One Hour Power Break Webinar: Vaping and Ecigs among Behavioral Health Populations: Research Evidence and Research Needs

Judith (Jodi) Prochaska, PhD, MPH

9/12/18
Moderator

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Disclosures

This UCSF CME activity was planned and developed to uphold academic standards to ensure balance, independence, objectivity, and scientific rigor; adhere to requirements to protect health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and include a mechanism to inform learners when unapproved or unlabeled uses of therapeutic products or agents are discussed or referenced.

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Jon Jovi Bodestyne, Christine Cheng, Brian Clark, Jennifer Matekuare, Jessica Safier, Roxana Said, MPH, Catherine Saucedo, and Steven A. Schroeder, MD

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Jodi Prochaska:

• Pfizer – Consultant

• Carrot – Board Member, Consultant, Stock Shareholder

• MD Revolution – Consultant, Stock Shareholder

• Achieve - Consultant

• Plaintiffs Lawyers – Lawsuits against tobacco companies, Consultant
Thank you to our funders
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- 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.
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The University of California, San Francisco (UCSF) School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

UCSF designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation in the webinar activity.

Advance Practice Registered Nurses and Registered Nurses: For the purpose of recertification, the American Nurses Credentialing Center accepts AMA PRA Category 1 Credit™ issued by organizations accredited by the ACCME.

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New Behavioral Health Accreditation

California Association of Marriage and Family Therapists (CAMFT)

This webinar is accredited through the CAMFT for up to 1.0 CEUs for the following eligible California providers:

• Licensed Marriage and Family Therapists (LMFTs)
• Licensed Clinical Social Workers (LCSWs)
• Licensed Professional Clinical Counselors (LPCCs)
• Licensed Educational Psychologists (LEPs)

Instructions to claim credit for these CEU opportunities will be included in the post-webinar email and posted to our website.
California Behavioral Health & Wellness Initiative

For our CA residents, we are starting a new venture in CA helping behavioral health organizations go tobacco free and integrating cessation services into existing services thanks to the support of the CTCP.

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Tips® Campaign Overview

Presenter

Jodi Prochaska, PhD, MPH
Associate Professor of Medicine
Stanford Prevention Research Center
Stanford University
E-cigs & Behavioral Health
Research Evidence & Research Needs

Jodi Prochaska, PhD, MPH
Associate Professor
Department of Medicine
Stanford University

WHAT IS AN E-CIG?

- e-cigs
- e-hookahs
- mods
- vape pens
- vapes
- tank systems
- Juul, Suorin, Phix, Rubi
- electronic nicotine delivery systems (ENDS)
DISCLOSURES

• **Current Funding:** NHLBI R01HL117736; NCI R01CA204356, R01CA217165 and P01CA225597; NCI Cancer Moonshot funding; NIDA UHAG052168, R34DA046008 and R34DA041637; NIMHD R21MD011765; California TRDRP 24RT-0035, 25IR-0032 and 26IR-0004; American Cancer Society/CVS Health Foundation, Stanford Cancer Institute, Stanford Wood’s Institute for the Environment

• **Consulting:** Consultant to pharmaceutical (Pfizer, Achieve Life Sciences) and technology companies (Carrot, MD Revolution) focused on helping people quit smoking; expert witness for plaintiff counsel in litigation against the tobacco companies; expert consultant for the FTC

• **Discussion of off-label medication use:** None
Agenda

• Background on ecigs / vapes
  • Designs, sales, advertising, contents
  • Timeline: FDA Regulation

• Behavioral Health Populations
  • Prevalence
  • Correlates
  • Treatment
  • Policies

• Summary

• Q&A
Suorin
Phix
Rubi

E-pipe
E-cigar
Large-size tank devices
Medium-size tank device
Disposable e-cigarette
Rechargeable e-cigarette

Puff X Vaporizer: The world's first forced air portable vaporizer.

