must provide wetland monitoring reports, annually, for a period of five years or until the city accepts the restored wetlands as complying with the functions and values of pre-project conditions.

3. A construction permit is required. The permit will encompass right-of-way work, utility work, grading and erosion control, and physical construction of the rail line and appurtenance. No site work is allowed prior to issuance of this permit.

4. Prior to issuance of a construction permit:
   a) The SWLRT project must receive funding approval.
b) Negotiated application fees must be paid.

c) Acceptable ownership information and maintenance and operations agreements for all SWLRT property and infrastructure with Minnetonka must be submitted for staff review.

d) Formal documentation must be submitted to the city which notes that the Minnesota Department of Natural Resources waives its Wetland Conservation Act authority over wetlands MTA-MTA-07, MTA-MTA-08 and MTA-MTA-09.

5. This approval will expire on December 31, 2017 unless a construction permit has been issued or the city has received and approved a request for extension of this approval.

Adopted by the City Council of the City of Minnetonka, Minnesota, on August 22, 2016.

Terry Schneider, Mayor

Attest:

David E. Maeda, City Clerk

Action on this resolution:

Motion for adoption:  Wagner
Seconded by:  Bergstedt
Voted in favor of:  Acomb, Bergstedt, Wagner, Ellingson, Allendorf, Schneider
Voted against:  
Abstained:  
Absent:  Wiersum
Resolution adopted.
I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a duly authorized meeting held on August 22, 2016.

__________________________
David E. Maeda, City Clerk
WETLAND IMPACTS:

1. ALL STREETS IN AND ADJACENT TO THE PROJECT SHALL REMAIN CLEAN AND PASSABLE AT ALL TIMES. ANY SEDIMENT OR DEBRIS SHALL BE REMOVED WITHIN 24 HOURS OR AS OFTEN AS NEEDED TO ENSURE PUBLIC SAFETY.
2. STABILIZATION OF DISTURBED AREAS SHALL BE DONE BY PERMANENT TURF ESTABLISHMENT WHENEVER POSSIBLE.
3. IN THE EVENT THAT PERMANENT STABILIZATION CANNOT BE IMPLEMENTED WITHIN 7 DAYS AFTER CONSTRUCTION ACTIVITY IN THE DISTURBED AREA HAS CEASED, TEMPORARY STABILIZATION BMPs MUST BE SCHEDULED TO OCCUR WITHIN THAT 7 DAY TIME FRAME.
4. PERIMETER CONTROL MUST BE IN PLACE AND APPROVED BY THE ENGINEER.
5. FLOATING SILT CURTAIN SHALL BE INSTALLED AS CLOSE TO THE SHORELINE AS POSSIBLE.
6. THE CONTRACTOR MUST PROVIDE A REDUNDANT SEDIMENT CONTROL BMP WHEN WORK IS WITHIN 50 FT OF A SURFACE WATER/WETLAND.

LEGEND:
- IMPACTS (PERMANENT)
- IMPACTS (TEMPORARY)
- CONSTRUCTION LIMITS
- FLOATING SILT FENCE
- SILT FENCE
- SUPER DUTY SILT FENCE
- FILTER LOG
- DELIMITED WETLAND
- TURF REINFORCEMENT MAT
- RIPRAP

WETLAND IMPACTS:

MTA-MTA-03:
- 124 SF (PERMANENT)
- 0 SF (TEMPORARY)

MTA-MTA-04:
- 6,032 SF (PERMANENT)
- 0 SF (TEMPORARY)

MTA-MTA-05:
- 0 SF (PERMANENT)
- 0 SF (TEMPORARY)

RESTORATION:
- NA

SOUTHWEST LIGHT RAIL

WETLAND IMPACTS
MTA-MTA-03 AND MTA-MTA-04
SHEET 16 OF 26

REV: 4
DATE: 01/22/2016
ID #: 23

METROPOLITAN COUNCIL

AECOM

SOUTHWEST LIGHT RAIL

REV: 4
DATE: 01/22/2016
ID #: 23
NOTES:
1. ALL STREETS IN AND ADJACENT TO THE PROJECT SHALL REMAIN CLEAN AND PASSABLE AT ALL TIMES. ANY SEDIMENT OR DEBRIS SHALL BE REMOVED WITHIN 24 HOURS, OR AS OFTEN AS NEEDED TO ENSURE PUBLIC SAFETY.
2. STABILIZATION OF DISTURBED AREAS SHALL BE DONE BY PERMANENT TURF ESTABLISHMENT WHENEVER POSSIBLE.
3. IN THE EVENT THAT PERMANENT STABILIZATION CANNOT BE IMPLEMENTED WITHIN 7 DAYS AFTER CONSTRUCTION ACTIVITY IN THE DISTURBED AREA HAS CEASED, TEMPORARY STABILIZATION BMPS MUST BE SCHEDULED TO OCCUR WITHIN THAT 7 DAY TIME FRAME.
4. PERIMETER CONTROL MUST BE IN PLACE AND APPROVED BY THE ENGINEER.
5. FLOATING SILT CURTAIN SHALL BE INSTALLED AS CLOSE TO THE SHORELINE AS POSSIBLE.
6. THE CONTRACTOR MUST PROVIDE A REDUNDANT SEDIMENT CONTROL BMP WHEN WORK IS WITHIN 50 FT OF A SURFACE WATERWETLAND.

MTA-MTA-06:
343 SF (PERMANENT)
0 SF (TEMPORARY)

MTA-MTA-07:
2,005 SF (PERMANENT)
0 SF (TEMPORARY)

LEGEND:
- IMPACTS (PERMANENT)
- IMPACTS (TEMPORARY)
- CONSTRUCTION LIMITS
- FLOATING SILT FENCE
- SHORELINE Silt Fence
- SUPER DUTY SILT FENCE
- FILTER LOG
- DELINEATED WETLAND
- TURF REINFORCEMENT MAT

RESTORATION:
N/A

SOUTHWEST LIGHT RAIL

MTA-MTA-06 AND MTA-MTA-07 SHEET 17 OF 26
NOTES:
1. ALL STREETS IN AND ADJACENT TO THE PROJECT SHALL REMAIN CLEAN AND PASSABLE AT ALL TIMES. ANY SEDIMENT OR DEBRIS SHALL BE REMOVED WITHIN 24 HOURS, OR AS OFTEN AS NEEDED TO ENSURE PUBLIC SAFETY.
2. STABILIZATION OF DISTURBED AREAS SHALL BE DONE BY PERMANENT TURF ESTABLISHMENT WHENEVER POSSIBLE.
3. IN THE EVENT THAT PERMANENT STABILIZATION CANNOT BE IMPLEMENTED WITHIN 7 DAYS AFTER CONSTRUCTION ACTIVITY IN THE DISTURBED AREA HAS CEASED, TEMPORARY STABILIZATION BMPs MUST BE SCHEDULED TO OCCUR WITHIN THAT 7 DAY TIME FRAME.
4. PERIMETER CONTROL MUST BE IN PLACE AND APPROVED BY THE ENGINEER.
5. FLOATING SILT CURTAIN SHALL BE INSTALLED AS CLOSE TO THE SHORELINE AS POSSIBLE.
6. THE CONTRACTOR MUST PROVIDE A REDUNDANT SEDIMENT CONTROL BMP WHEN WORK IS WITHIN 50 FT OF A SURFACE WATER/WETLAND.

LEGEND:
- IMPACTS (PERMANENT)
- IMPACTS (TEMPORARY)
- CONSTRUCTION LIMITS
- CROWN WALL
- FLOATING SILT FENCE
- SILO TEE LOU
- DELINATED WETLAND
- TURF REINFORCEMENT MAT
- RPRAP

RESTORATION:
1. RESTORE TO EXISTING CONDITIONS
   USE SEED MIX 54-181 @ 5 LBS/AC
2. PLACE EROSION CONTROL BLANKET ON ERODED SLOPES
   ADJACENT TO ALL WETLAND AREAS

SOUTHWEST LIGHT RAIL
WETLAND IMPACT
MTA-08-08
SHEET 18 OF 26
REV: 4
DATE: 01/22/2016
ID #: 25
NOTES:
1. ALL STREETS IN AND ADJACENT TO THE PROJECT SHALL REMAIN CLEAN AND PASSABLE AT ALL TIMES. ANY SEDIMENT OR DEBRIS SHALL BE REMOVED WITHIN 24 HOURS, OR AS OFTEN AS NEEDED TO ENSURE PUBLIC SAFETY.
2. STABILIZATION OF DISTURBED AREAS SHALL BE DONE BY PERMANENT TURF ESTABLISHMENT WHENEVER POSSIBLE.
3. IN THE EVENT THAT PERMANENT STABILIZATION CANNOT BE IMPLEMENTED WITHIN 7 DAYS AFTER CONSTRUCTION ACTIVITY IN THE DISTURBED AREA HAS CEASED, TEMPORARY STABILIZATION BMPs MUST BE SCHEDULED TO OCCUR WITHIN THAT 7 DAY TIME FRAME.
4. PERIMETER CONTROL MUST BE IN PLACE AND APPROVED BY THE ENGINEER.
5. FLOATING SILT CURTAIN SHALL BE INSTALLED AS CLOSE TO THE SHORELINE AS POSSIBLE.
6. THE CONTRACTOR MUST PROVIDE A REDUNDANT SEDIMENT CONTROL BMP WHEN WORK IS WITHIN 50 FT OF A SURFACE WATER/WETLAND.

SOUTHWEST LIGHT RAIL
WETLAND IMPACT
MTA-MTA-09
SHEET 19 OF 25
REV: 4
DATE: 01/22/2016
ID #: 26
AECOM
WETLAND IMPACTS:
- IMPACTS (PERMANENT)
- IMPACTS (TEMPORARY)
- CONSTRUCTION LIMITS
- FLOATING SILT FENCE
- SILT FENCE
- DELINEATED WETLAND
- TURF REINFORCEMENT MAT
- RIPRIP

RESTORATION:
1. RESTORE TO EXISTING CONDITIONS
2. PLACE EROSION CONTROL BLANKET ON EXPOSED SLOPES ADJACENT TO ALL WETLAND AREAS

DRAFT-WORK IN PROCESS
WETLAND IMPACTS:

NOTES:

1. All streets in and adjacent to the project shall remain clean and passable at all times. Any sediment or debris shall be removed within 24 hours, or as often as needed to ensure public safety.
2. Stabilization of disturbed areas shall be done by permanent turf establishment whenever possible.
3. In the event that permanent stabilization cannot be implemented within 7 days after construction activity in the disturbed area has ceased, temporary stabilization BMPs must be scheduled to occur within that 7 day time frame.
4. Perimeter controls must be in place and approved by the engineer.
5. Floating silt curtain shall be installed as close to the shoreline as possible.
6. The contractor must provide a redundant sediment control BMP when work is within 50 ft of a surface water/wetland.

LEGEND:

- TMW — Turf Reinforcement Mat
- SDT Fence
- Floating Silt Fence
- Filter Log
- Filter Blanket
- Silt Fence
- Floating Silt Curtain

RESTORATION:

1. Restore to existing conditions
2. Use silt mat 34-961 @ 8 linear acres
3. Place erosion control blanket on opposed slopes adjacent to all wetland areas
NOTES:
1. ALL STREETS IN AND ADJACENT TO THE PROJECT SHALL REMAIN CLEAN AND PASSABLE AT ALL TIMES. ANY SEDIMENT OR DEBRIS SHALL BE REMOVED WITHIN 24 HOURS, OR AS OFTEN AS NEEDED TO ENSURE PUBLIC SAFETY.
2. STABILIZATION OF DISTURBED AREAS SHALL BE DONE BY PERMANENT TURF ESTABLISHMENT WHENEVER POSSIBLE.
3. IN THE EVENT THAT PERMANENT STABILIZATION CANNOT BE IMPLEMENTED WITHIN 7 DAYS AFTER CONSTRUCTION ACTIVITY IN THE DISTURBED AREA HAS CEASED, TEMPORARY STABILIZATION BMP'S MUST BE SCHEDULED TO OCCUR WITHIN THAT 7 DAY TIME FRAME.
4. PERIMETER CONTROL MUST BE IN PLACE AND APPROVED BY THE ENGINEER.
5. FLOATING SILT CURTAIN SHALL BE INSTALLED AS CLOSE TO THE SHORELINE AS POSSIBLE.
6. THE CONTRACTOR MUST PROVIDE A REDUNDANT SEDIMENT CONTROL BMP WHEN WORK IS WITHIN 20 FT OF A SURFACE WATER/WETLAND.

WETLAND IMPACTS:
81,598 SF (PERMANENT)

LEGEND:

RESTORATION:
1. RESTORE TO EXISTING CONDITIONS
2. PLACE EROSION CONTROL BLANKET ON EXPOSED SLOPES ADJACENT TO ALL WETLAND AREAS

DRAFT-WORK IN PROCESS
NOTES:
1. ALL STREETS IN AND ADJACENT TO THE PROJECT SHALL REMAIN CLEAN AND PASSABLE AT ALL TIMES. ANY SEDIMENT OR DEBRIS SHALL BE REMOVED WITHIN 24 HOURS, OR AS OFTEN AS NEEDED TO ENSURE PUBLIC SAFETY.
2. STABILIZATION OF DISTURBED AREAS SHALL BE DONE BY PERMANENT TURF ESTABLISHMENT WHENEVER POSSIBLE.
3. IN THE EVENT THAT PERMANENT STABILIZATION CANNOT BE IMPLEMENTED WITHIN 7 DAYS AFTER CONSTRUCTION ACTIVITY IN THE DISTURBED AREA HAS CEASED, TEMPORARY STABILIZATION BMPS MUST BE SCHEDULED TO OCCUR WITHIN THAT 7 DAY TIME FRAME.
4. PERIMETER CONTROL MUST BE IN PLACE AND APPROVED BY THE ENGINEER.
5. FLOATING SILT CURTAIN SHALL BE INSTALLED AS CLOSE TO THE SHORELINE AS POSSIBLE.
6. THE CONTRACTOR MUST PROVIDE A REDUNDANT SEDIMENT CONTROL BMP WHEN WORK IS WITHIN 50 FT OF A SURFACE WATERWETLAND.

