Evolving Challenges for Clinicians in the Treatment of Tobacco Use

Anne N. Thorndike, MD, MPH
Massachusetts General Hospital and
Harvard Medical School, Boston, MA

Department of Medicine Grand Rounds, Northwell Health, April 4, 2019

CME ACCREDITED UPDATES IN MEDICINE ELEARNING SERIES

COURSE NAME:

Medicine RSS eLearning Modules

CME eLEARNING ACTIVITY NAME:

Evolving Challenges for Clinicians in the Treatment of Tobacco Use

PROGRAM DESCRIPTION, EDUCATIONAL GOAL AND RATIONALE:

Evidence based guidelines are constantly changing and being updated for several core areas of Internal Medicine throughout the year. It is important for physicians to practice the most up-to-date standard of care in all specialties to promote patient health and well-being. Our series of lectures at the medicine regularly scheduled series promotes continuing education for the practicing internist and highlights important updates in medical practice in these core areas. Physicians in general practice often and do not have the time to keep themselves up-to-date with medical advances as they are busy seeing patients in the clinical setting. The Medicine Regularly Scheduled Series gives these physicians the opportunity to learn these advances in an academic setting.

CME ACCREDITED UPDATES IN MEDICINE ELEARNING SERIES

TARGET AUDIENCE:

Physician Partners and Premium Network community-based providers

LEARNING OBJECTIVES:

Upon successful completion of this activity, participants should:

- Identify Trends in Cigarette Smoking Rates.
- Understand the new challenges from Electronic Cigarettes.
- Understand the health risks and differences between E-Cigarettes and combustible cigarettes.
- Identify conclusions on the effectiveness of E-cigarettes for smoking cessation.
- Learn about the prevalence of E-cigarette use in young adults and adolescents.
- Identify treatment gaps in adults with Serious Mental Illness (SMI) that smoke.
- Learn about the Myths related to treating smoking in people with SMI.

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FACULTY PRESENTER/AUTHOR:

Anne N. Thorndike, MD, MPH
Associate Professor, Medicine
Harvard Medical School

Sandy Balwan, MD
Executive Director & Chief Medical Officer
Northwell Health IPA

Course Director:
George Boutis, MD
Attending Physician
Department of Medicine
Northwell Health

Planners:
John Raimo, MD
Division of Hospital Medicine
Site Director, Internal Medicine Residency Program

Sean LaVine, MD
Site Director, Division of Hospital Medicine
Long Island Jewish Medical Center

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Northwell Health designates this Continuing Medical Education activity for a maximum of ***1 AMA PRA Category I credits*** *TM.* Physicians should only claim credit commensurate with the extent of their participation in the activity

METHOD OF PHYSICIAN PARTICIPATION:

To receive credit the participants must:

Read/view the entire educational activity.

Input name and credentials to gain CME credit.

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COURSE HOST:

Department of Medicine

Northwell Health

ESTIMATED TIME TO COMPLETE ACTIVITY:

90 minutes

ACKNOWLEDGEMENT OF COMMERCIAL SUPPORT:

An announcement of program support will be made to all attendees at the beginning of each educational activity.

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FACULTY DISCLOSURES:

Drs. Sandy Balwan, Anne Thorndike, George Boutis, John Raimo and Sean LaVine have nothing to disclose.

