



**PHARMACY
VISION
20/20**

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RESORT

VAPING: IT TAKES YOUR BREATH AWAY

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DISCLOSURE

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- I have no potential conflict of interest to disclose.

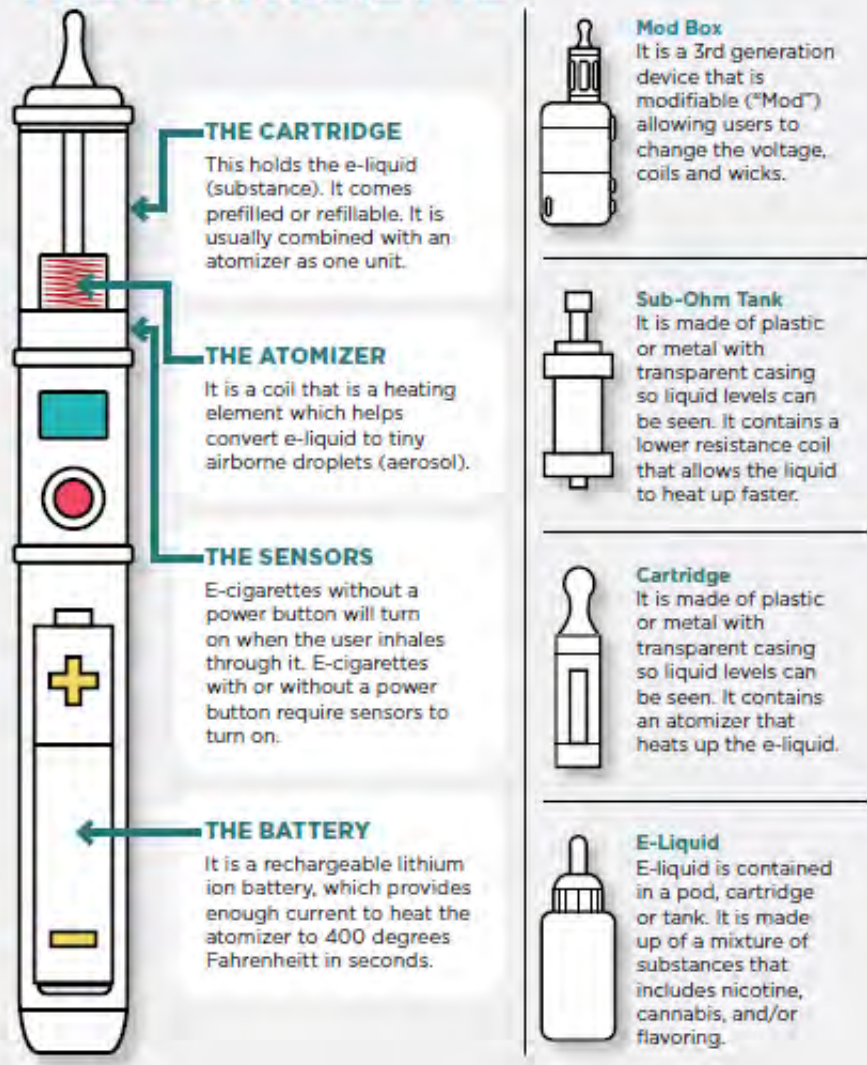
Rebecca Tran

- I have no potential conflict of interest to disclose.

LEARNING OBJECTIVES

1. Describe the latest safety and efficacy data of the use of electronic nicotine delivery systems (ENDS), which includes electronic cigarettes, vapes, and vaporizers.
2. Describe the public health implications of the popularity of vaping and the recommendations by the Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), and other entities.
3. Counsel patients who use electronic cigarettes and assist patients who are interested in quitting.

THE E-CIGARETTE



WHAT IS THE E-CIGARETTE?

- In the last decade, e-cigarettes have evolved into simple yet efficient delivery systems for nicotine and other chemicals.
- Basic components include:
 1. Cartridge
 2. Atomizer
 3. Sensors
 4. Battery
- Other Terms: “Mod Box”, Sub-Ohm Tank, “E-Liquid”

¹U.S. Department of Health and Human Services. E-Cigarette, or vaping, Products Visual Dictionary. Atlanta, GA: U.S. HHS, CDC, Accessed online on July 21, 2020 from URL: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html.

1ST GENERATION E-CIGARETTES



Disposable E-cigarettes

- A type of e-cigarette designed to be used one time, only.
- These devices are not rechargeable or refillable.
- They are discarded when it runs out of charge or e-liquid.
- They are designed to mimic the look and feel of combustible cigarettes. These are sometimes referred to as “cigalikes”

¹U.S. Department of Health and Human Services. E-Cigarette, or vaping, Products Visual Dictionary. Atlanta, GA: U.S. HHS, CDC, Accessed online on July 21, 2020: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html.



2ND GENERATION E-CIGARETTES

- Designed to be **re-used**, **refilled** and **recharged**.
- E-liquid can be pre-filled or refilled in cartridges.
- The **battery in direct contact to the cartridge** for heating.
- Sensors are attached on some products to **detect when to heat the cartridge/E-liquid**.
- **Colors, shapes (cylindrical), styles** offer variety to the consumer.
- **Prices vary.**

¹U.S. Department of Health and Human Services. E-Cigarette, or vaping, Products Visual Dictionary. Atlanta, GA: U.S. HHS, CDC.

https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html.

3RD GENERATION E-CIGARETTES



Tanks or Mods

- A type of rechargeable e-cigarette, or vaping, product designed to be used multiple times.
- They are modifiable devices (“mods”), allowing users to customize the substances in the device.

Sub-Ohm Tank

- Sub-ohm tank contains low resistance coils. It is designed to create a large cloud (aerosol) with a stronger delivery or hit of nicotine or other substances.

¹U.S. Department of Health and Human Services. E-Cigarette, or vaping, Products Visual Dictionary. Atlanta, GA: U.S. HHS, CDC, Accessed online on July 21, 2020 from URL:

https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html.



4TH GENERATION E-CIGARETTES

Pod Mods

- Pod Mod is an e-cigarette, or vaping, product with a prefilled or refillable “pod” or pod cartridge with a modifiable (mod) system (“Pod-Mods”)
- These are other examples of fourth generation devices. Pod Mods come in many shapes, sizes, and colors.
- Common Pod Mod brands include JUUL® and Suorin®
- There are compatible prefilled pod cartridges that contain nicotine, THC, or CBD with or without flavoring.

¹U.S. Department of Health and Human Services. E-Cigarette, or vaping, Products Visual Dictionary. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Accessed online on July 21, 2020 from URL: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html.

E-LIQUIDS: VARIETY & FLAVORS

Figure 1.3 Examples of e-liquid flavors



Source: Photo by Mandie Mills, CDC.

E-liquids cater to the younger age market with imagery and flavors that appeal to young buyers.

²U.S. Department of Health and Human Services. E-Cigarette use among youth and young adults: A report of the Surgeon General. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.



Source: Rolling Stone (2012).



Source: Rolling Stone (2015).

Sample of Marketing:

- Specific age groups targeted.
- Imagery promotes particular lifestyle.
- **Devices are sleek**, black, and appear sophisticated.
- Publication choice also **targets specific demographics.**

²U.S. Department of Health and Human Services. E-Cigarette use among youth and young adults: A report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

MARKETING & GROWTH OF E-CIGARETTES



Figure 1. Various vaping devices.