SOUTHWEST LIGHT RAIL
WETLAND IMPACT
NM-HOP-13 SHEET 22 OF 26

REV: 4 DATE: 01/22/2016 ID #: 30

DRAFT-WORK IN PROCESS

WETLAND IMPACTS:
18,436 SF (PERMANENT)
16,436 SF (TEMPORARY)

LEGEND:
- IMPACTS (PERMANENT)
- IMPACTS (TEMPORARY)
- CONSTRUCTION QUARRY
- RETAINING WALL
- FLOATING SILT FENCE
- FILTER LOG
- DELINEATED WETLAND
- TURF REINFORCEMENT MAT
- RIPRAP

RESTORATION:
1. RESTORE TO EXISTING CONDITIONS
2. PLACE EROSION CONTROL BLANKET ON EXPOSED SLOPES ADJACENT TO ALL WETLAND AREAS

SOUTHWEST METROPOLITAN COUNCIL
AECOM
"SWL" REV 4"
1. ALL STREETS IN AND ADJACENT TO THE PROJECT SHALL REMAIN CLEAN AND PASSABLE AT ALL TIMES. ANY SEDIMENT OR DEBRIS SHALL BE REMOVED WITHIN 24 HOURS, OR AS OFTEN AS NEEDED TO ENSURE PUBLIC SAFETY.

2. Stabilization of disturbed areas shall be done by permanent turf establishment whenever possible.

3. In the event that permanent stabilization cannot be implemented within 7 days after construction activity in the disturbed area has ceased, temporary stabilization BMPs must be scheduled to occur within that 7 day time frame.

4. Perimeter control must be in place and approved by the engineer.

5. Floating silt curtain shall be installed as close to the shoreline as possible.

6. The contractor must provide a redundant sediment control BMP when work is within 50 ft of a surface wetland.

WETLAND IMPACTS:

1. RESTORE TO EXITING CONDITIONS
2. PLACE EROSION CONTROL BLANKET ON EXPOSED SLOPES ADJACENT TO ALL WETLAND AREAS

RESTORATION:

1. USE SEED MIX 54-181 @ 5 LBS/ACRE
2. PLACE EROSION CONTROL BLANKET ON EXPOSED SLOPES ADJACENT TO ALL WETLAND AREAS

LEGEND:

- IMPACTS (PERMANENT)
- IMPACTS (TEMPORARY)
- CONSTRUCTION LIMITS
- RETAINING WALL
- FLOATING SILT FENCE
- SILT FENCE
- FILTER LOG
- DELINERATED WETLAND
- TURF REINFORCEMENT MAT
- RIPRAP

SOUTHWEST LIGHT RAIL
WETLAND IMPACT
MTA-MTA-12
SHEET 23 OF 26

REV: 4
DATE: 01/22/2016
ID #: 29

AECOM
METROPOLITAN SOURCE
WSB
Resolution No. 2016-083

Resolution approving a wetland replacement plan as regulated by the Wetland Conservation Act for the Southwest Light Rail Transit Line

BE IT RESOLVED by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01 To accommodate construction of that part of the Southwest Light Rail Transit (SWLRT) line located within the City of Minnetonka, 2.99 acres, or 130,076 square feet, of permanent wetland fill will occur in seven different wetland basins. These areas are generally illustrated on EXHIBIT A of this resolution.

1.02 On July 15, 2016, the Federal Transit Administration issued a formal "record of decision" that indicates that SWLRT line, as designed, complies with all relevant federal environmental requirements.

1.03 On August 4, 2016, the planning commission held a hearing on the proposed rail line construction. The commission considered all of the comments received and the staff report, which are incorporated by reference into this resolution. The commission recommended the city council approve various applications and request to allow for construction of the line.

1.04 On August 22, 2016, the city council reviewed the wetland replacement plan for the Southwest Light Rail Transit line.

Section 2. General Standards.

2.01 By City Code §300.23, the purpose of the wetland ordinance is to recognize, preserve and protect the environmental, aesthetic and hydrologic functions of the city's wetlands to the maximum extent possible while allowing a reasonable use of property.

2.02 By City Code §300.23 Subd.9(a), wetland rezoning, or wetland fill and
mitigation, must be consistent with the purpose of city code, the city's water resources management plan and the goals and policies of the comprehensive plan. In determining the appropriateness of a rezoning request, the city council will consider the size of the wetland overlay district, the magnitude of the area proposed for removal, the overall impact on the function and value of the wetland, the hydrological and ecological effects and the type and function of wetlands involved in order to provide the maximum feasible protection.

2.03 By City Code §300.23 Subd.9(b), wetlands within an overlay district may only be removed according to Wetland Conservation Act (WCA) rules and only if at least an equal area of new wetland is created to compensate for the wetland being filled. Unless otherwise approved by the city council, compensatory wetland area must be provided within the same subwatershed district as the wetland being altered, it must be located outside of any public easement and it must not result in the loss of regulated trees.

2.04 WCA requires the city to consider the overall wetland impact and the loss of function and value to determine if the wetland replacement plan meets its standards.

Section 3. Findings.

3.01 The Federal Transit Authority has issued a Record of Decision finding that as designed the SWLRT line complies with all relevant federal environmental requirements.

3.02 The city participated in monthly Technical Evaluation Panel (TEP) meetings beginning on July 2, 2013 to consider the wetland impacts of construction of the transit line and to review areas for possible wetland replacement. Staff of the Southwest Light Rail Project office considered over 500 potential mitigation sites within the city, county, and watershed district. Due to numerous issues relating to these sites, the TEP accepted that the purchase of wetland bank credits was the most satisfactory way to acquire and achieve the function and values of the wetlands to be lost while at the same time meeting WCA standards. The TEP recommended the approval of the wetland replacement plan using the purchase of wetland banking credits.

3.02 The wetland replacement plan outlines mitigation through the purchase of 5.97 acres or 260,152 square feet or wetland bank credits within major watershed 33/ Bank Service Area 9, Scott County. This plan would meet the intent of City Code §300.23 Subd.9.
Section 4. City Council Action.

4.01 The above-described wetland replacement plan is approved. Approval of the wetland replacement plan is subject to the following conditions:

1. Subject to staff approval, the site must be developed and maintained in substantial conformance with the following plans, except as modified by the conditions below:

   - Southwest Light Rail Transit Line package submittal for the City of Minnetonka dated May 6, 2016.

2. A construction permit is required. The permit will encompass right-of-way work, utility work, grading and erosion control, and physical construction of the rail line and appurtenance. No site work is allow prior to issuance of this permit.

3. Prior to issuance of a construction permit:
   
a) The SWLRT project must receive funding approval.

b) Negotiated application fees must be paid.

c) Acceptable ownership information and maintenance and operations agreements for all SWLRT property and infrastructure with Minnetonka must be submitted for staff review.

d) The Metropolitan Council must submit a copy of the wetland bank purchase agreement. The agreement must indicate the mutually agreed upon closing date for the credit purchase. The purchase agreement will confirm the final quantity of wetland credits. This must be provided to the TEP prior to construction.

e) The Board of Water and Soil Resources approved wetland bank withdrawal form must be submitted to the city.

f) Formal documentation must be submitted to the city which notes that the Minnesota Department of Natural Resources waives its Wetland Conservation Act authority over wetlands MTA-MTA-07, MTA-MTA-08 and MTA-MTA-09.
4. Permits may be required from outside agencies including the Nine Mile Creek Watershed District and the Army Corps of Engineers. It is the Metropolitan Council's responsibility to obtain any necessary permits prior to the start of work.


6. All regulations and minimum standards as outlined in the Wetland Conservation Act must be followed.

Adopted by the City Council of the City of Minnetonka, Minnesota, on August 22, 2016.

Terry Schneider, Mayor

Attest:

David E. Maeda, City Clerk

Action on this Resolution:

Motion for adoption: Wagner
Seconded by: Bergstedt
Voted in favor of: Acomb, Bergstedt, Wagner, Ellingson, Allendorf, Schneider
Voted against: 
Abstained: 
Absent: Wiersum
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a duly authorized meeting held on August 22, 2016.

David E. Maeda, City Clerk
Resolution No. 2016-084

Resolution approving wetland, wetland buffer, and floodplain variances to accommodate construction of the Southwest Light Rail Transit line

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01 To accommodate construction of that part of the Southwest Light Rail Transit (SWLRT) line located within the City of Minnetonka, the following variances are required:

<table>
<thead>
<tr>
<th>Item Requiring a Variance</th>
<th>Required</th>
<th>Proposed**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wetland Rail Line</td>
<td>25 foot setback</td>
<td>1 foot</td>
</tr>
<tr>
<td>Wetland Bridge Abutments</td>
<td>35 foot setback</td>
<td>1 foot</td>
</tr>
<tr>
<td>Wetland Transit Power Substation</td>
<td>35 foot setback</td>
<td>15 feet</td>
</tr>
<tr>
<td>Wetland Trails</td>
<td>25 foot setback</td>
<td>2 feet</td>
</tr>
<tr>
<td>Wetland Buffer Rail Line</td>
<td>25 foot buffer</td>
<td>5 feet</td>
</tr>
<tr>
<td>Wetland Buffer Bridge Abutments</td>
<td>25 foot buffer</td>
<td>1 foot</td>
</tr>
<tr>
<td>Wetland Buffer Transit Power Substation</td>
<td>25 foot buffer</td>
<td>15 feet</td>
</tr>
<tr>
<td>Wetland Buffer Trails</td>
<td>25 foot buffer</td>
<td>11 feet</td>
</tr>
<tr>
<td>Floodplain Rail Line</td>
<td>10 foot horizontal setback</td>
<td>0 feet</td>
</tr>
<tr>
<td>Floodplain Bridge Abutments</td>
<td>1 foot vertical separation</td>
<td>0 feet</td>
</tr>
</tbody>
</table>

** Varies within the corridor. Proposed numbers are minimums.

1.02 The areas requiring variances are generally illustrated on EXHIBIT A of this resolution.
1.03 Minnesota Statute §462.357 Subd. 6, and City Code §300.07 authorizes the city to grant variances.

1.03 On August 4, 2016, the planning commission held a hearing on the proposal. The commission considered all of the comments received and the staff report, which are incorporated by reference into this resolution. The commission recommended that the city council approve the variances.

Section 2. Standards.

2.01 By City Code §300.07 Subd. 1, a variance may be granted from the requirements of the zoning ordinance when: (1) the variance is in harmony with the general purposes and intent of this ordinance; (2) when the variance is consistent with the comprehensive plan; and (3) when the applicant establishes that there are practical difficulties in complying with the ordinance. Practical difficulties means: (1) The proposed use is reasonable; (2) the need for a variance is caused by circumstances unique to the property, not created by the property owner, and not solely based on economic considerations; and (3) the proposed use would not alter the essential character of the surrounding area.

Section 3. Findings

3.01 The variances associated with construction of the SWLRT line would meet the variance standard as outlined in City Code §300.07 Subd. 1:

1. Purpose and Intent of the Ordinance. The intent of wetland, wetland buffer, and floodplain standards is to recognize, preserve and protect the city's water resources to the maximum extent possible while allowing reasonable use of property. The proposed variances meet this intent. The area of variances would be relatively small given the large areas of water resources within the transit corridor and the variances would not negatively impact the hydrology of the resources.

2. Consistency with the Comprehensive Plan. One of the primary transportation goals of the comprehensive plans to provide and promote convenient and accessible transportation systems to residents and employees of Minnetonka business. The proposed variances are consistent with this goal, as they would allow for construction of a regional transit line.

3. Practical Difficulties: There are practical difficulties in complying with the ordinance:
a) Reasonableness and Unique Circumstances: The proposed variances are required to accommodate a regional transit line. Given the amount and location of wetlands and floodplain areas in Minnetonka, it is unlikely that a transit line could be constructed that both meets the community's locational preferences and all wetland and floodplain standards. Given this unique circumstance, the requested variances are reasonable.

b) Character of Locality: While construction and operation of the SWLRT line will have some impact on areas surrounding the transit corridor, the requested variances themselves will not.

Section 4. City Council Action.

4.01 The above-described variances are hereby approved, subject to the following conditions:

1. A construction permit is required. The permit will encompass right-of-way work, utility work, grading and erosion control, and physical construction of the rail line and appurtenance. No site work is allowed prior to issuance of this permit.

2. Prior to issuance of a construction permit:

a) The SWLRT project must receive funding approval.

b) Negotiated application fees must be paid.

c) Acceptable ownership information and maintenance and operations agreements for all SWLRT property and infrastructure with Minnetonka must be submitted for staff review.

3. This approval will expire on December 31, 2017 unless a construction permit has been issued or the city has received and approved a request for extension of this approval.
Adopted by the City Council of the City of Minnetonka, Minnesota, on August 22, 2016.

Terry Schneider, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption: Wagner
Seconded by: Bergstedt
Voted in favor of: Acomb, Bergstedt, Wagner, Ellingson, Allendorf, Schneider
Voted against:
Abstained:
Absent: Wiersum
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on August 22, 2016.

David E. Maeda, City Clerk
Resolution No. 2016-085

Resolution approving a conditional use permit for impervious trails within wetland buffers in and around the Southwest Light Rail Transit line

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. BACKGROUND.

1.01 To accommodate construction of that portion of the Southwest Light Rail Transit (SWLRT) line located within the City of Minnetonka, several impervious trails would be relocated. Small sections of some of these relocated trails would be situated within wetland buffer areas. These areas are generally illustrated on EXHIBIT A of this resolution.

1.02 By City Code §300.23 Subd.7, impervious trails are allowed in wetland buffers only by conditional use permit.

1.03 On August 4, 2016, the planning commission held a hearing on the application. The commission considered all of the comments and the staff report, which are incorporated by reference into this resolution. The commission recommended that the city council approve the permit.

Section 2. Standards.

2.01 City Code §300.26 Subd.2 and Subd.3 outline general and specific standards that must be met for granting of conditional permits within the wetland overlay district. These standards are incorporated by reference into this resolution.

Section 3. Findings.

3.01 The proposed trails would meet all minimum conditional use permit standards outlined in City Code §300.26.

1. The impervious trails would:
a) Be consistent with the goals, policies and objectives of the comprehensive plan and city ordinances. The uses would allow for public enjoyment of the city's natural resources.

b) Have a low flood damage potential and only minimal interference with wetland buffer vegetation.

2. The proposed trails would not:

a) Have an undue adverse impact on governmental facilities, utilities, services or existing or proposed improvements.

b) Be inconsistent with the city's water resources management plan.

c) Have an undue adverse impact on the public health, safety or welfare.

d) Adversely impact the water quality of bodies receiving runoff entering wetlands, floodplain or shoreland areas.

e) Adversely affect the minimum required water storage capacity as defined in the water resources management plan.

f) Be designed for human habitation or be serviced with public utilities.

g) Include any electrical or heating equipment or the storage of materials which are flammable, explosive or otherwise dangerous to human, animal or plant life;

Section 4. City Council Action.

4.01 The above-described conditional use permit is approved, subject to the following conditions:

1. A construction permit is required. The permit will encompass right-of-way work, utility work, grading and erosion control, and physical construction of the rail line and appurtenance. No site work is allowed prior to issuance of this permit.

