They’re Smoking What?

An Overview of Nicotine and Tobacco use beyond cigarettes, with a special focus on Electronic Nicotine Delivery Systems

U-KanQuit Inpatient Tobacco Treatment Service
University of Kansas Hospital
OBJECTIVES

Learning objectives:

• Describe the possible delivery systems of nicotine (vape, smokeless chew/snus, pipe, water pipe/hookah, cigar, cigarillo, little cigar, cigarettes)

• Discuss the prevalence of the use of alternatives to cigarettes

• Discuss the impact of electronic nicotine delivery systems (ENDS) for public health

• Describe the regulatory requirements
TYPES OF TOBACCO

SMOKING TOBACCO
• Manufactured cigarettes
• Little cigars
• Full sized cigars
• Cigarillos
• Roll your own cigarette
• Pipes
• Sticks
• Bidis
• Kreteks
• Water pipe/hooka/sheesha

SMOKING TOBACCO
• Smoking tobacco involves burning dried or cured leaves of the tobacco plant and inhaling the smoke.
• Combustion uses the heat to create new chemicals that are not found in unburned tobacco such as tobacco specific nitrosamines (TSNAs) and benzopyrene and allows them to be absorbed through the lungs.
TYPES OF TOBACCO

SMOKELESS TOBACCO
- Chewing tobacco
- Moist snuff
- Dry snuff
- Dissolvable smokeless tobacco products (snus)

• Smokeless tobacco is usually consumed orally or nasally without combustion.
• Smokeless tobacco increases risk of cancer and leads to nicotine addiction similar to that of cigarette smoking.
Electronic Nicotine Delivery Systems
ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

• Electronic cigarettes, e-cigarettes or e-cigs
• E-hookah, personal vaporizers, mechanical mods, vape pens, tank systems, etc.
• Vaping or Juuling are common terms used by youth
• Not = “nicotine inhaler”, which is an FDA approved medication for tobacco cessation
WHICH ARE ENDS? THEY ALL ARE!!!
ANATOMY OF AN ELECTRONIC CIGARETTE

• ENDS produce an aerosol which is inhaled into the lungs
• Contains nicotine but no tobacco, although some liquids contain no nicotine
• All e-cigs have similar parts:
  • place for liquid or cartridge
  • heating element
  • battery/power source
  • mouthpiece
  • light indicator so you know when you are getting a “hit”
  • flow trigger
ANATOMY OF AN ELECTRONIC CIGARETTE

Nicotine cartridge or “e-liquid” or vape “juice” contains:
• Nicotine
• Flavoring
• Propylene glycol
• Vegetable glycerin
• Other additives (i.e. THC) and chemicals

Aerosol – first, second and third hand exposure to:
• Heavy metals: nickel, tin and lead
• Flavorants like diacetyl, a chemical linked to serious lung disease
• Volatile organic compounds like benzene

Source: https://e-cigarettes.surgeongeneral.gov/
JUUL

• Looks like a flash drive
• 1 pod = 20 cigarettes
• Nicotine concentration 2x other e-cigs
• Flavors – mango, fruit, crème brulee, mint, etc.
• Pods can be opened and other substances added
• 76% of e-cig market
• 63% of users don’t know JUUL pods always contain nicotine
NICOTINE SALTS AND BENZOIC ACID

• Juul and now other e-cigarette manufacturers are discovering the benefits of adding benzoic acid to their vaping solutions:

  • Nicotine Salt will vaporize at lower temperatures.
  • Nicotine Salt pH level is lowered, which produces a smoother hit and allows greater doses of nicotine (25-50 mg Nicotine Salts, which mimics smoking a combustible cigarette)
  • Allows more nicotine to be readily available for pulmonary absorption

BLOOD PLASMA NICOTINE LEVELS

Figure 4

Comparison between tobacco cigarette and electronic cigarette devices in plasma nicotine levels.

Prevalence
ADULT PREVALENCE \textit{ALL} TOBACCO

• In 2017, an estimated 19.3% (47.4 million) U.S. adults currently used any tobacco

• Among cigarette smokers, 75.0% smoked every day.

