Moderator

Catherine Saucedo
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University of California, San Francisco

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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.

The following faculty speakers, moderators, and planning committee members have disclosed they have no financial interest/arrangement or affiliation with any commercial companies who have provided products or services relating to their presentation(s) or commercial support for this continuing medical education activity:

Christine Cheng, Brian Clark, Jennifer Lucero, MA, MS, Jennifer Matekuare, Ma Krisanta Pamatmat, MPH, Jessica Safier, MA, Catherine Saucedo, Steven A. Schroeder, MD, and Aria Yow, MA

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Neal Benowitz, MD - Pfizer – Consultant

Achieve Life Sciences - Consultant
Thank you to our funders

Robert Wood Johnson Foundation

truth initiative
INSPIRING TOBACCO-FREE LIVES

National Behavioral Health Network
For Tobacco & Cancer Control

SAMHSA
Substance Abuse and Mental Health Services Administration

UCSF Smoking Cessation Leadership Center | National Center of Excellence for Tobacco-Free Recovery
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- 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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Visit [CABHWI.ucsf.edu](http://CABHWI.ucsf.edu) for more information.
Tips® Campaign Overview

Free 1-800 QUIT NOW cards

✓ Refer your clients to cessation services
Presenter

Neal L. Benowitz, MD
Emeritus Professor of Medicine and Bioengineering & Therapeutic Sciences
University of California, San Francisco
Disclosures

Dr. Benowitz has been a consultant to pharmaceutical companies that market smoking cessation products, including Pfizer and Achieve Life Sciences and a paid expert in litigation against tobacco companies.
The Question

- The harms and risks of nicotine are an essential consideration in assessing the public health impact of nicotine-based harm reduction.
- What do we know about the safety of long-term use of nicotine delivered without tobacco combustion?
Some Nicotine-related Clinical Concerns

• Should the vaper who has switched from cigarette smoking to e-cigarettes be counseled to quit vaping?
• What are the health risks of primary nicotine addiction in never-smokers?
Brief Summary

• Nicotine has effects on every part of the body, and basic research suggests many potential harms

• Long term nicotine use, while not harmless, is much less harmful than cigarette smoking

• The harms of long term inhalation of nicotine without tobacco combustion have not been determined and need to be studied

• The acceptability of nicotine addiction per se in non-smokers is both a health and socio-cultural question
Pharmacologic Mechanisms
Nicotine Mimics the Neurotransmitter Acetylcholine: Both Bind to “Nicotinic Cholinergic Receptors”

NICOTINE

ACETYLCOLINE
Structure of Nicotinic ACh Receptors

Muscle type nicotinic receptor

Neuronal type nicotinic receptors

Acetylcholine pore

Picciotto M. Emerging neuronal nicotinic receptor targets. SRNT 9th Annual Meeting; February 2003; New Orleans, La.
Pharmacologic mechanisms by which nicotine might cause harm

<table>
<thead>
<tr>
<th>NACHR subtype</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>α4β2*</td>
<td>Dopamine release, addiction, neuroplasticity</td>
</tr>
<tr>
<td>α3β4</td>
<td>Sympathetic stimulation, catecholamine release, CV toxicity</td>
</tr>
<tr>
<td>α7 homomeric</td>
<td>Endothelial dysfunction, angiogenesis, inhibition of apoptosis, anti-inflammation</td>
</tr>
</tbody>
</table>

Caveat regarding in vitro studies-normal homeostatic mechanisms not operative
Pharmacologic Effects of Nicotine

- Facilitates neurotransmitter release (e.g. dopamine)
- Sympathetic neural stimulation
- Immune suppression
- Oxidant stress
- Endothelial dysfunction
- Inhibition of apoptosis
- Promotes cell growth, including angiogenesis
Major Safety Concerns for Nicotine

- Addiction
- Cardiovascular disease
- Reproductive Toxicity
- Impaired Adolescent Brain development
- Infectious Disease Risk
- Cancer
- COPD

- Definite
- Probable
- Probable
- Possible
- Possible
- Possible
- Unlikely
Nicotine and Addiction

• Nicotine essential for tobacco addiction, but other factors enhance addictiveness

• Speed of nicotine delivery to brain is a key determinant

• Pattern of nicotine dosing and potential for addiction varies by delivery device
NICOTINE ADDICTION CYCLE