RELEASE DATE: 4/04/19
REVIEW DATE: 4/04/19
PROGRAM EXPIRATION: 7/30/19

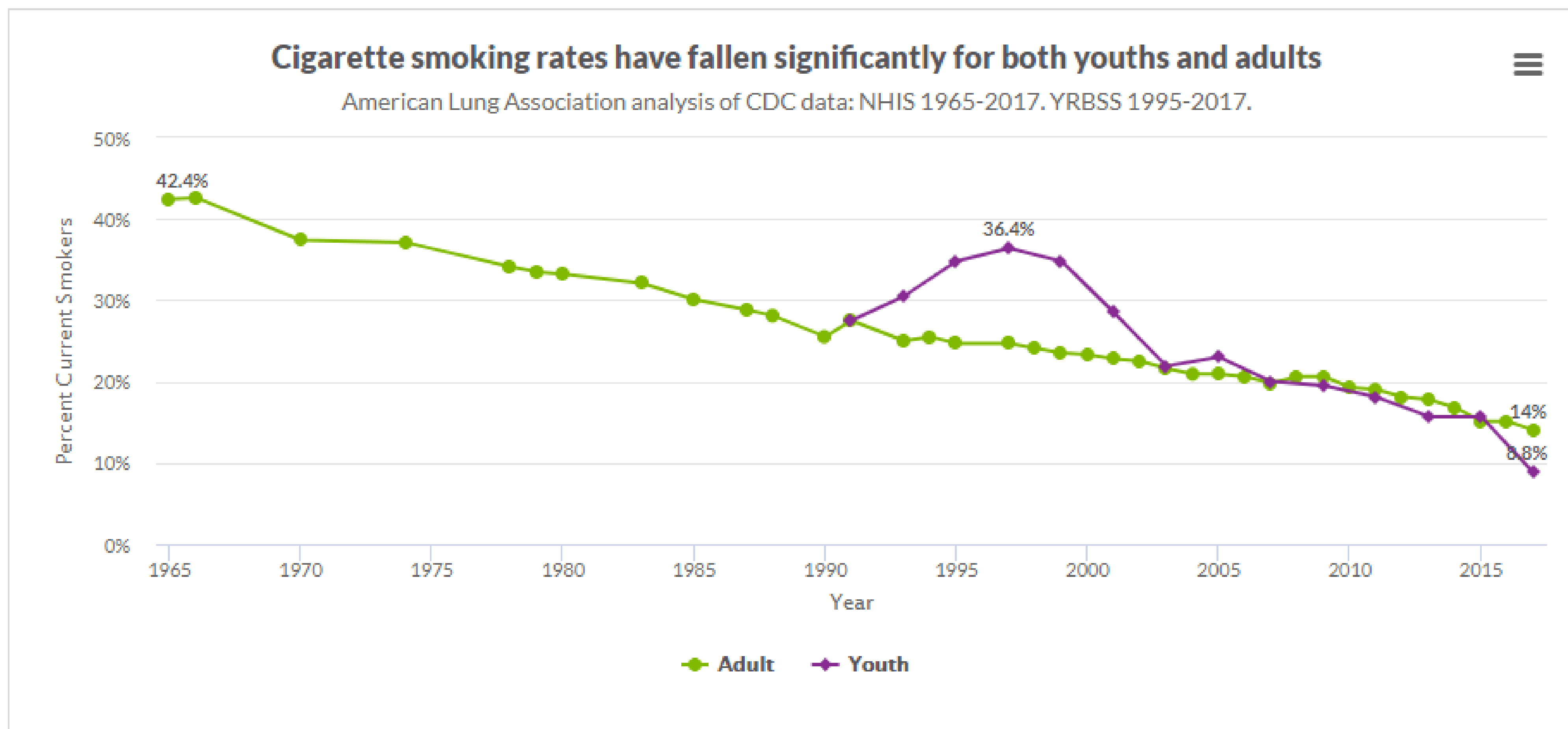
Outline

Evolving trends in tobacco use in the US

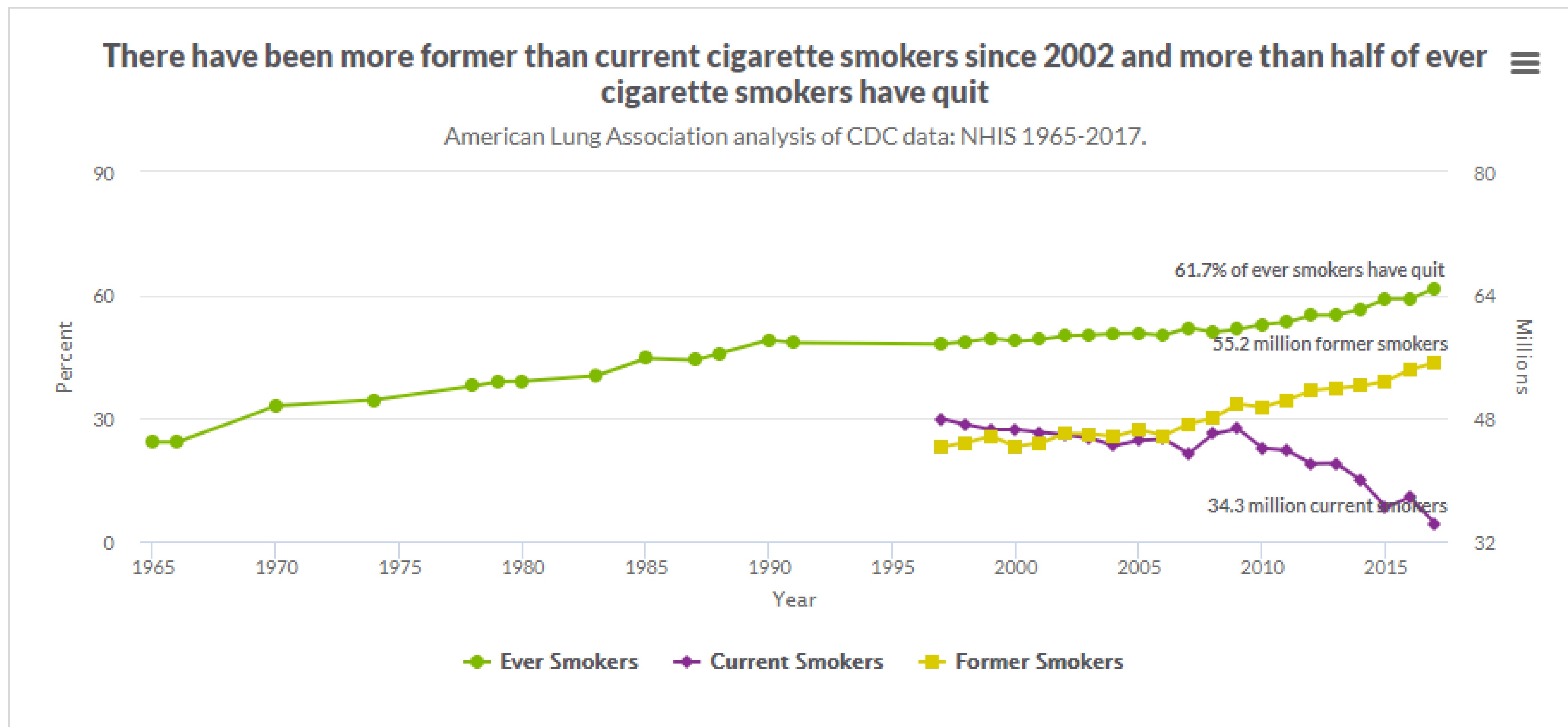
Electronic cigarettes: *new challenges*

Combustible cigarettes and adults with serious mental illness:
old challenges, new solutions

Trends in Cigarette Smoking Rates

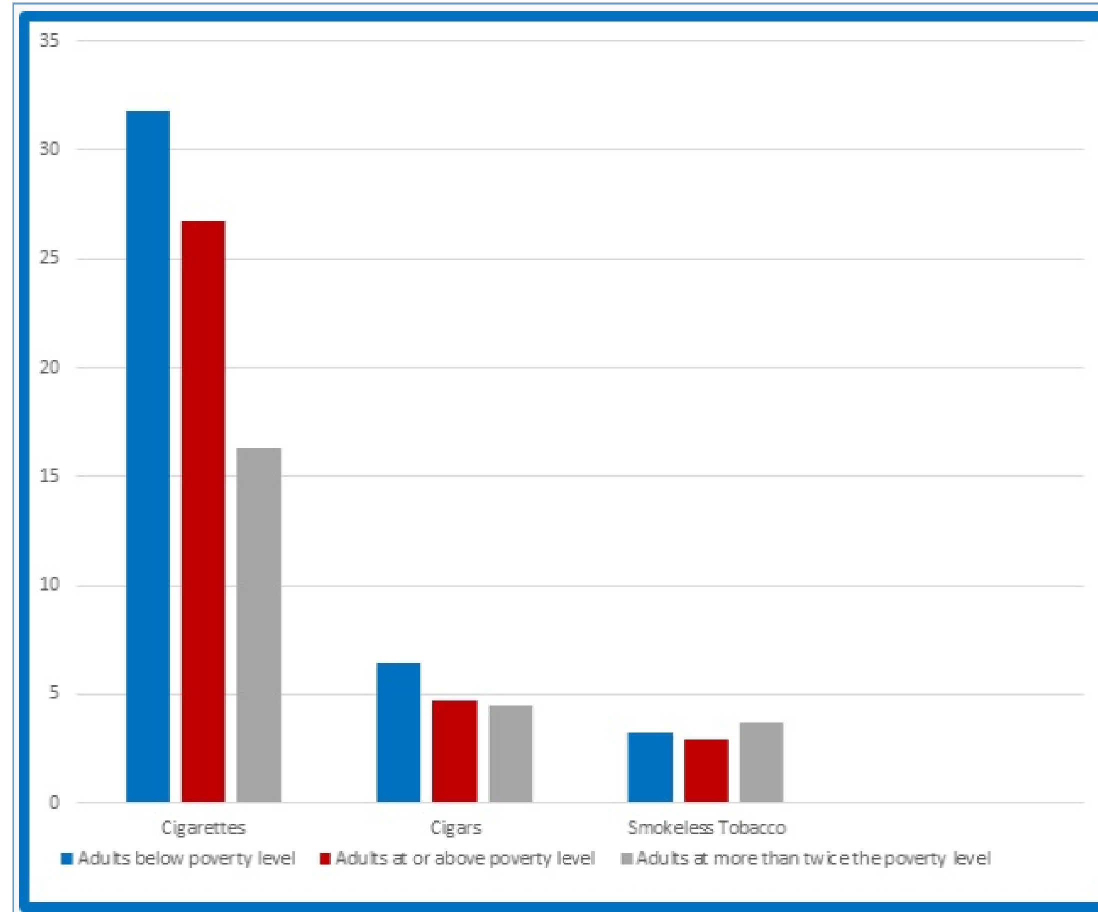


Trends in Number of People Who Smoke Cigarettes and Have Quit



The 34.3 million current cigarette smokers in 2017 marked the fourth time in a row there were less than 40 million current cigarette smokers in the United States since the government began collecting this date in 1997.

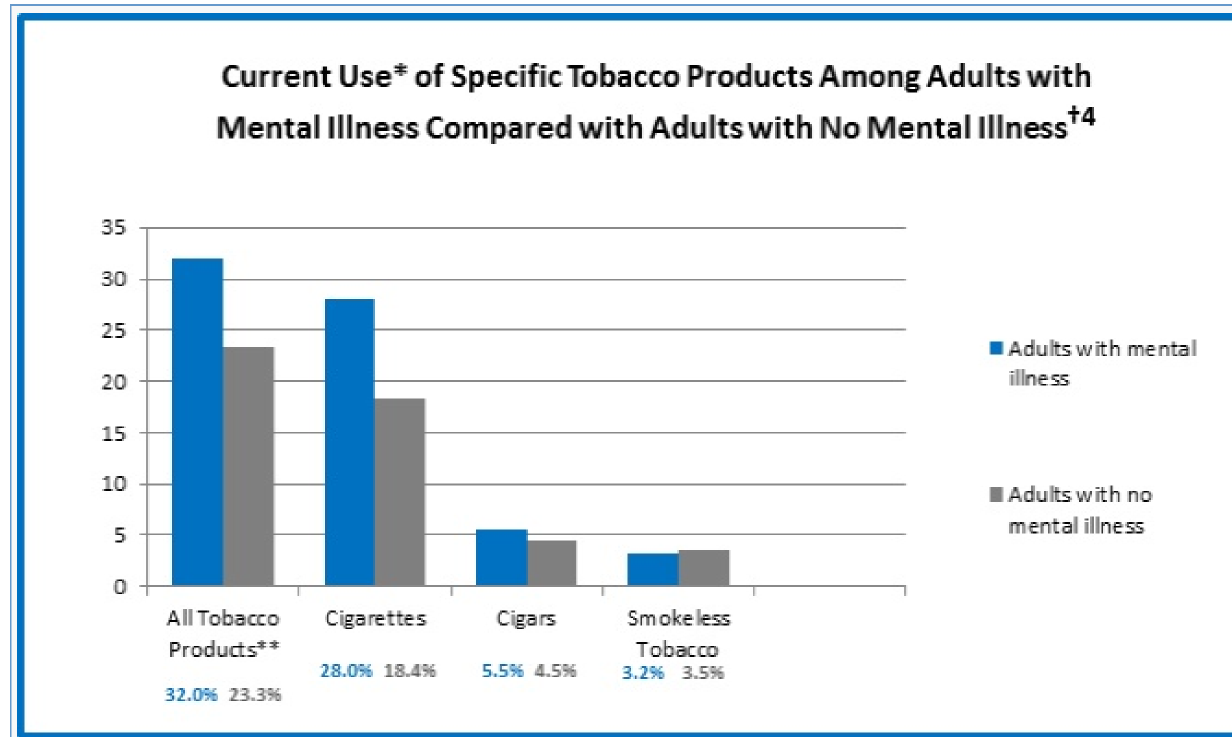
Current Use* of Cigarettes, Cigars, and Smokeless Tobacco among Adults Living Below Poverty Level Compared with Adults Living At or Above Poverty Level



* "Current Use" is defined as self-reported consumption of cigarettes, cigars, or smokeless tobacco in the past 30 days (at the time of survey).

