The profile or ‘vapers’ and how e-cigarettes should be regulated

Jean-François ETTER, PhD
Associate Professor
Faculty of Medicine
University of Geneva
Switzerland

University of California Webcast

October 3, 2013
Disclosure

- Tobacco industry:
  - never received any funding
  - no conflict of interest

- Pharmaceutical industry
  - no funding in past 7 years
  - no conflict of interest

- E-cigarette industry
  - plane ticket + hotel (London + China)
Outline

- Profile of vapers:
  - representative surveys, including use in non-smokers
  - surveys in convenience samples of vapers

- How should e-cigarettes be regulated
  - regulation today (USA, EU)
  - future regulation
    - as tobacco products?
    - as medications?
    - as consumer products?
    - as a specific category?
Sales (Millions of Dollars) of E-cigarettes in the U.S., 2008-2013
(Source: UBS)

Projected
Surveys in representative samples of the general population

2. ASH-UK. Use of e-cigarettes in Great Britain among adults and young people (May 2013)
5. COREY. MMWR. (NYTS survey) 2013.
USA: use in the general population

- 0.6% in 2009
- 2.7% in 2010
- 6.2% in 2011

Sources:
Regan. *Tobacco Control* 2011
McMillen *Journal Of Environmental & Public Health.* 2012
U.K.: current use in smokers

- In representative samples of the general population, only in smokers:
  - 2.7% in 2010
  - 6.7% in 2012
  - 11% in 2013

Source: Dockrell, ASH UK, 2013
Age and gender, education and income

- From 6 surveys in representative samples of the general population

- Compared with non-users, vapers tend to be:
  - younger
  - better educated
  - higher income
  - no clear association with gender

Sources:
Li.  New Zealand Med J.  2013
King.  Nicotine Tob Res.  2013
Conversion from ‘trying out’ to ‘use in past 30 days’

- This was documented in 10 surveys in representative samples of the general population
- UK, US, Australia, New Zealand, Canada, Poland, Switzerland
- 30-38%

Sources:
Corey  *MMWR*  2013
Dockrell  *Nic Tob Res*  2013
Douptcheva  *J Epidemiol Comm H*  2013
Pearson  *Am J Public Health*  2012
Popova  *Am J Public Health*  2013
Regan  *Tob Control*  2011
Sutfin  *Drug Alc Depend*  2013
Conversion from ‘trying out’ to ‘daily use’

This was documented in 2 surveys in representative samples of the general population.

- Switzerland, Czech Republic.

- 12%, 14%

Sources:
Doupcheva J Epidemiol Comm H 2013
Kralikova Chest 2013
Experimentation and use by never smokers

- From 11 surveys in representative samples of the general population
- UK, USA, Australia, New Zealand, Canada, Poland, Switzerland, Czech
- Ever use in never smokers:
  - range : 0.1% to 3.8%
  - median : 0.5%
- Use in past 30 days, in never smokers:
  - range : 0% to 2.2%
  - median : 0.3%

Sources:
- Corey  *MMWR* 2013
- Dockrell  *Nic Tob Res* 2013
- Douptcheva  *J Epidemiol Comm H* 2013
- King.  *Nicotine Tob Res*. 2013
- Pearson  *Am J Public Health* 2012
- Regan  *Tob Control* 2011
- Sutfin  *Drug Alc Depend* 2013
‘Daily use’ by never smokers

- Was assessed in 2 surveys in representative samples of the general population
- UK, Switzerland

- To date, no ‘daily use’ in never smokers has been reported

Sources:
Douptcheva. *J Epidemiol Comm Health*. 2013
ASH-UK. 2013
MMWR report, CDC press release

- USA, 2011-2013, National Youth Tobacco Survey
- Representative sample, middle+high school, grades 6-12
- Reported on:
  - ever use: (3.3% in 2011 and 6.8% in 2012)
  - use in past 30 days: (1.1% in 2011 and 2.1% in 2012)
- No data were reported on daily use
- No data on addiction to e-cigs
- No data on progression to smoking

- CDC press release: main message not based on their published data:
- CDC Director Tom Frieden: “Many teens who start with e-cigarettes may be condemned to struggling with a lifelong addiction to nicotine and conventional cigarettes”