Source: The US Food and Drug Administration (www.fda.gov).

There is an estimated 7,700 unique vaping flavors.

- Most popular flavors are **tobacco** and **mint**, followed by **fruit**, **dessert**, and **candy flavors**
- Juul device (Juul Labs, www.juul.com), developed in 2015, has a goal of a “**more satisfying and cigarette-like vaping experience**”.

3. Dinardo P, et al. Cleveland Clinic Journal of Medicine. 2020; 86(12):789-798.

ARGUMENTS FOR E-CIGARETTE USE

- Tobacco smoke: “E-cigs don’t have as many toxic substances as combustible cigarettes”
 - Tobacco smoke contains **7,357 chemical compounds** from different classes.⁴
 - Past research **indicates significant cancer risk, respiratory irritants, and chemicals** associated with cardiovascular risk.⁴
- Majority of tobacco-related **disease and death are attributed to substances in tobacco smoke** other than nicotine.

⁴U.S. Department of Health and Human Services. How tobacco smoke causes disease: the biology and behavioral basis for smoking-attributable disease: A report of the Surgeon General. Rockville, MD: Dept. of Health and Human Services, Public Health Service, Office of Surgeon General, 2010.

ARGUMENTS AGAINST E-CIGARETTE USE

Even though there are more than 7,000 compounds associated with burning leaf compounds, **e-cigarettes still contain chemical compounds that have proven harmful.**

- There are **chemical compounds that exist in e-liquids**, that when heated, can prove harmful.
- Chemical compounds have been **identified that are proven carcinogenic.**
- Chemical compounds have been identified that are associated with **respiratory disease risk.**

BACKGROUND: ENDS & YOUNG ADULTS

Electronic Nicotine Delivery Systems (ENDS) have grown in popularity in the last decade. Recent data focuses on morbidity and mortality of ENDS-usage on young adults.

- **ENDS Usage in young adults:** Most commonly cited reasons for using e-cigs among young people are “curiosity, flavoring/taste, and low perceived harm compared to other tobacco products”.
- Use of e-cigs as an aid to quit conventional cigarettes is not reported as a primary reason for use among youth.

²U.S. Department of Health and Human Services. E-Cigarette use among youth and young adults: A report of the Surgeon General. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

BACKGROUND: ENDS, YOUTH & YOUNG ADULTS

- Among US middle and high school students, both ever and past-30-day e-cigarette use have more than tripled since 2011. ²
- Among young adults 18–24 years of age, ever e-cigarette use more than doubled from 2013 to 2014 following a period of relative stability from 2011 to 2013. ²
- Most recent data shows that prevalence of past-30-day use of e-cigarettes is similar among high school students (16% in 2015, 13.4% in 2014) and young adults 18–24 years of age (13.6% in 2013–2014) compared to middle school students (5.3% in 2015, 3.9% in 2014) and adults 25 years of age and older (5.7% in 2013–2014). ²

²U.S. Department of Health and Human Services. E-Cigarette use among youth and young adults: A report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

BACKGROUND: ENDS, YOUTH & YOUNG ADULTS

- Flavored e-cigarette use among young adult current users (18–24 years of age) exceeds that of older adult current users (25 years of age and older).²
- Among youth who have ever tried an e-cigarette, a majority used a flavored product the first time they tried an e-cigarette.²
- E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, particularly the use of combustible tobacco products.²
- For example, in 2015, 58.8% of high school students who were current users of combustible tobacco products were also current users of e-cigarettes.²

²U.S. Department of Health and Human Services. E-Cigarette use among youth and young adults: A report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

WHO USES E-CIGARETTES: YOUNG PEOPLE OR ADULTS?

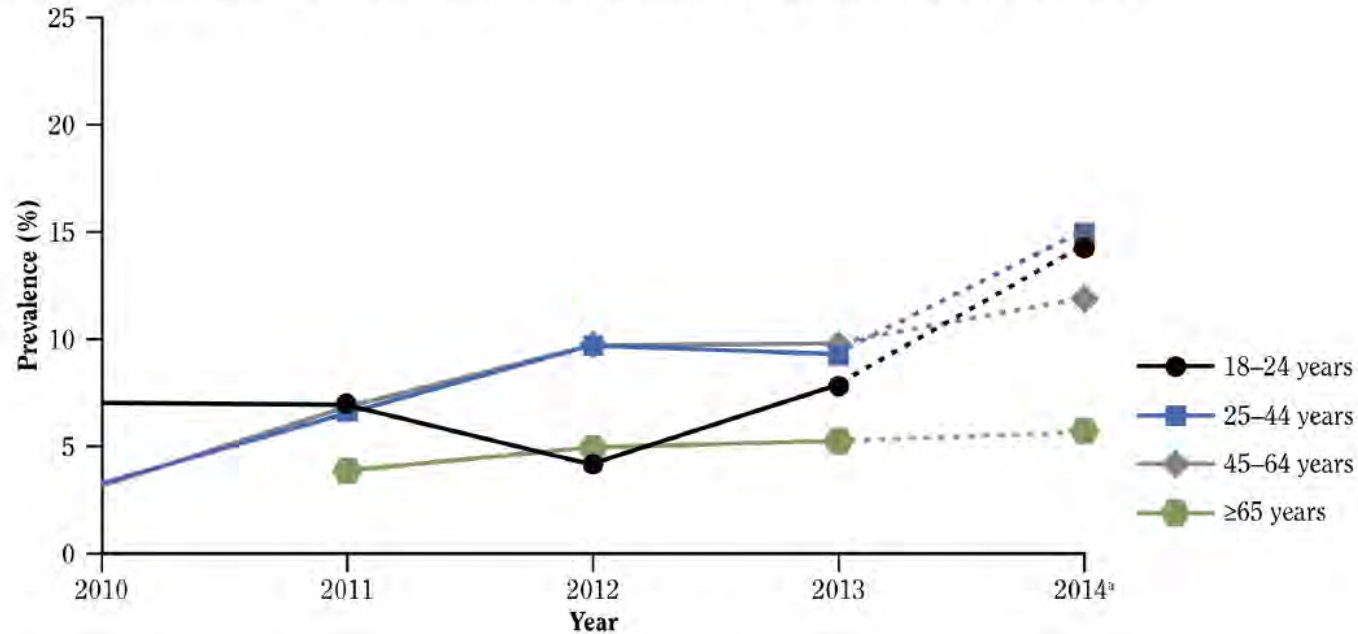
Current research indicates, e-cigarettes are the most commonly used tobacco product among youth.

