Agenda

City of Minnetonka

Study Session

Monday, June 11, 2018

6:30 p.m.

Minnehaha Room

1. Tobacco 21
2. 2040 Comprehensive Plan – Housing Update
3. Ward 2 City Council Vacancy
4. Adjournment

The purpose of a study session is to allow the city council to discuss matters informally and in greater detail than permitted at formal council meetings. While all meetings of the council are open to the public, study session discussions are generally limited to the council, staff and consultants.
City Council Study Session Agenda Item #1  
Meeting of June 11, 2018

Brief Description  
Tobacco 21

Background

In January of 2018, Tobacco 21 advocates approached the city council to consider adopting more restrictive standards for tobacco sales in Minnetonka. There have been various jurisdictions that have adopted a variety of regulations that have strengthened local control. Over the last few months, staff has been collecting information, conducting community inventory information with Hennepin County Environmental Health staff, and convening a discussion group with current tobacco licensees and advocates for changes in the regulations.

Overview of Potential Changes

Potential changes for regulations are generally in four categories: minimum age to purchase (not consume) tobacco is changed from 18 to 21; specialty flavored tobacco products are prohibited; size of packages and/or prices of tobacco are regulated; and number/density/location of retailers are regulated. The different type of regulations are outlined below:

Minimum Age

The only change that is necessary to increase the purchasing age is in Minnetonka City Code, Section 625.040, Prohibited Sales:

625.040. Prohibited Sales.
A person must not sell or give away any tobacco-related product to any person below the age of 18-21 years.

There are a number of communities that have adopted this change, and specific information is attached.

Flavored Tobacco Products

The premise of this change is about regulating flavored tobacco that is more directed at younger buyers of tobacco. Some cities have banned flavors, exempting menthol, mint and wintergreen products. Some cities exempt establishments from the flavor regulations if there is a prohibition for the facility of having someone under the age of 21 from entering. An addition to the city code would be necessary to incorporate this change.

Packaging and Pricing

The theory behind regulating packaging and/or pricing is the smaller the package and the more affordable, the more attractive the products are to youth. The pricing regulation can be adopted with the packaging size or stand-alone pricing, where the regulation addresses multi-pack discounts. An addition to the city code would be necessary to incorporate this change.
Number, Density and Location of Retailers

This category of regulation is not unlike the discussion the city council had about liquor licenses. The idea would be to regulate where tobacco establishments can be located, e.g., not near a school. Also there could be a cap on how many tobacco establishments could be in Minnetonka. Lastly, the city could indicate there are maximums for the number of stores in the specific geography or area, sometimes referred to as “store density”. The summary from the county indicates that no cities have adopted these regulations. An addition to the city code would be necessary to incorporate this change.

Community Observations and Current Assessment

Hennepin County Environmental Health assisted the city by providing a current evaluation and assessment of facilities that are licensed to sell tobacco products in the city. The evaluation reviewed types of retailers, the type of advertising in the store, number of flavored products, price and e-cigarette products available. The research also summarized an “environmental scan” which indicates the number of students using tobacco and the ages of these students. See the attached report from the county.

Community Input

Annual Community Survey

The city’s annual community survey conducted in March included two questions that relate to this matter. The results indicate a strong desire for increasing the age to 21 for purchasing tobacco products and support for local control, rather than waiting for the state to adopt various laws.
Retailer/Advocate Meeting

A letter was sent to all 31 tobacco license holders and community advocates to attend a meeting to discuss the potential for tobacco regulation changes in the community. There were two opportunities provided on May 22 to discuss the issue. A total of 21 people attended the meetings.

Some representatives from retailers in the community indicated they were not supportive of law changes in Minnetonka. They argued that an unfair advantage would be created for surrounding stores not located in Minnetonka that have not adopted such regulations. It was portrayed that law change is more appropriate at the state level. Some retailers also indicated tobacco can be up to 40% of their overall store sales. It was clarified that the impact of the regulation would only affect a small percentage of this larger percentage, in that the regulation is for a specific age group. The advocates for greater controls countered that the intention of the regulations were aimed at youth prevention and not to create an unfair disadvantage for retailers. They indicated their advocacy would continue in other communities as well.

There was a fair amount of discussion and debate about research that advocates presented to support their work for changing the regulations. Retailers countered with other resources and research. Rather than debate the research, staff recommended the group talk more about the specifics of changing regulations rather than philosophical debates about whether regulatory changes were effective.

Retailers that sell primarily “e-cigarettes” or vaping products indicated that they would be impacted more in that all of their sales are related to tobacco or non-tobacco products. The retailers in that category also stated their products have less harmful ingredients than more traditional tobacco products.

In general, the discussion of the various sides of the issue was helpful for the city to understand the impacts to businesses in the community as well as the effectiveness of reducing consumption of tobacco products by youth. Staff indicated to all parties that they would continue to be informed of the discussion at the city council level.

Discussion Questions

- Does the council wish to consider changing the tobacco regulations in the city?
• *If yes, which regulatory changes should the city consider?*

Should the city council wish to consider further regulation of tobacco products and/or sales, staff would proceed with preparing the city code changes for review and discussion at an upcoming regular city council meeting.

Originated by:

Julie Wischnack, AICP, Community Development Director
City of Minnetonka
Summary of tobacco retailer observational visits, March 2018

This summary provides key information and data on the City of Minnetonka's tobacco retail environment. By bringing education and awareness to concerns about places where tobacco is sold, we can work towards strategies that reduce youth exposure to tobacco products and marketing.

In the City of Minnetonka, observational visits were completed at 30 businesses licensed to sell tobacco in March, in order to understand how tobacco products are being sold in stores.

**Tobacco retailers by store type and location**

- Drug store: 1
- Bar/restaurant: 2
- Hotel: 3
- Grocery store: 6
- Convenience store with or without gas: 15
- E-cigarette only: 3
- Tobacco only: 6
- Liquor store: 2

**Why it is significant:** Researchers define “tobacco swamps” as any area that is double the national average (3+ retailers/1,000 residents). Minnetonka would not be considered a tobacco swamp.

**Advertising, product placement, and price promotions**

- 10 stores have exterior advertisements.
  - Products most often advertised were cigarettes (menthol and non-menthol), chew/snuff/dip/snus and e-cigarette products.
- 16 stores have tobacco ads within 3 feet of the floor.
  - In some cases, there are multiple ads at this level in a store.
- 8 stores have tobacco products placed within 12 inches of toys, candy, or soda machines.
- 50% of stores have price promotions for cigarettes (menthol and non-menthol) inside the store.
- 27% of stores have price promotions for chew/snuff/dip/snus inside the store.
- 20% of stores have price promotions for cigarillos/little cigars inside the store.
- 13% of stores have price promotions for e-cigarette products inside the store.

**Why it is significant:** Even if youth don’t enter the store, they are likely to be exposed to tobacco marketing through outdoor advertising at tobacco retailers. When inside, there is often an abundance of tobacco products, ads, and price promotions. Children and youth are more likely to see ads and products when they are placed near items they are interested in, such as candy and toys, or when they are placed at their sight level. This begins the process of familiarizing children and youth with products, normalizing tobacco. Tobacco point-of-sale advertising encourages youth initiation, causes their progression, as well as discourages cessation.
Flavored products

87% of tobacco retailers sell some type of menthol-flavored tobacco product, and 70% of the stores sell at least one other flavored tobacco product. 87% of the stores sell regular cigarettes and 77% sell menthol cigarettes. 72% of the single cigar products were flavored (menthol or non-menthol).

<table>
<thead>
<tr>
<th>Tobacco product</th>
<th># of stores selling product</th>
<th># of stores selling menthol flavored</th>
<th># of stores selling other flavor (e.g., candy, fruit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes</td>
<td>26</td>
<td>23</td>
<td>NA*</td>
</tr>
<tr>
<td>Cigarillos/little cigars</td>
<td>20</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>Large cigars</td>
<td>11</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Chew, snuff, dip, snus</td>
<td>18</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>E-cigarette products</td>
<td>14</td>
<td>14</td>
<td>14</td>
</tr>
</tbody>
</table>

*Not applicable

Why it is significant: The 2017 Minnesota Youth Tobacco Survey (MYTS) reports that over 60% of students who use tobacco reported using menthol or other flavored products.6 In 2009, the Federal Tobacco Control Act prohibited flavored cigarettes, except menthol, as they were seen as a gateway for children and youth to become regular smokers. Subsequently, the tobacco industry developed other flavored tobacco products that are not cigarettes. Those products are increasingly popular among youth. Fruit, candy, and alcohol-flavored products with brightly colored packaging appeal to youth. The flavors mask the harshness and taste of tobacco. Once youth start using one tobacco product, they are more likely to experiment with others. Restricting flavored products to adult only tobacco shops will reduce youth exposure to these products and prevent youth from starting.

Price

- The price of a pack of cigarettes ranges from $5.69-$12.90 in Minnetonka. The average price is $8.55, yet over half (17) of stores sell them for less than the average.
- 18 stores sell single cigar products.
  - Price range of cigars in a single pack is $0.89-$7.79.
  - 11 stores have single cigarillos/little cigars advertised for less than $1.
  - 13 stores sell single cigars for less than $2.60, the minimum cigar price established in Minneapolis and some other metro cities.

Why it is significant: Teens are especially sensitive to price. Every 10% increase in the price of a tobacco product reduces the number of youth who smoke by 6-7%.8 Because cigar products are sold in smaller packages, they are cheaper. Raising the prices of tobacco products by requiring a minimum pack size or pricing, or restricting the redemption of coupons, will prevent youth from starting.

E-cigarette and e-cigarette products

- Nearly half (14) of the stores sell e-cigarette products.
  - The products are flavored, with the cheapest single disposable e-cigarette being $6.40.
- 13 stores sold e-juice.
  - It was difficult for auditors to determine if e-juice packaging was child resistant, which is required by Minnesota state law.

Why it is significant: Statewide, 1 in 5 high-school students use e-cigarettes, nearly a 50% increase since 2014.9 The 2017 MYTS reports that 64% of students who currently use e-cigarettes reported using menthol or other flavored e-cigarettes in the past 30 days.10 In Minnetonka, 9th and 11th graders now use e-cigarettes at a much greater rate than conventional tobacco, with 9th graders using e-cigarettes three times and 11th graders using two times more than conventional tobacco. Products like e-cigarettes often contain liquid nicotine, which is highly addictive, and can harm adolescent brain development. These products are currently unregulated.

Sources:

Heart disease, cancer, diabetes, and stroke are among the most common causes of illness, disability, and death in the United States. These chronic conditions, and the factors that lead to them, can be more common or severe for certain populations such as minority groups, those experiencing poverty, or having less education. Local demographic information brings awareness to those who may be at risk for chronic disease disparities. Chronic disease data in Hennepin County western suburbs, which includes Minnetonka, is also provided.

Demographics

- Population by Age:
  - 10% or 5,274 people are 0-9 years old
  - 6% or 3,164 people are 10-14 years old
  - 5% or 2,637 people are 15-19 years old
  - 4% or 2,110 people are 20-24 years old
  - 75% or 39,556 people are 25+ years old

- Race/ethnicity:
  - White, alone: 87%
  - Black or African American, alone: 4%
  - Hispanic or Latino: 2%
  - Two or more races: 3%
  - Asian, alone: 4%
  - American Indian or Alaska Native, alone: 0.1%
  - Some other race, alone: 0.4%

- Poverty:
  - Persons below the Federal poverty level: 5%
  - Persons between 100% and 150% of the Federal poverty level: 3%

- Highest level of education:
  - Did not graduate high school: 2%
  - High school graduate: 13%
  - Some college, no degree: 18%
  - Associate degree: 9%
  - Bachelor degree: 36%
  - Graduate/professional degree: 23%

- Income:
  - Per capita personal income: $52,500
  - Median household income: $83,500
### Chronic Disease and Conditions Data (Metro SHAPE 2014 Adult Survey)^*^*

<table>
<thead>
<tr>
<th>Chronic Disease and Conditions</th>
<th>Hennepin County Suburban Western Outer Ring**</th>
<th>Hennepin County Suburban Totals</th>
<th>Hennepin County</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage who have ever had diabetes</td>
<td>6.1% ±2.5</td>
<td>5.9% ±0.9</td>
<td>6.1% ±0.7</td>
</tr>
<tr>
<td>Percentage who have ever had a heart attack</td>
<td>3.0% ±1.6</td>
<td>2.1% ±0.4</td>
<td>2.0% ±0.3</td>
</tr>
<tr>
<td>Percentage who have ever had a stroke</td>
<td>1.5% ±0.8</td>
<td>1.5% ±0.4</td>
<td>1.7% ±0.3</td>
</tr>
<tr>
<td>Percentage who have ever had an angina</td>
<td>3.5% ±1.4</td>
<td>3.1% ±0.5</td>
<td>2.9% ±0.4</td>
</tr>
<tr>
<td>Percentage who have ever had a heart attack, angina, or stroke</td>
<td>5.6% ±1.8</td>
<td>5.0% ±0.7</td>
<td>4.8% ±0.5</td>
</tr>
<tr>
<td>Percentage who have ever had asthma</td>
<td>11.6% ±3.2</td>
<td>10.8% ±1.3</td>
<td>11.8% ±1.0</td>
</tr>
</tbody>
</table>

*The figure above describes percentages for adults aged 25 and older.
**Includes: Deephaven, Excelsior, Greenfield, Greenwood, Independence, Long Lake, Loretto, Maple Plain, Medina, Minnetonka, Minnetonka Beach, Minnetrista, Mound, Orono, Rockford, St. Bonifacius, Shorewood, Spring Park, Tonka Bay, Wayzata, Woodland

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Youth tobacco use is still a problem

- Tobacco kills more Minnesotans than alcohol, homicides, car accidents, AIDS, illegal drugs, and suicide combined.¹
- Nearly all tobacco users start smoking by age 21.²
- 2,500 kids in Minnesota become new daily smokers each year; 102,000 now under age 18 will die prematurely from smoking.³
- The tobacco industry spends over $300,000 a day marketing tobacco, most of which is spent in retail stores—the most important channel for reaching kids.⁴
- Annual health care costs in Hennepin County directly caused by tobacco exceed $585 million in excess medical costs. This does not include the cost of lost productivity and other costs indirectly attributed to smoking.⁵

**Tobacco retailers (Sources: City of Minnetonka; FDA Compliance Checks Inspections database)**

<table>
<thead>
<tr>
<th>Tobacco retailers</th>
<th>30, or 0.6 per 1,000 residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco or e-cigarette shops/lounges</td>
<td>6</td>
</tr>
<tr>
<td>Frequency of local compliance checks</td>
<td>1 time annually</td>
</tr>
<tr>
<td>Retailers with compliance check violations in 2014, 2015, 2016, 2017</td>
<td>4, 1, 2, 6</td>
</tr>
<tr>
<td>Retailers with FDA violations in 2014, 2015, 2016, 2017*</td>
<td>6, 1, 1, 1</td>
</tr>
</tbody>
</table>

* 2014 violations for sale of cigarettes to a minor, failure to check ID, and self-service displays; 2015-2017 violations for sale of cigarettes or e-liquid to a minor.

**Youth tobacco use (Sources: Minnesota Student Survey 2010, 2013, and 2016, Minnetonka & Hopkins School Districts)**

<table>
<thead>
<tr>
<th>Percentage of youth who reported using the following products within the past 30 days:</th>
<th>Minnetonka &amp; Hopkins School Districts, combined</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9th Grade</td>
</tr>
<tr>
<td></td>
<td>2013</td>
</tr>
<tr>
<td>Conventional tobacco*</td>
<td></td>
</tr>
<tr>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Any tobacco use (includes e-cigarettes, hookah)</td>
<td>NA**</td>
</tr>
<tr>
<td>Cigarettes</td>
<td></td>
</tr>
<tr>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Cigars, cigarillos, little cigars</td>
<td></td>
</tr>
<tr>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td>Electronic cigarettes</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>6%</td>
</tr>
<tr>
<td>Flavored tobacco</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>3%</td>
</tr>
<tr>
<td>Menthol cigarette</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>2%</td>
</tr>
<tr>
<td>Of those who use any tobacco, proportion who report using menthol cigarettes</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>24%</td>
</tr>
<tr>
<td>Of those who use any tobacco, proportion who report using flavored tobacco</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>42%</td>
</tr>
</tbody>
</table>

*Conventional tobacco use includes cigarettes, chewing tobacco/snuff/dip, or cigars/cigarillos/little cigars.
**NA = Not Asked.

**Key findings from Minnetonka and Hopkins School District’s MN Student Survey**

- The good news: fewer youth are smoking and using conventional tobacco products.
- The bad news: overall, there is an increase in tobacco use driven by the dramatic increase in e-cigarette use.
- Nearly one in five 11th graders used e-cigarettes in the past 30 days.
- Many Minnetonka and Hopkins youth who use tobacco are using menthol and other flavored tobacco products.
- Flavored products are considered a starter product, and some, such as menthol, are harder to quit.⁶
  - Over two in five tobacco users in grades 9 and 11 use flavored tobacco and one in four tobacco users use menthol.

Sources:
2 Ibid.
4 Ibid.
City of Minnetonka
Tobacco Retailers near Schools

Point Details

- School locations
- Retailer is within 1,000 feet of a school
- Retailer is not near a school
- 1,000 feet parameter around schools

Hennepin County Public Health

ship statewide health improvement partnership

COUNTER TOOLS
ADVANCING PLACE-BASED PUBLIC HEALTH

March 2018
Youth Tobacco Use Rises for First Time in 17 Years

Over 26 percent of high-school students surveyed reported using tobacco products in past 30 days

What's Driving This Trend?

Explosion of E-Cigarette Use
- Nearly one in five high-school students used e-cigarettes in past 30 days
- Nearly a 50 percent increase since 2014
- E-cigarettes have disrupted a 17-year downward trend in youth tobacco use

Why the Rise?

Flavors Appeal to Kids
- Over 60 percent of students who use tobacco reported using menthol or other flavored products

Easy Access
- Nearly a third of high school e-cigarette users report they got their e-cigarettes from retail outlets, about one in five got them from vape shops

Aggressive Marketing
- Most students (88 percent) have seen ads for e-cigarettes – of those who are heavily exposed on social media, nearly 40 percent use e-cigarettes

Changing Landscape
- One in three high-school e-cigarette users reported they had used an e-cigarette to vape marijuana or THC oil/wax

The Good News: Less Youth Smoking
- Fewer than 10 percent of high-school students now report smoking cigarettes – a 70 percent decrease since 2000. Due to high cigarette prices and decades of tobacco prevention efforts, youth cigarette smoking is at an all-time low – but that progress is threatened by the changing tobacco industry.

Proven Strategies to Decrease Tobacco Use:
- Increase the price of tobacco products
- Increase prevention and cessation funding
- Restrict the sale of flavored and menthol tobacco products
- Raise the minimum legal sale age for tobacco products to 21

DEPARTMENT OF HEALTH

2017 Minnesota Youth Tobacco Survey • www.health.mn.gov/tobacco
Tobacco 21 (T21)
Municipalities prohibiting the sale of all tobacco products, including electronic cigarettes, to persons under the age of 21.

Flavored Tobacco
Municipalities prohibiting the sale of all flavored tobacco products, including electronic cigarettes.

Notes
Minneapolis:
Currently exempts menthol, mint and wintergreen flavors. The menthol exemption has been removed, effective August 2018. Adult tobacco stores are allowed to sell all flavors; and liquor stores are allowed to sell menthol, mint and wintergreen.

Robbinsdale:
All flavors except menthol, mint and wintergreen will be restricted. Adult tobacco stores will be exempt from all restrictions.

St. Louis Park:
All flavors except menthol, mint and wintergreen will be restricted (implementation May 2018).

Minimum Cigar Pricing & Packaging
Municipalities prohibiting at minimum: the sale of cigar packages containing less than 5 cigars and/or sets a minimum cigar price of at least $2.10 per cigar in a package of 1-5 cigars with the minimum price determined after any price promotion or discount.

Legend
- Municipalities with the tobacco restriction
- Municipalities where the County is the Tobacco License Authority

Map Published: January, 2018

Map Disclaimer: This map is furnished "AS IS" with no representation as to completeness or accuracy; is furnished with no warranty of any kind; and is not suitable for legal, engineering or surveying purposes. Hennepin County shall not be liable for any damage, injury or loss resulting from this map.
# Tobacco Prevention Policies – Hennepin County and the Surrounding Area
## Cigar minimum price/package, flavored product restriction, Tobacco 21

<table>
<thead>
<tr>
<th>City</th>
<th>Policy(ies)</th>
<th>Adopted</th>
<th>Implemented</th>
<th>Ordinance link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brooklyn Center</td>
<td>Cigar minimum price/package</td>
<td>4/28/14</td>
<td>6/7/14</td>
<td><a href="https://www.brooklyncitymn.gov/departments/police/police-code-of-ordinances">Brooklyn Center City Code</a></td>
</tr>
<tr>
<td><strong>Population: 30,870</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>Tobacco Related Products, Section 23-101</strong></td>
</tr>
<tr>
<td><strong>Population: 88,299</strong></td>
<td>Tobacco 21</td>
<td>11/06/2017</td>
<td>11/30/17</td>
<td>Same</td>
</tr>
<tr>
<td>Edina</td>
<td>Tobacco 21</td>
<td>5/2/17</td>
<td>7/1/17</td>
<td><a href="https://www.cityofedina.org/index.php?option=com_content&amp;view=article&amp;id=367">City of Edina Code of Ordinances</a></td>
</tr>
<tr>
<td><strong>Population: 51,804</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>Chapter 12, Article VI: Sale of Tobacco; Licensing</strong></td>
</tr>
<tr>
<td><strong>Population: 419,952</strong></td>
<td>- Flavored product restriction, excluding menthol, mint and wintergreen (some retailers exempted)</td>
<td></td>
<td></td>
<td><strong>Same</strong></td>
</tr>
<tr>
<td></td>
<td>- Flavored product restriction, including menthol, mint and wintergreen (some retailers exempted)</td>
<td>8/4/17</td>
<td>8/1/18</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Population: 75,452</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>Proposed amendment</strong> – An ordinance amending section 1146 of the city code pertaining to tobacco sales and the regulation of smoking**</td>
</tr>
<tr>
<td>Richfield</td>
<td>Cigar minimum price/package</td>
<td>11/10/15</td>
<td>12/19/15</td>
<td><a href="https://www.richfieldmn.gov/sites/default/files/Richfield_City_Code_4_19_17.pdf">Code of Ordinances of the City of Richfield, MN, Section 1146.-Tobacco</a></td>
</tr>
<tr>
<td><strong>Population: 36,338</strong></td>
<td>Tobacco 21</td>
<td>Approved first reading 5/22/18</td>
<td>If approved, 8/1/18</td>
<td>Proposed amendment – <a href="https://www.richfieldmn.gov/sites/default/files/Richfield_City_Code_4_19_17.pdf">An ordinance amending section 1146 of the city code pertaining to tobacco sales and the regulation of smoking</a></td>
</tr>
<tr>
<td>Robbinsdale</td>
<td>Resolution indicating support for raising legal age for tobacco sales from 18 to 21</td>
<td>11/7/17</td>
<td>NA</td>
<td><a href="https://www.robbinsdalemn.gov/Default.aspx?tabid=5871">City of Robbinsdale, Resolution No. 7604</a></td>
</tr>
<tr>
<td></td>
<td>- Flavored product restriction, excluding menthol, mint and wintergreen (some retailers exempted)</td>
<td></td>
<td></td>
<td><strong>Rev. 2017</strong></td>
</tr>
</tbody>
</table>
# Tobacco Prevention Policies – Hennepin County and the Surrounding Area

## Cigar minimum price/package, flavored product restriction, Tobacco 21

<table>
<thead>
<tr>
<th>City</th>
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<th>Implemented</th>
<th>Ordinance link</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. Louis Park</td>
<td>Tobacco 21</td>
<td>7/17/17</td>
<td>10/1/17</td>
<td>St. Louis Park City Code, <a href="#">Chapter 8, Subdivision X, Tobacco Products and Tobacco Related Devices</a></td>
</tr>
<tr>
<td></td>
<td>Flavored product restriction, excluding menthol, mint and wintergreen (no retailers exempted)</td>
<td>12/4/17</td>
<td>5/1/18</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Surrounding area</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falcon Heights</td>
<td>Flavored product restriction, including menthol, mint and wintergreen (some retailers exempted)</td>
<td>5/9/18</td>
<td>7/1/18</td>
<td>City of Falcon Heights <a href="#">Request for Council Action, Ordinance 18-03 Amending Chapter 14, Article IX Pertaining to Tobacco Regulations</a></td>
</tr>
<tr>
<td>Mendota Heights</td>
<td>Flavored product restriction, excluding menthol, mint and wintergreen (no retailers exempted)</td>
<td>5/15/18</td>
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5/31/18
Statement by Attorney General Tom Miller on Electronic Cigarette Key Facts

“The harm of the combustible cigarette is dramatically greater than the harm of the e-cigarette”

“The harm of the combustible cigarette is dramatically greater than the harm of the e-cigarette. The combustible cigarette is by far the most harmful consumer product known to mankind, killing 480,000 people each year in the United States alone. This is largely due to the many deadly toxins created and released by the combustion. A panel of experts estimates that the e-cigarette is 95% less harmful. Some push back on this study, in part questioning the ability to put an exact number on it. Another estimate is 90-98% less harmful. But whatever number is correct, e-cigarettes are dramatically less harmful than combustible cigarettes.

“There has been an effort to say that combustible cigarettes and e-cigarettes are equally harmful, that their companies are equally evil, and that they should be strongly regulated the same way. This view is incorrect, but it has gotten significant traction. Polling indicates that 32% of Americans believe that combustible cigarettes and e-cigarettes are equally harmful. This means that as many as 13 million adult smokers believe them to be equally harmful, and are very unlikely to switch when switching may save their lives. People making misstatements about e-cigarettes have the best of intentions—to keep kids from being addicted to nicotine through e-cigarettes. But adults misleading kids to get them to do what we want has always been a failed strategy.

“There also is a misconception about the prevalence of teen e-cigarette smoking. According to the National Youth Tobacco Survey, 13% of American high school students smoked an e-cigarette once or more in the last 30 days. This includes regular use and experimental use. As the figure is repeated, the number 13% is used without that qualification. After a few repetitions, people then tend to assume that 13% are regular users. However, regular use—if defined by usage in 20 or more days in the last 30 days—is actually 2%. The numbers should be seen together—13% used e-cigarettes once or more in the last 30 days; 2% have used an e-cigarette 20 or more days in the last 30 days.”

###

Submitted by Tom Madden, owner of E-Cigs
Press release

E-cigarettes around 95% less harmful than tobacco estimates landmark review

First published: 19 August 2015
Part of: Smoking (https://www.gov.uk/government/policies/smoking)

Expert independent review concludes that e-cigarettes have potential to help smokers quit.

An expert independent evidence review (https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update) published today by Public Health England (PHE) concludes that e-cigarettes are significantly less harmful to health than tobacco and have the potential to help smokers quit smoking.

Key findings of the review include:

- the current best estimate is that e-cigarettes are around 95% less harmful than smoking
- nearly half the population (44.8%) don’t realise e-cigarettes are much less harmful than smoking
- there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers

The review, commissioned by PHE and led by Professor Ann McNeill (King’s College London) and Professor Peter Hajek (Queen Mary University of London), suggests that e-cigarettes may be contributing to falling smoking rates among adults and young people. Following the review PHE has published a paper on the implications of the evidence for policy and practice (https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update).

The comprehensive review of the evidence finds that almost all of the 2.6 million adults using e-cigarettes in Great Britain are current or ex-smokers, most of whom are using the devices to help them quit smoking or to prevent them going back to cigarettes. It also provides reassurance that very few adults and young people who have never smoked are becoming regular e-cigarette users (less than 1% in each group).

However, the review raises concerns that increasing numbers of people think e-cigarettes are equally or more harmful than smoking (22.1% in 2015, up from 8.1% in 2013: ASH Smokefree GB survey) or don't know (22.7% in 2015, ASH Smokefree GB survey).

Despite this trend all current evidence finds that e-cigarettes carry a fraction of the risk of smoking.

Emerging evidence suggests some of the highest successful quit rates are now seen among smokers who use an e-cigarette and also receive additional support from their local stop smoking services.

Professor Kevin Fenton, Director of Health and Wellbeing at Public Health England said:

"Smoking remains England’s number one killer and the best thing a smoker can do is to quit completely, now and forever.

E-cigarettes are not completely risk free but when compared to smoking, evidence shows they carry just a fraction of the harm. The problem is people increasingly think they are at least as harmful and this may be keeping millions of smokers from quitting. Local stop smoking services should look to support e-  

Submitted by Tom Madden, owner of E-Cigs

cigarette users in their journey to quitting completely.”

Professor Ann McNeill, King’s College London and independent author of the review, said:

“ There is no evidence that e-cigarettes are undermining England’s falling smoking rates. Instead the evidence consistently finds that e-cigarettes are another tool for stopping smoking and in my view smokers should try vaping and vapers should stop smoking entirely.

E-cigarettes could be a game changer in public health in particular by reducing the enormous health inequalities caused by smoking.”

Professor Peter Hajek, Queen Mary University London and independent author of the review said:

“ My reading of the evidence is that smokers who switch to vaping remove almost all the risks smoking poses to their health. Smokers differ in their needs and I would advise them not to give up on e-cigarettes if they do not like the first one they try. It may take some experimentation with different products and e-liquids to find the right one.”

Professor Linda Bauld, Cancer Research UK’s expert in cancer prevention, said:

“ Fears that e-cigarettes have made smoking seem normal again or even led to people taking up tobacco smoking are not so far being realised based on the evidence assessed by this important independent review. In fact, the overall evidence points to e-cigarettes actually helping people to give up smoking tobacco.”

“ Free Stop Smoking Services remain the most effective way for people to quit but we recognise the potential benefits for e-cigarettes in helping large numbers of people move away from tobacco.

Cancer Research UK is funding more research to deal with the unanswered questions around these products including the longer-term impact.”

Lisa Surtees, acting director at Fresh Smoke Free North East, the first region where all local stop smoking services are actively promoted as e-cigarette friendly, said:

“ Despite making great strides to reduce smoking, tobacco is still our biggest killer. Our region has always kept an open mind towards using electronic cigarettes as we can see the massive potential health benefits from switching.

All of our local NHS Stop Smoking Services now proactively welcome anyone who wants to use these devices as part of their quit attempt and increase their chance of success.”

Ends

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Telephone 020 7654 8400
Out of hours telephone 020 8200 4400

Please contact PHE press office for:


Submitted by Tom Madden, owner of E-Cigs
• interviews with PHE spokespeople or the review’s independent authors

• case studies of stop smoking services who work with e-cigarette users and smokers who have quit completely with a combination of e-cigarettes and attending a service

Notes to Editors:
Public Health England exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health. www.gov.uk/phe (http://www.gov.uk/phe), Twitter: @PHE_uk (https://twitter.com/PHE_uk), Facebook: www.facebook.com/PublicHealthEngland (http://www.facebook.com/PublicHealthEngland)

PHE’s remit letter for 2014 to 2015 requested an update of the evidence around e-cigarettes. PHE commissioned Professors Ann McNeill and Peter Hajek to review the available evidence. The review builds on previous evidence summaries published by PHE in 2014.

The full list of authors of the report are:

• McNeill A, Brose LS, Calder R, Hitchman SC: Institute of Psychiatry, Psychology & Neuroscience, National Addiction Centre, King’s College London and UK Centre for Tobacco & Alcohol Studies

• Hajek P, McRobbie H (Chapters 9 and 10): Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry Queen Mary, University of London and UK Centre for Tobacco & Alcohol Studies

Implications of the evidence for policy and practice: Based on the findings of the evidence review PHE advises that:

• e-cigarettes have the potential to help smokers quit smoking, and the evidence indicates they carry a fraction of the risk of smoking cigarettes but are not risk free

• e-cigarettes potentially offer a wide reach, low-cost intervention to reduce smoking in more deprived groups in society where smoking is elevated, and we want to see this potential fully realised

• there is an opportunity for e-cigarettes to help tackle the high smoking rates among people with mental health problems, particularly in the context of creating smokefree mental health units

• the potential of e-cigarettes to help improve public health depends on the extent to which they can act as a route out of smoking for the country’s eight million tobacco users, without providing a route into smoking for children and non-smokers. Appropriate and proportionate regulation is essential if this goal is to be achieved

• local stop smoking services provide smokers with the best chance of quitting successfully and we want to see them engaging actively with smokers who want to quit with the help of e-cigarettes

• we want to see all health and social care professionals providing accurate advice on the relative risks of smoking and e-cigarette use, and providing effective referral routes into stop smoking services

• the best thing smokers can do for their health is to quit smoking completely and to quit for good. PHE is committed to ensure that smokers have a range of evidence-based, effective tools to help them to quit. We encourage smokers who want to use e-cigarettes as an aid to quit smoking to seek the support of local stop smoking services

• given the potential benefits as quitting aids, PHE looks forward to the arrival on the market of a choice of medicinally regulated products that can be made available to smokers by the NHS on prescription. This will provide assurance on the safety, quality and effectiveness to consumers who want to use these products as quitting aids

Submitted by Tom Madden, owner of E-Cigs
the latest evidence will be considered in the development of the next Tobacco Control Plan for England with a view to maximising the potential of e-cigarettes as a route out of smoking and minimising the risk of their acting as a route into smoking.

From October this year it will be an offence to sell e-cigarettes to anyone under the age of 18 or to buy e-cigarettes for them. The government is consulting on a comprehensive array of regulations (https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products) under the European Tobacco Products Directive.

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E-cigarettes: an evidence update
A report commissioned by Public Health England

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About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Foreword

The role and impact of electronic cigarettes has been one of the great debates in public health in recent years and we commissioned this independent review of the latest evidence to ensure that practitioners, policy makers and, most importantly of all, the public have the best evidence available.

Many people think the risks of e-cigarettes are the same as smoking tobacco and this report clarifies the truth of this.

In a nutshell, best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes, and when supported by a smoking cessation service, help most smokers to quit tobacco altogether.

We believe this review will prove a valuable resource, explaining the relative risks and benefits of e-cigarettes, in terms of harm reduction when compared with cigarettes and as an aid to quitting.

We will continue to monitor the position and will add to the evidence base and guidance going forward.

Duncan Selbie, Chief Executive, PHE
Key messages

1. Smokers who have tried other methods of quitting without success could be encouraged to try e-cigarettes (EC) to stop smoking and stop smoking services should support smokers using EC to quit by offering them behavioural support.

2. Encouraging smokers who cannot or do not want to stop smoking to switch to EC could help reduce smoking related disease, death and health inequalities.

3. There is no evidence that EC are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it. Despite some experimentation with EC among never smokers, EC are attracting very few people who have never smoked into regular EC use.

4. Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. More research is needed in this area.

5. When used as intended, EC pose no risk of nicotine poisoning to users, but e-liquids should be in ‘childproof’ packaging. The accuracy of nicotine content labelling currently raises no major concerns.

6. There has been an overall shift towards the inaccurate perception of EC being as harmful as cigarettes over the last year in contrast to the current expert estimate that using EC is around 95% safer than smoking.

7. Whilst protecting non-smoking children and ensuring the products on the market are as safe and effective as possible are clearly important goals, new regulations currently planned should also maximise the public health opportunities of EC.

8. Continued vigilance and research in this area are needed.
Executive summary

Following two previous reports produced for Public Health England (PHE) on e-cigarettes (EC) in 2014, this report updates and expands on the evidence of the implications of EC for public health. It covers the EC policy framework, the prevalence of EC use, knowledge and attitudes towards EC, impact of EC use on smoking behaviour, as well as examining recent safety issues and nicotine content, emissions and delivery. Two literature reviews were carried out to update the evidence base since the 2014 reports and recent survey data from England were assessed.

EC use battery power to heat an element to disperse a solution of propylene glycol or glycerine, water, flavouring and usually nicotine, resulting in an aerosol that can be inhaled by the user (commonly termed vapour). EC do not contain tobacco, do not create smoke and do not rely on combustion. There is substantial heterogeneity between different types of EC on the market (such as cigalikes and tank models). Acknowledging that the evidence base on overall and relative risks of EC in comparison with smoking was still developing, experts recently identified them as having around 4% of the relative harm of cigarettes overall (including social harm) and 5% of the harm to users.

In England, EC first appeared on the market within the last 10 years and around 5% of the population report currently using them, the vast majority of these smokers or recent ex-smokers. Whilst there is some experimentation among never smokers, regular use among never smokers is rare. Cigarette smoking among youth and adults has continued to decline and there is no current evidence in England that EC are renormalising smoking or increasing smoking uptake. Instead, the evidence reviewed in this report point in the direction of an association between greater uptake of EC and reduced smoking, with emerging evidence that EC can be effective cessation and reduction aids.

Regulations have changed little in England since the previous PHE reports with EC being currently governed by general product safety regulations which do not require products to be tested before being put on the market. However, advertising of EC is now governed by a voluntary agreement and measures are being introduced to protect children from accessing EC from retailers. Manufacturers can apply for a medicinal licence through the Medicines and Healthcare products Regulatory Agency (MHRA) and from 2016, any EC not licensed by the MHRA will be governed by the revised European Union Tobacco Products Directive (TPD).

A summary of the main findings and policy implications from the data chapters now follows.
Summary of Chapter 3: UK policy framework

The revised TPD will introduce new regulations for EC or refill containers which are not licensed by the MHRA. The cap on nicotine concentrations introduced by the TPD will take high nicotine EC and refill liquids off the market, potentially affecting heavier smokers seeking higher nicotine delivery products.

