The Meteoric Rise of e-Cigarettes (ENDS): Harm Reduction Promise or Peril

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“The significant problems we face cannot be solved by the same level of thinking that created them.”

A. Einstein

“Knowing is not enough, we must apply. Willing is not enough, we must do.”

Johann Wolfgang von Goethe (1749 – 1832).
Framing the Harm Reduction POLICY debate: Emerging products - e-cigs

**Agenda:**

- **Changing Landscape:**
  - non-combusted reduced harm, nicotine delivery products
- **The State of the Science:**
  - What we know about e-cigarettes: the leading edge of an innovative, appealing, reduced harm product, or not.
- **Discussion:**
  - Implications for tobacco control, regulation and policy
Framing the Harm Reduction POLICY debate

Tobacco Control Policy challenge:

• **Continue tradition:** no safe tobacco product - eliminate all tobacco/nicotine use.  OR

• **Adopt harm reduction:** allow cleaner, appealing, non combusted nicotine products to compete / win

• **The enemy is not nicotine:** its combustion - lethal tar & nicotine in most addictive form.

• **Goal is eliminate deaths:** cigarettes cause the vast majority of death by far.

*New goal?* Speed elimination of defective cigarettes - while minimizing the downsides of harm reduction
Tobacco Could Kill 1 Billion by 2100

By EDITH M. LEDERER. The Associated Press
Thursday, February 7, 2008; 11:52 PM

NEW YORK -- The World Health Organization warned in a new report Thursday that the "tobacco epidemic" is growing and could claim 1 billion lives by the end of the century unless governments dramatically step up efforts to curb smoking. World Health Organization Director-General Dr. Margaret Chan, right, speaks about the mpower box as New York Mayor Michael Bloomberg listens during a press conference announcing WHO's Report on the Global Tobacco Epidemic 2008 Thursday, Feb. 7, 2008 in New York. The mpower box is a symbol of the package being offered by the WHO in its effort.........
Prevention

Impact = Reach x Efficacy of the Intervention

Population Model of Tobacco Prevalence

PRO- and ANTI- tobacco vectors: Individual, group, organizational, community, societal, global levels

Initiation Rate
Never Smoker

Current Smoker

Cessation Rate
Ex Smoker

Relapse Rate

Disability and Disease Burden

Simplified dynamic model of pro and anti-tobacco forces on patterns of tobacco use
Trends in Per Capita Consumption of Various Tobacco Products – United States, 1880-2006

Source: US Department of Agriculture
Trends in Cigarette Smoking, Adults 18 and Older, US, 1965-2011

REACHING HEALTHY PEOPLE 2010 By 2020?


<table>
<thead>
<tr>
<th>Year</th>
<th>Smoking Prevalence, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>20.0</td>
</tr>
<tr>
<td>2009</td>
<td>19.5</td>
</tr>
<tr>
<td>2010</td>
<td>18.5</td>
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<tr>
<td>2011</td>
<td>17.5</td>
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<td>2012</td>
<td>16.5</td>
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<td>2013</td>
<td>15.5</td>
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<td>2014</td>
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<td>2015</td>
<td>13.5</td>
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<td>2016</td>
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<td>2017</td>
<td>11.5</td>
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<td>2018</td>
<td>10.5</td>
</tr>
<tr>
<td>2019</td>
<td>9.5</td>
</tr>
<tr>
<td>2020</td>
<td>8.5</td>
</tr>
</tbody>
</table>

- STATUS QUO (17.5)
- $2.00 TAX INCREASE / CLEAN INDOOR AIR / MEDIA (15.0, 16.4, 16.8)
- EVIDENCE BASED CESSATION TREATMENT POLICIES (14.8)
- ALL COMBINED (12.2)
- WITH PROMISING TX, INCREASING QUIT ATTEMPTS, USE, ABSTINENCE (9.7)

2010 goal: 17.5%
Note. The bottom 2 lines depict corresponding scenarios assuming that the United States as a whole achieves California’s 2005 rates (20% initiation rate and 3.33% cessation rate). The dotted line reflects the assumption that such rates are attained instantaneously (in 2006), whereas the solid line reflects the more plausible scenario that such rates will be achieved gradually (by 2010). The status quo initiation rate is 25% and the cessation rate is 2.59%.

