Updates on Vaping: Policy and Health Implications

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Disclosures: None

Gary Ewart is a full time employee of the American Thoracic Society – views expressed in his presentation are his and not necessarily reflective of the views of the American Thoracic Society
Objectives

1. Appreciate that vaping products are diverse and rapidly changing and therefore hard to study
2. Recognize that the epidemiologic trend in EC use is unprecedented and demands our attention as health care providers
3. Understand that health harms of EC use are incompletely understood but the potential for harm is real
4. Learn about the scope (and limitations) of the FDA’s authority to regulate tobacco products
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Atomiser
What’s in the e-Liquid/Juice?

1) Nicotine
2) Flavoring chemicals
3) Solvents (e.g. propylene glycol, glycerin)

+- Contaminants (e.g. toxic metals, endotoxin, fungal glucans)
Nicotine (e.g. 24 mg/mL)

• Bad for a developing brain
  • Long-term structural and functional changes
  • Reduced cell number & size of cells in the cerebral cortex, midbrain, hippocampus (memory and attention), prefrontal cortex (executive fn)
  • Higher rates of ADHD and poor impulse control

• Addictive
  • How do you help a 17 year old with a nicotine addiction?
7,700 different flavors\(^1\)

- Youth appealing (e.g. Mango, crème brulee)
- Diacetyl found in 76% of tested E-cig products
  - Even if a product explicitly stated otherwise\(^2\)
- Other toxic chemicals are common\(^3\)
  - E.g. Mint & Menthol contain high levels of Pugelone, a carcinogen\(^4\)

1. Zhu Tobacco Control 2014
2. Allen Environ Health Perspect 2016
4. Jadda JAMA 2019
Figure 6. Postulated pathways and byproducts formed during thermal dehydration of propylene glycol and glycerin.
Cannabis Concentrates

- **Crumble**: Dried oil with a honeycomb-like consistency.
- **Badder/Budder**: Concentrates whipped under heat to create a cake-batter-like texture.
- **Shatter**: A translucent, brittle, & often golden to amber colored concentrate made with a solvent.
- **Distillate**: Refined cannabinoid oil that is typically free of taste, smell & flavor. It is the base of most edibles and vape cartridges.

- **Crystalline**: Isolated cannabinoids in their pure crystal structure.
- **Dry Sift**: Ground cannabis filtered with screens leaving behind complete trichome glands. The end-product is also referred to as kief.
- **Rosin**: End product of cannabis flower being squeezed under heat and pressure.
- **Bubble Hash**: Uses water, ice, and mesh screens to pull out whole trichomes into a paste-like consistency.
Vaping cannabis

- Hash oil (dabs), THC wax/oil, or CBD
- Compared to the same doses of smoked cannabis:
  - Greater cognitive and psychomotor impairment
  - Higher blood THC concentrations
- Odorless
Cannabis Vape Products

• Not regulated by the FDA
  • Some states require companies to submit to random independent testing of their products before they go to market
• Hard for academic institutions to study
• Black market
Vaping Bad: Were 2 Wisconsin Brothers the Walter Whites of THC Oils?

As the authorities work to understand the spate of vaping-related lung illnesses, a small-town drug bust offers a closer look at the vast black market for vaping supplies.
How to take a vaping history?

• Type of device used
• Types of liquid used (nicotine, cannabis, flavors, homemade or commercial products)
• Details of vaping behavior (frequency of puffs, ‘stealth or zero vaping’)

UVA Health
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EC epidemic in youth

<table>
<thead>
<tr>
<th>Year</th>
<th>USA ¹</th>
<th>Canada ²</th>
<th>England ²</th>
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<tbody>
<tr>
<td>2017</td>
<td>11.7%</td>
<td>8.4%</td>
<td>8.7%</td>
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<tr>
<td>2018</td>
<td>20.8%</td>
<td>14.6%</td>
<td>8.9%</td>
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<tr>
<td>2019 ³</td>
<td>27.5%</td>
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11.7% of 12th graders in the US vape nicotine DAILY ⁴

1. 2018 CDC Youth Tobacco Survey
2. Hammond BMJ 2019
3. HHS.GOV
4. Miech NEJM Sept 18, 2019
University of Virginia