- In the US, youth are more likely than adults to use e-cigarettes.
- In 2015, among adult e-cig users overall, 58.8% also were current regular cigarette smokers, 29.8% were former regular cigarette smokers, and 11.4% had never been regular cigarette smokers.⁵
- In 2017, 2.8% of US adults were current e-cigarette users.⁷
- In 2019, over 5 million US middle and high school students used e-cigarettes in the past 30 days, including 10.5% of middle school students and 27.5% of high school students.⁶

5. MMWR. 2016;65:1177. 6. Cullen KA, et al. JAMA 2019;322:2095-2103. 7. MMWR. 2018;67: 1225-1232.

BACKGROUND: ADULT E-CIG USE

Figure 2.3 Trends in ever e-cigarette use^a among U.S. adults by age group; Styles 2010–2014

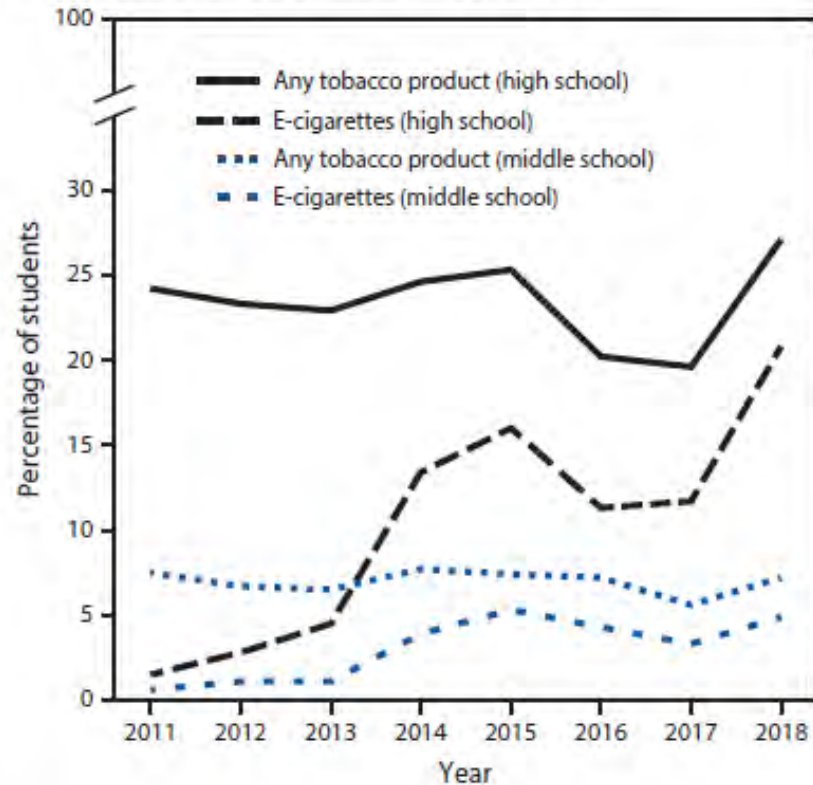


- Youth and young people generally are users of ENDS products.
- Older adults aged \geq 65 years did not show increases as high as younger age groups in ever using e-cigarettes.

²U.S. Department of Health and Human Services. E-Cigarette use among youth and young adults: A report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

TOBACCO USE VS. E-CIG USE AMONG HS AND MS STUDENTS

FIGURE. Percentage of middle and high school students who currently use e-cigarettes* and any tobacco product† — National Youth Tobacco Survey, United States, 2011–2018



After 2014, **increases in ENDS use exist** for:

- E-cigarettes among **high school (HS)** students
- E-cigarettes among **middle school (MS)** students.
- In both age groups, **tobacco product use was still higher** than E-cigarette use.

8. Cullen KA, et al. MMWR. 2018; 68(45): 1276-1277.

PUBLIC HEALTH CONCERNS: HARMFUL CHEMICALS

- **Tetrahydrocannabinol (THC)** - containing e-cigs or vaping products from “information sources like friends, family, or in-person or online dealers, are linked to EVALI” and play a major role in EVALI outbreak.
- **Vitamin E Acetate** is strongly linked to EVALI outbreak such that Vitamin E Acetate has been found in products tested by FDA and state laboratories. Vitamin E Acetate has not been found in lung fluid of people that do not have EVALI.
- **Nicotine** in e-cigs and tobacco products is addictive and is readily absorbed across respiratory epithelia.

9. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#overview

PUBLIC HEALTH CONCERNS: HARMFUL CHEMICALS

- Although E-cigs contain fewer toxic chemicals than the 7,359⁴ chemicals in smoke from regular cigarettes, they do contain toxicants from the heated and aerosolized e-liquids:
 - *There is **substantial evidence** that some chemicals present in e-cigarette aerosols (e.g. **formaldehyde, acrolein**) are capable of causing **DNA damage and mutagenesis**.*¹⁰
 - *Long-term exposure to e-cigarette aerosols could **increase risk of cancer and adverse reproductive outcomes**.*¹⁰
 - Formaldehydes, acetaldehydes, and acrolein which all **increase the risk of cancer**.¹⁰

10. National Academies of Sciences, Engineering, and Medicine. 2018. *Public health consequences of e-cigarettes*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/24952>.

EVALI & CURRENT STATUS

E-cigarette, or Vaping, product use-Associated Lung Injury (EVALI) has been evaluated vigorously in the last 19 months by CDC and FDA.

- In the US, first EVALI case was recorded in 2017.
- An outbreak of EVALI cases occurred **peaking in August 2019**. A decrease in EVALI cases, nationally, occurred possibly in response to:
 1. **Increased public awareness** of the risk associated with THC-containing e-cigarette
 2. **Removal of vitamin E acetate** from some products
 3. **Law enforcement actions** related to illicit products

11. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#epi-chart

CURRENT PUBLIC HEALTH UPDATES

- In the latest updates by the CDC, emergency department visits related to e-cig or vaping products increased dramatically in August 2019 and peaked in the following September.
- As of February 18, 2020, a total of 2,807 hospitalized EVALI cases or deaths have been reported to CDC from all 50 states, DC, Puerto Rico and U.S. Virgin Islands.
- 68 confirmed deaths in 29 states and DC.

9. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#overview

Figure 1: No. of patients (N=2,398) with EVALI by Week of Hospital Admission – US, Feb. 10, 2019-Jan. 14, 2020