Cancer Death Rates* Among Men, US, 1930-2009

*Age-adjusted to the 2000 US standard population.
Cancer Death Rates* Among Women, US, 1930-2009

*Age-adjusted to the 2000 US standard population.
National Center for Health Statistics, Centers for Disease Control and Prevention.
Total Number of Cancer Deaths Averted from 1991 to 2009 in Men and 1992 to 2009 in Women

The blue line represents the actual number of cancer deaths recorded in each year, and the red line represents the number of cancer deaths that would have been expected if cancer death rates had remained at their peak.
Trends in Tobacco Use and Lung Cancer Death Rates* in the US

*Age-adjusted to 2000 US standard population.

## Trends in Five-year Relative Cancer Survival Rates (%), 1975-2008

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>All sites</td>
<td>49</td>
<td>56</td>
<td>68</td>
</tr>
<tr>
<td>Breast (female)</td>
<td>75</td>
<td>84</td>
<td>90</td>
</tr>
<tr>
<td>Colon</td>
<td>51</td>
<td>61</td>
<td>65</td>
</tr>
<tr>
<td>Leukemia</td>
<td>34</td>
<td>43</td>
<td>58</td>
</tr>
<tr>
<td>Lung &amp; bronchus</td>
<td>12</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Melanoma</td>
<td>82</td>
<td>88</td>
<td>93</td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>47</td>
<td>51</td>
<td>71</td>
</tr>
<tr>
<td>Ovary</td>
<td>36</td>
<td>38</td>
<td>43</td>
</tr>
<tr>
<td>Pancreas</td>
<td>2</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Prostate</td>
<td>68</td>
<td>83</td>
<td>100</td>
</tr>
<tr>
<td>Rectum</td>
<td>48</td>
<td>58</td>
<td>68</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>73</td>
<td>79</td>
<td>80</td>
</tr>
</tbody>
</table>

5-year relative survival rates based on patients diagnosed from 2002 to 2008, all followed through 2009. 
FDA Regulation - Critical Opportunities For Tobacco Research and Policy
Family Smoking Prevention And Tobacco Control Act (2009)

Public Health Standard

Calls for the review of the scientific evidence regarding:

1. Risks and benefits to the population as a whole, including both users and non-users of tobacco products;

2. Whether there is an increased or decreased likelihood that existing users of tobacco products will stop using such products; and

3. Whether there is an increased or decreased likelihood that those who do not currently use tobacco products, most notably youth, will start to use tobacco products.
USING KEY REGULATORY TOOLS IN THE ACT

- **Product standards:** limit the allowable levels of ingredients (menthol, nicotine, ammonia, NNK, Polonium 210….)

- **New products:** robust premarket evaluation, or shortened process because the product is “substantially equivalent”

- Criteria to determine whether a manufacturer can make an exposure reduction or risk reduction claim (section 911 - “modified risk” tobacco products (MRTP))

FDA’s current rules do not automatically apply to cigars (e.g. flavored LCCs), e-cigarettes or other products containing nicotine derived from tobacco, including certain dissolvable tobacco products (e.g., Verve).

This has created a void. e-cigarettes and several other products reside in a regulatory “no man’s land” (i.e., sold without any regulatory oversight) (Zeller, 2012).
Modified Risk Tobacco Products (MRTPs)

“… the Secretary shall… issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as actually used by consumers, will

- benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.”
emerging Tobacco & Nicotine Products: Evolution / revolution?
How it works

The atomizer
When a user inhales the personal vaporizer, the rechargeable battery in the device creates a solid contact with positive and negative wires inside the metal casing of the atomizer that turns it on to produce the vapor in the metal mesh dome. It then pulls the liquid from the cartridge to produce the vapor. The virtually odorless vapor that simulates smoke quickly dissipates in the air when exhaled.
Main e-cigarette design

Cigarette “like”
- Disposable (non refillable, non rechargeable)
- Cartridge
- Refillable

Non cigarette “like”
- Water pipe
- Cigar
- Tank (active and passive delivery)
- Modified

New Design Features
- Dual coil
- Voltage Tunable
- 2nd generation: no mist
On New Generation Noncombustible Tobacco Products

• The next Generation Products (NGPs) will represent a potential paradigm shift for our business...risk reduction in combustible cigarettes through elimination of harmful constituents unlikely to provide material health benefits.

