Electronic Nicotine Delivery Systems (ENDS) and Youth Vaping: What Providers Need to Know

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Thursday, November 12
3:00 – 4:00 PM EDT
Welcome!

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Housekeeping

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  - [https://www.bhthechange.org/resources/resource-type/archived-webinars/](https://www.bhthechange.org/resources/resource-type/archived-webinars/)
• Jointly funded by CDC’s Office on Smoking & Health & Division of Cancer Prevention & Control
• Provides resources and tools to help organizations reduce tobacco use and cancer among people with mental illness and addictions
• 1 of 8 CDC National Networks to eliminate cancer and tobacco disparities in priority populations

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Electronic Nicotine Delivery Systems (ENDS) and Young People Resource Guide

Link available in chatbox and in post-webinar follow-up email
Electronic Nicotine Delivery Systems (ENDS) and Youth Vaping: What Providers Need to Know

Tamanna Patel, MPH
Director, Practice Improvement
National Council for Behavioral Health
Tobacco and Behavioral Health

• While individuals with **behavioral health conditions** account for almost **40%** of all traditional cigarettes smoked by adults, they are also a **significantly vulnerable** group for high e-cigarette use. [1,2]

• Studies have shown:
  • people living with behavioral health conditions, like depression and anxiety, are **twice as likely to have tried e-cigarettes** and **three times as likely** to be users of battery-powered electronic nicotine delivery devices. [3]
  • individuals with mental illness often **combine e-cigarettes with** concurrent use of traditional **combustible cigarettes** which make them more at risk for nicotine addiction and susceptible to the effects of traditional tobacco. [4,5]
Youth, Behavioral Health, and Nicotine Dependency

Transitioning Brain Age (13-25 years old)
> Half of all lifetime mental illness start by mid-teens and three-fourths by mid-twenties [6]
> Strong relationship between youth who smoke and depression, anxiety, and stress [7]
> More than 80% of youth with substance use disorders report current commercial tobacco use, most report daily smoking, and many become highly dependent, long-term commercial tobacco users. [8]

ENDS, or vaping, acts as entry nicotine products that may lead to more nicotine products. [9]

Nicotine exposure during adolescence can:
> Harm brain development, which continues until about age 25.
> Impact learning, memory, and attention.
> Increase risk for future addiction to other drugs. [10]
COVID-19 & Youth Vaping:

A national online survey among those 13-24 years old was conducted in May 2020 [11]

Findings:

> COVID-19 diagnosis was
  - five times more likely among ever-users of e-cigarettes only
  - seven times more likely among ever-dual-users (cigarette and e-cigarette)
  - and 6.8 times more likely among past 30-day dual-users

Heightened exposure to nicotine and other chemicals in e-cigarettes adversely affects lung function, with studies showing that lung damage caused by e-cigarettes is comparable to combustible cigarette
Adapting screening tools such as Screening to Brief Intervention and Brief Scanner for Tobacco, Alcohol and Other Drugs to inquire about ENDS use


Counseling using 5As

Pharmacotherapy

NRT, patch, gum

Engage in conversations about the risks of ENDS use with youth and their support systems

Partner with key youth-serving stakeholders to expand reach and impact on preventing ENDS use and cessation
Sources


NATIONAL BEHAVIORAL HEALTH NETWORK
YOUTH ENDS USE AND BEHAVIORAL HEALTH

Presented by
Priscilla Callahan-Lyon, MD
Director
Division of Individual Health Science
Office of Science, Center for Tobacco Products

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.
AGENDA

- What are E-cigarettes
- How significant is the youth e-cigarette problem
- Nicotine and the adolescent brain
- Health Risks of e-cigarettes
- What is FDA doing – overview of the regulatory approach
WHAT ARE E-CIGARETTES?
E-CIGARETTES*: A BRIEF OVERVIEW