When questioned if use in the past 30 days

• Vaping – 22%
  • IFC Chapter Members – 52%

• Tobacco (e.g., cigarettes, dip) – 11%
  • IFC Chapter Members – 39%
Tobacco product use among high school students—2018

- ANY TOBACCO PRODUCT: 27.1%
- E-CIGARETTES: 20.8%
- CIGARETTEs: 8.1%
- CIGARS: 7.6%
- SMOKELESS TOBACCO: 5.9%
- HOOKAH: 4.1%
- PIPE TOBACCO: 1.1%

‘Juuling’: The most widespread phenomenon you’ve never heard of

A Juul e-cigarette for sale at Fast Eddie’s Smoke Shop. Shoppers must be 21 years of age. –Suzanne Kreiter/Globe Staff
“Put in historical context, the absolute increases in the prevalence of nicotine vaping among [high school students] between 2017 and 2018 are the largest ever recorded by Monitoring the Future in the 44 years that it has continuously tracked dozens of substances.”
Why the teen epidemic?

1) It’s used by a friend or a family member (39%)
2) The available flavors such as mint, candy, fruit or chocolate (31%)
3) The belief that they are less harmful than other forms of tobacco such as combustible cigarette (17%)
   • 2 out of 3: “It can be part of a healthy lifestyle
   • 4 out of 10: didn’t know they were inhaling nicotine

2018 CDC Youth Tobacco Survey
Marketing & Access

• 78% of middle & high school students in 2016 had seen a TV advertisement for E-cigarettes\(^1\)

• Sold on every street corner & every corner of the internet
  • 400+ websites to buy E-cigarettes online\(^2\)

1. Marynak, MMWR 2018
2. Hsu, J Med Internet Res 2018

www.Reddit.com/nostalgia
Reece!
What 2 cereals?
E-liquid

Food product

https://www.fda.gov/
Figure 2  Number of JUUL-related tweets on twitter 2015–2017.
10.8 million US adults use EC’s
Cannabis Vaping Epidemiology

• 2019: North Carolina Youth Tobacco Study
  • 9.6% of high school students have vaped cannabis¹

• 2018: 7.8% of 10th graders never smoked combustible cannabis but had vaped²

• 10th graders in the US: 9% (2017) and 14% (2018)³

1. Kowitt BMJ Open 2019
2. Peters JAMA Net Open 2018
3. MonitoringtheFuture.org
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Combustible cigarettes kill people

- 600 ingredients
- >7,000 chemicals
- 50 known carcinogens
- Carbon monoxide
- Tar

Tobacco use causes 1 in 10 deaths among adults worldwide. More than 7 million deaths per year.

Tobaccofreekids.org
Long term **Cigarette smoke** MUCH more **toxic** than EC aerosol
<table>
<thead>
<tr>
<th>Toxin</th>
<th>Combustible: EC</th>
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<tbody>
<tr>
<td>Formadehyde</td>
<td>9</td>
</tr>
<tr>
<td>Acetaldehyde</td>
<td>450</td>
</tr>
<tr>
<td>Acrolein</td>
<td>15</td>
</tr>
<tr>
<td>Toluene</td>
<td>120</td>
</tr>
<tr>
<td>NNN</td>
<td>380</td>
</tr>
<tr>
<td>NNK</td>
<td>40</td>
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Are EC’s a Harm Reduction Tool Useful In Smoking Cessation?
Royal College of Physicians & American Thoracic Society

“E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking”

Very low quality of evidence: Small # of trials with small sample sizes, methodological flaws, wide confidence intervals and some trials show no benefit
Royal College of Physicians & American Thoracic Society

“The hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco”

Based on expert opinion in 2014
• Lots of evidence has subsequently emerged (carcinogens, irritants, VAPI, youth epidemic, etc)
Long term **Cigarette smoke** MUCH more **toxic** than EC aerosol

But that **DOESN’T mean** EC’s are a healthy choice
Lung Injury
Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping
380 cases of lung illness (6 deaths)