• Elimination of combustion via tobacco heating and other innovative systems for aerosol generation is the most promising path to secure risk reduction.

• First factory for NGPs to be ready in 2016 with a launch in the first markets between 2016 and 2017
NGPs: Our Product Platforms Have Huge Potential

- Our development is focused on products which:
  - Closely approximate consumers’ taste, sensory and ritual preferences
  - Have a risk profile similar to cessation

- Consumer interest in e-cigarettes, combined with relatively low adoption rates, confirms:
  - Strong demand for less harmful nicotine and tobacco products
  - Taste and sensory experience from existing e-cigarettes not close enough to traditional cigarettes

Note: The products described are subject to ongoing development and therefore the descriptions are illustrative and do not necessarily represent the latest stages of product development.
"We want to make sure the public health discussion about electronic cigarettes takes place based on the science, not on the politics or industry protectionism,"

NJOY would pursue a modified risk or reduced harm application with the FDA's Center for Tobacco Products.

At NJOY, we are proud to be a leader and believe our products have the potential to render traditional cigarettes obsolete.

Corporate Responsibility: NJOY deliberately does not offer flavors as part of our electronic cigarette, to avoid appealing to youth.
E-cigs SALES: revolutionizing the tobacco industry - here to stay

The e-cig market is expected to approach $2 billion in retail sales (including on-line) by the end of 2013 and eclipse $10 billion by 2017.

Entrance of the “Big 3” tobacco manufacturers into e-cig market

Deeming regulation and taxation of e-cigs is likely-but many believe long term growth trajectory will be robust.
Benefits vs. Concerns to individuals and to public health

Can cleaner, more appealing tobacco products be supported, while minimizing their downsides:

- Youth starter and progression to combusted products
- Undermining de-normalization - indoor air policy
- Dual / poly use when one can’t smoke without harm
- Delaying / Promoting cessation of cigarettes.
- Undermining clear messages about SOME tobacco dangers – blurring risk perception of harms, addiction,
- BUT the genie is out of the bottle, can we capitalize?
- Impact of Internet and social media marketing and KABBB
E-cigarette advertising: consumer patterns of use, beliefs, perceptions
40.2% of Americans over the age of 18 had heard of an e-cigarette

11.4% of smokers have ever tried an e-cigarette. Of these, about 1/3 (4.1%) had used an e-cigarette in the past 30 days

Over 70% of smokers who have heard of e-cigarettes believe that e-cigarettes are less harmful than regular cigarettes

Young smokers more likely to have tried e-cigarettes than older smokers
E-cigarette use Among U.S. Adults

State of the science: Patterns of consumer USE, and perceptions

- **Adults**: Awareness (76%) and use (21%) is growing fast among current smokers and young adults. Perceived as less harmful.

- **Youth** (CDC MMWR 2013)

  - Use doubled middle and high school students 2011–2012, estimated 1.78 million students ever used.
State of the science: marketing IMPACT

- **Radio and TV**: diverse, from over 300 manufacturers many with misleading claims of reduced harm or cessation

- **Online presence**: more widely searched than snus and NRT; YouTube videos

- **Appeal**: flavorings, freedom to use anywhere, undermining de-normalization of cigarettes indoor air laws, inexpensive

State of the science: marketing IMPACT: Blurring lines

• TV ads: first time in 40 years: ? Impact on adults, families

• Radio and TV: diverse ads, from over 300 manufacturers many with misleading claims of reduced harm or cessation

• Online sales. Viral spread by vocal proponents – digital media.

• Appeal: flavorings, freedom to use anywhere, undermining de-normalization of cigarettes indoor air laws, inexpensive

• Blurring boundaries between nicotine and tobacco products

• CDC comment: “need an education campaign for everyone”
What we know: State of the science on e-cigarettes - ENDS

- Product features and chemical/particulate content
- Health and safety
- Consumer perceptions and patterns of use
- Changing market: players and sales
  - Blurring the boundaries between products - poly use.
- Policy considerations
Product

- Nicotine (0% to 3.6%)
- Propylene Glycol (PG)
- Glycerin (VG)
- Water
- Flavorings

The Food and Drug Administration (FDA) has classified PG and VG as “generally recognized as safe” for use in food.

PG and VG are used in certain medicines, cosmetics, or food products.