Suorin
Phix
Rubi
JUUL Lab’s mission is to eliminate cigarette smoking by offering existing adult smokers with a better alternative to combustible cigarettes.

Juul dominates the U.S. e-cigarette market

Juul Labs represented 72.2 percent of dollar market share in the four-week period ended Aug. 11, 2018, according to Nielsen data.

Source: Wells Fargo
Sales ($) of ecigs in Nielsen-tracked retail channels: by brand 2011–2017

Jidong Huang et al. Tob Control
doi:10.1136/tobaccocontrol-2018-054382

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LIMITED EDITION FLAVOR

COOL CUCUMBER

Mondays Don't Need To Be Hard
Escape With A JUUL Moment

WARNING: This product contains nicotine. Nicotine is an addictive chemical. © 2017 JUUL Labs, Inc. ALL RIGHTS RESERVED.
- Increases Concentration ...
- Reduces Risk for Dementia and Alzheimer's ...
- Helps Fight Anxiety and Depression ...
- Fights Symptoms of PMS ...
- Helps Maintain Vision and Eye Health ...
- Helps Prevent or Treat ADHD ...
- Improves Libido ...
- Helps Treat Headaches and Migraines.

RELAXATION OIL

STRESS VAPOR
Stress & Anxiety Helper

VAPEMOOD.COM

SAY GOOD-BYE TO SLEEPLESS NIGHTS

NutriCigs

TRY NOW
E-cig aerosol may contain:

- Nicotine (even if marketed as 0% nicotine)
- Ultrafine particles that can be inhaled deep into the lungs
- Flavoring such as diacetyl, a chemical linked to a serious lung dz
- Volatile organic compounds (VOCs)
- Cancer-causing chemicals
- Heavy metals such as nickel, tin, and lead

* At lower levels than in combusted tobacco smoke

primary humectants are propylene glycol and glycerol (aka vegetable glycerin)
Yes, less harmful than combustibles, but... that doesn’t mean ecigs are safe

• **Nicotine**
  - Toxic to developing fetuses
  - Harm adolescent brain development, which continues into the early to mid-20s
  - Can be highly addictive

• **Cancer-causing chemicals**
• **Tiny particles into lungs**
  - Fewer harmful chemicals than smoke from burned tobacco products

• **Unintended injuries**
  - Defective batteries have caused fires and explosions, most happened when the e-cig batteries were being charged, stored improperly, modif.
  - Children and adults have been poisoned by swallowing, breathing, or absorbing e-cigarette liquid through their skin or eyes

Which account for 2:3 deaths among long-term smokers
Ecig Timeline in the US

• **2006** Ecigs enter US market

• **Dec 2010:** Smoking Everywhere v. FDA, U.S. Court of Appeals in Washington rules FDA can only regulate ecigs as a tobacco product, unless therapeutic claims are made

• **Aug 2016:** FDA Deeming Rule to regulate Ecigs
  - Jan 2007-Aug 2016 2 yrs to submit for review +1 yr to review (2019)
  - New/modified products must submit for pre-market review

• **July 2017 FDA Update**
  - Ecig submission date extended to **Aug 2022**
  - New products have appeared on market without apparent FDA review

• **April 2018:** six leading health groups sued the FDA for inaction on ecigs
Initial Timeline of the FDA Deeming Rule

- **PREPARATION PERIOD**
  - Regulations are officially publicized
  - 90-day window to continue selling and releasing new products

- **COMPLIANCE PERIOD**
  - Existing products (prior to 8/8/16) may be sold. No new products (without FDA authorization) may be released
  - Shops are required to verify customers' ages

- **ENFORCEMENT PERIOD**
  - FDA enforcement begins for all products
  - Health warning label enforcement begins

- **Timeline**
  - **MAY 10, 2016**
  - **AUG. 8, 2016**
  - **AUG. 8, 2018**
  - **SEPT. 7, 2018**
  - **2019**
  - **2022**
Ecig Use and Behavioral Health