2. Prior to issuance of a construction permit:
a) The SWLRT project must receive funding approval.

b) Negotiated application fees must be paid.

c) Acceptable ownership information and maintenance and operations agreements for all SWLRT property and infrastructure with Minnetonka must be submitted for staff review.

3. This approval will expire on December 31, 2017 unless a construction permit has been issued or the city has received and approved a request for extension of this approval.

Adopted by the City Council of the City of Minnetonka, Minnesota, on August 22, 2016.

__________________________
Terry Schneider, Mayor

Attest:

__________________________
David E. Maeda, City Clerk

Action on this Resolution:

Motion for adoption: Wagner
Seconded by: Bergstedt
Voted in favor of: Acomb, Bergstedt, Wagner, Ellingson, Allendorf, Schneider
Voted against: 
Abstained: 
Absent: Wiersum
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a duly authorized meeting held on August 22, 2016.

__________________________
David E. Maeda, City Clerk
Resolution No. 2016-086

Resolution approving construction on a steep slope and tree removal required to accommodate construction of the Southwest Light Rail Transit Line

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01 Roughly two miles of the Southwest Light Rail Transit (SWLRT) line will be located within the City of Minnetonka.

1.02 Portions of the line will be constructed within steep slopes, as defined by city code, and will result in removal of trees located within woodland preservation areas, as well as high priority and significant trees.

Section 2. Standards.

2.01 By City Code §300.28 Subd.20(b)(3), the city will approve construction/development within a steep slope only if certain standards are met. Those standards are incorporated by reference into this resolution.

2.02 By City Code §300.28 Subd.19(e)(5), the city council may approve the removal of trees located within woodland preservation areas and high priority and significant trees if it determines there is a greater public good.

Section 3. Findings

3.01 Construction of the SWLRT line would meet the standards as outlined in City Code §300.28 Subd.20(b)(3):

1. The transit line has been appropriately designed and sited with reference to steep slopes.
2. Construction of the transit line would not result in soil erosion, flooding, severe scarring, reduced water quality, inadequate drainage control, or other problems.

3. Adequate measures to protect public safety would be employed during construction of the transit line.

3.02 While valuing trees as an important natural resource and component of the community, the city recognizes that trees must be removed to accommodate construction of the SWLRT line. The line will promote the public good by providing a transportation alternative to residents, employees, and visitors to the region.

Section 4. City Council Action.

4.01 Construction within steep slopes is hereby approved based on the findings outlined in section 3 of this resolution.

4.02 Removal of trees within woodland preservation areas and high priority and significant trees is hereby approved based on the findings outlined in section 3 of this resolution.

4.03 These approvals are subject to the following conditions:

1. A construction permit is required. The permit will encompass right-of-way work, utility work, grading and erosion control, and physical construction of the rail line and appurtenance. No site work is allowed prior to issuance of this permit.

2. Prior to issuance of a construction permit:

   a) The SWLRT project must receive funding approval.

   b) Negotiated application fees must be paid.

   c) Acceptable ownership information and maintenance and operations agreements for all SWLRT property and infrastructure within Minnetonka must be submitted for staff review.

3. This approval will expire on December 31, 2017 unless a construction permit has been issued or the city has received and approved a request for extension of this approval.
Resolution No. 2016-086

Adopted by the City Council of the City of Minnetonka, Minnesota, on August 22, 2016.

Terry Schneider, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption: Wagner
Seconded by: Bergstedt
Voted in favor of: Acomb, Bergstedt, Wagner, Ellingson, Allendorf, Schneider
Voted against: 
Abstained: 
Absent: Wiersum
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on August 22, 2016.

David E. Maeda, City Clerk
Resolution No. 2018-

Resolution reaffirming previous approvals related to natural resource impact to accommodate construction of the Southwest Light Rail Transit line

Be it resolved by the City Council of the City of Minnetonka, Minnesota, as follows:

Section 1. Background.

1.01 On Aug. 22, 2016, the city council adopted a series of resolutions related to construction of the Southwest Light Rail Transit (SWLRT) line:

- Resolution No. 2016-082. A resolution approving a wetland and floodplain alteration permit.
- Resolution No. 2016-083. A resolution approving a wetland replacement plan as regulated by the Wetland Conservation Act for the Southwest Light Rail Transit line.
- Resolution No. 2016-084. A resolution approving wetland, wetland buffer, and floodplain variances.
- Resolution No. 2016-085. A resolution approving a conditional use permit for impervious trails within wetland buffers.
- Resolution No. 2016-086. A resolution approving construction on a steep slope development and tree removal.

1.02 The approval granted under these resolutions expired on Dec. 31, 2017.

1.03 The Metro Transit has requested reaffirmation of the 2016 approvals.

Section 2. Findings.

2.01 Reaffirmation is appropriate for three reasons:

1. There have been no substantive changes to the SWLRT plans.

2. There have been no changes to city code or policy that would affect the previous approvals.

3. Reaffirmation of the previous approvals is not anticipated to adversely affect the interests of neighboring property owners.

Section 3. City Council Action

3.01 The resolutions outlined in section 1, including all findings and conditions, are reaffirmed.
3.02 This reaffirmed approval will expire on Dec. 31, 2019 unless a construction permit has been issued or the city has received and approved a request for extension of this approval.

Adopted by the City Council of the City of Minnetonka, Minnesota, on Sept. 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:  
Seconded by:  
Voted in favor of:  
Voted against:  
Abstained:  
Absent:  
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on Sept. 17, 2018.

David E. Maeda, City Clerk
WHEREAS:

1. The Parties entered into a Southwest Light Rail Transit Project (“Project”) Master Funding Agreement (“MFA”) effective May 7, 2015.

2. The Parties provided in the MFA that certain aspects of funding for the Project would be determined in subsequent SFAs.

3. The Project scope includes Locally Requested Capital Improvements, hereby referred to as “Local Work,” for which the City will fund.

4. The Parties contemplate from time to time that the City will authorize transfers to the Council for changes to Local Work components and agree that execution of a single SFA that allows the Parties to process multiple small transfers would benefit both parties.

5. The City has delegated authority to its officers and staff as set forth below to enter into change order agreements under this SFA, where the value of the services provided by the Council for a single change order does not exceed $50,000 and the aggregate value does not exceed $160,000.

6. The Council has delegated authority to its officers and staff as set forth below to enter into change order agreements under this SFA, where the reimbursement from the City for a single change order does not exceed $50,000 and the aggregate reimbursement does not exceed $160,000.

7. The Parties desire to enter into this SFA in order to facilitate transfers of City funds to the Council as described below.
NOW, THEREFORE, in reliance on the statements in these recitals, the Parties hereby agree as follows:

1. **Amount of Authorized Funding.** The aggregate amount of funding authorized shall not exceed $160,000, unless authorized in a subsequent agreement or an amendment to this SFA.

2. **Specific Funding Agreement** The activities to be performed by the Council and reimbursed by the City will be described in the Change Order Authorizations, substantially in the form outlined in Attachment 1. Upon execution, the Change Order Authorization is integrated into and made part of this SFA. The City will reimburse the Council within 30 days after the execution of the Change Order Authorization.

3. **Project Activity Periods.** The project activity period for the purposes of this SFA shall be effective upon execution and shall terminate on the date all costs under this SFA have been reimbursed, unless terminated earlier consistent with the terms of the MFA.

4. **Authorized Signers.** In order for a Change Order Authorization under this SFA to be binding on the City, it must be signed by the Public Works City Engineer. In order for the Change Order Authorization to be binding on the Council, it must be signed by one of the following authorized signers: Council Authorized Representative (up to $10,000), Construction Manager (up to $20,000), Assistant Director of Construction (up to $50,000), Director of Construction (up to $100,000), Deputy Project Director (up to $250,000), Project Director (up to $350,000) or Program Director (up to $500,000).

5. **Incorporation.** The terms, conditions, and definitions of the MFA are expressly incorporated into this SFA except as modified herein.

---

**CITY OF MINNETONKA**

By: ____________________________

Its: ______ Mayor __________________

Date: ___________________________

By: ____________________________

Its: ______ City Manager **********

Date: ___________________________

---

**METROPOLITAN COUNCIL**

By: ____________________________

Its: ____________________________

Date: ___________________________
Change Order Authorization #________

1. Authorized work scope/description of the change funded by this Change Order Authorization: __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   ______.

2. Construction Contract Number #________.

3. Construction Change Order #________.

4. Amount payable by the City to the Council for this Change Order shall not exceed $_____ without further authorization from the City.

5. The asset that is the subject of this Attachment will, upon completion of the Project, be owned by the: [City] or [Council].

6. The terms, conditions, and definitions of the Southwest Light Rail Transit Project Master Funding Agreement dated ## and SFA ##, entered by and between the Parties, are expressly incorporated into this Change Order Authorization.

CITY OF MINNETONKA

By: ____________________________
Its: ____________________________
Date: ________________

METROPOLITAN COUNCIL

By: ____________________________
Its: ____________________________
Date: ________________
City of Minnetonka and the Metropolitan Council agree that the contract entered into on January 18, 2017, relating to “Subordinate Funding Agreement City of Minnetonka -04-Local Work Construction,” is amended in the following particulars.

1. **EXHIBIT A TO CONTRACT, Description of Local Work, Payment Schedule and Budget Detail** is amended in the following particulars

DELETE table labeled Payment Schedule for Local Work and REPLACE with the following:

<table>
<thead>
<tr>
<th>Payment #</th>
<th>Payable on or before</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30 Days Following SWLRT Project Civil Contract Limited Notice to Proceed 1</td>
<td>$1,178,608</td>
</tr>
<tr>
<td>2</td>
<td>154 Days Following SWLRT Project Civil Contract Limited Notice to Proceed 1</td>
<td>$392,870</td>
</tr>
</tbody>
</table>

Except as amended hereby, the provisions of the above-referenced contract shall remain in force and effect without change.
IN WITNESS WHEREOF, the parties have caused this amendment to be executed by their duly authorized officers on the dates set forth below.

<table>
<thead>
<tr>
<th>CITY OF MINNETONKA</th>
<th>METROPOLITAN COUNCIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>By:</td>
<td>By:  ____________________________</td>
</tr>
<tr>
<td>(Please print name legibly below)</td>
<td>Signer</td>
</tr>
<tr>
<td>________________________________</td>
<td></td>
</tr>
<tr>
<td>Its:</td>
<td>Its:  Regional Administrator</td>
</tr>
<tr>
<td>________________________________</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td>Date:  ________________________________</td>
</tr>
<tr>
<td>________________________________</td>
<td></td>
</tr>
</tbody>
</table>

By:  ________________________________

(Please print name legibly below)

______________________________
Its:  ________________________________

Date:  ________________________________
METROPOLITAN COUNCIL
390 North Robert Street, St. Paul, MN  55101-1805
(651) 602-1000

AMENDMENT NUMBER ONE
to
CONTRACT FOR SERVICES
Metropolitan Council Contract No. 14I067E

City of Minnetonka and the Metropolitan Council agree that the contract entered into on January 18, 2017, relating to “Subordinate Funding Agreement City of Minnetonka -05-Local Work Construction,” is amended in the following particulars.

1. EXHIBIT B TO CONTRACT, Payment Schedule for Funding Contribution is amended in the following particulars

DELETE table labeled Payment Schedule for Local Work and REPLACE with the following:

<table>
<thead>
<tr>
<th>Payment Schedule for Local Work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment #</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Except as amended hereby, the provisions of the above-referenced contract shall remain in force and effect without change.
IN WITNESS WHEREOF, the parties have caused this amendment to be executed by their duly authorized officers on the dates set forth below.

CITY OF MINNETONKA
By: ________________________________
   (Please print name legibly below)
   ________________________________
Its: ________________________________
Date: ________________________________

METROPOLITAN COUNCIL
By: ________________________________
   Signer
   ________________________________
Its: ________________________________
   Regional Administrator
Date: ________________________________

By: ________________________________
   (Please print name legibly below)
   ________________________________
Its: ________________________________
Date: ________________________________
Resolution No. 2018-
Resolution authorizing conveyance of real estate interests to the Metropolitan Council for the Southwest Light Rail Transit Project

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. The City of Minnetonka has been working with the Metropolitan Council and other public agencies in planning for the Southwest Light Rail Transit Project.

1.02. By Resolution 2016-107, the City of Minnetonka committed to transfer the City's property rights in certain parcels to the Metropolitan Council for the Project, without monetary compensation.

1.03. Resolution 2016-107 provided that the terms and conditions for transfer of the City property interests would be addressed in one or more subsequent resolutions or agreement.

Section 2. Council Action.

2.01. The mayor and city manager are authorized to execute a contract providing for the transfer of the real property interests identified below, and are further authorized to execute all instruments necessary to implement the contract and this resolution, subject to the conditions set forth below.

2.02. The contract must contain the following provisions:

1. The city will convey the real estate identified as Parcel 3000 to the Metropolitan Council by quit claim deed in substantial form as the attached Exhibit A, the final form of which must be approved by the city manager and city attorney.

2. The city will convey to Metropolitan Council a permanent transit easement and temporary construction and access easements over portions of the real estate identified as Parcel 3001, by an instrument in substantial form as the attached Exhibit B, the final form of which must be approved by the city manager and city attorney. The city will also cooperate in obtaining a partial release of restrictive covenant from Collins Drive Corporation and Nine Mile Creek Watershed District for the Parcel 3001 transit easement area.

3. The city will execute an amendment to a tree preservation easement in favor of the city over the private property at 5450 Feltl Road, upon approval by the planning commission of an amended site and building plan for that property.

4. The contract must contain assurances satisfactory to the city manager and city engineer that, following completion of construction of the SWLRT, the Metropolitan Council will convey to the city the easements necessary for the city's operation, maintenance, repair and replacement of city trails, roadways, utilities, or other city infrastructure that have been impacted by the SWLRT project. Per city code, easements are required to meet the standards set forth in Section 400.030.5, Easement Standards.
Adopted by the City Council of the City of Minnetonka, Minnesota, on Sept. 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on Sept. 17, 2018.

David E. Maeda, City Clerk
Quit Claim Deed
Business Entity to Business Entity

Minneapolis Uniform Conveyancing Blanks
Form 10.3.5 (2013)

E-CRV number: ____________________________

DEED TAX DUE: $__________________________ DATE: ____________________________ (month/day/year)

FOR VALUABLE CONSIDERATION, ____________________________ City of Minnetonka, ____________________________ (insert name of Grantor)

a municipal corporation under the laws of ____________________________ Minnesota

(“Grantor”), hereby conveys and quitclaims to ____________________________ Metropolitan Council ____________________________ (“Grantee”),

a public corporation and political subdivision under the laws of ____________________________ Minnesota ____________________________ (“Grantee”),

real property in ____________________________ Hennepin County, Minnesota, legally described as follows:

OUTLOT E, THE TOWNHOUSES OF SHADY OAK, Hennepin County, Minnesota, EXCEPT that part lying westerly of the following described line:

Commencing at the northeast corner of said OUTLOT E, THE TOWNHOUSES OF SHADY OAK; thence North 88 degrees 53 minutes 47 seconds West assumed bearing along the north line of said OUTLOT E a distance of 115.50 feet to the point of beginning of the line to be described; thence South 0 degrees 26 minutes 40 seconds West a distance of 293.14 to the westerly line of said OUTLOT E and said line there terminating.