• Cigarettes: 14% (34.3 million)
• Cigars, cigarillos, or filtered little cigars: 3.8% (9.3 million)
• E-cigarettes: 2.8% (6.9 million)
• Smokeless: 2.1% (5.1 million)
• Pipes, water pipes, or hookahs: 1.0% (2.6 million)

E-CIG PREVALENCE, AGE MATTERS

- Overall prevalence of current e-cigarette use 3.2% in 2018
- Age 18-24 yrs. current use 7.6%

YOUTH EPIDEMIC

Current e-cigarette use

• High school students
  • 1.5% (220,000 students) in 2011
  • 20.8% (3.05M students) in 2018

• Middle school students
  • 0.6% (60,000 students) in 2011
  • 4.9% (570,000 students) in 2018

YOUTH PREVALENCE ALL TOBACCO

Increase in prevalence, 2019

Past 30 day use
• 25.4%, 12th grade
• 20.2%, 10th grade

Past 12 month use
• 35.1%, 12th grade
• 31.1%, 10th grade

**Have you ever tried electronic cigarettes, e-cigarettes, vape pens, or e-hookahs?**

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<tr>
<th>County/Region:</th>
<th>Level:</th>
<th>Beginning Year</th>
<th>Ending Year</th>
<th>Response:</th>
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<td>Wyandotte County</td>
<td>Total</td>
<td>2015</td>
<td>2019</td>
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**Source:** Kansas Communities That Care (KCTC) youth survey

### Percentage of Ever Use

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<th>2016</th>
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<tr>
<td>County</td>
<td>11.82</td>
<td>10.26</td>
<td>16.15</td>
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<tr>
<td>State</td>
<td>18.84</td>
<td>16.31</td>
<td>17.87</td>
<td>22.98</td>
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</table>
E-CIGS SALES TO INCREASE BY 2025

- U.S. Is Largest Market & Most Lucrative Opportunity
  - 50% of U.S. adult smokers have tried or expressed interest in Vapor
  - Continued innovation is critical in our view (taste, quality, convenience & harm reduction)

- We Estimate E-Cigs Are <10% of the Total U.S. Nicotine Pool Today, Going to ~30% By 2025

- We Estimate the Total U.S. Nicotine Pool is ~$100B in Retail Sales Today, Going to ~$115B by '25
Public Health Impact
NICOTINE PROMOTES ADDICTION

“As an addictive substance, nicotine, on a milligram for milligram basis, is 10 times more potent than heroin…”

# Patient Symptoms of Withdrawal

<table>
<thead>
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<th>Psychological</th>
<th>Physical</th>
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<tbody>
<tr>
<td>Anxiety</td>
<td>Sweating</td>
</tr>
<tr>
<td>Restlessness</td>
<td>Heart palpitations</td>
</tr>
<tr>
<td>Irritability</td>
<td>Muscle tension</td>
</tr>
<tr>
<td>Insomnia</td>
<td>Tightness in the chest</td>
</tr>
<tr>
<td>Headaches</td>
<td>Difficulty breathing</td>
</tr>
<tr>
<td>Poor concentration</td>
<td>Nausea</td>
</tr>
<tr>
<td>Depression</td>
<td>Vomiting or diarrhea</td>
</tr>
</tbody>
</table>

![Symptoms of Nicotine Addiction](image)
JUUL STRONGER THAN OTHER ENDS

59 mg of nicotine per ml anywhere from 0 to 36 mg of nicotine per ml

salt-based nicotine freebase nicotine

pods not refillable refillable tank

ENDS VS Other Tobacco Nicotine Concentrations

J Am Heart Assoc. (Bhatnagar et. al) article exploring the possibility of e-cig for Tobacco cessation summarizes a few concerns:

- Even with the unsubstantiated claim that e-cigarettes are 95% safer than conventional smoking, simulation models estimate a net population-level harm (1.5 million years of life lost). (Soneji et. al)

- Some studies show that e-cigarette use is associated with marked changes in vascular, respiratory, and immune functions. (Bhatnagar et. al)

- Our analysis of the BRFSS data showed that dual use of e-cigarettes and combustible cigarettes is associated with higher odds of cardiovascular disease
E-CIGARETTES: A CAUSE FOR CONCERN?