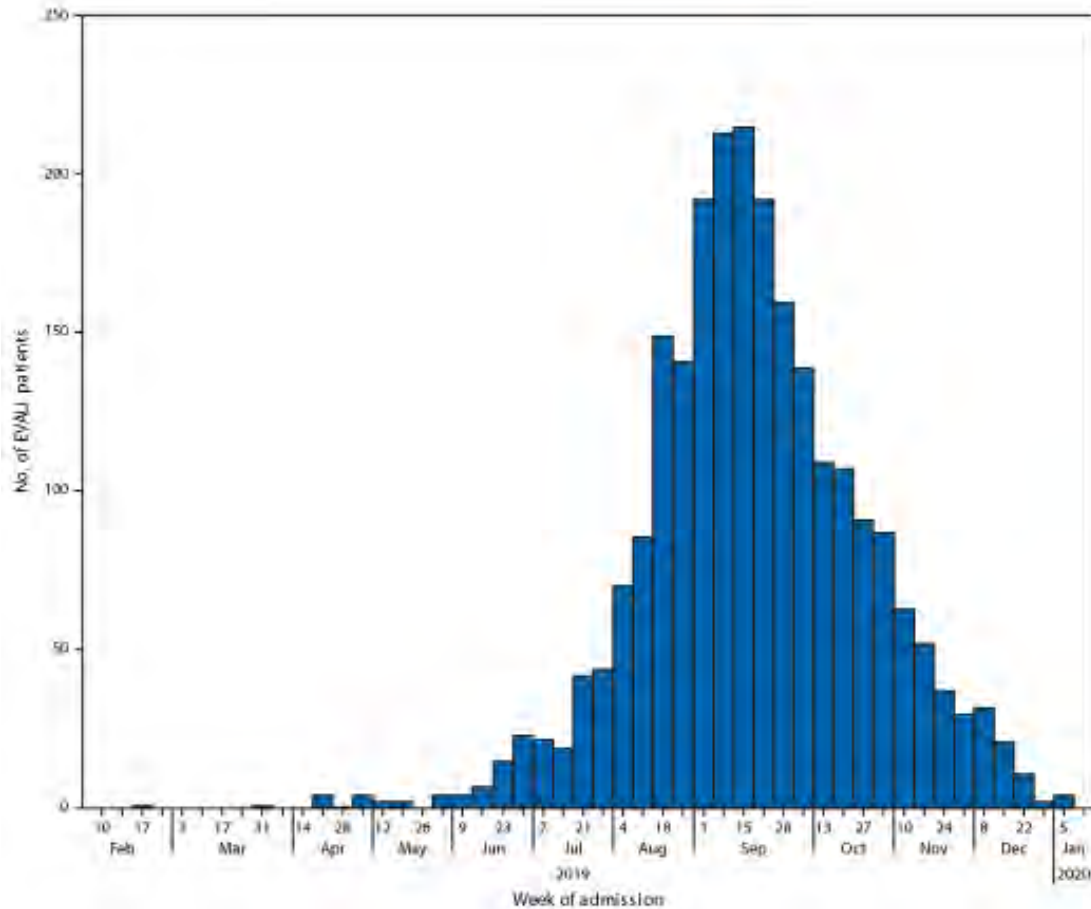
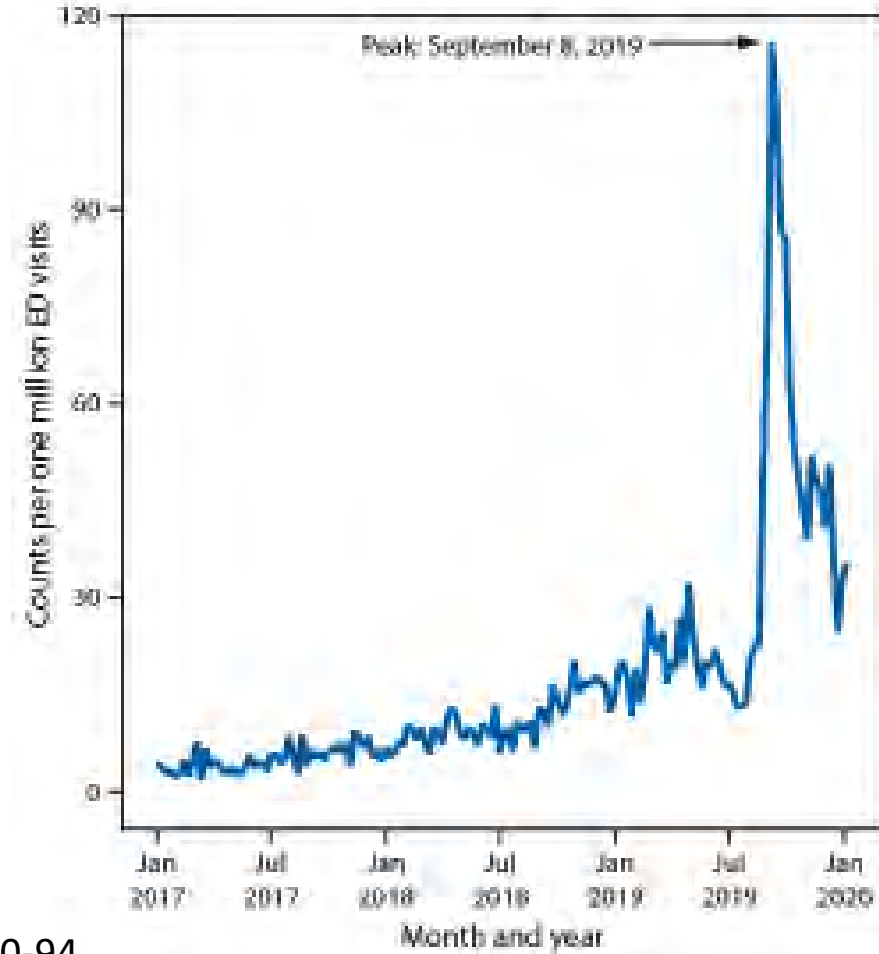


Figure 2: Emergency department visits with E-cig or Vaping, product use as chief complaint – US, Jan. 1, 2017-Jan. 11, 2020