† Data taken from the National Survey on Drug Use and Health, 2016, and refer to adults aged 18 years and older.

32.0% of adults with any mental illness reported current use* of tobacco in 2016 compared to 23.3% of adults with no mental illness.[4]

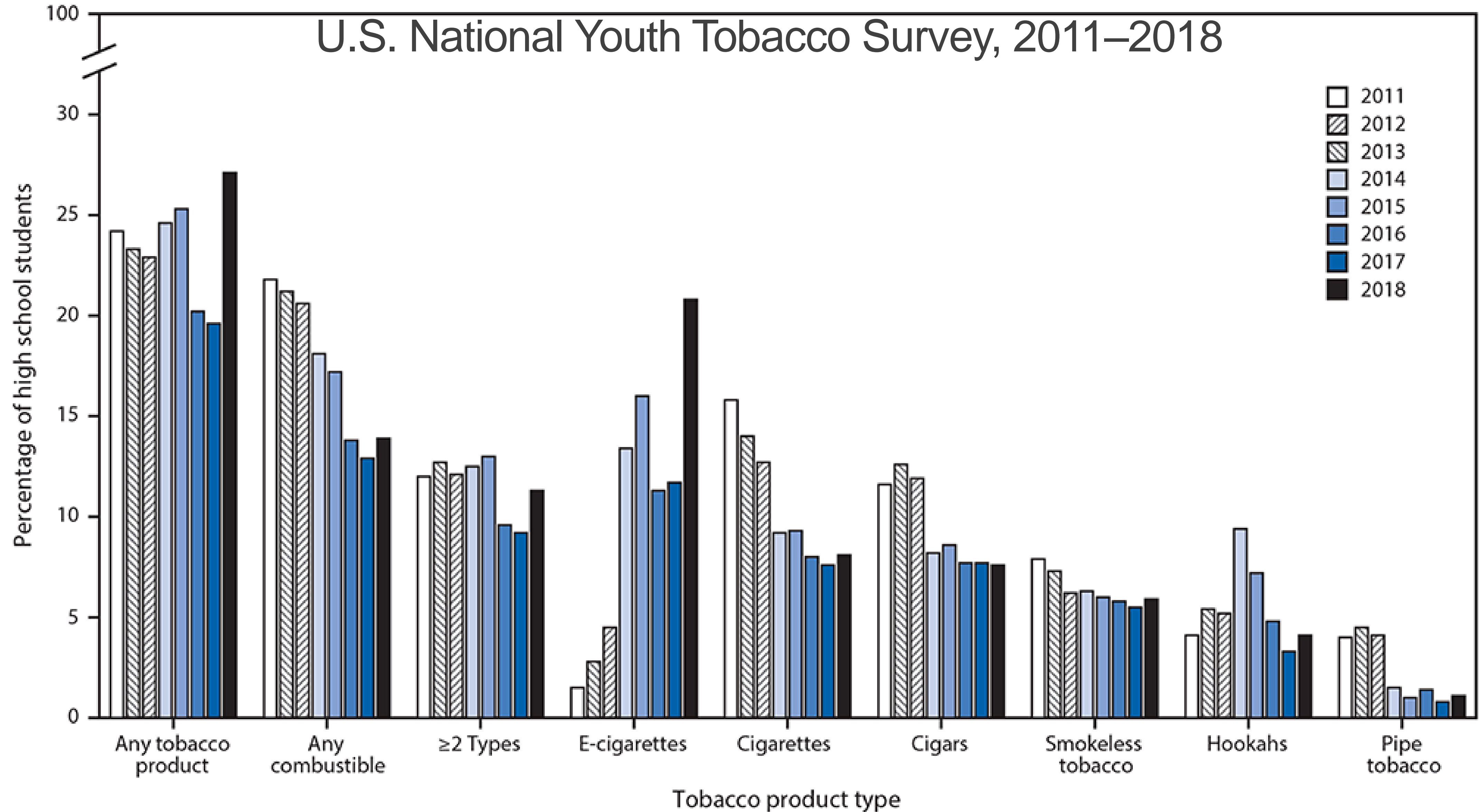


* "Current Use" is defined as self-reported consumption of cigarettes, cigars, and smokeless tobacco in the past month (at the time of survey).

** All Tobacco Products includes cigarettes, smokeless tobacco (i.e., snuff, dip, chewing tobacco, or "snus"), cigars, and pipe tobacco.

† Data taken from the National Survey on Drug Use and Health, 2016, and refer to adults aged 18 years and older self-reporting any mental illness in the past year, excluding serious mental illness.

Past 30-day tobacco product use by high school students



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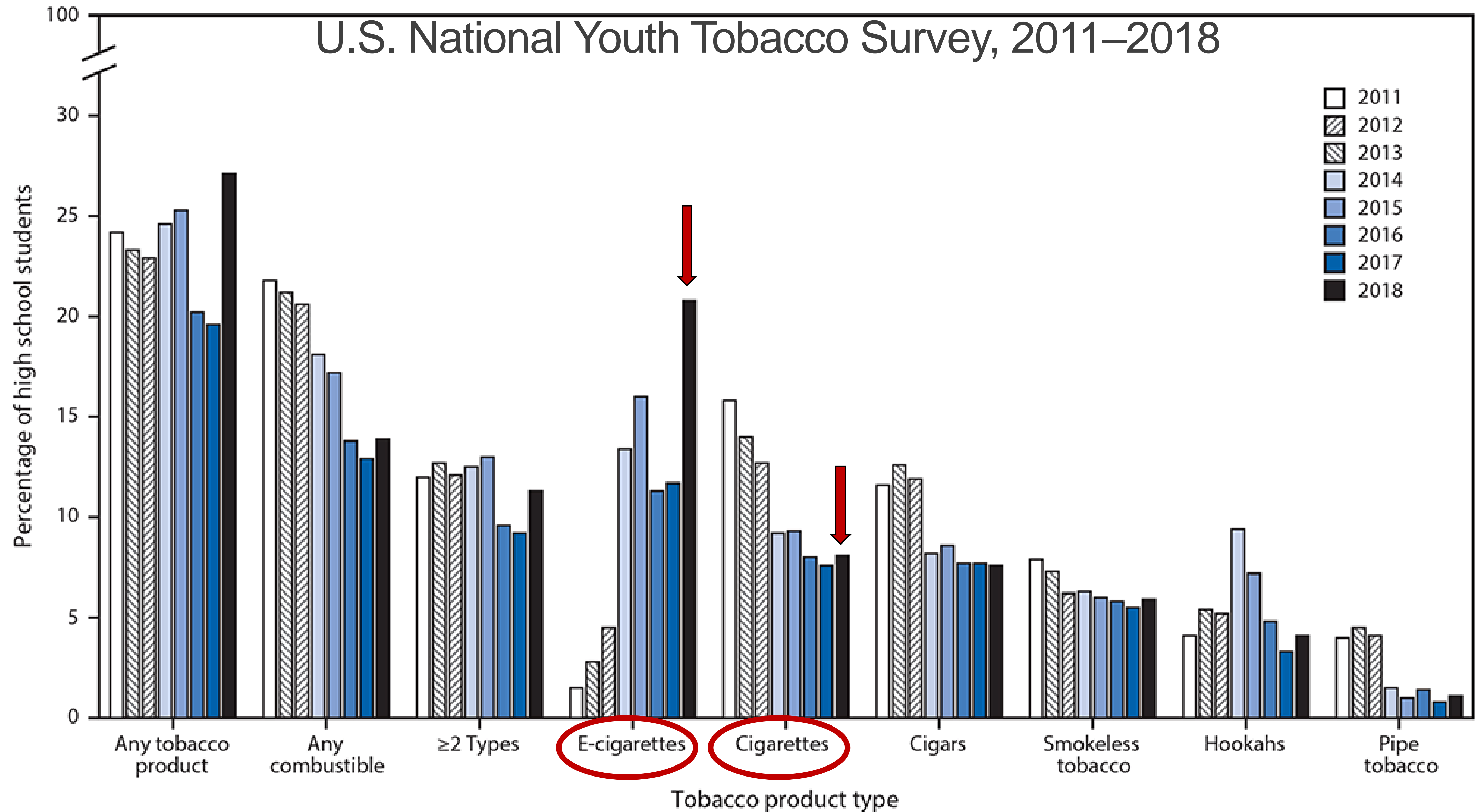