- Available in China ~ 2003
- Introduced into the U.S. ~ 2007
- Manufactured by large and small tobacco companies
- Generally a battery operated product designed to heat a liquid (referred to as “e-juice” or “e-liquid”) into an aerosol that is inhaled by the user
- The e-liquid may contain propylene glycol, glycerin, flavorings, water, and usually nicotine
- Products are diverse in appearance
  - May resemble combusted cigarettes
  - Some are disposable
  - Some are reusable with ‘customizable’ features
  - May be small and easily concealed
- Many users use more than one product type

*E-cigarettes refers to Electronic Nicotine Delivery Systems (ENDS)
BASIC E-CIGARETTE ANATOMY
DIVERSITY OF E-CIGARETTES
HOW BIG IS THE YOUTH E-CIGARETTE PROBLEM?
2020 National Youth Tobacco Survey Data\(^1\)

- 19.6% high school students (3.02 million) and 4.7% middle school students (550,000) reported current e-cig use
- Among current users
  - 38.9% of high school students and 20% of middle school student used on 20 or more of the past 30 days
  - 82.9% used flavored e-cigarettes
  - High school users most commonly used prefilled pods or cartridges (48.5%), followed by disposables (26.5%) and tanks (14.8%)
  - Middle school users most commonly used prefilled pods or cartridges (41.3%), followed by tanks (21.5%) and disposables (15.2%)
- The most popular flavors (among those using prefilled pods or cartridges or flavored disposables) were fruit, mint, candy/dessert/sweets, and menthol

\(^1\) MMWR Sept 18, 2020 Vol 69 No 37
Decrease in youth use compared with 2019 data

2019: 27.5% of high school students
2020: 19.6% of high school students

2019: 10.5% of middle school students
2020: 4.7% of middle school students
National Youth Tobacco Survey (NYTS) – 2019

• Since 2014, e-cigarette use has surpassed cigarette smoking in high school students
• Students reporting there is ‘little or no harm’ for intermittent tobacco product use
• 57.8% of current youth tobacco product users report they are seriously thinking of quitting use of all tobacco products
• 2020 NYTS data confirms youth strongly prefer flavored products
• Among high-schoolers who use any type of flavored e-cigarettes
  – Fruit: 73.1%
  – Mint: 55.8%
  – Menthol: 37%
  – Candy, Desserts, Other Sweets: 36.4%
• Among middle-schoolers who use any type of flavored e-cigarettes
  – Fruit: 75.6%
  – Candy, Desserts, Other Sweets: 47.2%
  – Mint: 46.5%
  – Menthol: 23.5%
AND DON’T FORGET THE SOCIAL INFLUENCES
NICOTINE AND THE ADOLESCENT BRAIN
HEALTH IMPACTS OF NICOTINE

- The primary addictive substance in tobacco
  - 87% of adult smokers stated smoking before age 18
  - Half of adult smokers were addicted by age 18
- Readily absorbed through skin or mucous membranes
- When inhaled it reaches the brain within seconds
- Increases heart rate and blood pressure
- Adverse impact on developing brain
- Adverse pregnancy outcomes
- Adverse impact on both male and female reproductive systems
NICOTINE AND ADOLESCENTS

- Adolescents who initiated use at earlier ages are more likely than those initiating at older ages to report symptoms of tobacco dependence\(^1\)
- Nicotine exposure can also have long-term effects, including:
  - Decreased attention
  - Increased impulsivity
  - Both may promote the maintenance of tobacco use behavior\(^2\)
- Surgeon General’s 2010 Report noted that symptoms of dependence could result from even limited nicotine exposure during adolescence\(^3\)
- Youth may be unaware the e-cigarettes contain nicotine\(^4\)

1 - Apelberg et al., 2014
2 - Counotte et al., 2011
3 - U.S. Department of Health and Human Services, 2010
4 – Boykan et al., 2019
Nicotine negatively effects the developing brain