CIGARETTE SMOKING

NICOTINE ABSORPTION

AROUSAL MOOD MODULATION PLEASURE

CRAVING FOR NICOTINE TO SELF-MEDICATE WITHDRAWAL SYMPTOMS

DRUG ABSTINENCE PRODUCES WITHDRAWAL SYMPTOMS

TOLERANCE AND PHYSICAL DEPENDENCE
Nicotine intake from cigarette smoking

• Typical systemic nicotine intake 1 to 1.5 mg per cig; can vary from 0 to 4 mg

• Regular daily smoking of 15 cpd corresponds to 15 to 22 mg nicotine per day

• Corresponding cotinine levels 120 to 180 ng/ml
Daily Nicotine Exposure with various Nicotine Delivery Systems

• Swedish snus users and former smokers who use ECig only have similar cotinine levels to typical cigarette smokers

• Experimental switching studies – ECig users can achieve similar nicotine intake to when smoking

• Titration of nicotine intake seen across ECig products
E-Liquid nicotine concentrations do not predict daily nicotine exposure

<table>
<thead>
<tr>
<th>Nicotine Concentration</th>
<th>Blood/saliva Cotinine</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 mg/ml</td>
<td>430 ng/ml</td>
</tr>
<tr>
<td>22.5 mg/ml</td>
<td>316 ng/ml</td>
</tr>
<tr>
<td>59 mg/ml</td>
<td>172 ng/ml (50 – 313)</td>
</tr>
</tbody>
</table>
Nicotine in E-cigarettes

• Nicotine levels in E-liquids vary from 0 to 100 mg/ml.
• Nicotine delivery depends on temperature of coil, nicotine content of liquid and PG/VG ratio.
• Higher nicotine concentration results in high pH. Nicotine salts result in lower pH.
• pH of liquid may influence sensory characteristics, site of nicotine absorption and absorption rate.
Characterization of Nicotine Salts in 23 E-cigarette Refill Liquids

(Harvanko et al, under review)

- Salts: lactic (11), benzoic (8), levulinic (4), salicyclic (2), malic (2), tartaric (1), unkn (1)
- 3 liquids contained multiple salts
- Nicotine avg 45, range 20 to 89 mg/ml
- pH avg 4.9, range 3.5 to 6.8
Free Base Nicotine Fraction in Commercial E-liquids

Flavor (nicotine)
- 'Placid' (3 mg/mL)
- JUUL 'Fruit Medley' (58 mg/mL)
- JUUL 'Crème Brulee' (56 mg/mL)
- 'Maui' (6 mg/mL)
- 'Taurus' (3 mg/mL)
- 'No. 88' (5 mg/mL)
- 'Galactica' (3 mg/mL)
- 'Snake Oil' (12 mg/mL)
- 'Snow White's Demise' (12 mg/mL)
- 'Maui' (27 mg/mL)
- 'Zen' (17 mg/mL)

α_{fb}
Nicotine pharmacokinetic profile differs by delivery system – could have implications for addiction and other toxicity
Nicotine PK with E-cigarette use during standardized session

Plasma nicotine (ng/mL)

Time after last of 15 puffs (min)

- Subj 2, cartridge
- Subj 6, tank
- Subj 7, tank

St. Helen, Addiction 2015
Nicotine Pharmacokinetics Comparing Cigarettes to JUUL

# 1

# 2

# 3

Plasma Nicotine (ng/ml) vs. Time after last puff (min)

- Combustible
- Pod
Nicotine PK with ad libitum E-cigarette use

**Subj 4, RBA**

**Subj 9, cartridge**
Circadian Plasma Nicotine and Cotinine Concentrations with ad lib smoking and vaping (N=36), UCSF
Circadian Plasma Nicotine While Smoking Cigarettes or JUULing in Dual Users

Plasma Nicotine (ng/ml)

Time of day

#1

#2

#3

Combustible
Pod
Nicotine and Adolescent Brain Development

Nicotine interferes with prefrontal cortex maturation
Adolescent Behavior and the Brain

- Increased risk-taking, impulsivity, novelty-seeking
- Increased vulnerability to initiation and subsequent addiction to drugs
- Incomplete development of the prefrontal cortex: decision making, impulse control and executive function
Nicotine has effects on adolescent rat brain that persist into adulthood

- Delayed maturation of prefrontal cortex
- Persistent changes in dopamine release
- Anxiogenic phenotype in adulthood
- Persistent deficit in cognitive function
- Greater rewarding effects of drugs of abuse. Enhanced acquisition of nicotine and cocaine self-administration in adulthood
Caveats in interpreting human causation

• Most data on nicotine and brain development from studies in rats
• In people, difficult to distinguish effects of nicotine/tobacco from genetic and social environmental influences
National Youth Tobacco Survey

Past 30-Day Product Use by High School Students (9th - 12th Grade)

