Welcome
Please stand by. We will begin shortly.

E-cigarettes: Challenges for Clinicians
Wednesday, April 23, 2014 · 1pm ET (90 minutes)

Moderator
Catherine Saucedo
• Deputy Director, Smoking Cessation Leadership Center, University of California, San Francisco
• csaucedo@medicine.ucsf.edu

Agenda
• Welcome
  – Catherine Saucedo
• Introduction to ATTUD
  – Thomas J. Payne, PhD
• Clinical Scenarios
  – Jonathan Foulds, PhD
  – Pamela M. Ling, MD, MPH
• Q&A
• Closing Remarks

Webinar objectives
• Describe the various types and components of electronic cigarettes (e-cigarettes)
• Describe the current evidence for the clinical use of e-cigarettes among tobacco users
• Understand the potential clinical and health risks and benefits of e-cigarette use
• Respond to clinical inquiries regarding e-cigarettes from patients and colleagues
Housekeeping

- All participants will be in **listen only mode**.
- Please **make sure your speakers are on** and adjust the volume accordingly.
- If you do not have speakers, please request the dial-in via the chat box.
- **This webinar is being recorded** and will be available on SCLC’s website, along with the slides.
- **Use the chat box to send questions** at any time for the presenters.

Today’s Speaker

**Thomas J. Payne, PhD**
- Professor, Department of Otolaryngology and Communicative Sciences; Director, ACT Center for Tobacco Treatment, Education and Research, University of Mississippi Medical Center; President, Association for the Treatment of Tobacco Use and Dependence (ATTUD)

ATTUD

- Association for the Treatment of Tobacco Use and Dependence
- Non-profit, multi-disciplinary organization of professionals
- Dedicated to increased access to evidence-based treatment of tobacco dependence
- Membership open to individuals with interest in the treatment of tobacco dependence
- www.attud.org

- Professional Association
  - Standards or Core Competencies as proficiencies
- Accreditation of Training Programs
  - Council for Tobacco Treatment Training Programs (CTTTP)
- Individual Credentialing or Certification
  - Collaboration with Center for Credentialing and Education
- Collaboration with other Professional Societies
  - SLC, SRNT
### [Poll Question #1]

1. How open are you to discussing the potential benefits of e-cigarettes as a smoking cessation tool?
   - Not at all open
   - Somewhat open
   - Very open

### [Poll Question #2]

How willing are you to incorporate e-cigarettes into a smoking cessation treatment plan?
   - I am against incorporating e-cigarettes into a smoking cessation treatment plan.
   - I am hesitant to incorporate e-cigarettes into a smoking cessation treatment plan.
   - I would consider incorporating e-cigarettes, with some patients, into a smoking cessation treatment plan.
   - I would incorporate e-cigarettes into a smoking cessation treatment plan.

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**Today’s Speaker**

**Jonathan Foulds, PhD**
- Professor of Public Health Sciences and Psychiatry, Penn State University, College of Medicine

**Today’s Speaker**

**Pamela M. Ling, MD, MPH**
- Associate Professor of Medicine, School of Medicine, University of California, San Francisco
Electronic Cigarettes: Challenges for Clinicians

Jonathan Foulds PhD
Penn State Tobacco Center of Regulatory Science
jfoulds@psu.edu
Penn State College of Medicine

Acknowledgements and conflicts.

• I am supported primarily by research funds from the National Institutes of Health and FDA Center for Tobacco Products (Award #s P50DA036107 and P50DA036105), but also Penn State Hershey Cancer Institute, and the Clinical & Translational Science Institute, Social Science Research Institute and the Center for Integrating Healthcare Delivery Systems at Penn State. The content of my presentation today is solely my responsibility and does not reflect the views of NIH, FDA or any other funder.

• I undertake research and consultancy for pharma companies that develop and manufacture smoking cessation medications (including GSK, Pfizer, Novartis, J&J).

• I don’t do consulting for tobacco companies or e-cig companies.

• Wrote a regular weblog for a health website at: www.healthline.com/blogs/smoking_cessation/

• Volunteer as a “Health Expert” on the smoking cessation community on www.WebMD.com

• Thanks to numerous colleagues for sharing their slides.

“If people have difficulty overcoming both nicotine dependence and long-term habit change, then surely the solution is to help them avoid most of the health risks with only a minimal alteration in their nicotine-seeking habits. This implies a nicotine replacement device which looks like a cigarette and delivers cigarette-like bolus of nicotine, but does not deliver the tar and carbon monoxide which cause the vast majority of smoking-related disease..... the development and promotion of such a product (and its eventual replacement of tobacco) could have massive beneficial public health implications lasting into the 21st century.” (Foulds, 1994)


“There is a fine line between being visionary and being wrong.