- Nicotine can rewire the brain to crave more nicotine, particularly because adolescent brains are still developing\(^1\)
- Nicotine exposure during adolescence may have long-lasting effects such as increased impulsivity and mood disorders\(^2, 3\)
- Nicotine exposure during adolescence may have long-term effects on parts of the brain responsible for addiction, learning, and memory\(^4-10\)
  - Higher levels of alcohol, tobacco, and marijuana use before age 19 correlated with smaller gray matter volume in parts of the brain involved in emotional processing and cognitive control
- Nicotine exposure during adolescence affects brain functions important for reward processing, which makes it easier for youth to become addicted to nicotine\(^11, 12\)

BUT IT’S JUST WATER VAPOR – RIGHT??
WHY ARE WE WORRIED ABOUT YOUTH AND E-CIGARETTES?
From 2015 – 2017 battery-related injuries from ENDS led to ~1000 ER visits/year\(^1,2\)

FDA received 41 reports to Safety Reporting Portal in 2018 and 25 in 2019

Rare events but the injuries can be devastating; at least one death\(^3\)

Exact causes are not clear

FDA published **Tips to Help Avoid "Vape" Battery Explosions** in Dec 2017
- Use devices with safety features – and don’t disable the features
- Keep loose batteries in a case; prevent contact with metal such as keys, coins
- Use the charger that came with your device, not a phone or tablet charger
- Don’t leave the device unattended to charge (e.g., overnight)
- Don’t charge it on a highly flammable surface (e.g., pillow or couch)
- Use only the recommended batteries for the device and replace damaged batteries
- Don’t expose the device to extreme temperatures (e.g., very hot or very cold car)

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1. CJ Corey et al., (2018)  
3. Rosenberg; Washington Post; May 17, 2018
SEIZURES/NEUROLOGICAL EVENTS

• From June-October 2018: CTP received three case reports of seizure in association with ENDS use*

• An additional 28 cases were identified through information submitted to American Association of Poison Control Centers (AAPCC)

• Due to the number of reports and the potential consequences, the FDA Commissioner made a public announcement April 3, 2019
  – Within one week, we received 73 reports
  – We know of 274 reports of seizures or neurological symptoms in e-cigarette users between Dec 19, 2010 and Dec 31, 2019
  – We continue to receive reports

* 5-10% of people will have a seizure in their lifetime

Graph created by CTP Tobacco Product Surveillance Team
SEIZURES AND ENDS: CURRENT STATUS

- FDA has not established if there is a direct relationship between the use of e-cigarettes (and other ENDS) and risk of seizures.
- The reports FDA has received to date have not identified a particular product, use pattern, or population of users that is at increased risk.
- FDA shared information to communicate potential safety concerns associated with the products we regulate.
- FDA continues to monitor all adverse experiences reported to the agency about the use of ENDS. We encourage clinicians, researchers and the public to report cases of individuals who use ENDS and have had a seizure or any other adverse experiences via CTP’s Safety Reporting Portal: www.safetyreporting.hhs.gov
E-CIGARETTE, OR VAPING, PRODUCT USE ASSOCIATED LUNG INJURY (EVALI)

FDA became aware in late July, 2019 after news reports from WI and IL

8 Wisconsin teens hospitalized with severe lung damage due to vaping, doctors suspect

By Susan Scutti, CNN
Updated 11:19 AM ET, Fri July 26, 2019

"All patients reported vaping prior to their hospitalization, but we don’t know all the products they used," Andrea Palm of the Wisconsin

Date: July 25, 2019

To: Wisconsin Healthcare Providers, Infection Preventionists, Local Health Departments, and Tribal Health Agencies

From: Jonathan Meiman, MD
Chief Medical Officer and State Occupational and Environmental Disease Epidemiologist, Bureau of Environmental and Occupational Health (BEOH)

Severe Pulmonary Disease Among Adolescents who Reported Vaping

PLEASE DISTRIBUTE WIDELY

During July 2019, 8 cases of severe pulmonary disease among adolescents were reported to the Wisconsin Department of Health Services (DHS). Patients resided in the counties of Milwaukee, Waukesha, and Winnebago and presented with respiratory symptoms including cough, shortness of breath, and fatigue. Symptoms worsened over a period of days or weeks before admission to the hospital. Other symptoms reported by some patients included fever, anorexia, pleuritic chest pain, nausea, and diarrhea. Chest radiographs showed bilateral opacities, typically in the lower lobes, and CT imaging of the chest showed diffuse ground-glass opacities, often with subpleural sparing. Evaluation for infectious etiologies was negative in all patients. Some patients had progressive respiratory compromise requiring endotracheal intubation but subsequently improved with systemic steroids.
EVALI INVESTIGATION