The fact that no licensed EC are yet on the market suggests that the licensing route to market is not commercially attractive. The absence of non-tobacco industry products going through the MHRA licensing process suggests that the process is inadvertently favouring larger manufacturers including the tobacco industry, which is likely to inhibit innovation in the prescription market.

Policy implications

○ From May 2016, following the introduction of the revised TPD, ECs will be more strictly regulated. As detailed elsewhere in the report, the information we present does not indicate widespread problems as a result of EC. Hence, the current regulatory structure appears broadly to have worked well although protecting non-smoking children and ensuring the products on the market are as safe and effective as possible are clearly important goals. New regulations currently planned should be implemented to maximise the benefits of EC whilst minimising these risks.

○ An assessment of the impact of the TPD regulations on the UK EC market will be integral to its implementation. This should include the degree to which the availability of safe and effective products might be restricted.

○ Much of England’s strategy of tobacco harm reduction is predicated on the availability of medicinally licensed products that smokers want to use. Licensed ECs are yet to appear. A review of the MHRA EC licensing process therefore seems appropriate, including manufacturers’ costs, and potential impact. This could include a requirement for MHRA to adapt the processes and their costs to enable smaller manufacturers to apply, and to speed up the licensing process. The review could also assess potential demand for the EC prescription market and what types of products would be most appropriate to meet that demand.

Summary of Chapter 4: Prevalence of e-cigarette use in England/Great Britain

Adults: Around one in 20 adults in England (and Great Britain) use EC. Current EC users are almost exclusively smokers (~60%) or ex-smokers (~40%), that is smokers who now use EC and have stopped smoking altogether. EC use among long-term ex-smokers is considerably lower than among recent ex-smokers. Current EC use among
never smokers is very low, estimated to be 0.2%. The prevalence of EC use plateaued between 2013-14, but appeared to be increasing again in 2015.

**Youth:** Regular EC use among youth is rare with around 2% using at least monthly and 0.5% weekly. EC use among young people remains lower than among adults: a minority of British youth report having tried EC (~13%). Whilst there was some experimentation with EC among never smoking youth, prevalence of use (at least monthly) among never smokers is 0.3% or less.

Overall, the adult and youth data suggest that, despite some experimentation with EC among never smokers, EC are attracting few people who have never smoked into regular use.

**Trends in EC use and smoking:** Since EC were introduced to the market, cigarette smoking among adults and youth has declined. In adults, overall nicotine use has also declined (not assessed for youth). These findings, to date, suggest that the advent of EC is not undermining, and may even be contributing to, the long-term decline in cigarette smoking.

**Policy implications**

- Trends in EC use among youth and adults should continue to be monitored using standardised definitions of use.

- Given that around two-thirds of EC users also smoke, data are needed on the natural trajectory of ‘dual use’, ie whether dual use is more likely to lead to smoking cessation later or to sustain smoking (see also Chapter 6).

- As per existing NICE guidance, all smokers should be supported to stop smoking completely, including ‘dual users’ who smoke and use EC.

**Summary of Chapter 5: Smoking, e-cigarettes and inequalities**

Smoking is increasingly concentrated in disadvantaged groups who tend to be more dependent. EC potentially offer a wide reach, low-cost intervention to reduce smoking and improve health in disadvantaged groups.

Some health trusts and prisons have banned the use of EC which may disproportionately affect more disadvantaged smokers.
Policy implications

- Consideration could be given to a proactive strategy to encourage disadvantaged smokers to quit smoking as quickly as possible including the use of EC, where appropriate, to help reduce health inequalities caused by smoking.

- EC should not routinely be treated in the same way as smoking. It is not appropriate to prohibit EC use in health trusts and prisons as part of smokefree policies unless there is a strong rationale to do so.

Summary of Chapter 6: E-cigarettes and smoking behaviour

Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. It is not known whether current EC products are more or less effective than licensed stop smoking medications, but they are much more popular, thereby providing an opportunity to expand the number of smokers stopping successfully. Some English stop smoking services and practitioners support the use of EC in quit attempts and provide behavioural support for EC users trying to quit smoking; self-reported quit rates are at least comparable to other treatments. The evidence on EC used alongside smoking on subsequent quitting of smoking is mixed.

Policy implications

- Smokers who have tried other methods of quitting without success could be encouraged to try EC to stop smoking and stop smoking services should support smokers using EC to quit by offering them behavioural support.

- Research should be commissioned in this area including:
  - longitudinal research on the use of EC, including smokers who have not used EC at the beginning of the study
  - the effects of using EC while smoking (temporary abstinence, cutting down) on quitting, and the effects of EC use among ex-smokers on relapse
  - research to clarify the factors that i) help smokers using EC to quit smoking and ii) deter smokers using EC from quitting smoking, including different EC products/types and frequency of use and the addition of behavioural support, and how EC compare with other methods of quitting which have a strong evidence base

- It would be helpful if emerging evidence on EC (including different types of EC) and how to use EC safely and effectively could be communicated to users and health professionals to maximise chances of successfully quitting smoking.
Summary of Chapter 7: Reasons for use and discontinuation

A number of surveys in different populations provide evidence that reducing the harm from smoking (such as through cutting down on their cigarette consumption or helping with withdrawal during temporary abstinence) and the desire to quit smoking cigarettes are the most important reasons for using EC. Curiosity appears to play a major role in experimentation. Most trial of EC does not lead to regular use and while there is less evidence on why trial does not become regular use, it appears that trial due to curiosity is less likely to lead to regular use than trial for reasons such as stopping smoking or reducing harm. Dissatisfaction with products and safety concerns may deter continued EC use.

Policy implications

- Smokers frequently state that they are using EC to give up smoking. They should therefore be provided with advice and support to encourage them to quit smoking completely.

- Other reasons for use include reducing the harm from smoking and such efforts should be supported but with a long-term goal of stopping smoking completely.

Summary of Chapter 8: Harm perceptions

Although the majority of adults and youth still correctly perceive EC to be less harmful than tobacco cigarettes, there has been an overall shift towards the inaccurate perception of EC being at least as harmful as cigarettes over the last year, for both groups. Intriguingly, there is also some evidence that people believe EC to be less harmful than medicinal nicotine replacement therapy (NRT).

Policy implications

- Clear and accurate information on relative harm of nicotine, EC and tobacco cigarettes is needed urgently (see also Chapter 10).

- Research is needed to explore how health perceptions of EC are developed, in relation to tobacco cigarettes and NRT, and how they can be influenced.

Summary of Chapter 9: E-cigarettes, nicotine content and delivery

The accuracy of labelling of nicotine content currently raises no major concerns. Poorly labelled e-liquid and e-cartridges mostly contained less nicotine than declared. EC used
as intended pose no risk of nicotine poisoning to users. However, e-liquids should be in ‘childproof’ packaging.

Duration and frequency of puffs and mechanical characteristics of EC play a major role in determining nicotine content in vapour. Across the middle range of nicotine levels, in machine tests using a standard puffing schedule, nicotine content of e-liquid is related to nicotine content in vapour only weakly. EC use releases negligible levels of nicotine into ambient air with no identified health risks to bystanders. Use of a cigalike EC can increase blood nicotine levels by around 5 ng/ml within five minutes of use. This is comparable to delivery from oral NRT. Experienced EC users using the tank EC can achieve much higher blood nicotine levels over a longer duration, similar to those associated with smoking. The speed of nicotine absorption is generally slower than from cigarettes but faster than from NRT.

Policy implications

- General labelling of the strength of e-liquids, along the lines used for example indicating coffee strength, provides sufficient guidance to consumers.
- Regulatory interventions should ensure optimal product safety but make sure EC are not regulated more strictly than cigarettes and can continue to evolve and improve their competitiveness against cigarettes.

Summary of Chapter 10: Safety of e-cigarettes in light of new evidence

Two recent worldwide media headlines asserted that EC use is dangerous. These were based on misinterpreted research findings. A high level of formaldehyde was found when e-liquid was over-heated to levels unpalatable to EC users, but there is no indication that EC users are exposed to dangerous levels of aldehydes; stressed mice poisoned with very high levels of nicotine twice daily for two weeks were more likely to lose weight and die when exposed to bacteria and viruses, but this has no relevance for human EC users. The ongoing negative media campaigns are a plausible explanation for the change in the perception of EC safety (see Chapter 8).

None of the studies reviewed above alter the conclusion of Professor Britton’s 2014 review for PHE. While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger. It has been previously estimated that EC are around 95% safer than smoking. This appears to remain a reasonable estimate.
Policy implications

- There is a need to publicise the current best estimate that using EC is around 95% safer than smoking.

- Encouraging smokers who cannot or do not want to stop smoking to switch to EC could be adopted as one of the key strategies to reduce smoking related disease and death.

Summary of Chapter 11: Other health and safety concerns

There is a risk of fire from the electrical elements of EC and a risk of poisoning from ingestion of e-liquids. These risks appear to be comparable to similar electrical goods and potentially poisonous household substances.

Policy implications

- The risks from fire or poisoning could be controlled through standard regulations for similar types of products, such as childproof containers (contained within the TPD but which are now emerging as an industry standard) and instructions about the importance of using the correct charger.

- Current products should comply with current British Standard operating standards.

- Records of EC incidents could be systematically recorded by fire services.

Summary of Chapter 12: International perspectives

Although EC use may be lower in countries with more restrictions, these restrictions have not prevented EC use. Overall, use is highest among current smokers, with low numbers of non-smokers reporting ever use. Current use of EC in other countries is associated with being a smoker or ex-smoker, similar to the findings in the UK. EC use is frequently misreported with experimentation presented as regular use. Increases in youth EC trial and use are associated with decreases in smoking prevalence in all countries, with the exception of one study from Poland.

Policy implications

- Future research should continue to monitor and evaluate whether different EC policies across countries are related to EC use and to smoking cessation and smoking prevalence.

- Consistent and agreed measures of trial, occasional and regular EC use among youth and adults are urgently needed to aid comparability.
1. Introduction

Despite the decline in smoking prevalence observed over the last few decades, there remain over eight million smokers in England. Most of these are from manual and more disadvantaged groups in society, including those with mental health problems, on low income, the unemployed and offenders. In some such population groups, the proportion who smoke is over two or three times higher than that in the general population, a level of smoking observed in the general population over 40 years ago. For those who continue to smoke regularly, much of their lives will be of lower quality and spent in poorer health than those who don’t smoke, and they will have a one in two chance of dying prematurely, by an average of 10 years, as a direct result of their smoking. Smoking is therefore the largest single contributor to health inequalities as well as remaining the largest single cause of preventable mortality and morbidity in England.

Moving forward, it is therefore important to maintain and enhance England’s comprehensive tobacco control strategy in order to motivate and support all smokers in society to stop smoking as quickly as possible, and prevent the recruitment of new smokers. Harm reduction guidance, published by the National Institute for Health and Care Excellence in England in 2013, recognised that some smokers struggled to quit abruptly and that cigarettes were a lethal delivery system for nicotine [1]; it is widely accepted that most smokers smoke for the nicotine but die from the other smoke constituents. Harm reduction has been identified as one of the more promising policy options to reduce smoking induced inequalities in health [2]. All experts agree that a well-resourced comprehensive strategy, involving cessation, prevention and harm reduction should make the goal of a smoke-free society in England quickly achievable.

However, the advent of electronic cigarettes (EC) over recent years has caused controversy. In 1991, Professor Michael Russell, a leading English smoking cessation expert from the Institute of Psychiatry, argued that "it was not so much the efficacy of new nicotine delivery systems as temporary aids to cessation, but their potential as long-term alternatives to tobacco that makes the virtual elimination of tobacco a realistic future target", and he recommended that “tobacco should be rapidly replaced by cleaner, less harmful, sources of nicotine” [3]. Professor Russell was one of the first to recognise the critical role that nicotine played in tobacco use and he identified that whilst there were good ethical and moral reasons not to promote nicotine addiction in society, the harm caused by nicotine was orders of magnitude lower than the harms caused by cigarette smoke. Professor Russell was also a pioneer of new treatments for smoking cessation, in particular, nicotine replacement therapies (NRT). Since then, the number of NRT products has proliferated such that there are now several different delivery routes and modes and countless different dosages and flavours. However, even with a relaxation of the licensing restrictions which increased their accessibility, NRT products have never become popular as an alternative to smoking.
In 2004, the first EC was marketed in China, and EC started to appear in England in 2006/7. The subsequent three years saw a rapid rise in their use. Whilst Professor Russell died in 2009, predating the arrival of these products in England, proponents of EC similarly recognised their potential to contribute towards making a smoke-free society more rapidly achievable [4]. Those against EC, however, believed that they were at best a distraction, at worst a means of undoing decades of progress in reducing smoking [5].

Any new tobacco control strategy for England must therefore incorporate a nicotine strategy, which should include recommendations and an appropriate regulatory framework for EC. This report attempts to inform that strategy by reviewing recent evidence and surveys relating to the use of EC and how they impact smoking behaviour. The focus is England, although we also draw on evidence from elsewhere in the UK and internationally.

Description of e-cigarettes

EC use battery power to heat an element to disperse a solution that usually contains nicotine. The dispersion of the solution leads to the creation of an aerosol that can be inhaled by the user. The heated solution typically contains propylene glycol or glycerine, water, nicotine, and flavourings. EC do not contain tobacco, do not create smoke and do not rely on combustion. Whilst EC ‘smoke’ is technically an aerosol, throughout this report we use the established terminology of vapour, vaping and vaper.

There is substantial heterogeneity between different types of EC and the speed with which they are evolving making them difficult to categorise. ECs available in England can be classified into three basic types: (1) EC that are either (a) disposable or (b) use pre-filled cartridges that need to be replaced once emptied. We will refer to these using their most common name, ‘cigalikes’. Most cigalikes resemble cigarettes, although it is important to note that some do not; (2) EC that are designed to be refilled with liquid by the user. We will refer to these using their common name ‘tank systems’. (3) Finally, some EC products, mostly tank systems that allow users to regulate the power delivery from the batteries to the atomizer. These we refer to as mods or ‘variable power EC’.

In the UK, the most prominent brands of cigalikes are now owned by the tobacco industry. To the authors’ knowledge only one tobacco company sells a tank model in the UK, with the rest of the market consisting of non-tobacco industry companies. Some products have also been introduced by the tobacco industry that could be referred to as ‘hybrids’ such that they use pre-filled nicotine cartridges but look like tank models. Additionally, a few EC that are similar to cigalikes in function are also sold that use cartridges that can be refilled, and some users will puncture holes/remove the ends of cigalike cartridges to refill them instead of buying new cartridges.
Studies have validated the ability of EC to deliver nicotine to the user. Blood plasma nicotine concentrations increase after inhalation of EC aerosol [6, 7], and cotinine, a biomarker for nicotine, has been detected in the saliva of EC users [8, 9]. Information about the overall and relative risks of EC in comparison with smoking has also been developing. Using a multi-criteria decision analysis (MCDA) model, the Independent Scientific Committee on Drugs selected experts from several different countries to compare a variety of nicotine products on variables of harm identified by the UK Advisory Council on the Misuse of Drugs [10]. EC were identified as having 4% of the relative harm of cigarettes overall (including social harm) and 5% of the harm to users, although it was acknowledged that there was a lack of hard evidence for the harms of most of the nicotine products on most of the criteria.

Structure of report

Following Chapter 2 on methodology, Chapter 3 assesses the current and future policy framework for EC. Chapters 4 and 5 assess trial and usage in England among adults and youth as well as different socioeconomic groups where evidence permits. Chapter 6 examines the evidence for the impact of EC on smoking behaviour including the use of EC in quit attempts as well as alongside smoking. Chapter 7 assesses reasons for trying and discontinuing EC and Chapter 8 perceptions of relative harms of EC and smoking. Chapter 9 discusses nicotine content and emissions of EC as well as nicotine uptake in users. Chapters 10 and 11 assess different aspects of safety drawing on recent published studies as well as national statistics. Chapter 12 examines international perspectives of EC policies and usage.
2. Methodology

For the present report we have included: (1) a synthesis of recent evidence (published since the two PHE 2014 EC reports) with the earlier evidence in the earlier PHE reports drawing on both national and international literature; and (2) where feasible, an analysis of any relevant national unpublished data available to PHE, KCL and partner organisations from England, Great Britain or the UK, including: i) Smoking Toolkit Study (UCL); ii) Action on Smoking and Health (ASH) Smokefree GB (adult and youth) surveys; iii) Internet Cohort GB survey; iv) Smokers’ surveys 2014 commissioned by ASH from YouGov; and v) the International Tobacco Control (ITC) policy evaluation project.

For the evidence review (1) above, given the short timeframe for this report, a systematic review of the literature was not possible. However, we followed systematic review methods where possible and searched PubMed for studies from 2014 onwards using the following search terms: ((("2014/01/01"[Date - Publication] : "3000"[Date - Publication])) AND (((((((e-cigarette) OR Electronic cigarettes) OR e-cig*) OR electronic cig*) OR ENDS) OR electronic nicotine delivery systems) OR electronic nicotine delivery system) OR ((Nicotine) AND Vap*))).

The term ENDS was used as some studies have referred to e-cigarettes as Electronic Nicotine Delivery Systems (ENDS). This search returned 3,452 records. The titles of all records were screened and 798 articles were identified as potentially relevant to the report. The full papers of abstracts considered relevant by two reviewers were retrieved and reviewed as identified in Appendix A.

We wanted to ensure we included the most up-to-date information on EC use and impact in England. In order to do this we used routine national data sources to retrieve measures of EC use prevalence, fires, poisoning and other adverse events. Specifically for (2) above, we assessed, in addition to published papers, unpublished national survey data relevant to this work, identifying where findings are peer reviewed/published. The methods of the surveys that we have accessed are as follows:

Smoking Toolkit Study (STS, University College London)

The STS consists of monthly cross-sectional household interviews of adults (aged 16 and over) in England that has been running since November 2006. Each month involves a new nationally representative sample of about 1,800 respondents. Since 2009, all respondents who smoked in the last year have been asked questions on EC; since November 2013 all respondents complete questions on EC. For more information, see www.smokinginengland.info
ASH Smokefree GB (adult and youth) surveys

**Adult:** ASH has conducted **cross-sectional internet surveys** of adults (aged 18 and over) in Great Britain (GB) since 2007. These surveys cover a wide range of tobacco control policies and smoking behaviour and are carried out on ~12,000 adults each year. Questions on EC were included first in 2010, with new EC questions added in each subsequent survey (2012, 2013, 2014, 2015).

**Youth:** ASH has conducted **cross-sectional surveys of British youth** (aged 11-18) three times to date (2013, 2014, 2015). Younger participants are recruited, **online,** through the adult YouGov participants with older participants contacted **directly.** It has been used to give a more contemporaneous and comprehensive snapshot of youth attitudes towards smoking and their behaviours (and includes a breakdown of trial and more prolonged use of EC) than UK Government national surveys have been able to.

**Internet Cohort GB survey (King’s College London, University College London)**

A unique longitudinal internet survey of smokers and recent ex-smokers in GB (aged 16 and over) surveyed first in 2012 and then again in December 2013 and 2014. Of the 5,000 respondents in the initial sample, 1,031 respondents (20.7%) used EC at all at the time of the survey in 2012. The prevalence of past-year smoking in this baseline sample was similar to that identified through the STS (which, as stated above, recruited representative samples of the population in England), over a comparable period.

In 2013, 2,182 of the 5,000 were followed up and in 2014, 1,519 were followed up. EC use was 32.8% (n=717) in 2013 and 33.2% (n=505) in 2014. The study sample was recruited from an online panel managed by Ipsos MORI who were invited by email to participate in an online study and were screened for smoking status. The survey included questions on smoking and quitting behaviour and stress and general health as well as detailed questions on EC usage.

**ASH GB Smokers’ survey 2014**

This is an online survey carried out by YouGov for ASH specifically to assess more detailed attitudinal measures concerning nicotine containing products. The 2014 survey involved 1,203 adult smokers and recent ex-smokers selected from the ASH Smokefree adult survey to have roughly equal numbers of smokers who had (n=510) and had not (n=470) tried EC and a smaller number of ex-smokers who had tried EC (n=223).

**ITC Policy Evaluation project**

A longitudinal cohort survey of smokers and recent ex-smokers (aged 18 and over), surveyed by telephone and internet. The ITC UK survey started in 2002 and surveys
have been conducted approximately annually since that time. Probability sampling methods are utilised through telephone surveys using random digit dialling, but in more recent survey waves participants could opt to complete surveys on the internet. The ITC UK study benefits from parallel cohort surveys in Australia, Canada and the United States, enabling comparisons across countries with different tobacco and EC policies. Each wave of the survey includes approximately 1,500 UK respondents. EC questions were added to the last three waves. Data from the last wave (in 2014) were not available for inclusion in this report, but published papers from earlier waves are included. More details of the methodology are available at www.itcproject.org
3. UK policy framework

E-cigarette regulations in England: current and proposed

Regulations have changed little in England since the previous PHE reports. Currently EC are governed by general product safety regulations (UK and EU) which do not require that the products be tested before being put on the market. However, manufacturers can apply for a medicinal licence through the Medicines and Healthcare products Regulatory Agency (MHRA) [11] and from next year any EC not licensed by the MHRA will be governed by the revised European Union Tobacco Products Directive (TPD)[12]. Both the MHRA licensing and the TPD regulatory routes are described below. The TPD regulations are extensive and will have a significant impact on the EC market.

One change from the previous PHE report, which was introduced by the Advertising Standards Authority in October 2014, is that until the TPD comes into force, advertising of EC is governed by a voluntary agreement. This agreement indicates, inter alia, that advertising must be socially responsible, not 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, make clear that the product is an EC and not a tobacco product, not undermine quit tobacco messaging, and must not contain health or medicinal claims unless the product is licensed. These guidelines will be reviewed in October 2015 and when more is known about the application of the TPD the role of the Code will be clarified.

A further recent change is the introduction of measures to protect children from EC: an age of sale lower limit of 18 years of age (in line with tobacco cigarettes) is being introduced and a ban on proxy purchasing of EC.

EU Tobacco Products Directive (TPD) route

The revised TPD will introduce new regulations for EC or refill containers (referred to below as products) which are not licensed by the MHRA. We have listed these in detail below because they are wide-ranging and will impose a significant step change for manufacturers, importers and Member State (MS) authorities:

- **notification**: Manufacturers must inform competent authorities of the MS six months before placing new products on the market. For those already on the market by 20 May 2016, the notification needs to be submitted within six months of this date. Each substantial modification of the product requires a new notification
- **reporting obligations** (for which manufacturers/importers might be charged) include:
• details (including quantification) on all the ingredients contained in, and emissions resulting from the use of, the product, by brand name
• toxicological data regarding ingredients and emissions, including when heated, with reference particularly to health of consumers when inhaled including any addictive effect
• information on nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions
• description of the product components, including where appropriate opening and refill mechanisms of product or refill containers
• description of the production process and declaration that it conforms with the TPD
• declaration that manufacturer/importer bear full responsibility for the quality and safety of the product when placed on market and used under normal or reasonably foreseeable conditions

• **nicotine-containing liquid** restrictions:
  • EC must not contain more than 20 mg/ml of nicotine
  • nicotine-containing liquid must be in dedicated refill containers not exceeding 10ml volume, and cartridges or tanks do not exceed a volume of 2ml
  • additives are not prohibited but the nicotine-containing liquids cannot contain additives that are otherwise prohibited by the other Articles in the TPD
  • high purity ingredients must be used and substances other than those declared should only be present in trace quantities which are unavoidable during manufacture
  • ingredients must not pose a risk to health either when heated or not heated
  • nicotine doses must be delivered at consistent levels under normal conditions of use
• products are required to be child and tamper proof, protected against breakage and leakage and have a mechanism that ensures refilling without leakage
• products must include a leaflet with information on:
  • instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers
  • contra-indications
  • warnings for specific groups
  • possible adverse effects
  • addictiveness and toxicity
  • contact details of manufacturer/importer and a legal or natural contact person within the EU

• **outside packaging of products** must include:
  • list of all ingredients contained in the product in descending order of the weight
  • an indication of the nicotine content and delivery per dose
  • batch number
  • recommendation to keep the product out of reach of children
• no promotional element or feature or such that suggests the product is harm reducing (or other features described in Article 13 of the Directive)

• health warnings:
  • One of the following must be shown:
    ▪ ‘This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers’ or
    ▪ ‘This product contains nicotine which is a highly addictive substance’
  • Member States shall determine which health warning to use
  • health warnings must comply with regulations concerning specific provisions on position and size

• cross-border advertising and promotion, sponsorship etc of products will be prohibited (unless trade information)

• cross-border sales of products may be prohibited or subject to a registration scheme

• manufacturers/importers of products to submit an annual submission on their products to competent authorities in MS which should include:
  • comprehensive data on sales volumes, by brand name and product type
  • information on preferences of various consumer groups, including young people, non-smokers and the main types of current users
  • mode of sale of the products
  • executive summaries of any market surveys carried out in respect of the above, including an English translation thereof products

• MS shall monitor the market developments concerning products, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers. This information to be made publicly available on a website although the need to protect trade secrets should be taken into account

• MS should on request, make all information relevant to this Article available to the Commission and other Member States who will respect confidential information

• MS shall require manufacturers, importers and distributors of products to establish and maintain a system for collecting information about all of the suspected adverse effects on human health

• corrective action should be taken immediately if economic operators consider or have reason to believe that products are not safe or of good quality or not conforming to the Directive, ensuring conformity or withdrawal or recall from the market. In such cases, operators are required to inform immediately market surveillance authorities of the MS giving details of risk to human health and safety, corrective action taken and results of such corrective action. MS may request additional information from the economic operators on safety and quality aspects or any adverse effect of products

• the Commission will submit a report to the European Parliament and the Council on potential risks to public health by 20 May 2016 and as appropriate thereafter
where a competent authority believes specific products could pose a serious risk to human health it should take appropriate provisional measures, immediately inform Commission and competent authorities of other MS of measures taken and communicate any supporting data. The Commission will determine whether provisional measure is justified informing the MS concerned of its conclusions to enable appropriate follow-up measures to be taken

- the Commission can extend any prohibition to other MS if such an extension is justified and proportionate
- the Commission is empowered to adapt wording of health warnings and ensure factual
- the Commission will give a common format for notification and technical standard for the refill mechanism outlined above

The exact date of implementation in England is yet to be specified but full compliance is likely to be necessary by 2017. One UK company, Totally Wicked, has challenged the UK’s intention to transpose the Directive into UK law. The case rests on whether the TPD was properly made and has been referred to the European Court of Justice for a preliminary ruling. This is expected in late 2015/early 2016.

During implementation, government will need to undertake an impact assessment for the UK market on the final proposals as set out in the Directive and this will be consulted upon. The TPD certainly raises the barrier for bringing EC products to market or continuing to market existing products, and will undoubtedly constrain the EC market. Understanding any unintended consequences of the EU TPD as well as intended ones will be important. For example, the cap on nicotine concentrations introduced by the TPD will take high nicotine EC and refill liquids off the market, potentially affecting heavier smokers seeking higher nicotine delivery products.

Medicines and Healthcare products Regulatory Agency (MHRA) licensing route

Following a consultation in 2010, the UK MHRA introduced a mechanism for the licensing of EC and other nicotine containing products as medicines requiring medicinal purity and delivery standards. Such a licence would be required for products to be prescribed on the NHS. As with other licensed nicotine containing products, advertising controls would be applied and VAT of 5% would be imposed.

The licensing process has been described by the MHRA [11]. This regulation was described initially as ‘light touch’ recognising a product that delivered nicotine could be effectively used for harm reduction or cessation purposes, thus implying a relatively speedy route to licensing. This was subsequently changed to ‘right touch’ as it was apparent that the process was more lengthy and costly than originally envisaged. We understand that the MHRA estimated costs for a one-off application of between £252K and £390K with an annually recurring cost of between £65K and £249K, for each
product. This does not include the costs of making manufacturing facilities and products MHRA compliant – estimated at several million pounds.

At the time of writing one non-EC nicotine inhaler product, Voke, developed by Kind Consumer, and to be marketed by British American Tobacco (BAT), had received a medicinal licence, although it is not yet being marketed in England. A further BAT product (an EC) is currently going through the application process. Other EC products are currently in the pipeline with the MHRA but it is not clear at what stage the applications are or what types of products, eg cigalikes or tank models, are involved.

The absence of a licensed product, five years after the MHRA’s consultation took place, suggests that this route to market is not commercially attractive. The fact that the only product at the application stage is a BAT product suggests that the process is very resource intensive. As well as cost, other possible reasons include complexity, a lack of desire to engage with medicinal licensing or the MHRA, the entrepreneurial nature of the EC manufacturers and a possible lack of perceived benefits to acquiring a licence. This could be problematic when the EU TPD is implemented, which is likely to constrain the over-the-counter market. Additionally, having a diverse range of EC on prescription is likely to be beneficial (similar to nicotine replacement tobacco (NRT) products – when new products are introduced, evidence suggests that they do not cannibalise the existing NRT product market but instead expand the use of medications). This means that small manufacturers, particularly non-tobacco industry manufacturers, who may be producing a greater variety or more satisfying EC, will not compete with larger corporations such as the tobacco industry in the prescriptions market. There are several consequences of this which should be explored. These could include an inhibition of innovation and damage public health. Alternatively, given the demand for prescribed EC products is as yet unknown, particularly in the population groups where smoking prevalence is elevated, the medicinal route may not impact public health. The appeal of EC may rest in the fact that they are not medicines. A review of the MHRA licensing process for EC, and its likely impact, is recommended.

Summary of findings

The revised TPD will introduce new regulations for EC or refill containers which are not licensed by the MHRA. The cap on nicotine concentrations introduced by the TPD will take high nicotine EC and refill liquids off the market, potentially affecting heavier smokers seeking higher nicotine delivery products.

The fact that no licensed EC are yet on the market suggests that the licensing route to market is not commercially attractive. The absence of non-tobacco industry products going through the MHRA licensing process suggests that the process is inadvertently favouring larger manufacturers including the tobacco industry, which is likely to inhibit innovation in the prescription market.
Policy implications

- From May 2016, following the introduction of the revised TPD, ECs will be more strictly regulated. As detailed elsewhere in the report, the information we present does not indicate widespread problems as a result of EC. Hence, the current regulatory structure appears broadly to have worked well although protecting non-smoking children and ensuring the products on the market are as safe and effective as possible are clearly important goals. New regulations currently planned should be implemented to maximise the benefits of EC whilst minimising these risks.

- An assessment of the impact of the TPD regulations on the UK EC market will be integral to its implementation. This should include the degree to which the availability of safe and effective products might be restricted.

- Much of England’s strategy of tobacco harm reduction is predicated on the availability of medicinally licensed products that smokers want to use. Licensed ECs are yet to appear. A review of the MHRA EC licensing process therefore seems appropriate, including manufacturers’ costs, and potential impact. This could include a requirement for MHRA to adapt the processes and their costs to enable smaller manufacturers to apply, and to speed up the licensing process. The review could also assess potential demand for the EC prescription market and what types of products would be most appropriate to meet that demand.

This chapter assesses the use of EC by adults and young people in England by drawing on recent surveys carried out in England and Great Britain (GB). A later chapter discusses EC prevalence internationally.

Measures used

One of the main issues in measuring EC use is the lack of consistent and appropriate terminology, for example some studies equate ever having used EC with current use of EC which is clearly inappropriate. We recommend that definitions of usage categories should be standardised similar to those used in smoking surveys. Appendix B lists the different measures used in surveys focused on in this report, and gives definitions used in the other studies included in this review.

Use of e-cigarettes by adults

First, we assess e-cigarette use in the adult population in England. We summarise various data sources to provide an overview of EC use among the general population, and then specifically smokers, recent and long-term ex-smokers, and never-smokers. The two main surveys used in this chapter are the Smoking Toolkit Study (STS) and the ASH Smokefree GB surveys. However, in addition to these surveys, findings from the Office for National Statistics Opinions and Lifestyle Survey (ONS survey), a randomised probability sample omnibus survey in GB, have also been included in this section although the exact question used is not available [13]; preliminary released data from Q1 2014 are reported here in advance of the complete data due for publication later in 2015.

Population use of e-cigarettes

Of the available datasets, just two – the Smoking Toolkit Study (STS, England) and the ASH Smokefree GB adult surveys – provide information on population prevalence (Table 1). Using the STS, it is estimated that 5.5% of the adult population of England used EC in the first quarter of 2015 indicating a marked rise from 0.5% in 2011. The measure of use in the STS is compiled from four survey questions and assesses current use for any reason (Appendix B). A very similar estimate is obtained for GB using the 2015 ASH survey, with 5.4% of the population estimated to be current (defined as tried EC and still use them, see Appendix B) EC users. This translates to about 2.6 million EC users in GB in 2015 [14](for comparison there are about nine million tobacco
E-cigarettes: an evidence update

Smokers in GB and as discussed later, most EC users are smokers or ex-smokers. The ASH survey also assessed trial and about 17% of the adult GB population was estimated to have tried EC.

Table 1: Adult EC current use

<table>
<thead>
<tr>
<th>Source (date of data collection)</th>
<th>Population Prevalence</th>
<th>Never smokers</th>
<th>Ex-smokers</th>
<th>Smokers (‘Dual users’)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASH Smokefree GB adult survey (2015 - March)</td>
<td>5.4%</td>
<td>0.2%</td>
<td>6.7%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Office for National Statistics (2014 - Q1)</td>
<td>N/A</td>
<td>0.1%</td>
<td>4.8%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Smoking Toolkit Study (2015 – Q1)</td>
<td>5.5%</td>
<td>0.2%2</td>
<td>3.3%2</td>
<td>21.2%</td>
</tr>
</tbody>
</table>

1For definitions of current use please see Appendix B. The ONS question is unavailable.
2Figures for never and long-term ex-smokers are derived from n=22489 never and long-term ex-smokers surveyed between November 2013 and March 2015

Never smokers and long-term ex-smokers

All three surveys estimate current EC use among adult never smokers to be very rare at 0.2% or less, and between 3% and 7% among ex-smokers – the latter estimates may vary because in the STS recent ex-smokers (last-year) are not included in this category (Table 1). Prevalence of current EC use among recent ex-smokers in the STS was around 40% in the first quarter of 2015 [15].

The ASH survey estimated that around 1.5% of never smokers and 16% of ex-smokers had ever tried EC.

Smokers

Recent surveys estimate current EC use among smokers, sometimes referred to as ‘dual users’ of cigarettes and e-cigarettes, is between 12 and 21% (Table 1). The prevalence of EC use among last-year smokers (defined as smokers and recent ex-smokers) using the STS in England is estimated at 22.9% for any use of EC and 14.9% for daily EC use. The ASH 2015 survey indicated that 17.6% of current smokers use EC currently (18% of occasional and 17% of daily smokers); the same survey indicated that a small majority of smokers (59%) have now tried EC.

The Q1 2014 ONS Survey data estimates for current use are considerably lower, suggesting that just under 12% of current smokers used EC in early 2014. The survey question/s used to determine this is/are not available to assess whether different ways of assessing use may be a reason for this discrepancy in findings.
The ASH survey indicates that about 60% of current EC users are current smokers, and about 40% are ex-smokers. The proportion of EC users among never smokers remains negligible.

Summary

Around one in 20 of the general adult population in England (and GB) use EC. Current EC users are almost exclusively smokers or ex-smokers. EC use among long-term ex-smokers is considerably lower than among recent ex-smokers.

Trends in e-cigarette use among adults

Both the STS and ASH surveys demonstrate that there was a steady increase in EC use in the population from 2011 to 2013.

Smoking Toolkit Study (STS) data

The STS data indicate that this increase slowed down, even declining at the end of 2014 from 5.3% in Q3 to 4.5% in Q4 (Figure 1). However, as Q1 data from 2015 show a recent upswing to 5.5%, this decline may have been temporary. The STS data show that alongside the increase in EC use, smoking of tobacco cigarettes declined. Overall nicotine use, ie any consumption via cigarette smoking, NRT use or EC use, has also declined.

Figure 1: Prevalence of smoking and e-cigarette use among the adult English population (STS)
The overall pattern of EC use in the population is mirrored among last year smokers for whom EC prevalence increased from 2011, but declined from 22% for any use and 14% for daily use in Q3 2014, to 19% and 11% respectively in Q4 2014; however, any and daily use increased again to 23% and 15% respectively in Q1 2015 (Figure 2).

Figure 2: Prevalence of e-cigarette use among last year smokers (STS)

From www.smokinginengland.info/latest-statistics/

ASH Smokefree GB adult survey

The ASH surveys indicated a slowing down in the increase of EC use in the population between 2014 and 2015 and use among current smokers in 2015 remained at the 2014 level (17.6% of smokers in 2014 and 2015). Use among ex-smokers increased from 1.1% in 2012, to 4.5% in 2014 and 6.7% in 2015, whereas no increase in use was observed among never smokers over the last few years, remaining at 0.2% since 2013. This means that the increase in EC use observed overall was accounted for by an increase in use by ex-smokers. It is not clear to what extent this is due to smokers stopping smoking using EC or ex-smokers taking up ECs.

Summary

The prevalence of EC use among adults has plateaued. Most of the recent increase in use appears to be among ex-smokers. Cigarette smoking has declined over the period when EC use increased and overall nicotine use has also declined. These findings suggest that the advent of EC is not undermining and may be contributing to the long-term decline in cigarette smoking.

