Update: Electronic Cigarettes

4th Joint Meeting of the NCI Board of Scientific Advisors and the National Cancer Advisory Board
December 2, 2014

Michele Bloch, MD, PhD
Chief, Tobacco Control Research Branch
Behavioral Research Program
Division of Cancer Control and Population Sciences

Contributors:
Mirjana Djordjevic, PhD, Rachel Grana, PhD, MPH, and Ami Bahde, MPH
Overview of Presentation

• Cigarettes vs. Electronic Cigarette
• Emissions and Health Effects
• Prevalence, Adults and Youth
• The Debate
• Marketing and “Vaping culture”
• Potential as Cessation Tool
• Regulatory Efforts, Federal and State level
• NIH Research
What Is an Electronic Cigarette?

Traditional

Electronic

- Cartridge
- Atomizer
- Battery
- LED light
Disposable e-cigarette

Rechargeable e-cigarette

Pen-style, medium-sized rechargeable e-cigarette

Tank-style, rechargeable e-cigarette
### E-cigarette Aerosol (not Vapor!)

<table>
<thead>
<tr>
<th>CHEMICAL</th>
<th>CHEMICAL EMISSIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>µG/150 puffs – 27 mL/puff</td>
</tr>
<tr>
<td></td>
<td>MINIMUM</td>
</tr>
<tr>
<td>ACETALDEHYDE</td>
<td>2.0</td>
</tr>
<tr>
<td>ACROLEIN</td>
<td>&lt;0.02</td>
</tr>
<tr>
<td>FORMALDEHYDE</td>
<td>3.2</td>
</tr>
<tr>
<td>CADMIUM</td>
<td>&lt;0.04</td>
</tr>
<tr>
<td>LEAD</td>
<td>0.03</td>
</tr>
<tr>
<td>NICKEL</td>
<td>0.11</td>
</tr>
<tr>
<td>NICOTINE</td>
<td>5,770</td>
</tr>
<tr>
<td>NNK*</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>PROPYLENE GLYCOL</td>
<td>250,950</td>
</tr>
</tbody>
</table>

*NNK = 4 (n-nitrosomethylamino)-1-(3-pyridyl)1-butanone

Aerosol Composition

e-liquid

Device Characteristics

User Topography
E-Cigarette Aerosol Hazards

- Propylene glycol/vegetable glycerin
- Nicotine
- Metals
- Particle size distribution (nanoparticles)
- Flavorings

“..regardless of the potential long-term harm reduction benefits of [e-cigarettes], an important policy question is whether the still uncertain risk of potentially serious lung disease merits precautionary regulation of e-liquid composition in the face of considerable scientific uncertainty.”

E-cigarette Use, U.S. Adults

National Adult Tobacco Survey, 2012-2013
(compared to 18.0% Cigarette Use)

Note: Use = every day, someday, or rarely
Source: CDC. MMWR. June 27, 2014 / 63(25);542-547.
Prevalence, U.S. High School Students
National Youth Tobacco Survey, 2013

<table>
<thead>
<tr>
<th>Tobacco Product</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes</td>
<td>12.7</td>
</tr>
<tr>
<td>Cigars</td>
<td>11.9</td>
</tr>
<tr>
<td>Smokeless Tobacco</td>
<td>5.7</td>
</tr>
<tr>
<td>Hookah</td>
<td>5.2</td>
</tr>
<tr>
<td>Electronic Cigarettes</td>
<td>4.5</td>
</tr>
<tr>
<td>Any Tobacco Use 2 or more products</td>
<td>12.6</td>
</tr>
</tbody>
</table>

Note: Use = past 30 day
Source: CDC. MMWR. November 14, 2014 / 63(45);1021-1026.
Use by Non-smoking Youth

• U.S. youth who had never smoked use e-cigarettes
  – 263,000 in 2013; 79,000 in 2011
• Intention to smoke conventional cigarettes was expressed by 44% of ever e-cigarette users and 22% of never e-cigarette users
• Key concerns: lead to nicotine addiction, and/or use of cigarettes among youth who would not otherwise become tobacco users

E-cigarettes: Intense Debate

“We’ve worked very hard to reduce smoking in this country, and I think its been a fantastic success. Now I think we’re on the verge of destroying all the progress that we’ve [made].”

- Denise Kandel, Time Magazine, 09/03/14

“E-cigarette use has been a consumer led revolution… The use of e-cigarettes could save millions of lives during this century, and have the most important public health impact in the history of tobacco use.”

- Jacques le Houezec, 09/05/14
Potential Benefit vs. Harm

• Potential Benefit
  – Harm reduction if smokers use them as a substitute (whole or in part) for cigarettes

• Potential Harm
  – Youth/Young adults: nicotine addiction, lead to use of other tobacco products, facilitate other drug use
  – Former smokers: return to smoking
  – Smokers: dual use, or deter quitting
  – Long term use: hazards unknown
  – Society: renormalize smoking behavior, erode gains in smoke-free air laws
World Health Organization
Position Statement

“Electronic Nicotine Delivery Systems (ENDS), therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates.”