Used to create artificial smoke or fog in theatrical productions.

Practically odorless and tasteless.
State of the science: Cardiovascular effects

• Significant nicotine exposure and resulting cardiovascular changes (heart rate increase↑) have been observed during e-cigarette use.
  – 10 e-cigarette puffs = average HR ↑ 2.4 to 6.2 bpm (within 5 min)
  – 10 conventional cigarette puffs = average HR↑ 14.6 bpm (within 5 min)
• Nicotine use alone is not innocuous to the cardiovascular system, but the risks of NRT use among smokers appear to be small.
• Whether nicotine or constituents delivered by e-cigarettes are associated with increased cardiovascular risks (among smokers or non-smokers) is still unknown.

### Suggested Biomarkers for Studying e-Cigarettes

<table>
<thead>
<tr>
<th>Biomarker</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Total nicotine equivalents in urine</td>
<td>1. Nicotine</td>
</tr>
<tr>
<td>2. Nicotine metabolite ratio in plasma (3-OH-Cot/Cot)</td>
<td>2. Nicotine</td>
</tr>
<tr>
<td>3. Total NNAL in urine</td>
<td>3. NNK</td>
</tr>
<tr>
<td>4. Total NNN in urine</td>
<td>4. NNN or nornicotine</td>
</tr>
<tr>
<td>5. Mercapturic acids of acrolein and propylene oxide in urine</td>
<td>5. Acrolein and propylene oxide</td>
</tr>
<tr>
<td>6. DNA adducts of formaldehyde and acrolein in leukocytes</td>
<td>6. Formaldehyde and acrolein</td>
</tr>
<tr>
<td>7. 8-epi-PGF-2α in urine</td>
<td>7. Oxidative damage</td>
</tr>
</tbody>
</table>

*Selected based on current knowledge of e-cigarette vapor.*
Rationale for the Biomarkers

- *Nicotine equivalents*: Comprise 73-96% of the nicotine dose; will provide an estimate of nicotine uptake
- *Nicotine metabolite ratio*: a phenotypic indicator of cytochrome P450 2A6 activity and addiction potential
- *Total NNAL*: an indicator of uptake of the potent lung carcinogen NNK
- *Total NNN*: an indicator of uptake and/or formation of the potent oral cavity and esophageal carcinogen NNN
- *Mercapturic acids of acrolein and propylene oxide*: provide an estimate of exposure to these toxicants/carcinogens
- *DNA adducts of formaldehyde and acetaldehyde*: indicate potential genotoxicity associated with these compounds
- *8-epi-PGF-2α*: gives an indication of oxidative damage associated with e-cigarette use.
Advantages of Using Biomarkers

- Validated analytical methods of sufficient sensitivity already exist for all of these biomarkers.
- Bypass uncertainties associated with artificial smoking conditions
- Provide data on uptake under actual conditions of use
- Successfully used to evaluate tobacco use and secondhand smoke exposure
- Can be used to ascertain dual use of e-cigarettes and other tobacco products
  - Nicotine equivalents: total NNAL ratio will be significantly higher in pure e-cigarette users compared to dual users of e-cigarettes and other tobacco products (both cigarettes and smokeless)
  - Minor tobacco alkaloids might also be used for this.
- DNA adduct biomarkers can indicate genetic damage potential.
- Oxidative damage from e-cigarettes has not been evaluated.


E-cigarettes generate vapor that contains nicotine, but brands and models differ in efficacy and consistency of nicotine vaporization.

<table>
<thead>
<tr>
<th>Brand</th>
<th>Nicotine in vapor with 300 puffs (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intelicig</td>
<td>2.3 (29%)</td>
</tr>
<tr>
<td>SkyCig</td>
<td>2.5 (21%)</td>
</tr>
<tr>
<td>Liberro</td>
<td>11.2 (59%)</td>
</tr>
<tr>
<td>Njoy</td>
<td>7.5 (47%)</td>
</tr>
<tr>
<td>Gamucci</td>
<td>10.7 (71%)</td>
</tr>
</tbody>
</table>

In e-cigarettes which vaporize nicotine effectively, the amount inhaled from 15 puffs is lower compared with smoking a conventional cigarette.