Submitted by Tom Madden, owner of E-Cigs
Types and flavours of e-cigarettes used among adults

When those who had tried EC in the 2015 ASH survey were asked about which EC they used first, 24% reported a disposable, 41% a rechargeable with replaceable pre-filled cartridges and 28% rechargeable with tank/reservoir filled with liquids (7% didn’t know/couldn’t remember). The different types were in the same order of popularity for first use regardless of smoking status (Figure 3).

For those still using EC from the same survey, only 5% were now mostly using a disposable, 26% a rechargeable with replaceable pre-filled cartridges and 66% rechargeable with tank/reservoir filled with liquids (2% didn’t know/couldn’t remember). This suggests that a considerable proportion of those who continue to use EC over time switch to the tank models. Among EC users, ex-smokers were particularly likely to use tank models mostly and very few ex-smokers were using disposables (Figure 3). This is in agreement with findings reported in Chapter 6 of this report, where tank models were found to be associated with having quit smoking [16].

Figure 3: Type of e-cigarettes first used and currently used (ASH Smokefree GB data 2015)

The ASH Smokefree GB 2015 adult survey also shows that the most popular flavour was tobacco flavour, followed by fruit and menthol flavours (Figure 4).
Use of e-cigarettes among young people

The main source for estimating smoking prevalence in England among youth is the 'Smoking, drinking and drug use among young people' surveys [17], however, EC use was first assessed in 2014 and these data are not yet available. This section therefore draws on the ASH Smokefree GB youth surveys to assess EC usage in young people, supplemented by a study in the North West of England, two cross-sectional national surveys in Wales and one national survey in Scotland. The measures used are detailed in Appendix B.

In 2015, the ASH survey found that 12.7% of 11 to 18-year olds reported having tried EC; of these, 80.9% had only used one once or twice (10.2% of all respondents). Current EC use was considerably lower: 0.7% had used an EC sometimes but not more than once a month; 1.2% more than once a month but not weekly; and 0.5% weekly (Table 2). The prevalence of EC use (2.4% overall) among people aged between 11 and 18 was therefore lower than among the general population. In comparison, 21% of all 11 to 18-year olds reported having tried cigarettes, of whom 54% only tried once (11.4% of all respondents). Current smoking was reported by a total of 6.7%; 2.7% smoked less than weekly and 4% at least weekly.

Submitted by Tom Madden, owner of E-Cigs
Experimentation increased with age: 2.9% of 11-year olds and 20.2% of 18-year olds had tried EC. In comparison, among 11-year olds, 3.9% had tried cigarettes (0.7% current smokers), whereas 40.9% of 18-year olds had tried cigarettes (14.3% current smokers).

Use of EC was very closely linked with smoking status. Among never smokers, 0.3% used EC monthly or more often, compared with 10.0% of ever smokers and 19.1% of current smokers. The majority of EC users had tried tobacco cigarettes first (Table 2).

Table 2: E-cigarette use among young people

<table>
<thead>
<tr>
<th>Source</th>
<th>Ever tried</th>
<th>Use more than /at least once a month</th>
<th>Use more than once a week</th>
<th>Use (at least monthly) in never smokers</th>
<th>Those using e-cigarettes who had tried tobacco first</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASH Smokefree GB youth survey (11-18 years) (2015 – March)</td>
<td>12.7%</td>
<td>1.9%</td>
<td>0.5%</td>
<td>0.1%</td>
<td>63.7%</td>
</tr>
<tr>
<td>Health Behaviour in School-aged Children, Wales (11-16 years) (Nov 2013 – Feb 2014) [18]</td>
<td>12.3%</td>
<td>1.5%</td>
<td>Not reported</td>
<td>0.3%</td>
<td>Not reported</td>
</tr>
<tr>
<td>CHETS Wales survey (10—11 year olds)[19] 2014</td>
<td>5.8%</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>SALSUS Scotland survey (15 and 13 year olds)[20] 2013/2014</td>
<td>12%</td>
<td>0.4%</td>
<td>0%</td>
<td>0%</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

1For question on e-cigarette categories please see Appendix B. Use more than/ at least once a month excludes those using more than once a week who are reported separately
2N=9055, use defined as at least monthly

Similar findings have been observed in Scotland. A national survey carried out in 283 schools across Scotland in late 2013/early 2014 involved more than 33,000 schoolchildren aged 13 and 15 years old [20]. Seven per cent of 13-year olds, and 17% of 15-year olds, had ever used an EC. Trial was associated with smoking status – 4% of never smokers had tried EC (3% trying them once and 1% having tried a few times) compared with 24% of ever smokers, 39% of ex-smokers, 46% of occasional smokers and 66% of regular smokers. Eleven per cent of regular smokers and 6% of occasional smokers reported using e-cigarettes at least monthly.

Very similar findings have been reported from a survey in Wales (Table 2). A survey of secondary schoolchildren was carried out under the auspices of the Health Behaviour of
School Children (HBSC) study and more than 9,000 participants aged 11–16 from 82 schools were included [18]. Overall, 12.3% had tried EC, 1.5% were monthly users, compared with 12.1% reporting ever having smoked and 5.4% current smokers (reported smoking less than once a week or more frequently). Whilst many experimental EC users had never smoked, most regular EC users had also smoked tobacco. The authors commented that “the very low prevalence of regular use…suggests that e-cigarettes are unlikely to be making a significant direct contribution to adolescent nicotine addiction”.

Additionally, around 1,500 10 to 11-year olds were surveyed in Wales, from 75 schools in the CHETS Wales study [18, 19] (Table 2). Overall, 5.8% (n=87) had ever used an EC; most reported only using once (3.7%, n=55 overall) and only 2.1% (n=32) reported using them more than once. Again, EC use was associated with smoking. Just under half (47.6%) of those who reported having used tobacco had ever used an EC compared with 5.3% of never smokers. Controlling for other variables associated with EC use, parental use of EC and peer smoking remained significantly associated with having ever used an EC. Having ever used an EC was associated with weaker anti-smoking intentions. Parental EC use was not associated with weakened anti-smoking intentions whereas parental smoking was [19]. This study, published prior to the one above, concluded that EC represented a new form of experimentation with nicotine that was more common than tobacco usage. It also commented that the findings added “some tentative support for the hypothesis that use of e-cigarettes may increase children’s susceptibility to smoking”. However, as this was a cross-sectional survey, causal connections cannot be inferred. It is possible that children who had used EC would have smoked cigarettes in their absence and this could explain the relationship between intentions and EC usage (see below).

An additional survey of schoolchildren has been carried out in England. Trading Standards in the North West of England have been running biennial surveys of schoolchildren since 2005. The 2013 findings on EC, smoking and alcohol were published [21]. The survey was not designed to be representative (no compliance or completion rates were collected) but instead “to provide a broad sample of students from a range of community types”. More than 100 schools participated and more than 16,000 participants aged 14–17 years of age were included in the analyses. It is important to acknowledge that the question about EC was “Have you ever bought or tried electronic cigarettes?”, and this study cannot therefore add to knowledge on current usage. Around one in five of the sample had accessed EC, with access being higher in those who had experience of smoking. Around 5% of those who had never smoked cigarettes reported accessing EC; around half of ex-smokers and over two thirds of regular smokers had accessed them. Parental smoking and alcohol use were also associated with EC access.
Summary

Regular use of EC among youth is rare with around 2% using at least monthly and 0.5% weekly. A minority of British youth report having tried EC (national estimates suggest around 12%). Whilst there was some experimentation with EC among never smokers, nearly all those using EC regularly were cigarette smokers.

Trends in e-cigarette use among young people (ASH Smokefree GB youth)

The ASH Smokefree GB youth surveys indicate that awareness of EC has increased markedly, with the proportion of individuals who had *never heard* of EC falling from 33.1% in 2013 to 7.0% in 2015. *Ever having tried* EC also increased, from 4.5% in 2013, to 8.1% in 2014, and to 12.7% in 2015. However, the proportion using an EC monthly or more frequently remained virtually unchanged from 2014 (1.6%) to 2015 (1.7%). Over the same period, the proportion of regular smokers (at least weekly) remained at around 4% (2013: 4%, 2014: 3.6%, 2015: 4%).

Type and flavour among youth

The proportion of youth reporting current use was too small to assess the most frequently used types or flavours in current users, so Figures 5 and 6 include everyone who *had tried* an EC. One third had first used a tank model and the most popular flavours among triers by far were fruit flavours. The responses for adults and youth are not directly comparable given flavours were assessed for adult current EC users, but in the latter group, fruit flavours were less popular than tobacco flavours.
Figure 5: First type of e-cigarette tried by youth, ASH Smokefree GB youth survey, 2015

Note: The proportion of youth reporting current use was too small to assess the most frequently used types.

Figure 6: Last flavour tried by youth, ASH Smokefree GB youth survey, 2015

Note: The proportion of youth reporting current use was too small to assess flavours in current users.
Concerns about impact of e-cigarette use on smoking

Three main concerns raised about EC use are that they might 1) renormalise smoking 2) reduce quitting and 3) act as a ‘gateway’ to smoking or nicotine uptake. An ultimate test for the first concern, and to some extent all three concerns, is the impact of EC use on smoking prevalence nationally which is explored first below. Evidence for effectiveness of EC on quitting smoking is explored in more detail in Chapter 6. Whilst other concerns have been raised such as renormalising the tobacco industry, we are only able to comment on issues pertaining to the objectives of our report.

Recent trends in smoking prevalence

Since EC arrived on the market in England, smoking prevalence has continued to decline among both adults and youth (Figures 1, 7 and 8). Evidence to date therefore conflicts with any suggestion that EC are renormalising smoking. Whilst other factors may be contributing to the decline in smoking, it is feasible that EC may be contributing to reductions in smoking over and above any underlying decline.

Figure 7: Adult smoking prevalence in England 1980–2013

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1 General Lifestyle Survey aged 16+(1980-2010); Integrated Household Survey aged 18+ (2011). Diagram courtesy of ASH.
Gateway

The gateway theory or hypothesis is commonly invoked in addiction discourse, broadly to suggest that the use of one drug (sometimes a legal one such as tobacco or alcohol) leads to the use of another drug (sometimes an illegal one) but its definition is contested. No clear provenance exists and its origin appears to derive from lay, academic and political models [22]. It is apparent that discussions about the natural progression of drug use observed in longitudinal studies of young people appear to have morphed into implicit conclusions on causality without any evidential backing. Some have argued that the effect could be causal if the use of one drug, biochemically or pharmacologically, sensitises the brains of users to the rewarding effects of other drugs [23] making the dependent use of these other drugs more likely. However, there are many plausible competing hypotheses for such a progression [24] including i) shared networks and opportunities to purchase the drugs; and ii) individual characteristics such as genetic predispositions or shared problematic environment. Academic experts have stated that the gateway concept “has been one of the most controversial hypotheses…in part because proponents and opponents of the hypothesis have not always been clear about what the hypothesis means and what policies it entails” [24]. Indeed, a recent analysis of gateway concluded “Although the concept of

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the gateway theory is often treated as a straightforward scientific theory, its emergence is rather more complicated. In effect, it is a hybrid of popular, academic and media accounts – a construct retroactively assembled rather than one initially articulated as a coherent theory” [22].

Despite these serious and fatal flaws in the arguments, the use of the term ‘gateway’ is commonplace both in the academic literature and the lay press, particularly in relation to EC use and whether EC are a gateway to smoking. Some have suggested that if EC use increases at the same time as smoking increases then EC are acting as a gateway to smoking. Similarly, it’s been argued that if someone uses an EC first and then initiates smoking, EC are a gateway. These arguments are clearly erroneous. To give one example of the misuse of the gateway concept, a BMJ news item on the Moore et al., 2014 [18] cross-sectional study discussed above commented that “[EC} could be a gateway into smoking” [25].

Kandel recently argued that evidence from mice offers a biological basis for the sequence of nicotine to cocaine use in people [26], but there is limited evidence for this. In reality, the gateway theory is extremely difficult to test in humans. For example, a clean test of the gateway hypothesis in relation to EC and smoking would require randomising people to an environment with EC and one without, and then following them up over a number of years to assess uptake of EC and smoking.

We strongly suggest that use of the gateway terminology be abandoned until it is clear how the theory can be tested in this field. Nevertheless, the use of EC and smoking requires careful surveillance in young people. The preferred option is that young people do not use EC but it would be preferable for a young person to use an EC instead of smoking, given the known relative risks of the EC and smoking cigarettes [10].

Summary

Since EC were introduced to the market, smoking prevalence among adults and youth has declined. Hence there is no evidence to date that EC are renormalising smoking, instead it’s possible that their presence has contributed to further declines in smoking, or denormalisation of smoking. The gateway theory is ill defined and we suggest its use be abandoned until it is clear how it can be tested in this field. Whilst never smokers are experimenting with EC, the vast majority of youth who regularly use EC are smokers. Regular EC use in youth is rare.

Summary of findings

Adults: Around one in 20 adults in England (and Great Britain) use EC. Current EC users are almost exclusively smokers (~60%) or ex-smokers (~40%), that is smokers
who now use EC and have stopped smoking altogether. EC use among long-term ex-smokers is considerably lower than among recent ex-smokers. Current EC use among never smokers is very low, estimated to be 0.2%. The prevalence of EC use plateaued between 2013-14, but appeared to be increasing again in 2015.

Youth: Regular EC use among youth is rare with around 2% using at least monthly and 0.5% weekly. EC use among young people remains lower than among adults: a minority of British youth report having tried EC (~13%). Whilst there was some experimentation with EC among never smoking youth, prevalence of use (at least monthly) among never smokers is 0.3% or less.

Overall, the adult and youth data suggest that, despite some experimentation with EC among never smokers, EC are attracting few people who have never smoked into regular use.

Trends in EC use and smoking: Since EC were introduced to the market, cigarette smoking among adults and youth has declined. In adults, overall nicotine use has also declined (not assessed for youth). These findings, to date, suggest that the advent of EC is not undermining, and may even be contributing to, the long-term decline in cigarette smoking.

Policy implications

- Trends in EC use among youth and adults should continue to be monitored using standardised definitions of use.
- Given that around two-thirds of EC users also smoke, data are needed on the natural trajectory of ‘dual use’, ie whether dual use is more likely to lead to smoking cessation later or to sustain smoking (see also Chapter 6).
- As per existing NICE guidance, all smokers should be supported to stop smoking completely, including ‘dual users’ who smoke and use EC.
5. Smoking, e-cigarettes and inequalities

Smoking and inequalities

Whilst smoking prevalence overall has been declining over the past 50 years, smoking has become increasingly concentrated in more disadvantaged groups in society. Over the last decade, the gap between smoking in the different social groups has not narrowed (Figure 9) and some of the most disadvantaged groups in society (such as people with serious mental illness or prisoners) have shown no change in smoking prevalence over time (e.g. Figure 10). Furthermore, among smokers, the level of nicotine dependence increases systematically as deprivation increases [2]. A key challenge in tobacco control is therefore how to encourage smokers from disadvantaged groups to stop smoking.

Whilst quitting cigarettes and all nicotine use should remain the main goal across all social groups, EC are of interest because, as with other cleaner nicotine delivery systems, they potentially offer a wide reach, low-cost, intervention to reduce smoking and improve health in these more deprived groups in society where smoking is elevated [2]. It is therefore important to examine the potential impact of EC on inequalities.

Figure 9: Smoking trends by socioeconomic group status (GHS data)
E-cigarette use and different social groups

Earlier surveys in GB and internationally suggested a social gradient in the use of EC, with smokers of higher income and education being more likely to have used and tried [28, 29]. However, the 2015 ASH Smokefree GB adult 2015 survey indicated only small differences across groups, with lower socioeconomic groups slightly more likely to have tried and be using EC. At the population level, 14.4% of ABC1 groups ('non-manual' occupational groups) had tried EC compared with 19.4% in C2DE groups ('manual' occupational groups); 4.6% of ABC1 were still using EC compared with 6.3% of C2DE groups. Nevertheless, given the higher prevalence of smoking in C2DE groups, when examined within the smoker population by social class, 20.0% of ABC1 smokers compared with 16.0% of C2DE smokers were EC current users.

The STS data surveys show an increase in EC use in all social groups between 2012 and 2014 (Figures 11 and 12) but at a relatively similar rate such that socioeconomic differences are still apparent both for current and daily use of EC.
Figure 11: *Current* use of e-cigarettes by social class among last year smokers (STS data)

![Graph showing current use of e-cigarettes by social class among last year smokers.](From www.smokinginengland.info/latest-statistics/)

Figure 12: *Daily* use of e-cigarettes by social class among last year smokers (STS data)

![Graph showing daily use of e-cigarettes by social class among last year smokers.](From www.smokinginengland.info/latest-statistics/)
Nevertheless, EC are penetrating the lower socioeconomic groups. Figure 13 shows the social class breakdown of EC users by quarter over time, also derived from STS data.

**Figure 13: E-cigarette use by social class over time (STS data)**

From www.smokinginengland.info/latest-statistics/

E-cigarette use in other disadvantaged groups

There are no GB data, to our knowledge, on EC use among groups where smoking prevalence is known to be very high, such as offenders and people with serious mental illness. There is emerging evidence on the effectiveness of EC in people with mental illness (see Chapter 6). However, to some extent, usage among these groups will be dependent on EC policies being introduced in prisons and mental health settings.

Recent NICE guidance on smoking cessation in secondary care settings [30] recommended the implementation of smokefree policies in these settings, alongside advice to stop smoking and nicotine dependence treatment. Trusts are now implementing this guidance but many prohibit EC usage as well as cigarettes. The rationale for such prohibition is unclear.

The South London and Maudsley NHS Foundation Trust (SLaM) was the second NHS mental health trust to go comprehensively smoke free in England. It has developed an EC policy alongside the smokefree policy which allows EC to be used in private spaces or grounds, although EC are not to be offered as first line treatment or replace tobacco cigarette smoking and can only be used as part of a care treatment pathway [31]. Currently, the use of disposable products or rechargeable models with cartridges is allowed (the latter only under supervision), but tanks are prohibited because of fears...
that they might be used for new psychoactive substances (sometimes also known as ‘legal highs’). The basis for this fear is being assessed and the use of tank models may be assessed in a restricted pilot shortly. During the first six months of the policy, the EC policy has been implemented smoothly.

A more general concern has been raised that EC can be used as a vehicle for other drugs. This concern needs exploring and is not something that should be promoted. Nevertheless, if true, EC are likely to offer a less harmful delivery route for the drugs than smoking which could be the subject of research.

Prisons are likely to introduce comprehensive smokefree policies over the next few years [32]. Similar to mental health trusts, it would seem inappropriate to prohibit EC and disposable EC are currently being piloted in at least three prisons [33]. Consideration should also be given to the use of other models of EC in pilots. The use of EC in prisons has been considered in other jurisdictions which should also be informative [34].

Summary of findings

Smoking is increasingly concentrated in disadvantaged groups who tend to be more dependent. EC potentially offer a wide reach, low-cost, intervention to reduce smoking and improve health in disadvantaged groups.

Some health trusts and prisons have banned the use of EC which may disproportionately affect more disadvantaged smokers.

Policy implications

- Consideration could be given to a proactive strategy to encourage disadvantaged smokers to quit smoking as quickly as possible including the use of EC, where appropriate, to help reduce health inequalities caused by smoking.

- EC should not routinely be treated in the same way as smoking. It is not appropriate to prohibit EC use in health trusts and prisons as part of smokefree policies unless there is a strong rationale to do so.
6. E-cigarettes and smoking behaviour

Introduction

Studies examining the relationship between EC use and smoking behaviour have focused on two main questions to date: (1) do EC help people to quit when used on a quit attempt, and, (2) what is the effect of using EC while smoking, on reductions in smoke intake, cigarettes per day, quit attempts, and stopping smoking? Because EC use is a relatively new phenomenon and the products are constantly changing with technological innovation, the studies examining these questions to date are heterogeneous. As mentioned earlier, studies vary in their definitions of EC use, including ever use, which could include one puff, to studies that discriminate between daily and non-daily use. Additionally, it is evident that many of the studies were not originally designed to study the effects of EC use on smoking behaviour due to the absence of rigour and omitted/unmeasured variables.

Current recommendations for use of e-cigarettes to quit

The National Centre for Smoking Cessation and Training (NCSCT) has published current recommendations for practice regarding the use of EC for stopping smoking [35]. The NCSCT recommends that practitioners be open to EC use among smokers trying to quit, particularly if they have tried other methods of quitting and failed. The NCSCT also provides more detailed guidelines for smokers wanting to use EC to quit, including differences in puffing on EC versus regular cigarettes, the need to try different types of EC to find one that works for them, and that multi-sessional behavioural support is likely to improve their success of quitting. Some services have welcomed smokers who wish to stop with the help of EC [36].

The NICE guidelines for tobacco harm reduction cover recommendations for the use of licensed EC for quitting, cutting down (reduction in cigarettes per day), and temporary abstinence [1], similar to NRT. Use for both cutting down and temporary abstinence have been shown to be precursors to quitting among smokers using NRT. As discussed in Chapter 3, no licensed EC are currently available.

Use of e-cigarettes for stopping smoking

STS data have shown that EC have quickly become the most common aid that smokers in England use to help them stop smoking (Figure 14). The rise in the use of EC as a stop smoking aid is occurring despite the fact that no licensed EC are available. Although the most effective way for stopping smoking, currently supported by the research literature [37, 38] is a combination of behavioural support (NHS in Figure 14)
and medication (NRT on prescription or Champix), the problem is that few smokers access these services, limiting their impact on population health.

This section reviews the evidence regarding the use of EC for stopping smoking that has been published since the Cochrane Review [39] on the use of EC for smoking cessation and reduction (cutting down). The Cochrane Review is briefly summarised below.

**Figure 14: Support used in quit attempts**

![Chart showing support used in quit attempts](image)

N=10078 adults who smoke and tried to stop or who stopped in the past year.

From: smokinginengland.info/latest-statistics

**Randomised controlled trials**

To date, two randomised controlled trials (RCTs) have tested the efficacy of EC for stopping smoking, one among smokers wanting to stop and the other among smokers not intending to quit within the next month [40, 41]. Both were among highly dependent smokers. A recent Cochrane Review of these RCTs [39] concluded that they demonstrated that EC with nicotine help smokers reduce their cigarette consumption and stop smoking compared with no nicotine EC (placebo). However, the authors cautioned that there was uncertainty in the findings, and gave their findings a ‘low’ confidence rating using GRADE standards. The Cochrane Review also considered observational studies of EC use and cessation. They concluded that these observational studies were generally consistent with the findings of RCTs. Since the Cochrane Review, one RCT[41], and a secondary analysis of one of the RCTs in the Cochrane Review[42] have been published and are discussed below.
O’Brien et al., 2015 [42] conducted a secondary analysis of the RCT data from Bullen et al., 2013 [43] to examine the effectiveness of EC with and without nicotine compared to the nicotine patch among individuals with mental illness (MI). They identified 86 participants among the original 657 participants (all motivated to quit) using secondary data from the trial on reported use of any medications associated with MI. Overall, when compared to participants without MI, there were no significant differences for those with MI on the primary outcomes of smoking reduction and smoking cessation. One exception was that the six-month quit rate was higher among participants with MI in the patch condition compared to those without MI. Although not a primary outcome, there was evidence of a greater rate of relapse among participants with MI. In the analysis that only included participants with MI, there were no significant differences in quit rates across the three conditions, however participants allocated to 16mg EC showed greater smoking reduction than those allocated to patch. The authors concluded that EC appear to be equally effective for smoking cessation among individuals with and without MI, building on other promising research involving EC and people with MI.

Adriaens et al., 2014 [41] conducted an eight-week RCT in Belgium with control where they randomised 48 smokers who did not want to quit to one of two conditions: (1) use of tank model EC, and training on how to use, with no encouragement to quit, and (2) no use of EC. Both groups attended similar periodic lab sessions over an eight-week period where measurements of craving, withdrawal, saliva cotinine, and expired-air CO levels were taken. Adriaens found that after eight weeks of use 34% of those given EC had quit smoking compared to 0% of those not given EC, the EC group also showed substantially greater cigarette reduction. After eight weeks, the group which did not receive EC at baseline was given EC, but no training on how to use the products. At the final eight-month follow-up, 19% of the original EC group and 25% of the control group (given EC at week eight) had quit smoking. Significant reductions in cigarette consumption were also found.

Population studies

One problem with RCTs is that because of the time taken to set up and implement trials, the EC used in the trials are often no longer available for sale by the time the research is published. This is problematic because many new EC enter onto the market and it is possible they may be more effective at delivering nicotine than the products used in the trial, and possibly more effective for smoking cessation. Additionally, the controlled environment of RCTs is unable to provide evidence of the effectiveness of EC in the real world where use is much more subject to external forces, such as availability, price and social norms around use. RCTs also reveal little about the attractiveness of the products and thus likely uptake of the products used and what happens after a successful or failed attempt to stop smoking with an EC in the long-term.
Observational and natural history studies are therefore important. Only one population-based survey has examined the effectiveness of EC used during quit attempts. A large cross-sectional study of 5,863 English smokers who attempted to quit in the past year without using professional support [29] found that those who used EC on their last quit attempt were more likely to quit than those who used over the counter NRT – (the most common help sought by smokers after EC, see Figure 14), or no quit aid, controlling for factors related to quitting. This study was, however, unable to explore prospective predictors of quitting, including pre-quit nicotine dependence. Still, this study offers some of the best evidence to date on the effectiveness of EC for use in quit attempts.

Other recent population studies [16, 44, 45] have also examined the association between EC use and quitting. However, because these studies (1) included smokers who were already using EC at baseline, and (2) did not examine the use of EC during a specific quit attempt, we discuss them below in the section on use of EC while smoking.

Pilot studies

Polosa et al., 2014 [46] conducted a six-month pilot study of tank-type EC users with no control group among 72 smokers who did not want to quit (smokers were enrolled after rejecting participation in smoking cessation program at a hospital). At six months, they found significant 50% and 80% reductions in cigarette consumption, and a quit rate of 36% [46]. Another study by Polosa et al., 2014 [47] followed 71 vape shop customers (seven different shops) after their first visit to the shop. The first visit included instructions on how to use EC and encouragement to use their EC of choice to reduce their smoking, along with a telephone number they could call for help. At six and twelve months after their initial visit they found that the smokers reported significant 50% and 80% reductions in cigarettes per day at six and twelve months, and that at six and twelve months, 42.2% and 40.8% had quit smoking.

E-cigarettes and stop smoking services

Some English stop smoking services and practitioners support the use of EC in quit attempts [48], and provide behavioural support for EC users trying to quit smoking. The most recent monitoring data from the stop smoking services show the self-reported success rates for different medications and nicotine-containing products used (Figure 15). Data are not given by validated success rates but overall, 69% of those who self-report stopping smoking are carbon-monoxide validated [49]. Hence, there are limitations with these data as they are self-reported success rates and it is possible that they may vary by treatment used. Additionally, the data are not adjusted for other factors, such as dependence, known to influence success rates, and it is likely that they emanate from a limited number of services who record unlicensed nicotine-containing products and who might therefore be more supportive of their use. Nevertheless, the
evidence is consistent with evidence from trials and other observational data that e-cigarettes are likely to support successful quitting.

**Figure 15: Support used and stop smoking service self-reported quit rates**

Note: Figures in brackets represent the number of quit attempts in which each type of support was used. The number of clients with recorded e-cigarette use is very small in comparison to those recorded to have used other types of support.

**Use of e-cigarettes while smoking**

**Population studies**

Two studies using data drawn from a longitudinal population sample of more than 1,500 smokers in GB recently examined the impact of EC use on quitting, considering the effects of frequency of EC used and type of EC. Brose et al., 2015 [45] found that respondents who used EC daily at baseline were more likely to make a quit attempt one year later, but were no more or less likely to quit than those who did not use EC. Daily EC use at follow-up was found to be associated with reduced cigarette consumption since baseline. No effects of non-daily EC use on quit attempts, quitting, or reduction in consumption were found. Using data from the same Internet Cohort GB study, Hitchman et al., 2015 [16] found differences in quitting between baseline and follow-up.

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Submitted by Tom Madden, owner of E-Cigs
depending on the type and frequency of EC used at follow-up: compared to no EC use, non-daily cigalike users were less likely to have quit smoking since baseline, daily cigalike or non-daily tank users were no more or less likely to have quit, and daily tank users were more likely to have quit. Overall, the two studies showed that daily use of EC does not lead to lower cessation, and is associated with making quit attempts, cigarette reduction, and if tank-type EC is used, is associated with smoking cessation. Non-daily use of EC is not associated with quit-related outcomes, and may, if cigalike-type EC are used, be associated with lower cessation.

Supporting these findings, using data from a longitudinal population study of smokers in two metropolitan areas in the US, Biener et al., 2015 [44] measured use and intensity of EC use at follow-up in a longitudinal sample of smokers at baseline from two US cities. Biener also found that it was only intensive EC users (used daily for at least one month) that were more likely to quit, less intensive EC users were no more likely to quit than those not using EC.

There are limitations with these studies. For example, an unavoidable methodological problem is that only people who currently smoke are included in these studies meaning that smokers who switched completely to EC and stopped smoking are excluded. The efficacy of EC is thus invariably underestimated.

A longitudinal telephone survey reported by Al-Delaimy et al., 2015 [50] among a sample of 368 current smokers from California at baseline (2011) investigated the relation between ‘ever have used’ versus ‘never will use’ EC, and making a quit attempt, a 20% reduction in cigarettes per month, and quitting for more than one month at follow-up (2012). Al-Delaimy included smokers at baseline who at both baseline and follow-up reported the same EC status: never will use EC at both baseline and follow-up OR ever have used EC at both baseline and follow-up, excluding anyone who gave different responses. Also excluded were respondents who said they might use EC in the future at baseline or follow-up, and respondents who had never heard of EC, reducing sample size from n=980 to n=368. Al-Delaimy concluded that compared to smokers who reported they never will use EC, respondents who had ever used EC were significantly less likely to have reduced their cigarette consumption and quit at follow-up, with no differences reported of quit attempts at follow-up. This study has serious methodological problems that make its conclusions uninterpretable, first, the measure of EC use is ‘ever use’, which could include even a puff on an EC and second, they applied several exclusion criteria that are not clearly justified.

**Studies of smokers enrolled in smoking cessation programs**

Two recent studies have examined the use of EC among smokers enrolled in smoking cessation programmes in longitudinal studies [51, 52]. Pearson et al., 2015 [51] examined the relation between reporting using an EC for quitting at follow-up and
smoking cessation (30-day abstinence) in a sample of smokers enrolled in a web-based cessation programme in the US with three-month follow-up. Pearson illustrated how the relation between using EC to quit and successful smoking cessation depended on the factors that were adjusted for and how the data were analysed, finding that under some conditions EC use was related to being less likely to quit and in others there was no relationship. The authors concluded that caution needs to be exerted when interpreting observational studies of the effects of EC use on smoking cessation.

Borderud et al., 2014 [52] examined whether any use of EC in the past 30 days was related to smoking cessation outcomes in a group of cancer patients enrolled in a smoking cessation programme in the US. When treating all smokers who dropped out of the study as smoking cessation failures, the authors found that any use of EC in the last 30 days was related to being less likely to quit; however, this treatment of the data may have been problematic because more EC users than non-users dropped out of the study. No relationship between EC use in the last 30 days and smoking cessation was observed when drop-outs were excluded from the analyses. One potential problem with this study is the measure of any EC use in the last 30 days, as this could range from using an EC once in the last 30 days to using an EC daily for the past 30 days. As illustrated [16, 44, 45] and discussed in previous studies [51], measurements of EC use that do not fully capture frequency of use may influence the relation between EC use and smoking cessation. As with studies in the previous section, the Borderud study started with smokers who had tried EC but did not stop smoking. This, of course, seriously reduces the chance of detecting a positive effect.

Summary of findings

Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. It is not known whether current EC products are more or less effective than licensed stop-smoking medications, but they are much more popular, thereby providing an opportunity to expand the number of smokers stopping successfully. Some English stop smoking services and practitioners support the use of EC in quit attempts and provide behavioural support for EC users trying to quit smoking; self-reported quit rates are at least comparable to other treatments. The evidence on EC used alongside smoking on subsequent quitting of smoking is mixed.

Policy implications

- Smokers who have tried other methods of quitting without success could be encouraged to try EC to stop smoking and stop smoking services should support smokers using EC to quit by offering them behavioural support.
E-cigarettes: an evidence update

- Research should be commissioned in this area including:
  - longitudinal research on the use of EC, including smokers who have not used EC at the beginning of the study
  - the effects of using EC while smoking (temporary abstinence, cutting down) on quitting, and the effects of EC use among ex-smokers on relapse
  - research to clarify the factors that i) help smokers using EC to quit smoking and ii) deter smokers using EC from quitting smoking, including different EC products/types and frequency of use and the addition of behavioural support, and how EC compare with other methods of quitting which have a strong evidence base

- It would be helpful if emerging evidence on EC (including different types of EC) and how to use EC safely and effectively could be communicated to users and health professionals to maximise chances of successfully quitting smoking.
7. Reasons for use and discontinuation

Reasons for using e-cigarettes

Reasons for using EC have been assessed for adult smokers and ex-smokers in a number of different ways. Across different populations, help to quit smoking and harm reduction were the top reasons endorsed for using EC [44, 53-57].

In the Internet Cohort GB survey, the list of possible reasons for using EC was extended after the first year (the survey was carried out in 2012, 2013 and 2014). Nevertheless, the most frequently endorsed reasons were health, to cut down and to quit smoking. These were endorsed by approximately 80% of current users at all three time points. The biggest change over time was recorded for ‘they are cheaper’ which appeared to be more popular in 2014 than 2013 (Table 3). Because of the way the question is phrased, a user endorsing a reason does not indicate that current use is for this particular reason, for example, 80% of current users agree that e-cigarettes may help you quit, but this does not mean that 80% of all users were using them in a quit attempt.

Table 3: Internet cohort GB survey, reasons for using e-cigarettes (in order of frequency of endorsement in 2014)

<table>
<thead>
<tr>
<th>Reason</th>
<th>2012 (n=1031)</th>
<th>2013 (n=717)</th>
<th>2014 (n=505)</th>
</tr>
</thead>
<tbody>
<tr>
<td>They may make it easier for you to cut down the number of cigarettes you smoke</td>
<td>81.0</td>
<td>78.1</td>
<td>79.4</td>
</tr>
<tr>
<td>They may not be as bad for your health</td>
<td>81.7</td>
<td>79.8</td>
<td>79.2</td>
</tr>
<tr>
<td>They might help you quit</td>
<td>81.8</td>
<td>79.9</td>
<td>79.0</td>
</tr>
<tr>
<td>No tobacco smoke</td>
<td>not asked</td>
<td>70.9</td>
<td>71.3</td>
</tr>
<tr>
<td>They are cheaper</td>
<td>not asked</td>
<td>36.1</td>
<td>65.5</td>
</tr>
<tr>
<td>The smell or cleanliness</td>
<td>not asked</td>
<td>65.4</td>
<td>65</td>
</tr>
<tr>
<td>So you can use them in places where smoking regular cigarettes is banned</td>
<td>67.2</td>
<td>66.5</td>
<td>61</td>
</tr>
<tr>
<td>They may be more socially acceptable</td>
<td>not asked</td>
<td>55.8</td>
<td>54.3</td>
</tr>
<tr>
<td>Because I enjoy it</td>
<td>not asked</td>
<td>38.6</td>
<td>48.7</td>
</tr>
<tr>
<td>They taste better</td>
<td>28.5</td>
<td>26.1</td>
<td>34.1</td>
</tr>
<tr>
<td>Friends or family use them</td>
<td>not asked</td>
<td>37.0</td>
<td>33.3</td>
</tr>
<tr>
<td>The technology</td>
<td>not asked</td>
<td>34.2</td>
<td>30.3</td>
</tr>
<tr>
<td>A health professional advised you to do so</td>
<td>not asked</td>
<td>16.7</td>
<td>16.4</td>
</tr>
</tbody>
</table>

Submitted by Tom Madden, owner of E-Cigs
The ASH Smokefree GB survey similarly found that EC users who were ex-smokers most frequently endorsed that they used or had used EC to help them stop smoking entirely (Table 4). Among smokers, this was the second most frequently endorsed reason, with curiosity being the most frequent reason. Smokers also often reported use to help them cut down on smoked tobacco, which was rarely reported by ex-smokers.

**Table 4: Reasons for use, ASH Smokefree GB adult survey, 2015 (weighted)**

<table>
<thead>
<tr>
<th>I use/used electronic cigarettes...</th>
<th>Smokers</th>
<th>Ex-smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Just to give it a try</td>
<td>35%</td>
<td>29%</td>
</tr>
<tr>
<td>To help me stop smoking tobacco entirely</td>
<td>30%</td>
<td>44%</td>
</tr>
<tr>
<td>To help me reduce the amount of tobacco I smoke, but not stop completely</td>
<td>29%</td>
<td>9%</td>
</tr>
<tr>
<td>Because I had made an attempt to quit smoking already and I wanted an aid to help me keep off tobacco</td>
<td>27%</td>
<td>35%</td>
</tr>
<tr>
<td>To save money compared with smoking tobacco</td>
<td>24%</td>
<td>22%</td>
</tr>
<tr>
<td>Because I felt I was addicted to smoking tobacco and could not stop using it even though I wanted to</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>Because I want to continue to smoke tobacco and I needed something to help deal with situations where I cannot smoke (e.g. workplaces, bars or restaurants)</td>
<td>15%</td>
<td>8%</td>
</tr>
<tr>
<td>To avoid putting those around me at risk due to second-hand tobacco smoke</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
<td>3%</td>
</tr>
</tbody>
</table>

A smaller number of surveys specifically assessed reasons for trial and gave the option of selecting curiosity, which was frequently endorsed as an important reason for experimentation in US adults from the general population as well as in a sample of opioid-dependent smokers [58-60].