Unfortunately you have to be a visionary to see it.”

Dr Sheldon Cooper
The Big Bang Theory
Fig. 2. Overall weighted scores for each of the products. Cigarettes, with an overall harm score of 99.6, are judged to be most harmful, and followed by small cigars at 67. The heights of the colored portions indicate the part scores on each of the criteria. Product-related mortality, the upper dark red sections, are substantial contributors to these two products, and they also contribute moderately to cigars, pipes, water pipes, and smokeless unrefined. The numbers in the legend show the normalized weights on the criteria. Higher weights mean larger differences that matter between most and least harmful products on each criterion.


Mean data for nicotine blood plasma (A) and heart rate (B) as a function of condition and time.

Farsalinos et al, 2014, Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices

There is no such thing as “an e-cig”. There are many different e-cigs

Examples of electronic cigarette devices currently available on the market (Farsalinos and Polosa, 2014)
Some e-cigs can produce a boost in blood nicotine levels of >12 ng/ml from 10 puffs in 5 mins. (Spindle, Breland & Eissenberg, SRNT 2014)

Mean plasma nicotine concentration (+/− SEM) from 5 experienced ECIG users using their preferred device and strength/flavor in two sessions that differed by whether a mouthpiece-based topography system was attached to the ECIG. Nicotine levels increased significantly in each session, independent of mouthpiece condition.

Prevalence of electronic cigarette use: smokers and recent ex-smokers

Growth in prevalence of e-cigarette use may have slowed

N=11,666 adults who smoke or who stopped in the past year; increase p<0.001

www.smokinginengland.info/latest-statistics/

Aids used in most recent quit attempt

Increase in use of e-cigarettes for quitting has been accompanied by a small reduction in use of other aids except behavioural support which has been static

N=4,935 adults who smoke and tried to stop or who stopped in the past year

www.smokinginengland.info/latest-statistics/

Success rate for stopping in those who tried

Graph shows prevalence estimate and upper and lower 95% confidence intervals
Conclusions

- The increase in electronic cigarette use prevalence continues but may have slowed.
- Growth in electronic cigarette use has been accompanied by a reduction, albeit smaller, in use of licensed nicotine products and prescription medication but not use of behavioural support.
- Evidence does not support the view that electronic cigarettes are undermining motivation to quit or reduction in smoking prevalence.
- Use of e-cigarettes by never smokers remains extremely rare.
- Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or ‘renormalizing’ smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking.
Circumvent smokefree laws

71% of websites

Circumvent laws: 71% of websites
**Health Claims:** 95%, Cessation 64% of websites

*I have been able to quit smoking because of your product.*

--Debbie from Sacramento, CA

Doctors = 22% of websites
Clinical Scenario #1 (Foulds)

• “I’m a heavy smoker and both my parents were smokers who died of lung cancer. I’ve tried all the meds but never quit for more than a week. I’ve heard that e-cigarettes can help smokers to quit and I really want to give it a shot. What can you tell me about them?”
Clinical Scenario #1 (Foulds)

1. Support Quit Attempt
2. Assess motivation and dependence
3. Assess prior quit attempts and inform about all treatment/support options
4. Inform on what we know and what we don’t know about e-cigs.
5. Assist smoker to develop a plan to quit smoking
6. Arrange a follow-up

Clinical Scenario #1 (Foulds)

• If patient has only tried NRT monotherapy, inform about (a) combination NRT (b) reduce to quit (c) bupropion and varenicline options.
• Inform about additional support available: 1-800 QUIT-NOW
• www.smokefree.gov www.becomeanex.org
• Inform on what we know and what we don’t know about e-cigs.

• Many different types, currently unregulated, no smoke
• Not proven as safe and effective, no clear instruction for use
• Clinical trials to date have had disappointing results but have exclusively used first generation models.

Liquid

Contents
• Propylene glycol and/or
  Vegetable glycerine (glycerol)
• Nicotine (in mg/ml; ranging from 0-36)
• Flavourings (e.g. tobacco, mint, fruit, menthol etc)
• Additives

Clinical Scenario #1 (Foulds)

• “The evidence from clinical trials suggests that the best quit rates are achieved by maximizing your psychosocial support (e.g. group face-to-face support plus quitline plus online) and pharmacological support (e.g. combination NRT or varenicline for as long as it takes). If you choose to use these treatments they will likely increase your chances of quitting by 2 to 4 times”

• An e-cigarette may help, but we don’t yet have very solid data on how helpful they are or what the longer term health risks may be.