> Symptoms
> Psychological distress
> Diagnosed disorders
Depressive Sxs & Ecigs in College Student

• Survey of 5445 college students in Texas: B, 6 mo, 1 Yr follow-ups
• **Depresssive symptoms predicted ecig use**
• Ecig use did not predict elevated depressive symptoms

Bandiera FC et al. (2017) Nicotine Tobacco Research
Prevalence: Ecig Use & Psychological Distress
NHIS 2014  (Park et al. 2017 Plos One)

- Psychological distress was significantly associated with:
  - Current use of cigs only: aOR = 2.1
  - Current dual use of cigs and ecigs: aOR = 4.6
  - Former cig use + ever use of ecig: aOR = 3.2
  - Exclusive ecig ever use: aOR = 3.7
E-CIGARETTES & MH Dxs

• N=10,041 US adult smokers

Cummins et al. (2014) Tobacco Control
Prevalence: E cig Use & Chronic Mental Illness
NHIS 2016 Data (Bianco CL, in press Addict Bxs)

- Nationally representative adult sample N=33,028
  - 97% no chronic mental illness
  - 2.7% chronic depression, anxiety or emotional problem
  - 0.2% chronic ADD, bipolar, schizophrenia or other disorder
- 15% of US adult population tried an e-cig
  - 2.5 to 2.8 xs more likely to try an ecig if have chronic mental illness
- 3% of US adult population current ecig users
  - 2.7 to 3.0 xs more likely to regularly use ecigs if have chronic mental illness
E-CIG USE: SMOKERS with SERIOUS MENTAL ILLNESS (N=956)

Growth in Reported Ever E-cig Use by Year of Study Enrollment

% reporting recent e-cigarette use

0% 1% 9% 19% 25%

2009 2010 2011 2012 2013

Prochaska & Grana 2014 Plos One
PREDICTORS of E-CIG USE

- Later year of enrollment: OR=29.2 (95% CI 10.5 - 80.7)
- Younger age (18-25): OR =2.6 (1.2 - 5.7)
- nonHispanic vs. Hispanic: OR=4.0 (1.8 - 8.9)
- Preparation vs. precontemplation: OR=2.7 (1.4 - 5.2)

NS: gender, race, employment status, hospital site, study condition, psychiatric or substance use diagnosis, mental health severity, time to 1st AM cig, cigs/day

Prochaska & Grana (2014) PLOS ONE
E-CIG USE & SMOKING (N=956)

• Not more likely to be tobacco free @ follow-up:
  • 21% for EC users and 19% for non-EC users, p=.726

• Not more likely to reduce cigarettes/day @ follow-up:
  • >50% reduction in cigarettes/day (cpd)
    • EC (51%) vs. non-EC users (51%), p=.978
    • Median reduction in cpd: 7.1 (EC) vs. 6.6 (non-EC), p=.730
    • CPD at latest FU: 10.0 (EC) vs. 10.1 (non-EC), p=.915

• All smoking outcomes NS by EC use in adjusted models
Ecigs among Clients in Behavioral Health Tx

- N=60 patients with schizophrenia, **37% tried an ecig** (Miller et al 2017 Ann Clin Psych)

- N=188 veterans seeking bxl health treatment, **31% used ecigs**
  - Eicg users more likely to have a MH disorder and less likely to have SUD
  - More likely to have tried to quit “cold turkey” (Heffner et al. 2016 J Dual Diag)
  - Knowledge of ecigs originated most often from TV, radio, or personal contacts
  - 86% dual using; 7% stated ecigs helped them quit smoking

- N=231 community MH centers; **22% current ecig use** (Chen et al. 2017 Comm MH J)
Do e-cigs help people quit smoking?

- Switch
- Satisfying alternative
- It works
- Fin
E-cigs Help People Quit Combustibles?

- N=657 smokers interested in quitting

E-cigs Help People Quit Combustibles?