Case Definition:
1) Vaping or Dabbing during the 90 days before symptom onset
2) Chest infiltrate
3) Absence of infection on initial workup (RVP, sputum)
4) No evidence of alternative cause (cardiac, rheumatologic, etc)

CDC.Gov (As of 9/11/2019)
Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin — Preliminary Report

Jennifer E. Layden, M.D., Ph.D., Isaac Chinai, M.B., B.S., Ian Pry, Ph.D., Anne Kimball, M.D., Mark Layer, M.D., Mark Tenforde, M.D., Ph.D., Livia Navon, M.S., Brooke Hoots, Ph.D., Phillip P. Salvatore, Ph.D., Megan Elderbrook, M.P.H., Thomas Haupt, M.S., Jeffrey Kanne, M.D., et al.

• N=53
• Median age 19 (range: 16 to 53)
  • 32% < 18 years old
  • 83% white males
• Rare underlying PMH other than asthma (30%)
• No geographic clustering
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<tbody>
<tr>
<td><strong>N=53</strong></td>
<td></td>
</tr>
<tr>
<td>Nicotine</td>
<td>61%</td>
</tr>
<tr>
<td>Nicotine ONLY</td>
<td>17%</td>
</tr>
<tr>
<td>THC</td>
<td>80%</td>
</tr>
<tr>
<td>THC ONLY</td>
<td>37%</td>
</tr>
<tr>
<td>Nicotine and THC</td>
<td>44%</td>
</tr>
<tr>
<td>CBD</td>
<td>7%</td>
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WDHS and IDPH Cohort

- 87% dyspnea, 83% cough, 55% chest pain
  - Not common: rhinorrhea, sneezing, congestion
- Tachycardia, tachypnea, hypoxia
- 87% with leukocytosis
  - Median WBC 15.9K, PMN predominant
  - None with Eo’s > 2%
- 70% with Nausea / Vomiting
- All had bilateral chest infiltrates
2 patients met *definite* case definition
- 56M (Nicotine, 2017)
- 43M (CBD in Juul, 2019)

2 patients met *probable* case definition
- 43F no infxn w/o (Nicotine, 2019)
- 37M bacterial PNA (Nicotine, 2019)
6 VAPI cases in Utah underwent BAL

<table>
<thead>
<tr>
<th>Lipid-Laden Macrophages (Oil-Red-O Stain)</th>
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<tbody>
<tr>
<td>50%+</td>
<td></td>
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<td>50%</td>
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<tr>
<td>30%</td>
<td></td>
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<tr>
<td>25%</td>
<td></td>
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<tr>
<td>75%+</td>
<td></td>
</tr>
<tr>
<td>60%</td>
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Is Vitamin E Acetate to blame?

- Found in 10 of the 18 THC samples tested by the FDA and in “nearly all” of the THC products tested by the NY state health department lab
- Not found in any of the nicotine products used by those with VALI
Is it the flavorings? Oils? Contaminants?

• Or a combination?
New or Newly Recognized?

• Newly recognized!
  • Surveillance systems (state and national) are newly established

• New!
  • The rate of severe respiratory illness doubled in Illinois from the summer of 2018 to summer of 2019
Injury from E-Cigarette Explosion
7,700 flavors, some of which are toxic?
Epidemic in teenagers?
Devices exploding & breaking faces?
Mystery Lung Illness kills 6 and harms ~380?

Where are all the grownups?
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What Do Medical Societies Do?
Medical Professional Societies

The Obvious Things Professional Societies Provide

We Meet
We Provide CME
We Publish Peer Reviewed Journals
We Publish Clinical Practice Guidelines
ATS International Conference

3rd week of May annually

- Attracts 16,000 attendees, 45% outside of US
- Key international scientific meeting for pulmonary, critical care and sleep research
- CME Opportunities via PG courses, symposia, etc
ATS Journals

- American Journal of Respiratory and Critical Care Medicine (15.24)
- American Journal of Respiratory Cell and Molecular Biology (3.79)
- Annals of the American Thoracic Society (4.01)
- ATS Scholar (open access journal starting 2020)
ATS Clinical Practice Guidelines – Published 2018

• Primary Ciliary Dyskinesia
• Idiopathic Pulmonary Fibrosis
• Weight management in OSA
• Malignant Pleural Effusions
ATS Clinical Practice Guidelines – Expected 2019

- Pediatric Home Oxygen Therapy
- Community-acquired pneumonia
- Drug-resistant tuberculosis
- Fungal infections
- Non-tuberculous Mycobacterial infections
- Severe asthma
- Obesity hypoventilation syndrome
What Do I Do for the ATS?