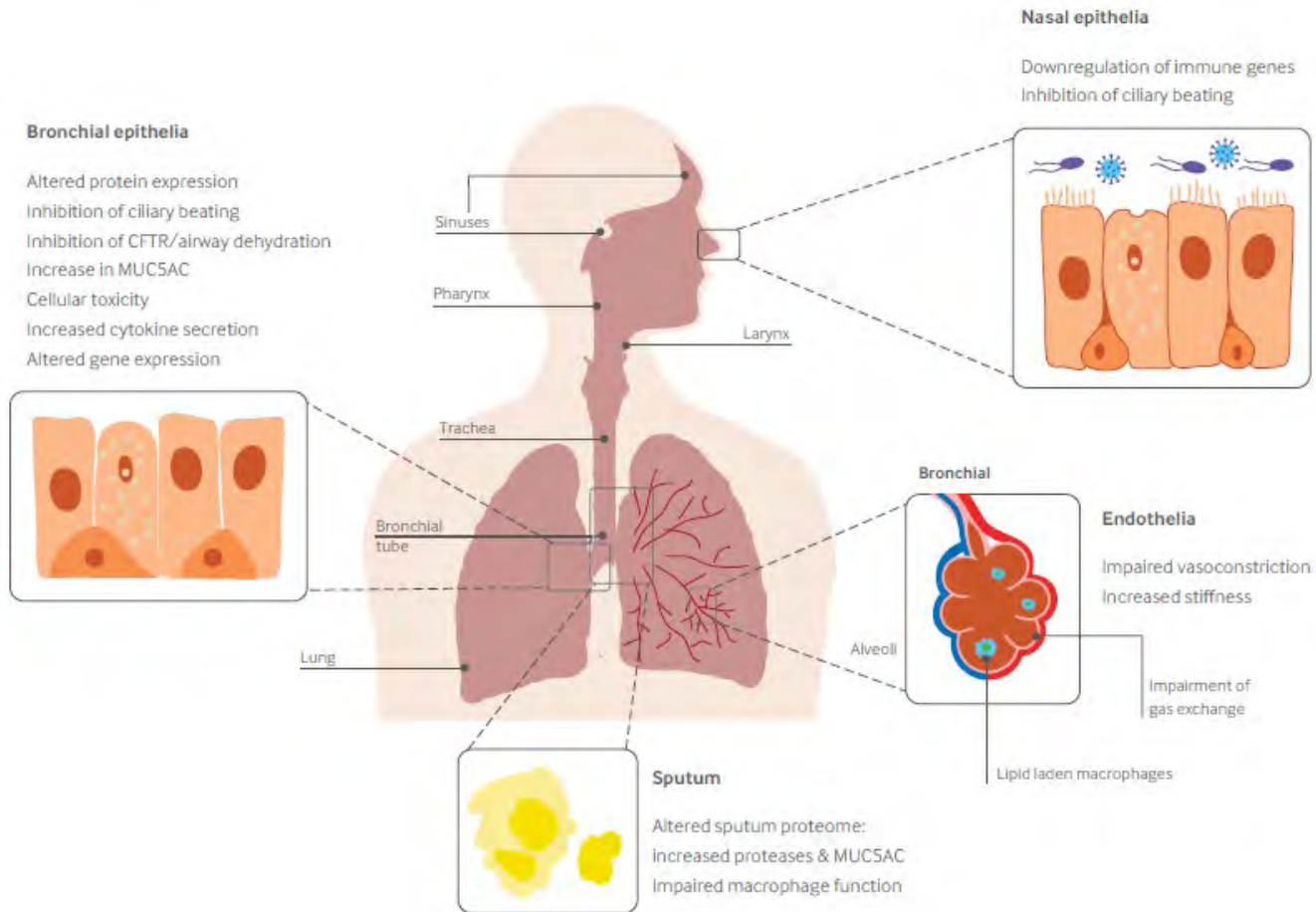


12. Krishnasamy VP, et al. MMWR Morb Mortal Wkly Rep. 2020; 69:90-94.

EVALI AS A DISEASE STATE

- August 2019: CDC, FDA and State/Local health departments investigated a national outbreak of e-cigarette or vaping, product use-associated lung injury (EVALI).¹³
- Most patients with EVALI reported using THC-containing products and were hospitalized – critical care and respiratory support needed.¹³
- What did they find? **Vitamin E Acetate (additive in THC-containing products), was strongly linked to EVALI cases in the outbreak.**¹³
- Evidence is not sufficient to rule out contribution of chemicals in either THC-containing/non-THC-containing products.¹³

13. Werner AK, et al. *NEJM*. 2020;382(17):1589-1598.



REPORTED EFFECTS OF VAPING ON THE HUMAN PULMONARY SYSTEM¹⁴

1. Bronchial Epithelia: Effects of vaping have dramatically altered bronchial functioning
2. Bronchial tubes: Impairment in gas exchange & Impaired vasoconstriction
3. Sputum: Altered sputum proteome, impaired macrophage function

¹⁴ Gotts JE, et al. BMJ. 2019;366: I5275.

WHY E-CIGS AND VAPING ARE IMPLICATED

EVALI is an acute or subacute respiratory illness with damage to the alveoli that can be severe and life-threatening.¹⁵

- With so many products, the common culprit implicated is vitamin E acetate:
 - Oily chemical commonly added to THC vaping liquids to dilute or thicken the e-liquid.
 - Acknowledged as a potential toxin of concern by CDC: Can remain in the lungs for long periods of time

¹⁵ Boudi FB, et al. Cureus. 2019;11(12): e6350.

E-CIGS, VITAMIN E ACETATE, AND “BAL”

Detection of toxicants in bronchoalveolar-lavage (BAL) fluid from patients with EVALI, as it is a presumed site of lung injury.¹⁶

- In a study by Blount and colleagues (2020)¹⁶, **Vit. E acetate was found in BAL fluid in patients with EVALI** compared to healthy comparator group patients. This was also discovered in previous studies as well.¹⁷
- E-cigs or vaping products can **deliver Vit. E acetate to respiratory epithelial-lining fluid**, which is the presumed injury site in the lungs.¹⁶

¹⁶Blount BC, et al. NEJM. 2020;382(8): 697-705. ¹⁷Blount BC, et al. MMWR. 2019;68(45):1040-1041.

DISCUSSING E-CIGARETTES WITH PATIENTS

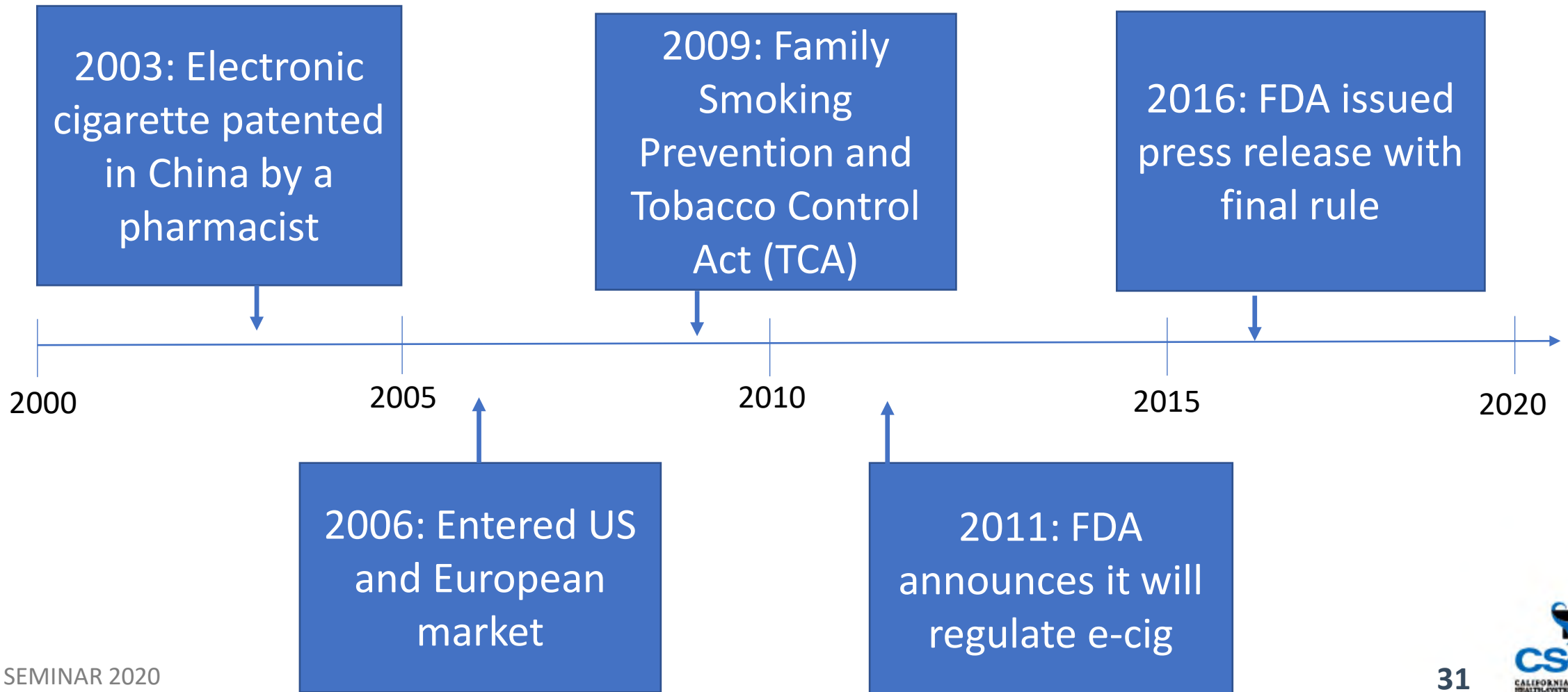
1. The patient interested in e-cigs for smoking cessation purposes
2. The patient who wants to quit using e-cigs

E-CIGARETTES/ENDS FOR SMOKING CESSATION

- Can ENDS be used as a smoking cessation aid?
 - **NOT FDA approved for this purpose**
 - FDA has authority to regulate tobacco products, including electronic cigarettes
- No conclusive evidence that e-cig increase smoking cessation¹⁸
 - Suggestive evidence that e-cig containing nicotine is associated with increased smoking cessation
 - To achieve any benefit from e-cig, must fully switch from other tobacco products.
 - Ultimate goal is to stop using e-cig completely

[18. https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html#:~:text=Adult%20smokers%20who%20are%20not,reduce%20smoking%2Drelated%20health%20risks.](https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html#:~:text=Adult%20smokers%20who%20are%20not,reduce%20smoking%2Drelated%20health%20risks.)