In youth, reasons for use has rarely been surveyed; one survey on reasons for experimentation among 1,175 students (middle school, high school and college) who had ever tried EC reported that the top three reasons for e-cigarette experimentation were curiosity (54.4%), the availability of appealing flavours (43.8%) and friends’ influence (31.6%). Compared with never smokers, however, ever cigarette smokers (OR=37.5, 95% CI: 5.0 to 283.3) and current cigarette smokers (OR=102.2, 95% CI: 13.8 to 755.9) were many times more likely to say they tried EC to stop smoking [61].
A national survey in New Zealand of 3,127 year 10 students (mostly aged 14 to 15) also showed that the most frequently given reason for first trying EC was curiosity, irrespective of smoking status (64.5% overall) [62].

Reasons not to use EC are rarely assessed. The ASH Smokers’ survey 2014 asked current and ex-smokers about advantages and disadvantages of EC. Among those who had never used EC, the three most important disadvantages were “They might be too expensive” (46%), “They might not be safe enough as a product” (39%) and “They might not satisfy my desire to smoke enough” (31%).

**Reasons why trial does not become use**

The rates of ever having tried an EC in the ASH GB Smokefree adult survey are more than three times those of current use; in the ASH GB Smokefree youth survey, about five times as many respondents had tried an EC as were currently using an EC, indicating that most of those who try EC do not progress to current use. A small number of surveys assessed why respondents who had tried an EC did not continue use.

In a national sample of 3,878 US adults who reported ever trying EC, two-thirds did not continue to use them and this was linked to the main reason for trying them. Trial turned into continued use for only a minority (19%) of those who did not know their main reason for trying them or whose main reasons were curiosity, friends or family members or advertising. Continued use was more common for those whose main reasons for trial included help to quit smoking or reduce harm. Those who did not continue use were asked for their reasons for stopping. The reason most often given was that they were just experimenting (49%) [58].

In the survey by Kong et al., reported previously, it appears that 98.5% of experimenting students did not continue use. Reasons for discontinuation were assessed but unfortunately the most commonly chosen response was ‘other’ (23.6%, open-ended responses included “I don’t like it”, “I just tried once”) followed by “uncool” (16.3%) and health risks (12.1%) [61].

Some surveys can be used to assess why smokers may not continue to use EC. The ASH Smokers’ survey in 2014 indicates that disappointment with the help EC provide in reducing smoking urges may be an important reason. Among smokers who had tried EC but did not continue using them, 44% said that a disadvantage of the products was that “They might not satisfy my desire to smoke enough”. No other reason got a higher rate of agreement in this group. A high proportion of smokers who were currently using EC also stated this reason (37%), but the proportion was significantly (p<0.05) lower in ex-smokers who had used (32%) or were currently using EC (7%), suggesting that satisfaction with the device/s may be a correlate of stopping smoking.
Of concern is that data suggest that some smokers may not continue to use EC instead of smoking because of a misguided belief that EC would be harmful to their health. In the ASH Smokers’ survey 2014, the second most frequently endorsed disadvantage was “They might not be safe enough as a product” (35%) among smokers who had tried an EC but were not using one anymore. Similarly, in a survey of US respondents, among 227 respondents who had tried EC in the past, were no longer using them but were still smoking cigarettes [44], the most frequently endorsed reason was that EC didn’t feel enough like smoking cigarettes, followed by dislike of the taste and that they were bad for health. It would appear therefore that these respondents stopped EC use in favour of continuing to smoke more deadly cigarettes.

Summary of findings

A number of surveys in different populations provide evidence that reducing the harm from smoking (such as through cutting down on their cigarette consumption or helping with withdrawal during temporary abstinence) and the desire to quit smoking cigarettes are the most important reasons for using EC. Curiosity appears to play a major role in experimentation. Most trial of EC does not lead to regular use and while there is less evidence on why trial does not become regular use, it appears that trial due to curiosity is less likely to lead to regular use than trial for reasons such as stopping smoking or reducing harm. Dissatisfaction with products and safety concerns may deter continued EC use.

Policy implications

- Smokers frequently state that they are using EC to give up smoking. They should therefore be provided with advice and support to encourage them to quit smoking completely.

- Other reasons for use include reducing the harm from smoking and such efforts should be supported but with a long-term goal of stopping smoking completely.
8. Harm perceptions

Perceptions of the harmfulness of EC are frequently assessed in surveys, most commonly relative to conventional tobacco cigarettes. However, a recent Eurobarometer survey [63] asked smokers in absolute terms whether EC were harmful to the health of those using them. Overall in Europe, 40.6% perceived EC as not harmful (UK: 48.6%), 28.5% as harmful (UK: 14.6%) and 30.9% did not know if they were or were not harmful (UK: 36.8%).

Harm perception relative to cigarettes

In GB, the ASH surveys and the Internet Cohort survey have included questions on the perceived relative harm of EC. These surveys consistently show that compared with conventional tobacco products, EC were perceived as less harmful by a small majority of respondents, but with a sizeable minority inaccurately judging them to be more harmful, about as harmful or being unsure about their relative risks. For example, in the 2015 ASH Smokefree GB adult survey, 2% thought that EC were more harmful than cigarettes, 20% equally harmful, 52% less harmful, 2% completely harmless and 23% did not know.

Harm perception differed by smoking status ($\chi^2=104.05$, p<0.001) and by EC use status ($\chi^2=453.4$, p<0.001) (Figure 15). Overall, smokers were more likely to judge EC to be less harmful compared with cigarettes (63.7%, including 'completely harmless') than ex-smokers (55.6%), whereas never-smokers were least likely to judge EC as less harmful (51.2%, all p<0.05). A higher proportion of current EC users (87.4%) thought that they were less harmful compared with cigarettes than those who had tried but were not using (68.8%) or never-users (50.4%), among whom the proportion was lowest (all differences p<0.05). Perceptions among youth were similar to adults. For example, in the 2015 ASH Smokefree GB youth survey, 2% thought that EC were more harmful than cigarettes, 21% equally harmful, 67% less harmful and 10% did not know.

In the STS, the proportion believing EC to be less harmful appears to be even lower. Only 44.1% of current smokers in England between November 2014 and March 2015 believed that EC were less harmful than cigarettes [15].
Since 2013, perceptions of the relative harmfulness of EC have become less accurate. Significantly larger proportions perceived EC to be at least as harmful as cigarettes in 2014 than in 2013 both in the Internet Cohort GB surveys (Figure 16) and in the ASH youth surveys (Figure 17 [64]). In the Internet Cohort GB survey, there was no significant change from 2012 to 2013, but from 2013 to 2014 the proportion thinking that EC were less harmful decreased in favour of equally or more harmful (p<0.001). For youth, between 2013 and 2014, the decrease in the proportion endorsing ‘less harmful’ and the increase in the proportion endorsing ‘equally harmful’ were significant (p<0.01). There were no significant changes in the proportion endorsing ‘more harmful’ or ‘don’t know’.

In the ASH adult surveys, data on harm perception are available for 2013 to 2015 (Figure 17). In line with the other GB surveys, this survey found a steep increase in the proportion perceiving EC to be equally harmful as cigarettes (p<0.001).
Figure 16: Perceptions of relative harmfulness of e-cigarettes in comparison with tobacco cigarettes. Internet Cohort GB surveys (N=1,209 respondents with data at all three time points)

Figure 17: Perceptions of relative harmfulness of e-cigarettes in comparison with tobacco cigarettes. ASH Smokefree GB adult surveys (weighted)

Notes: “Less harmful” includes those saying “Electronic cigarettes are completely harmless”. “Not applicable – I do not think regular cigarettes are harmful” not shown (2013: 1.2%, 2014: 0.9%, 2015: 0.8%)
Surveys from the US also suggest that from 2010 to 2013, the proportion of current smokers aware of EC who believed that EC were less harmful than smoking cigarettes declined considerably [65]. Youth in the US appear to have a less realistic perception of the relative harm of EC compared with cigarettes than UK youth. In the 2012 National Youth Tobacco Survey, of those who were aware of EC, around one-third perceived them to be less harmful than cigarettes and around half were unsure [66, 67].

The ASH Smokefree GB youth survey in 2013 and 2014 further included a question on the harm of EC to persons around a user. Again, the proportion who thought them less harmful than traditional cigarettes decreased from 2013 to 2014 (p<0.05), and the proportion who thought they caused similar levels of harm increased (p<0.01) (Figure 19).
Harm perception relative to nicotine replacement therapy (NRT)

The ASH Smokers’ survey in 2014 asked respondents about their perception of EC compared with NRT (Table 20). The largest group of respondents thought EC were about as safe. Notably, a higher proportion thought that EC were safer than NRT than believed that NRT was safer than EC. This was particularly pronounced in current EC users.

Table 5: Relative harm perception by e-cigarette use status ASH Smokers’ survey 2014

<table>
<thead>
<tr>
<th>E-cigarette use status</th>
<th>Never (n=470)</th>
<th>Current (n=256)</th>
<th>Ex (n=477)</th>
<th>Total (n=1203)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safer</td>
<td>14 (66)</td>
<td>28.1 (72)</td>
<td>22 (105)</td>
<td>20.2 (243)</td>
</tr>
<tr>
<td>About as safe</td>
<td>28.1 (132)</td>
<td>44.1 (113)</td>
<td>35.6 (170)</td>
<td>34.5 (415)</td>
</tr>
<tr>
<td>Less safe</td>
<td>16.2 (76)</td>
<td>6.3 (16)</td>
<td>13 (62)</td>
<td>12.8 (154)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>41.7 (196)</td>
<td>21.5 (55)</td>
<td>29.4 (140)</td>
<td>32.5 (391)</td>
</tr>
</tbody>
</table>

One US survey of 1,400 current and former smokers also assessed expected outcomes of using EC compared with NRT [68]. EC were perceived to be less risky, cost less, cause fewer negative physical feelings, taste better, provide more satisfaction, and be better at reducing craving, negative affect, and stress.
Summary of findings

Although the majority of adults and youth still correctly perceive EC to be less harmful than tobacco cigarettes, there has been an overall shift towards the inaccurate perception of EC being at least as harmful as cigarettes over the last year, for both groups. Intriguingly, there is also some evidence that people believe EC to be less harmful than medicinal nicotine replacement therapy (NRT).

Policy implications

- Clear and accurate information on relative harm of nicotine, EC and tobacco cigarettes is needed urgently (see also Chapter 10).
- Research is needed to explore how health perceptions of EC are developed, in relation to tobacco cigarettes and NRT, and how they can be influenced.
9. E-cigarettes, nicotine content and delivery

Background

We have undertaken a review of available evidence concerning nicotine released by EC. The review is divided into four parts, covering nicotine that EC use (vaping) releases into ambient air, nicotine content of e-liquid, nicotine content in e-vapour, and nicotine delivery to EC users (vapers). The main concern with nicotine in EC relates to the question of whether EC use exposes users or bystanders to the risk of nicotine poisoning. For this reason, we start with a short introductory review of this topic.

Toxicity of nicotine

Nicotine in the form of tobacco and more recently NRT has been available to thousands of millions of people and large numbers of them, including small children, have ingested considerable doses of nicotine. Fatal nicotine poisoning, however, is extremely rare. This fact strongly contradicts the often-repeated claim that an ingestion of 30-60mg of nicotine is fatal. The source of this claim proved difficult to locate – textbooks just cite older textbooks. Eventually, the assertion was found to be based on dubious self-experiments conducted in the 1890s [69].

We are aware of one unconfirmed newspaper report of a fatal poisoning of a two-year old child [70] and of three published case studies of small children who drank e-liquid. A two-year old was admitted to hospital with vomiting, ataxia, and lethargy, and was discharged after 24 hours of observation [71]. In the second report, an 18-month old girl drank 24mg nicotine in e-liquid, vomited and was irritable, and recovered fully within an hour or so [72]. The third article presented a case of a 30-month old child suspected to have ingested e-liquid. The quantity of e-liquid was uncertain and the child was asymptomatic with all clinical observations reported to be normal [73].

With the increase in EC use, there has been an increase in calls to poison centres following accidental exposures but these remain lower than calls following such exposure from tobacco and none resulted in any serious harm [74] (see next chapter for UK data). Serious nicotine poisoning seems normally prevented by the fact that relatively low doses of nicotine cause nausea and vomiting, which stops users from further intake.

Apart from accidental poisoning, nicotine has also been used in suicide attempts. Suicide attempts with large amounts of pesticides containing nicotine sulphate often succeed [75] but completed suicides using e-liquids are extremely rare. Where adults
drank up to 1,500mg of nicotine in e-liquid, the result was vomiting and recovery within a few hours [76]. One fatal outcome was recorded with 3,950mg of nicotine found in gastric content. The victim seems to have drunk three vials of e-liquid totalling over 10,000mg of nicotine[76]. An intravenous injection of unknown quantity of e-liquid also resulted in death [77].

E-liquid normally comes in 10ml bottles containing up to 360mg of nicotine (see below). This poses no risk to vapers if used as intended. The liquid however should be in ‘childproof’ packaging to prevent small children, who may find the flavouring appealing, from drinking it. This seems to have been widely accepted by the EC industry. All e-liquids we have seen so far in the UK and globally were sold in child-resistant packaging.

**Review methods**

We searched the US National Library of Medicine (Pubmed) using the following search terms: ((cotinine OR nicotine) AND (blood OR plasma OR urine OR saliva OR liquid OR aerosol OR pharmacokinetic$)) AND (electronic cigarette$ OR e-cig$ OR ENDS). This search returned 161 records. The abstracts of all records were screened.

Papers were included if they were peer-reviewed and presented data regarding nicotine in e-liquid, aerosol, or body fluids (blood, saliva or urine). Studies that reported data on blood, salivary, or urine cotinine were also included.

A total of 112 records were excluded as they did not contain any relevant information, leaving 49 records. The full papers of these records were retrieved and reviewed.

From the full text review, 25 studies provided data regarding nicotine content of ambient air, e-liquid and vapour, and 16 provided data on nicotine delivery to users. The remaining eight papers did not contain any relevant information. Three further relevant papers were published during the writing of this report and were also included.

**Nicotine in ambient air, e-liquid and e-vapour**

We identified five studies of nicotine in ambient air, 14 studies of nicotine in e-liquid and nine studies of nicotine vapour. The results are summarised below. We tabulate the results where appropriate and provide a narrative summary where there are only a few studies available. Each section is concluded with a brief summary.

**Passive vaping: Nicotine from e-cigarette use in ambient air**

Four studies examined nicotine exposure from passive vaping. Long et al., 2014 measured nicotine content of EC exhalations. EC exhalations contained eight times less
nicotine than cigarette exhalations [78]. Estimating environmental nicotine exposure, however, has to take into account the fact that side-stream smoke (ie the smoke from the lighted end of the cigarette, which is produced regardless of whether the smoker is puffing or not) accounts for some 85% of passive smoking and there is no side-stream EC vapour. A study measuring nicotine residue on surfaces in houses of smokers and vapers reported only negligible levels from vaping, 169 times lower than from smoking [79].

Colard et al., 2015 describe a model for estimating environmental workplace exposure [80]. The model predicts much lower nicotine exposure from vaping than from smoking, at levels negligible in health terms.

Goniewicz and Lee 2014 found that nicotine from EC vapour gets deposited on surfaces, but at very low levels [81]. This poses no concerns regarding exposure to bystanders. At the highest concentration recorded (550 μg/m$^2$), an infant would need to lick over 30 square metres of exposed surface to obtain 1mg of nicotine.

Ballbe et al., 2014 provide the most informative data collected to date as this study measured the actual levels of airborne nicotine in homes of ex-smokers who live either with smokers (N=25) or with vapers (N=5) and also in 24 control homes [82]. The study also measured salivary and urinary cotinine in partners of smokers and vapers. As expected, there was little nicotine in non-smokers’ homes. The air in the homes of vapers contained six times less nicotine than the air in the homes of smokers. There was less of a difference between cotinine levels of partners of vapers and smokers (1.4 to 2 fold difference), most likely due to some ‘ex-smokers’ still occasionally smoking, but even with this possible contamination, the nicotine levels absorbed via passive vaping were negligible. Partners of vapers had mean cotinine concentrations of 0.19 ng/ml in saliva and 1.75 ng/ml in urine, which is about 1,000 times less than the concentrations seen in smokers and similar to levels generated by eating a tomato [83].

Summary

EC release negligible levels of nicotine into ambient air with no identified health risks to bystanders.

Nicotine in e-liquids

Fourteen studies tested more than 400 different e-liquids, mainly to check the accuracy of product labelling. Their results are summarised in Table 6, updated from an earlier review by Cheng et al., 2014 [84].
### Table 6: Nicotine in refill solutions, cartridges and aerosols of e-cigarette products
*(Adjusted from Cheng et al. 2014)*

<table>
<thead>
<tr>
<th>Study</th>
<th>Matrix</th>
<th>Units</th>
<th>Nicotine level</th>
<th>Maximum deviation from label*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Westenberger</td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>0.00 to 6.76</td>
<td>N.A.</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>µg/100mLpuff</td>
<td>0.35 to 43.2</td>
<td>N.A.</td>
</tr>
<tr>
<td></td>
<td>Refill solution</td>
<td>µg/mL</td>
<td>N.D. to 25.6</td>
<td>N.A.</td>
</tr>
<tr>
<td>Cobb et al</td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>3.23±0.5 to 4.07±0.54</td>
<td>−80 to −77%†</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>µg/35 mL puff</td>
<td>0.3 for puffs 11 to 50 to 1 for puffs 1 to 10</td>
<td>N.A.</td>
</tr>
<tr>
<td>Trehy et al</td>
<td>Refill solutions</td>
<td>mg/mL</td>
<td>0 to 25.6</td>
<td>−100 to 100%†</td>
</tr>
<tr>
<td></td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>0 to 21.8</td>
<td>−100 to 100%†</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>µg/100 mL puff</td>
<td>0 to 43.2</td>
<td>N.A.</td>
</tr>
<tr>
<td>Cheah et al</td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>0.00 to 15.3</td>
<td>−89 to 105%†</td>
</tr>
<tr>
<td>Pellegrino et al</td>
<td>Cartridge</td>
<td>% W/W</td>
<td>&lt;0.001 to 0.25</td>
<td>N.A.</td>
</tr>
<tr>
<td>McAuley et al</td>
<td>Indoor air</td>
<td>ng/L</td>
<td>538 to 8770</td>
<td>N.A.</td>
</tr>
<tr>
<td>Goniewicz et al</td>
<td>Refill solution</td>
<td>mg</td>
<td>0±0.0 to 25±1.1</td>
<td>−75 to 28%</td>
</tr>
<tr>
<td></td>
<td>Cartridge</td>
<td>mg</td>
<td>0±0.0 to 19±0.5</td>
<td>−89 to 25%</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>mg/150 puffs</td>
<td>0.3±0.2 to 8.7±1.0</td>
<td>N.A.</td>
</tr>
<tr>
<td>Etter et al</td>
<td>Refill solution</td>
<td>mg/mL</td>
<td>N.D. to 29.0</td>
<td>−15 to 21%†</td>
</tr>
<tr>
<td>Kirschner et al</td>
<td>Refill solution</td>
<td>mg/mL</td>
<td>14.8±0.2 to 87.2±2.7</td>
<td>−50 to 40%†</td>
</tr>
<tr>
<td>Cameron et al</td>
<td>Refill solution</td>
<td>mg/mL</td>
<td>8.5±0.16 to 22.2±0.62</td>
<td>−66 to 42%†</td>
</tr>
<tr>
<td>Goniewicz et al</td>
<td>Liquids</td>
<td>mg/mL</td>
<td>N.D. to 36.6 (150.3 ‘pure nicotine’)</td>
<td>-92 to 104%</td>
</tr>
<tr>
<td>Geiss et al</td>
<td>Liquids</td>
<td>mg/mL</td>
<td>N.D. to 20.8</td>
<td>-0 to 16%</td>
</tr>
<tr>
<td>Kavvalakis et al</td>
<td>Liquids</td>
<td>%w/v</td>
<td>1.01 to 1.62</td>
<td>-17 to +6%</td>
</tr>
<tr>
<td>Farsalinos et al</td>
<td>Liquids</td>
<td>mg/mL</td>
<td>Labelled 12-18</td>
<td>-21 to +22%</td>
</tr>
</tbody>
</table>

*Deviation from label = (measured value – labelled value) * 100/labelled value.

†Calculation performed by this analysis based on reported data in each study.

N.A. = not available; N.D. = none detected.
A range of analytical methods was used, which may have contributed some variation. There is no established standard and different studies use different approaches. Cheah et al., used gas chromatography coupled with flame ionization detector [88]; Etter et al., gas chromatography coupled with mass spectrometry and ultra high-performance liquid chromatography coupled with diode array detector [92]; McAuley et al., gas chromatography coupled with nitrogen-phosphorus detector [90]; Goniewicz et al., gas chromatography coupled with thermionic specific detector [95]; Trehy et al., high-performance liquid chromatography coupled with diode array detector [87]; Westenberger high-performance liquid chromatography coupled with ultraviolet/visible spectroscopic detector [85]; Kubica et al., liquid chromatography coupled with tandem mass spectrometry [99]; and Kirschner et al., liquid chromatography coupled with time-of-flight mass spectrometry [93].

The data generated so far provide answers to three questions:

**Do e-liquids pose a poisoning hazard?**

The vast majority of vapers use ‘ready-made’ liquids in 10ml bottles, but some aficionados, primarily in the US, buy high concentration nicotine solutions in larger quantities for DIY dilution. An e-liquid was identified labelled as containing 210mg/ml which in fact contained only 150mg/ml [95] but even this may pose risk if ingested in larger volume. DIY liquids are rarely used in Europe, but for spurious reasons, Europe is poised to prohibit sales of products with nicotine concentrations above 20mg/ml. When this happens, the popularity of DIY e-liquids among dependent vapers, who now cannot access the products they need but can mix them themselves at home at low cost, may increase.

‘Ready-made’ e-liquids come in strengths of up to 36mg/ml nicotine, with the highest concentration recorded of 36.6mg/ml. This poses no risk of nicotine poisoning if used as intended. An overenthusiastic vaper, like someone who is over-smoking, receives a reliable warning via nausea. If the 10ml bottle of e-liquid was drunk, it would cause nausea and vomiting but would be unlikely to inflict serious harm. To protect young children from accidental exposure though, e-liquids should be in ‘childproof’ packaging.

**How accurate is product labelling?**

The real content exceeded markedly the labelled concentration only in samples where the declared content was very low (6mg/ml) and the real concentrations ranged up to 12mg/ml (ie still low levels). The most striking examples of inaccurate labelling concerned much lower nicotine levels than those declared in e-liquids confiscated in Singapore where EC are banned, for example, a liquid labelled as containing 24mg of nicotine contained only 3mg [88]. This however was most likely due to samples being several years old. Market competition seems to have led to improved standards as
poorly labelled products are now less common and overall the labelling accuracy has improved. For instance in the latest study which sampled 263 liquids from 13 manufacturers, the correlation between the declared and measured concentrations was r=0.94 with the samples ranging from -17% to +6% of the declared value [85]. In another study testing the five most popular EC brands, the consistency of nicotine content across different batches of nicotine cartridges of the same products was found to be within the accuracy required from medicinal nebulisers [100]. Given the generally adequate labelling accuracy and the fact that the actual nicotine intake by vapers is dictated by a host of other factors discussed below, the accuracy of labelling of common e-liquids poses no major concerns.

Is there a risk from e-liquids inaccurately labelled as containing 0 nicotine?

All samples labelled as containing 0 nicotine were nicotine free in the newer studies, but three early studies found nicotine in some samples of ‘0 nicotine’ e-liquids. One sample reported in 2011 was clearly mislabelled [87] but in all other cases, only trace contamination was detected (below 1mg/ml). This would have no central effect on users.

Summary

Poorly labelled e-liquid and e-cartridges mostly contained less nicotine than declared and so posed no risk to users. The accuracy of product labelling currently raises no major concerns.

Nicotine in e-vapour

A number of studies evaluated nicotine in EC vapour generated by puffing machines. A recent experiment [101] has shown that parameters of puffing topography, especially puff duration and puff frequency, have a major influence on nicotine delivery. This poses a serious problem in interpreting the existing studies. The key parameters used by puffing machines differ widely across studies, and may not correspond well or at all with vapers’ behaviour generally and especially with the way individual EC products are used. To illustrate the point, Table 7 below, from Cheng et al. 2014 [84], shows the wide range of settings used in different studies. (Table 7 includes some unpublished studies).

Table 7. Settings of EC puffing parameters. From Cheng et al 2014 [84].

<table>
<thead>
<tr>
<th>Study</th>
<th>Puff volume</th>
<th>Puff interval</th>
<th>Puff duration</th>
<th>Puffs/session</th>
<th>Smoking machine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goniewicz et al [100]</td>
<td>70</td>
<td>10</td>
<td>1.8</td>
<td>15</td>
<td>Palaczbot*</td>
</tr>
<tr>
<td>Pellegrino et al [89]</td>
<td>498</td>
<td>8</td>
<td>3</td>
<td>16</td>
<td>Aspiration</td>
</tr>
</tbody>
</table>
For instance, the average puff duration in experienced vapers is 2.8 seconds [101], but some studies used puffs lasting for up to 4 seconds. This can overheat the e-liquid and provide unrealistically high readings (see Chapter 11).

Although it would be feasible to establish some empirical standards, eg of puff duration and frequency, by observing vapers, any general standard would have to average values across different products. As different products, and especially products from different ‘generations’, are used differently, such a blanket regimen would still provide inaccurate and potentially misleading information.

A recent study discovered another serious problem with trying to make sense of nicotine content in e-vapour. Across five common e-liquids with middle ranges of strength, the actual nicotine concentration in the e-liquid had almost no relationship with the nicotine content in vapour when the devices were puffed on by a machine at a standard rate [100]. The e-liquid of course had to contain a certain minimal level of nicotine as with little or no nicotine in e-liquid, there would be little or no nicotine in vapour. This finding concerning machine testing also does not mean that nicotine levels in e-liquids are irrelevant for EC users. Although EC technology is developing to maximise nicotine delivery, a vaper seeking high blood nicotine levels is likely to struggle to achieve them with a weak e-liquid. The reason for the low correlation between nicotine in e-liquid and in e-vapour is that the battery output, type of wicks, ventilation holes and other mechanical characteristics of each individual EC product determine how much vapour and nicotine is released – before the individual puffing style and preferences generate yet another key determinant of nicotine delivery to users.
These findings have an important implication. Above the necessary minimum level of nicotine, nicotine concentrations in e-liquid and even the concentrations in vapour, if measured by standard puffing schedules, are of limited relevance. For light smokers, 18mg/ml ‘mild’ e-liquid may be sufficient, but they may also prefer a stronger liquid and take shorter and less frequent puffs. A heavy smoker who would be expected to prefer a 28mg/ml ‘strong’ liquid may in fact choose a ‘moderate’ strength if they favour long and frequent puffs.

In real-life use, vapers have no way of knowing in advance what liquid strength and product characteristics they will prefer. As with other consumer products of this type, such as cigarettes, coffee and soft drinks, vapers have to try several EC models and different e-liquids before settling on a preferred product that matches their preferences.

For practical purposes, general labelling of the strength of e-liquid, along the lines used for indicating coffee strength, may provide sufficient information for consumers. The current vapers’ preferences suggest as a rough rule of thumb that ‘mild’ equates to 16–20mg/ml, ‘medium’ to 21–26mg/ml and ‘strong’ to 27–36mg/ml.

Translating these findings into regulatory recommendations, it would seem that regulation to enforce standard nicotine delivery may not be needed because nicotine delivery is influenced by a host of factors, including user puffing preferences, and because consumer preferences differ. EC products will hopefully continue to evolve guided by differential market success, with the result that more smokers find EC helpful and switch to them.

**Summary**

Across the middle range of nicotine levels, nicotine delivery to vapour is determined primarily by mechanical and electrical characteristics of EC products and by the duration and frequency of puffs. General labelling of the strength of e-liquids, along the lines used for indicating coffee strength (eg mild, medium and strong), is likely to provide sufficient information for consumers.

**Nicotine delivery to e-cigarette users**

To assess nicotine intake from EC, a number of studies took blood samples from smokers during and after vaping. Table 8 summarises data from 17 studies that investigated nicotine delivery from EC in humans. The narrative description of the studies and additional details concerning their findings are presented in Appendix C.

The two key questions in this field are:

a) How much nicotine EC deliver compared to cigarettes, and

b) How fast EC deliver nicotine compared to cigarettes.
As in every new field, methodological problems limit the usefulness of some of the data collected so far. Two problems in particular are prominent.

1) Almost all studies used prescribed puffing regimes, sometimes derived from observations of smokers rather than vapers. We described above the evidence that puffing schedules have a major influence on nicotine delivery to vapour. Puffing schedules that do not correspond with vapers’ behaviour are thus unlikely to provide realistic nicotine delivery data. Only three studies allowed vapers to puff ad-lib on first use.

2) Regarding the question of the speed of nicotine delivery, all existing studies started blood sampling only after five minutes of vaping. Cigarettes provide peak nicotine plasma levels very quickly (eg peak arterial nicotine concentrations of around 20ng/ml nicotine are reached within 20 seconds of starting to puff on an cigarette [107]). Data collected so far do not allow an appraisal of whether EC are approaching cigarettes in this key parameter.

Despite these limitations, the studies above have generated several strands of useful information on how much nicotine vapers obtain over time and how this compares with nicotine intake from cigarettes.

Cotinine is a metabolite of nicotine with a long half-life which shows nicotine exposure over time. Cotinine data are thus not influenced by the laboratory puffing schedules. Some studies suggest that experienced vapers can, over time, reach nicotine levels comparable to those obtained from smoking [108-110], although others have found plasma or salivary cotinine levels that are still lower than those observed in daily smokers [111-113].

Cigalike EC deliver lower levels of nicotine than cigarettes [114-116], especially to novice users [117-119]. Vapers obtain slightly more nicotine from them with practice, but nicotine delivery is comparatively low and slow [115]. Experienced users can obtain a rise in blood nicotine concentration of between 8 and 16ng/ml [120, 121]. Tank systems deliver nicotine more efficiently than cigalikes and somewhat faster [120, 122, 123].

Overall, the data indicate that within five minutes of use of a cigalike EC, blood nicotine levels can rise by approximately 5ng/ml. For comparison, after chewing a piece of 2mg nicotine chewing gum, peak plasma concentrations of 3–5ng/ml are observed within approximately 30 minutes [124, 125]. For experienced users of tank systems the increase in blood nicotine concentration within five minutes of use can be 3–4 times higher.
Speed of nicotine delivery seems important for smokers’ satisfaction. Cigarettes deliver nicotine very fast via the lungs. It is likely that to out-compete cigarettes, EC will need to provide nicotine via the lungs as well. Although some EC products may already provide a degree of lung absorption, most nicotine is probably delivered via a much slower route through buccal mucosa and upper airways, in a way that is closer to the delivery from nicotine replacement medications than to the delivery from cigarettes.

This tallies with two other observations. Vapers feel they are less dependent on EC than they were on cigarettes [126]; and non-smokers experimenting with EC do not find them attractive and almost none progress to daily vaping [127]. This contrasts with the fact that about half of adolescents who experiment with cigarettes progress to daily smoking [128].

In addition to mechanical characteristics of EC and user puffing behaviour discussed in previous sections, the composition of the chemicals used to produce the vapour, typically vegetable glycerol and/or propylene glycol (PG), may also influence nicotine delivery. E-liquid with a mix of vegetable glycerol/PG was associated with better nicotine delivery than a vegetable glycerol-only e-liquid with the same concentration of nicotine [129]. The presumed effect is that PG vaporises at a faster rate than vegetable glycerol when heated in the EC and so is able to carry more nicotine to the user.

If EC continue to improve in the speed of nicotine delivery, they are likely to appeal to more smokers, making the switch from smoking to vaping easier. It may be important in this context to note that if the smoking-associated risk is removed, nicotine use by itself, outside pregnancy, carries little health risk and in fact conveys some benefits.

Table 8: Studies examining nicotine intake in vapers

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>EC Device</th>
<th>Methods</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vansickel et al 2012 [119]</td>
<td>20 smokers</td>
<td>Vapor King (cigalike), 18mg/ml nicotine</td>
<td>Overnight abstinence, baseline blood sample, after 5 mins 10 puffs, 30 sec inter-puff interval, 5 mins after last puff blood sample. Repeated 5x, 30 mins in between</td>
<td>At end of last puffing bout plasma nicotine increased from 2.2 ng/ml at baseline to 7.4 ng/ml.</td>
</tr>
<tr>
<td>Vansickel &amp; Eissenberg 2012 [121]</td>
<td>8 vapers using EC for average of 12 months</td>
<td>Own EC 1 used 9 mg/ml 6 used 18 mg/ml 1 used 24 mg/ml</td>
<td>Overnight abstinence, Baseline blood, after 5 mins 10 EC puffs at 30 sec intervals, 5 and 15 mins after first puff blood sample, 60 min ad-lib vaping</td>
<td>Increase in plasma nicotine from 2.0 ng/ml to 10.3 ng/ml in 5 mins. Cmax = 16.3 ng/ml at end of ad lib period</td>
</tr>
<tr>
<td>Yan &amp; D’Rujz 2014 [129]</td>
<td>23 smokers</td>
<td>4 types of Blu (cigalike) EC (1.6% to 2.4%) Marlboro cigarette</td>
<td>Randomised 6 sessions 7-days get used to EC, 36 h abstinence. EC = 50x5 sec puffs, 30 sec</td>
<td>During controlled puffing Cmax (ng/ml): EC 10.3 to 18.9; cig 15.8</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>EC Device</td>
<td>Methods</td>
<td>Results</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>Vansickle et al 2010 [118]</td>
<td>32 smokers</td>
<td>Own brand cig NJOY EC (18mg) Crown 7 EC (16mg) Sham (unlit cig) EC were cigalike</td>
<td>Randomised crossover, overnight abstinence. Baseline blood, EC – 10 puffs at 30 sec intervals, blood at 5, 15, 30, 45, 60 mins</td>
<td>Only cig produced significant rise in nicotine (18.8 ng/ml at 5 mins)</td>
</tr>
<tr>
<td>Van Staden et al 2013 [113]</td>
<td>13 smokers</td>
<td>Twisp eGo (18mg/ml nicotine)</td>
<td>Provided with EC and asked to use this and stop smoking for two weeks</td>
<td>Cotinine ng/ml Baseline: 287, at 2 weeks 97 (p=0.0011)</td>
</tr>
<tr>
<td>Spindle et al 2015 [120]</td>
<td>13 vapers &gt; 3 months, e-liquid ≥12mg/ml</td>
<td>Own EC (all tank systems) 1 x 12 mg/ml 3 x 18 mg/ml 9 x 24 mg/ml</td>
<td>Overnight abstinence, two sessions. Baseline blood, EC – 10 puffs at 30 sec interval. Blood at 5 and 15 min.</td>
<td>Plasma nicotine at Baseline: 2.4 ng/ml 5 mins: 19.2 ng/ml 10 mins: 10.2 ng/ml</td>
</tr>
<tr>
<td>Bullen et al 2010 [117]</td>
<td>8 smokers</td>
<td>Ruyan V8 (cigalike) 16mg/ml (puff for 5 mins) Inhalator 10mg (puff for 20 mins) Own brand cig (puff for 5 mins)</td>
<td>Randomised crossover, overnight abstinence. Baseline blood, product use, blood at 5, 10, 15, 30, and 60 mins.</td>
<td>Cmax (ng/ml): EC=1.3; Inh=2.1; Cig=13.4 Tmax (mins): EC=19.6; Inh=32.0; Cig=14.3</td>
</tr>
<tr>
<td>Flouris et al 2013 [130]</td>
<td>15 smokers</td>
<td>Giant (cigalike) 11mg/ml</td>
<td>Smoked 2 cigs, puffed EC to match smoking. Cotinine immediately and 1 h after puffing</td>
<td>No difference between products</td>
</tr>
<tr>
<td>Caponnetto et al 2013 [40]</td>
<td>Sample size not stated</td>
<td>Categoria (cigalike) 7.2mg for 12 weeks 7.2mg/5.4mg for 12 weeks</td>
<td>RCT – 12 weeks of EC use</td>
<td>Salivary cotinine 6 weeks: 42 ng/ml; 12 weeks: 91 ng/ml 6 weeks: 68 ng/ml; 12 weeks: 70 ng/ml</td>
</tr>
<tr>
<td>Etter &amp; Bullen 2011 [110]</td>
<td>30 vapers Mean EC use 94 days</td>
<td>Own brand EC Mean nicotine content 18mg/ml</td>
<td>Ad libitum use</td>
<td>Salivary cotinine 322 ng/ml</td>
</tr>
<tr>
<td>Dawkins &amp; Corcoran 2014 [114]</td>
<td>14 vapers, 7 dual users,</td>
<td>Skycig (cigalike) 18mg/ml</td>
<td>10 puffs in 5 mins, then 1 hour ad lib</td>
<td>After 10 mins: 0.74 – 6.77 ng/ml After ad lib: 4.35-25.6 ng/ml</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>EC Device</td>
<td>Methods</td>
<td>Results</td>
</tr>
<tr>
<td>------------------------------</td>
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<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Nides et al 2014 [116]</td>
<td>29 smokers, 55% used EC in past</td>
<td>NJOY® King Bold (cigalike) 26mg</td>
<td>EC ad lib 1 week, 12 h abstinence. 2x10 puffs (30 sec inter-puff interval) 60 mins apart Blood before and 5, 10, 15, 30 minutes after</td>
<td>N=16 had no baseline plasma nicotine Rise 5 min after first puffs: 3.5 ng/ml; after second puffs: 5.1 ng/ml</td>
</tr>
<tr>
<td>Norton et al 2014 [112]</td>
<td>16 smokers</td>
<td>Smoke 51 TRIO (cigalike) 11 mg/ml</td>
<td>Day 1: own brand, saliva sample Given EC and stopped smoking. Saliva at day 5. Analysis of 16 who abstained from smoking for 72 hours</td>
<td>Significant decrease in saliva cotinine between baseline (338.0 ng/ml) and day 5 (178.4 ng/ml), p&lt;0.001</td>
</tr>
<tr>
<td>Hecht et al 2014 [111]</td>
<td>28 vapers (median 9 months), 96% daily users</td>
<td>Average nicotine 12.5 +/- 7.0 mg/ml All tank system EC</td>
<td>Measured toxicants, carcinogens, nicotine and cotinine in urine</td>
<td>Nicotine: 869 ng/ml Cotinine: 1880 ng/ml Smokers normally Nicotine: 1380 ng/ml, cotinine: 3930 ng/ml</td>
</tr>
<tr>
<td>Hajek et al 2014 [115]</td>
<td>40 smokers, 35% used EC in past</td>
<td>Greensmoke (cigalike) EC (2.4% nicotine)</td>
<td>Overnight abstinence Baseline blood, first EC use ad-lib 5 mins, blood at 5, 10, 15, 20, 30 and 60 mins. Repeated after 4-weeks of ad lib use</td>
<td>Baseline: Cmax: 4.6, Tmax: 5, AUC: 96 4-weeks: Cmax: 5.7, Tmax: 5, AUC: 142</td>
</tr>
<tr>
<td>Farsalinos et al 2014 [122]</td>
<td>N=23 vapers (19 months use)</td>
<td>A: V2 (cigalike) B: Tank system EVIC at 9 watts, EVOD Same 18mg/ml liquid</td>
<td>Abstained for 8 hrs Blood baseline and after 10 puffs over 5 mins, 1 h ad lib, blood every 15 mins</td>
<td>A: 5 mins: 4.9 ng/ml 1h: 15.8 ng/ml B: 5 mins: 6.6 ng/ml 1h: 23.5 ng/ml</td>
</tr>
<tr>
<td>Oncken et al 2015 [123]</td>
<td>N=20 smokers given EC for 2 weeks</td>
<td>Menthol or non-menthol tank system with 18mg/ml liquid</td>
<td>Blood baseline, 5 min ad lib vaping, blood at 5,10,15,20,30 min</td>
<td>At 5 min nicotine increased by 4-5 ng/ml</td>
</tr>
</tbody>
</table>

**Summary of findings**

The accuracy of labelling of nicotine content currently raises no major concerns. Poorly labelled e-liquid and e-cartridges mostly contained less nicotine than declared. EC used as intended poses no risk of nicotine poisoning to users. However, e-liquids should be in ‘childproof’ packaging.
Duration and frequency of puffs and mechanical characteristics of EC play a major role in determining nicotine content in vapour. Across the middle range of nicotine levels, in machine tests using a standard puffing schedule, nicotine content of e-liquid is related to nicotine content in vapour only weakly. EC use releases negligible levels of nicotine into ambient air with no identified health risks to bystanders. Use of a cigalike EC can increase blood nicotine levels by around 5ng/ml within five minutes of use. This is comparable to delivery from oral NRT. Experienced EC users using the tank EC can achieve much higher blood nicotine levels over a longer duration, similar to those associated with smoking. The speed of nicotine absorption is generally slower than from cigarettes but faster than from NRT.