Electronic cigarettes
New challenges

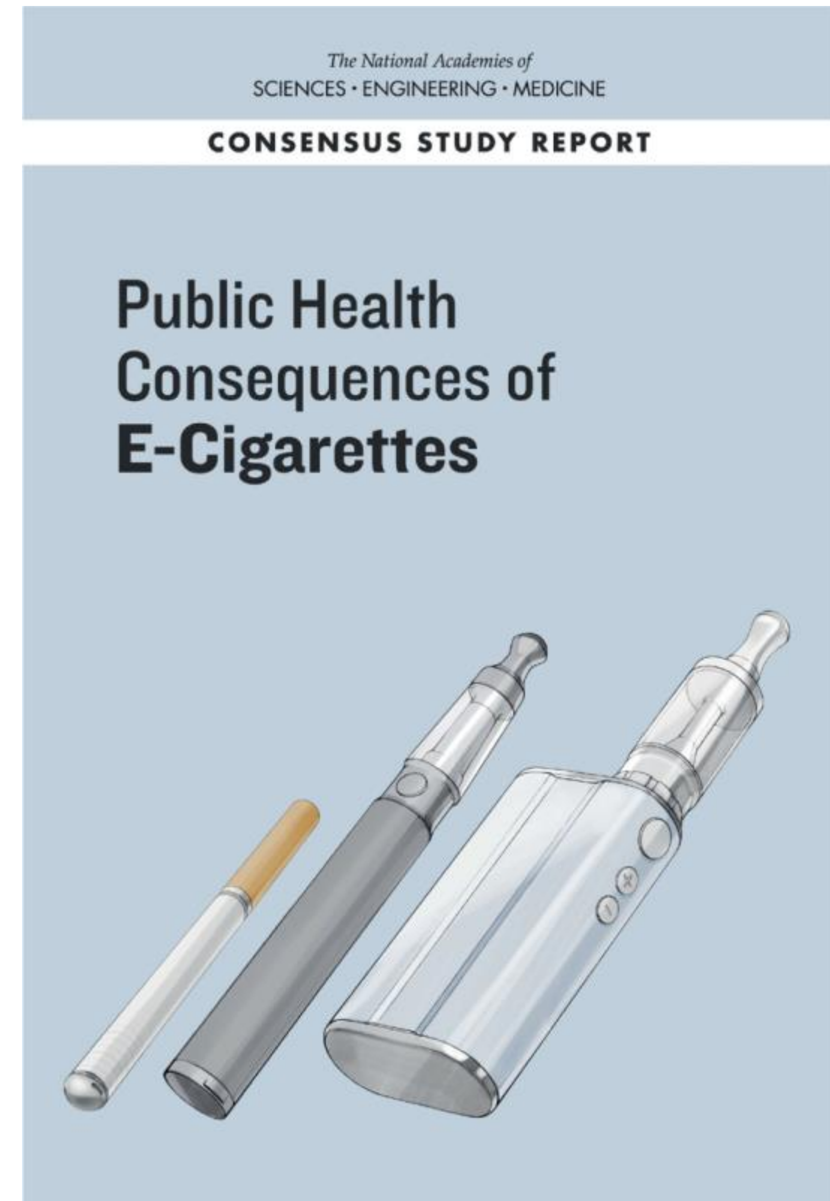
Electronic Cigarettes

- Invented in China ~ 2003
- Rapid growth in US sales started ~ 2011
- FDA tried to regulate as “drug/device” but was thwarted by courts
- FDA regulated as “tobacco products” in Aug 2016 - but brands on market can delay “modified risk” approval until 2022

U.S. National Academies of Sciences, Engineering and Medicine (NASEM) Report

Released January 23, 2018

nationalacademies.org/eCigHealthEffects



Overall Report Summary

- While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible cigarettes.
- E-cigarettes contain fewer toxic substances than combustible cigarettes.
- The long-term health effects of e-cigarettes are not yet clear.

NASEM Report. Jan. 2018.

Public Health Effects of E-cigarettes

The net public health effect of e-cigarettes will depend on the balance of 3 factors:

1. Potential to help current smokers to quit (adults)
2. Potential to increase the uptake of combustible tobacco product use (youth)
3. Inherent toxicity
   - Absolute – youth non-smokers
   - Relative to combustible tobacco – adult smokers

NASEM Report. Jan. 2018.

Conclusions about effectiveness of e-cigarettes for smoking cessation

- Moderate evidence from RCTs: e-cigs with nicotine are more effective than e-cigs without nicotine

- Insufficient evidence from RCTs: e-cigs as cessation aids compared with no treatment or with approved smoking treatments

- Moderate evidence from observational studies: more frequent use of e-cigs is associated with increased likelihood of cessation

NASEM Report. Jan. 2018.

Youth & Young Adult Smoking
Research Questions

Among adolescents and young adults with no history of smoking:

1. Does e-cigarette use affect risk of <u>ever use</u> of cigarettes?

2. Does e-cigarette use affect risk of <u>progression</u> to greater frequency, intensity, or duration of tobacco use?

NASEM Report. Jan. 2018.

Overall report summary: Net public health effects

- Using e-cigarettes may help adults who smoke combustible cigarettes quit smoking, but more research is needed.

- Among youth, e-cig use increases the risk of initiating smoking of combustible cigarettes.

- Modeling results suggest the use of e-cigs in the population will result in a net public health benefit.

NASEM Report. Jan. 2018.

What about e-cigarette use by adult non-smokers?

- Not discussed in the NASEM report

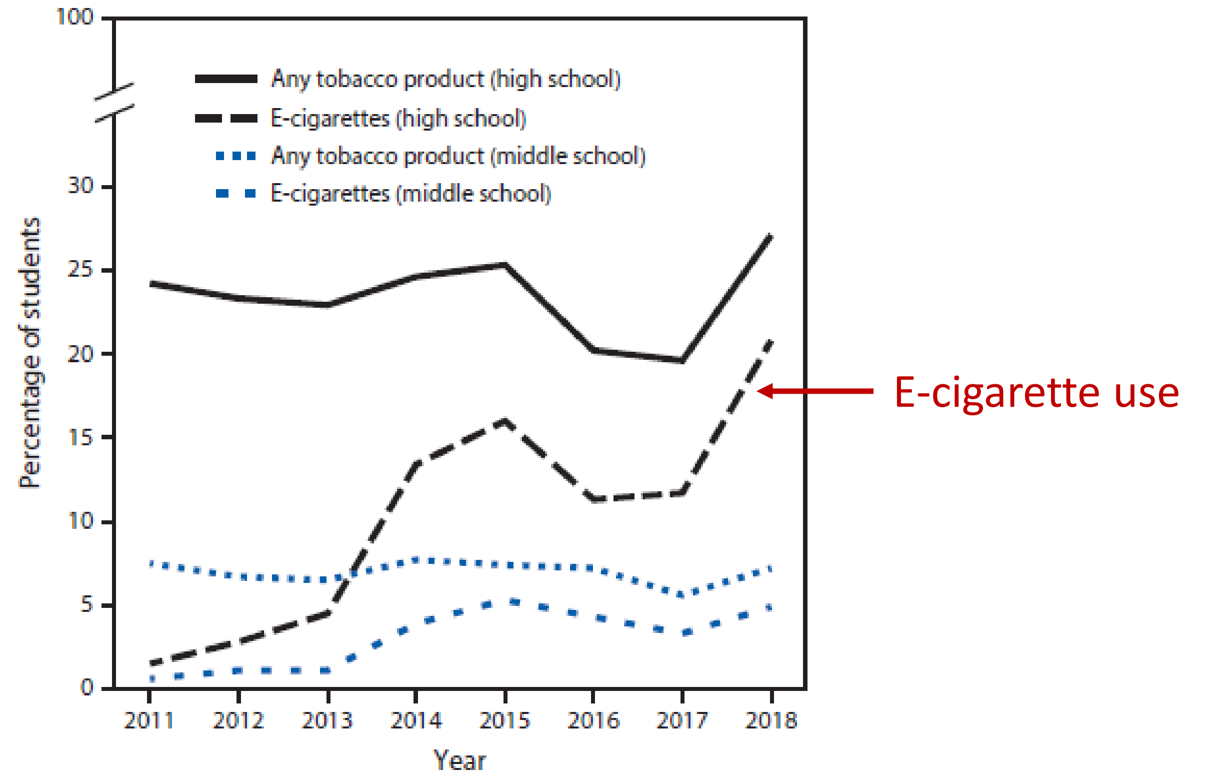
- 2016 Behavioral Risk Factor Surveillance System: prevalence of e-cig use by adult non-smokers was 1.4% (Mirbolouk, 2018)
  - Translated to 1.9 million US adult sole e-cig users

- National Health Interview Survey: overall e-cig use by adults decreased from 3.7% in 2014 to 3.2% in 2016 (Bao, 2018)
  - **Never smokers increased e-cig use from 0.4% to 0.7% (P=0.02)**

But everything changed in 2018. . .