• If you choose one that provides you with a decent amount of nicotine it is likely it will help you in much the same way as NRT. As the e-cig delivers nicotine plus a few more chemicals it is very likely to be much less harmful than smoking.
Clinical Scenario #1– Ling response

- E-cigarettes are unregulated devices that are not approved by FDA for smoking cessation
- Device variability makes it near impossible to recommend a product or type
- Not “Harmless Water Vapor”
- Data on cessation is scant
  - Convenience samples of users report success
  - One reasonably sized RCT

Electronic cigarettes for smoking cessation: a randomised controlled trial

<table>
<thead>
<tr>
<th></th>
<th>Nicotine e-cigarette (N=289) n (%)</th>
<th>Placebo e-cigarettes (N=73) n (%)</th>
<th>Nicotine Patch (N=295) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>67 (23.2)*</td>
<td>12 (16.4)</td>
<td>47 (15.9)*</td>
</tr>
<tr>
<td>3 months</td>
<td>38 (13.1)</td>
<td>5 (6.8)</td>
<td>27 (9.2)</td>
</tr>
<tr>
<td>6 months (Primary outcome)</td>
<td>21 (7.3)</td>
<td>3 (4.1)</td>
<td>17 (5.8)</td>
</tr>
</tbody>
</table>

*p<0.05

Data from: Lancet 2013, 382: 1629-37

Quitting: Population Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Location/ Length of followup</th>
<th>Odds of quitting (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adkison (2013)</td>
<td>US, UK, Canada, Australia (ITC) (1 yr)</td>
<td>0.81 (0.43,1.53)*</td>
</tr>
<tr>
<td>Grana (2014)</td>
<td>US (1 yr)</td>
<td>0.76 (0.36,1.60)</td>
</tr>
<tr>
<td>Vickerman (2013)</td>
<td>US quit line callers (7 mo)</td>
<td>0.50 (0.40,0.63)**</td>
</tr>
</tbody>
</table>

*Odds ratios obtained by contacting authors
**Computed by authors of this report based on the numbers reported in the paper

Thanks to: Rachel Grana, PhD MPH
Advice for Clinical Scenario #1

• Support quit attempt
• Guide towards approved therapies
• Encourage complete switching not dual use
  – Most e-cigarette users → dual use
  – This is unlikely to reduce cardiovascular risk
• If patient truly only wants to use e-cigarette, set a quit date for e-cigarette too


Clinical Scenario #2 (Ling)

• 50 yo woman primary care patient with back pain, hypertension, hyperlipidemia, depression and PTSD, here for routine follow up, incidentally noted she is still smoking 3 to 5 cpd, reduced from 10 cpd.
• She quit once “cold turkey” for 9 months 2 years ago
• “not interested” in any medications, counseling, or nicotine replacement
• She is willing to set a quit date in the next 30 days (her son’s birthday) and remarks, “Maybe I’ll get one of those electric cigarettes to quit, what do you think?”

Clinical Scenario #2

• Opportunity to engage patient in counseling
• This is a “light” smoker
• Significant psychiatric history
• ASK: why is she interested in e-cigarette?
• What does she think is different from approved therapies?
• History of past quit attempts and assistance?

“not interested”

• “I’ve tried everything”
  – Frequently NRT misused or incorrectly used
  – Unassisted quit attempts
• Correct misperceptions of approved therapies
• Correct misperceptions of e-cigarettes
• Treat Depression, PTSD

While doctors seem to readily encourage patch usage, few get any more involved – offering advice, discussing side effects, suggesting behavior modification.

There appears to be an extremely casual approach to the medical requirements surrounding patch usage, typical of an OTC mentality. Examples of this behavior include physically cutting the patch to reduce dosage, removal of the patch for occasional smoking and sharing patches with friends/family.

- There appears to be an unorthodox approach to the medical requirements surrounding patch usage, typical of an OTC mentality. Examples of this behavior include physically cutting the patch to reduce dosage, removal of the patch for occasional smoking and sharing patches with friends/family.
- Retailers are known to sell patches, even if they have not been properly stored, to pregnant women, when asked how to best purchase the patches if they will be shared among family members.
- Patch users improperly removed represented a wide range of side effects – this includes nausea and dizziness.