Source: Corey MMWR 2013
Smoking status

- Across 8 surveys in representative samples, the proportion of EC users was 2 to 8 times higher in current smokers than in former smokers
- Most users = dual users (e-cig + cig)

Sources:
Dockrell *Nic Tob Res* 2013
Douptcheva. *J Epidemio Comm H* 2013
King. *Nicotine Tob Res.* 2013
Pearson *Am J Public Health* 2012
Regan *Tob Control* 2011
Sutfin *Drug Alc Depend* 2013
% of those trying to quit who used e-cigs to help them quit - U.K. Smoking Toolkit Study
Surveys in convenience samples of users

Surveys in convenience samples of users

- Not representative samples: interpret with caution

- In daily users:
  - 120 to 235 puffs per day on average
  - Spend $33 to $52 per month on ecigs
  - 97-100% of daily users use e-cigs containing nicotine
  - 18 mg/ml: most popular nicotine concentration in e-liquid
  - Most popular flavors (in order of popularity):
    - Tobacco
    - Mint
    - Fruit
Cigarettes per day in dual users

In dual users, cig./day when vaping = less than cig./day before they started to vape

<table>
<thead>
<tr>
<th>Cig./day before</th>
<th>Cig./day when vaping</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>15</td>
<td>(1)</td>
</tr>
<tr>
<td>50% &gt;20 cig</td>
<td>2% &gt;20 cig</td>
<td>(2)</td>
</tr>
</tbody>
</table>

Sources:
1) Etter. Addiction, 2011
Perceived effects on smoking reduction, cessation

- In 8 studies in convenience samples of vapers
- 42-99% of ex-smokers said e-cigs helped them quit smoking
- 60-86% of smokers said e-cigs helped them reduce cig./day

Sources:
ETTER (2010), BMC Public Health, 10, 231.
GONIEVICZ (2013), Drug and Alcohol Review, 32, 133-140.
KRALIKOVA (2013), Chest.
Addictiveness of e-cigs

- In 4 studies in convenience samples of vapers:
  - E-cigarettes were perceived as less addictive than cigarettes
  - Time (minutes) between waking up and time to first use was longer for e-cigs than for cigarettes
  - Only 18% craved e-cigs as much as tobacco

- Sources: Foulds 2011, Goniewicz 2013, Dawkins 2013, Farsalinos 2013

- Definition of addiction = 2 elements:
  - Compulsive use in spite of adverse consequences for the user’s health, family and social life
  - The adverse consequences element is not proven so far
Addictiveness of e-cigs

- Definition of addiction = 2 elements:
  Compulsive use in spite of adverse consequences for the user’s health, family and social life

- The *adverse consequences* element is not proven so far

- E-cigs are not very addictive, even if e-cigs were addictive, this would not be a significant public health problem

- Legislation cannot be based on moral disapproval of recreational nicotine use
Summary

- E-cigs are used by current and former smokers, as a cheaper and safer alternative to tobacco
- Most users report that e-cigs help them quit or reduce smoking
- Regular use in non-smokers has not been documented so far
- E-cigs are less addictive than cigarettes
Regulation

- Alms:
  - to decrease the number of cases of disease and death
  - freedom of citizens

- Should cover not just e-cigs but also ‘next generation’ products
E-cigs are regulated as consumer products or tobacco, not regulated as medicines in any country.

USA:
- FDA cannot regulate e-cigs as drugs: court decision (Sottera 2010)
- FDA regulates all non-medicinal nicotine as tobacco: FSPTCA 2009
- State and local regulations (e.g. bans in public places)
- FDA: «deeming regulation», due October 2013

European Union (EU): Tobacco Products Directive: article 18
- EU Parliament votes on October 8
- Will they regulate e-cigs as medicines?
- There is no such thing as “light touch” regulation

In October: EU TPD, FDA regulation will be extraordinarily important, because once written, laws are very hard to change.
Regulation

- Currently there is intensive lobbying of FDA, EU Parliament

- In general, governments + parliaments are excessively responsive to special interests, rather than to the general interest