Public Policy for the ATS

I staff committees:

• Joint ATS/CHEST Clinical Practice Committee – coding, billing, regulation
• Environmental Health Policy Committee – air quality, climate change
• Health Equality and Diversity Committee – internal diversity, external access to quality care
• Quality Improvement and Implementation Committee – development and implementation of physician quality measures
• Tobacco Action Committee – tobacco control policy
FDA Regulation of E-cigarettes: What Is Going On?
Regulation of Tobacco Products

1994 – FDA issues a proposed rule to regulate tobacco products as medical devices. FDA asserts the tobacco industry was aware of the pharmacological effects of nicotine and manipulated nicotine levels to increase addiction.

1996 – Court rules (Brown & Williamson v FDA) the agency oversteps its regulatory authority. Essentially says only Congress can explicitly grant FDA authority to regulate tobacco products.

2009 – Congress passes Family Smoking Prevention and Tobacco Control Act. Law gives FDA broad power to regulate the manufacture, content, marketing, labeling and distribution of tobacco products.
Tobacco Control Act - Authority

• Granted FDA immediate authority to regulate cigarettes
  – Manufacture
  – Ingredients/nicotine levels
  – Marketing/advertising
  – Labeling
  – Health or reduced harm claims
• Immediately banned flavored cigarettes (except menthol)
• Established timeline for graphic warning labels for cigarettes
• Banned deceptive terms like “light” “low-tar” from tobacco advertising
• Gave FDA authority to “deem” authority over other tobacco products via regulation
• Products on the market as of 2/15/2007 are “grandfathered products” i.e. not subject to FDA new product review
• Products entering the market after 2/15/2007 must either
  – Demonstrate substantial equivalence to existing tobacco product, or
  – Be reviewed by FDA as a new tobacco product
• New tobacco products will be held to a public health standard – approval of the product is intended to improve public health (reduce harmed, reduce addiction etc.)
Tobacco Control Act - Limits

FDA cannot ban tobacco products
FDA can limit nicotine content, but cannot reduce nicotine levels to zero
FDA cannot raise the federal purchase age
FDA cannot raise taxes on tobacco**
2009 – FDA seeks to block importation of Smoking Everywhere and Njoy e-cigarettes from China saying e-cigarette products are medical devices and therefore subject to FDA authority and intervention

2010 District Court rules (Sottera v FDA) FDA overstepped its authority and cannot regulate e-cigarettes as medical devices. FDA appeals and Court of Appeals reaffirms lower court decision

**Key Take Away** – as long as e-cigs companies don’t make therapeutic health claims, FDA must regulate e-cigarettes as tobacco products
• 2016 FDA issues final deeming rule expressing authority over all tobacco products (e-cigs, cigars, hookahs, smokeless and novel nicotine products)
• Establishes August 2018 deadline for all tobacco products to
  – Document presence in the US market as of 2/15/2017, or
  – Document “substantial equivalence” to existing tobacco product, or
  – Submit pre-market tobacco application (PMTAs) for review by FDA
• Industry files several lawsuits challenging FDA authority to regulate tobacco products (Cigar Association v FDA status: oral arguments pending) (En Feugo v FDA status: oral arguments held) (Nicopure Labs v FDA status: oral arguments held)
In addition to being a physician, Dr. Gottlieb held a position with Kure, a vape store franchiser that both sells electronic cigarette products and promotes “vaping” lounges that the company says will 'bring the passionate art of vaping to the everyday consumer.' The nominations documents state that Dr. Gottlieb held a position with the company until May 2016 and had a financial interest in the company during his nomination process.

Dr. Gottlieb has made many public statements indicating his support for e-cigarettes as a potential tobacco harm reduction strategy for adult smokers.