TASTES & SMOKES BETTER THAN A REAL CIGARETTE!

No Tar or Yellow Teeth
No Smelly Clothes
No Toxic Chemicals!
Smoke Anywhere!

NO: TAR
NO: CARCINOGENS
NO: SECOND HAND SMOKE

freedom to have a cigarette without the guilt.
— Jenny McCarthy

Quit smoking with electronic cigarettes

NO: Odor, No Ash
No Tobacco Smoke, Only Vapor
Slim, Rechargeable Pack

Try Now

SAY GOOD-BYE TO SLEEPLESS NIGHTS

NutriCigs

WHY QUIT?

Visit blucigs.com

NutriCigs

Copyright © 2009 blu, Inc. All rights reserved.
E-cigarettes and Smoking Cessation?

• Studies have examined:
  – nicotine delivery
  – effect on withdrawal from nicotine
  – effect on smoking cessation

• **Preliminary Conclusion**: E-cigarettes can deliver nicotine, may reduce urge to smoke, and may facilitate quitting and reduced consumption.

Vaping “Culture” and Testimonials

“I tried every single one of the FDA-approved smoking cessation products... One day I decided to try one more thing, the e-cigarette. The day I started it was the day I quit smoking for good.”

- Former Smoker
FDA Proposed Deeming Rule

• 2010: U.S. District Judge ruled that FDA may not regulate e-cigarettes as drugs or medical devices, unless marketed for therapeutic purposes

• 2014 Proposed Rule: deem products meeting the statutory definition of “tobacco product” including e-cigarettes
  – Subject to FDA’s authorities, including adulteration/misbranding, reporting HPHCs, registration, require premarket review, minimum age of purchase, health warnings, prohibit sales through vending machines
  – Requested comments on various topics

NO SMOKING
WITHIN 15 FT OF ENTRYWAY
INCLUDING E-CIGARETTES
If you see someone smoking, please notify the manager.
If the problem persists, please call 311 and report it.

E-Cigs & Liquid
If you weren't born on or before TODAY’S DATE in 1996
Then you CAN’T buy E-CIG’S, Electronic Cigarettes, Liquids and Supplies.

AT&T is a "SMOKE FREE"
Facility
Including:
- Electronic Cigarettes
- Smoke by Vaporization
IS NOT PERMITTED
Anywhere Inside AT&T Park

SmokeFree!
N.D.C.C. 23-12-9 to 23-12-11
Smoking, including the use of e-cigarettes, is prohibited by law indoors and within 20 feet of entrances and windows.

NO SMOKING
Including E-CIGARETTES
AND ALL OTHER ELECTRONIC SMOKING DEVICES
Need help quitting? Call the California Smokers’ Helpline 1-800-NO-DUTTS.
Clinical Guidance

• “There is not yet enough evidence for clinicians to counsel their patients who are using combustible tobacco products to use e-cigarettes as a primary cessation aid.”

• “If a patient has failed initial treatment, has been intolerant to or refused to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt.”

• “However, subjects should be informed that these products are unregulated, may contain low levels of [toxicants], and have not been proven as cessation devices or safe over the long term.”

• “Patients should quit smoking cigarettes entirely as soon as possible, because continued cigarette smoking, even at reduced levels, continues to impose health risks.”

NIH Research: Tobacco Regulatory Science Program

• Tobacco Centers of Regulatory Science (TCORS)
  – 11 of 14 TCORS
• Other Tobacco Regulatory Science
  – 5 NCI grants
  – 1 NHGRI grant
  – 3 NHLBI grants
  – 9 NIDA grants
• Research Topics: addiction, appeal, communication, marketing, and messaging, economics, health effects, initiation, point-of-sale, measures standardization, product characteristics, risk/harm perception, toxicity, vulnerable populations

NIH Research: Research Project Grants

• NCI State and Community Tobacco Control Research Initiative (SCTC), RFA-CA-10-008
  – Electronic nicotine delivery systems (ENDS): New evidence from the State and Community Tobacco Control Research Initiative (9 articles, editorial)

• NIDA 3 grants within the RPG
  – Research Topics: topography and abuse liability in smokers, models of e-cigarette use among hospital-based sample of smokers, identify new biomarkers of exposure to e-cigarettes
Development of a Standardized Electronic Cigarette for Clinical Research

• Currently available research data on electronic cigarettes are insufficient to fully understand their impact on public health

• NIDA Small Business Innovation Research Contract Proposal, June 2014

• Standardized electronic cigarette that will have defined nicotine delivery characteristics and be available for 5+ years, sufficient for the full term of a multi-year study

• Drug Master File will be created to allow the device to obtain IND approval

NIH Workshop on E-Cigarettes

Research Questions

• Standards to measure contents and emissions
• Biomarkers of exposure and health effects
• Physiological effects on tissues and organ systems, including pulmonary and cardiovascular
• Information on users, how devices are used and identification of best tools to assess these measures
• Factors that drive use and influence patterns of use
• Appropriate methods to evaluate a potential role for e-cigarettes in smoking or nicotine cessation
• Vulnerable populations: youth, women of reproductive age