National Youth Tobacco Survey

MMWR 2018

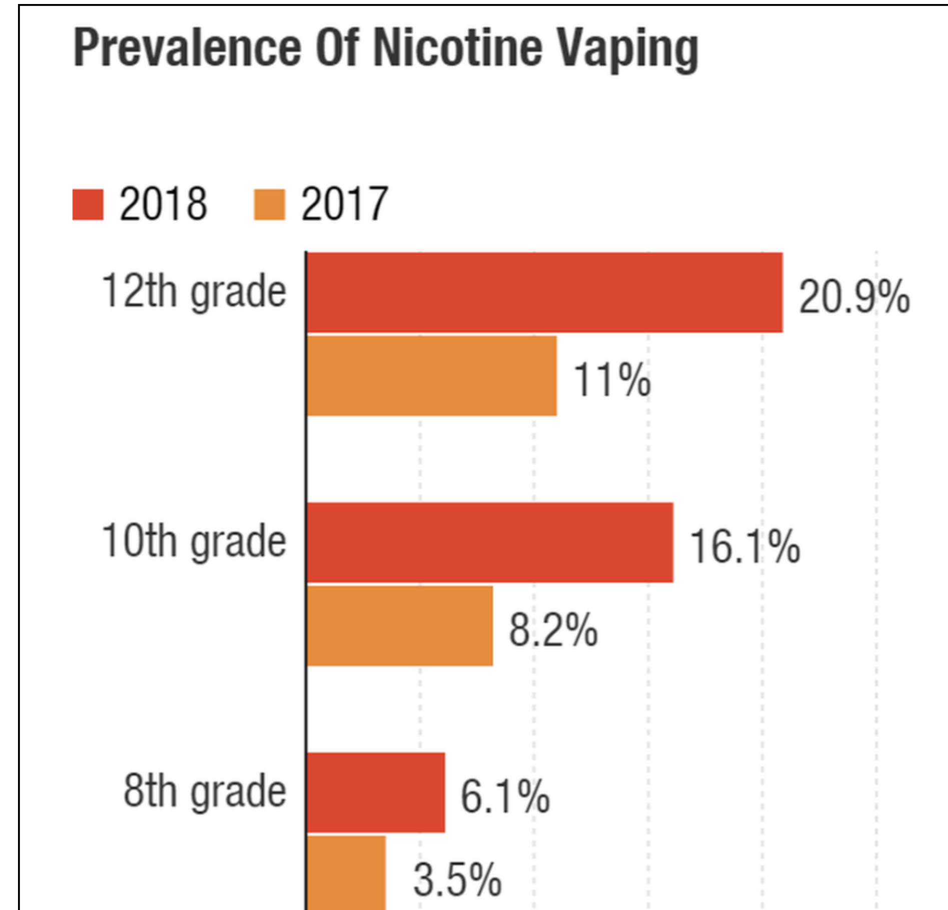


But everything changed in 2018. . .

Monitoring the Future Study

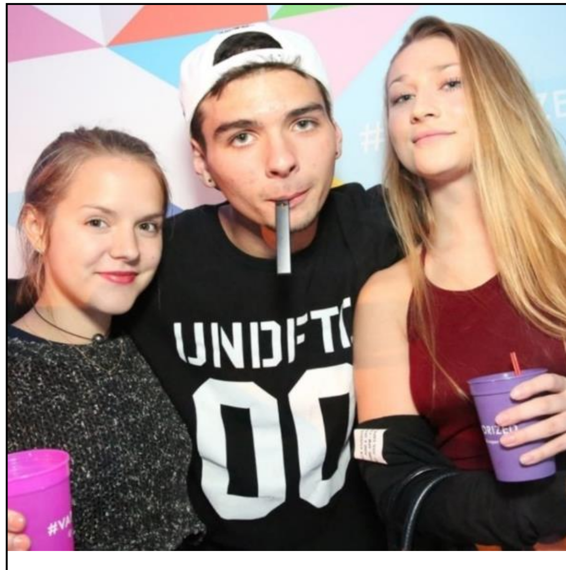
NEJM Dec. 2018

Annual cross-sectional school survey of US adolescents in grades 8-12



JUUL Phenomenon

- Sleek high-tech design
- Better nicotine delivery
- Social media marketing



"Invasion" of the Pod Mods?

MAY 14, 2018 ISSUE

THE PROMISE OF VAPING AND THE RISE OF JUUL

Teens have taken a technology that was supposed to help grownups stop smoking and invented a new kind of bad habit, molded in their own image.

Public Safety

Juuling: If you don't know what it is, ask your kids

'I Can't Stop': Schools Struggle With Vaping Explosion

Did Juul Lure Teenagers and Get 'Customers for Life'?

FDA Response

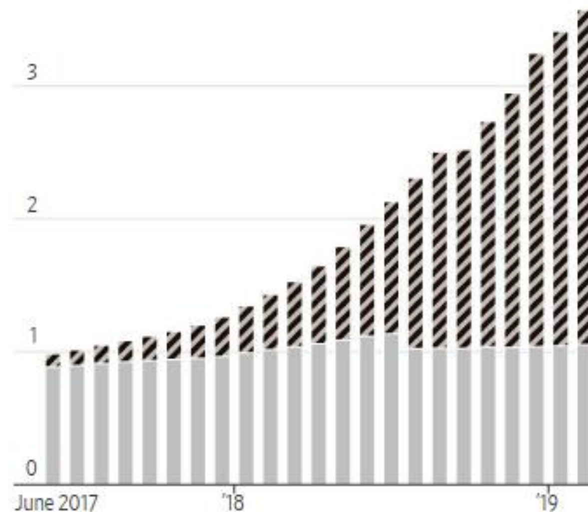
“The FDA now believes that youth use of e-cigarettes is reaching epidemic proportions.”

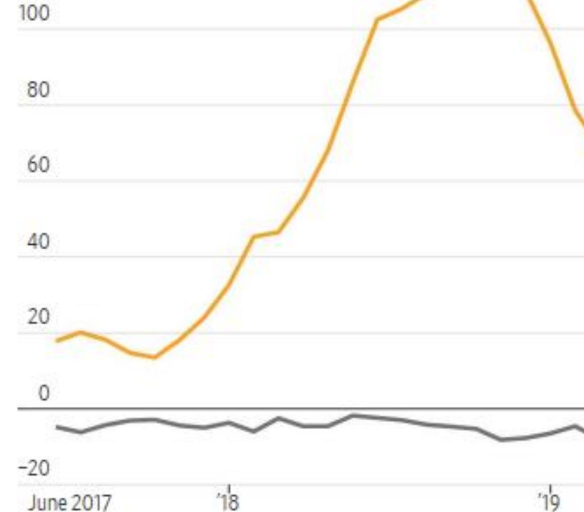
- **September 2018:**
  - Preliminary data showed ~75% increase in e-cig use in students
  - Illegal sales to minors: >1300 retailers sold JUUL to minors in “nationwide undercover blitz”
  - Actions: warn, fine retailers who sold e-cigs to minors; manufacturers had 60 days to show plans to decrease youth use
- **November 2018:**
  - Banned sales of flavored e-cigs in retail stores and gas stations (except tobacco, menthol, and mint flavors)
  - Required age-verification for on-line sales

Sales of JUUL continue to grow, while cigarette sales decline

Tobacco's New Landscape

E-cigarette sales are booming, while cigarette sales are shrinking, and Juul is the biggest player.





Note: Sales from retail stores tracked by Nielsen for the 52-week period ended on each date; web sales not included. Volume growth for four-week period.

Sources: Wells Fargo analysis of Nielsen data

Wall Street Journal, March 23, 2019.

What does a teenage epidemic mean for the next generation of young adults?

- Gateway theory: teen e-cig use will lead to increased smoking
- Gateway theory may be outdated:
  - Vaping high-dose nicotine may be the endpoint
  - On-line poll: two-thirds of teens who vaped believed it could be part of a "healthy life" (WSJ, Sept. 2018)
- Nicotine-dependent teens become nicotine-dependent adults (we've seen this before. . .)