For more information about Kure visit:  www.kurevapes.com
Gottlieb FDA

2017 – Dr. Gottlieb announces delay in FDA tobacco product review
- E-cigarette product applications delay from August 2018 to August 2022
- Cigar product applications delayed from August 2018 to August 2021
- Additional time is granted to allow industry time to prepare product applications
- Skeptics think the delay will be used to increase e-cigarette market share

2018 – Dr. Gottlieb issues 3 advanced notice of proposed rule makings
- Low nicotine cigarette proposal
- Regulation of cigars
- Regulation of tobacco flavors
Things start to go wrong...
November 2018 – Data shows 78% increase in youth e-cigarette use
  – Youth e-cigarettes rose from 11.7% in 2016 to 20.8% in 2018
  – 2015 to 2016 decrease youth use (16.0% - 11.3%) while 2016 to 2017 showed small increase (11.3% - 11.7%)

Gottlieb announces several steps FDA “intends” to take
  – Accelerating e-cigarette application deadline from August 2022 to August 2021
  – Limiting sales of flavored e-cigarette products to mint and menthol only in brick and mortar stores (except for 18 only establishments)
  – Creating enhanced verification for online sales of other e-cigarettes
  – Moving forward with a ban on menthol cigarettes and candy flavored cigars
  – No final rule or guidance was issued to implement the above actions

March 2019 – Dr. Gottlieb steps down as FDA Commissioner
American Academy of Pediatric sues FDA in federal court for failure to appropriately regulation e-cigarette products. ATS joins case as an amicus filer. Court initially holds case in abeyance siting FDA’s announced intent to regulate e-cigarettes. Court later reverses decision and orders (AAP v FDA) FDA to accelerate product application deadline from August 2021 to March 2020 with final decision required by May 2021.
More things go wrong...
Case reports start coming in on acute illnesses

- 530 CDC confirmed cases in 38 states of vape-associated pulmonary injury (as of 9/19/19)
- 7 CDC confirmed deaths from vape-associated pulmonary injury
- First confirmed case in Canada
“The Trump Administration is making it clear that we intend to clear the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use that is impacting children, families, schools and communities” HHS Sec Alex Azar (9/11/19).

“..thank the President for his unqualified support for this critical public health initiative...” HHS Sec. Alex Azar (9/11/19)

"It'll take several weeks for us to put out the final guidance that will announce all the parameters around the enforcement policy, and then there will likely be about a 30-day delay to effective date, as is customary," Azar said. “…at that point all flavored e-cigarettes other than tobacco flavor would have to be removed from the market.” HHS Alex Azar.

Sounds like a ban, right? Well....
“clearing the market...” is not a regulatory or a legal term. There is some of wiggle room in that statement.

And then Trump muddies the water...via tweet...
"While I like the Vaping alternative to Cigarettes, we need to make sure this alternative is SAFE for ALL! Let's get counterfeits off the market, and keep young children from Vaping!“ (President Trump tweet 9/13/2019)

Prior to Trump tweet, counterfeit e-cigarettes had not been a key part of the vaping associated lung disease discussion.
ATS Position on E-cigarette

- FDA should ban all characterizing e-cigarette flavors
- If FDA chooses not to ban characterizing flavors FDA should require pre-market testing of flavoring agents with known or suspected respiratory toxicity (benzaldehyde, vanillin, cinnamaldehyde, diacetyl)
- Require full disclosure of all e-cigarette ingredients
- Require graphic warning labels on e-cigarette products
- Regulation of explicit and implied health claims related to e-cigarette products (harm reduction, smoking cessation)
- Regulation of the nicotine level in cigarettes
- Call upon Congress to raise excise taxes on e-cigarette products*
E-cigarette Regulation – What’s Next?