- Investigation involved coordinated response from FDA, CDC, and state health officials
- As of Feb 18, 2020, 2807 hospitalized cases had been reported to CDC from 50 states, DC, Puerto Rico, and US Virgin Islands; 68 deaths
- More common in non-Hispanic white males, 18 – 34 years old
- Many products were acquired from informal sources; e.g., friends, pop-up sales
- As of Oct 9, 2020, FDA had received > 1600 product samples; 1238 product samples have been linked to EVALI patients (the other samples were not suitable for analysis)
  - Many patients submitted several (up to 48) different product samples
  - Many product samples could not be tested (inadequate product quantity)
  - Tetrahydrocannabinol or other cannabinoids were commonly found in the products (53%)
  - Vitamin E acetate or other diluting agents were common in cannabinoid-containing products
  - Many patients submitted both nicotine- and cannabinoid-containing products
EVALI: CURRENT STATUS

- FDA and CDC are aware cases are still occurring, although less frequently – the current pandemic makes evaluation challenging
- Vitamin E acetate:
  - Is strongly linked to the EVALI outbreak and is a toxicant of concern
  - Has been found in product samples tested by FDA and state laboratories and in patient lung fluid samples tested by CDC from geographically diverse states
  - Has not been found in the lung fluid of people that do not have EVALI
  - Appears it began to be used as a diluent in THC vaping products in late 2018 – early 2019
  - Popular cutting agent – increases profit for seller, not readily detectible
  - Mouse-model study found evidence of pulmonary injury in mice that inhaled VEA that was not seen in mice inhaling air or propylene glycol/vegetable glycerin

There is not sufficient evidence to rule out the contribution of other chemicals to EVALI. FDA and CDC recommend people not use THC-containing e-cigarette, or vaping, products, particularly from informal sources. E-cigarette, or vaping, products should never be used by youths, young adults, or women who are pregnant. Adults who currently do not use tobacco products should not use e-cigarettes.
WHAT IS FDA DOING – AND HOW CAN YOU HELP?
On Dec. 20, 2019, the President signed legislation amending the FD&C Act to raise the federal minimum age of sale of tobacco products from 18 to 21 years

- Effective immediately, retailers must not sell any tobacco products to anyone under 21
- FDA & retailers are updating practices to implement the new law
- FDA expects retailers to follow the law & take measures to ensure an individual purchasing a tobacco product is 21 or older, including manually checking IDs when needed
- FDA has updated our website and is working to update other materials, including our regulations, to reflect the change in law
On Feb. 6, 2020, a new FDA policy prioritizing enforcement against certain unauthorized flavored e-cigarette products, including fruit and mint flavors, that appeal to children (also known as the ‘Compliance Policy’)* became effective.

The Deeming Rule, effective Aug 8, 2016, gave FDA regulatory authority over all e-cigarette and ENDS products – meaning all of these products need FDA authorization to be legally marketed. Some ENDS products have been marketed under enforcement discretion. This policy specifies which products that were on the market as of August 8, 2016 will be enforcement priorities for FDA.

The policy attempts to balance public health concerns related to youth use of ENDS products with considerations regarding addicted adult cigarette smokers who may try to use ENDS products to transition away from combustible tobacco products.

Because of the relatively low numbers of youth using menthol- and tobacco-flavored, cartridge-based ENDS products, these products were not among the initial enforcement priorities. FDA is taking actions to address youth use and can take additional steps if needed.

* https://www.fda.gov/media/133880/download
NEW TOBACCO PRODUCT APPLICATION REVIEW

- As of September 9, 2020, manufacturers were required to submit Premarket Tobacco Product Applications to FDA for all ENDS products.