Prevalence (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cigarettes</th>
<th>E-Cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>2013</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>2014</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>2015</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>2016</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>2017</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>2018</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>2019</td>
<td>28</td>
<td>29</td>
</tr>
</tbody>
</table>
National Youth Tobacco Survey - 2017

Past 30-Day Use by 6th - 12th Grade E-Cig Users

- 1-2 Days: 40%
- 3-5 Days: 16%
- 6-9 Days: 9%
- 10-19 Days: 8%
- 20-29 Days: 6%
- All 30 Days: 9%
Among E-Cigarette Users: Frequency in Past 30 Days

- High Schoolers:
  - < 20 Days: 60%
  - ≥ 20 Days: 30%
  - Daily: 10%

- Middle Schoolers:
  - < 20 Days: 80%
  - ≥ 20 Days: 15%
  - Daily: 5%
Reproductive Toxicity of Nicotine
Reproductive Toxicity of Nicotine

- Fetal neuroteratogenesis
- Impaired neonatal lung development
- Adverse effects of snus on pregnancy:
  - Low birth weight
  - Pre-term delivery
  - Preeclampsia
  - Spontaneous abortion

*Smoking, Snus and Pregnancy Outcomes*

<table>
<thead>
<tr>
<th></th>
<th>Cigarette</th>
<th>Snus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small for Gestational Age</td>
<td>2.99</td>
<td>1.25</td>
</tr>
<tr>
<td>Preterm Delivery</td>
<td>1.57</td>
<td>1.98</td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>1.58</td>
<td>0.63</td>
</tr>
</tbody>
</table>

Risk of Swedish Snuff Use (Snus) during Pregnancy

7000+ pregnant snus users

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stillbirth</td>
<td>1.6</td>
<td>1.1-2.3</td>
</tr>
<tr>
<td>Preterm birth</td>
<td>1.38</td>
<td>1.04-1.83</td>
</tr>
<tr>
<td>Pre-eclampsia</td>
<td>1.11</td>
<td>0.97-1.28</td>
</tr>
</tbody>
</table>

Wikstrom et al. Epidemiology 21: 772, 2010
BJOG 117: 1005, 2010
Hypertension 55: 1100, 2010
Cardiovascular Safety of Nicotine
Constituents of Tobacco Smoke and EC Aerosol that could contribute to CVD

- Oxidizing chemicals #
- Carbon monoxide *
- Volatile organic compounds #
- Particulates
- Heavy metals #
- Nicotine

* Not present in EC aerosol
# Present at much lower levels
Hemodynamic Effects of Nicotine

- Increased heart rate and BP
- Increased myocardial contractility and myocardial work
- Coronary vasoconstriction & Reduced coronary flow reserve
- Cutaneous vasoconstriction
- Skeletal muscle vasodilation
Circadian Heart Rate Effects of Cigarette Smoking and E-Cigarette Use

Heart rate acceleration indicates persistent sympathetic neural activation
Other Consequences of Nicotine-induced Sympathetic Neural Activation

- Arrythmogenesis (risk of sudden cardiac death)
- Lipid abnormalities
- Insulin resistance and diabetes
- Inflammation (splenocardiac axis)
Mechanisms by which E-cigarettes could cause Acute CV Events

E-cigarette Aerosol

- Oxidizing Chemicals
  - Particulates
  - Acrolein
- Nicotine
  - Sympathetic Nervous System Activation
  - Catecholamine Release
- Inflammation
- Platelet Activation
  - Thrombosis
- Endothelial Dysfuncion
- Coronary Vasoconstriction
- Myocardial Blood Flow
- Coronary Occlusion
- Myocardial Ischemia
- Myocardial Infarction
- Sudden Death

- ↑ Heart Rate
- ↑ Blood Pressure
- ↑ Myocardial Contractility
- ↑ Myocardial Demand for oxygen and nutrients
  - Ventricular Arrhythmogenesis

- Myocardial Demand for oxygen and nutrients
- Heart Rate
- Blood Pressure
- Myocardial Contractility

- Coronary Vasoconstriction
  - Myocardial Blood Flow
  - Coronary Occlusion
  - Myocardial Ischemia
  - Myocardial Infarction
  - Sudden Death
Health Effects of Smokeless Tobacco: Natural Experiment on Effects of Nicotine without Combustion Toxicants
Snus Products

Swedish snus

American snus

WARNING: This product is not a safe alternative to cigarettes.
Smokeless Tobacco and CVD: Swedish Snus

• Similar daily nicotine exposure, but slower absorption
• No effect on platelet activation or carotid intimal thickness
• Case control studies – no increase in risk of MI or stroke; small but significant increase in case fatality
• Increased mortality with continued snus after MI
• Increased risk of heart failure, but not atrial fibrillation