E-cigarette use by adults

- New study suggests benefits for smoking cessation (Hajek, *NEJM* 2019)
  - 886 smokers in UK who wanted to quit
    - randomized to NRT vs. e-cigs
  - Smokers using e-cigs were **1.8 x more likely to quit** than those using NRT
  - Among those who were quit at 1 year:
    - **80% in the e-cig group were still using e-cigs**
    - **9% in the NRT group were still using NRT**
- Sole e-cigarette users (both former and never smokers) will continue to increase
- There is little guidance for clinicians

Guidance for Clinicians' Discussions of E-cigarettes with Patients
2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment

Recommendations:

- Emphasize to smokers the importance of the goal of *complete* cessation of all combustible tobacco products
- Recommend smokers use evidence-based, FDA-approved smoking cessation aids
- Clinicians should be prepared to discuss evidence about e-cigarettes' risks/benefits with patients who ask

Barua, et al. *JACC.* 2018.

Guidance for Clinicians' Discussions of E-cigarettes with Patients
2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment

Points to cover in discussion about e-cigs:

- E-cigs heat nicotine-containing liquid and produce aerosol different from smoke
- Contain chemicals (e.g., propylene glycol, glycerin, flavorings) that may be risky
- Expose users to fewer and lower levels of toxic compounds than smoking

Barua, et al. *JACC.* 2018.

Guidance for Clinicians’ Discussions of E-cigarettes with Patients
2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment

Points to cover in discussion about e-cigs:

- If used as substitute for smoking: less harmful in the short-term, but long-term safety uncertain
- Scientific information about health effects and effectiveness of e-cigs for quitting is limited and evolving
- Not currently approved by the FDA for cessation
- E-cigs vary in design, contents of e-liquids, and nicotine and toxicant delivery

Barua, et al. *JACC.* 2018.

Guidance for Clinicians' Discussions of E-cigarettes with Patients
2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment

If a smoker chooses to use e-cigs, advise:

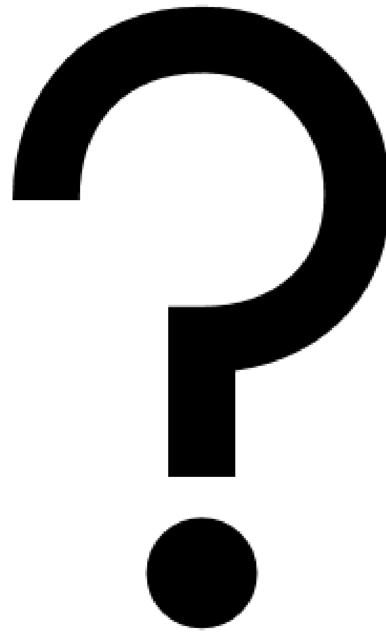
- Switch completely to e-cigs from combustible cigarettes; avoid dual use
- The goal is cessation of e-cigs; after stopping combustible tobacco, plan to taper off e-cigs
- Heed safety instructions; choose child-proof packaging
- Avoid using e-cigs around children

Barua, et al. *JACC.* 2018.

Guidance for Clinicians' Discussions of E-cigarettes with Patients

2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment

If a non-smoker chooses to use e-cigs, advise:



Barua, et al. *JACC.* 2018.

Most electronic health records do not currently have a place to record e-cigarette use

Tobacco documentation in Epic at Massachusetts General Hospital

Social History

Mark as Reviewed 3/22/2019

Tobacco

Smoking Tobacco Status: Never Smoker

Started smoking tobacco:

Quit smoking tobacco:

Types: Cigarettes | Pipe | Cigars

Packs/day: 0.25 | 0.5 | 1 | 1.5 | 2 | 3

Years: 0.5 | 1 | 2 | 3 | 4 | 5 | 10 | 15

Counseling Given: Yes | No

Comments:

Smokeless Tobacco Status: Never Used

Types: Snuff | Chew

Quit Date:

Additional points to consider when talking to non-smoking patients about e-cigarette use

- Most e-cigs contain nicotine, and nicotine is addictive

- Chronic e-cigarette use fulfills DSM-V definition of “tobacco use disorder” including:
  - tolerance
  - withdrawal
  - time spent in activities to obtain or use it
  - interference with obligations or important activities at work, home, or school

Additional points to consider when talking to non-smoking patients about e-cigarette use

- Chronic exposure to heated and aerosolized liquids in e-cigs may have long-term health effects
- For women of child-bearing age: nicotine has adverse effects on a developing fetus
- Offer assistance with quitting; first line treatment is NRT but could consider varenicline or bupropion; no data available

Combustible cigarettes and adults with serious mental illness

Old challenges, new solutions

Smoking in People with Serious Mental Illness (SMI)

- SMI = schizophrenia, schizoaffective disorder, bipolar, and major depressive disorder
- Smoking prevalence is higher:
  - 64% in schizophrenia
  - 44% in bipolar disorder
  - 14% in general population
- Overall mortality in SMI is 3.7 times higher than those without SMI
  - **> 25-year mortality gap**

Olfson, *JAMA Psych*. 2015; Cook, *JAMA*. 2014.

We know smoking and SMI is a problem, but there is a treatment gap

- Data from the National Ambulatory Medical Care Survey 1991-1996 (Thorndike, *Nic & Tob Res.* 2001):
  - MD's more likely to identify smoking status and counsel about smoking in patients with psychiatric diagnoses compared to patients without psychiatric diagnoses.

- In 1996, the American Psychiatric Association recommended the routine treatment of smoking for people with psychiatric diagnoses

We know smoking and SMI is a problem, but there is a treatment gap

Data from Health Center Patient Survey in **2014:**

Table 3 Quitting-Related Characteristics of Ever and Current Smokers by the Presence of Serious Mental Illness (SMI)

	No. (weighted %)		Unadjusted OR (95% CI)	aOR (95% CI)*
	SMI	No SMI		
Being a former smoker (among ever smokers)	232 (30%)	743 (46%)	*0.50 (0.33–0.76)*	0.68 (0.46–1.003)
Received advice to quit in past 12 months (among current smokers)	555 (87%)	760 (74%)	*2.30 (1.20–4.42)*	*2.47 (1.20–5.07)*
Past-12-month quit attempt (among current smokers)	372 (59%)	555 (48%)	*1.56 (1.01–2.40)*	1.47 (0.93–2.30)
Plans to quit in next 30 days (among current smokers)	117 (17%)	169 (17%)	0.96 (0.44–2.11)	1.19 (0.51–2.77)

Italics indicates statistical significance ($p<0.05$)

**Adjusted for age, sex, race/ethnicity, education, being uninsured for 6 or more months in the past year, income, clinic type, ever use of illicit drugs, symptoms of alcohol use disorder, and number of medical comorbidities. Analyses among current smokers also controlled for being a daily smoker*

Kalkhoran, *JGIM.* 2019.

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Quit ratio = the ratio of former smokers to ever smokers

For individuals with SMI: 30%

For individuals without SMI: 46%

Kalkhoran, *JGIM.* 2019.

Myths about treating smoking in people with SMI

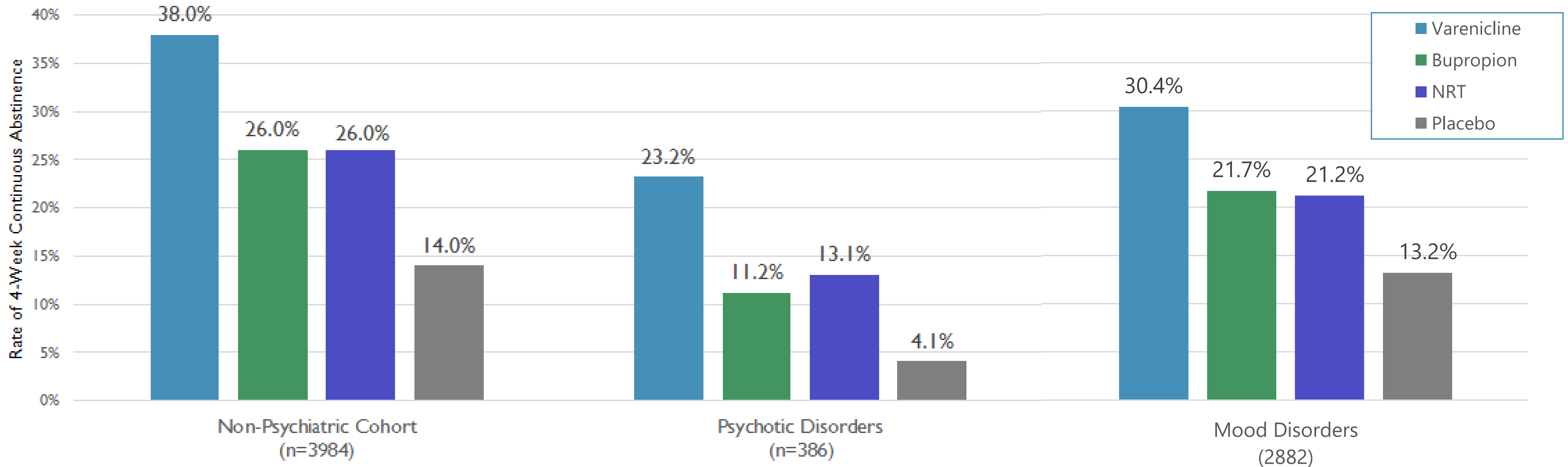
1. People with SMI don't want to quit smoking
2. People with SMI can't quit smoking and medications don't help
3. Medications for smoking and quitting smoking exacerbate mental health symptoms
4. Medications should only be prescribed for smokers ready to quit completely
5. Smoking is a low priority for people with acute psychiatric symptoms

Prochaska, *NEJM.* 2011.