• N=657 smokers interested in quitting

• N=657 smokers interested in quitting

Quit rates for those with mental illness:
14% for NRT patch [5/35]
5% for 16 mg e-cig [2/39]
0% for 0 mg e-cig 0% [0/12]

O’Brien et al. (2015) Tob Induc Diseases
E-CIGS to QUIT or REDUCE

- Longitudinal observational study, N=1463 UK smokers

A systematic review of 20 controlled studies concluded that the odds of quitting cigarettes was 28% lower in those who used e-cigarettes compared with those who did not use e-cigarettes.

Brose et al., Addiction 2015
• Among **current smokers**, documented ECIG users had increased odds of quitting smoking
  • OR=1.26, 95% CI=1.13-1.40, p<0.001

• Among **former smokers**, ECIG users had increased odds of relapsing to smoking
  • OR=1.79, 95% CI=1.45-2.21, p<0.001

• Among **never-smokers**, ECIG users had elevated odds of becoming a smoker
  • OR=8.17, 95% CI=3.50-19.1, p<0.001

Young-Wolff et al. 2018 Prev Med
NAS Report Key Conclusions

• Moderate evidence from RCTs that e-cigs with nicotine are more effective than e-cigs without nicotine for smoking cessation
• Insufficient evidence from RCTs on effectiveness of e-cigs as cessation aids compared to no treatment or to FDA-approved cessation treatments
• Moderate evidence from observational studies that more frequent use of e-cigs associated with increased likelihood of cessation
• Substantial evidence that e-cig use increases risk of ever using combustible tobacco cigarettes among youth and young adults
US Adult Smokers’ Quit Methods, 2014–16 (n=15,943)

Quit @ Once: 60%
Reduced cigs: 60%
Subst Reg w. Ecig: 30%
NRT: 30%
Switched completely to Ecig: 25%
Switched to "mild" cig: 25%
Help from health prof: 20%
Bupropion or Chantix: 15%
Website (Smokefree.gov): 10%
Quitline: 5%
Any Research on Ecigs for Quitting among Behavioral Health Populations?

• N=14 smokers with schizophrenia not intending to quit
  • At wk 52, 50% (7/14) had 50% reduction in # of cigarettes/day
  • 14% (2/14) were smoking abstinence  (Caponnetto et al. 2013 I J Enviro Res Pub Health)
  • Schizophrenia symptoms did not increase with smoking reduction/ cessation

• N=50 smokers with a psychotic disorder, 6 wks ecigs
  • \geq 50\% \text{ reduction in cigs consumed per day between baseline and wk 6}
  • Verified by significant CO reductions  (Hickling et al. 2018 Psycholog Med)
Giving psychiatric patients access to e-cigarettes, particularly on closed wards, is definitely something to consider.
California Smokefree Air Laws: Tx Facilities

- Legal epidemiologic study by Stanford & ChangeLab Solutions
- Examined closure of loopholes in California’s 1994 Labor Code
  - Coded 536 of 539 cities and counties in California (IRR=87%)
- Few jurisdictions have closed loopholes to prohibit smoking in:
  - Long-term facilities: 31%
  - Medical research/treatment sites: 29%
- 42% of California’s cities and counties specifically prohibit ecigs and vaping in their smokefree ordinances

➢ Hence, few of California’s cities/counties appear to prohibit ecigs or vaping in behavioral health treatment and long-term care settings

Prochaska, Henriksen, Daza, Watts, Zellers, Huang, & Peters. unpublished data, TRDRP grant #25IR-0032
For example, Sacramento County

- Operators of facilities treating psychiatric or chemically impaired patients may permit smoking by patients in designated areas provided the medical director of such facility has determined in writing that the practice is beneficial for the recovery or treatment of such patients and that the practice will not interfere with the recovery and treatment of nonsmoking patients, and provided that adequate nonsmoking areas are made available for nonsmoking patients.