Lack of warning implies safety

Advertising implies safety
Clinical Scenario #2

- Use e-cigarette question to open door to patient perceptions and expectations
- Exhaust all options prior to e-cigarettes
- Correct misperceptions
  - About NRT or medications
  - About electronic cigarettes

52 year-old woman, smoked a pack a day, had more than 7 quit attempts over past 10 years. Some success with meds (NRT or Varenicline) and counseling, but always relapsed between 2 and 6 months after the initial quit date. She returns for an annual follow-up, and this time is 9 months tobacco free (exhaled CO=1ppm, FEV1 improved significantly compared with smoking baseline), ever since started using an e-cig on a daily basis….initially a disposable from a gas station, then a rechargeable cigalike, then an “Ego Tank” with a button, and now she is in love with some fancy e-cig called a “Provari” that she found online. I asked her to complete the Penn State Electronic Cigarette Dependence Index, and she obtained a very high score (15/20), only a couple of points lower than she obtained on the PS Cigarette Dependence Index at initial assessment. She feels the e-cig has really helped her stay off cigarettes and has no plans to quit, but asks about the long term health effects.

Clinical Scenario #3 (Foulds)

52 year-old woman, smoked a pack a day, had more than 7 quit attempts over past 10 years. Some success with meds (NRT or Varenicline) and counseling, but always relapsed between 2 and 6 months after the initial quit date. She returns for an annual follow-up, and this time is 9 months tobacco free (exhaled CO=1ppm, FEV1 improved significantly compared with smoking baseline), ever since started using an e-cig on a daily basis….initially a disposable from a gas station, then a rechargeable cigalike, then an “Ego Tank” with a button, and now she is in love with some fancy e-cig called a “Provari” that she found online. I asked her to complete the Penn State Electronic Cigarette Dependence Index, and she obtained a very high score (15/20), only a couple of points lower than she obtained on the PS Cigarette Dependence Index at initial assessment. She feels the e-cig has really helped her stay off cigarettes and has no plans to quit, but asks about the long term health effects.
Penn State Electronic Cigarette Index

1. How many times per day do you usually use your electronic cigarette? (assume one “time” consists of around 15 puffs, or lasts around 10 minutes)
   ____30____ times per day (5)

2. On days that you can use your electronic cigarette freely, how soon after you wake up do you first use your electronic cigarette? ____20____ minutes (3)

3. Do you sometimes awaken at night to use your electronic cigarette? Yes No [1]

4. If yes, how many nights per week do you typically awaken to use your electronic cigarette? ____3____ nights (2)

5. Do you use an electronic cigarette now because it is really hard to quit? Yes Nox (0)

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Penn State Electronic Cigarette Index

6. Do you ever have strong cravings to use an electronic cigarette? xYes No (1)

7. Over the past week, how strong have the urges to use an electronic cigarette been? (check one) No urges Slight Moderate xStrong Very strong Extremely strong (1)

8. Is it hard to keep from using an electronic cigarette in places where you are not supposed to? Yes Nox

   When you haven’t used an electronic cigarette for a while… Or when you tried to stop using--

9. Did you feel more irritable because you couldn’t use an electronic cigarette? xYes No (1)

10. Did you feel nervous, restless or anxious because you couldn’t use an electronic cigarette? xYes No (1)

11. What concentration of nicotine is in the liquid you typically use with your e-cig? ____18____ mg/ml.
Clinical Scenario #3 (Foulds)

- The long term health effects of inhaling nicotine, propylene glycol, vegetable glycerin, flavorings and other unknown additives are unknown
- They are very likely worse for health than inhaling fresh air
- They are very likely much less harmful to health than smoking cigarettes.
- The most important thing for this patient is to stay off cigarettes in the immediate future
- Encourage to start thinking about weaning herself off the e-cigs, possibly by gradually reducing the nicotine concentration in her liquid...but only if she feels secure in not relapsing back to smoking

Clinical Scenario #3 – Ling response

- Support quit attempt (already quit)
- Long term health effects unknown
- Rapidly evolving products have unknown effects

Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol

Metal and silicate particles including nanoparticles are present in electronic cigarette cartomizer fluid and aerosol. This finding highlights the potential health risks associated with vaping, and underscores the need for further research to fully understand the health effects of these products.