1. Promote addiction
2. Lead to sustained tobacco use
3. Cause lasting harm to brain development
4. Recent lung illnesses and DEATH
CDC ACTIVATES EMERGENCY OPERATIONS CENTER

• There are 1,299* cases of lung illness
• 26* deaths have been reported from 21 states. All reported cases have a history of e-cigarette product use or vaping.
• 80% <35 yrs. old and 16% <18 yrs. old
• Most patients have reported a history of using e-cigarette products containing THC (78%).
• Most patients report a history of using THC-containing products. The latest national and regional findings suggest products containing THC play a role in the outbreak.
• Some have reported the use of e-cigarette products containing only nicotine (17%).

*As of 10/10/19, Deaths in Kansas (2), Missouri (1)

Source: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html
CONFIRMED AND SUSPECTED CASES, JULY – SEP 2019

Possible causes

- Aerosolization of flavoring compounds of e-cigarette liquids (e.g. dacetyl)
- Adulteration of devices with tetrahydrocannabinol (THC)–based oils or vitamin E
- Black market vaping products
- Volatile organic compounds
- Heavy metals

SYMPTOMS AND ETIOLOGY

• Shortness of breath, chest pain, coughing, nausea, vomiting, diarrhea, fever, fatigue
• Many developed acute respiratory distress syndrome
• Chemical pneumonitis
• Etiology unknown: appears to be infection-mediated
• Infiltrates found in both lungs, elevated white blood cells
• Case definition
  • vape use in the past three months
  • scans that show spots on the lungs
  • no sign of pulmonary infection
  • no evidence to support other diagnoses

VAPING ASSOCIATED PULMONARY INJURY

• Vaping nicotine damages natural ability of lungs to clear (other particles from air)

• Airways inflamed when you vape and clearance mechanism of clearing mucus from lung is damaged

• Vaping can kill cells that are lining airways

FDA ACTIONS

• FDA’s laboratory is working closely with our federal and state partners to identify the products or substances causing the illnesses

• The Federal Drug Administration and Drug Enforcement Administration have opened a criminal probe into the vaping illnesses

• CDC and the FDA encourage clinicians to report possible cases of vaping-associated respiratory illness to their local or state health department for further investigation.
  • A detailed history of the substances used, the sources, and the devices used should be obtained and any remaining products obtained
  • Health care providers may contact their local poison control center
PROPOSED EPIC SOCIAL HISTORY QUESTIONS

**Vaping/E-Liquid Use**

- **Vaping device use:** Every day, Some days, Former, Never
- **Substances:** Nicotine, Nicotine-Salt, Flavored, THC, CBD, Synthetic cannabinoids, Mixture of cannabinoids, Other
- **Cartridges/day:**
- **Start date:** 0 May 2026
- **Quit date:** 0 May 2026
- **Comments:**
Regulatory Requirements
FDA REGULATION OF TOBACCO AND ENDS

• Since 2009, FDA has regulated cigarettes, smokeless, and roll-your-own tobacco
• In 2016, FDA finalized a rule extending regulatory authority to cover **ALL** tobacco products, including: cigars, hookah, pipe tobacco, and electronic nicotine delivery systems (ENDS)
• FDA regulates
  • Manufacture of ENDs and components (liquid, flavoring, cartridges, batteries, tanks, etc.)
  • Import
  • Packaging
  • Labeling
  • Advertising
  • Promotion
  • Sale
WHAT DOES THE NEW RULE DO?