Myths 1 and 2: People with SMI don’t want to and/or can’t quit smoking

- Increasing evidence that 60-70% of people with SMI do want to quit.
- There is now strong evidence that medications to treat smoking are effective in people with SMI:
  - Varenicline
  - Bupropion
  - Nicotine replacement therapy
- EAGLES: largest smoking cessation trial ever; also included largest sample of smokers with psychotic, anxiety, and mood disorders
  - conducted by Pfizer in collaboration with GlaxoSmithKline
  - designed in consultation with the FDA and the European Medicines Agency

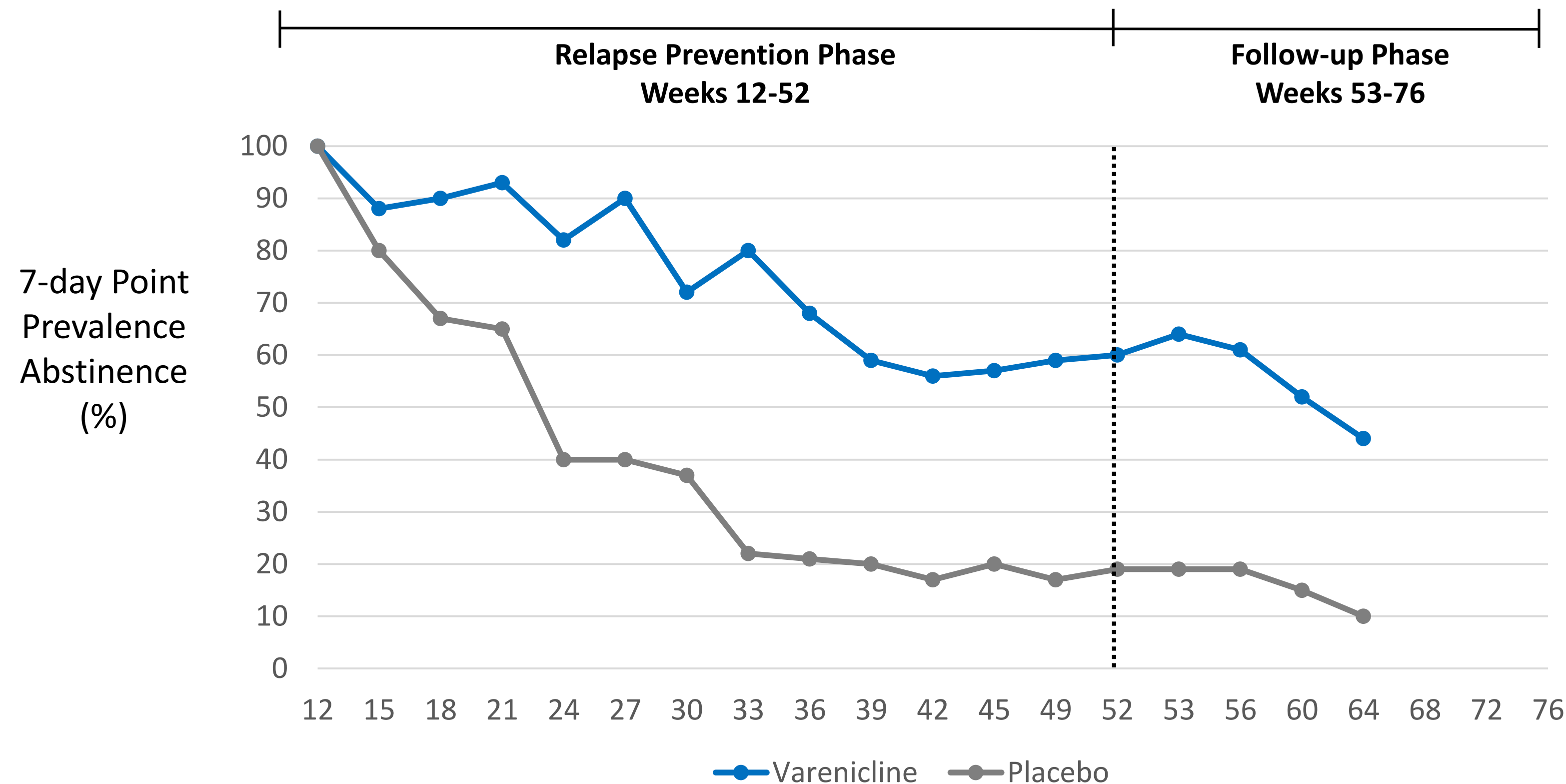
EAGLES Trial: Comparative efficacy of smoking medications



Evaluating Adverse Events in a Global Smoking Cessation Study (EAGLES) published in *The Lancet* (2016).

Extended medication treatment may be the most effective strategy

Smokers with SMI who had stopped smoking with 12 weeks of varenicline sustained cessation more successfully with 1 year of continued varenicline.

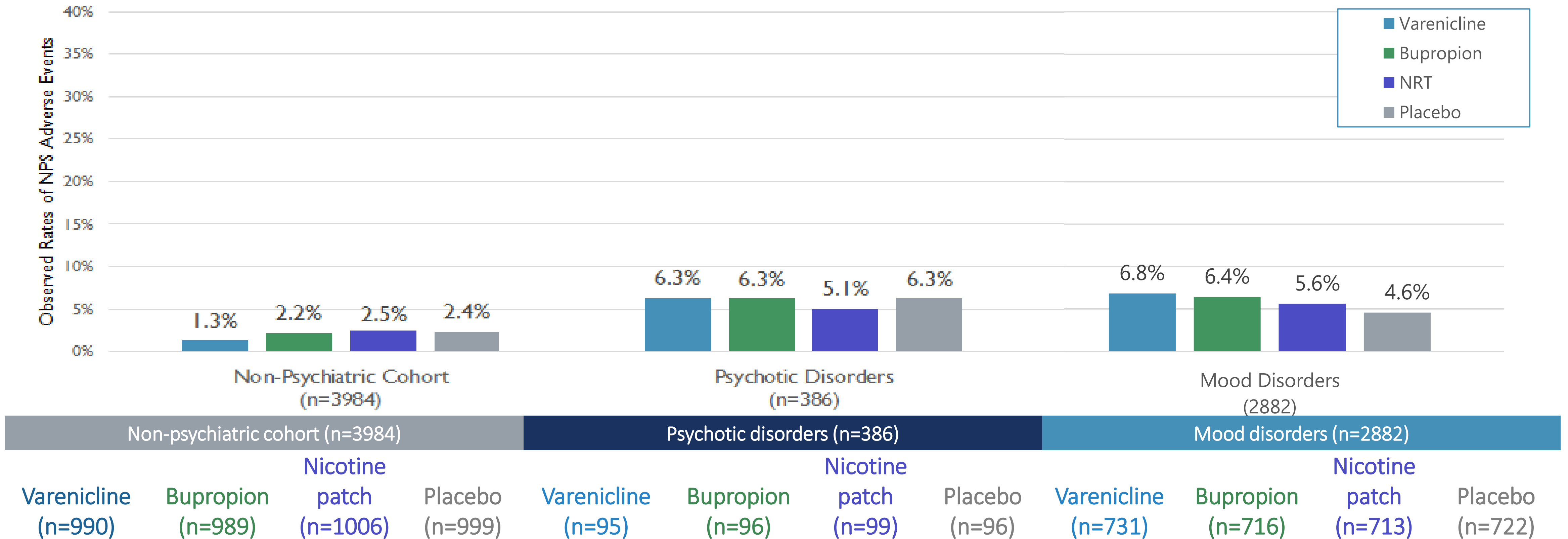


Evins, *JAMA.* 2014

Myth 3: Smoking medications and quitting smoking exacerbate mental health symptoms