Check here if all or part of the described real property is Registered (Torrens) X

together with all hereditaments and appurtenances belonging thereto, subject to the following exceptions:

Excepting and reserving to the Grantor, its successors and assigns, the easements for public purposes described on the attached Exhibit A and depicted on the attached Exhibit B.

Check applicable box:

☐ The Seller certifies that the Seller does not know of any wells on the described real property.

☐ A well disclosure certificate accompanies this document or has been electronically filed. (If electronically filed, insert WDC number: _____________________________.)

☐ I am familiar with the property described in this instrument and I certify that the status and number of wells on the described real property have not changed since the last previously filed well disclosure certificate.

Grantor
CITY OF MINNETONKA

(name of Grantor)

By: ____________________________

(signature)

Its: Mayor

(type of authority)

By: ____________________________

(signature)

Its: City Manager

(type of authority)
State of Minnesota, County of Hennepin

This instrument was acknowledged before me on _____________, 2018, by Brad Wiersum, as mayor of City of Minnetonka, a municipal corporation under the laws of Minnesota, on behalf of the corporation.

(Stamp)

Signature of notarial officer

Title (and Rank): 

My commission expires: _____________

(month/day/year)

State of Minnesota, County of Hennepin

This instrument was acknowledged before me on _____________, 2018, by Geralyn Barone, as city manager of City of Minnetonka, a municipal corporation under the laws of Minnesota, on behalf of the corporation.

(Stamp)

Signature of notarial officer

Title (and Rank): 

My commission expires: _____________

(month/day/year)

THIS INSTRUMENT WAS DRAFTED BY:

(insert name and address)

City of Minnetonka
Legal Dept. (CAH)
14600 Minnetonka Blvd.
Minnetonka, MN 55345

TAX STATEMENTS FOR THE REAL PROPERTY DESCRIBED IN THIS INSTRUMENT SHOULD BE SENT TO:

(insert legal name and residential or business address of Grantee)

Metropolitan Council

_______________________

_______________________
EXHIBIT A

(Easement No. 1)

A perpetual easement for roadway, drainage and utility purposes over, under and across the north 10.00 feet, as measured at a right angle, of the hereinafter described Parcel A. EXCEPT that part thereof lying within the public right-of-way easement described in Document Number 1188618 on file and of record in the Office of the Registrar of Titles, Hennepin County, Minnesota.

AND

(Easement No. 2)

A perpetual easement for drainage and utility purposes, 5.00 feet wide, over, under and across that part of the hereinafter described Parcel A, lying westerly of and adjoining a line described as follows:

Commencing at the northeast corner of said Parcel A; thence on an assumed bearing of South 00 degrees 26 minutes 24 seconds West along the east line of said Parcel A, a distance of 100.57 feet to the point of beginning of the line to be described; thence continuing South 00 degrees 26 minutes 24 seconds West along said east line, a distance of 946.45 feet and said line there terminating.

AND

(Easement No. 3)

A perpetual easement for drainage and utility purposes, 20.00 feet wide, over, under and across that part of the hereinafter described Parcel A. The centerline of said easement is described as follows:

Commencing at the northeast corner of said Parcel A; thence on an assumed bearing of South 00 degrees 26 minutes 24 seconds West along the east line of said Parcel A, a distance of 100.57 feet to the point of beginning of the centerline to be described; thence North 78 degrees 39 minutes 53 seconds West, a distance of 117.62 feet to the west line of said Parcel A, and said centerline there terminating.

The sidelines of said perpetual easement shall be prolonged or shortened to terminate on the east and west lines of said Parcel A.

AND
(Easement No. 4)

A perpetual easement for drainage and utility purposes over, under and across that part of the hereinafter described Parcel A, described as follows:

Commencing at the northeast corner of said Parcel A; thence on an assumed bearing of South 00 degrees 26 minutes 24 seconds West along the east line of said Parcel A, a distance of 260.20 feet to the point of beginning of the easement to be described; thence continuing South 00 degrees 26 minutes 24 seconds West along said east line, a distance of 25.00 feet; thence North 90 degrees 00 minutes 00 seconds West, a distance of 88.73 feet; thence South 41 degrees 00 minutes 40 seconds West, a distance of 20.79 feet; thence South 09 degrees 18 minutes 07 seconds East, a distance of 107.74 feet; thence South 03 degrees 04 minutes 29 seconds East, a distance of 88.73 feet; thence North 90 degrees 00 minutes 00 seconds West, a distance of 72.64 feet; thence South 89 degrees 45 minutes 00 seconds East, a distance of 45.73 feet; thence North 00 degrees 35 minutes 07 seconds East, a distance of 84.05 feet; thence North 86 degrees 11 minutes 47 seconds East, a distance of 23.48 feet to said east line; thence South 00 degrees 26 minutes 24 seconds West along said east line, a distance of 100.71 feet; thence North 00 degrees 45 minutes 00 seconds West, a distance of 79.94 feet to the west line of said Parcel A; thence northerly along the west line of Parcel A to the intersection with a line bearing North 90 degrees 00 minutes 00 seconds West from said point of beginning; thence North 00 degrees 26 minutes 40 seconds East along said west line, a distance of 11.71 feet; thence South 14 degrees 16 minutes 06 seconds East, a distance of 12.08 feet; thence North 90 degrees 00 minutes 00 seconds East, a distance of 18.77 feet; thence North 41 degrees 00 minutes 40 seconds East, a distance of 8.54 feet; thence South 48 degrees 59 minutes 20 seconds East, a distance of 9.82 feet; thence North 90 degrees 00 minutes 00 seconds East, a distance of 80.67 feet to the point of beginning.

AND

(Easement No. 5)

A perpetual easement for trail purposes, 30.00 feet wide, over, under and across that part of the hereinafter described Parcel A, lying above an elevation of 909.00 feet based on the North American Vertical Datum of 1988 (NAVD 88). The centerline of said easement is described as follows:

Commencing at the northeast corner of said Parcel A; thence on an assumed bearing of South 00 degrees 26 minutes 24 seconds West along the east line of said Parcel A, a distance of 462.88 feet to the point of beginning of the centerline to be described; thence North 87 degrees 47 minutes 02 seconds West, a distance of 86.24 feet to the west line of said Parcel A, and said centerline there terminating.

The sidelines of said perpetual easement shall be prolonged or shortened to terminate on the east and west lines of said Parcel A.

AND
(Easement No. 6)

A perpetual easement for drainage and utility purposes, 20.00 feet wide, over, under and across that part of the hereinafter described Parcel A. The centerline of said easement is described as follows:

Commencing at the northeast corner of said Parcel A; thence on an assumed bearing of South 00 degrees 26 minutes 24 seconds West along the east line of said Parcel A, a distance of 750.23 feet to the point of beginning of the centerline to be described; thence North 89 degrees 49 minutes 23 seconds West, a distance of 79.95 feet to the west line of said Parcel A, and said centerline there terminating.

The sidelines of said perpetual easement shall be prolonged or shortened to terminate on the east and west lines of said Parcel A.

AND

(Easement No. 7)

A perpetual easement for drainage and utility purposes, 30.00 feet wide, over, under and across that part of the hereinafter described Parcel A. The centerline of said easement is described as follows:

Commencing at the northeast corner of said Parcel A; thence on an assumed bearing of South 00 degrees 26 minutes 24 seconds West along the east line of said Parcel A, a distance of 1021.74 feet to the point of beginning of the centerline to be described; thence North 90 degrees 00 minutes 00 seconds West, a distance of 79.98 feet to the west line of said Parcel A, and said centerline there terminating.

The sidelines of said perpetual easement shall be prolonged or shortened to terminate on the east and west lines of said Parcel A.

AND
(Easement No. 8)

A perpetual easement for trail purposes, 15.00 feet wide, over, under and across that part of the hereinafter described Parcel A. The centerline of said easement is described as follows:

Commencing at the northeast corner of said Parcel A; thence on an assumed bearing of North 88 degrees 53 minutes 47 seconds West along the north line of said Parcel A, a distance of 103.59 feet to the point of beginning of the centerline to be described; thence South 00 degrees 26 minutes 40 seconds West, a distance of 294.16 feet; thence southerly a distance of 37.17 feet along a tangential curve, concave to the east, having a radius of 70.00 feet and a central angle of 30 degrees 25 minutes 24 seconds; thence southerly a distance of 42.48 feet along a reverse curve, concave to the west, having a radius of 80.00 feet and a central angle of 30 degrees 25 minutes 24 seconds; thence South 00 degrees 26 minutes 40 seconds West, tangent to said reverse curve, a distance of 68.66 feet; thence southwesterly a distance of 13.38 feet along a tangential curve, concave to the northwest, having a radius of 20.00 feet and a central angle of 38 degrees 20 minutes 01 second to the west line of said Parcel A, and said centerline there terminating.

EXCEPT those parts thereof lying within the public right-of-way easement described in Document Number 1188618 on file and of record in the Office of the Registrar of Titles, Hennepin County, Minnesota, and lying within the above described roadway, drainage and utility easement (Easement No. 1).

The sidelines of said perpetual easement shall be prolonged or shortened to terminate on the west line of said Parcel A.
THIS EASEMENT AGREEMENT (this “Agreement”) is made and entered into this _____ day of ___________, 201__, by and between City of Minnetonka, a Minnesota municipal corporation (the “Grantor”) and the METROPOLITAN COUNCIL, a public corporation and political subdivision under the law of the State of Minnesota (the “Grantee”). This Agreement sometimes refers to the Grantor and Grantee individually as a “Party” and collectively as the “Parties.”

WITNESSETH:

WHEREAS, Grantor is the fee owner of the real property that is legally described on Exhibit A attached hereto (the “Property”); and

WHEREAS, the Grantee intends to construct, operate and maintain a light rail transit system (“LRT”) over, under and across a portion of the Property.

NOW THEREFORE, in consideration for the mutual promises made herein, the parties agree as follows:

1. Grant of Easements. Grantor hereby grants and conveys to Grantee, its agents, permittees, successors and assigns, the following described easements:

   a. Permanent Transit Easement. A permanent transit easement over, under and across that part of the Property legally described on the attached Exhibit B and depicted on the attached Exhibit D (the “Permanent Transit Easement Area”) to, without limitation, locate, install, construct, inspect, maintain, repair, replace, use, and operate the LRT and other related improvements (the “Permanent Transit Easement”). The Permanent Transit Easement includes the rights of ingress and egress over and across the Property by Grantee and its agents, employees, permittees and contractors, for the use of the Easement Area as may be necessary in the exercise of the rights and privileges herein granted. The Permanent Transit
Easement further includes the right to cut, trim, or remove from the Permanent Transit Easement Area any trees, shrubs, undergrowth or other vegetation as in the Grantee’s judgment unreasonably interferes with the use of the Permanent Transit Easement Area by Grantee, its permittee’s, successors and assigns, provided that Grantee shall take all reasonable precautions to prevent any damage to the Grantor’s property.

Grantor, its heirs, successors and assigns, will not erect, construct, or create any building, improvement, obstruction, perpendicular utility crossing, or structure of any kind, either above or below the surface of the easement area or plant any trees, or stockpile construction debris or construction equipment, or change the grade thereof of the Permanent Transit Easement Area without the express written consent of the Grantee, except as provided in paragraph 5 below.

b. Temporary Construction Easement. A temporary, non-exclusive construction easement over, under and across that part of the Property legally described and depicted on the attached Exhibit C and depicted in Exhibit D (the “Temporary Construction Easement Area”) to, without limitation, locate, install and construct the LRT and associated improvements (the “Temporary Construction Easement”).

c. Temporary Access Easement. A temporary, non-exclusive access easement legally described and depicted on the attached Exhibit D and D.1 (the “Temporary Access Easement”) over and across the Property.

The Temporary Construction Easement and the Temporary Access Easement are referred to, collectively, as the “Temporary Easements”. Subsequent to the commencement date of the Temporary Easements as written below, and until such Temporary Easements have expired, Grantor, its heirs, successors and assigns, will not erect, construct, or create any building, improvement, obstruction, perpendicular utility crossing, or structure of any kind, either above or below the surface of the Temporary Easements or plant any trees, or stockpile construction debris or construction equipment, or change the grade thereof of the Temporary Easements without the express written permission of the Grantee.

2. Term of Temporary Easements. The Temporary Easements defined above shall commence on ______________, 201__ and, subject to paragraph 3 below, expire on ______________, 201__.

3. Extension Option of Temporary Easements and Payment. With respect to the term of the Temporary Easements, the Grantee shall have the option (the “Extension Option”) to extend the term of this temporary easement for one (1) six (6) month period (the “Extension Term”), in accordance with the following terms:

a. Such options shall be exercised by written notice (the “Extension Notice”) from Grantee delivered to Grantor not less than fourteen (14) days prior to the expiration of the term of the Temporary Easements.
b. The Grantee is not required to pay any monetary compensation to Grantor for an extension pursuant to this paragraph 3. All of the terms and provisions of this easement shall remain in full force and effect during the Extension Term.

4. **Restoration for Temporary Easements.** Grantee shall make reasonable efforts to restore the Temporary Easements matching the original surface grade as far as practicable, and restoration of the surface to like condition, with prairie grass seeding.

5. **Reservation of Drainage and Utility Easement.** In conjunction with its construction of the LRT, Grantee will install a storm sewer drainage pipe (the “Facility”) within a portion of the Permanent Transit Easement Area, which Facility will connect to the Grantor’s public storm sewer system. The Permanent Transit Easement Area is granted subject to a permanent easement, reserved to the Grantor, for public drainage and utility purposes, over, under and across that part of the Property as legally described in Exhibit E and depicted in Exhibit F (the “Permanent Reserved Easement Area”). The Grantor and Grantee will address their respective rights and responsibilities regarding the Facility in a separate operation and maintenance agreement.

6. **Covenant of Ownership.** Grantor covenants that it is the lawful owner and is in lawful possession of the above described real estate and has lawful right and authority to convey and grant the easements described herein.