FDA AND REGULATORY TIMELINE



E-CIGARETTES/ENDS FOR SMOKING CESSATION

Survey of 5939 current and former smokers in 4 countries (Canada, US, UK, and Australia)¹⁹

- 79.8% reported using ENDS because they were considered less harmful than traditional cigarettes
- 85.1% reported using ENDS to help quit smoking
- 75% stated they used ENDS to help reduce smoking

19. Adkison SE, et al. Am J Prev Med. 2013;44:207-215.

Author (Year)	Comparators	Primary Endpoint	Results	Comments
Bullen et al (2013) ²⁰	<ol style="list-style-type: none"> 1. E-cig with 16 mg nicotine (n=289) 2. Nicotine patch 21 mg (n=295) 3. Placebo e-cig (n=73) 	Smoking abstinence at 6 months via exhaled breath CO	<ul style="list-style-type: none"> • Nicotine e-cig = 7.3% • Patch = 5.8% • Placebo e-cig = 4.1% • RR 1.26 (95% CI 0.68-2.34) between nicotine e-cig and patch 	<ul style="list-style-type: none"> • No difference between groups • Significantly under-powered • New Zealand study • Compliance rate to nicotine e-cig 29%

20. Bullen C, et al. Lancet. 2013;382:1629-37.

Author (Year)	Comparators	Primary Endpoint	Results	Comments
Caponetto et al (2013) ²¹	A. E-cig with 7.2 mg nicotine x 12 weeks (n=100) B. E-cig with 7.2 mg nicotine x 6 weeks, then 5.4 mg x 6 weeks (n=100) C. E-cig with no nicotine (n=100)	Abstinence or reduction in smoking at 12 months	Quit rates <ul style="list-style-type: none"> • Group A = 13% • Group B = 9% • Group C = 4% Reduction rates <ul style="list-style-type: none"> • Group A = 10% • Group B = 9% • Group C = 12% 	<ul style="list-style-type: none"> • E-cig, with or without nicotine, decreased cigarette consumption in smokers not intending to quit • Italy study

21. Caponetto P, et al. PLoS One. 2013;8:e66317.

Author (Year)	Comparators	Primary Endpoint	Results	Comments
O'Brien et al (2015) ²²	<ul style="list-style-type: none"> E-cig 16 mg nicotine (n=250) Nicotine patch 21 mg (n=260) Placebo e-cig (n=61) 	<ul style="list-style-type: none"> Continuous smoking abstinence at 6 months via exhaled breath CO 	<p>With mental illness</p> <ul style="list-style-type: none"> Nicotine e-cig 5% Nicotine patch 14% Placebo e-cig 0% P=0.245 <p>Without mental illness</p> <ul style="list-style-type: none"> Nicotine e-cig 7% Nicotine patch 5% Placebo e-cig 5% 	<ul style="list-style-type: none"> E-cig equally effective and acceptable for smoking cessation in people with mental illness Compliance with e-cig was much higher (51%) than with patch (18%) High acceptability rate to e-cig New Zealand study

22. O'Brien B, et al. Tobacco Induced Diseases. 2015;13:5.

Author (Year)	Comparators	Primary Endpoint	Results	Comments
Tseng et al (2016) ²³	<ul style="list-style-type: none"> E-cig 4.5% nicotine (n=50) Placebo e-cig (n=49) 	<ul style="list-style-type: none"> ≥ 50% reduction in cig/day (self-reported) at 3 weeks E-cig use 7-day abstinence 	<ul style="list-style-type: none"> Avg daily e-cig use similar between groups (nicotine 0.92 vs. placebo 1.06, P=0.43) Number of cig/day decreased in both groups 	<ul style="list-style-type: none"> E-cig with or without nicotine resulted in decreased cigarette use Greater use of e-cig was associated with achieving 50% reduction of cig use USA study

23. Tseng TY, et al. Nic Tob Res. 2016;18:1937-1943.

E-CIG VS. NICOTINE REPLACEMENT THERAPY (NRT)

Multi-center, randomized trial of adult smokers in United Kingdom

- Nicotine-replacement group: 439 participants received 3 month supply of their preferred product (patch, gum, lozenge, nasal spray, inhalator, mouth spray, mouth strip, microtab)
- E-cigarette group: 447 participants received started kit of refillable e-cigarette plus Tobacco Royale flavor e-liquid (18 mg/mL of nicotine). Participants asked to purchase their future e-liquid online or from vape shop.

24. Hajek P, et al. NEJM. 2019;380:629-37.

Outcome	E-cig (N=438)	Nicotine Replacement (N=446)	Primary Analysis: RR (95% CI)
Primary outcome Abstinence at week 52	79 (18%)	44 (9.9%)	1.83 (1.30-2.58)
Abstinence between week 26 and 52	93 (21.2%)	53 (11.9%)	1.79 (1.32-2.44)
Abstinence at week 4	192 (43.8%)	134 (30%)	1.45 (1.22-1.74)
Abstinence at week 26	155 (35.4%)	112 (25.1%)	1.40 (1.14-1.72)
Reduction of smoking >50% by CO validation	44/345 (12.8%)	29/393 (7.4%)	1.75 (1.12-2.72)

24. Hajek P, et al. NEJM. 2019;380:629-37.

E-CIG VS. NRT

Use of assigned product at 52 weeks

- E-cigarette = 39.5% (173/438)
- Nicotine replacement = 4.3% (19/446)

Use of assigned product at 52 weeks in those who are abstinent

- E-cigarette = 80% (63/79)
- Nicotine replacement = 9% (4/44)

Greater satisfaction with e-cigarette and rated as more helpful to refrain from smoking.