Goniewicz et al. Nicotine Tob Res 2013
Goniewicz et al. Addiction 2013
## Tobacco Specific Nitosamines

<table>
<thead>
<tr>
<th>Product</th>
<th>NNN</th>
<th>NNK</th>
<th>NAT</th>
<th>NAB</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicorette gum</td>
<td>2.00</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>2.00</td>
</tr>
<tr>
<td>Nicoderm CQ patch</td>
<td>ND</td>
<td>8.00</td>
<td>ND</td>
<td>ND</td>
<td>8.00</td>
</tr>
<tr>
<td>E-cigarettes</td>
<td>3.87</td>
<td>1.46</td>
<td>2.16</td>
<td>0.69</td>
<td>8.18</td>
</tr>
<tr>
<td>Swedish Snus</td>
<td>980</td>
<td>180</td>
<td>790</td>
<td>60</td>
<td>2010</td>
</tr>
<tr>
<td>Marlboro (Ultra-light)</td>
<td>2900</td>
<td>750</td>
<td>1100</td>
<td>58</td>
<td>4808</td>
</tr>
<tr>
<td>Marlboro (Red)</td>
<td>2900</td>
<td>960</td>
<td>2300</td>
<td>100</td>
<td>6260</td>
</tr>
</tbody>
</table>

*Cahn et al. J Pub Health Pol 2010*
## TOXICANTS IN VAPOR

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>0.85-10</td>
<td>0.20-5.61</td>
<td>2</td>
</tr>
<tr>
<td>Acetaldehyde</td>
<td>52-140</td>
<td>0.11-1.36</td>
<td>130</td>
</tr>
<tr>
<td>Acrolein</td>
<td>4.6-14</td>
<td>0.07-4.19</td>
<td>4</td>
</tr>
<tr>
<td>Toluene</td>
<td>6.4-9.0</td>
<td>0.02-0.63</td>
<td>23</td>
</tr>
<tr>
<td>NNN</td>
<td>0.012-0.37</td>
<td>0.00008-0.00043</td>
<td>145</td>
</tr>
<tr>
<td>NNK</td>
<td>0.009-0.08</td>
<td>0.00011-0.00283</td>
<td>30</td>
</tr>
<tr>
<td>Cd</td>
<td>0.03-0.35</td>
<td>0.001-0.022</td>
<td>16</td>
</tr>
<tr>
<td>Ni</td>
<td>0.003-0.60</td>
<td>0.011-0.029</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: Goniewicz et al. Tob Control 2013
ECIG use behavior: unintended use.

![ECIG image]

**Formaldehyde, µg**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;0.1</td>
<td>3.59</td>
<td>14.26</td>
<td>23.48</td>
</tr>
</tbody>
</table>

ECIG formaldehyde for 1.8s, 3.7V case (<0.1 µg)

**Max temperature, °C**

- Puff 1
- Puff 2
- Puff 3
- Puff 4

Time after start of first puff, s
State of the science: PRODUCT FEATURES AND INGREDIENTS

- **Liquid/propylene glycol** not studied for long-term safety

- Vapor contains measurable amounts of **flavorings**.

- **Particulate matter** similar in size to cigarette smoke, but inconclusive in amount.

- **Other toxicants** (VOCs, TSNAs, heavy metals): Although variable, fewer total constituents at lower levels than in cigarette smoke.

State of the science: HEALTH AND SAFETY: SECONDHAND VAPOR

Figure 3.3
Concentration of PM$_{2.5}$ ($\mu$g/m$^3$) in indoor air before and after of using an e-cigarette and a conventional cigarette. Blue line: WHO air quality guideline value for PM$_{2.5}$ for short term exposure (24 hour mean).
Source: Pellegrino et al.
SECOND- AND THIRDHAND EXPOSURE

No sidestream vapor is generated from e-cigarettes between puffs, although some of the vapor is exhaled by the user.

- E-cigarettes have created the new scenario under which bystanders are exposed to low levels of nicotine but not to the other toxins found in tobacco smoke.

- The vapor from e-cigarettes might be easily deposited on surfaces to form “thirdhand” e-cigarette vapor.
State of the science: Cessation and REASONS FOR USE

• Reasons for use
  – The most commonly cited reasons for use by e-cigarette users include: the perception that they are healthier/less toxic than traditional cigarettes, they are less expensive than regular cigarettes, and they aid in tobacco craving/withdrawal symptoms, smoking reduction/cessation aid, and relapse prevention. E-cigarette users also report using e-cigarettes because they could be smoked everywhere and to avoid disturbing people with secondhand smoke.