Policy implications

- General labelling of the strength of e-liquids, along the lines used for example indicating coffee strength, provides sufficient guidance to consumers.
- Regulatory interventions should ensure optimal product safety but make sure EC are not regulated more strictly than cigarettes and can continue to evolve and improve their competitiveness against cigarettes.
10. Safety of e-cigarettes in the light of new evidence

Introduction

PHE commissioned a review of EC in 2014, which covered EC safety [131]. The review found that the hazard associated with use of EC products currently on the market “is likely to be extremely low, and certainly much lower than smoking” and “the health risks of passive exposure to electronic cigarette vapour are likely to be extremely low”.

These conclusions tally with a review by an international team of experts, which estimated the risks of vaping at less than 5% of the risks of smoking [10] and a comprehensive review of relevant literature by another international team which concluded that “EC aerosol can contain some of the toxicants present in tobacco smoke, but at levels which are much lower. Long-term health effects of EC use are unknown but compared with cigarettes, EC are likely to be much less, if at all, harmful to users or bystanders” [132].

Over the past few months, however, several reports have suggested that EC may pose more risks than previously thought [133-137].

We were asked to review these studies to see if in the light of this new evidence, the conclusions of the PHE 2014 review need to be adjusted. We present below the details of these studies together with any additional data that may assist with their interpretation.

Aldehydes in vapour from e-cigarettes

Two recent reports raised a possibility that under certain conditions, EC may release high levels of aldehydes. Aldehydes, including formaldehyde, acrolein and acetaldehyde, are released in tobacco smoke and contribute to its toxicity. Aldehydes are also released with thermal degradation of propylene glycol and glycerol in e-liquids. Previous studies detected the presence of aldehydes, especially formaldehyde, in the vapour from some EC, but at levels much lower than in cigarette smoke [138]. Across brands, EC released 1/50th of the level of formaldehyde released by cigarettes. The highest level detected was six times lower than the level in cigarette smoke [138].

In November 2014, following a press release from Japan [136], major media around the world reported variations of a headline: “E-cigarettes contain 10 times the carcinogens of regular tobacco”. This was based on a Japanese researcher reporting at a press conference that during tests on a number of EC brands, one product was identified
which released 10 times more formaldehyde than cigarettes. The press release states that the formaldehyde was released when the e-liquid was over-heated. The study has not been published yet and so no further details are available, but the two experiments described below provide the explanation for this finding.

In January 2015, a similar report was published as a research letter to the New England Journal of Medicine (NEJM) [133]. In this study, negligible levels of formaldehyde were released at lower EC settings, but when a third generation EC (EC with variable power settings) was set to the maximum power and the apparatus was set to take puffs lasting 3–4 seconds, this generated levels of formaldehyde that, if inhaled in this way throughout the day, would exceed formaldehyde levels in cigarette smoke between five and 15 times.

The EC was puffed by the puffing machine at a higher power and longer puff duration than vapers normally use. It is therefore possible that the e-liquid was overheated to the extent that it was releasing novel thermal degradation chemicals. Such overheating can happen during vaping when the e-liquid level is low or the power too high for a given EC coil or puff duration. Vapers call this phenomenon ‘dry puff’ and it is instantly detected due to a distinctive harsh and acrid taste (it is detected by vapers, but not by puffing machines) [139]. This poses no danger to either experienced or novice vapers, because dry puffs are aversive and are avoided rather than inhaled.

A study has just been published testing the hypothesis that the NEJM report used dry puffs [140]. An equivalent EC product was set to the same or normal settings and used by seven vapers. The vapers found it usable at normal settings, but all received dry puffs and could not use the device at the settings used in the NEJM report [133]. The product was then machine tested. At the dry puff setting, formaldehyde was released at levels reported in the NEJM letter and the Japanese press release. At normal settings, there was no or negligible formaldehyde release.

We are aware of two studies that examined aldehyde levels in vapers. In a cross-sectional study, vapers had much lower levels of acrolein and crotonaldehyde in urine than smokers [111]. The other study, funded by the Medicines and Healthcare products Regulatory Agency (MHRA), examined changes in acrolein levels in smokers who switched to exclusive EC use and in those who continued to smoke while also using EC. As both EC and cigarettes release acrolein, there was a concern that ‘dual users’ may increase their acrolein intake compared to smoking only. The results showed a substantial decrease in acrolein intake in smokers who switched to EC, but it also found a significant decrease in acrolein intake in dual users (ie people that were both smoking and vaping). This was because they reduced their smoke intake as indexed by exhaled CO levels. Normal vaping generated negligible aldehyde levels [141].

Submitted by Tom Madden, owner of E-Cigs
Although e-liquid can be heated to a temperature which leads to a release of aldehydes, the resulting aerosol is aversive to vapers and so poses no health risk.

**Summary**

There is no indication that EC users are exposed to dangerous levels of aldehydes.

**Effects of e-cigarette vapour on mice lungs**

A paper published in February 2015 [135] generated worldwide media coverage with claims that it linked EC to lung inflammation, lung infection, and even lung cancer.

Groups of mice were put in a small container exposing them to vapour from six EC ('Menthol Bold' 1.8% nicotine) puffed on a rotating wheel at six puffs per minute for 1.5 hours, twice daily, over two weeks. The control mice were not exposed to this treatment.

Animals were infected with either streptococcus pneumonia via intranasal instillation and killed 24 hours later, or with tissue culture influenza virus and monitored for weight loss, mortality, and lung and airways inflammation. Compared to the control group, the experimental animals had an increase in pro-inflammatory cytokines, diminished lung glutathione levels, higher viral titre, and were more likely to lose weight and die. The study identified free radicals in EC vapour as the potential culprit.

There are several problems with the study and with the way its results have been interpreted.

EC vapour is inhaled as a replacement for tobacco smoke, but the study attempted no comparison of the effects on the lungs from smoke and vapour exposures. This makes a meaningful interpretation of the results difficult. A comparison was made, however, of the levels of free radicals. Even at the very high vapour density generated by the study procedure, the level of free radicals identified in vapour was “several orders of magnitude lower than in cigarette smoke”.

In addition to this, the mice in the experimental group were exposed to a much higher level of stress than the control group, and stress affects bacterial and viral response. Long and repeated containment in the small and crowded smoke chamber emitting an overpowering smell is a stressor in itself, but the animals also suffered repeated nicotine poisoning. The mice showed an average cotinine concentration of 267ng/ml. Cotinine is the primary metabolite of nicotine and in humans the amount of nicotine needed to give similar cotinine levels are tolerated by heavy smokers, but highly aversive to non-smokers, who would be expected to feel sick and vomit at this level of exposure. Mice are much more sensitive to nicotine than humans (LD50 in mice is 3mg/kg, in humans
6.5–13mg/kg [69]). Accelerated weight loss, reduced immunity and early death in the experimental group were much more likely the result of protracted stress and nicotine poisoning than the result of exposure to free radicals (which were in any case 1,000 times lower than from cigarettes).

A similar study from 2015 [134] reported oxidant reactivity (which is linked to free radicals) of e-liquid and cytokine release in exposed lung tissue and in mice exposed to EC vapour. Again, no comparison with exposure to smoke was reported.

Human studies do not corroborate any of the findings reported here. A case study of lipid pneumonia, which could have been caused by EC flavouring, received worldwide attention in 2012 [142] but despite extensive interest in the phenomenon, no further cases were published. Adverse effects of vaping are primarily local irritation and dry mouth [132]. A study that monitored asthma patients who switched from smoking to vaping found significant improvements in symptoms and in respiratory function [143]. The recent Cochrane Review found no significant adverse effects associated with EC use for up to 1.5 years [39].

**Summary**

The mice model has little relevance for estimating human risk and it does not raise any new safety concerns.

**Particles in e-cigarette vapour**

For completeness we are including information on another recent report which was interpreted as showing that EC may be dangerous to bystanders. At an EC Summit conference in London in November 2014, Harrison and McFiggans reported on particles present in EC vapour. Their presentation was reported in the British Medical Journal under the title “E-cigarette vapour could damage health of non-smokers” [137]. McFiggans and Harrison requested a retraction of the piece because their findings did not concern any health risks. It is the content of the particles rather than their presence or size which has health implications [144].

**Impact of media reports that e-cigarettes are dangerous**

Together with previous health scares, the articles reviewed here may be having a significant impact on public perception of EC safety. In the US, 82% of responders believed that vaping is safer than smoking in 2010, but the figure has shrunk to 51% in 2014 [65]. A perception that EC pose as much risk as smoking is the most likely explanation of the recent decline in adoption of EC by smokers [145].
Summary of findings

Two recent worldwide media headlines asserted that EC use is dangerous. These were based on misinterpreted research findings. A high level of formaldehyde was found when e-liquid was over-heated to levels unpalatable to EC users, but there is no indication that EC users are exposed to dangerous levels of aldehydes; stressed mice poisoned with very high levels of nicotine twice daily for two weeks were more likely to lose weight and die when exposed to bacteria and viruses, but this has no relevance for human EC users. The ongoing negative media campaigns are a plausible explanation for the change in the perception of EC safety (see Chapter 8).

None of the studies reviewed above alter the conclusion of Professor Britton’s 2014 review for PHE. While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals that are present pose limited danger. It had previously been estimated that EC are around 95% safer than smoking [10, 146]. This appears to remain a reasonable estimate.

Policy implications

- There is a need to publicise the current best estimate that using EC is around 95% safer than smoking.

- Encouraging smokers who cannot or do not want to stop smoking to switch to EC could be adopted as one of the key strategies to reduce smoking related disease and death.
11. Other health and safety concerns

There have been a number of newspaper reports about the hazards of EC use including e-liquid ingestion/poisonings, fires, battery explosions etc [147-149]. In this chapter we review available national data on these issues to endeavour to quantify the risk.

Poison reports

Data on e-liquid exposures in the UK are available from the National Poisons Information Service (NPIS)[150]. The NPIS provides information about poisoning to NHS staff and publishes data based on enquiries made by phone, using their online database TOXBASE, and by consultant referrals. The NPIS report for 2013/14 [150] details 204 enquiries related to the liquid content of EC and their refills, most of which reported accidental exposure, however 21 enquiries were related to intentional overdoses using e-liquids. Most incidences concerned ingestion of the liquid in EC or their refills (n=182) although small numbers of inhalation (n=17), eye contact (n=13) and skin contact (n=12) enquiries were also reported. The NPIS further reported that the number of enquiries about e-liquids has increased since 2007 (Figure 20) broadly reflecting the increasing popularity of EC.

A large proportion of exposures to e-liquids were in children under five years old (Figure 21), a finding that is replicated in a US study on calls to poison centres [151]. However, the concentration of events concerning children is not unique to e-liquids. Children under five years old appear to be more vulnerable than adults to accidental poisoning in general (Figure 22).
Figure 20: Number of telephone enquiries to National Poisons Information Service (NPIS) about e-cigarettes over time

![Graph showing the number of telephone enquiries to NPIS about e-cigarettes over time. The x-axis represents the years 2007/8 to 2013/14, and the y-axis represents the number of enquiries. The graph shows an increase in enquiries from 2007/8 to 2013/14.](image1)

Figure 21: Number of enquiries about e-cigarettes to NPIS by age

![Graph showing the number of enquiries about e-cigarettes to NPIS by age. The x-axis represents patient age groups from <5 years to 70+ years, and the y-axis represents the number of enquiries. The graph shows the highest number of enquiries for the 20-29 age group, followed by the 30-39 age group.](image2)
Exposures to poisonous liquid among children are of concern; however they should be taken in context. The same report from the NPIS recorded 208 exposures to liquid in reed diffusers, 1,168 exposures to pesticides and more than 600 to paracetamol. E-liquids seem to contribute towards domestic poisoning incidents but regulations, such as child safety caps, could limit this risk.

The clinical outcomes of exposures to e-liquids, as detailed in the NPIS report, were predominantly either ‘no toxicity’ or ‘mild toxicity’. There were two reported cases of ‘moderate toxicity’ and one ‘severe’ case that required treatment in an intensive care unit. Toxicity symptoms included conjunctivitis, irritation of the oral cavity, anxiety, vomiting, hyperventilation and changes in heart rate.

Fire

A number of news articles report the risk of fire and explosions from EC [147, 149, 152]. These reports suggest that faulty or incompatible chargers are the main causes of EC related fires along with faults relating to lithium batteries [152]. In order to assess the risks of fire we used the two data sources below:

1) In 2014, the BBC made Freedom of Information requests to UK fire services [153] and reported that there were 43 recorded call outs for fires related to EC in 2013 and 62 between 1 January 2014 and 15 November 2014. They added that call outs to EC related fires were rising in frequency. This report was based on responses from 43 out of 46 fire services in the UK [153, 154]
2) The official reporting statistics for the UK [155] do not specifically report EC as a cause of fire. There were 2,360 accidental fires between April 2013 and March 2014 where the source of ignition was “smokers’ materials” causing 80 fatalities and 673 non-fatal casualties. Additionally, there were 3,700 fires from faulty appliances and electrical leads causing 19 fatalities and 820 non-fatal casualties. It is not clear what proportion of these were caused by EC.

Regulations covering chargers and quality standards of production could help reduce the risk of fire and explosion in EC. An unpublished Department for Business, Innovation and Skills (BIS) funded market surveillance exercise in 2013/14 found that six out of 17 EC had no instructions for charging, and that eight out of 17 EC did not have a charging cut-off device and therefore did not meet the requirements of BS EN 62133:2013 ‘Safety requirements for portable sealed secondary cells and batteries for use in portable devices'. It seems likely that the risk of fire and electrical fault is similar to other domestic electrical products, indicating that EC should be subject to the same guidelines and safety mechanisms.

Summary of findings

There is a risk of fire from the electrical elements of EC and a risk of poisoning from ingestion of e-liquids. These risks appear to be comparable to similar electrical goods and potentially poisonous household substances.

Policy implications

- The risks from fire or poisoning could be controlled through standard regulations for similar types of products, such as childproof containers (contained within the TPD but which are now emerging as an industry standard) and instructions about the importance of using the correct charger.

- Current products should comply with current British Standard operating standards.

- Records of EC incidents could be systematically recorded by fire services.

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12. International perspectives

Overview

Internationally, countries have taken a wide variety of approaches to regulating EC [156]. Current approaches range from complete bans on the sale of any EC, to applying existing laws on other products to EC (poison, nicotine, and/or tobacco laws), to allowing EC to be sold under general consumer product regulations. Similarly, within countries, different laws have also been applied at the state/provincial level, along with municipal by-laws, extending into areas including taxes on EC, and bans on use in places where smoking is banned. Furthermore, several nuances in laws exist, making it difficult to make broad statements about the regulations in a given country. This section focuses on presenting (1) studies that have compared the use of EC internationally across countries using representative samples and comparable methods, (2) a brief review of adolescent surveys internationally, and (3) the cases of Australia and Canada, two countries that have very similar tobacco control policies to the UK but very different policies relating to EC.

Use of e-cigarettes among adults internationally

Three studies have compared the use of EC internationally: (1) International Tobacco Control Project (described in the Methodology section), (2) Eurobarometer study and (3) Global Adult Tobacco Survey.

The International Tobacco Control Project compared EC use (use defined as less than monthly or more often) among smokers and ex-smokers across 10 countries [157]. Gravely et al., 2014 found significant variability in use across countries, but data were gathered across different years. Gravely et al., 2014 concluded that the study provided evidence of the rapid progression of EC use globally, and that variability was due partly to the year the survey was conducted, but also market factors, including different regulations on EC. Notably, EC use was highest in Malaysia at 14%, where a ban on EC was in place.

Two studies using secondary data from the 2012 Eurobarometer 385 survey have examined EC use. Vardavas, et al., 2014 [158] examined ever use (tried once or twice) of EC among smokers, ex-smokers and never smokers aged 15 years and over across 27 EU countries. The study found wide variation in ever EC use among smokers and non-smokers, with ever use varying from 20.3% among smokers, 4.4% among ex-smokers, and 1.1% among never smokers. Of those who had tried, 69.9% reported using EC once or twice, and 21.1% and 9% reported ever using or currently using occasionally or regularly (use or used regularly or occasionally). It is important to note that the question asked about ever using or currently using occasionally or regularly,
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and thus would overestimate actual current use. Overall, being a smoker was the strongest predictor of ever using an EC, younger age was also predictive. Respondents who were uncertain about the harmfulness of EC were less likely to have tried an EC. Among current smokers, those who had made a quit attempt in the past year were most likely to have ever used EC, along with heavier smokers. With regards to use as a smoking cessation aid, 7.1% of smokers who had ever made a quit attempt reported having used EC, compared to 65.7% who used no help, 22.5% who used nicotine replacement therapy, and 7.3% who received behavioural counselling. Geographical differences in EC use noted by the authors included higher ever use in Northern and Eastern Europe compared to Western Europe. The study did not go into detail on occasional or regular users of EC because the numbers were too low for any detailed analyses.

A 2012 study using the same Eurobarometer 385 survey data gave further detail on ever having used or currently using EC occasionally or regularly among smokers and non-smokers [63]. The study found that regular/occasional use was highest in Denmark at 4.2% and lowest in Lithuania and Portugal at 0.6%, and 2.5% in the UK [63].

The Global Adult Tobacco Survey [159] published findings on EC use in Indonesia (2011), Malaysia (2011), Qatar (2013) and Greece (2013) among smokers and non-smokers, the first countries with available data. Of those respondents who were aware of EC, they asked, “Do you currently use e-cigarettes on a daily basis, less than daily, or not at all?” and considered those who said they used ‘less than daily’ or ‘daily’ to be current EC users.

Overall, awareness of EC was highest in Greece (88.5%), followed by Qatar (49%), Malaysia (21%), and Indonesia (10.9%). Use of EC among smokers was highest in Malaysia (10.4%), followed by Qatar (7.6%), Indonesia (4.2%) and Greece (3.4%). Use of EC among non-smokers was highest in Greece (1.3%), followed by the other three countries, Malaysia (0.4%), Indonesia (0.4%) and Qatar (0.4%). Similar to findings from the ITC Project, these numbers are likely influenced by timing of the survey, due to the rapid progression of use of EC globally, and other market factors. Together with the findings from Gravely et al., 2014 [157] they show the rapid global progression of EC use across both high income and lower middle income countries.

Use of e-cigarettes among youth internationally

Whilst there are very few international or European studies which use consistent methodology, there is a rapidly growing body of research on the prevalence of EC use in young people at the country level, as well as reviews in this area [eg [160]]. However, much of this literature on EC use among adolescents is incomparable because of inconsistent measurements of use (confusing ever use, trial, current use), and different age ranges involved. In addition, many of the studies have been poorly reported. For
example, much has been made of the increase in EC observed in the US using the cross-sectional Centers for Disease Control & Prevention (CDC) National Youth Tobacco Surveys [161-163]. These reports and press coverage have been heavily criticised [164-166]. The most important feature of the NYTS data was the fall in smoking prevalence over the same period (as observed in the UK, France [167] and elsewhere).

The CDC findings indicated that past 30-day use of EC increased among middle and high school students. For example, the 2014 data indicated that among high school students use increased from 4.5% to 13.4% between 2013 and 2014. Among middle school students, current EC use increased from 1.1% in 2013 to 3.9% in 2014. However, cigarette smoking had continued to decline during this period (high school students: 15.8% to 9.2%; middle school students: 4.7% to 2.5%) such that smoking was at a 22-year low in the US. These findings strongly suggest that EC use is not encouraging uptake of cigarette smoking.

Whilst most of the recent studies examining youth EC use emanated from North America, the common pattern emerging worldwide is of a very high awareness of EC and an increase in trial of these products among young people [168-178]. Nevertheless, estimates of prevalence of current use of EC vary widely with the highest being reported in Poland at around 30% [174] and Hawaii (29% tried, 18% current) [178]. Most other estimates indicate that a very small minority of youth, less than 3%, currently or recently used EC. Whilst EC experimentation is increasing, regular or current use of EC appears to be largely concentrated in those already smoking conventional cigarettes. The most recent Europe-wide data indicated that 1.1% of never-smokers aged 15 and above had ever tried an EC [158]. Yet little research has focused on how EC are being used among young people, with limited qualitative research studies in this area [179, 180]. Other findings relate to the influence of parents who smoke on EC experimentation in youth [eg [170] and associations between EC experimentation and other substance use [eg [170, 181]. Several studies have also found an association between EC use and openness to cigarette smoking [eg [182] or intentions to smoke cigarettes [eg [168].

The cases of Australia and Canada

Australia has applied existing laws on poisons, therapeutic goods, and tobacco products to EC. Very broadly speaking, the current laws in Australia have resulted in a ban on the sale and importation of EC with nicotine (although there is a mechanism for legal import as an unapproved medicine with a doctor's prescription). There are no national level prevalence data on EC use in Australia available at this time. One study comparing trends in awareness, trial, and use of EC among nationally representative samples of smokers and ex-smokers (use defined as less than monthly or more often) in Australia and the UK in 2010 and 2013 found reported EC use in Australia in 2013 at 6.6% and use in the UK at 18.8% [183]. Although the use of EC was found to be
significantly lower in Australia than in the UK in 2013, the use of EC increased at the same rate in Australia and the UK between 2010 and 2013 [183].

Canada took a similar approach to regulating EC as Australia by prohibiting the sale of EC with nicotine through existing laws. However, a recent House of Commons report stated that the current regulatory approach was not working to restrict access to EC with nicotine [184]. Canada has now put forward recommendations to develop a new legislative framework for EC that would most likely allow the sale of EC with nicotine [184]. There has been only one population-level survey of EC use in Canada. The 2013 Canadian Tobacco, Alcohol and Drugs Survey (CTADS) of Canadians 15 years and older found that 9% had ever tried an EC, with trial being higher among young people aged 15–19 years at 20% [185]. Use in the past 30 days was lower at 2%, with past 30 day use being higher among young people aged 15–19 years at 3%. Of those who tried an EC, 55% stated the EC did not contain nicotine, while 26% reported it did contain nicotine, with 19% reporting uncertainty. Whether the EC they tried contained nicotine is uncertain given (1) the ban on the sale of EC with nicotine, and (2) reports that many EC sold and bought in Canada are labelled as not containing nicotine but actually contain nicotine [184]. Although it is difficult to make comparisons due to different survey methods and questions, the percentage of young people (15–19 years) who have tried EC in Canada (20%) is roughly similar to the percentage who have tried EC in GB in 2014 (reported at 8%, 15%, 18%, and 19%, for ages 15 to 18, respectively).

Summary of findings

Although EC use may be lower in countries with more restrictions, these restrictions have not prevented EC use. Overall, use is highest among current smokers, with low numbers of non-smokers reporting ever use. Current use of EC in other countries is associated with being a smoker or ex-smoker, similar to the findings in the UK. EC use is frequently misreported, with experimentation presented as regular use. Increases in youth EC trial and use are associated with decreases in smoking prevalence in all countries, with the exception of one study from Poland.

Policy implications

- Future research should continue to monitor and evaluate whether different EC policies across countries are related to EC use and to smoking cessation and smoking prevalence.
- Consistent and agreed measures of trial, occasional and regular EC use among youth and adults are urgently needed to aid comparability.
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Declaration of interests

Professor Ann McNeill leads the Nicotine Research Group at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King’s College London (KCL). She is a Deputy Director of the UK Centre for Tobacco and Alcohol Studies (UKCTAS), President-Elect of the Society for Research on Nicotine and Tobacco European Chapter and a member of the Royal College of Physicians tobacco advisory group. She is a trustee of the Society for the Study of Addiction, a Member of the Board of Tobacco Free Futures and of the Advisory Council of Action on Smoking and Health, and Senior Editor for the journal Addiction. She has no financial or other conflicts of interest and no links with any tobacco or e-cigarette manufacturers.

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Robert Calder is a research assistant and PhD student at the IoPPN, KCL, and has no financial or other conflicts of interest and no links with any tobacco or e-cigarette manufacturers.

Dr Sara Hitchman is a Lecturer in Addictions in the Nicotine Research Group, IoPPN, KCL and a member of the UKCTAS. She has no financial or other conflicts of interest and no links with any tobacco or e-cigarette manufacturers.

Professor Peter Hajek is director of Health and Lifestyle Research Unit at Wolfson Institute of Preventive Medicine, Queen Mary University of London (QMUL). He 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.

Dr Hayden McRobbie is a researcher at QMUL and Director of the Dragon Institute for Innovation (New Zealand), which has no links with any tobacco or e-cigarette manufacturers. He contributed to educational sessions sponsored by Pfizer and Johnson & Johnson, manufacturers of stop-smoking medications, and received investigator-led research funding from Pfizer. He was an investigator on a study of e-cigarettes (EC) produced by Ruyan Group, Beijing and Hong Kong. Ruyan sponsored Health New Zealand Ltd. who provided funding to the University of Auckland to conduct the trial, independently of Ruyan. He was also an investigator on an EC trial funded by the Health Research Council of New Zealand that used EC supplied at no charge by PGM international, a retailer of EC.

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Submitted by Tom Madden, owner of E-Cigs
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References


E-cigarettes: an evidence update


25. Wise, J., *Children are three times as likely to try e-cigarettes as tobacco products, study finds.* BMJ, 2014. 349: p. g7508.


Submitted by Tom Madden, owner of E-Cigs
E-cigarettes: an evidence update


71. Shaw, L. and L.S. Nelson, Smoking cessation can be toxic to your health. EMERGeNcy MEDICInE, 2013.


76. Christensen, L.B., T. van't Veen, and J. Bang. *Three cases of attempted suicide by ingestion of nicotine liquid used in e-cigarettes.* in Clinical Toxicology. 2013. INFORMA HEALTHCARE 52 VANDERBILT AVE, NEW YORK, NY 10017 USA.


E-cigarettes: an evidence update


140. Farsalinos, C., *E-cigarette aerosols generates high levels of formaldehyde only in ‘dry puff’ conditions.* Addiction, (in press).


Submitted by Tom Madden, owner of E-Cigs
E-cigarettes: an evidence update


Submitted by Tom Madden, owner of E-Cigs
167. Houezec, J., *According to a new survey, youth smoking decreased during the last 4 years while e-cig used increased.* 2014.


APPENDIX A: PRISM Flow Diagram

Please note that we did not carry out a full systematic review for this report but followed systematic review methods. We assessed 94 papers and 9 additional reports included those that were relevant to our objective of describing the use of e-cigarettes and how they impact smoking behaviour, with a particular focus on the UK.
APPENDIX B: Measures of e-cigarette use

Measures of EC use in studies referenced, in most cases respondents were only asked about EC use if they first answered yes to ever trying an EC/had heard of EC.

Surveys

These questions in all surveys below may have been slightly altered from year to year as the EC market evolved and awareness grew.

Smoking Toolkit Study (STS)

The following four questions are used to assess current use of e-cigarettes: (if already responded they are cutting down)

Q632e37. Which, if any, of the following are you currently using to help you cut down the amount you smoke?
Nicotine gum
Nicotine replacement lozenges\tablets
Nicotine replacement inhaler
Nicotine replacement nasal spray
Nicotine patch
Electronic cigarette
Nicotine mouthspray
Other (specify)

Q632e1. Do you regularly use any of the following in situations when you are not allowed to smoke?
Nicotine gum
Nicotine lozenge
Nicotine patch
Nicotine inhaler\inhalator
Another nicotine product
Electronic cigarette
Nicotine mouthspray
Other (specify)

NEWW53a. Can I check, are you using any of the following either to help you stop smoking, to help you cut down or for any other reason at all?

Nicotine gum
Nicotine lozenge
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Nicotine patch
Nicotine inhaler/inhalator
Another nicotine product
Electronic cigarette
Nicotine mouthspray
Other (specify)

QIMW86_1. Can I check, are you using any of the following?
PROBE FULLY: Which others? PROBE UNTIL RESPONDENT SAYS ‘NO OTHERS’
PLEASE TYPE IN OTHER ANSWERS CAREFULLY AND USE CAPITAL LETTERS
Nicotine gum
Nicotine lozenge
Nicotine patch
Nicotine inhaler/inhalator
Another nicotine product
Electronic cigarette
Nicotine mouthspray
Other (specify)

ASH Smokefree GB adult survey

Which of the following statements BEST applies to you?
- I have heard of e-cigarettes and have never tried them
- I have heard of e-cigarettes but have never tried them
- I have tried e-cigarettes but do not use them (anymore)
- I have tried e-cigarettes and still use them
- Don’t know

The fourth option constitutes ‘current use’

ASH Smokefree GB youth survey

An e-cigarette is a tube that looks like a normal cigarette, has a glowing tip and puffs a vapour that looks like smoke but unlike normal cigarettes, they don’t burn tobacco.
Have you ever heard of e-cigarettes?
- Yes, I have
- No, I haven’t

All those who have heard of e-cigarettes: Which one of the following is closest to describing your experience of e-cigarettes?
- I have never used them
- I have tried them once or twice
- I use them sometimes (more than once a month)
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- I use them often (more than once a week)
- Don’t want to say

Internet cohort survey

Have you ever heard of electronic cigarettes or e-cigarettes? These are electronic devices that contain nicotine in a vapour and are designed to look like cigarettes, but contain no tobacco.
Yes/No/Don’t know

If Yes, Have you ever tried an electronic cigarettes?
Yes/No/Don’t know

If Yes, How often if at all, do you currently use an electronic cigarette? (PLEASE SELECT ONE OPTION)
1. Daily
2. Less than daily, but at least once a week
3. Less than weekly, but at least once a month
4. Less than monthly
5. Not at all
6. Don’t know

Other studies

Amrock et al., 2015 (US)

Which of the following tobacco products have you ever tried, even just one time?” to which they could select, “electronic cigarettes or e-cigarettes, such as Ruyan or NJOY” alongside other tobacco products. A related question asked if students used e-cigarettes on at least one of the past 30 days.

Biener & Hargraves, 2014 (US)

At baseline, three questions were asked about e-cigarettes: whether the respondent had “ever heard of electronic cigarettes, also known as e-cigarettes”; if so, whether he/she had ever used an e-cigarette even one time, and if so, on how many of the past 30 days the respondent had used an e-cigarette. To assess how intensively and for how long the respondent had used e-cigarettes during the period between interviews, the follow-up interviews included questions to describe e-cigarette usage. Those who were not aware of e-cigarettes at baseline were asked if they had heard of them at follow-up. Those who had not tried e-cigarettes at baseline were asked if they had done so by follow-up. All respondents who reported ever trying them by follow-up were asked
whether they currently used e-cigarettes every day, some days or not at all. If not at all, they were asked if they ever used e-cigarettes “fairly regularly.” If not, whether they had used only once or twice or more often than that. All who had used more than once or twice, were asked a series of questions about their patterns of use: for how long they had used e-cigarettes (less than a month, 1–6 months, more than 6 months); whether they had ever used e-cigarettes daily for at least one week; if so for how long they had used e-cigarettes daily. From these variables, a 3-level measure of intensity of e-cigarette usage was computed: 3 = intensive (used daily for at least 1 month); 2 = intermittent (more than once or twice but not daily for a month or more); 1 = non-use or at most once or twice.

Borderud et al., 2014 (US)

Patients were asked if they had used E-cigarettes within the past 30 days, with the response options being yes or no.

Brose et al, 2015 and Hitchman et al., 2015 (GB)

How often, if at all, do you currently use an electronic cigarette? [Asked of respondents who had ever heard of e-cigarettes and had ever tried one.]
1. Daily
2. Less than daily, but at least once a week
3. Less than weekly, but at least once a month
4. Less than monthly
5. Not at all
6. Don't know

What electronic cigarette equipment do you currently use the most?
1. A disposable electronic cigarette (non-rechargeable)
2. A commercial electronic cigarette kit which is refillable with pre-filled cartridges
3. A commercial electronic cigarette kit which is refillable with liquids
4. A modular system (I use my own combination of separate devices: batteries, atomizers, etc.)
5. Don’t know

Brown et al., 2014 (England)

Which, if any, of the following did you try to help you stop smoking during the most recent serious quit attempt?
1. E-cigarettes
2. NRT bought over-the-counter
3. No aid
Canadian Tobacco, Alcohol and Drugs Survey 2013 (CTADS)

**Trial**
Have you ever tried an electronic cigarette, also known as an e-cigarette?

1. Yes
2. No
3. Refused
4. Don’t know

**Last 30 day use**
In the past 30 days did you use an electronic cigarette, also known as an e-cigarette?

1. Yes
2. No
3. Refused
4. Don’t know

CDC/NYTS and Dutra and Glantz

During the past 30 days, on how many days did you use electronic cigarettes or e-cigarettes such as Blu, 21st Century Smoke, or NJOY?

- Gravely et al., 2014 (Republic of Korea, US, UK, Canada, Australia, and Malaysia);
- Yong et al., 2014 (UK and Australia)

How often, if at all, do you currently use an electronic cigarette? (dichotomised into current use and non-current by combining any use responses vs. not at all)

1. Daily, Less than daily but at least once a week
2. Less than weekly but at least once a month
3. Less than monthly
4. Not at all

Gravely et al., 2014 (Netherlands)

How often do you currently use an electronic cigarette? (dichotomised into current use and non-current by combining any use responses vs. have you stopped altogether)

1. Daily
2. Less than daily, but at least once a week
3. Less than weekly, but at least once a month
4. Less than monthly versus, or
5. Have you stopped altogether?
E-cigarettes: an evidence update

Gravely et al., 2014 (China)

Are you currently using an electronic cigarette at least weekly? (Yes vs. No)
1. Yes
2. No

Hughes et al., 2014 (Trading Standards NW Study)

“Have you ever bought or tried electronic cigarettes?”