- E-cigarette fluid and vapor contains toxic metals and nanoparticles
- Vapor contains tobacco-related toxins and chemicals – less than cigarettes, more than nicotine inhaler
  - Formaldehyde
  - Acrolein
  - Acetaldehyde
  - VOCs
  - NNK and NNK
- Exposure studies - Puff Topography not accounted for

Gornicki et al, Tobacco Control 2013.
Clinical Scenario #3 - Advice

- Note product being used, perhaps liquid
- Set a quit date for e-cigarette
  - Can patient transition to an approved therapy?
- Continue dialogue, symptom review
Clinical Scenario #4 (Ling)

- 21 yo female presents for work physical for restaurant job. Denies significant PMH except Asthma, treated with Albuterol PRN (once or twice a day)
- Denies smoking. Drinks 4-5 alcoholic drinks on weekends. Has been using a vapor pen when out at parties sometimes.
- She lives with his mom and five siblings. Mom (39) recently quit smoking using an electronic cigarette, which she continues to use.
- Is his nicotine exposure significant? How do you counsel her?

Clinical Scenario #4

- Screening challenges
  - Binge drinkers frequently smoke
  - May present themselves as nonsmokers
  - Need to screen specifically (pt smokes when drinks)
  - Vapor pens = e-cigarettes
    - Also e-hookah, vapes, sticks, hookah pens
- Recreational use common
  - Young adults have highest rates of use
  - May lead to or increase nicotine addiction

Electronic Cigarettes

![Electronic Cigarettes](image)

![Flavor Vapes](image)
Clinical Scenario #4 - Asthma

• Inadequately controlled
• Personalized reason not to smoke or be exposed to secondhand smoke or aerosol
• One study found acute pulmonary effects
  – 5 minutes of e-cigarette use in healthy smokers increased airway resistance
  – Unknown clinical significance
  – May affect susceptible people

“But who knows? Maybe the research will show that e-cigs (without nicotine) are just fine and dandy through pregnancy.”

Nicotine and the Developing Brain

- Nicotine alters the structure and function of the brain and is highly addictive
- Animal studies demonstrate that the adolescent brain is sensitive to nicotine and results in long-lasting neurochemical and behavior changes
- Nicotine interferes with maturation of the prefrontal cortex

Nicotine effects on prefrontal cortex functions

- Nicotine in adolescent rats results in long-term cognitive impairment (accuracy, impulse control)
- Adolescent smokers show reduced PFC activity, including memory and attention
- Adolescent smoking associated with later life behavioral disturbances, including substance abuse and mental health problems
Clinical Scenario #4 – what about Mom?

• Aerosol exposure results in detectable serum cotinine levels in nonsmokers
• Modeling what appears to be smoking for kids
• Products themselves are attractive “toys”
**Notes from the Field**

Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014

- Average 1 per month increased to 215/month
- Most common adverse events were vomiting, nausea, and eye irritation

**Clinical Scenario #4 - Advice**

- Discourage recreational “vapor pen” use
- Personalize to patient’s medical conditions
- Fetal exposure to nicotine not harmless
- Support mom’s quit attempt!
- Preserve smoke – and vapor free homes
- E-cigarettes are not harmless toys

**Advice for Clinicians**

- Screen for poly tobacco use including e-cigarettes
- Field and devices are rapidly evolving
- Engage with new opportunities to discuss smoking cessation
- Misinformation and false claims are rampant
- Data is scarce
- Continue to recommend approved therapies
- Monitor use in your patients, document and report health concerns

**Advocacy and Community Action**

- Include e-cigarettes in tobacco free policies
- Prohibit cessation and health claims
- Apply cigarette advertising restrictions to electronic cigarettes
Clinical Scenario #4– Foulds response

Questions and Answers

• Feel free to submit questions via the chat box

[Repeat Poll Question #1]

1. How open are you to discussing the potential benefits of e-cigarettes as a smoking cessation tool?
   • Not at all open
   • Somewhat open
   • Very open

[Repeat Poll Question #2]

How willing are you to incorporate e-cigarettes into a smoking cessation treatment plan?
   • I am against incorporating e-cigarettes into a smoking cessation treatment plan.
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Visit us online
• http://smokingcessationleadership.ucsf.edu

Call us toll-free
• 1-877-509-3786

CME/CEUs of up to 1.5 credits are available to all attendees for a fee of $35 per certificate. Instructions will be emailed after the webinar.

Contact SCLC for technical assistance

Closing remarks

• Please help us by completing the post-webinar survey.

• Thank you for your continued efforts to combat tobacco.

• Register now for SCLC’s next webinar, “Tobacco Cessation Coverage: Implementation of the Affordable Care Act in 2014” at 1pm ET on May 15, 2014.

CME/CEU Statement

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