Citation 6.84.125
ATTENTION to TOBACCO in BEHAVIORAL HEALTH TREATMENT SETTINGS

<table>
<thead>
<tr>
<th>Service</th>
<th>MH Tx</th>
<th>Addiction Tx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco Ban</td>
<td>49%</td>
<td>35%</td>
</tr>
<tr>
<td>Tobacco Screening</td>
<td>49%</td>
<td>64%</td>
</tr>
<tr>
<td>Cessation Counseling</td>
<td>38%</td>
<td>47%</td>
</tr>
<tr>
<td>NRT</td>
<td>26%</td>
<td>26%</td>
</tr>
<tr>
<td>Rx Cess Med</td>
<td>22%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Marynak et al (2018) MMWR
% of FACILITIES PROHIBITING SMOKING: INDOORS & OUTDOORS

Mental Health Tx Settings

Addiction Treatment Settings

Marynak et al (2018) MMWR
TOBACCO TREATMENT SERVICES at SMOKE-FREE FACILITIES

Marynak et al (2018) MMWR
A tobacco-free agency is a treatment setting that has policies, training, assessments, and services in place to protect clients and staff from secondhand smoke exposure and smoking cues and is aimed at supporting client and staff efforts to quit smoking and live life tobacco-free. Successful agency attention to tobacco control requires:

1. Written policy **banning tobacco** (and e-cigarettes) from the agency setting
2. Written policy requiring **zero evidence** of tobacco use among staff at work
3. **Training of staff** in the treatment of tobacco dependence
4. Availability of **cessation treatment for staff** who smoke
5. **Assessment** of client tobacco use (and e-cigarettes) with documentation
6. Tobacco **treatment planning** for all identified smokers to include FDA-approved cessation pharmacotherapy, such as NRT and cessation support
7. **Referrals** for cessation treatment, such as the state quitline
CHARTING RECOMMENDATIONS

• EHR should include a fixed field to document ECIG use
• Healthcare providers should use inclusive language for ECIG screening
  • E.G., “Do you currently use any type of e-cigarette or vaping device?”
• And characterize other aspects of ECIG use, including:
  • Frequency of use
  • Product design (e.g., closed vs open systems, nicotine vs non-nicotine containing products)
  • Product flavoring
  • Use with other substances (e.g., cannabis)
Conclusions

• As in the general population, we see for those with MH conditions:
  • increase in ecig use over time
  • suggestive evidence that ecigs may aid cessation, but lacking strong evidence
  • evidence of dual use with combustibles, with unknown health effects

• As seen with combustible tobacco, ecigs are:
  • more frequently used among those with sxs and diagnosed mental illness
  • uniquely permitted in MH treatment settings

• A need for more research... AND a need for more action in clinical practice (treating tobacco use) and health policy (smokefree air laws)
Thank you, questions?
Low Nicotine Content Cigarettes

• Less reinforcing than regular cigarettes in smokers with co-morbid substance use + affective disorders

• Reduced smoking + dependence without worsening depressive symptoms in smokers with depressive symptoms

• Reduced smoking and dependence in smokers with a history of cannabis or ETOH use without increases in ETOH or cannabis