7. **Notices and Demands.** All notices, requests, demands, consents, and other communications required or permitted under this Easement Agreement shall be in writing and shall be deemed to have been duly and properly given three (3) business days after the date of mailing if deposited in a receptacle of the United States mail, first class postage prepaid, addressed to the intended recipient as follows:

   **Grantor:**
   City of Minnetonka  
   14600 Minnetonka Blvd.  
   Minnetonka, MN 55345  
   Attn: City Manager

   **Grantee:**
   Metropolitan Council  
   390 Robert Street North  
   St. Paul, MN 55101-1805  
   Attn: Real Estate Office

The provisions and conditions of this easement shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns, and shall constitute a covenant running with the land.

8. **Termination or Amendment of Easements.** The Permanent Transit Easement declared, granted, established and conveyed herein is permanent in nature and may be terminated or amended only by an agreement in writing signed by the Parties or their successors and assigns. In the event of any such termination or amendment, the Parties agree to execute a recordable document to memorialize of record any such termination or amendment.
9. **Miscellaneous.**

a. **Further Actions.** The Parties shall execute and deliver all further documents and take all further actions reasonably necessary or appropriate to effectuate the purposes of this Agreement.

b. **Time of the Essence.** Time is of the essence of each provision in this Agreement where time is a factor.

c. **Waiver.** No waiver of any provision of this Agreement shall be binding unless executed in writing by the Party making the waiver. No waiver of any provision of this Agreement shall be deemed to constitute a waiver of any other provision, whether or not similar, nor shall any waiver constitute a continuing waiver unless the written waiver so specifies.

d. **Governing Law.** This Agreement has been made under the laws of the State of Minnesota and such laws shall control its interpretation.

e. **Counterparts.** This Agreement and any amendments to this Agreement may be executed in counterparts, each of which shall be fully effective and all of which together shall constitute one and the same instrument.

f. **Severability.** In case any one or more of the provisions contained in this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provision had never been contained herein.

g. **No Presumption against Drafter.** This Agreement has been negotiated at arm's length and between persons sophisticated and knowledgeable in the matters dealt with herein. Accordingly, this Agreement shall be interpreted to achieve the intents and purposes of the Parties, without any presumption against the Party responsible for drafting any part of this Agreement.

*The remainder of this page is intentionally left blank.*
IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first set forth above.

METROPOLITAN COUNCIL,
a public corporation and political subdivision under the laws of the State of Minnesota,

By: ______________________________
Title: Regional Administrator

STATE OF MINNESOTA  )
COUNTY OF RAMSEY    ) ss

I, the undersigned, a Notary Public in and for Ramsey County, Minnesota, do hereby certify that ______________________, the Regional Administrator of the Metropolitan Council, a public body appeared before me this day in person and acknowledged that he signed and delivered said instrument on behalf of said public body.

Given under my hand and official seal this __________ day of __________, 201__. 

_________________________
Notary Public

This instrument drafted by:

Office of the General Counsel
Metropolitan Council
390 North Robert Street
Saint Paul, MN 55101
CITY OF MINNETONKA

By: ________________________________
Title: Mayor

By: ________________________________
Title: City Manager

STATE OF MINNESOTA )
COUNTY OF HENNEPIN ) ss

I, the undersigned, a Notary Public in and for Hennepin County, Minnesota, do hereby certify that Brad Wiersum, the mayor of the City of Minnetonka, a Minnesota municipal corporation, appeared before me this day in person and acknowledged that he signed and delivered said instrument on behalf of said corporation.

Given under my hand and official seal this ____________ day of __________, 201__.

_________________________
Notary Public

STATE OF MINNESOTA )
COUNTY OF HENNEPIN ) ss

I, the undersigned, a Notary Public in and for Hennepin County, Minnesota, do hereby certify that Geralyn Barone, the city manager of the City of Minnetonka, a Minnesota municipal corporation, appeared before me this day in person and acknowledged that she signed and delivered said instrument on behalf of said corporation.

Given under my hand and official seal this ____________ day of __________, 201__.

_________________________
Notary Public
EXHIBIT A
PROPERTY DESCRIPTION

Outlot A, OPUS 2 FOURTH ADDITION, Hennepin County, Minnesota
EXHIBIT B

PERMANENT TRANSIT EASEMENT AREA DESCRIPTION

That part of Outlot A, OPUS 2 FOURTH ADDITION, Hennepin County, Minnesota, described as follows:

Beginning at the southwest corner of said Outlot A, OPUS 2 FOURTH ADDITION; thence North 01 degree 05 minutes 50 seconds East, assumed bearing, along the southwesterly line of Outlot A; thence North 51 degrees 19 minutes 04 seconds East along said southwesterly line a distance of 162.67 feet; thence South 00 degrees, 26 minutes 40 seconds West a distance of 200.06 feet; thence North 89 degrees 44 minutes 28 seconds East a distance of 34.34 feet; thence South 00 degrees 00 minutes 00 seconds East a distance of 100.00 feet; thence North 89 degrees 38 minutes 17 seconds West a distance of 79.94 feet; thence South 00 degrees 11 minutes 57 seconds West a distance of 92.10 feet to the south line of said outlot A; thence North 88 degrees 54 minutes 10 seconds West along said south line a distance of 85.04 feet to the point of beginning.
EXHIBIT C

TEMPORARY CONSTRUCTION EASEMENT AREA DESCRIPTION

That part of Outlot A, OPUS 2 FOURTH ADDITION, Hennepin County, Minnesota, lying southerly of the following described line:

Commencing at the southeast corner of said Outlot A, OPUS 2 FOURTH ADDITION; thence North 01 degrees 05 minutes 50 seconds East, assumed bearing along the east line of said Outlot A, a distance of 472.91 feet to an angle point in said east line and to the point of beginning of the line to be described; thence South 89 degrees 20 minutes 11 seconds West a distance of 104.06 feet to the west line of Outlot A, OPUS 2 FOURTH ADDITION and said line there terminating.

Except that part of said Outlot A, OPUS 2 FOURTH ADDITION, described as follows:

Beginning at the southwest corner of said Outlot A, OPUS 2 FOURTH ADDITION; thence North 01 degree 05 minutes 50 seconds East along the west line of said Outlot A and its northerly extension a distance of 288.28 feet to the southwesterly line of Outlot A; thence North 51 degrees 19 minutes 04 seconds East along said southwesterly line a distance of 162.67 feet; thence South 00 degrees 26 minutes 40 seconds East a distance of 34.34 feet; thence South 00 degrees 00 minutes 00 seconds East a distance of 100.00 feet; thence North 89 degrees 38 minutes 17 seconds West a distance 79.94 feet; thence South 00 degrees 11 minutes 57 seconds West a distance of 92.10 feet to the south line of said Outlot A; thence North 88 degrees 54 minutes 10 seconds West along said south line a distance of 85.04 feet to the point of beginning.
PROPERTY DESCRIPTION

Parcel 3001 Permanent Transit Easement Description

That part of Outlot A, OPUS 2 FOURTH ADDITION, Hennepin County, Minnesota, described as follows:

Beginning at the southwest corner of said Outlot A, OPUS 2 FOURTH ADDITION, thence North 01 degree 05 minutes 50 seconds East, assumed bearing, along the west line of said Outlot A and its northerly extension a distance of 205.20 feet to the southerly line of Outlot B, thence North 01 degree 10 minutes 04 seconds East along said southerly line of Outlot B a distance of 162.07 feet; thence South 06 degrees 28 minutes 45 seconds West a distance of 200.00 feet; thence North 09 degrees 44 minutes 38 seconds East a distance of 53.34 feet; thence South 06 degrees 33 minutes 03 seconds East a distance of 100.00 feet; thence North 09 degrees 35 minutes 17 seconds West a distance of 79.04 feet; thence South 00 degrees 11 minutes 57 seconds West a distance of 92.15 feet to the south line of said Outlot A; thence North 06 degrees 34 minutes 10 seconds West along said south line a distance of 86.04 feet to the point of beginning.

Parcel 3001 Temporary Easement Description

That part of Outlot A, OPUS 2 FOURTH ADDITION, Hennepin County, Minnesota, lying southeasterly of the following described line:

Commencing at the southeast corner of said Outlot A, OPUS 2 FOURTH ADDITION, thence North 01 degree 05 minutes 50 seconds East, assumed bearing along the east line of said Outlot A, a distance of 472.91 feet to an angle point in said east line and to the point of beginning of the line to be described; thence South 09 degrees 20 minutes 11 seconds West a distance of 104.00 feet to the west line of Outlot A, OPUS 2 FOURTH ADDITION and said line there terminating.

Except that part of said Outlot A, OPUS 2 FOURTH ADDITION, described as follows:

Beginning at the southwest corner of said Outlot A, OPUS 2 FOURTH ADDITION, thence North 01 degree 05 minutes 50 seconds East along the west line of said Outlot A and its northerly extension a distance of 288.20 feet to the southerly line of Outlot A, thence North 01 degree 19 minutes 04 seconds East along said southerly line a distance of 162.07 feet; thence South 06 degrees 28 minutes 40 seconds West a distance of 300.08 feet; thence North 06 degrees 44 minutes 28 seconds East a distance of 34.34 feet; thence South 06 degrees 00 minutes 00 seconds East a distance of 100.00 feet; thence North 09 degrees 38 minutes 17 seconds West a distance of 79.04 feet; thence South 00 degrees 11 minutes 57 seconds West a distance of 92.15 feet to the south line of said Outlot A; thence North 06 degrees 34 minutes 10 seconds West along said south line a distance of 86.04 feet to the point of beginning.
EXHIBIT E
PERMANENT RESERVED EASEMENT AREA DESCRIPTION

That part of Outlot A, OPUS 2 FOURTH ADDITION, Hennepin County, Minnesota, described as follows:

Beginning at the southwest corner of said Outlot A, OPUS 2 FOURTH ADDITION; thence North 01 degree 05 minutes 50 seconds East, assumed bearing along the west line of said Outlot A and its northerly extension a distance of 288.28 feet to the southwesterly line of Outlot A; thence north 51 degrees 19 minutes 04 seconds East along said southwesterly line a distance of 162.67 feet; thence South 00 degrees 26 minutes 40 seconds West a distance of 200.08 feet; thence North 89 degrees 28 seconds East a distance of 34.34 feet; thence South 00 degrees 00 minutes 00 seconds East a distance of 100.00 feet; thence North 89 degrees 38 minutes 17 seconds West a distance of 79.94 feet; thence South 00 degrees 11 minutes 57 seconds West a distance of 92.10 feet to the south line of said Outlot A; thence North 88 degrees 54 minutes 10 seconds West along said south line a distance of 85.04 feet to the point of beginning.
EXHIBIT F

PERMANENT RESERVED EASEMENT AREA DEPICTION

[see attached depiction]
PROPOSED EASEMENT DESCRIPTION

A perpetual easement for drainage and utility purposes over, under and across the most southerly 25.00 feet, as measured at a right angle, of the hereinafter described Parcel A.

Parcel A:

That part of Outlot A, OPUS 2 FOURTH ADDITION, Hennepin County Minnesota, described as follows:

Beginning at the southwest corner of said Outlot A, OPUS FOURTH ADDITION; thence North 01 degree 05 minutes 50 seconds East, assumed bearing along the west line of said Outlot A and its northerly extension a distance of 288.28 feet to the southwesterly line of Outlot A; thence North 51 degrees 19 minutes 04 seconds East along said southwesterly line a distance of 162.67 feet; thence South 00 degrees 26 minutes 40 seconds West a distance of 200.08 feet; thence North 89 degrees 44 minutes 28 seconds East a distance of 34.34 feet; thence South 00 degrees 00 minutes 00 seconds East a distance of 100.00 feet; thence North 89 degrees 38 minutes 17 seconds West a distance of 79.94 feet; thence South 00 degrees 11 minutes 57 seconds West a distance of 92.10 feet to the south line of said Outlot A; thence North 88 degrees 54 minutes 10 seconds West along said south line a distance of 85.04 feet to the point of beginning.

SURVEYOR'S CERTIFICATION

I hereby certify that this survey, plan, or report was prepared by me or under my direct supervision and that I am a duly Licensed Land Surveyor under the laws of the State of Minnesota.

_______________________________
Eric R. Wilfahrt
License Number 46166

REVISED: LABELS   6/30/2018
Addenda
Minnetonka City Council
Meeting of September 17, 2018

13A Resolutions for special assessment of 2017-2018 projects

Attached is updated information about two special assessments and the amended resolutions to reflect the payments.

14A Ordinances related to tobacco-related products

The attached feedback was received after the council packet was distributed.

14B Concept plan review for redevelopment of the property at 1809 Plymouth Road

The attached letter was received after the council packet was distributed.

14D Ordinances related to franchise fees.

The attached feedback was received after the distribution of the council packet.
ADDENDUM
City Council Agenda Item #13A
Meeting of September 17, 2018

Brief Description: Resolutions for special assessment of 2017-2018 projects

Since publication of the council agenda packet, additional information has developed regarding two of the proposed special assessments, as indicated below:

The owner of 14101 Council Circle has paid the assessment (1-year tree) in full. The attached resolution for this assessment has been revised to reflect this payment, and should be adopted in place of the resolution contained within the packet.

The owner of 5101 Boarshead Road has paid the assessment (3-year tree) in full. The attached resolution for this assessment has been revised to reflect this payment, and should be adopted in place of the resolution contained within the packet.

Submitted through:
Geralyn Barone, City Manager
Merrill King, Finance Director
Colin Schmidt, City Assessor
Jo Colleran, Natural Resource Manager

Originated by:
Denise Oslund, Assessment Specialist
Resolution No. 2018-

Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902, one-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Diseased Tree Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-14</td>
<td>14806</td>
<td>Walker Pl</td>
<td>21-117-22-12-0039</td>
<td>$81.10</td>
</tr>
<tr>
<td>T-6</td>
<td>14021</td>
<td>Minnehaha Pl</td>
<td>15-117-22-23-0028</td>
<td>$93.94</td>
</tr>
<tr>
<td>T-59</td>
<td>4905</td>
<td>Mayview Rd</td>
<td>27-117-22-24-0050</td>
<td>$105.00</td>
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<td>T-47</td>
<td>4441</td>
<td>Gaywood Dr</td>
<td>22-117-22-34-0004</td>
<td>$658.94</td>
</tr>
<tr>
<td>T-57</td>
<td>5990</td>
<td>Covington Ter</td>
<td>31-117-22-42-0054</td>
<td>$675.39</td>
</tr>
<tr>
<td>T-61</td>
<td>15120</td>
<td>Stone Ridge Trace</td>
<td>09-117-22-13-0015</td>
<td>$790.32</td>
</tr>
</tbody>
</table>

Subtotal $2,404.69

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 3.48 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.

2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.
2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

Action on this resolution:


I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

David E. Maeda, City Clerk
Resolutions No. 2018-

Resolution adopting special assessments for 2018 Diseased Trees Project No. 4902,
three-year assessment term

Be it resolved by the City Council of the City of Minnetonka, Minnesota as follows:

Section 1. Background.