24. Hajek P, et al. NEJM. 2019;380:629-37.

E-CIG VS. NRT

Conclusion

- Refillable e-cigarettes had greater rate of smoking cessation at 1 year in UK
- Those in e-cig group had large % still on e-cig at 1 year

24. Hajek P, et al. NEJM. 2019;380:629-37.

Author (Year)	Comparators	Primary Endpoint	Results	Comment
Walker et al. (2020) ²⁵	<ol style="list-style-type: none"> Nicotine patches 21 mg (n=125) Patches plus nicotine e-cig (n=500) Patches plus placebo e-cig (n=499) 	Continuous smoking abstinence at 6 months via self-report and CO verification	<ul style="list-style-type: none"> Patches plus nicotine e-cig = 7% Patches plus placebo e-cig = 4% RR 1.75 (95% CI 1.02-2.98) Patches plus nicotine e-cig = 7% Patches only = 2% RR 2.92 (95% CI 0.91-9.33) 	<ul style="list-style-type: none"> Higher rate of smoking abstinence with combination of patch plus nicotine e-cig Sample size was less than planned (ran out of time and funding) New Zealand

25. Walker N, et al. Lancet Respir Med. 2020;8:54-64.

ENDS FOR SMOKING CESSATION

Summary of RCT data

- RCT evidence that use of e-cigarettes with or without nicotine replacement therapy reduces self-reported and biochemically validated short-term abstinence and reduced cigarette use.
- E-cig users are more likely to stay on e-cigs by end of study (up to 12 months).
- Higher rate of patient preference and acceptability for e-cig over other smoking cessation products.
- Increased use of e-cig is associated with greater rates of smoking abstinence.

ENDS FOR SMOKING CESSATION

What is still unknown?

- Comparison of e-cigarettes to bupropion or varenicline
- Long-term abstinence rates
- Effect of switching addictions, from traditional cigarettes to e-cig
- Dual use of traditional and electronic cigarettes
 - May impede quit attempts²⁶ or increase exposure to toxins
- Optimum dosing schedule for e-cigarette use for smoking cessation

26. Kulik MC, et al. Am J Prev Med. 2018;54:603-609.

SELECTED NATIONAL ORGANIZATION STATEMENTS

Organization	
National Academies of Science, Engineering, and Medicine (NASEM) ¹⁰	Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation. There is insufficient evidence from RCTs about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to FDA-approved smoking cessation treatments.
World Health Organization ²⁷	“Potential for ENDS to play a role as a population-level tobacco cessation intervention is unclear.”
American Cancer Society ²⁸	Does not recommend electronic cigarettes for smoking cessation

SELECTED NATIONAL ORGANIZATION STATEMENTS

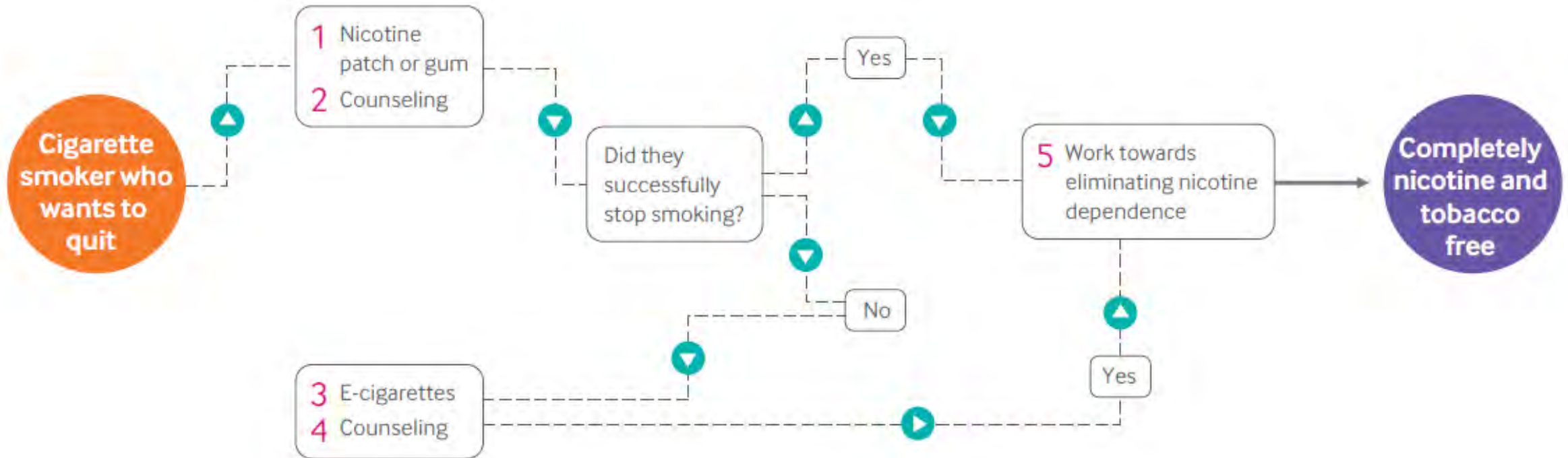
Organization	
American College of Cardiology ²⁹	Does not advise adult patients to switch to e-cigarettes.
American Thoracic Society ³⁰	For tobacco-dependent adults, varenicline is suggested over electronic cigarettes
National Health Service (UK) ³¹	Strongly support use of e-cigarettes for smoking cessation

PROPOSED SMOKING CESSATION REGIMEN

- Recommend evidence-based pharmacotherapy first
 - Nicotine replacement
 - Bupropion
 - Varenicline
- Behavioral therapy and counseling
- Supportive environment

14. Gots JE, et al. BMJ. 2019;366:l5275

PROPOSED SMOKING CESSATION REGIMEN



14. Gots JE, et al. BMJ. 2019;366:l5275

KEY COUNSELING POINTS

- Consider using e-cigarettes after considering all other forms of approved smoking cessation products.¹⁸
- Recommend fully switching from traditional cigarette to electronic cigarette to achieve any meaningful health benefit.¹⁸
- Unclear how to stop using e-cigarettes.
 - May still need FDA-approved NRT and treatments to discontinue e-cigarette use.

18. https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html#:~:text=Adult%20smokers%20who%20are%20not,reduce%20smoking%2Drelated%20health%20risks.

KEY COUNSELING POINTS

- Address perceptions of safety and harm
 - “Lower risk” ≠ no risk
 - Nicotine itself is still very addictive, no matter the source
 - Long term toxicities of e-cigs are still unknown
 - Unknown net effects on pulmonary function, cardiovascular risks, immunosuppression, cancer risks
- Education for parents and children
 - Prevention of smoking initiation among school-aged children and adolescents ³²

32. US Preventive Services Task Force. JAMA. 2020;323:1590-1598.

CONCLUSION

- Popularity of e-cigarette use and vaping is growing in US and world-wide, especially among adolescents and young adults.
- Acute lung injury (EVALI) in 2019 was linked to vitamin E acetate and THC in vaping.
- Long term effects of e-cigarettes and vaping as an alternative to traditional cigarette smoking is still unknown.
- E-cigarettes (although not FDA approved) seem to be effective for short-term smoking cessation compared to NRT alone.

TEST QUESTION #1

Based on the presentation notes, which of the following responses refers to a compound that was found in bronchoalveolar lavage (BAL) fluid and was associated with lung injury in patients who used e-cigarettes or vaping products in the recent EVALI outbreak in 2019?

- A. Tetrahydrocannabinol (THC)
- B. Vitamin E acetate
- C. Nicotine
- D. Cannabidiol (CBD)

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TEST QUESTION #2

Which of the following responses represents the primary reason that youth and young adult e-cigarette or vaping product users choose to use various ENDS products? Select all that apply.

- A. Younger users tend to use ENDS products for their potential as an aid to quit conventional cigarettes.
- B. Younger users believe that ENDS products have lower perceived harm compared to other tobacco products.
- C. Younger users are attracted to the variety of flavors and taste of e-liquids used in ENDS products.