Hummel et al., 2014 (Netherlands)

Respondents who had ever tried e-cigarettes were asked how often they currently used an e-cigarette (daily, at least once a week, at least once a month, less than monthly, or stopped altogether)

Lee et al., 2014 (US)

E-cigarette use questions were:

Have you ever used e-cigarettes?
1. yes
2. no

Have you used e-cigarettes in the past 30 days?
1. yes
2. no

Moore et al., 2014 (Welsh study 10-11 year olds)

“Have you heard of e-cigarettes before this survey?”
‘Have you ever used an e-cigarette? with response options of ‘no’, ‘yes, once’ or’ yes, more than once’

Moore et al., 2015 (Welsh study HBSC)

Asked whether they had ever used an e-cigarette with response options of:
- I have never used or tried e-cigarettes
- I have used e-cigarettes on a few occasions (1-5 times);
- I regularly use e-cigarettes (at least once a month)’.

Submitted by Tom Madden, owner of E-Cigs
Palipudi et al., 2015 (Global Adult Tobacco Survey)

“Do you currently use e-cigarettes on a
  1. Daily basis,
  2. Less than daily,
  3. Or, not at all?”

Pearson et al., 2014 (US)

Participants were asked which methods they had used to quit in the past 3 months and were presented a list of common quit methods. Participants were considered e-cigarette users if they selected “e-cigarettes” in response to this question or if they entered terms like “vapors,” “vaping,” “vape,” or “ecigs” in the “other quit methods” open-ended response option.

Pepper et al., 2014 (US)

Have you ever used an e-cigarette, even one puff?
Do you now use e-cigarettes every day, some days, or not at all?

Richardson et al., 2014 (US)

Please indicate whether you have ever heard of these products, if you have ever tried them and if you have ever purchased them. Products included ENDS; dissolvables; chew, dip, or snuff (assessed in 1 question); and snus, each presented with brand names to increase validity of responses. Respondents could choose multiple options from the following choices: (1) heard of; (2) tried; (3) purchased; (4) never heard of, tried, or purchased (for those to whom options 1, 2, and 3 were not applicable); (5) refused; and (6) don’t know.

Rutten et al., 2014 (US)

Do you now use e-cigarettes (eg BluCig, NJoy, V2, Red Dragon, etc)? [Picture of three different e-cigarettes included]
  1. Every day
  2. Some days
  3. Not at all
Schmidt et al., 2014 (US)

Have you ever used an electronic cigarette, even just one time in your entire life? Do you now use electronic cigarettes every day, some days, rarely, or not at all?

Vardavas et al., 2014 (Eurobarometer 27 countries), dichotomised into regularly, occasionally, tried once or twice vs. otherwise; Agaku et al., 2014 (Eurobarometer, 25 countries), dichotomised into regularly or occasionally vs. otherwise;

Have you ever tried any of the following products? (Electronic cigarettes)
1. Yes, you use or used it regularly.
2. Yes, you use or used it occasionally.
3. Yes, you tried it once or twice.
4. No.
5. Don’t Know.

White et al., 2015, New Zealand national youth tobacco use survey in 2012 and 2014

Ever use: Have you ever tried electronic cigarettes?
Appendix C: Narrative summary of studies on nicotine delivery from e-cigarettes

Early studies

Two studies, both published in 2010, examined nicotine delivery from cigalike EC.

Bullen et al., 2010 used a cross-over design to compare nicotine delivery of a 16mg/ml Ruyan V8 EC with a 0mg/ml EC, a nicotine inhalator (10mg) and a conventional cigarette among 8 smokers who abstained from smoking overnight [43]. Participants puffed on their cigarettes and EC ad libitum over 5 minutes, and on the inhalator over 20 minutes. The nicotine containing EC had similar pharmacokinetic parameters to the inhalator (Cmax: 1.3 vs. 2.1 ng/ml; Tmax: 19.6 vs. 32.0 mins), and both were outperformed by a conventional cigarette (Cmax 13.4 ng/ml; Tmax 14.3 mins).

Vansickel et al., 2010 also used a cross-over design and tested nicotine delivery of two EC (NJOY EC (18mg) and Crown 7 EC (16mg) and participants own brand cigarette[118]. Participants abstained overnight and then took 10 puffs on the EC with a 30 sec inter-puff interval. Only the conventional cigarette produced a significant rise in plasma nicotine, from baseline 2.1 ng/ml (SD 0.32) to a peak at 5 minutes 18.8 ng/ml (SD 11.8).

The poor nicotine delivery of these EC was likely to be due to several factors. The EC tested were some of the first to market. The EC used in the Bullen 2010 study were noted to leak and the vaporising component did not always function. Both of these early studies recruited EC naïve smokers, without opportunity to practice using the EC prior to experimentation.

There are other factors that are associated with nicotine delivery, which we have summarised below.

1) More intensive vaping regimens
Vansickel et al., examined nicotine delivery associated with the use of Vapor King (cigalike EC with 18mg/ml nicotine) in 20 smokers naïve to EC [119]. After overnight abstinence, participants used the EC for 5 minutes on a total of six occasions (10 puffs, 30 sec inter-puff interval) 30 minutes apart. A significant increase in plasma nicotine was observed after the fourth bout of puffing, and mean blood nicotine levels had increased from 2.2 ng/ml (SD 0.78) at baseline to 7.4 ng/ml (SD 5.1) at the end of the last bout of puffing.

2) Experience with EC
Vansickel & Eissenberg (2012) report nicotine pharmacokinetics in eight vapers who had been using EC for aaverage of 11.5 (SD 5.2) months [7]. They used their own EC and e-liquid (the majority used an e-liquid with a concentration of 18 mg/ml).
Participants attended the laboratory after overnight abstinence and used their EC under a standardised vaping regimen (10 puffs with a 30 second inter-puff interval) and then a 60 minutes period of *ad lib* vaping. The PK analyses showed a significant increase in plasma nicotine from baseline 2.0 ng/ml to 0.3 ng/ml within five minutes of the first puff. At the end of the ad-lib vaping period the maximum plasma nicotine concentration was 16.3 ng/ml.

Dawkins and Corcoran (2014) examined nicotine delivery associated with the use of the Skycig 18 mg Crown tobacco bold cartridges in 14 vapers, who had been vaping for almost 5 months on average[6]. Using a similar methodology to Vansickle & Eissenberg (2012), the analysis of plasma nicotine from the seven participants that provided a full blood set, showed that levels had increased from 0.74 to 6.77 ng/ml in 10 minutes. However there was individual variation (2.5 ng/ml to 13.4 ng/ml). After an hour of *ad lib* use the maximum nicotine concentration reached was 13.91 ng/ml, again with a wide range of levels observed between individuals (4.35-25.6 ng/ml).

Spindle et al., 2015 studied 13 experienced EC users (> 3 months, with the majority 9/13 using e-liquid strength of 24mg/ml and all using tank systems)[120]. Taking 10 puffs over 5 minutes resulted in an increase in mean blood nicotine levels from 2.4 ng/ml baseline to 19.2 ng/ml at 5 minutes.

Practice in EC use also results in a modest increase in blood nicotine levels. Hajek et al., 2014 tested Greensmoke EC (a cigalike EC with 2.4% nicotine) in 40 smokers, naïve to EC[115]. Participants abstained from any nicotine use overnight and after a baseline blood sample was collected used the EC, *ad lib*, for 5 minutes. This procedure was undertaken twice, on first use and then again after 4 weeks of use. The maximum plasma concentrations increased from 4.6 ng/ml (range 0.9-9.0) to 5.7 ng/ml (range 1.9-11.0), although this increase was not significant. The area under the curve (AUC), however, did show a significant increase, from 96 (range 12-198) to 142 (range 56-234). The time to maximum plasma concentration (5 minutes) did not change.

Nides et al., 2014 provided EC to participants (29 smokers, mean cigarette consumption of 20 cpd, and of 55% of whom had used EC in past) but also allowed them to practice using the EC (NJOY®King Bold, a cigalike EC, with 26mg nicotine) for a week prior to undertaking a PK analysis [116]. Participants (who abstained from all nicotine products for at least 12 hours) then were asked to use EC (10 puffs with a 30 second inter-puff interval) on two occasions 60 minutes apart. Pharmacokinetic (PK) analyses were undertaken in 16 participants who had no detectable plasma nicotine at baseline. The mean rise in blood nicotine was 3.5 ng/ml (range 0.8-8.5 ng/ml) at 5 minutes after the first round of puffing and 5.1 ng/ml (range 1.1 – 7.1 ng/ml) at 10 minutes after the second.
3) Nicotine concentration and chemical composition of e-liquid
Yan & D’Ruiz (2014) examined nicotine delivery from Blu cigalike EC with differing levels of nicotine (2.4% and 1.6%), glycerin/propylene glycol (75% glycerin and 50% glycerin/20% propylene glycol), and flavours (classic tobacco and menthol)[129]. Participants (23 smokers) were randomized to 5 different EC conditions and smoking a regular cigarette in a cross over design. They were given 7 days to familiarize with EC use, and then abstain from all nicotine products for 36 hours prior to test days. On test days participants were asked to take 50 x 5 second puffs on EC at 30 sec intervals (in the cigarette arm they smoked 1 cigarette with usual puff duration at 30 sec intervals). After the controlled puffing testing ppts were allowed 60 minutes of *ad lib* use.

Peak plasma nicotine concentrations were reached sooner for cigarettes (5 minutes) than for EC (30 minutes). During the 30 minutes controlled puffing phase, within EC conditions the highest Cmax was seen with the 2.4% nicotine, 50% glycerin/20% PG (18.09 ng/ml, SD=6.47 ng/ml). The lowest Cmax was observed in the 1.6% nicotine, 75% glycerine (10.34 ng/ml SD=3.70 ng/ml). The Cmax associated with smoking one conventional cigarette was 15.84 ng/ml (SD = 8.64 ng/ml). At the end of the *ad lib* period, the highest Cmax was seen with the conventional cigarette (29.23 ng/ml SD = 10.86 ng/ml), followed by the 2.4% nicotine, 50% glycerin/20% PG EC (22.42 ng/ml; SD = 7.65ng/ml). The glycerine/PG mix resulted in better nicotine delivery than the 75% glycerine solution, which was confirmed in the bench top tests that measured nicotine content in vapour using the Canadian Intense regimen. The high nicotine content in vapour is a likely consequence of the lower boiling point of PG (187.6 degrees Celsius) compared with glycerine (290 degrees Celsius).

4) Type of EC device
Although many vapers start off with using a cigalike EC experienced vapers are more likely to be using tank systems or variable power EC. One of the reasons for this observation is that the tank systems and variable power ECs deliver nicotine more nicotine to the user.

Farsalinos et al., (2014) examined plasma nicotine levels in experienced vapers (n=23) who used a cigalike (V2 with cartomiser) and a new generation (EVIC set at 9 watts with EVOD atomizer) EC with standardized flavour and nicotine concentration (18mg/ml) in a cross-over design[129]. Participants’ abstained from EC use for at least 8 hours before completing a bout of 10 puffs over 5 minutes followed by one hour of *ad lib* use. Use of the cigalike EC was associated with an increase in blood nicotine from 2.80 ng/ml at baseline, to 4.87 ng/ml at 5 minutes and 15.75 ng/ml at the end of *ad lib* use. Significantly greater increases were observed with use of the new generation EC from 2.46 ng/ml to 6.59 ng/ml to 23.47 ng/ml at baseline, 5 minutes and at the end of the *ad lib* period.
Oncken et al., (2015) also examined nicotine delivery in a tank system EC (Joye eGo-C with 18 mg/ml nicotine e-liquid) in 20 smokers who were asked to use an EC for two weeks[123]. Participants were asked to use the EC for 5 minutes ad lib in two laboratory sessions where blood samples were taken for PK analysis. Blood nicotine concentrations increased, significantly, by 4 ng/ml (Cmax 8.2 ng/ml) at the first session and 5.1 ng/ml (Cmax 9.3 ng/ml) at the second session. These levels were reached at five minutes.

Studies that examine cotinine as a measure of nicotine replacement in vapers

We found eight studies that reported on cotinine in urine, blood or saliva as a marker of nicotine exposure in people using EC.

In an RCT of nicotine containing EC versus placebo Caponnetto and colleagues (2013) measured salivary cotinine in participants who had stopped smoking cigarettes, but were still vaping EC (Categoria 7.5mg/ml)[40]. After 12 weeks of use the mean salivary cotinine concentration was 67.8 ng/ml, which is at the lower end of what is typically observed in smokers (eg 66.9-283.7 ng/ml).

In a study that randomised 48 smokers unwilling to quit to one of two tank system EC (18mg/ml nicotine) or to continue to smoke found that at 8 month follow-up mean salivary cotinine did not significantly differ between those who had stopped smoking but were vaping (428.27 ng/ml), achieved a ≥50% reduction in cigarette consumption (356.49 ng/ml) and those who continued to smoke (545.23 ng/ml, SD = 46.32)[41].

Van Staden et al., (2013) examined the change in serum cotinine in 13 smokers who were asked to stop smoking and instead use a Twisp eGo (18mg/ml nicotine) tank system EC for two weeks[113]. There was a significant decrease in cotinine from baseline 287.25 ± 136.05 to two weeks 97.01 ± 80.91 ng/ml suggesting that the EC used did not provide as much nicotine as participants usual cigarettes.

Norton et al., (2014) observed a similar result in 16 abstinent smokers who used a cigalike EC (11 mg/ml) for five days, finding a significant decrease in saliva cotinine between baseline (338.0 ng/ml) and day five (178.4 ng/ml)[112].

Flouris et al., (2013) measured serum cotinine in 15 smokers, who had abstained overnight, after smoking two of their usual cigarettes over 30 minutes and after 30 minutes of vaping a cigalike EC (Giant, 11mg/ml)[130]. EC and cigarettes produced similar effects on serum cotinine levels (60.6 ± 34.3 versus 61.3 ± 36.6 ng/ml). However measurement of cotinine would not give an accurate indicator of exposure in an acute study such as this.
Experienced vapers, using their own devices, however obtain much better nicotine substitution. Etter and Bullen (2011) measured salivary cotinine concentrations in 30 vapers who had been using EC for approximately 3 months on average and no longer smoking[9]. The mean nicotine content of e-liquid was 18mg/ml. Mean salivary cotinine was found to be 322 ng/ml indicating a high level of nicotine replacement via EC.

Similarly Etter (2014) found mean cotinine levels of 374 ng/ml (95% CI: 318-429) in 62 vapers who had not used any other nicotine containing products in the last 5 days [8].

Hecht et al., 2014 measured nicotine and cotinine in urine of 28 EC users (median use of 9 months, using tank system EC with e-liquid containing, on average 12.5 ± 7.0 mg/ml)[111]. Nicotine and cotinine levels in urine were 869 ng/ml (95% CI: 604-1250) and 1880 ng/ml (95% CI: 1420-2480) respectively, although these levels are lower than what are typically observed in smokers (eg nicotine 1380 ng/ml 95% CI: 1190-1600 and cotinine 3930 ng/ml; 95% CI: 3500-4400).
MISSION STATEMENT OF THE TOBACCO HARM REDUCTION EXPERT GROUP

As experts in the science, economics and policy of tobacco harm reduction, we have come together here in Delhi to provide balanced and evidence-based information on harm reduction to delegates to the Seventh Conference of the Parties of the World Health Organization’s Framework Convention on Tobacco Control. Policies that increase access to less harmful substitutes to cigarettes, such as vape products, will provide an additional tool for smokers in their efforts to quit the deadly habit, supplementing and possibly strengthening many other tobacco control measures.

Long-term inhalation of smoke from burnt tobacco causes a wide range of non-communicable diseases, including lung cancer, chronic obstructive lung disease, peripheral arterial disease, and heart disease. One in two life-long smokers will die prematurely from a smoking related disease. In spite of its dangers, which are now widely known even among smokers, hundreds of millions of people continue to smoke, and more start every day. If current smoking patterns and trends continue, a billion people might die from smoking-related diseases in the 21st century.

Despite the availability of smoking cessation medications, many smokers do not want to try them. Of those who use them, the majority either fail or relapse within a year. To accelerate the reduction in smoking prevalence, public health experts have recommended that smokers be encouraged and assisted to switch completely to less harmful substitutes. WHO’s FCTC also identifies harm reduction strategies as a core principle of tobacco control and has recently stated that:

“If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health benefit.”

New technologies have recently emerged that comply with this principle. One such is the “electronic cigarette” (which the WHO refers to as Electronic Nicotine Delivery Systems – ENDS), which deliver nicotine without burning tobacco. Relative to cigarette smoke, the vapor from e-cigarettes and personal vaporizers (the name given to larger, more powerful devices) contains very low levels of potentially harmful chemicals. Even nicotine itself is largely benign – contrary to widespread misconceptions – and is already approved for long-term use through nicotine replacement therapies. As Public Health England recently concluded, vaping is at least 95 per cent safer than smoking and acknowledged that e-cigarettes can be an effective aid to quitting smoking.

In the past five years, use of these products has increased dramatically in many countries. In the European Union alone, the use of such products has helped more than 6 million people to quit smoking and 9 million more have reduced smoking. Smoking prevalence is declining in all countries where e-cigarettes are readily available.

Based upon this evidence, we support government policies that seek to remove barriers to the availability of better, safer, non-combustible nicotine delivery products, with appropriate quality standards and regulations. Disproportionate restrictions, such as regulation of e-cigarettes as medical products, applying similar restrictions as for tobacco cigarettes, or bans on advertising, will only make such products extremely expensive, limit access of smokers to proper information, and create misconceptions that they are as harmful as smoking. These measures are counter-productive, ignore the risk continuum principle and unintentionally form a protective environment for tobacco cigarette sales.

The WHO has an opportunity now to improve radically the life expectancy of today’s smokers by applying the principle of harm reduction that is already one of the core principles of WHO’s tobacco control strategy.

Submitted by Tom Madden, owner of E-Cigs
Biographies of Members of the Tobacco Harm Reduction Expert Group

Konstantinos E. Farsalinos M.D. is a research fellow at the Onassis Cardiac Surgery Center in Athens, Greece, and at the Department of Pharmacy, University of Patras, Greece. He has been conducting laboratory and clinical research on vape products as principle investigator since 2011. He undertook the first study on the cytotoxic effects of “e-cigarette” vapor on cultured cells and the immediate effects of vaping on cardiac function and coronary circulation. He ran a worldwide online survey of almost 20,000 vapers, identifying patterns of use and experience with vape products among consumers. Dr Farsalinos has presented his research findings at major international scientific congresses and his research was used in preparing the regulatory framework on vape products by the European Union. As of 2016, he has published more than 40 studies and articles in international peer-reviewed scientific journals about smoking, tobacco harm reduction, and vape products.

Professor Riccardo Polosa is Director of the Institute for Internal and Emergency Medicine of the University of Catania in Italy. He is also in charge of the University’s Centre for Tobacco Research (CPCT), and Honorary Professor of Medicine at Southampton University (UK). He is author of more than 250 peer reviewed articles and books mainly covering respiratory medicine, clinical immunology, and tobacco addiction. Professor Polosa and his research team have lead several clinical trials on vape products.

Christopher Russell Ph.D. is a behavioural psychologist and senior research fellow at the Centre for Substance Use Research, Glasgow, Scotland. Dr Russell leads the Centre’s tobacco harm reduction research studies, with a particular focus on how vapers and e-cigarettes are helping smokers to quit. Dr Russell collects and collates the stories and experiences of thousands of vapers in order to identify antecedents of successful and unsuccessful attempts to switch from smoking to vaping. The results of this work are used to guide public health professionals and e-cigarette manufacturers as to how smokers can be better encouraged, supported, and informed to vape as an aid to quitting or reducing smoking, and to advise regulatory authorities against legislation that may reduce the accessibility, affordability and appeal of vape products as a way of quitting smoking.

Amir Ullah Khan Ph.D. is an economist who has worked on development issues primarily in the Health, education and agriculture sectors. He is senior policy advisor to the Bill and Melinda Gates Foundation and a member in the Telangana Government’s Commission of Inquiry on Socio economic conditions headed by G Sudhir. He co-edits Sage’s Journal of Development Policy and Practice and teaches at the Indian School of Business in Hyderabad, the Manipal Institute of Technology, and the Indian Institute of Foreign Trade in Delhi. Dr Khan is the co-author, with Julian Morris, of The Vapour Revolution: How Bottom Up Innovation is Saving Lives.

Julian Morris is Vice President of Research at Reason Foundation. He is the author of over 50 scholarly articles and the editor of several books on the economics and law of innovation, regulation, health, and development. In addition to his role at Reason, Mr Morris edits the Electronic Journal of Sustainable Development, is a Senior Fellow of the International Center of Law and Economics, and a Fellow of the Royal Society of Arts. He is the author, most recently, of The World Health Organization’s Opposition to Tobacco Harm Reduction: A Threat to Public Health? And co-author, with Dr Amir Ullah Khan, of The Vapour Revolution: How Bottom Up Innovation is Saving Lives.

Prof. Rajesh N. Sharan is an accomplished biochemist and molecular biologist working in the fields of cancer and radiation molecular biology with special interest in molecular mechanisms of carcinogenesis and radiation induced DNA damage for last over 3 decades at Department of Biochemistry, North-Eastern Hill University, Shillong. He has over 100 research publications in international and national journals and books of repute to his credit and is serving as an Associate (Processing) Editor of the Journal of Radiation Research (Japan). He has recently co-authored a study on “Electronic Nicotine Delivery System (ENDS) as a substitute to conventional cigarette: an evidence-based audit”.

Submitted by Tom Madden, owner of E-Cigs
Dr. Brad Rodu, a renowned Professor of Medicine at the University of Louisville who holds an endowed chair in tobacco harm reduction research, has called for the retraction of a *Pediatrics* article by University of California San Francisco’s Benjamin W. Chaffee, Shannon Lea Watkins, and Stanton A. Glantz.

The article claims that “Among adolescent cigarette experimenters, using e-cigarettes was positively and independently associated with progression to current established smoking.”

“The findings and the claim are false,” wrote Dr. Rodu. “In their analysis, the authors ignore the fact that their study group consisted entirely of experimental smokers with widely varied experience....”

“When we added lifetime cigarette consumption (LCC),” Dr. Rodu explained, “the positive results for e-cigarettes essentially disappeared, negating Chaffee’s core claim.”

“Their study should be retracted.”
Kathy,
I have attached a link to a Department of Health in England update from the 2015 report, the update is from February of this year. Below I cut and pasted what I thought was the most relevant part of the review for the City Council.

Thanks,
Tom

UK update

Professor Linda Bauld, author and Professor of Health Policy, University of Stirling and Chair in Behavioural Research for Cancer Prevention, Cancer Research UK said:

Concern has been expressed that e-cigarette use will lead young people into smoking. But in the UK, research clearly shows that regular use of e-cigarettes among young people who have never smoked remains negligible, less than 1%, and youth smoking continues to decline at an encouraging rate. We need to keep closely monitoring these trends, but so far the data suggest that e-cigarettes are not acting as a route into regular smoking amongst young people.

PHE is calling on smokers and a number of bodies to act on the evidence

E Cig Pod USA LLC
14645 Excelsior Blvd
Minnetonka, MN 55345
952-931-9900

Submitted by Tom Madden, owner of E-Cigs
A new Public Health England (PHE) e-cigarette evidence review, undertaken by leading independent tobacco experts, provides an update on PHE's 2015 review.

Published 6 February 2018

From:


The report covers e-cigarette use among young people and adults, public attitudes, the impact on quitting smoking, an update on risks to health and the role of nicotine. It also reviews heated tobacco products.

The main findings of PHE’s evidence review are that:

- vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits
- e-cigarettes could be contributing to at least 20,000 successful new quits per year and possibly many more
- e-cigarette use is associated with improved quit success rates over the last year and an accelerated drop in smoking rates across the country
- many thousands of smokers incorrectly believe that vaping is as harmful as smoking; around 40% of smokers have not even tried an e-cigarette
- there is much public misunderstanding about nicotine (less than 10% of adults understand that
most of the harms to health from smoking are not caused by nicotine)
- the use of e-cigarettes in the UK has plateaued over the last few years at just under 3 million
- the evidence does not support the concern that e-cigarettes are a route into smoking among young people (youth smoking rates in the UK continue to decline, regular use is rare and is almost entirely confined to those who have smoked)

PHE's evidence review comes just a few weeks after a US National Academies of Sciences, Engineering and Medicine report on e-cigarettes. Their conclusion on e-cigarette safety also finds that based on the available evidence 'e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes.'

Professor John Newton, Director for Health Improvement at PHE said:

Every minute someone is admitted to hospital from smoking, with around 79,000 deaths a year in England alone.

Our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don’t know.

It would be tragic if thousands of smokers who could quit with the help of an e-cigarette are being put off due to false fears about their safety.

Professor Ann McNeill, lead author and Professor of Tobacco Addiction at King’s College London said:

It’s of great concern that smokers still have such a poor understanding about what causes the harm from smoking. When people smoke tobacco cigarettes, they inhale a lethal mix of 7,000 smoke constituents, 70 of which are known to cause cancer.

People smoke for the nicotine, but contrary to what the vast majority believe, nicotine causes little if any of the harm. The toxic smoke is the culprit and is the overwhelming cause of all the tobacco-related disease and death. There are now a greater variety of alternative ways of getting nicotine than ever before, including nicotine gum, nasal spray, lozenges and e-cigarettes.

Professor Linda Bauld, author and Professor of Health Policy, University of Stirling and Chair in Behavioural Research for Cancer Prevention, Cancer Research UK said:

Concern has been expressed that e-cigarette use will lead young people into smoking. But in the UK, research clearly shows that regular use of e-cigarettes among young people who have never smoked remains negligible, less than 1%, and youth smoking continues to decline at an encouraging rate. We need to keep closely monitoring these trends, but so far the data suggest that e-cigarettes are not acting as a route into regular smoking amongst young people.

PHE is calling on smokers and a number of bodies to act on the evidence.
Smokers

Anyone who has struggled to quit should try switching to an e-cigarette and get professional help. The greatest quit success is among those who combine using an e-cigarette with support from a local stop smoking service.

Local stop smoking services and healthcare professionals

These should provide behavioural support to those smokers wanting to quit with the help of an e-cigarette. A new training course on e-cigarettes for healthcare professionals by the National Centre for Smoking Cessation and Training is now live.

Medicines and Healthcare products Regulatory Agency (MHRA)

MHRA continue their work in regulating and licensing e-cigarette products and support manufacturers to expedite the licensing of e-cigarettes as medicinal quit aids. PHE believes there is compelling evidence that e-cigarettes be made available to NHS patients.

NHS Trusts

To become truly smokefree, Trusts should ensure

- e-cigarettes, alongside nicotine replacement therapies are available for sale in hospital shops
- vaping policies support smokers to quit and stay smokefree
- smoking shelters be removed
- frontline staff take every opportunity to encourage and support patients to quit

The government’s new Tobacco Control Plan for England includes a commitment to ‘maximise the availability of safer alternatives to smoking’. It makes clear that e-cigarettes have an important part to play in achieving the ambition for a smokefree generation.

Background

2. Over the past few years, e-cigarette use has hovered at just under 6% of the adult population in Britain. The most common reason for e-cigarette use continues to be to help with quitting and they are the most popular quitting tool in England. At the same time, quit success rates have been improving and we are also seeing an accelerated drop in smoking rates (currently 15.5% in England): smokinginengland.info/latest-statistics (http://www.smokinginengland.info/latest-statistics/).

Submitted by Tom Madden, owner of E-Cigs
3. 79,000 people in England die every year as a result of smoking, and over half of long-term smokers will die from a smoking-related illness if they do not quit: digital.nhs.uk/catalogue/PUB24228.


7. Smoking Toolkit Study (http://www.smokinginengland.info/).


About Public Health England

Public Health England (https://www.gov.uk/phe) exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and providing specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific expertise and support. Follow us on Twitter: @PHE_uk (https://twitter.com/PHE_uk) and Facebook: www.facebook.com/PublicHealthEngland (https://www.facebook.com/PublicHealthEngland).

Public Health England press office

Submitted by Tom Madden, owner of E-Cigs

May 21, 2018

Mayor Brad Wiersum
City Council Member Deb Calvert,
City Council Member Patty Acomb,
City Council Member Bob Ellingson,
City Council Member Tony Wagner,
City Council Member Mike Happe, and
City Council Member Tim Bergstedt

Mayor Wiersum and City Council Members,

I’m writing on behalf of the members of the TwinWest Chamber of Commerce to express concerns regarding the possible implementation of new rules changing the legal age for purchasing tobacco products in the city of Minnetonka from age 18 to age 21.

We have concerns about enacting additional local regulation on a legal product in an effort to solve a problem that has little to do with the businesses selling the products. Minnetonka businesses are committed to keeping tobacco out of the hands of youth as demonstrated by their strong record of passing compliance checks, yet they will be greatly impacted by this change in the ordinance. Because the vast majority of youth get access to tobacco from social sources, not local businesses, ordinances to further limit youth access to tobacco don’t actually achieve the goal intended. Instead, consumers respond and sales are shifted to border communities leaving Minnetonka businesses challenged to sustain their operations and number of employees.

We strive to ensure that no business or community is at a disadvantage in the free market system and the regional marketplace remains competitive. A city to city regulatory patchwork creates distinct inequities for companies located in communities that have chosen to adopt symbolic ordinances at the expense of their local businesses.

We appreciate your efforts to seek the input and counsel from businesses on policies that directly impact them. Thank you for the opportunity to weigh in. Please don’t hesitate to contact me with questions or comments.

Sincerely,

Deb McMillan
Vice President, Public Policy, TwinWest Chamber of Commerce

Cc: Geralyn Barone, City Manager
Cigarettes account for 35% of convenience stores' in-store sales.

Menthol cigarettes account for 43% of total cigarettes volume in Minneapolis.

In Minneapolis, 73% of menthol cigarettes are sold in convenience stores.

MPLS retailers would lose $37M to $40M in annual sales losses per store, equating to an annual loss of $238,000 to $259,000 in annual sales losses per store excluding tobacco sales.

940 impacted jobs

This would be a MAJOR BLOW to the community. Minneapolis retailers will be devastated by this menthol ban.

Submitted by Coalition of Neighborhood Retailers

https://www.mackinac.org/high-taxes-on-cigarettes-increase-smuggling

Submitted by Coalition of Neighborhood Retailers
A new report finds that more than one out of every three cigarettes smoked in Minnesota in 2014 was trafficked in from across state lines.

JANUARY 18, 2017

SAM SCHAUST

LAW + CRIME (HTTP://TCBMAG.COM/LAW___CRIME)

Cigarette Smuggling Is On The Rise In Minnesota

In recent years, as Minnesota lawmakers have steadily raised the tax on tobacco products, a cigarette smuggling movement has emerged to avoid the high prices.

More than one in three cigarettes smoked in Minnesota in 2014 were trafficked into
the state from other lower-taxed environs, the Tax Foundation said in its report published Tuesday.

When the Washington D.C.-based think tank began its cigarette smuggling study in 2006, just over 23 percent of cigarettes consumed in Minnesota were brought in from across state lines. Eight years later and that rate has increased to 35.5 percent.

During that eight-year period, Minnesota’s tax on cigarettes has more than doubled. (In 2014, the state's tax on each pack was $3.34.) Legislation passed in 2013 included steep per-pack increases and an annual inflation-adjustment formula that will continue to drive prices up.

“High cigarette tax rates can result in a variety of different tax avoidance scenarios,” said Scott Drenkard, one of the authors on the Tax Foundation’s report. “A smoker traveling to another state with lower taxes (and cigarette prices) might stock up before heading back home. In other instances, the smuggling is larger scale and could involve an organized network that moves large quantities of cigarettes from low-tax states such as Virginia to high-tax states like New York. There have also been reported incidents of counterfeit tax stamps.”

In all, Minnesota has the fifth-highest cigarette-smuggling rate in the country.

Taking the top spot was New York with both the highest 2014 tax rate ($4.35 per pack) and smuggled cigarette consumption rate (55.4 percent). The only other states with a higher smuggled cigarette consumption rate than Minnesota were Arizona (49.6 percent), New Mexico (46.2 percent) and Washington (45.2 percent).

“Policymakers that want to curb cigarette smuggling have to think about more than just enforcement,” Drenkard said a state enacts an excessively high tax rate on a product, consumers will naturally look to other jurisdictions for lower cost options.”

Among Minnesota’s neighboring states, North Dakota had the lowest 2014 tax on cigarettes (44 cents per pack). Iowa was the next closest ($1.36 per pack), followed by South Dakota ($1.56 per pack) and then Wisconsin ($2.52 per pack).

“It’s important for policy makers to consider the tax rates in surrounding states,” Drenkard added. “Being too far out of line with neighboring jurisdictions could increase the likelihood of smuggling.”

Submitted by Coalition of Neighborhood Retailers
Economic Impact Analysis: Menthol Tobacco Ban

August 2017

Submitted by Coalition of Neighborhood Retailers
Management Science Associates ("MSAi") was founded in 1963 by Dr. Alfred A. Kuehn, a faculty member at Carnegie Mellon University.

MSAi has been providing tobacco-related reporting and analysis for over 40 years.

Named in the 1998 Master Settlement Agreement as a neutral 3rd party and tasked with confirming the cigarette volumes for those manufacturers that have agreed to the settlement.

MSAi’s confirmed shipment volumes are used to determine the payment amounts made by manufacturers as defined in the Master Settlement Agreement.
Menthol Economic Impact Study

- Menthol cigarettes currently account for 43% of total cigarette volume and 88% of total menthol tobacco volume in Minneapolis.

- The convenience store channel represents 73% of menthol cigarette volume in Minneapolis. Together, tobacco outlets and liquor stores comprise only 9% of menthol cigarette volume.

- In the U.S., 35% of convenience stores’ in-store revenue comes from tobacco. Tobacco is convenience stores’ 2\textsuperscript{nd} largest source of in-store gross margin dollars.

- Management Science Associates leveraged distributor to retail shipment data and retail sales data to develop statistical models and estimate the potential sales impact of the proposed menthol, mint and wintergreen regulations on retailers within the city of Minneapolis.
Menthol Restrictions’ Impact on Convenience Stores

- It is estimated that Minneapolis convenience stores would lose $36.7MM - $39.9MM annually in menthol, mint and wintergreen tobacco sales and ancillary in-store purchases.

- This equates to an annual sales loss of $238K - $259K and an annual gross margin loss of $38K - $44K per convenience store.

<table>
<thead>
<tr>
<th></th>
<th>Scenario #1 100% Ancillary Sales Lost</th>
<th>Scenario #2 50% Ancillary Sales Lost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales Loss in MPLS C-Stores Tobacco Purchases</td>
<td>-$33,554,337</td>
<td>-$33,554,337</td>
</tr>
<tr>
<td>Sales Loss in MPLS C-Stores Ancillary Purchases</td>
<td>-$6,322,077</td>
<td>-$3,161,039</td>
</tr>
<tr>
<td>Tax Revenue Loss in MPLS C-Stores Ancillary Purchases</td>
<td>-$31,610</td>
<td>-$15,805</td>
</tr>
<tr>
<td>TOTAL</td>
<td>-$39,908,024</td>
<td>-$36,731,180</td>
</tr>
</tbody>
</table>

Submitted by Coalition of Neighborhood Retailers
Economic impact at the store level

- The average US convenience store provides 15 jobs, split about equally between full- and part-time workers.

- At the current minimum wage of $7.75 per hour for small businesses in Minnesota, this is equivalent to 2,900 – 3,600 hours of employee wages.

- If those 30 stores would close and the other remaining stores in MPLS (excl. tobacco outlets) cut employee hours in line with their lost menthol tobacco profits, it is estimated that this would affect approximately 940 employees (a mix of full-time and part-time jobs) or the equivalent of 630 full-time jobs*.

Source: NACS, Distributor to Retail Shipments

*This assumes that any stores that remain open will offset their lost menthol tobacco gross margin dollars by making equivalent cuts to employee hours. The number of employees in MPLS stores is assumed to be in line with the U.S. average (per NACS).
FOR IMMEDIATE RELEASE:
May 17, 2017

Contact: Ryan Brown
ryan.brown@state.mn.us

Illinois men plead guilty to smuggling untaxed tobacco products into Minnesota

ST. PAUL, Minn. – The Minnesota Department of Revenue announced that the Washington County Attorney’s Office recently reached plea agreements with Mohammad A.M. Abdul Majid from Bridgeview, IL, and Iman Gencehan Ugurlu, from Oak Lawn, IL. Both men received five years of probation for felony aiding and abetting the sale of untaxed tobacco. The men also agreed to pay the state more than $74,000 in restitution.

Washington County charged Mr. Majid and Mr. Urgulu earlier this year with one count each of felony aiding and abetting the sale of untaxed tobacco products and one count each of felony aiding and abetting aggravated forgery. The charges stemmed from a traffic stop by the Minnesota State Patrol, in which the men were found to be in possession of more than $78,000 worth of untaxed tobacco products. The amount of untaxed tobacco products seized was the largest known seizure of such products in Minnesota history.

“The department works closely with licensed tobacco wholesalers to gain information about possible smuggled tobacco products to prevent that contraband product from entering the marketplace. Smuggled tobacco creates an unfair advantage for businesses that do not follow the law,” said Revenue Commissioner Cynthia Bauerly. “This case is a prime example of the partnership we have with state and local law enforcement agencies, and shows how we work together to ensure that the state’s tax laws are enforced fairly and evenly.”

The Minnesota Department of Revenue has a 24-hour tip line for anyone who suspects that a person or business is violating Minnesota tax laws. Local callers may dial 651-297-5195 or call toll-free by dialing 1-800-657-3500. Tips can also be submitted to the department via email at tax.fraud@state.mn.us. Tipsters may choose to remain anonymous.