• Reduction/Cessation devices
  – A qualitative study found that five themes explain users’ perceptions of why e-cigarettes are efficacious in quitting smoking: 1) bio-behavioral feedback; 2) social benefits; 3) hobby elements; 4) personal identity; and 5) distinction between smoking cessation and nicotine cessation.
  – One study found that 99% of participants believed e-cigarettes helped them quit smoking. 2 studies found poor outcomes in 7-12% range, some harm reduced use of combusted, one study same as NRTs
Behavioral transitions: combusted, dual use, non-combusted, none

Time

TIME 01
- Combustible use
  - Dual use
  - Non-combustible use
  - Never Use / Former Use

TIME 02
- Combustible use
  - Dual use
  - Non-combustible use
  - Never use / Former use

TIME...N+1
- Combustible use
  - Dual use
  - Non-combustible use
  - Former use
Data from Vansickel and Eissenberg, 2013 + additional participants. Similar results with SkyCig (Dawkins and Corcoran, 2013). See also Nides et al., 2013.
State of the science: cessation

- **New Zealand-based study 2011-2013** (Bullen et al., 2013)
  - N=657 current smokers motivated to quit. **No difference in abstinence between treatment arms at 6 months**
    - Nicotine e-cig=7.3%, Placebo e-cig=4.1%, NRT patch=5.8%
    - Rates of smoking reduction (≥50%) were higher for nic e-cig (57%) relative to the NRT.

- **Italy-based study 2010-2011** (Caponnetto et al., 2013)
  - N=300, current smokers curious about trying e-cigs (not motivated to quit)
  - **No difference (nicotine or placebo e-cigs) at 52 weeks. 8.7% quit and 10.3% reduced** their smoking by ≥50% Those who at first dual used were likely to relapse.

- **Among quitline callers from 6 states in 2011-2012** (Vickerman et al., 2013)
  - E-cig groups (used for 1 mo or more than 1 mo) **were less likely to be abstinent** at 7-months compared with participants who had never tried e-cigs. 21.7%, 16.6% vs. 31.3%

- **In 2011 a nationally rep. study of U.S. adults** (Popova & Ling, 2013):
  - **E-cig ever users were 78% more likely to be an unsuccessful quitter** compared with non-users of e-cigs (OR: 1.78, p<.05).
  - Population impact? : studies have methods limitations. E.g. observational, indication bias: Could be the users are more addicted smokers / have harder time to start with (like limits of Alpert, Connolly Biener NRT study )


Latest trends on smoking in England: from the Smoking Toolkit Study

Robert West
Jamie Brown

Last updated: 2\textsuperscript{nd} Sept 2013

www.smokinginengland.info
jamie.brown@ucl.ac.uk
Harm reduction? Using e-cigs to cut down

% of cigarettes smokers (3 month moving average)
Support used in quit attempts

% of those trying to stop in the past year who used support

NRT OTC: Nicotine replacement therapy bought over the counter; Med Rx: Prescription medication; NHS: NHS Stop Smoking Service; E-cig: Electronic cigarette
State of the science: Policy & regulation, federal and state

- Product classification (medicinal, recreational, other)
- Product safety standards – regulation - light or heavy
- Claims of modified risk / reduced harm.
- Use in public places (indoor air laws, de-normalization)
- Youth protection (14 states restrict sales to minors)
- Taxation
- FTC: correction of misleading labels and claims
- FDA and WHO expressed concerns
POLICY CHALLENGES, QUESTIONS

• **Primary goal**: Reduce the death and disease - almost all caused by combusted tobacco -- cigarettes.

• Up to now “Tobacco/Nicotine free” was the norm for policy: clean indoor air laws, media campaigns, taxes, youth prevention, cessation treatment and regulation - federal and state.
Public Health Impact: Appeal/Addictiveness versus Toxicity/Harmfulness

Non-Combusted Tobacco and Nicotine Products:

- e-cigs ENDS
- Next Generation: Pyruvate
- Swedish Snus
- Smokeless
- Cessation NRT’s: inhaler, patch, gum...