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TEST QUESTION #3

Of the four different “generations” of e-cigarettes and ENDS products, which of the following responses represents the generation of e-cigarettes that often have a prefilled or refillable “pod” or cartridge with a modifiable system. These products often have various shapes, sizes, and colors.

- A. 4th generation e-cigarettes
- B. 3rd generation e-cigarettes
- C. 2nd generation e-cigarettes
- D. 1st generation e-cigarettes

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TEST QUESTION #4

Electronic cigarettes are shown in randomized controlled trials to be as effective as nicotine replacement therapy for smoking abstinence and reduced cigarette use in adult smokers.

- A. True
- B. False

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A. True

B. False

REFERENCES

1. U.S. Department of Health and Human Services. E-Cigarette, or vaping, Products Visual Dictionary. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Accessed online on July 21, 2020 from URL: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html.
2. U.S. Department of Health and Human Services. E-Cigarette use among youth and young adults: A report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
3. Dinardo P, Rome ES. Vaping: The new wave of nicotine addiction. *Cleveland Clinic Journal of Medicine*. 2020;86(12):789-798.
4. U.S. Department of Health and Human Services. How tobacco smoke causes disease: the biology and behavioral basis for smoking-attributable disease: A report of the Surgeon General. Rockville, MD: Dept. of Health and Human Services, Public Health Service, Office of Surgeon General, 2010.
5. QuickStats: Cigarette Smoking Status Among Current Adult E-cigarette Users, by Age Group — National Health Interview Survey, United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;65:1177.
6. Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. *JAMA*. 2019;322:2095-2103.
7. Wang TW, Asman K, Gentzke AS, et al. Tobacco Product Use Among Adults — United States, 2017. *MMWR Morb Mortal Wkly Rep* 2018;67:1225-1232
8. Cullen KA, Ambrose BK, Gentzke AS, et al. Notes from the Field: Use of electronic cigarettes and any tobacco product among middle and high school students – United States, 2011-2018. *MMWR Morb Mortal Wkly Rep*. 2018; 67: 1276-1277.

REFERENCES

9. Centers for Disease Control and Prevention. Outbreak of lung injury associated with the use of e-cigarette, or vaping, products. Reviewed February 25, 2020. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#overview Accessed September 10, 2020.
10. National Academies of Sciences, Engineering, and Medicine. 2018. Public health consequences of e-cigarettes. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24952>.
11. Centers for Disease Control and Prevention. Outbreak of lung injury associated with the use of e-cigarette, or vaping, products. Reviewed February 25, 2020. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#epi-chart Accessed September 10, 2020.
12. Krishnasamy VP, Hallowell BD, Ko JY, et al. Update: Characteristics of a nationwide outbreak of e-cigarette, or vaping, product use-associated lung injury – United States, August 2019-January 2020. *MMWR Morb Mortal Wkly Rep.* 2020; 69:90-94.
13. Werner AK, Koumans EH, Chatham-Stephens K, et al. Hospitalizations and Deaths Associated with EVALI. *New Engl J Med.* 2020; 382: 1589-1598.
14. Gotts JE, Jordt SE, McConnell R, et al. What are the respiratory effects of e-cigarettes? *BMJ.* 2019;366: I5275.
15. Boudi FB, Patel S, Boudi A, et al. Vitamin E acetate as a plausible cause of acute vaping-related illness. *Cureus.* 2019; 11: e6350.
16. Blount BC, Karwowski MP, Shields PG, et al. Vitamin E acetate in bronchoalveolar-lavage fluid associated with EVALI. *New Engl J Med.* 2020; 382: 697-705.
17. Blount BC, Karwowski MP, Morel-Espinosa M, et al. Evaluation of bronchoalveolar lavage fluid from patients in an outbreak of e-cigarette, or vaping, product use-associated lung injury – 10 States, August-October 2019. *MMWR Morb Mortal Wkly Rep.* 2019; 68: 1040-1041.

REFERENCES

18. Centers for Disease Control and Prevention. Adult Smoking Cessation – The Use of E-cigarettes. Reviewed January 23, 2020. https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html#:~:text=Adult%20smokers%20who%20are%20not,reduce%20smoking%2Drelated%20health%20risks. Accessed September 10, 2020.
19. Adkison SE, O'Connor RJ, Bansal-Travers M, et al. Electronic nicotine delivery systems: International tobacco control four-country survey. *Am J Prev Med.* 2013;44:207-215.
20. Bullen C, Howe C, Laugesen M, et al. Electronic cigarettes for smoking cessation: a randomized controlled trial. *Lancet.* 2013;382:1629-37.
21. Caponetto P, Campagna D, Cibella F, et al. Efficiency and safety of an electronic cigarette (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. *PLoS One.* 2013;8:e66317.
22. O'Brien B, Knight-West O, Walker N, et al. E-cigarettes versus NRT for smoking reduction or cessation in people with mental illness: a secondary analysis of data from the ASCEND trial. *Tobacco Induced Diseases.* 2015;13:5.
23. Tseng TY, Ostroff JS, Campo A, et al. A randomized trial comparing the effect of nicotine versus placebo electronic cigarettes on smoking reduction among young adult smokers. *Nic Tob Res.* 2016;18:1937-1943.
24. Hajek P, Phillips-Waller A, Przulj D, et al. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New Engl J Med.* 2019;380:629-37.
25. Walker N, Parag V, Verbiest M, et al. Nicotine patches used in combination with e-cigarettes (with and without nicotine) for smoking cessation: a pragmatic, randomized trial. *Lancet Respir Med.* 2020;8:54-64.

REFERENCES

26. Kulik MC, Lisha NE, Glantz SA. E-cigarettes associated with depressed smoking cessation: a cross-sectional study of 28 European Union countries. *Am J Prev Med.* 2018;54:603-609.
27. World Health Organization. E-cigarettes. Posted January 29,2020. <https://www.who.int/news-room/q-a-detail/e-cigarettes-how-risky-are-they>. Accessed July 29, 2020.
28. American Cancer Society. American Cancer Society position statement on electronic cigarettes. <https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html>. Accessed July 29, 2020.
29. American College of Cardiology. E-cigarettes in light of the new primary prevention of cardiovascular disease guideline. Posted October 22, 2019. <https://www.acc.org/latest-in-cardiology/articles/2019/10/21/07/32/e-cigarettes-in-light-of-the-new-primary-prevention-of-cvd-guideline#:~:text=In%20addition%20to%20the%20cardiovascular,heart%2C%20lungs%2C%20and%20circulation>. Accessed July 29, 2020.
30. Leone FT, Zhang Y, Evers-Case S, et al. Initiating pharmacologic treatment in tobacco-dependent adults: an official American Thoracic Society clinical practice guideline. *Am J Respir Crit Care Med.* 2020;202:e5-31.
31. Action on Smoking and Health. Use of e-cigarettes (vaporisers) among adults in Great Britain. Posted September 2019. <https://ash.org.uk/wp-content/uploads/2019/09/Use-of-e-cigarettes-among-adults-2019.pdf>. Accessed July 29, 2020.
32. US Preventive Services Task Force. Primary care interventions for prevention and cessation of tobacco use in children and adolescents: US Preventive Services Task Force Recommendation Statement. *JAMA.* 2020;323::1590-1598.

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