Get the latest news and updates from the Minnesota Department of Revenue by following the department on Facebook and Twitter or by signing up for our email subscription list.

###

Submitted by Coalition of Neighborhood Retailers
From: Meghan T. Shea <meghan.shea@gmail.com>  
Sent: Friday, May 25, 2018 1:45 PM  
To: Julie Wischnack <jwischnack@eminnetonka.com>  
Subject: Substance Abuse in Minnesota: A State Epidemiological Profile 2018

Julie,

As mentioned, below is a link to the latest report prepared for the Minnesota Department of Health. I think this report helps to shed some light on youth tobacco use and gives some valuable perspective.

**Substance Abuse in Minnesota: A State Epidemiological Profile 2018**

Developed for the Minnesota Department of Human Services, Alcohol and Drug Abuse Division by EpiMachine, LLC


In this study:

Substances used in the last 30 days:

<table>
<thead>
<tr>
<th></th>
<th>Tobacco (Extensive education campaign)</th>
<th>Marijuana (Illegal substance in MN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8th graders</td>
<td>2.8%</td>
<td>5.4%</td>
</tr>
<tr>
<td>9th graders</td>
<td>4%</td>
<td>6.7%</td>
</tr>
<tr>
<td>11th graders</td>
<td>8.4%</td>
<td>22.7%</td>
</tr>
</tbody>
</table>

Please let me know if you have any questions.

Thanks again!

Meghan
City Council Study Session Agenda Item #2  
Meeting of June 11, 2018

Brief Description  
2040 Comprehensive Plan – Housing Update

**Comprehensive Plan Schedule**

Over the upcoming months, the comprehensive plan update process is entering the draft plan review phase. A number of Comprehensive Guide Plan Steering Committee, boards, commissions and city council meetings are identified during the summer to review the draft plan. Looking ahead to the fall are community open houses (October). Similar to the outreach that occurred over the winter, a number of live, social media and website announcements will be made. The planning commission will hold a public hearing in November and the city council will approve the plan and circulate it for review in December. Below is an outline of key events leading through plan approvals.

<table>
<thead>
<tr>
<th>Date</th>
<th>Plan Progress</th>
<th>Meetings</th>
</tr>
</thead>
<tbody>
<tr>
<td>June</td>
<td>Review Drafts</td>
<td>June 20 - Steering Committee</td>
</tr>
<tr>
<td>July</td>
<td>Review Drafts</td>
<td>July 18 – Steering Committee</td>
</tr>
<tr>
<td>September</td>
<td>Final Drafts</td>
<td>September – (date TBD)</td>
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<tr>
<td></td>
<td></td>
<td>Council – Board and Commissions Workshop –</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Preparing for Community Open Houses</td>
</tr>
<tr>
<td>September</td>
<td></td>
<td>Community Open Houses (multiple dates) –</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Coffees, Farmer’s Market</td>
</tr>
<tr>
<td>October</td>
<td></td>
<td>Community Open Houses (multiple dates) –</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Coffees, Community Center, Williston, City Open</td>
</tr>
<tr>
<td></td>
<td></td>
<td>House</td>
</tr>
<tr>
<td>November</td>
<td></td>
<td>November 15 - Planning Commission Public Hearing</td>
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<tr>
<td>December</td>
<td></td>
<td>December 3 – City Council Approval</td>
</tr>
<tr>
<td>January – May 2019</td>
<td>6-month review/comment period</td>
<td>No meetings</td>
</tr>
<tr>
<td>June – July</td>
<td>Met Council review and approval</td>
<td></td>
</tr>
<tr>
<td>July</td>
<td>Revisit any comments as may be necessary</td>
<td>Final City Council Action</td>
</tr>
</tbody>
</table>

**Comprehensive Plan - Housing Chapter Background**

On Aug. 18, 2017, the Comprehensive Guide Plan Steering Committee met to review the city’s draft housing market assessment prepared by Brent Wittenburg of Marquette Advisors. The presentation focused on the current and future housing needs. The assessment is being utilized to assist in developing short and long range plans to address housing needs in the community.

Housing is a critical element in economic development and promoting community livability, attractiveness and competitiveness. In addition to providing support data for the preparation of the comprehensive plan, the following housing study objectives were identified by staff:
• Understand demographic and economic growth factors which impact the housing supply/demand balance, and the attractiveness and/or affordability of the housing stock in the city of Minnetonka.

• Identify current and future housing needs by product type and price/rent level, based on demographics and market factors, city planning and economic development and housing goals.

• Identify housing gaps and other specific housing needs for the city based on existing and projected demand for housing and identify barriers to development of various types of housing and/or housing products by affordability level.

• Assess the relationship between housing needs and economic development in Minnetonka and the surrounding west-metro market.

• Recommend strategies to enhance the availability of well-designed and appropriately priced housing products which are complementary to the goals/objectives of the city and supports its economic development, housing, and livability goals.

Staff is analyzing the data and has prepared a summary of existing housing needs and efforts, as well as suggestions on strategies to meet future housing need based on forecasted growth in the community. This information is required to be included in the 2040 comprehensive plan.

Current Demographic and Economic Conditions

• Minnetonka had an estimated 53,394 residents and 23,479 households in 2017. (from Metropolitan council estimates published May 2018)
  o Total housing units = 24,223 in 2016
    ▪ 16,759 ownership
    ▪ 7,464 rental units
  o Affordability in 2016
    ▪ 783 units affordable below 30% Area Median Income (AMI)
    ▪ 1,485 units affordable 31-50% AMI
    ▪ 7,269 units affordable 51-80% AMI
    ▪ Total of 9,537 of all housing units affordable under 80% AMI
  o Housing Type in 2016
    ▪ 16,288 single family units (67%)
    ▪ 7,921 multifamily units (32%)
    ▪ 14 other (<1%)

• Employment in the community was estimated at 44,788 in 2016
  o Presently, Minnetonka accounts for 2.6% of metro area employment.

• The median household income for the Minnetonka resident base in 2016 was estimated at $86,559, compared to the metro area median income of $67,795. The median household income in Minnetonka is projected to increase to $99,801 in 2021, reflecting a 15% increase over five years. This compares to a similar increase of 16% for the Metro Area.
Metropolitan Council Forecasts

- The Met Council forecasts suggest the city will add an average of 240 households per year between 2020 and 2030 (2,400), decreasing to 170 per year between 2030 and 2040 (1,700) for a total of 4,100 new households between 2020 and 2040. These forecasts equate to 1.5% to 2.0% of expected Minneapolis-St. Paul metropolitan area household growth.

- The total population is forecasted to be 61,500 in 2040, with 28,300 households and 63,200 jobs.

- The Met Council projects that Minnetonka will account for more than 3.6% of regional employment growth over the next 20 years.

Housing History

The city of Minnetonka has a long history of promoting diversity in the types and size of housing units available in Minnetonka, including the production of new affordable rental and ownership opportunities. Over the past 20 years, the city has analyzed and implemented dozens of housing centric policies and programs to address the changing needs of the community. A summary of key milestones is outlined below:

- 1996-2010 - Livable Communities Act Participant
- 1998 – Draft Policy - City Assistance to Affordable Housing Developments (incorporated into 1999 comprehensive plan)
- 1999 Comprehensive Plan
- 8/6/2001 – WHAHLT Business Plan/History
- 2/3/2004 – Economic Development Authority resolution supporting 10% to 20% of units in new housing developments as affordable housing.
- 2008 – 2030 Comprehensive Plan
- 2009 ULI Minnesota – Opportunity City Pilot Program Summary Report
- 2012 – first Economic Improvement Program
- 2013 – Southwest Corridor Housing Inventory
- 2016 – Southwest LRT Corridor Housing Strategy
- 2017 – Draft Housing Study (Marquette Advisors)

Additionally, staff from Minnetonka are participating in several affordable housing work groups that are researching, lobbying for, and implementing new approaches to fund affordable housing programs, preserve existing naturally occurring affordable housing (NOAH), and protect tenants. Some of the organizations leading this coordinated effort include: The Housing Justice Center, Urban Land Institute Regional Council of Mayors, Minnesota Housing Finance Agency, the Governor’s Task Force on Housing, and the Local Initiatives Support Corporation. Several cities and counties in Hennepin and Ramsey Counties are also attending the housing workgroup meetings to share their efforts and streamline legal review of new concepts and programs.
Metropolitan Council Affordable Housing Need Allocation (2021-2030)

The Metropolitan Council forecasts future affordable housing needs using a regional economic model, then allocates a share of the overall need to all communities expecting sewer-serviced household growth over the next decade. Cities are not required to create enough units to meet their share of the need, but they must plan for the possibility of these units by guiding sufficient land at higher residential densities.

The need number is calculated every 10 years in preparation of a community's comprehensive plan update—therefore it only applies to the upcoming decade, not the full 30-year scope of their comprehensive plan.

As part of the 2030 Comprehensive Plan update resources, the Metropolitan Council has forecasted the region and each community's need for affordable housing between 2021-2030. The region's total need is 37,900 and Minnetonka's portion of affordable units was determined to be 1,064 units. The comprehensive plan must determine housing goals and objectives to address the city's affordable housing need. The following chart demonstrates the Affordable Housing Need Allocation:

<table>
<thead>
<tr>
<th>Affordable Housing Need Allocation (2021-2030)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At or Below 30% AMI</td>
</tr>
<tr>
<td>From 31% to 50% AMI</td>
</tr>
<tr>
<td>From 51% to 80% AMI</td>
</tr>
<tr>
<td>Total Units</td>
</tr>
</tbody>
</table>

For communities that participate in the Livable Communities Program, the Metropolitan Council encourages the production of lifecycle housing which is defined as housing that can provide appropriately sized housing for all stages of life including young professionals, families, empty-nesters, and elderly. The lifecycle goals are included in the Housing Action Plan in addition to the production goals for new affordable ownership and rental units.

History of Area Median Income for Livable Communities Program

For program years 1996-2010, the Metropolitan Council identified a purchase price ceiling for owner-occupied homes based on what a family of four with an income at or below 80% AMI could afford at prevailing interest rates. For affordable rental units, the limit was maximum monthly rents affordable for households at 50% AMI.

From 2011 through 2014, the Metropolitan council used 60% AMI as the income limit for both rental and ownership costs.

For 2018, the affordability limit is 80% of the AMI for both rental and ownership housing as set by the Metropolitan Council. In 2018, the AMI for a household of four is $94,300. Under these limits, a family of four can earn up to $71,900 to qualify for affordable housing.
Key Findings from Draft Housing Study (Marquette Advisors)

In Aug. 2017, the Comprehensive Plan Steering Committee met to discuss the draft housing report prepared by Brent Wittenburg of Marquette Advisors. The presentation included several key findings on factors that will impact future housing needs of the community. Below are several key components of the report that guide the additional housing opportunities outlined in the staff report.

- **Jobs/Housing Balance** – Minnetonka has a strong and expanding business community. However, given the very limited production of new housing units in the community over several years, paired with low turnover rates in the existing housing stock with many seniors aging in place, much of the Minnetonka-based workforce resides elsewhere.

- **An Aging Resident Base** – Senior households are prominent in Minnetonka, with higher incomes compared to the metro area (choosing to age in place). Minnetonka’s population base is older, with a median age of 46.2 compared to 37.0 for the metro area. The large base of seniors in Minnetonka, where the age 65+ population comprises approximately 20% of the resident base, compares to 13% regionally. Minnetonka also has a large number of adults ages 55-64, comprising about 17% of the resident base, compared to about 13% for the metro area as a whole. Many in this age group have become or will soon become “empty nesters,” and will consider a housing product alternative to their current single-family home.

- **ESRI**, a data analytics company, projects that Minnetonka will capture virtually no growth in the 25-34 age population group, and only 757 residents ages 35-44 between 2016-2021, or less than 2% of regional population growth in the age 35-44 cohort. This relates in part to a very tight housing market and limited supply of new housing options in Minnetonka which meet the preferences and affordability threshold of many in these age groups.

- **Limited Production of New For-Sale Construction** - The city has seen limited new construction and features a housing stock with increasing numbers of older adults and seniors aging in place. There are limited opportunities for young to middle age buyers in Minnetonka.

- **Low Inventory of For-Sale Housing** - Minnetonka has accounted for 1.5% to 1.9% of metro area annual sales volume since 2008, and less than 1.3% of sales at <$300,000 during this period. The average sales price in Minnetonka increased to $355,000 in 2016, and $386,000 through the first half of 2017.

- Minnetonka features large numbers of homes constructed in the 1970’s and 1980’s, including both single family homes, as well as larger multi-family buildings. A large number of apartments were built in the 1980’s and there were very few new units added in Minnetonka between 2000 and 2015.
A shift in household tenure – While the homeownership rate in Minnetonka, at 70.5%, is slightly higher when compared with the metro area, there have been slight declines in the homeownership rate. In today’s market, in the Twin Cities and other markets across the US, large numbers of households are choosing to rent, rather than buy, for a variety of reasons, both economic and lifestyle-related.

Affordable housing – This is an increasingly scarce resource in Minnetonka. The number of housing units affordable to households earning <80% of the AMI decreased by more than 2,200 residential units between 2010 and 2015. Rental rates increased 7.4% since the second quarter of 2017. Additionally, the city sustained low apartment vacancy levels of 2.3% over the past year (historically low), making it difficult for renters to secure housing.

Increasing Propensity Among Households to Rent, Rather Than Buy – Based on analysis of recent apartment developments in the Twin Cities and interviews with property managers, many household groups at a full range of income levels are currently
showing a much greater propensity to rent, rather than buy, in the Twin Cities market. This is particularly true in urban locations, but also suburban sites with good access to employment nodes and goods/services. There are several lifestyle and economic factors which contribute to this trend:
  o Very few new affordable ownership units for sale, greater production of newer high-end amenity apartments.
  o Mobility access is an important factor for young renters and seniors.
  o Millennials lacking savings for down-payment for ownership (Avg. price $355,000: 5% down payment = $17,750)
  o Millennials carry significant college debt (average $40,000 per student).

- Increasing number of households with housing cost burden – According to the Met Council, utilizing American Community Survey (ACS) data, an estimated 29% of Minnetonka residents have an “excess housing cost burden” – meaning their housing cost is greater than 30% of their income. An estimated 10% of owners and 19% of renters have a “severe housing cost burden,” with a housing cost of >50% of their incomes.

Additional Strategies to Consider to Meet Future Housing Need

Below are several strategies that are currently being discussed and implemented on a regional level. The attached matrix of “Housing Strategies and Tools for the City of Minnetonka” provides additional descriptions of several of the strategies below along with the Hennepin County cities that are considering each of the opportunities.

1. Housing Production Opportunities

- Encourage the increase of new apartment construction for general occupancy and senior housing = (assisted living, independent, few-service senior housing, memory care) at various price points.
- Explore options to increase affordable home purchase opportunities at or below $300,000.
- Continue to strongly encourage the inclusion of 10-20% of affordable housing units in all new multifamily housing developments and medium to high density housing developments or consider a mixed-income policy to encourage the production of new affordable housing units in all multifamily housing developments, distributed throughout the community.
  o The city currently requires the inclusion of affordable housing for projects receiving city financing assistance or when zoning/comprehensive plan changes are required.
- Guide land densities that support affordable housing and consider density bonuses.
  o Specifically, support high density and walkable housing along the SWLRT corridor, employment centers, and commercial areas.
  o Encourage housing with walkability, transit connections, and a mix of amenities.
- Participate in site assembly in locations identified in future land use maps for higher housing density.
The city acquired 4312 Shady Oak Road and 5937 County Road 101 as properties impacted by county road projects. The acquisition of the properties allows the city to select the redevelopment activity that is the best fit for each site.

2. **Housing Preservation and Rehabilitation Opportunities**

   - Use affordable housing funds (such as NOAH Impact Fund) and other financial resources to partner with apartment communities on reinvestment projects.
     - Limited resources available for larger scale multifamily housing acquisitions, particularly for Minnetonka properties.
   - Identify at-risk buildings to preserve naturally occurring affordable housing within all bands of affordability, especially near future transit stations.
   - Help preservation buyers purchase at-risk buildings
   - First Right of Refusal for tenants or government.
   - Offer local financial assistance to preserve existing housing (e.g., rehab dollars for continued affordability – previously done at Beacon Hill)
   - Facilitate 4d (LIRC) Tax Benefit

3. **Tenant Protection Opportunities**

   Explore adopting tenant protection ordinances that would require landlord notice of non-renewal leases, significant rent increases, or changes in screening criteria, including:
   - Advance notice period for sale of existing properties
   - Prohibition of Section 8 discrimination
   - Just cause eviction requirement
   - Education of landlords about renting to certain groups, such as voucher holders

4. **Additional Housing Opportunities**

   - Establish a Fair Housing Policy – This will be required by the Metropolitan Council for cities participating in the Livable Communities Program in 2018. This policy would ensure that fair housing opportunities are granted to all persons in all housing opportunities and development activities funded by the city regardless of race, color, religion, gender, sexual orientation, marital status, status with regard to public assistances, familial status, national origin, or disability. This will be done through external policies that provide meaningful access to all residents and fair housing information and referral services; and internal practices and procedures that affirmatively further fair housing.
     - The city currently contributes a portion of its Community Development Block Grant (CDBG) award to participate in the Hennepin County Fair Housing Consortium.
     - This policy would provide internal guidance on how to handle fair housing complaints and how to communicate fair housing information to its residents.
   - Explore establishing a Rental Licensing Program for multifamily housing communities. The program could provide the city with the authority to monitor all rental properties and ensure they are properly maintained for safety of occupants. Additionally, the licensing could be a mechanism by which the city is notified in the event of a sale.
The city currently has a strong housing inspection program through its building and public health divisions and fire department for construction of new buildings and review of remodeling for existing structures. The city has also adopted the 2015 International Property Maintenance Code that established the maintenance standards for basic equipment, light, ventilation, heating, sanitary, and fire safety standards for existing buildings, in the interest of the social and economic welfare of the community.

Staff Recommendation

The city council is requested to review the housing information in this report and provide direction to the Comprehensive Guide Plan Steering Committee as the 2040 housing chapter is developed.

Further, staff recommends several other actions outside of the comp plan process related to housing, including directing staff to draft a fair housing policy and recommend additional housing strategies (including affordable housing) for EDAC review and city council consideration. Additionally, staff recommends continuing to review and consider regional efforts to implement tenant protections and housing preservation/rehabilitation opportunities.

Discussion Questions:

Does the city council wish to offer any additional direction regarding the housing chapter in the comprehensive plan?

Does the city council agree with pursuing other actions related to affordable and fair housing, tenant protections, and housing preservation?

Submitted through:
Geralyn Barone, City Manager

Originated by:
Julie Wischnack, AICP, Community Development Director
Alisha Gray, EDFP, Economic Development and Housing Manager

Attachments:
Metropolitan Council Housing Chapter Required Elements
Metropolitan Council AMI and Housing Affordability
Metropolitan Council Existing Housing Assessment
2011-2020 Affordable Housing Action Plan
Housing Strategies and Tools for the City of Minnetonka
Land Use Map
Housing Market Value Map

Supplemental Information

Aug. 23, 2017 Comprehensive Steering Committee Meeting - Draft Housing Market Assessment

2030 Comprehensive Plan
HOUSING

The Council’s overall housing policy priority is to:

*Create housing options that give people in all life stages and of all economic means viable choices for safe, stable and affordable homes.*

Housing choices allow households to find housing affordable to them in the communities where they want to live. A full range of housing types can help increase resiliency as local governments experience changing demographics and economic conditions. Housing elements are an opportunity to state a local government’s specific policy priorities around housing choice within their community.

The information found here will help you develop a Housing Element and related Implementation Plan that meets minimum requirements of the Metropolitan Land Planning Act and is consistent with the adopted 2040 Housing Policy Plan. Counties may have different requirements than cities depending on their location. If you are preparing a County Comprehensive plan this FAQ will provide more information.

Housing Plan

EXISTING HOUSING NEEDS

An assessment of the existing housing conditions in your community is the first step in determining existing housing needs. Communities may use alternative data to meet minimum requirements if the sources are reasonably credible.

**Minimum Requirements:**

- Complete an existing housing assessment, including:
  - A table of existing local conditions (found on your Community Page), including the following information:
    1. Total number of housing units.
    2. Number of housing units affordable to households with incomes at or below 30% Area Median Income (AMI), between 31 and 50% AMI, and between 51 and 80% AMI. What these income ranges mean and how they translate to affordable housing costs.
    3. Number of housing units that are owner occupied.
    4. Number of housing units that are rental.
    5. Number of single family homes.
    6. Number of multi-family homes.
    7. Number of publicly subsidized housing units by the following types: senior housing, housing for people with disabilities, and all other publicly subsidized units. Include expiration dates of affordability requirements when applicable.
    8. Number of existing households that are experiencing housing cost burden with incomes at or below 30% Area Median Income (AMI), between 31 -50% AMI, and 51 -80% AMI.
  - A map of owner-occupied housing units (found on your Community Page) identifying their assessed values. At a minimum, differentiate the values above and below $243,500. What is this number and how is it calculated?
  - A narrative analysis of existing housing needs. At a minimum address the components of the existing housing assessment within the local context of your community. Plans consistent with Council policy will clearly identify existing housing needs and priorities for the community.

Get More Out of Your Plan:

https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx
Your analysis of existing housing needs will be more effective if it addresses potential barriers to meeting those needs. Consider different types of barriers in your analysis, including but not limited to physical, financial, and political challenges. For deeper consideration of barriers to meeting housing needs, check out the [2014 Analysis of Impediments to Fair Housing Choice: Twin Cities Region](https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx) and the [2017 Addendum to the 2014 Regional Analysis of Impediments](https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx), or the Metropolitan Council’s [Choice, Place and Opportunity report](https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx).

Many communities have more detailed information about their existing housing conditions than needed to meet minimum requirements. Communities are encouraged to include additional information for their existing housing needs analysis if available, including:

- Historical data on housing needs (for context)
- How a community’s needs align with the relevant Consolidated Plan
- School District boundaries within the community
- The geographic distribution of rental housing costs in the community

Prioritize creating green and healthy housing for all household sizes and incomes. Healthy housing is beneficial in many ways. ([Minnesota Healthy Planning: How-To Guide](https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx), page 10)

Consider using a housing-cost burden that incorporates the cost of transportation to employment opportunities, goods and services (i.e., no more than 30-40% of monthly income spent on housing and transportation). ([Minnesota Healthy Planning: How-To Guide](https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx), page 30)

We Can Help!

- You can find your existing housing assessment tables and maps on your [Community Page](https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx).
- We’ve provided a detailed explanation of [data sources and methodologies](https://metrocouncil.org/Handbook/Plan-Elements/Housing.aspx) used in the tables and maps provided.
The Area Median Income (AMI) is the midpoint of a region’s income distribution – half of families in a region earn more than the median and half earn less than the median. For housing policy, income thresholds set relative to the area median income—such as 50% of the area median income—identify households eligible to live in income-restricted housing units and the affordability of housing units to low-income households.

Low-income households and levels of affordability
Your housing element and implementation program must address affordable housing needs within three levels of affordability:

- At or below 30% AMI
- Between 31 and 50% AMI
- Between 51 and 80% AMI

The U.S. Department of Housing and Urban Development (HUD) defines and calculates different levels of AMI for geographic areas across the country by household size. For the Twin Cities region in 2017, HUD has defined the three levels of affordability as:

<table>
<thead>
<tr>
<th>Household Size:</th>
<th>Extremely Low Income (30% of AMI)</th>
<th>Very Low Income (50% of AMI)</th>
<th>Low Income (80% of AMI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-person</td>
<td>$19,000</td>
<td>$31,650</td>
<td>$47,600</td>
</tr>
<tr>
<td>Two-person</td>
<td>$21,700</td>
<td>$36,200</td>
<td>$54,400</td>
</tr>
<tr>
<td>Three-person</td>
<td>$24,400</td>
<td>$40,700</td>
<td>$61,200</td>
</tr>
<tr>
<td>Four-person</td>
<td>$27,100</td>
<td>$45,200</td>
<td>$68,000</td>
</tr>
<tr>
<td>Five-person</td>
<td>$29,300</td>
<td>$48,850</td>
<td>$73,450</td>
</tr>
<tr>
<td>Six-person</td>
<td>$32,960</td>
<td>$52,450</td>
<td>$78,900</td>
</tr>
<tr>
<td>Seven-person</td>
<td>$37,140</td>
<td>$56,050</td>
<td>$84,350</td>
</tr>
<tr>
<td>Eight-person</td>
<td>$41,320</td>
<td>$59,700</td>
<td>$89,800</td>
</tr>
</tbody>
</table>

Thinking about specific jobs helps make this more concrete. For a four-person household with only one wage-earner, positions as home health aides or funeral attendants would provide an income at 30% of AMI; positions as interior designers or bus drivers would provide an income at 50% of AMI; and positions as accountants or police officers would provide an income at 80% of AMI. For a more in depth look at how full-time jobs do not always mean there are affordable housing choices, visit the Family Housing Fund’s website.

Having an income below these thresholds makes households eligible for certain housing programs (other social programs use thresholds relative to the federal poverty guidelines). For example, to be eligible for a Housing Choice Voucher, household income must be at or below 50% of AMI; a three-person household with an income up to $40,700 would be eligible for a voucher as would a five-person household with an income up to $48,850.

Translating incomes into affordable housing costs
These income levels are also a way to assess housing affordability. We say that a housing unit is “affordable at 80% of AMI” if a household whose income is at or below 80% of AMI can live there without spending more than 30% of their income on housing costs. What this means in practice differs for rental and ownership units.

Affordable rents for housing units vary by the number of bedrooms in the housing unit. This is because the income limits vary by household size, and the number of bedrooms affects how many people a unit can comfortably house. Here are affordable monthly rents at the different income levels for 2017:
Calculations of affordability for ownership units are more complicated because there are more variables in monthly housing costs – such as generalized assumptions about down-payments and mortgage interest rates – and each homeowner will have a different experience. Each year, the Council develops affordability limits based on forecasting what those annual assumptions will be; these are used to inform development funded through the Livable Communities Act programs. While we can’t predict what future home prices will be, we can look backward at the estimated market values for 2016; these are the basis of the Council-provided maps showing ownership units that are affordable to households at 80% of AMI.

Affordable purchase prices are provided for both 2015 and 2016 below. If your community chooses to develop a map with a different data source to satisfy this requirement, please contact Council staff to find out which affordability limit you should use.

<table>
<thead>
<tr>
<th>Number of bedrooms:</th>
<th>Affordable rent (including utilities) at 30% of AMI</th>
<th>Affordable rent (including utilities) at 50% of AMI</th>
<th>Affordable rent (including utilities) at 80% of AMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studio</td>
<td>$474</td>
<td>$791</td>
<td>$1,265</td>
</tr>
<tr>
<td>1-BR</td>
<td>$508</td>
<td>$848</td>
<td>$1,356</td>
</tr>
<tr>
<td>2-BR</td>
<td>$610</td>
<td>$1,017</td>
<td>$1,627</td>
</tr>
<tr>
<td>3-BR</td>
<td>$705</td>
<td>$1,175</td>
<td>$1,880</td>
</tr>
<tr>
<td>4-BR</td>
<td>$786</td>
<td>$1,311</td>
<td>$2,097</td>
</tr>
</tbody>
</table>

1. For a full explanation of how these amounts were calculated, see HUD’s website.

2. These rents assume that a household should pay no more than 30% of its monthly income on rent (including utilities), and (in keeping with IRS regulations) that a housing unit can comfortably hold 1.5 times as many people as the number of bedrooms it has.

3. For all years, in addition to the 29% housing debt to household income ratio, we assumed a 30-year fixed-interest mortgage, a 3.5% down-payment, a property tax rate of 1.25% of property sales price, and $100 / month for hazard insurance. For 2017, we assumed a 4.375% interest rate and mortgage insurance premiums at 0.85% of unpaid principal. For 2016, we assumed a 3.60% interest rate (the average rate in the Midwest in 2016) and mortgage insurance premiums at 0.85% of unpaid principal. For 2015, we assumed a 3.84% interest rate (the average rate in the Midwest in 2015) and mortgage insurance premiums at 1.35% of unpaid principal.
CITY OF MINNETONKA

An Existing Housing Assessment is the first step in identifying current housing needs for your community. This information meets the minimum data requirements for your Existing Housing Assessment. You are free to copy and paste this table directly into your Housing Element, recreate it using the same data, or incorporate it into a table with additional or alternative data using reliable sources. This table is not a comprehensive picture of your community’s housing stock, but a solid starting point to identify and address your existing housing needs. Please contact Council staff if you have any questions.

Total housing units \(^1\) = 24,223
Total households \(^2\) = 23,367

Table 1 Affordability in 2016 \(^3\)

<table>
<thead>
<tr>
<th>Units affordable to households with income at or below 30% of AMI</th>
<th>Units affordable to households with income 31% to 50% of AMI</th>
<th>Units affordable to households with income 51% to 80% of AMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>783</td>
<td>1,485</td>
<td>7,269</td>
</tr>
</tbody>
</table>

Table 2 Tenure in 2016 \(^4\)

<table>
<thead>
<tr>
<th>Ownership units</th>
<th>Rental units</th>
</tr>
</thead>
<tbody>
<tr>
<td>16,759</td>
<td>7,464</td>
</tr>
</tbody>
</table>

Table 3 Housing Type in 2016 \(^1\)

<table>
<thead>
<tr>
<th>Single-family units</th>
<th>Multifamily units</th>
<th>Manufactured homes</th>
<th>Other housing units</th>
</tr>
</thead>
<tbody>
<tr>
<td>16,288</td>
<td>7,921</td>
<td>0</td>
<td>14</td>
</tr>
</tbody>
</table>

Table 4 Publicly Subsidized Units \(^5\)

<table>
<thead>
<tr>
<th>All publicly subsidized units</th>
<th>Publicly subsidized senior units</th>
<th>Publicly subsidized units for people with disabilities</th>
<th>Publicly subsidized units: All others</th>
</tr>
</thead>
<tbody>
<tr>
<td>555</td>
<td>45</td>
<td>0</td>
<td>510</td>
</tr>
</tbody>
</table>

Table 5 Housing Cost-Burdened Households in 2016 \(^6\)

<table>
<thead>
<tr>
<th>Income at or below 30% of AMI</th>
<th>Income 31% to 50% of AMI</th>
<th>Income 51% to 80% of AMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,092</td>
<td>1,466</td>
<td>1,409</td>
</tr>
</tbody>
</table>

\(^1\) Source: Metropolitan Council, 2016 housing stock estimates. Single-family units include single-family detached homes and townhomes. Multifamily units include units in duplex, triplex, and quadplex buildings as well as those in buildings with five or more units.

\(^2\) Source: Metropolitan Council, 2016 household estimates.

\(^3\) Source: Metropolitan Council staff estimates for 2016 based on 2016 and 2017 MetroGIS Regional Parcel Datasets (ownership units), 2010-2014 Comprehensive Housing Affordability Strategy data from HUD (rental units and household income), and the Council’s 2016 Manufactured Housing Parks Survey (manufactured homes). Counts from these datasets were adjusted to better match the Council’s estimates of housing units and households in 2016 as well as more current tenure, affordability, and income data from the American Community Survey, home value data from the Federal Housing Finance Agency, and rents from HousingLink’s Twin Cities Rental Revue data.

\(^4\) Source: U.S. Census Bureau, 2012-2016 American Community Survey five-year estimates; counts adjusted to better match the Council’s 2016 housing stock estimates.

\(^5\) Source: HousingLink Streams data (covers projects whose financing closed by December 2016), http://www.housinglink.org/streams

\(^6\) Housing cost burden refers to households whose housing costs are at least 30% of their income. Source: U.S. Department of Housing and Urban Development, 2010-2014 Comprehensive Housing Affordability Strategy (CHAS) data, with counts adjusted to better match Metropolitan Council 2016 household estimates.

March 2018
Introduction

In 1995, the Minnesota Legislature created the Livable Communities Act (LCA) to address the affordable and life-cycle housing needs in the Twin Cities metropolitan area. When the LCA was established, Minnetonka was one of the communities to sign up to participate in the program, negotiating a series of affordable and lifecycle housing goals with the Metropolitan Council for 1996-2010.

In August 2010, the Minnetonka City Council passed a resolution electing to continue participating in the LCA for the years 2011-2020. As part of that resolution, the city agreed to the following affordable and lifecycle housing goals:

<table>
<thead>
<tr>
<th>New Affordable Units (rental and ownership)</th>
<th>246 to 378</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Lifecycle Units</td>
<td>375 to 800</td>
</tr>
</tbody>
</table>

The purpose of this Housing Action Plan is to outline the steps and tools that the city may use between the years 2011-2020 to help meet its LCA goals.

Overview of Minnetonka Housing Trends

Development Conditions

Minnetonka is a desirable community in which to live. Its natural environment, good schools, and homes on large lots contribute to the attraction of Minnetonka as a great place to live, work and play. As such, the demand for these community attributes has led to increased home values that have risen to the point that most single-family homes, despite their age, are not affordable to low and moderate income families. Land values, in particular, have increased substantially, making it difficult for developers to build affordable and mid-priced single-family homes.

Additionally, Minnetonka is a fully developed city with little vacant or underdeveloped land available for new housing development. With the combination of increasing land values and little developable land, most of the affordable homes in the community are rental units and for-sale condominiums and townhomes.

Aging of the Population

One of the biggest demographic shifts affecting this nation is the aging of the “baby boomer” generation (the large generation of people born between 1946 and 1964). This trend is already apparent in Minnetonka, where the median age in 2007 was 52 years old and 44% of the households were age 55 and older. As the population continues to
age, housing location, types, and proximity to public transit or transit alternatives will become increasingly important.

Preservation and Rehabilitation of the Existing Housing Stock

Much of Minnetonka’s single-family housing stock was built between 1950 and 1970 while most multi-family housing was built in the 1970s and 1980s. As the housing stock continues to age, additional maintenance and repairs will be needed in order to keep homes in adequate condition and to preserve neighborhood character. Older homes may need to be updated in order to attract younger families to the community. Also, as both Minnetonka’s population and housing age, older residents may require increased support through funding and in-kind service programs that will help them to maintain and make necessary repairs to ensure that their homes are safe, accessible, energy efficient, and habitable.

While not all older homes are affordable, older homes tend to be the more affordable housing stock in Minnetonka. The preservation of these homes is critical to providing homeownership opportunities for those who could normally not afford to live in the community.

Current Housing Conditions

In 2007, there were approximately 22,500 housing units in Minnetonka, of which 76.6% are owner-occupied. The housing stock includes a mix of the following types:

- 57% single-family
- 20% condominium/townhome
- 18% general-occupancy rental
- 5% senior (including independent and assisted living facilities)

Land values in Minnetonka continue to greatly influence the cost of housing. In Minnetonka, land accounts for about one-third of a home’s total value, thus making up a large proportion of the home value. For a single-family home, the median value is $326,850, with only about 1% of the single-family homes valued under $200,000. The median value of Minnetonka’s multi-family for-sale homes (i.e. condominiums and townhomes) in 2007 was $200,000. Multi-family homes contribute to the bulk of the city’s affordable for-sale housing stock because they are generally more affordable than Minnetonka’s single-family detached homes.

The average monthly rents at Minnetonka’s market-rate multi-family apartments are much higher than other market-rate apartments in the metropolitan area. In the 1st Quarter 2007, Minnetonka’s average apartment rents were $1,106 compared to the metropolitan area’s average apartment rental rate of $876. Additionally, only about 20% of Minnetonka rental units are considered affordable under the Metropolitan Council’s definition.
**Housing Goals**

In addition to the city’s agreement to add new affordable and lifecycle housing units as set out in the 2011-2020 affordable and lifecycle housing goals with the Metropolitan Council, the city’s 2008 Comprehensive Plan update also provides a series of housing goals that the city will be working towards achieving. These goals include:

1. Preserve existing owner-occupied housing stock.
2. Add new development through infill and redevelopment opportunities.
3. Encourage rehabilitation and affordability of existing rental housing and encourage new rental housing with affordability where possible.
4. Work to increase and diversify senior housing options.
5. Continue working towards adding affordable housing and maintaining its affordability.
6. Link housing with jobs, transit and support services.

More details on these goals as well as action steps are provided in the 2008 City of Minnetonka Comprehensive Plan Update.

**Tools and Implementation Efforts to Provide Affordable and Lifecycle Housing**

**Housing Assistance Programs**

The purpose of housing assistance programs is to provide renters or homeowners help in obtaining a housing unit. These programs can be federal, state, or local programs. For the years 2011-2020, Minnetonka anticipates the following programs will be available to Minnetonka residents.

**Section 8 Voucher Program**
The Section 8 Voucher Program is funded by the U.S. Department of Housing and Urban Development (HUD), and administered by the Metro HRA on behalf of the city. The program provides vouchers to low income households wishing to rent existing housing units. The number of people anticipated to be served depends on the number of voucher holders wishing to locate in Minnetonka as well as the number of landlords wishing to accept the vouchers.

**Shelter Plus Care**
The Shelter Plus Care program is another federal program administered by the Metropolitan Council and sometimes the City of St. Louis Park. This program provides rental assistance and support services to those who are homeless with disabilities. There are a small number of these units (less than 10) in the city currently, and it is unlikely there will be any more added.

**Minnesota Housing Finance Agency Programs**
The Minnesota Housing Finance Agency (MHFA) offers the Minnesota Mortgage Program and the Homeownership Assistance Fund for people wishing to purchase a
home in Minnetonka. The Minnesota Mortgage Program offers a below market rate home mortgage option, while the Homeownership Assistance Fund provides downpayment and closing cost assistance. It is unknown how many people are likely to use these services as it seems to depend on what the market conditions are.