1.01. Pursuant to proper notice duly given as required by Minnesota statute, the Council has met on September 17, 2018 to hear and to pass upon all objections to the proposed special assessments for 2018 Diseased Tree Projects at the following properties lying within the City of Minnetonka:

<table>
<thead>
<tr>
<th>Project No.</th>
<th>Street No.</th>
<th>Street Name</th>
<th>PID</th>
<th>Assessment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-52</td>
<td>n/a</td>
<td>Stone &amp; Oakland Rd</td>
<td>10-117-22-34-0005</td>
<td>$1,120.76</td>
</tr>
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<td>T-35</td>
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<td>29-117-22-41-0012</td>
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<td>11405</td>
<td>Timberline Rd</td>
<td>02-117-22-44-0036</td>
<td>$1,779.02</td>
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<td>T-2</td>
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<td>08-117-22-33-0027</td>
<td>$2,697.70</td>
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</tbody>
</table>

Subtotal: $13,443.53

Section 2. Council Action.

2.01. The proposed special assessments listed above are hereby adopted, and each tract of land is found to be benefited by the improvement in the amount of the assessment levied against it.

2.02. The special assessment may be paid within 30 days from the date of this resolution, or may be paid in a single installment in the same time and manner as the payment of real estate taxes with interest at the rate of 3.78 percent per annum. To the first installment of each assessment will be added interest on the entire assessment from the date of this resolution to December 31 of the year in which the first payment is payable. Subsequently, one year's interest on the remaining balance will be added to each subsequent installment. Any property owner may pay the entire unpaid balance of the assessment against his/her property at any time with interest accrued to December 31 of the year in which the payment is made, provided the payment is made before November 30 in the first year and before November 15 in subsequent years.
2.03. The owner of any property assessed may, at any time within 30 days following the adoption of this resolution, pay all or part of the assessment to the city, provided that partial payments are made in increments of not less than $100 and provided that any balance remaining unpaid is not less than $100 no interest will be charged on the amount paid.

2.04. The city clerk is directed to transmit a certified duplicate of this assessment to the county auditor to be extended on the property tax lists and to be collected and paid over in the same manner as other municipal taxes.

Adopted by the City Council of the City of Minnetonka, Minnesota, on September 17, 2018.

Brad Wiersum, Mayor

Attest:

David E. Maeda, City Clerk

**Action on this resolution:**

Motion for adoption:
Seconded by:
Voted in favor of:
Voted against:
Abstained:
Absent:
Resolution adopted.

I hereby certify that the foregoing is a true and correct copy of a resolution adopted by the City Council of the City of Minnetonka, Minnesota, at a meeting held on September 17, 2018.

David E. Maeda, City Clerk
ITEM 14A – Ordinances related to tobacco-related products

The attached feedback was received following distribution of the agenda packet.

ITEM 14B – Concept plan review for 1809 Plymouth Road

The attached letter was received following distribution of the agenda packet.
For change memo.

Dear Ms. Shea:

Thank you for your letter. I appreciate knowing the perspective of your group of retailers regarding flavored tobacco.

Sincerely,

Brad Wiersum
Mayor
City of Minnetonka

Coalition of Neighborhood Retailers

DATE: September 17, 2018

TO: Minnetonka Mayor Brad Wiersum
Minnetonka Council Members

Dear Mayor Wiersum and City Council Members,

Please see the attached letter in regard to the proposal on tobacco flavors from certain retailers in the City of Minnetonka for this evening. We appreciate your time and consideration on this very important matter.
Coalition of Neighborhood Retailers

September 17, 2018

Mayor Brad Wiersum  
Council Member Deb Calvert  
Council Member Patty Acomb  
Council Member Bob Ellingson  
Council Member Rebecca Schack  
Council Member Mike Happe  
Council Member Tim Bergstedt  
14600 Minnetonka Boulevard  
Minnetonka, MN 55345

Re: Issue of Banning the Sale of Flavored Tobacco Products

Dear Mayor Wiersum and Minnetonka City Council Members:

We are writing to follow up our letter dated June 7, 2018 in which we expressed our concerns about a proposed retail tobacco ordinance that would raise the legal age to purchase tobacco products from 18 to 21 and ban the sale of certain flavored tobacco products. This letter provides additional and more recent information why banning the sale of flavored tobacco products is unnecessary.

No Scientific Basis that Flavorings in Tobacco Products Cause Underage Tobacco Use

Proponents of flavor bans suggest that the mere existence of flavored tobacco products cause young people (teenagers or young adults) to initiate or continue tobacco use. However, there is no scientific basis for such a conclusion.

Teenagers and young adults begin to use tobacco for many reasons. They naturally want what adults have, whether that be using tobacco products, consuming alcohol, experimenting with drugs, or other engaging in other adult behavior. These are simply what teenagers do, whether caused by peer pressure, experimentation, curiosity, assertion of independence, or any number of other reasons. We urge you to read the article in Psychology Today (click link below) to better understand all of these factors that influence why teens engage in risky behavior.

The U.S. Center for Disease Control bi-annually quantifies these activities in its Youth Risk Behavior Surveillance Survey (YRBSS) of high school students. The 2017 YRBSS results\(^1\) show that 19.5\% of high school students said they had used some kind of tobacco product on any given day, even a single puff, in the most recent 30-day period prior to the survey. Similarly, 29.8\% of youth reported that they had consumed alcohol products in the same period.\(^2\) Bearing in mind that legal age to purchase and consumer alcohol 21 nationwide, and that in 41 states (including Minnesota) the legal age to purchase and use tobacco legal is 18, this is a significant finding because being of legal age does not prevent youth from engaging in these otherwise adult behaviors.

The survey also indicates that slightly more high schoolers (19.8\%) said they had used marijuana in the 30 days prior to the survey, even though it is a product that is federal contraband everywhere for all age groups and illegal for all under most states’ laws.

Use of tobacco products by underage youth should also be considered in their long-term context. Past 30-day high school cigarette use has declined from 12.7\% to 2.6\% since 1991; cigar use from 22.0\% to 8.0\% since 1997 (its first survey year); and e-cigarette use from 24.1\% in its first survey in 2015 to 13.2\% in the 2017 survey.\(^3\) These statistics show that tobacco use in any form is in a long-term decline among high school students.

From this survey data, two conclusions can be reached. First, a small and declining number of youth are using tobacco products of any kind, flavored or otherwise. Second, the scientific evidence does not support the assumption and claim by advocates that flavors, rather than other factors, \textit{cause} teens to use tobacco products. Not one single Minnesota city council that has considered tobacco flavored restrictions has even suggested the need for a ban of flavored alcohol products, even though more underage youth drink alcohol than use tobacco products. This despite the fact for every flavored tobacco product there is an identical flavored alcohol product. In short, there is no evidence that adding flavors to tobacco products is the reason \textit{why} teens use tobacco.

Another important study sponsored by the U.S. Food and Drug Administration and the National Institutes of Health results in a similar conclusion. This study, called the Population Assessment of Tobacco and Health (PATH) Study,\(^4\) is a long-term study of 46,000 people age 12 and older that is tracking tobacco use and behaviors. The first set of data from the PATH Study known as Wave 1 data found that among 12-17-year-olds, 1.8\% stated they used flavored cigars; among young adults 18-24, that figure was 3.9\%. In either case, the use of flavored cigars is a very small percentage of young people that use tobacco products. In other words, at this point, the data from the PATH Study does not support a conclusion that flavors cause tobacco use.

Proponents claim that because young people report that they use flavored tobacco products, then flavors in cigars must have caused them to try cigars. However, no study has asked young people why they started to use flavored tobacco products. Rather, the question is whether or not they use flavored products. This is a significant factor that you as local policymakers must remember because a correlation is not the same thing as causation, and to suggest that because a small percentage of underage persons used flavored tobacco products, given the many reasons they might experiment with tobacco products, it does not follow that the flavors was the reason why they use tobacco.

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\(^1\) YRBSS at https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/ss6708.pdf
\(^2\) Id. pages 42-43.
\(^3\) YRBSS Trend Fact sheets at https://www.cdc.gov/healthyyouth/data/yrbs/results.htm. There may be overlap among the three groups, that is, a student may use two or three products and appear in each group.
\(^4\) https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx
Moreover, a blanket flavor ban is contrary to the scientific evidence that does exist. The U.S. Food and Drug Administration’s Office of Science has recognized that some flavors in tobacco products are not likely to appeal to youth. In a process that approved the marketing of certain flavored smokeless tobacco products, the Office of Science stated:

The proposed products are reported to have flavors such as mint, wintergreen, or tobacco character with citrus. While flavored smokeless tobacco products are a potential concern of youth initiation, these proposed flavors are consistent with traditionally available [smokeless tobacco] flavors and are not novel flavors that likely increase appeal to youth.5

This finding from the FDA’s Office of Science demonstrates that a blanket prohibition on all flavors does not target youth initiation and use. Although this FDA Office of Science approval process focused on mint, wintergreen and citrus flavors, other flavors may also not “increase appeal to youth.” In fact, on September 12, 2018, FDA Commissioner Scott Gottlieb, in announcing an enforcement action addressing electronic cigarettes, stated “I believe certain flavors are one of the principal drivers of the youth appeal of these [e-cigarette] products.”6 It is important to note what FDA Commissioner Gottlieb did not say. He did not state that “all flavors” youth appeal to electronic cigarettes.

Consequently, a complete ban on all flavors is overbroad in at least two ways. First, a complete ban on flavors is not targeted to flavors that “increase appeal to youth” and will only affect legal, adult users of tobacco products who will simply patronize stores in neighboring cities or turn to the Internet as a source for their preferred tobacco products. Second, it applies the ban equally to all types of tobacco products, although some products are also less likely to be used by youth such as the reference by the FDA Office of Science about certain flavored smokeless tobacco products or traditional pipe tobacco, a product used by adults with an average age in the mid-fifties.

Some Flavored Tobacco Products May be Less Harmful and Should Not be Restricted

Some tobacco products, both those that have been available for some time and some of the newer types of products only recently introduced into the market, are more likely to have flavors and are also more likely to be less harmful to consumers. A blanket flavor ban would take large portions of these categories off the market, leaving adult tobacco users to choose only more harmful products.

As a matter of public health policy, the FDA has taken an approach to encourage harm reduction in the consumption of tobacco products, noting that a continuum of risk exists among the various categories of products.7 Recognizing that some risk comes from the use of any product, there remain compelling arguments that some products are less harmful and adult consumers should be able to choose these products. However, if those products are removed from the shelves because they are frequently flavored, those options are not available to adult consumers. Prohibiting the sale of less harmful products is a byproduct of blanket flavor bans. The interest of public health is not advanced when a total flavor ban removes all flavored product options from the marketplace for adult tobacco users to choose from, especially when no evidence exists that flavors actually cause youth tobacco use and evidence does exist that some flavors do not “increase appeal to youth.”

5 https://www.fda.gov/downloads/tobaccoproducts/labeling/tobaccoproductreviewevaluation/ucm472123.pdf (emphasis added)
6 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm (emphasis added)
7 Remarks by Scott Gottlieb, M.D., Commissioner of Food and Drug Administration, July 28, 2017
In conclusion, adopting an ordinance that bans legal products will not respond to the underlying reasons why underage youth use tobacco products. This means that restricting or banning flavored tobacco products is not necessarily the solution to the issue of minors using tobacco. Rather, understanding youth behavior and continuing to educate youth why they should not initiate tobacco use may be the more prudent and ultimately, more successful, approach.

We appreciate you consideration of our concerns and urge you to not pass an ordinance that would prohibit the sale of flavored tobacco products. At the same time, if you still have concerns, please consider meeting with us so we can collectively discuss how best to respond to the issue without unduly impacting law-abiding retailers. The Coalition and its members are committed to preventing underage individuals from accessing tobacco products and oppose any marketing to or targeting of underage individuals.

Sincerely,

Lance Klatt, Executive Director
Minnesota Service Station Association

Jamie Pfuhl, President
Minnesota Grocers Association

Kevin Thoma, Executive Director
Minnesota Petroleum Marketers Association

Thomas Briant, Executive Director
National Association of Tobacco Outlets

Bruce Nustad, President
Minnesota Retailers Association
From: Geralyn Barone  
Sent: Monday, September 17, 2018 11:24 AM  
To: Julie Wischnack <jwischnack@eminnetonka.com>  
Cc: David Maeda <dmaeda@eminnetonka.com>  
Subject: FW:

Julie,

For tonight’s addendum.

Geralyn

From: Mike Happe  
Sent: Saturday, September 15, 2018 8:12 PM  
To: Geralyn Barone <gbarone@eminnetonka.com>  
Subject: Fwd:

Same with this one.

Begin forwarded message:

From: Kinn Elliott  
Date: September 13, 2018 at 6:22:56 PM CDT  
To: Mike Happe <mhappe@eminnetonka.com>

Councilman Happe,

I sent a previous email outlining our support for the Tobacco 21 initiative. As we discussed, our concern with the pending ordinance involves the access to flavors. We believe that responsible flavors play a key role in helping adult smoker switch from traditional cigarettes to ENDS that pose a significantly reduced risk to overall health.

We are actively working with the FDA on youth prevention initiatives.

I have provided the Canadian guidelines that we discussed.

If you have any questions, please do not hesitate to contact me.

Sincerely,
### FLAVOURS

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<tr>
<th>Item</th>
<th>Flavour</th>
<th>Column 2 Vaping Product</th>
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<tr>
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<td>Confectionery</td>
<td>Vaping products, except prescription vaping products and vaping products that are manufactured or sold for export</td>
</tr>
<tr>
<td>2</td>
<td>Dessert</td>
<td>Vaping products, except prescription vaping products and vaping products that are manufactured or sold for export</td>
</tr>
<tr>
<td>3</td>
<td>Cannabis</td>
<td>Vaping products, except vaping products that are manufactured or sold for export</td>
</tr>
<tr>
<td>4</td>
<td>Soft drink</td>
<td>Vaping products, except vaping products that are manufactured or sold for export</td>
</tr>
<tr>
<td>5</td>
<td>Energy drink</td>
<td>Vaping products, except vaping products that are manufactured or sold for export</td>
</tr>
</tbody>
</table>

Note: In column 2, *prescription* has the same meaning as in subsection 13(2).
From: Geralyn Barone
Sent: Monday, September 17, 2018 11:23 AM
To: Julie Wischnack <jwischnack@eminnetonka.com>
Cc: David Maeda <dmaeda@eminnetonka.com>
Subject: FW: Tobacco 21 Ordinance

Julie,

Please include in tonight’s addendum. Also print out the press release from the link. Thanks!