• Evaluate important factors such as ingredients, product design and health risks, as well as products’ appeal to youth

• It requires health warnings

• Newly regulated tobacco products that were not on the market as of 2/15/07 will have to show that products meet the applicable public health standard set by the law

• Not allowing products to be sold to those younger than 18 and requiring age verification via photo ID

• Gives a foundation for future FDA actions related to tobacco
FDA ISSUES PROPOSED RULE

• Issued a proposed rule to set forth requirements for premarket tobacco product applications (PMTAs)

• “This proposed rule follows our announcement last week that we intend to finalize a compliance policy in the coming weeks that would prioritize enforcement to clear the market of unauthorized, non-tobacco-flavored e-cigarette products. These important regulatory actions are part of our ongoing oversight of e-cigarettes and other tobacco products that is critical to our public health mission and, especially, to protecting kids from the dangers of nicotine addiction and tobacco-related disease and death.” –FDA Commissioner
FDA WARNS JUUL LABS

• September 2019, the U.S. Food and Drug Administration issued a warning letter to JUUL Labs Inc. for illegally marketing e-cigarettes as less harmful than regular cigarettes

• Under federal regulations, such “modified-risk claims” must be authorized by the FDA. Juul’s failed to get such authorization.

• The FDA is also raising questions about Juul’s “Make the Switch” campaign, which the agency worries presents Juul as “a safer alternative to cigarettes” — despite the fact that the FDA has not authorized such a message.
What about ENDS as a Cessation Aid?
WHAT ABOUT ENDS FOR CESSATION?

• Concerns
  • Unknown health effects
  • Re-normalization of smoking
  • Uptake by youth
  • Lack of quality control
  • Fire hazard

• Possible benefits
  • Reduction of exposure to CO and tobacco carcinogens
  • Possible cessation tool, appealing to smokers
  • Regulation by FDA
RCT E-CIGS FOR CESSION (HAJEK ET. AL)

- 886 smokers (U.K National Health Service) all got 4 sessions support
- Randomized to
  - NRT of their choice, including combination
  - E-cig starter pack
- After 1 year:
  - 18% cig-free in e-cig group (80% still vaping)
  - 9.9% cig-free in NRT group (9% still using NRT)
- E-cigs promote complete substitution (“switching) in 20% of smokers – but many continue vaping
HOW TO QUIT VAPING/JUULING?

• 25% of adult e-cig users reported trying to quit in past year
• One published case report – adult cessation
  • Administered FTND – moderate dependence
  • 14mg patch + lozenge
  • Behavioral support
• Adolescent cessation – online and text resources
  • See Truth Initiative – Quitting e-cigarettes
    • Text DITCHJUUL to 88709
    • This is Quitting
    • BecomeAnEx
NICOTINE INHALERS, FDA APPROVED
NICOTINE REPLACEMENT THERAPY

• Nicotine plugs in a blister pack; Reusable plastic mouthpieces

• Instructions: Take several short puffs and hold vapor in the back of the throat where absorption occurs in the membranes in the mouth and throat (similar to cigar smoking). Use 6-16/day.

• Each cartridge contains 10 mg of nicotine, but only delivers about 4 mg of nicotine inhaled and roughly half (2 mg) is absorbed.

• This is not heated like electronic cigarettes, so does not make “puffs” of smoke-like vapor like they do.
CONCLUDING THOUGHTS

• All tobacco/vape products are highly addictive
• Nicotine replacement medications (patch, gum, lozenge, inhaler, spray) can reduce cravings and aide in quitting
• UKanQuit provides one-on-one inpatient bedside tobacco/vape treatment consultation at The University of Kansas Health System
• 1-800-QUIT-NOW provides free telephone counseling
• For updates on the current outbreak of e-cigarette related lung disease go to the CDC website. Data is updated every Thursday. [https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)
REFERENCES


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Youth Epidemic

• 17% of high school students current e-cig users
• 21% of college students current users
• Compared to non-users, youth who use e-cigs more likely to transition to
  • Cigarettes
  • Other drugs
• Even if “95% safer” will result in net harms
• Does marginal potential to reduce harm for current smokers justify recruiting new generation to addiction?