- In the coming weeks – FDA to issue final guidance on e-cigarettes
  - Remove all non-tobacco flavored e-cigarettes from the U.S. market
  - 30 day implementation period
  - Require all e-cigarette products to go through FDA review
- HHS Sec. Azar/Acting FDA Commission Sharpless say FDA may take further action if youth use of tobacco-flavored e-cigs increases
- FDA may issue stricter rules on where and how e-cigarettes can be sold
- Wpost reports FDA opens criminal investigation of vape supply chain (9/19/19)
- Note: The FDA review process DOES NOT preclude FDA from reviewing/approving flavored e-cigs
Industry Response

- Juul has stated publicly is intent to preserve mint and menthol flavors
- Vape association was on the Hill this week urging enactment of Tobacco-21 in exchange for preserving flavors
- Small business out reach to Republican members/Administration – don’t do this!
- And when FDA finally does act...take FDA to court!
Likely Issues to Be Challenged in Court

• What is a tobacco-flavored e-cigarette?
• What is a characterizing flavor?
• How do you define these terms for regulatory purposes?
• Expect these questions, and many more, to be litigated in court!
If You Believe E-cigs Should Be Regulated – What Can You Do?

• Contact your member of Congress and urge Congress to do nothing (don’t stop, weaken or delay FDA action).
• Contact the White House to express your support for removing flavored e-cigarette products from the market
• Social media posts in support of FDA action on e-cigarettes
• Consider submitting comments on other tobacco policies
  – Hazardous or Potentially Hazardous Substances in Tobacco Products (10/4/19)
  – Tobacco Products; Required Warnings for Cigarette Packages and Advertisements (10/15/19)
Things I didn’t talk about today but could have...

• Why are menthol cigarettes still on the market and is FDA going to do anything about them?
• Why are candy flavored cigars on the market and is FDA going to do anything about them?
• How does the state and federal push for Tobacco-21 impact e-cigarette youth use?
• What is the correct ICD-10-CM code for recording e-cigarette related disease?
Questions
ATS Health Alert—
Vaping Associated Pulmonary Illness (VAPI)

Using electronic cigarettes, also called vaping or juuling, can be dangerous. There are many risks associated with vaping, regardless of which vaping system you use, or which vaping liquid you use. There are many different nicotine solutions of various concentrations, plus added chemicals and/or flavors, and none have been established as safe.

Recently, healthcare providers have seen a growing number of health concerns associated with vaping, including very serious lung problems. These problems are called “Vaping Associated Pulmonary Illness (VAPI)” or Vape Lung. In fact, as of September 2019, six people have likely died from VAPI, while others have become very sick, and required treatment in the intensive care unit (ICU) to recover. VAPI has been reported with use of nicotine, tetrahydrocannabinol (THC) and cannabidiol (CBD) products. Yet, the cause of vape lung is still not known and is being actively investigated.

Symptoms of Vaping Associated Pulmonary Illness

- Shortness of Breath
- Fever
- Cough
- Vomiting
- Diarrhea
- Headache
- Dizziness
- Chest pain

If you have any of these symptoms after vaping, contact your healthcare provider.

Key Points about Vaping

- Avoid use of electronic cigarettes
- Always keep all electronic cigarette devices, including concentrated nicotine solutions, out of reach of children
- If you are trying to stop smoking/vaping, talk with your healthcare provider about safe and effective medicinals to treat nicotine addiction and to help you to feel comfortable when not smoking/vaping or using tobacco
- For additional help in stopping smoking/vaping, join a local support group, call QUITNOW or visit The Truth Initiative Website at https://truth Initiative.org/research-resources/quit smoking-vaping/quitting-e-cigarettes

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Readers: Marloong Sookchar MD, DPH; Frank Leone, MD; Michelle Calio, PhD; and Francesca Katherine, MD
**Question:** We understand there are no specific ICD-10-CM codes to report for the use of e-cigarettes in 2018. In the absence of a specific code what should I report?

**Answer:** You are correct, presently there is no unique code(s) to document e-cigarette use. Absent a unique code, the ATS recommends F17.200 because the use of e-cigarettes is in patients who are nicotine dependent. We also believe that new ICD-10-CM codes to document e-cigarette use are necessary and the ATS has submitted a proposal for a new set of ICD-10-CM codes to document the use of e-cigarettes and/or electronic nicotine delivery systems (ENDS). The proposed codes work in parallel structure with the existing tobacco and nicotine codes. The ATS is optimistic that our proposed codes will be adopted soon.