- As a result almost any regulation will favor those who are best at lobbying (Big Tobacco, Big Pharma)

- Even before seeing them, financial analysts already say that future regulations will be favorable to Big Tobacco

- In each country, regulation will differ because it depends on specific:
  - history of tobacco regulation
  - political process, weight of lobbies
  - stage of development of e-cig market
Regulation as a tobacco product

- **Aim:**
  to offer consumers the same level of protection as for tobacco products

- Bans in public places
- Restrictions on advertisements, marketing
- Sale restrictions to minors
- Content, additives
Problems with tobacco regulation

- E-cigs do not contain tobacco (even though nicotine is extracted from tobacco)

- Measures used to control tobacco are excessive, disproportionate

- Bans in public places
  - no evidence that passive vaping is toxic
  - no evidence that vaping in public encourages smoking

- Advertising bans
  - no evidence that the product is toxic
  - no evidence that non-smokers become regular users

- Sale restrictions to minors who smoke
  - minors can buy nicotine gums, patches
  - e-cigs may protect both minors and adults against smoking
Regulation as a medicine

Aim:

to give consumers the same level of protection as for medicines
- efficacy
- safety, toxicity
- quality requirements
- stability of the product
- protect young non-smokers (advertising, age limits)
Problems with medicines regulation (1)

- No therapeutic claim: e-cigs are not medicines
- Medicines regulation has been and will be challenged in court
- Inequality with tobacco (makes e-cigs less competitive)
- Inadequate impact assessment by proponents of medicines regulation
- Costs associated with obtaining drug approval
- Administrative barriers
- Many products, manufacturers and retailers will disappear
- Only Big Tobacco will survive (+ Big Pharma if they step in)
- Prices will increase
Problems with medicines regulation (2)

- Will kill innovation
  e.g. nicotine gum + patch ‘frozen’ in same stage as when they were first approved, in the 1970s
- Almost all flavors will be banned (e-cigs will attract fewer smokers)
- Excessive restrictions on marketing
- Ban of unlicensed product = incompatible with quality control
- No tax on banned products
- Sends the wrong message about nicotine
- More smokers, more healthcare costs
- Internet + high street shops will close: negative impact on employment
Problems with medicines regulation (3)

- Contrary to constitutional free market principles
- Lack of popular support: not viable in democracy
- Bans of unlicensed products cannot be enforced
- Enforcement would be costly and ineffective
- Internet sales will continue
- Development of home made brews + e-cigs: unsafe
- Black market

2 main consequences of tobacco or medicines regulations:

- Fewer users, fewer smokers will quit, more will die
- Only Big Tobacco will survive
Regulation as a consumer product

Aims:
offer consumer the same protection as for many other consumer products, including food, cosmetics, chemicals, electrical devices, etc.

Several EU Directives + national laws already apply to e-cigs:
- safety
- RAPEX system (alerts)
- chemical safety (hazardous substances: RoHS Directive)
- electrical safety
- packaging, labeling
- weights and measures
- commercial practice (advertising, Internet)
- data protection

Is regulation as a consumer product sufficient?

- First, apply and enforce *existing* laws and EU Directives
- If necessary, create a specific category or specific norms for recreational nicotine products:
  - manufacturing process, components, e-liquid content
  - advertisement
  - sales to minors
- This does *not* require regulation of e-cigs as medicines or tobacco
- Create a tax on e-cigs, earmarked for
  - research
  - education of the public, Drs, journalists, policy makers, legislators
Conclusions (1)

- E-cigs = major innovation that has the potential to save many lives
- Regulation: balance public health impact vs risks
- Relative risk is relevant, compared with tobacco, not absolute risk
- Regulation as medicines or tobacco: disproportionate
- Prohibition of unlicensed products: not feasible, nor desirable

- Main danger for public health = excessive regulation, not e-cigs
Conclusions (2)

- Current laws cannot survive, which allow nicotine only in tobacco (deadly) and in medications (gum, patch), which are not appealing, not very effective.

- Laws need to change, to accommodate this very popular product and ‘next generation’ products.

- One of the most important public health debates in recent decades:

  To redefine the place of nicotine in society and in the law, and make room for recreational nicotine products.