• Evidence of minimal compensatory smoking

Higgins et al (2017) JAMA Psych;
Tidey et al (2017) NTR;
<table>
<thead>
<tr>
<th>Patient Question</th>
<th>Doctor Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are electronic ciggerettes safer than tobacco?</td>
<td>Probably, but they are far from safe. they have simply not be studied for long-term effects. The amount of &quot;tars,&quot; the organic compounds in smoke that primarily cause cancer, is certainly less, but the impact of the propellant, propylene glycol, the flavorings and other additives, as well as the oil itself, is not known. They may lure younger people in, cause nicotine dependency, and lead to smoking.</td>
</tr>
<tr>
<td>Is it safe to smoke a vapor hookah pen around a child of any age - no flame no tar just contains 12mg of odorless nicotine?</td>
<td>Unknown. Ecigarettes of various types, including a vapor hookah, have not been studied in terms of sidestream smoke, and what harms may occur. They are not being adequately regulated now, and a lot of the ingredients differ between brands. Your smoking may not only effect the child through second-hand smoke but the example you are setting will increase the chance of him/her smoking when older.</td>
</tr>
<tr>
<td>Patient Question</td>
<td>Doctor Answer</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>I am trying to quit smoking using electronic cigarettes. I have cut down. Are these as harmful as real cigarettes? I recently had 3 stents /lad.</td>
<td>No. Electronic cigarettes, though less well proven as a smoking cessation method, are not as harmful as real cigarettes. Regardless of how you quit, the most important thing is if you keep trying until you fully succeed in smoking cessation. Get help from your friends and family as well.</td>
</tr>
<tr>
<td>Doctors, can my girlfriend smoke an ecig containing no nicotine while pregnant?</td>
<td>If the choice is between doing that and smoking cigarettes, then I would support the nicotine-free e-cigs. However, what I cannot do is tell you that it is completely safe, because we really don't know what the propellant, flavorings, additives and preservatives that are put into these products even are, let alone what harm they might do short or long-term. However, again, it is far better than smoking cigarettes.</td>
</tr>
</tbody>
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### DOCTOR ECIG ATTITUDES by THEME

<table>
<thead>
<tr>
<th>Theme</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harm reduction, n=301</td>
<td>66%</td>
<td>0%</td>
</tr>
<tr>
<td>Specific side effects and harms, n=287</td>
<td>12%</td>
<td>57%</td>
</tr>
<tr>
<td>General safety concerns, n=212</td>
<td>10%</td>
<td>67%</td>
</tr>
<tr>
<td>Use as a quit-aid, n=164</td>
<td>9%</td>
<td>74%</td>
</tr>
<tr>
<td>Other chemicals &amp; flavors, n=151</td>
<td>28%</td>
<td>29%</td>
</tr>
<tr>
<td>Use with medical conditions, n=144</td>
<td>17%</td>
<td>62%</td>
</tr>
<tr>
<td>Research evidence, n=127</td>
<td>12%</td>
<td>72%</td>
</tr>
<tr>
<td>Nicotine health risks, n=114</td>
<td>9%</td>
<td>74%</td>
</tr>
<tr>
<td>Addiction, n=89</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Nicotine-free e-cigarettes, n=74</td>
<td>19%</td>
<td>20%</td>
</tr>
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Doctors’ responses deemed as positive in attitude toward ECIGs were twice as likely to be “thanked” by patients.
STANFORD OCME
ECIGs: HARMFUL or HARM-REDUCING?

727 completed to-date (Feb-Dec 1 2017)
342 received CME
56% MD
29% allied health prof

Overall Evaluation for E-Cigarettes: Harmful or Harm-Reducing?

22% Average
43% Above Average
33% Outstanding

e-Cigarettes: Harmful or Harm-reducing?

This CME activity focuses on the science of e-cigarettes – particularly health risks and benefits. Based on observed patterns in questions from real patients and answers from practicing physicians, we emphasize potential health impacts of e-cigarettes and regulated alternatives such as nicotine replacement therapy. Opportunities focus on special issues related to youth and use by patients in perioperative phase, cancer treatment or cardiovascular disease treatment. Online learners are engaged through interactive video role-play, expert interviews, and interactive activities.
Q&A

• Submit questions via the chat box
Post Webinar Information

• You will receive the webinar recording, presentation slides, information on certificates of attendance, and other resources, in our follow-up email. All of this information will be posted to our website.

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Upcoming SCLC Webinar

SCLC’s next live webinar will be on **October 17, 2018 at 2:00pm ET** with Dr. Mitch Zeller Director for the Center of Tobacco Products, at the FDA.

Registration is coming soon!
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