Arefalk, 2014

Mortality (per 1000 pyr)

<table>
<thead>
<tr>
<th></th>
<th>Snus</th>
<th>Cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q</td>
<td>9.7</td>
<td>13.7</td>
</tr>
<tr>
<td>U</td>
<td>18.7</td>
<td>28.4</td>
</tr>
</tbody>
</table>

UCSF Center for Tobacco Control Research and Education
Conclusions: Nicotine and Cardiovascular Disease

• Biological plausibility and epidemiological evidence that nicotine may contribute to acute CV events
• Short term nicotine use poses little CV risk
• Long term nicotine use may be harmful in the presence of CVD
Nicotine and Respiratory Disease
Nicotine and respiratory disease: possible mechanisms

• Immune suppression
• Promotion of airway and smooth muscle proliferation
• Oxidative stress
• Reduced cough reflex and ciliary function
• Acute lung injury (high dose)
• Impaired in utero lung development
• Emphysema-like changes in rodents
Nicotine cholinergic immunosuppression:

Enhances survival in animal models of immune disease

Nasal mRNA changes in Ecig users suggest immune down-regulation

Ecig aerosol increases mortality from respiratory infection in mice

No human epidemiology on nicotine and infection

Sussan, PLoS ONE 2015
Nicotine Impairs Clearance of Influenza Virus in Mice

Viral Load, qPCR

Failure to control the infection

mRNA Expression Relative to GAPDH

Days Post Infection

FFU/ml at day 7/ mean of group at day 1

Gotts, UCSF, 2019
Unpublished Data
Nicotine and Chronic Lung Disease
Emphysema-like changes in mice
No human epidemiology

PBS 0 mg/ml Nicotine 18 mg/ml Nicotine

Garcia-Arcos, Thorax 2016
Electronic cigarettes disrupt lung lipid homeostasis and innate immunity independent of nicotine

Matthew C. Madison, … , David B. Corry, Farrah Kheradmand

*J Clin Invest.* 2019. [https://doi.org/10.1172/JCI128531](https://doi.org/10.1172/JCI128531).
Histological Changes in Lung Tissues Following 4 Months of Exposure
Lipid Accumulation in Alveolar Macrophages

**A**

- **Air**
- **Smoke**
- **ENDS-vehicle** (arrows indicate lipid accumulation)
- **ENDS-nicotine** (arrows indicate lipid accumulation)

**B**

- **Oil Red O**
  - **Air**
  - **Smoke**
  - **ENDS-vehicle**
  - **ENDS-nicotine**
Conclusions: Nicotine and Respiratory Disease

• Biological plausibility that nicotine may result in greater and/or more severe respiratory infection risk

• While such risk has been observed in cigarette smokers, there are no data in snus or e-cigarette users

• Conflicting evidence on nicotine and emphysematous changes
Statement from FDA Commissioner Scott Gottlieb, M.D., and Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., on FDA’s ongoing scientific investigation of potential safety issue related to seizures reported following e-cigarette use, particularly in youth and young adults.

For Immediate Release: April 03, 2019
Statement From: Commissioner of Food and Drugs - Food and Drug Administration
Scott Gottlieb M.D.
Principal Deputy Commissioner - Office of the Commissioner
Amy Abernethy MD PhD.
Conclusions

• Nicotine can potentially affect every organ system in the body. Various potential harmful effects and mechanisms are suggested by studies of nicotine in cells and animals.

• Addiction is expected with regular use of nicotine, but its health consequences are determined primarily by the delivery system.

• Primary nicotine addiction associated with vaping in non-smokers (youth and young adults) is increasing with unknown long-term health consequences.
Conclusions

• Nicotine is a reproductive hazard and should be avoided during pregnancy, unless it is used to support smoking cessation

• Nicotine is much less hazardous to cardiovascular health than smoking, but may contribute to acute CV events, particularly in the presence of CV disease

• There is biological plausibility for nicotine to enhance infectious disease risk, promote cancer and to contribute to chronic lung disease, but risk likely low based on safety record of Swedish snus
SAFETY IS NOT AN ABSOLUTE MEASURE BUT RATHER REFLECTS A CONCLUSION THAT THE DRUG’S BENEFITS OUTWEIGH THE RISKS
Q&A

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SCLC’s next live webinar

• January 30, 2020
• On the social stigma of smoking with Dr. Jason Satterfield of UCSF
• Registration will be available after the New Year!
Contact us for technical assistance

- Visit us online at smokingcessationleadership.ucsf.edu
- Call us toll-free at 877-509-3786
- Please complete the post-webinar survey