Geralyn

Begin forwarded message:

From: Kinn Elliott <>
Date: September 13, 2018 at 5:53:19 PM CDT
To: Mike Happe <mhappe@eminnetonka.com>
Subject: Tobacco 21 Ordinance

Councilman Happe,

Thank you for taking the time to talk about the Tobacco 21 Ordinance pending in the Minnetonka City Council. As we discussed, JUUL fully supports efforts to raise the minimum age to 21 in order to purchase cigarettes, tobacco or vaping products. We want to keep JUUL out of the hands of young people, and we believe raising the minimum purchase age is a step in the right direction.

I have also included a link to our website with the press statement we released when Massachusetts Governor Charlie Baker signed Tobacco 21 legislation into
law earlier this year.

https://support.juul.com/learn/read/statement-from-matt-david-juul-labs-chief-communications-officer

Sincerely,

Kinn Elliott

--
Kinn Elliott
Director, State Affairs
Juul Labs
WARNING: This product contains nicotine. Nicotine is an addictive chemical.

Statement from Matt David, JUUL Labs Chief Communications Officer, Regarding the Press Conference Held by the Massachusetts Attorney General

We welcome the opportunity to work with the Massachusetts Attorney General because, we too, are committed to preventing underage use of JUUL. We utilize stringent online tools to block attempts by those under the age of 21 from purchasing our products, including unique ID match and age verification technology.

Furthermore, we have never marketed to anyone underage. In fact, we have done very little marketing relative to our growth:

JUUL Monthly Net Revenue and Marketing Spend Since Inception

Like many Silicon Valley technology startups, our growth is not the result of marketing but rather a superior product disrupting
Our ecommerce platform utilizes unique ID match and age verification technology to make sure minors are not able to access and purchase our products online.

We market our products responsibly, following strict guidelines to have material directed toward adult smokers and not to youth audiences. (Please read our Marketing & Social Media Code)

We support effective legislation and regulation to prevent the purchase and use of our products by minors.

We have reseller terms that include monitoring and penalties for noncompliance with underage restrictions.

Our packaging will include a prominent nicotine label and the additional statement “The alternative for adult smokers.”

We collaborate upon request with school districts and law enforcement on local youth prevention initiatives.

Because of the regulated nature of our product, we conduct random compliance checks of independent retail stores using our secret shopping program. We evaluate hundreds of locations every month.

We actively monitor the internet and process thousands of enforcement actions per month. Our goal is to ensure only authorized retailers who are subject to our youth prevention controls are selling JUUL products.
For tonight’s addendum.

From: Rebecca Schack
Sent: Sunday, September 16, 2018 10:50 AM
To: Kelly Krapek <[
Cc: Geralyn Barone <gbarone@eminnetonka.com>
Subject: Re: Concerns about youth vaping

Kelly,
Thank you for your message. I appreciate hearing from you and receiving your input regarding this issue.

Thank you for your continued engagement.

Sincerely,
Rebecca

Sent from my iPad

On Sep 13, 2018, at 12:48 PM, Kelly Krapek <[
 wrote:

Dear Minnetonka City Council Members,

I live in Minnetonka and have worked at Lake Minnetonka Orthodontics for the past 23 years. During that time, I’ve had the privilege of knowing hundreds of our community’s youth as they grow into intelligent, caring and passionate adults. I’ve seen many trends throughout the years, but the recent epidemic in youth vaping is one of the most concerning.

As you probably remember from your own adolescence, youth don’t always consider the long-term consequences of their decisions. Many youth who begin vaping think it a cool new trend to try or way to fit in, and only realize they’ve become addicted to nicotine once it is too late. As a community, we need to do all that we can to help teens succeed, and that includes creating an environment where youth are less able to get e-cigarettes and other tobacco products by passing Tobacco 21. I see too many youth with bright futures ahead of them putting their health and future in jeopardy by vaping. Can I count on you to put our kid’s health first and vote in favor of Tobacco 21 next week?

Kelly Krapek
9700 Waterstone Pl
Minnetonka, 55305
For tonight’s addendum.

From: Rebecca Schack
Sent: Sunday, September 16, 2018 11:20 AM
To: Freeman, Robert A <[redacted]>
Cc: Geralyn Barone <gbarone@eminnetonka.com>
Subject: Re: HealthPartners Support for T21 Ordinance

Robert,
Thank you for the follow-up message. I appreciate hearing from you and receiving your input regarding this issue.

Thank you for your continued engagement.

Sincerely,
Rebecca Schack

Sent from my iPad

On Sep 4, 2018, at 3:11 PM, Freeman, Robert A wrote:

Dear Councilmember Schack:

I hope all is well. Congratulations on your recent appointment to the Minnetonka City Council.

I wanted to forward you the letter which we sent to your colleagues in July in advance of the upcoming vote on Tobacco-21, so you can see that we support this both as a health care provider and a business. As you may know, our Park Nicollet Clinic in Minnetonka employs about 190 people.

Please don’t hesitate to contact me if you have any questions about our support of the ordinance. We hope that you will support it too!

Sincerely,

Robert

Robert Freeman
From: Freeman, Robert A  
Sent: Friday, July 06, 2018 2:56 PM  
To: 'bwiersum@eminnetonka.com' <bwiersum@eminnetonka.com>; 
'dcalvert@eminnetonka.com' <dcalvert@eminnetonka.com>; 
'pacomb@eminnetonka.com' <pacomb@eminnetonka.com>; 
'bellingson@eminnetonka.com' <bellingson@eminnetonka.com>; 
'twagner@eminnetonka.com' <twagner@eminnetonka.com>; 
'mhappe@eminnetonka.com' <mhappe@eminnetonka.com>; 
'tbergstedt@eminnetonka.com' <tbergstedt@eminnetonka.com>  
Subject: HealthPartners Support for T21 Ordinance

Dear Mayor Wiersum and City Council Members:

Please find attached a letter of support for the proposed ordinances on Tobacco 21 from our medical director, Dr. Thomas Kottke, M.D. We would appreciate it if you would include this letter in any handouts when this issue is considered by the city council.

Thank you for your leadership on this important issue. If you have any questions, please do not hesitate to contact me.

Sincerely,

Robert
This e-mail and any files transmitted with it are confidential and are intended solely for the use of the individual or entity to whom they are addressed. If you are not the intended recipient or the individual responsible for delivering the e-mail to the intended recipient, please be advised that you have received this e-mail in error and that any use, dissemination, forwarding, printing, or copying of this e-mail is strictly prohibited.

If you have received this communication in error, please return it to the sender immediately and delete the original message and any copy of it from your computer system. If you have any questions concerning this message, please contact the sender. Disclaimer

R001.0

<HealthPartners Letter to Minnetonka T21.pdf>
For tonight’s addendum.

From: Rebecca Schack  
Sent: Sunday, September 16, 2018 10:46 AM  
To: [redacted]  
Cc: Geralyn Barone <gbarone@eminnetonka.com>  
Subject: Re: Please support Tobacco 21, message from parent educator

Hi Bev,
Thank you for the follow-up message. I appreciate hearing from you and receiving your input regarding this issue.

Thank you for your continued engagement.

Sincerely,
Rebecca Schack

Sent from my iPad

On Sep 14, 2018, at 8:54 AM, [redacted] wrote:

Dear Council Member Schack,

I am touching base again as we near the important vote by Minnetonka City Council on Tobacco 21.

As an educator, I teach parents about brain development and its impact on youth decision making. Young brains are not fully developed until 25, which is why this age group is so vulnerable to Big Tobacco marketing.

I urge the council not to exclude e-cigarettes from the ordinance, as these products are the reason youth tobacco use has increased for the first time in 17 years. In fact, the FDA just issued a News Release this week which e-cigarette use was acknowledged as a youth epidemic.

By voting to SUPPORT Tobacco 21 (including e-cigarettes) you can:

- Save a life
- Show your support for Minnetonka’s youth - our future!
- Attract new residents to Minnetonka as a city that values health and wellness

My husband and I look forward to attending the council meeting on
Monday.

Best Regards,

Beverly Gillen
5000 Mayview Road
Minnetonka, MN 55345
Re: Concept Plan Review: Redevelopment of the Wells Fargo Building at 1809 Plymouth Road (Ridgedale)

Dear Minnetonka Elected Officials, City Staff, Ridgedale Community, and Valued Customers:

Wells Fargo thanks our neighbors and Minnetonka elected officials, and staff for allowing us to present our plans for the future of Wells Fargo in the Ridgedale Community. We value your interest and take seriously your input in helping us right-size our current Ridgedale branch.

Since we first opened at Ridgedale in 1974, the banking industry has changed dramatically. In order to keep serving our customers with the access, convenience and quality they expect, we propose to modernize our neighborhood branch with a smaller, sleeker, free-standing building. As a result of our move, our development partner, Oppidan Investment Company, will renovate and modernize our current office building into a vibrant and upscale multi-tenant office building.

We wanted to address some of the questions that were asked at the neighborhood meeting and by the Plan Commission:

Why is Wells Fargo moving out of their own building?

Due to the evolution of retail banking, customer expectations and technology in the industry, Wells Fargo no longer requires a large building or five drive-thru lanes. In order to continue to best serve our Ridgedale clients, we propose to provide a 3,500 SF free-standing building with easy access and visibility.

How many drive-thru lanes will be at the new free-standing branch?

The building will have two drive-up teller lines and one drive-up ATM.

What lines of service will the new bank branch?

Wells Fargo continually assesses the needs of our customers and adjusts the services we provide through our branches. We will continue to provide general retail and business banking services at Ridgedale through our Tellers and Personal Bankers.

What is the current status of the existing Wells Fargo building?

In anticipation of selling our building and moving into a new, free-standing branch, Wells Fargo has not actively pursued new tenants. We believed it was important to allow an experienced real estate group to completely renovate and modernize the existing building in order to attract an office tenant mix that reflects the Ridgedale 2035 Vision.

The Plymouth Road Wells Fargo location is a key branch for our customers. In order to maintain our presence and continue to provide the level of service our customers have come to expect, it is important that we maintain a
continuous presence at Ridgedale from a permanent building. We are also excited for our partner, Oppidan Investment Company, to breathe new life into and bring exciting new tenants to the existing office building.

We love this neighborhood, are honored to be a part of it, and plan to be an integral part of the Ridgedale Community for years to come.

Sincerely,

[Signature]

Brittany Price

Wells Fargo Bank, N.A.
For tonight's addendum.

From: Rebecca Schack
Sent: Sunday, September 16, 2018 10:36 AM
To: Bob
Cc: Geralyn Barone <gbarone@eminnetonka.com>
Subject: Re: Plymouth Road / Wells Fargo Proposal

Hi Bob,
Thank you for the e-mail. As you may know, this project is coming before the City Council tomorrow for a concept review. Your input is helpful as I consider this concept plan.

I agree, we must be deliberate in considering redevelopment of that area of Plymouth Road being that it is such a busy area in our community where we want to showcase what a great city we have in Minnetonka.

We are very early in this process so please stay engaged as the potential application moves forward.

Sincerely,
Rebecca Schack

Sent from my iPad

On Sep 14, 2018, at 12:04 PM, Bob <thamanine@aol.com> wrote:

Hello Council Member Schack,

Last night, I watched the TV channel that carries the City of Minnetonka sessions. It was mainly on the proposed redevelopment of the current Wells Fargo bank building and construction of a new one-story bank building on the current parking lot.

The man who heads up the planning commission didn't seem exactly thrilled with the proposal and I am not either. (not Mr. Gordon but the man who sits in center where the mayor does) Considering that there will be a new 6-story complex behind in the Ridgedale parking lot and renewed pedestrian and car traffic, it seems like a total waste of valuable property. With all of the greater emphasis being placed on Ridgedale as Minneotnka's "downtown" - what a terrible and bland impression the main street (Plymouth) will project. Maple Grove might be a good example of what could be. The new TCF building is also horrible to me. The stores don't even face Cartway Drive but instead people turning in from Plymouth see the building's backside!

I understand the difficulty there is with three owners of that parcel of land that the three banks are on but surely the developers and Minnetonka can come up with something MUCH better than proposed.

Best regards,
Bob Thaman
12200 Golden Acre Drive
Minnetonka Ward 2
TO: City Council
FROM: Merrill King, Finance Director
DATE: Sept. 17, 2018
SUBJECT: Addendum – Sept. 17, 2018

Item 14D – Ordinances related to franchise fees

Additional feedback received since Thursday, Sept. 13.
Hi, Mr. Bartholomay.

Thank you for writing. I’ll try to answer the questions you pose in your email.

Yes, the proposed franchise fees would impact all companies and persons in Minnetonka who have accounts with Xcel Energy and CenterPoint Energy. Therefore, tax exempt properties that currently do not pay property taxes for basic city services would pay a share of the costs for constructing the trails and sidewalks that are proposed to be financed by the revenue from the franchise fees.

The City of Minnetonka has a long history of expressing a desire for improved trails, which goes beyond the current community emphasis. As a result, a city trails plan that has been in place for many years and is updated regularly. The plan includes a defined ranking system designed to address some of your long term concerns. You may find the plan on the city’s website at: https://eminnetonka.com/images/trails/2019_Trail_Improvement_Plan_080818update.pdf

The proposal to use this funding source is acting upon the common practice of charging “rent” to the private utilities for their use of the public’s assets, the rights of way. Seventy‐five percent of the cities in the seven‐county metro charge franchise fees to support city costs that results in reducing the property taxes that would otherwise be required to finance their services. The proposed fees would expire with the terms of the city’s franchise agreements with the two private energy companies.

Your questions are good ones, and it’s important that others benefit by your thoughts. I will be sharing your email and my answers with the council tonight as they deliberate on the proposal. Thank you again.

Sincerely,

Merrill King

---

My apologies, I missed the "e"!

---------- Forwarded message ----------
From: Mark Bartholomay
Sent: Monday, September 17, 2018 8:55 AM
To: Merrill King <mking@eminnetonka.com>
Subject: Fwd: Franchise fee

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From: Mark Bartholomay
Sent: Monday, September 17, 2018 1:27 PM
To: 'Mark Bartholomay'
Subject: Citizen input - Bartholomay RE: Franchise fee

Hi, Mr. Bartholomay.

Thank you for writing. I’ll try to answer the questions you pose in your email.

Yes, the proposed franchise fees would impact all companies and persons in Minnetonka who have accounts with Xcel Energy and CenterPoint Energy. Therefore, tax exempt properties that currently do not pay property taxes for basic city services would pay a share of the costs for constructing the trails and sidewalks that are proposed to be financed by the revenue from the franchise fees.

The City of Minnetonka has a long history of expressing a desire for improved trails, which goes beyond the current community emphasis. As a result, a city trails plan that has been in place for many years and is updated regularly. The plan includes a defined ranking system designed to address some of your long term concerns. You may find the plan on the city’s website at: https://eminnetonka.com/images/trails/2019_Trail_Improvement_Plan_080818update.pdf

The proposal to use this funding source is acting upon the common practice of charging “rent” to the private utilities for their use of the public’s assets, the rights of way. Seventy‐five percent of the cities in the seven‐county metro charge franchise fees to support city costs that results in reducing the property taxes that would otherwise be required to finance their services. The proposed fees would expire with the terms of the city’s franchise agreements with the two private energy companies.