- The applications must be reviewed by FDA and marketing authorization granted – otherwise, the products may not be legally marketed.

- There is a one year period for FDA review; products may continue to be marketed during this ‘grace period’ if the application has been submitted to FDA and is still under review.
FDA wants to know about unexpected health or safety problems that may have been caused by use of or exposure to a particular tobacco product.

www.safetyreporting.hhs.gov

What to Report:

- Overheating, fires, explosions, burns
- Neurological events
- Unusual events, toxic reactions
- Foreign material in the product
- Packaging, labeling issues

Anyone can submit a report

Provide as much detailed information as possible
THE REAL COST: TACKLING TEEN VAPING

Presented by
Alison Kulas, MSPH
Social Scientist, Office of Health Communication & Education
FDA Center for Tobacco Products

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.
As teen vaping has continued to increase, there is an increased importance to counteract this with large-scale, national media campaigns.

The evidence-based model used to develop “The Real Cost” cigarette advertisements is proven effective through years of research. This proven strategy is used to address the rise of youth vaping.

Since fall of 2018, we have released a suite of e-cigarette prevention advertisements for teens. This includes advertisements on TV, online radio, social media, and digital platforms popular to teens.

Additionally, in 2019 the campaign created posters to be displayed in high school bathrooms, distributed to all high schools across the country.
1. LEVEL OF AD AWARENESS AND RECEPTIVITY

- Audience exposure to and recall of campaign
- Audience reactions to and perceptions of campaign messages

Short-term Outcomes

2. CHANGE CAMPAIGN-TARGETED ATTITUDES AND BELIEFS

- Knowledge, attitudes, and beliefs

Intermediate Outcomes

3. CHANGE TOBACCO USE INTENTIONS AND BEHAVIORS

- Intention to use tobacco
- Tobacco use initiation, progression to established tobacco use

Longer-term Outcomes

Contextual factors (e.g., state-level policies, individual characteristics, other media campaigns)
UNDERSTANDING TEEN ENDS ADDICTION
• Our ads are steeped in research, using the following process:
BETWEEN 2019-2020 SIGNIFICANT DECLINE IN YOUTH E-CIG USE; BUT LEVELS REMAIN HIGH
• Teens are starting to see that addiction is a bad thing. In previous research, teens were dismissive of addiction, saying they are addicted to lots of things. Teens are starting to believe that addiction to vaping is a consequence and are starting to see negative emotional costs from vaping. However, they still want to hear about stronger, harmful health consequences.

• Teens acknowledged that addiction is emotional, not just physical. For some teens, vaping is a consistent part of their daily life and don’t like when it’s disrupted or suddenly limited.

• Teens mentioned friends or peers who would “fiend” for a vape or a hit. They acknowledge they’ve seen negative behavior like irritability and irrational anxiety about losing access to vaping during time away – e.g., a weekend trip with parents.

“I remember one time before a cheer competition this girl had a panic attack, she was like ‘I need my Suorin, I need my Suorin.’ We all ran to the bathroom right before we went on so she could hit it.”
– Hip Hop, ENDS Experimenter, Older, LA
Experimenter Older

- It makes people very irritable. Anything you say makes them want to just snap on you. I have this one friend, he’s super addicted, he walks into the bathroom every five minutes and his head twitches if he doesn’t have nicotine for more than five minutes. It literally looks like he’s possessed by it.

- Honestly, two of my best friends, actually, almost stopped being friends, because he refused to give the other guy the Juul. They literally got into a screaming match, cussed each other out, almost started fighting, because he refused to give it to him.

Dual Experimenter Older

- I think, yeah, they do blow things out of proportion. I remember one of my friends – he’s pretty addicted to nicotine – and we forgot to pick him up for the beach. We offered him an Uber, but he kept yelling at us and was just really upset at us. He would just blow things out of proportion.

Experimenter Younger

- A lot of people don’t consider themselves addicted. They are like “I like doing it when I want to do it.” They don’t consider it necessary but it is but they don’t really consider it like that. They don’t want to say they are addicted because it is not a nice word.