**Homes Within Reach**
Homes Within Reach, the local non-profit community land trust, acquires both new construction and existing properties for their program to provide affordable housing in the city. Using a ground lease, it allows the land to be owned by Homes Within Reach and ensures long-term affordability. Additionally, if rehabilitation is needed on a home, Homes Within Reach will rehabilitate the home before selling the property to a qualified buyer (at or less than 80% area median income). It is anticipated that approximately three to five homes per year will be acquired in Minnetonka as part of this program.

**City of Minnetonka First Time Homebuyer Assistance Program**
In 2010, the city levied for funds to begin a first time homebuyer assistance program. The program is anticipated to begin in 2011. General program details include funds for downpayment and closing costs of up to $10,000, which would be structured as a 30 year loan and available to those at incomes up to 115% of area median income or those that can afford up to a $300,000 loan. The number of households to be assisted depends on the amount of funding available for the program. Currently, this program is anticipated to be funded with HRA levy funds.

**Employer Assisted Housing**
Through employer assisted housing initiatives, Minnetonka employers can help provide their employees with affordable rental or home ownership opportunities. There are several options that employers can use to both increase the supply of affordable housing, as well as to provide their employees with direct assistance by:

- Providing direct down payment and closing cost assistance
- Providing secondary gap financing
- Providing rent subsidies

No employer assisted housing programs have been set up to date; however, it is a tool that the city has identified in the past as an opportunity for those who work in Minnetonka to live in Minnetonka.

**Housing Development Programs**

Housing development programs provide tools in the construction of new affordable housing units—both for owner-occupied units as well as rental units.

**Public Housing**
There are currently 10 public housing units, located in two rental communities, which offer affordable housing options for renters at incomes less than 30% of area median income. The Metropolitan Council and Minneapolis Public Housing Authority administer
the public housing program on behalf of the city. It is not anticipated that more public housing units will be added to the city.

HOME Program
HOME funds are provided through Hennepin County through a competitive application process. The city regularly supports applications by private and non-profit developers that wish to apply for such funds. Homes Within Reach has been successful in the past in obtaining HOME funds for work in Minnetonka and suburban Hennepin County.

Other Federal Programs
The city does not submit applications for other federal funding programs such as Section 202 for the elderly or Section 811 for the handicapped. However, the city will provide a letter of support for applications to these programs.

Minnesota Housing Finance Agency Programs
The Minnesota Housing Finance Agency (MHFA) offers a variety of financing programs, mainly for the development of affordable rental housing. Similar to federal programs, the city does not usually submit applications directly to MHFA; however, it will provide letters of support for applications to the programs.

Metropolitan Council Programs
The Metropolitan Council, through participation in the LCA, offers the Local Housing Incentives Account and Livable Communities Demonstration Account programs to add to the city’s affordable housing stock. Over the past 15 years, the city has received nearly $2 million in funds from these programs, and will continue to seek funding for projects that fit into the criterion of the programs.

Twin Cities Habitat for Humanity
The Twin Cities Habitat for Humanity chapter has had a presence in Minnetonka in the past, completing four affordable housing units. At this time there are no projects planned for Minnetonka, as land prices make it significantly challenging unless the land is donated. The city is willing to consider projects with Habitat for Humanity in the future to assist those with incomes at or below 50% of area median income.

Tax Increment Financing
Minnetonka has used tax increment financing (TIF) to offset costs to developers of providing affordable housing in their development projects. The city will continue to use TIF financing, as permitted by law, to encourage affordable housing opportunities. Unless the state statutes provide for a stricter income and rental limit, the city uses the Metropolitan Council's definition of affordable for housing units.

Housing Revenue Bonds
The City has used housing revenue bonds for eight rental projects since 1985. Housing revenue bonds provide tax exempt financing for multi-family rental housing. The bond program requires that 20 percent of the units have affordable rents to low and moderate income persons. The city will continue to use housing revenue bonds for projects that
meet housing goals and provide affordable units meeting the Metropolitan Council’s
guidelines.

**Housing and Redevelopment Authority (HRA) Levy**
By law, the city’s Economic Development Authority (EDA) has both the powers of an
economic development authority and a housing and redevelopment authority (HRA). It
can use these powers to levy taxes to provide funding for HRA activities, including
housing and redevelopment. The city first passed an HRA levy in 2009 to support
Homes Within Reach, and now uses the funds to support its own housing rehabilitation
and homeownership activities for those at 100-115% of area median income.

**Community Development Block Grant (CDBG) funds**
CDBG funds are allocated to the city by HUD each year. Based upon the needs,
priorities, and benefits to the community, CDBG activities are developed and the
division of funding is determined at a local level. CDBG funds are available to help fund
affordable housing.

**Livable Communities Fund**
In 1997, special legislation was approved allowing the City to use funds remaining from
Housing TIF District No. 1 for affordable housing and Livable Communities Act
purposes. The city can use these funds to help achieve its affordable housing goals.

**Housing Maintenance and Rehabilitation**

As the city’s housing stock continues to age, a number of programs are already in place
to help keep up the properties.

**Minnesota Housing Finance Agency Programs--Rental**
The Minnesota Housing Finance Agency (MHFA) offers a variety of financing programs,
for the rehabilitation of affordable rental housing. The city does not submit applications
for these programs as the city does not own any rental housing; however, it will provide
letters of support for those wishing to apply.

**Minnesota Fix-up Fund**
The Minnesota Housing Fix-Up Fund allows homeowners to make energy efficiency,
and accessibility improvements through a low-interest loan. Funded by MHFA, and
administered by the Center for Energy and Environment, the program is available to
those at about 100% of area median income.

**Community Fix-up Fund**
The Community Fix-Up Fund, offered through Minnesota Housing, is similar to the Fix-
Up Fund, but eligibility is targeted with certain criteria. In the city, Community Fix-Up
Fund loans are available to Homes Within Reach homeowners, since community land
trust properties cannot access the Fix-Up Fund due to the ground lease associated with
their property.
Home Energy Loan
The Center for Energy and Environment offer a home energy loan for any resident, regardless of income, wishing to make energy efficiency improvements on their home.

Emergency Repair Loan
Established in 2005, the City’s Emergency Repair Loan program provides a deferred loan without interest or monthly payments for qualifying households to make emergency repairs to their home. The amount of the loan is repaid only if the homeowner sells their home, transfers or conveys title, or moves from the property within 10 years of receiving the loan. After 10 years, the loan is completely forgiven. This loan is funded through the City’s federal Community Development Block Grant (CDBG) funds in order to preserve the more affordable single-family housing stock by providing needed maintenance and energy efficiency improvements. The program is available to households with incomes at or below 80% of area median income. On average, 10 to 15 loans are completed each year.

City of Minnetonka Home Renovation Program
In 2010, the city levied for funds to begin a home renovation program. The program is anticipated to begin in 2011. This program would be similar to the existing federal community development block program (CDBG) rehabilitation program. The challenge with CDBG funding involves the maximum qualifying household income of 80% of AMI, Use of HRA funds, would allow the City of Minnetonka Home Renovation Program more flexibility to include households up to 115% AMI, which equates to 82% of all Minnetonka households. The program would be geared toward maintenance, green related investments and mechanical improvements. Low interest loans would be offered up to $7,500 with a five year term.

H.O.M.E. program
The H.O.M.E. program is a homemaker and maintenance program that is designed to assist the elderly. The H.O.M.E. program assists those who are age 60 and older, or those with disabilities with such services as: house cleaning, food preparation, grocery shopping, window washing, lawn care, and other maintenance and homemaker services. Anyone meeting the age limits can participate; however, fees are based on a sliding fee scale. Nearly 100 residents per year are served by this program.

Home Remodeling Fair
For the past 17 years, the city has been a participant in a home remodeling fair with other local communities. All residents are invited to attend this one day event to talk to over 100 contractors about their remodeling or rehabilitation needs. Additionally, each city has a booth to discuss various programs that are available for residents. Approximately 1,200 to 1,500 residents attend each year.
Local Official Controls and Approvals

The city recognizes that there are many land use and zoning tools that can be utilized to increase the supply of affordable housing and decrease development costs. However, with less than two percent of the land currently vacant in the city, most new projects will be in the form of redevelopment or development of under-utilized land. New infill development and redevelopment is typically categorized as a planned unit development (PUD), which is given great flexibility under the current zoning ordinance.

Density Bonus
Residential projects have the opportunity to be developed at the higher end of the density range within a given land use designation. For example, a developer proposing a market rate townhouse development for six units/acre on a site guided for mid-density (4.1-12 units/acre) could work with city staff to see if higher density housing, such as eight units/acre, would work just as well on the site as six units/acre. This is done on a case by case basis rather than as a mandatory requirement, based on individual site constraints.

Planned Unit Developments
The use of cluster-design site planning and zero-lot-line approaches, within a planned unit development, may enable more affordable townhome or single-family cluster developments to be built. Setback requirements, street width design, and parking requirements that allow for more dense development, without sacrificing the quality of the development or adversely impacting surrounding uses, can be considered when the development review process is underway.

Mixed Use
Mixed-use developments that include two or more different uses such as residential, commercial, office, and manufacturing or with residential uses of different densities provide potential for the inclusion of affordable housing opportunities.

Transit Oriented Development (TOD)
TOD can be used to build more compact development (residential and commercial) within easy walking distance (typically a half mile) of public transit stations and stops. TODs generally contain a mix of uses such as housing, retail, office, restaurants, and entertainment. TODs provide households of all ages and incomes with more affordable transportation and housing choices (such as townhomes, apartments, live-work spaces, and lofts) as well as convenience to goods and services.

Authority for Providing Housing Programs

The City of Minnetonka has the legal authority to implement housing-related programs, as set out by state law, through its Economic Development Authority (EDA). The EDA was formed in 1988; however, prior to that time, the city had a Housing and Redevelopment Authority (HRA).
Affordable Housing Goals

Progress on the city’s affordable housing goals.

In 1995, the Minnesota Legislature created the Livable Communities Act (LCA) to address the affordable and life-cycle housing needs in the Twin Cities metropolitan area. When the LCA was established, Minnetonka was one of the first communities to sign up to participate in the program. At that time, a series of affordable housing goals for the city was established for 1996 to 2010. The city has elected to continue to participate in the LCA program, establishing affordable and lifecycle housing goals for 2011 to 2020.

1995-2010 Affordable Housing Goals

<table>
<thead>
<tr>
<th>Goals (1995-2010)</th>
<th>Results</th>
<th>Percent Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Affordable Ownership Units</td>
<td>180 Units</td>
<td>202</td>
</tr>
<tr>
<td>New Affordable Rental Units</td>
<td>324 Units</td>
<td>213</td>
</tr>
<tr>
<td>New Rental Units (All)</td>
<td>540 Units</td>
<td>697</td>
</tr>
</tbody>
</table>

1995-2010 New Affordable Ownership Units

<table>
<thead>
<tr>
<th>Project</th>
<th>Year Completed</th>
<th>Affordable Units</th>
<th>EIP Program Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gables of West Ridge Market</td>
<td>1996-1997</td>
<td>90</td>
<td>Boulevard Gardens TIF</td>
</tr>
<tr>
<td>Habitat for Humanity</td>
<td>1999</td>
<td>4</td>
<td>None</td>
</tr>
<tr>
<td>Ridgebury</td>
<td>2000</td>
<td>56</td>
<td>Ridgebury TIF</td>
</tr>
<tr>
<td>The Enclave</td>
<td>2002</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>The Sanctuary</td>
<td>2005-2007</td>
<td>3</td>
<td>-Grants -Homes Within Reach</td>
</tr>
<tr>
<td>Lakeside Estates</td>
<td>2005</td>
<td>1</td>
<td>Homes Within Reach</td>
</tr>
<tr>
<td>Cloud 9 Sky Flats</td>
<td>2006</td>
<td>34</td>
<td>Homes Within Reach</td>
</tr>
<tr>
<td>Wyldewood Condos</td>
<td>2006</td>
<td>8</td>
<td>None</td>
</tr>
<tr>
<td>Minnetonka Drive</td>
<td>2007</td>
<td>1</td>
<td>Homes Within Reach</td>
</tr>
<tr>
<td>Deephaven Cove</td>
<td>2007</td>
<td>2</td>
<td>-Grants -Homes Within Reach</td>
</tr>
<tr>
<td>Meadowwoods</td>
<td>2007/2008</td>
<td>2</td>
<td>Homes Within Reach</td>
</tr>
</tbody>
</table>

1995-2010 New Affordable Rental Units

<table>
<thead>
<tr>
<th>Project</th>
<th>Year Completed</th>
<th>Affordable Units</th>
<th>EIP Program Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excelsior Court Apartments</td>
<td>1996</td>
<td>24</td>
<td>Boulevard Gardens TIF</td>
</tr>
<tr>
<td>West Ridge Retirement</td>
<td>1997</td>
<td>45</td>
<td>Boulevard Gardens TIF</td>
</tr>
<tr>
<td>Boulevard Gardens</td>
<td>1997</td>
<td>46</td>
<td>Boulevard Gardens TIF</td>
</tr>
<tr>
<td>Crown Ridge Apartments</td>
<td>1997</td>
<td>46</td>
<td>Boulevard Gardens TIF</td>
</tr>
<tr>
<td>Minnetonka Mills</td>
<td>1997</td>
<td>30</td>
<td>Minnetonka Mills TIF</td>
</tr>
<tr>
<td>Cedar Pointe Townhouses</td>
<td>1997</td>
<td>9</td>
<td>Cedar Pointe</td>
</tr>
<tr>
<td>The Oaks at Glen Lake</td>
<td>2008</td>
<td>13</td>
<td>Glenhaven TIF</td>
</tr>
</tbody>
</table>
### 2011-2020 AFFORDABLE HOUSING GOALS

<table>
<thead>
<tr>
<th>Goals (2011-2020)</th>
<th>Results</th>
<th>Percent Achieved (to date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Affordable Units (rental &amp; ownership)</td>
<td>246 to 378</td>
<td>130</td>
</tr>
<tr>
<td>New Lifecycle Units</td>
<td>375 to 800</td>
<td>684</td>
</tr>
</tbody>
</table>

#### 2011-2020 New Affordable Units (rental and ownership)

<table>
<thead>
<tr>
<th>Project</th>
<th>Year Completed</th>
<th>Affordable Units</th>
<th>EIP Program Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Glenn by St. Therese</td>
<td>2011</td>
<td>30</td>
<td>Glenhaven TIF</td>
</tr>
<tr>
<td>The Ridge</td>
<td>2013</td>
<td>51</td>
<td>TIF Pooling</td>
</tr>
<tr>
<td>Tonka on the Creek</td>
<td>2016</td>
<td>20</td>
<td>Tonka on the Creek TIF</td>
</tr>
<tr>
<td>At Home</td>
<td>2016</td>
<td>21</td>
<td>Rowland Housing TIF</td>
</tr>
<tr>
<td>Cherrywood Pointe</td>
<td>2017</td>
<td>8</td>
<td>N/A</td>
</tr>
<tr>
<td>Shady Oak Apartments</td>
<td>2017*</td>
<td>49</td>
<td>TIF Pooling</td>
</tr>
<tr>
<td>The Mariner</td>
<td>2017*</td>
<td>55</td>
<td>TIF Pooling</td>
</tr>
<tr>
<td>Opus Station Apartments</td>
<td>Proposed 2018*</td>
<td>450</td>
<td>TIF Housing</td>
</tr>
</tbody>
</table>

*Indicates projects that are approved, but not yet constructed therefore affordable and lifecycle units are not counted in 2011-2020 goals.

#### 2011-2020 New Lifecycle Units

<table>
<thead>
<tr>
<th>Project</th>
<th>Year Completed</th>
<th>Lifecycle Units</th>
<th>EIP Program Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Glenn by St. Therese</td>
<td>2011</td>
<td>150</td>
<td>Glenhaven TIF</td>
</tr>
<tr>
<td>The Ridge</td>
<td>2013</td>
<td>64</td>
<td>TIF Pooling</td>
</tr>
<tr>
<td>Tonka on the Creek</td>
<td>2016</td>
<td>100</td>
<td>Tonka on the Creek TIF</td>
</tr>
<tr>
<td>At Home</td>
<td>2016</td>
<td>106</td>
<td>Rowland Housing TIF</td>
</tr>
<tr>
<td>Applewood Pointe</td>
<td>2017</td>
<td>89</td>
<td>Applewood Pointe TIF</td>
</tr>
<tr>
<td>Lecesse*</td>
<td>2017</td>
<td>32</td>
<td>N/A</td>
</tr>
<tr>
<td>Cherrywood Pointe</td>
<td>2017</td>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td>Zvago</td>
<td>2017</td>
<td>54</td>
<td>Glenhaven TIF</td>
</tr>
</tbody>
</table>

*Indicates projects that are approved, but not yet constructed therefore affordable and lifecycle units are not counted in 2011-2020 goals.
The following is a list of EIP programs and their contribution to the city’s affordable housing goals.

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>AFFORDABLE HOUSING CONTRIBUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Housing</strong></td>
<td></td>
</tr>
<tr>
<td>CDBG Program Administration</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Emergency Repair Program</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Employer Assisted Housing</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Fair Housing</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Homes Within Reach</td>
<td>Preservation of affordable housing</td>
</tr>
<tr>
<td>Housing Improvement Area (HIA)</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Minnetonka Heights Apartments</td>
<td>172 affordable units participate in program</td>
</tr>
<tr>
<td>Minnetonka Home Enhancement program</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Owner-Occupied Housing Rehabilitation</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Public Services</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Next Generation Program</td>
<td>Program could preserve affordable units</td>
</tr>
<tr>
<td>Tax Exempt Financing</td>
<td>Program may add or preserve affordable units</td>
</tr>
<tr>
<td>TIF Pooling</td>
<td>51 units added through The Ridge</td>
</tr>
<tr>
<td>Welcome to Minnetonka program</td>
<td>No direct impact</td>
</tr>
<tr>
<td><strong>Business</strong></td>
<td></td>
</tr>
<tr>
<td>Economic Gardening</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Fire Sprinkler Retrofit</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Grants</td>
<td>May assist with components of projects that have affordable units</td>
</tr>
<tr>
<td>Industrial Revenue Bonds (Common Bond)</td>
<td>No direct impact</td>
</tr>
<tr>
<td>GreaterMSP</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Minnesota Community Capital Fund (MCCF)</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Minnesota Investment Fund (MIF)</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Open to Business</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Outreach</td>
<td>No direct impact</td>
</tr>
<tr>
<td>PACE</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Economic Development Infrastructure</td>
<td>No direct impact</td>
</tr>
<tr>
<td>TwinWest</td>
<td>No direct impact</td>
</tr>
<tr>
<td><strong>Transit</strong></td>
<td></td>
</tr>
<tr>
<td>Commuter Services</td>
<td>No direct impact</td>
</tr>
<tr>
<td>LRT</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Transit Improvements</td>
<td>No direct impact</td>
</tr>
<tr>
<td><strong>Redevelopment</strong></td>
<td></td>
</tr>
<tr>
<td>Predevelopment Projects</td>
<td>May assist projects that are developing affordable housing</td>
</tr>
<tr>
<td>Village Center</td>
<td>Help to guide areas where affordable housing may be developed</td>
</tr>
<tr>
<td><strong>Tax Increment Financing (TIF)</strong></td>
<td></td>
</tr>
<tr>
<td>Development Agmt/TIF Admin</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Beacon Hill TIF District</td>
<td>44 affordable units added in 1994 (prior to affordable housing goals). Preserved in 2010.</td>
</tr>
<tr>
<td>Boulevard Gardens TIF District</td>
<td>227 affordable units added in 1996/1997</td>
</tr>
<tr>
<td>Glenhaven TIF District</td>
<td>43 affordable units added in 2008 and 2011</td>
</tr>
<tr>
<td>Minnetonka Mills TIF District</td>
<td>30 affordable units added in 1997. Even though district has expired, units remain affordable</td>
</tr>
<tr>
<td>Tonka on the Creek TIF District</td>
<td>20 affordable units expected in 2015</td>
</tr>
<tr>
<td>Applewood Pointe TIF District</td>
<td>9 affordable units completed in 2017 (will not meet Met Council guidelines, therefore not included in goals)</td>
</tr>
<tr>
<td>At Home Apartments</td>
<td>21 affordable units completed in 2016</td>
</tr>
<tr>
<td><strong>Tax Abatement</strong></td>
<td></td>
</tr>
<tr>
<td>Ridgedale</td>
<td>No direct impact</td>
</tr>
<tr>
<td>Tools</td>
<td>Description</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Identification of buildings; Document the problem</td>
<td>There should be an organized effort to track the most significant examples of this trend as well as identify buildings as soon as they come on the market (if possible before that). The City can also do a housing study that will identify the housing inventory and at-risk properties.</td>
</tr>
<tr>
<td>Advanced Notice</td>
<td>The City must be given advanced notice prior to the sale of any building.</td>
</tr>
<tr>
<td>Help preservation buyers to buy at risk buildings</td>
<td>Several of our non-profit housing providers are actively competing in the market for these properties, but they are disadvantaged in competing against for-profit purchasers on price and timing with the complex financial process. The City can help notify preservation buyers when they know properties will be up for sale (e.g. Seasons Park).</td>
</tr>
</tbody>
</table>
### Right of First Refusal

When owners offer their buildings for sale, they would be required to notify tenants and the designated unit of government. Tenants or the government unit would then have a defined period of time to match the essential terms of the offer (price, timeline, etc.). If they are able to do so, they have the right to purchase the building themselves.

- Prevents tenant displacement and can help a preservation buyer be competitive.
- It can be hard to anticipate where these purchase opportunities will materialize, making it difficult to know where to push for local ordinances.
- Could get complicated determining what the offer’s “essential terms” are.

Minnesota has a ROFR for manufactured home parks.

### Local programs offering rehab financing in return for affordability commitments

Many cities, like Richfield, have a supply of aging complexes that have deferred maintenance. Many managers of these complexes cite the costs of improvements as a reason to either 1) not make improvements or 2) increase the rents once improvements are made. Municipalities could offer rehab financing (low interest loans, forgivable grants) with commitments to maintain affordability over a set period of time. This could be done with CDBG dollars.

- Preserves affordable housing units in the City as well as makes the property safe housing for residents.
- Administration of the financing (could be done in conjunction with a local nonprofit), funds for the financing.

Bloomington- using their HRA levy money to put $50,000 every year for a NOAH fund to preserve developments. It has been proposed to Brooklyn Park, in conjunction with their Rental Rehab Program.

### 4d Property Tax Program

This is essentially a tax credit given to housing providers who receive a government subsidy, and in exchange provide a percentage of their units at affordable levels (60%/50% AMI) for a set period of time. This is a program Richfield had when it was funded at the state level. That funding has dried up, and it seems that most people think 4D has gone away. However, the statute allows for “local subsidies.”

- Increases the number of new affordable housing units in the City.
- Providing the pot of money for developers to tap into; the program is voluntary.

Suggested to Brooklyn Park.
**Prohibition of Section 8 Discrimination**

Changes to business practices in Richfield resulted in the following properties no longer accepting Housing Choice Vouchers:
- Christopherson Properties (no new) (2014)
- Concierge Apartments (2015)
- Woodlake Park Apartments (2016)
- New Orleans Court Apartments (2016)
- Winton Housing Apartments (2016)
- Richland Court Apartments (2016)
- Fountainhead Apartments (2016)
- Seasons Park (2017)

This ordinance would say that properties cannot exclude applicants simply because they use a rent subsidy.

| Voucher holders would not lose housing every time a building changes policies and practices. |
| There would also more housing options available to voucher holders. |
| Oftentimes the challenge will be for the HRA to lessen the administrative burden on landlords participating in the HCV program. However, given Richfield has its own HRA, landlords have said their experiences with the program are positive and feel the city is very responsive. Therefore, the challenge is minimal for the City. |

**Just Cause Eviction**

Just Cause Eviction protects tenants from eviction for improper reason as well as prevents involuntary displacement through lease non-renewals or notices to vacate. This would allow landlords to evict a tenant only for certain reasons, such as failure to pay rent or for violation of the lease terms. As we saw at Crossroads, the new screening criteria was the reason many tenants’ leases to not be renewed. Just Cause would allow these renters to continue living there until they break a condition of their new lease. It can be tied in with rental licensing.

| Prevents involuntary displacement and protects tenants from eviction without a proper reason. |

**Incentives to address landlord concerns about renting to certain groups of tenants**

Risk Mitigation Fund is oftentimes associated with the Housing Choice Voucher program. This Fund can be created as a response to the extremely low vacancy rate and the disparity between cost of living and wages. It serves as a damage fund to supplement costs the security deposit does not fulfill. It also has been offered as short-term vacancy reimbursement.

| Incentivizes landlords to participate in voucher programs, providing voucher holders with more access to housing options. |
| Provides insurance to landlords for any monetary losses from potential damage to property. |
| Funding the RMF; perpetuating stigma that voucher holders cause more damage (no evidence to support this) |

**St. Louis Park, Minneapolis, Suggested to Golden Valley, Bloomington and Eden Prairie**
## Inclusionary Housing

While this is in Richfield’s guidelines to develop housing with 20% affordability, a policy would ensure that this happens with every development. It also can be applied to rehAbbed developments.

- Increases the number of new affordable housing units in the City.
- Only applies to new construction, therefore not addressing the need to preserve and maintain NOAH.
- St. Louis Park, Edina, Minnetonka, Golden Valley, Eden Prairie, Minneapolis and others are considering.

## Increasing local government leverage through zoning

Richfield could structure its zoning so as to prevent an owner engaging in conversion actions from doing so before obtaining the city’s zoning related approval.

- Provides the City of Richfield with more leverage to intervene.
- Minneapolis.

## Rental assistance

51% of Richfield households are cost burdened (ACS 2015). Rental assistance would lessen the burden by supplementing income, so housing costs are no more than 30% of income.

- Residents would be able to afford housing costs without sacrificing other basic needs.
- It is costly and unsustainable. As rent increases, rental assistance is insufficient and cannot serve as many households.
- Hennepin County & a number of cities.

## Comp Plan: Include strong language and solutions regarding affordable housing

As Richfield completes its Comprehensive Plan, it is encouraged that the Plan has detailed solutions with strong language around the preservation of naturally occurring affordable housing. This plan will guide the City’s housing efforts in the next ten years.

- Strong language can positively guide the City’s housing efforts in the next ten years.
- A number of Hennepin County cities.
Generalized Land Use: Communities and Affected School Districts
City of Minnetonka, Hennepin County

School Districts in the Community

2016 Generalized Land Use

- Farmstead
- Seasonal/Vacation
- Single Family Detached
- Manufactured Housing Park
- Single Family Attached
- Multifamily
- Retail and Other Commercial
- Office
- Mixed Use Residential
- Mixed Use Industrial
- Mixed Use Commercial and Other
- Industrial and Utility
- Extractive

Institutional
Park, Recreational or Preserve
Golf Course
Major Highway
Railway
Airport
Agricultural
Undeveloped
Water

School District Boundaries
NCompass Street Centerlines
Owner-Occupied Housing by Estimated Market Value

Minnetonka

Minnetonka

County Boundaries
City and Township Boundaries
Streets
Lakes and Rivers

Owner-Occupied Housing
Estimated Market Value, 2016

1 in = 0.97 miles


Note: Estimated Market Value includes only homesteaded units with a building on the parcel.
City Council Study Session Item #3
Meeting of June 11, 2018

Brief Description: Ward 2 City Council Vacancy

Background

At the June 4, 2018 City Council meeting, Councilmember Tony Wagner, Ward 2 representative, announced he and his family plan to move their primary residence outside of the Ward 2 boundary. Wagner has represented Ward 2 since his election in 2003. This move makes him ineligible to represent that ward according to the City Charter. Wagner plans to resign his position mid-July when their move will be finalized. If Wagner does not resign, in accordance with the City Charter, the council must declare by resolution that a vacancy exists.

Based on an anticipated approximate resignation date of July 9 or 23, 2018 there will be approximately 17 months remaining in the term for that seat. City Charter allows for either an appointment or a special election for vacant terms of less than two years. Since Councilmember Wagner has announced his intention to resign, the City Council can begin deliberations about the process to fill the vacancy.

Within 60 days after the vacancy occurs, the council must either appoint a replacement or schedule a special election to take place within 90 days. If the council does neither, the mayor has seven days to appoint an eligible person to fill the vacancy. If after 37 days no appointment is made nor an election scheduled, the clerk must schedule a special election to be held within 90 days after expiration of this 37-day period. To the extent that the deadlines in the city charter conflict with state election laws, the state law will control with respect to the dates on which a special election may be held.

Appointment Process

According to the City Charter the council has the ability to appoint an eligible resident of Ward 2 to serve until the expiration of the term in January 2020. If an appointment process is selected the following schedule allows the Ward 2 seat to be filled in less than 60 days after the vacancy arises:

Monday, June 18, 2018: City Council approves a resolution calling for an appointment process to fill the Ward 2 vacancy. Council would approve the application template, score sheet and allow public feedback on the appointment selection process.

Tuesday, June 19, 2018: Staff prepares and begins mailing postcards to Ward 2 residents announcing the upcoming vacancy and appointment process. Information is posted on the city’s website, social media accounts, an email is pushed to the subscription network and a brief article will be included in the July edition of the Minnetonka Memo. Announcements will be sent to the Lakeshore Weekly and Sun Sailor
newspapers. The application is posted on the city’s website and available at city hall.

Monday, July 16, 2018: Interested applicants must return the completed application by noon local time.

Tuesday, July 17, 2018: Applications will be sent to the City Council for review. Applicant names and applications will be posted on the city’s website, with private data redacted.

Friday, July 20, 2018: City Council returns scoring sheets for tabulation by staff.

Monday, July 23, 2018: At a 5:00 p.m. special City Council meeting (prior to the regular meeting) council will review scoring tabulations, review scoring results and select finalists to interview. The meeting will be broadcast and streamed locally on cable TV and the city’s website.

Monday, July 30, 2018: At a special 6:30 p.m. meeting the selected applicants will be interviewed. The interviews will be broadcast and streamed locally on cable TV and the city’s website. This is an added council meeting.

Wednesday, Aug. 1, 2018: City Council returns completed interview scoring sheets for tabulation by staff.

Thursday, Aug. 2, 2018: Rating tabulation sheets are included in the Aug. 6, 2018 regular meeting packet.

Monday, Aug. 6, 2018: Council appoints Ward 2 Councilmember, or,

Council selects finalists for additional interviews (if needed).

Monday, Aug. 20, 2018 If already appointed, new Ward 2 Councilmember is sworn in prior to the study session, or,

Monday, Aug. 13, 2018: At a special 6:30 p.m. meeting the City Council interviews selected finalists for further interviews. The interviews will be broadcast and streamed locally on cable TV and the city’s website. This is an added council meeting (if needed).

*The next four dates listed below apply only if the City Council decides to conduct further interviews.*

Wednesday, Aug. 15, 2018: City Council returns completed interview scoring sheets for tabulation by staff.

Thursday, Aug. 16, 2018: Rating tabulation sheets are included in the Aug. 27, 2018 special meeting packet.

Tuesday, Sept. 4, 2018: The new Ward 2 Councilmember is sworn in prior to the study session.

Friday, Sept. 7, 2018: 60-Day deadline to appoint if resignation received on July 9, 2018,

Friday, Sept. 21, 2018: 60-Day deadline to appoint if resignation received on July 23, 2018,

November 2019: Ward 2 seat is up for election.

As outlined above the earliest date the Ward 2 vacancy would be filled would be Aug. 6, 2018 using an appointment process.

Special Election

According to the City Charter the council has the ability to call for a special election for only Ward 2 voters, to elect a Ward 2 councilmember to serve until the expiration of the term in January 2020. Within 60 days after the vacancy occurs, the council may instead of appointment schedule a special election, which the charter requires to be held within 90 days. However, as a result of a recent change in state law, municipal special elections may only be held on five specified Tuesdays in each calendar year. It may not be possible to comply with the deadlines under both state law and the City Charter. If so, state election law requirements will control over City Charter requirements, and it may be necessary to schedule a special election more than 90 days after the call for a special election is made.

The anticipated cost for a stand-alone Ward 2 special election is $7,500 – $10,000, with election judge pay as the largest expense. If the council chooses to have a special election, these rules apply:

(a) candidates must file for office no later than four weeks before the election,
(b) no primary will be held,
(c) the candidate receiving the highest number of votes is elected, and
(d) the election must be held on a Tuesday.

If a special election process is used, the earliest possible schedule would be:

**Special Election Option A**

If Councilmember Wagner’s resignation occurs on July 9, 2018 and the vacancy begins on July 10, 2018:

Friday, June 29 –

Monday, July 16, 2018: At a special council meeting a resolution calling for the special election is adopted.
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>Thursday, July 19, 2018</td>
<td>A legal notice is published by the City Clerk to call for a special election filing period.</td>
</tr>
<tr>
<td>Tuesday, July 31 – Tuesday, Aug. 14</td>
<td>Filing period for cities with even year elections without primaries.</td>
</tr>
<tr>
<td>Tuesday, Aug. 14, 2018</td>
<td>State Primary occurs.</td>
</tr>
<tr>
<td>Monday, Aug. 6 – Monday, Aug. 20, 2018</td>
<td>Ward 2 special election candidate filing period.</td>
</tr>
<tr>
<td>Wednesday, Aug. 22, 2018</td>
<td>Last day to withdraw from Ward 2 special election.</td>
</tr>
<tr>
<td>Friday, Aug. 24, 2018</td>
<td>Deadline for City Clerk to notify Hennepin County of special election.</td>
</tr>
<tr>
<td>Friday, Sept. 21 – Monday, Nov. 5, 2018</td>
<td>Absentee voting for State General and Ward 2 Special Elections.</td>
</tr>
<tr>
<td>Tuesday, Nov. 6, 2018</td>
<td>State General and Ward 2 Special Elections.</td>
</tr>
<tr>
<td>Friday, Nov. 9 – Friday, Nov. 16, 2018</td>
<td>Time period to certify special election results. A special council meeting would need to occur within this timeframe to do so.</td>
</tr>
<tr>
<td>Monday, Nov. 19, 2018</td>
<td>New Ward 2 Councilmember is sworn into office.</td>
</tr>
<tr>
<td>November 2019</td>
<td>Ward 2 seat is up for election.</td>
</tr>
</tbody>
</table>

While the date for the Ward 2 special election date coincides with the State General Election, the filing periods are different in Option A. There is a probability that this could cause confusion. The additional cost to run a special election in this scenario is minimal, primarily limited to picking up the costs for all the ballots for Ward 2. The city normally does not incur ballot costs in even year elections. Expenses related to election judges, the main cost of conducting elections, has been budgeted for the general election.

**Special Election Option B**

If Councilmember Wagner’s resignation occurs on July 23, 2018 and the vacancy begins on July 24, 2018 the special election would have to occur in February because the timing for the statutory required notice of filing and a two week filing period would extend beyond Hennepin County’s ballot printing deadline for the November State General Election. State law specifies the dates municipal special elections can occur, and the second Tuesday in February is the next date available after the November date.

Here is the schedule showing why a July 24 vacancy would require holding the special election next February:
Wednesday, July 25:  At a special council meeting a resolution calling for the special election is adopted.

Thursday, Aug. 2:  City clerk publishes notice of filing

Monday, Aug. 15 – Tuesday, Sept. 4:  Ward 2 special election candidate filing period

Friday, Aug. 24:  Deadline for City Clerk to notify Hennepin County of special election.

Friday, Aug. 31:  Deadline for Hennepin County to submit ballot order to printer

Under this option, the candidate filing period goes beyond the county’s deadline for submitting the ballot order to the printer.

In conducting a February special election, there would be some flexibility in scheduling the filing period but staff would recommend filing would begin the second week of November to allow for ballot production and a full 45 day absentee voting period.

Monday, Aug. 6, 2018  At the regularly scheduled council meeting, resolution calling for the special election is adopted.

Tuesday, Nov. 6, 2018:  State General Election.

Thursday, Nov. 15, 2018  City clerk publishes notice of filing


Wednesday, Dec. 19, 2018:  Last day to withdraw from Ward 2 Special Election

Friday, Dec. 28, 2018 – Monday, Feb. 11, 2019;  Absentee voting for Ward 2 Special Election

Friday, Dec. 30, 2018  Deadline for City Clerk to notify Hennepin County of special election

Tuesday, Feb. 12, 2019:  Ward 2 Special Election

February 2019:  Ward 2 Councilmember is sworn in depending on 2019 official meeting schedule.

November 2019  Ward 2 seat is up for election

In addition to the cost ($7,500 - $10,000), there would be a nearly seven-month delay in a special election.
Discussion Points

- *Does the council wish to pursue an appointment process, and if so is there any feedback on the proposed schedule?*

- *Does the council wish to pursue a special election, and if so is there any feedback on Option A or B based on the timeline?*

Summary

Based upon the anticipated resignation of Ward 2 Councilmember Wagner, staff requests direction from the City Council on a preferred method to fill the upcoming vacancy.

Per Minnesota State Statute, Councilmember Wagner is able to participate in the discussion and voting on the method to fill the vacancy. If an appointment process is selected, Councilmember Wagner would be precluded from participating in the selection process.

Submitted through:
   Geralyn Barone, City Manager

Originated by:
   Corrine Heine, City Attorney
   David Maeda, City Clerk
   Perry Vetter, Assistant City Manager