Your questions are good ones, and it’s important that others benefit by your thoughts. I will be sharing your email and my answers with the council tonight as they deliberate on the proposal. Thank you again.

Sincerely,

Merrill King
Hello Ms. King:

As a newer resident in Minnetonka I am trying to become aware of what is going on and offering an opinion where I feel it is valid (and limiting it to only that!). I saw in the recent Minnetonka Memo that thoughts on the franchise fee should be directed to you and was comforted by that as you were the person I was going to seek out. As a "recovering" CPA I like the idea of the facts taking the lead and not emotions, with numbers leading the way.

My first thought when I read of the proposal was that it was a tricky way to skirt the issue of a mill rate increase but after speaking with a friend who is a mayor in another city he pointed out that this is sometimes a way to get a fair contribution from those entities who are not taxed in the city, thus increasing the base of payers. I guess this is a way to get that done and, if so, is this what is going to happen here? Everything I have read has shown the average of $66 per year increase to the residential customers. I would like to make sure that everyone in the city is paying their fair share.

It still seems an odd way to finance this type of activity. I would rather it be handled through the budget or bonding process versus the franchise fee. Shouldn't those fees be used specifically for the purpose of providing the support to those service areas? Also, how is it that the fee would end in ten years and how will the project priorities funded be ranked? I assume that through a budget process things are weighed against each other for the benefit of the entire city and these projects would avoid that scrutiny because of the preexisting funding?. Lastly, how can the city government propose a ten year plan on these items when we know that trails are a very "hot" topic right now but may not be in seven years?

I like the idea but feel the funding for them should flow through established processes for clarity and rank versus being funded off the books on electric and gas bills.

If there is ever any way I can help you please feel free to reach out and thanks for the consideration.

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Mark Bartholomay
11630 Vista Drive
Minnetonka

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Merrill King

From: Stephan Furlich
Sent: Monday, September 17, 2018 11:20 AM
To: Bob Ellingson; Patty Acomb; Deborah Calvert
Cc: Merrill King; Geralyn Barone
Subject: Citizen input - Furlich - Ordinance related to franchise fees

Councilmembers Ellingson, Acomb and Calvert:

I am writing as a 30 year resident of the City of Minnetonka, Ward 1. I am writing to express my displeasure with the proposed Ordinances related to franchise fees, agenda item 14D on tonight's council agenda. Unfortunately, volunteer commitments with the Boy Scouts of America prevents my attendance at tonight's council meeting where I had hoped to voice my concerns as outlined below.

My displeasure is based on three basic concerns with using franchise fees to finance city government.

The first concern is that a franchise fee is simply a general revenue tax, plain and simple. As indicated in the full agenda packet, "The city's gas franchise ordinance does not restrict the use of franchise fees. The current electric franchise ordinance does not restrict the use of the franchise fees, provided that the city imposes equivalent franchise fees on both gas and electric utilities." So with the adoption of these ordinances the city is unrestricted in the use of the franchise fee revenue. In other words this is a general revenue tax, being sold as a "franchise fee". While being sold as being used to pay for popular enhancements to the city recreational trail and sidewalk system, there is no language in the ordinance requiring this use in the future. The trouble with such a policy is that it circumvents the Minnesota truth in taxation process. It allows the Minnetonka city government to claim to be holding taxes at a level consistent with or slightly above inflation, when indeed the general taxes, including franchise fees, are higher than required reporting. As stated in the information provided on page 4 of the agenda packet related to this ordinance, the revenue generated by the franchise fee is equivalent to a property tax levy increase of 4.8 percent which when added to the preliminary levy increase would result in a 9.5 percent increase in the city property taxes for 2019. I do not have an issue with raising taxes for needed city expenses once the case has been made that the expenses are needed. But an "off the books" franchise fee used for general fund expenses makes city government less accountable in justifying needed expenses in the future. If the city needs to increase general revenue, then be truthful about it and raise property taxes! If you can't make the case to raise property taxes then find another way to live within the existing funding means.

My second concern with the franchise fee is that it is a regressive tax that disproportionately impacts lower income households and fixed income senior citizens. The standard property tax which should be used to fund general revenue expenses more fairly allocates taxes to the property value. Most general fund expenses add value proportionally to existing property values and therefore should be taxed proportionally.

My third concern with the proposed franchise fee is that with increased use of renewable energy, primarily residential solar, the city will become dependent on an ever decreasing revenue stream. If budgets are set with this as "guaranteed" revenue, the City of Minnetonka, could face substantially larger tax increases in the future as it looks to make up for lost revenue as city residents go off-grid and disconnect from the public gas and electric utilities. A more prudent approach would be to build the required revenue incrementally into the general property tax levy.

Thank you for your serious consideration of this matter. Please vote no on the proposed franchise fee ordinance.
Respectfully,

Stephan Furlich
14616 Wildcrest Road
Minnetonka, MN
Mr. Brad Wiersum - Minnetonka Mayor
Ms. Patty Acomb - 2018 Alternate Acting Mayor & Minnetonka At Large, Seat B Council Member
Mr. Mike Happe - Minnetonka Ward 3 Council Member
Ms. Geralyn Barone - Minnetonka City Manager
Ms. Merrill King - Minnetonka Finance Director

Subject:  Franchise Fee debate for more trails

Good afternoon. After living and paying taxes in Minnetonka for 39+ years, we have agreed and supported the Minnetonka City Council’s decisions with respect to the citizens of this great community. Not once in all these years have we felt so strongly we needed to provide our input concerning a topic the Minnetonka City Council is discussing. However, having read the article and information provided in “Minnetonka debates upping franchise fees to pay for more trails” in the Thursday, September 6, 2018 Sun Sailor and the article “City council to discuss franchise fee increases on Sept 17” in the September 2018 Minnetonka Memo, my wife and I both agreed, we needed to provide our input and feedback. Unfortunately, we will not be able to attend the Monday, September 17, 2018 City Council meeting due to a previously scheduled appointment.

This communiqué will provide our reaction and comments to the Minnetonka City Council considering adopting two new ordinances to: One (1) - increase the utility franchise fees by $5.50 per month for residential customers to fund the construction of new walking and biking paths and Two (2) increase by $1.00 per month to fund utility line burial; NEITHER ORDINANCE DOES NOT HAVE OUR SUPPORT, as currently outlined. We are both in favor of new walking trails or sidewalks, bike paths and utility line burial. It is the financial classification and utilizing franchise fees on customer utility bills which we take issue with. New walking trails or sidewalks and biking paths in Minnetonka have absolutely nothing to do with existing electric or gas utility bills. Bottom line, the funding should be clear and transparent, not concealed in a franchise fee.

Our recommendation to fund these two projects are as follows:

Option 1:

Add to the tax levy; i.e. property taxes and/or create a new line item such as “Walking/Bike paths”

Option 2:

Have a referendum allowing Minnetonka residents to vote on this subject matter

Thank you for your consideration of the above and allowing Minnetonka residents to provide their feedback concerning this issue.

Steve and Bonnie Graupner
Steve Graupner  Bonnie Graupner

14427 Lennell Drive
Minnetonka, MN  55345-2318

P.S. To whom it may concern at the City of Minnetonka . . . I was informed by the Minnetonka City Manager if this e-mail relates to a specific city council agenda item, and will be included as public comment in the council packet, our specific “Graupner” e-mail address would be stricken/removed/redacted so it would not be public information. Thank you for keeping our e-mail private.
Although I support recreational trails, the proposed $5.50/mo fee and $1 utility line fee increases are quite excessive in combination. I encourage you to take a more moderate approach as I strongly oppose such a significant increase. I am considered well to do and still find the fee increase significant. I can't imagine what someone making minimum wage would think of this increase.
Hi, Ms. Rabe.

Thank you for writing. Your suggestion of a referendum to fund trails has been and will likely continue to be an option discussed by the city council. I am happy to provide your input to the council for their continued deliberation at their meeting this evening.

Sincerely,

Merrill King

Merrill King | Finance Director/Treasurer | City of Minnetonka | eminnetonka.com
14600 Minnetonka Blvd. | Minnetonka, MN 55345
Office: 952-939-8253

Mr. King -

I am NOT in favor of the plan to increase residential customer's utility fees to fund trail development.

Although trails and sidewalks are important to our community, raising residents' utility bills to finance this will unfairly affect many folks who already struggle to pay their bills for essential services. If "85% of residents" support this, let them voluntarily contribute rather than take money from all residents. $5.50 per month can be a large increase for each resident to shoulder for a non-essential project.

Why not let the voters decide via referendum, rather than rely entirely on survey responses?
Laurel Rabe
Hi, Ms. Riebe.

Thank you for writing. I will ensure your comments are included with the council’s discussion this evening on the franchise fee proposal for funding trails.

Sincerely,

Merrill King

Finance Director King, Councilperson Acomb, and Cavert:

I am writing to express my disagreement with your appalling regressive tax suggestion of adding a proposed $6.50 monthly fee (or $78/per year) that will have an impact on “lower income” groups. Anyone familiar with the stress of tight financial management for lower income groups would never even consider imposing such an unwelcome proposal. I am a longer living choosing to reside in Minnetonka for the past four years. I’ve enjoyed it, until this. All of my expenses are tightly watched with little options. My budget is completely necessary expenses. I have Blue Cross and Blue Shield of Minnesota, Platinum Blue. Recent Congress Legislation requires discontinuing Cost plans in most counties in 2019. I have no idea what my new costs will be, but an unwelcome big increase is expected in the upcoming enrollment period. Please do not allow this proposal to go forward. Having a career in fundraising, what many other options have you considered: grant applications, foundations support, legacy funding, permit options (like fishing licenses), etc.? I don’t know government procedures, but could this be added to voting in November similar to school issues for funding? I’ve always thought all are welcome here. As a good tax-paying and law-abiding citizen, show me this is correct. I’m always willing to pay my fair share but not more, especially when unexpected.

Thank you for your time and consideration,

Mary Riebe. Ph.D.
Retired Entrepreneurship/Marketing Professor
(Still recovering from 2009)
Ok thank you very much! Appreciate your time to answer my questions.

Best,

Kristin

On Mon, Sep 17, 2018 at 12:19 PM Merrill King <mking@eminnetonka.com> wrote:

Yes, a proposed change to the franchise fees would require a change to the city’s ordinances exactly as required for this proposal, whereby the ordinance is introduced at a first meeting and then adopted or rejected at a second meeting. The City of Minnetonka has a protocol that invites and generally goes beyond statutory and charter requirements to ensure public input, such as publishing the issue several times in our monthly newsletter inviting comment and announcing the council meeting dates on the issue. Nonetheless, the decisions are required to be made in public meetings that are legally noticed.
Thank you for your informative response. Just a follow-up question. Would any kind of proposed change to the franchise fees require a public process like the current one, with a public hearing and Council vote?

Thank you,

Kristin Soo

On Mon, Sep 17, 2018 at 11:08 AM Merrill King <mking@eminnetonka.com> wrote:

Hi, Ms. Soo.

I am happy to answer your questions as best I can, and I will copy this response and your questions to the city engineer, Will Manchester, so that he will be aware of the information you provided regarding CR 73.

The process, design and construction for each specific trail will likely vary by the conditions required for each, and often a project requires the purchase of additional right of way. Mr. Manchester explained that Hennepin County generally allows the city to use its right of way for trails, but must approve of any design. He said that meeting county specifications often requires the additional purchase of right of way from private property owners.

Generally, the City of Minnetonka does not use special assessments for any capital improvements to the public infrastructure, and the city council has not considered special assessments as an option for funding the cost of trail and sidewalk construction in the city.

If the proposed franchise fees for trails are adopted, the city council may remove or change the franchise fees any year. Regardless, the city has 20-year individual franchise agreements with both Xcel Energy and CenterPoint Energy for their use of the public rights of way, which would require reinstatement of any such fees if/when the agreements are renegotiated at the end of the terms. The agreements end in the years 2022 for CenterPoint Energy and 2038 for Xcel; the latter was just renegotiated this year.

I hope this information is helpful to you. I am happy to share your questions and my answers with the city council as they continue their deliberation on the trails funding issue this evening. Thank you for writing.

Sincerely,
Dear Merrill,

The addition of trails to busy roadways in Minnetonka is a much needed amenity to make them safer. Thanks for your work on this. I have some questions - thanks for your attention to them:

1) In addition to purchasing property for the trails, will Minnetonka be purchasing the right-of-way from the County as well?

2) Will there be a special assessment to residents in addition to the franchise fees?

3) How long (specifically how many months/years) will the fee be in place?

4) Will the County need to approve the city’s plan and design for a trail?

We have been watching a fair amount of repair of what looks to be the culvert/drainage system near the watershed by the Hillside/Hopkins Crossroads (Co Rd 73) intersection the past few days, right where a trail would go. Earlier this year a sinkhole on the road resulted due to issues with the culvert. In planning a trail along Co Rd 73 hopefully the City and County would work in tandem especially in trouble spots such as this one.
Thank you,

Kristin Soo
2391 Vernon Circle
Minnetonka

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Kristin Soo
Instructional Design Consultant
David,

If there’s time, please add this to the addendum on franchise fees. Thanks!

Geralyn

FYI

Patty

Begin forwarded message:

From: Luke Van Santen  
Date: September 17, 2018 at 1:07:12 PM CDT  
To: bwiersum@eminnetonka.com, pacomb@eminnetonka.com, dcalvert@eminnetonka.com  
Subject: Support for Franchise Fee Ordinances

Mayor and Councilmembers At Large -

As you can probably guess from the subject line, I am writing this message to you to express my full support for both ordinances related to increasing utility franchise fees to fund bike and walking trail construction. I hope you will vote in favor of the ordinances. I'm sending this to you after I've sent a similar message to Mike Happe, the Councilmember for my Ward of residence.

As much as I agree with Councilmember Happe that a tax is in general a more appropriate mechanism for generating City revenue, I feel even more strongly that a vote against these ordinances is making perfect the enemy of good.

A very large number (85%, if I remember correctly) of Minnetonka residents support more trails (including, by their own words, all of the people who spoke against the proposed ordinances at the last Council meeting). City staff has closely examined alternatives to provide funding to meet this expressed support, and I trust they have arrived at the best, most equitable solution, even given the flaws.
Again, please know that I fully support these fees and would support even higher fees to strengthen Minnetonka’s bike network. I hope you will support them as well!

Cordially,

Luke Van Santen
2148 Sheridan Hills Road
952.261.2818