At Risk Older

- I knew a friend that wouldn’t even be able to sleep the night, have to wake up in the middle of the night like someone would get water, she would have to hit it.

At Risk Younger

- Yeah, my best friend. It’s where he’s desperate, like he needs it. He says he needs it, he can’t live without it. I don’t know why.
22.5%
Of high school current e-cig users used e-cigs daily

9.4%
Of middle school current e-cig users used e-cigs daily

Source: NYTS 2020
TEEN STORIES: MY VAPING MISTAKE

• The Real Cost campaign created **four video episodes** featuring different aspects of teen stories on how vaping affected their lives, through a collaboration with Awesomeness TV (media vendor).

• Launched in January 2020, the four videos (approx. 4 minutes each) aired on Awesomeness TV YouTube channel first. Then, **amplified through The Real Cost media** buy that includes TV, pre-roll online videos and social media channels such as Instagram, Facebook, Snapchat, and TikTok.

• The call-to-action at the end of video is to drive teens to **NCI’s How to Quit Vaping** page.
TEEN STORIES: MY VAPING MISTAKE

- https://www.youtube.com/playlist?list=PLBQgA3Kndk7d9sezilJ6rrDwU1T899wNJ
COPY TESTING: CHLOE

• Particularly effective among ENDS experimenters in both Perceived Ad Effectiveness and Messaging Effectiveness.
  – Particularly strong for being “informative,” “meaningful” and “convincing.”

• After viewing the ad, participants described the ad as:
  – “I would tell them it is about the consequences of vaping and that if they are already vaping they can quit like Chloe did.” -Male, 15, At-Risk
  – “Vaping damaged this girl’s mental health. It can worsen your anxiety and it is addicting.” -Male, 15, Exp

• Chloe made vaping look like something that teens DO NOT want to do
  – 95% of ENDS experimenters
  – 77% of ENDS established users
  – 88% of ENDS susceptible teens
• The “My Vaping Mistake” series has garnered over 2 million views in two months.

• The campaign’s online videos has generated nearly 3.6 billion teen views in 16 months. Across social media platforms, The Real Cost has engaged teen audiences with more than 958,000 likes, 132,000 shares, and 54,000 comments.

• Initial outcome evaluation results are positive and confirm that the majority of youth in the U.S. are being exposed to our ads and are receptive to our messages.

• Since launch, youth perceive e-cigarettes to be more harmful and have greater understanding that e-cigarette use can lead to serious consequences.

• Awareness of e-cigarette ads among teens nationwide is 81% and receptivity to campaign ads remains high based on perceived effectiveness.
Most vapes contain seriously addictive levels of nicotine.
Addiction isn’t pretty.
What drug is so addictive you’d hurt the ones you love to get more?

Most vapes contain seriously addictive levels of nicotine.

Addiction isn’t pretty.
• ‘The Real Cost’ Youth E-Cigarette Prevention Campaign is laser-targeting the media to effectively reach 12- to 17-year-olds via their media passion points

• Over 10.5 Billion teen impressions (eyes on messaging) since campaign launch
NCI and CTP launched new e-cigarette cessation content on SmokeFree Teen, giving comprehensive behavioral techniques to help teens deal with cravings, navigate peer pressure, prepare to quit, and make it through their quit day.

Since launch in July 2019, there have been over half a million page views.

The most time is spent on these pages:

- How to Quit Vaping – over 4 minutes spent
- Vaping Addiction and Nicotine Withdrawal – over 5 minutes spent
Free print materials, web content and social media content are available to download and order on CTP’s Exchange

https://digitalmedia.hhs.gov/tobacco/

Content includes messages on:

• Harms of vaping
• Harms of cigarette use
• Federal rules and regulations
• Tobacco control research
FDA and Scholastic developed a co-branded educational program to help middle and high school students understand the dangers of vaping.
THANK YOU
Thank you for joining us!

Please be sure to complete the brief post-webinar evaluation.

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