Combusted Tobacco:
- Cigarettes, Cigars
- Hookah

Toxicity (“Harmfulness”)
Chemosensory Effects of CSAs
PM Conference on Chemical Senses

“The chain of events from stimulation of the mouth, the throat and at the olfactory epithelium leads to trans-membrane electrical signals...integrated as precepts. These precepts contribute to accepting or rejecting the product.”

Source: PM; 1991 Bates Number 2024847432
Trends in Per Capita Consumption of Various Tobacco Products – United States, 1880 - and BEYOND
BACK TO THE FUTURE?

Source: Tobacco Situation and Outlook Report, U.S. Department of Agriculture, U.S. Census

Note: Among persons > 18 years old.

Beginning in 1982, fine-cut chewing tobacco was reclassified as snuff.

Source: US Department of Agriculture

Non-combusted: - e-cigs, snus,...?
Patterns of Use and Harm Reduction:
Behavioral transitions from combustibles to dual use of combustible and non-combustibles; exclusive use of non-combustibles and desistence of all or of combustibles.
State of the science: PRODUCT FEATURES AND INGREDIENTS

- **Product design:** Variety. Less harmful than cigarettes. Quality?

- **Nicotine:** Doses vary, mislabel. Can deliver nicotine effectively, reduces craving. Appeal and Abuse liability less than cigarettes. Future?

- **Liquid/propylene glycol:** Liquids and vapor, not studied for long-term inhalational safety in humans, local irritant

- **Secondhand Vapor:** Health effects not well-studied. Mainstream and secondhand vapor produces ultrafine and fine particulate matter.

- **Other toxicants** (VOCs, TSNAs, heavy metals, flavoring, additives): Fewer constituents at much lower levels than in cigarette smoke but higher in poor quality products.
Framing the Harm Reduction POLICY debate

- The new generation of tobacco-based nicotine products (non-combusted) are here to stay...
  - How do we regulate and communicate about emerging products. Guiding principles.
  - Can non-combusted products speed the demise of combusted cigarettes?
  - How do these developments change the core principles of tobacco control that have been in place for the last 50 years?
  - And speed the ultimate goal: elimination of the death and disease burden from tobacco use behavior.
State of the science: statements from public health organizations

• The World Health Organization (WHO) expressed concern with e-cigarettes, stating they may undermine tobacco control efforts, such as smoking bans and FDA-approved NRTs.

• FDA has stated that they are “concerned about the safety of these products and how they are marketed to the public.

• There is extreme polarization emerging from the tobacco control community.. Prohibitionists versus none or minimal regulation of ENDS.

• Reflects deeper divisions on harm reduction as a strategy for the “end game” versus total elimination of all tobacco/nicotine use.
If we cement the current cigarette status quo by preventing the move to alternative nicotine products.

This worst-case scenario could come about through...

- bans (as with snus in the EU) or effective bans through too-onerous regulation (like e-cigs here in Canada), or
- regulatory/PR initiatives that discourage smokers from switching (such as the misinformation on NRT, smokeless and e-cigs and efforts to prevent alternatives from having any tax or other marketplace advantages).
End Game Strategies
Robert Proctor: Golden Holocaust

- Reduction/elimination of combustible tobacco use and/or nicotine: Abolition of cigarettes

- Provide only “clean” recreational nicotine products (pharmaceutical grade, clean nicotine delivery systems), or even in “safer” non-combustible forms (snus, smokeless and dissolvables):

- FDA role in new noncombustible products
In the United States, smoking tobacco is the only legal method of being killed.
SCIENCE Questions, SUMMARY

• How does e-cigarette use and marketing affect current smokers?
  – Delay cessation? Promote cessation? No impact? compared to?
  – Reduce cigarette consumption significantly or give the impression of less harm because of imagined reduced cigarette consumption?
  – Dual use when one can not smoke and alleviate discomfort,

• Do e-cigarettes encourage former smokers to return to nicotine use and then relapse to cigarette smoking? Over and above usual rates

• How do e-cigarettes affect never-smokers?
  – Potential uptake among youth and young adults over and above what would happen anyway
  – “SHV” exposure and use indoors where smoking is banned

• How do poly-patterns impact public health standard? Need representative sample with micro assessment of behavior patterns over time and then modeling
  – Methods challenges for observational studies (e.g. indication bias)