- Stopping smoking does not worsen psychiatric symptoms and may improve depressive symptoms
- Smoking medications do not worsen psychiatric symptoms
- The FDA removed “black box” warnings for varenicline and bupropion based on safety data from the EAGLES trial

EAGLES Trial: Safety

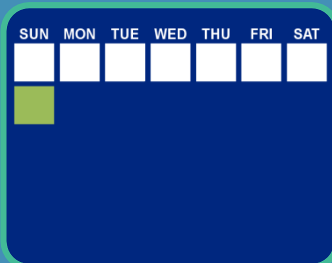


Evaluating Adverse Events in a Global Smoking Cessation Study (EAGLES), *Lancet.* 2016

Myth 4: Medications should only be prescribed for smokers ready to quit completely

Fixed Quit

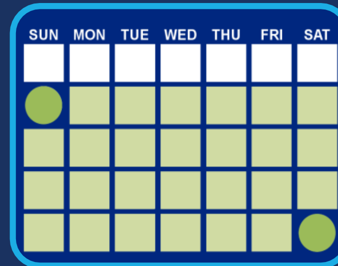
For people who want to quit smoking in a week



- Set a target quit date that is 1 week after starting smoking cessation medication
- Can keep smoking for the first week while they prepare to quit
- Take smoking cessation medication for 12-24 weeks

Flexible Quit

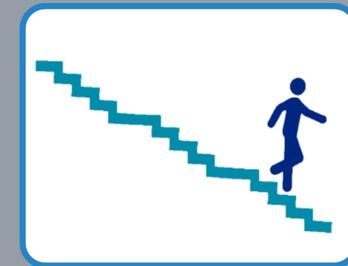
For smokers with serious mental illness (SMI)



- Start taking smoking cessation medication and pick a quit date 8 to 35 days after starting treatment
- *Can keep smoking for up to a month on smoking cessation medication while they prepare to quit*
- Take smoking cessation medication for 12-24 weeks

Gradual Quit

For patients who are not able/willing to quit abruptly

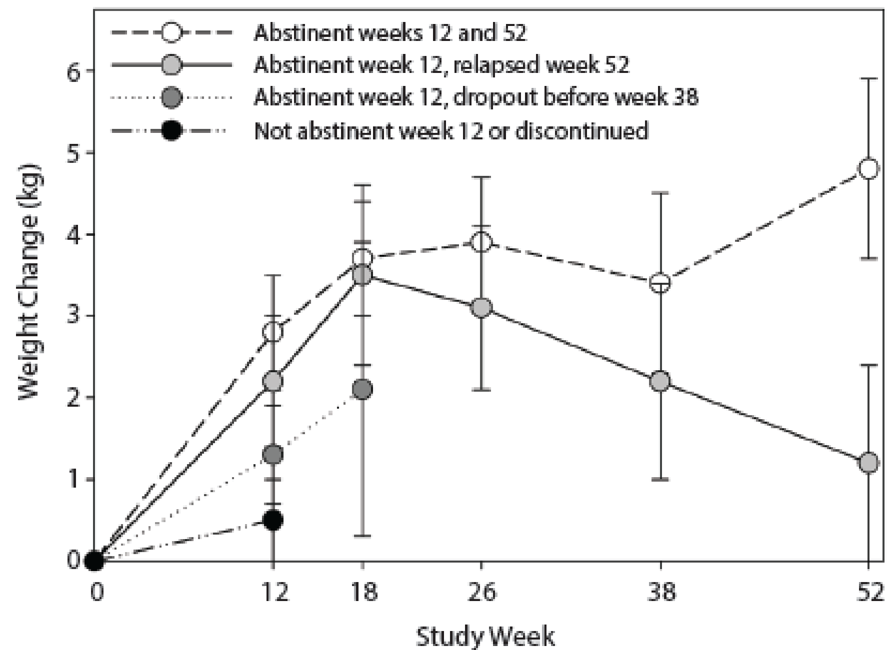


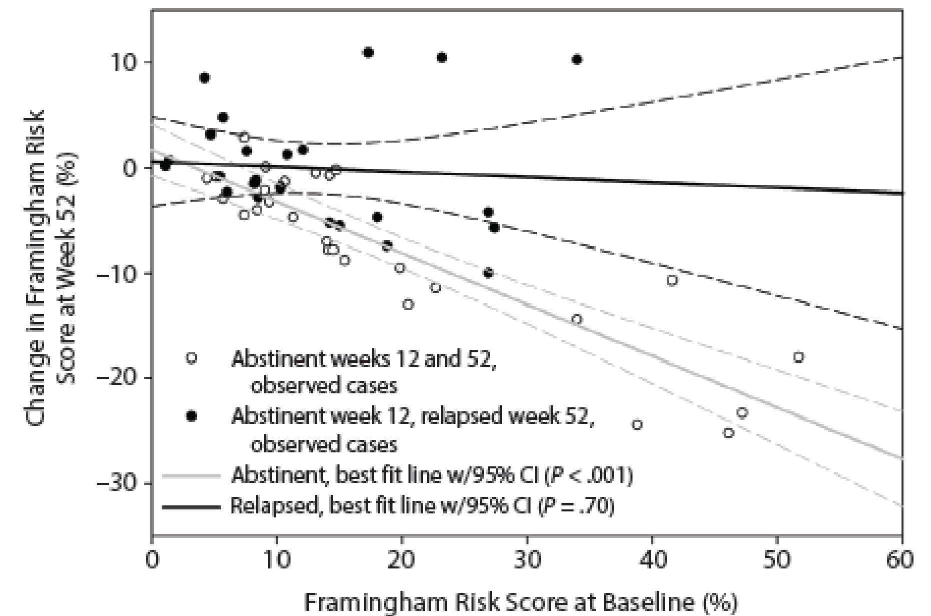
- Start taking smoking cessation medication and reduce smoking by 50% over 4 weeks, by an additional 50% in the next 4 weeks, and continue reducing with the goal of quitting by 12 weeks.
- Continue smoking cessation medication for an additional 12 weeks, for a total of 24 weeks

Myth 5: Smoking is a low priority for people with acute psychiatric symptoms

- Smoking in people with SMI is a public health crisis that should be a top priority for clinicians
- People with SMI: largest disparity in CVD morbidity and mortality than any other racial/ethnic or socioeconomic group
- Quitting smoking reduces cardiovascular risk despite weight gain associated with quitting

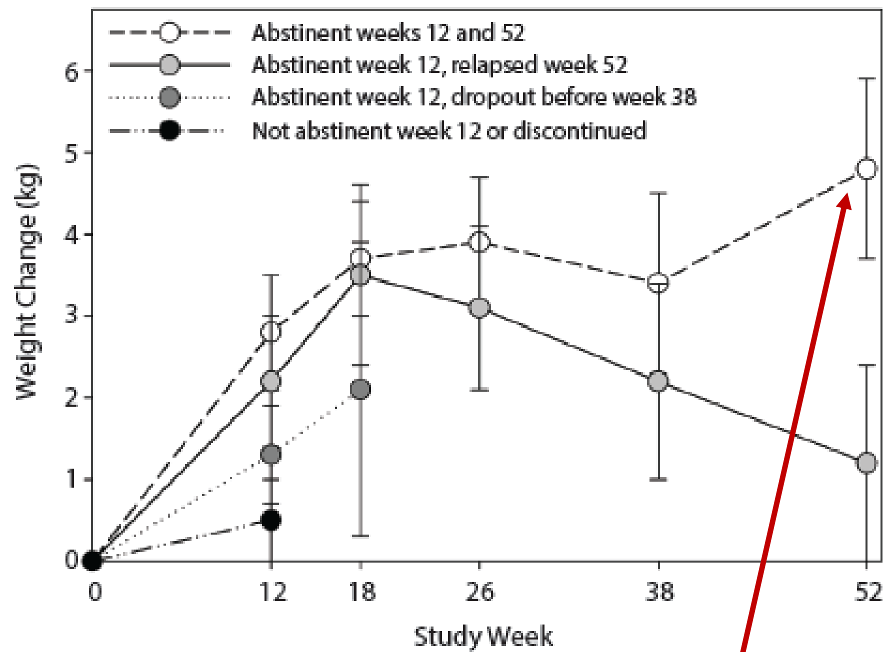
Change in weight and Framingham risk score by smokers who remained quit vs. those who relapsed over 1 year

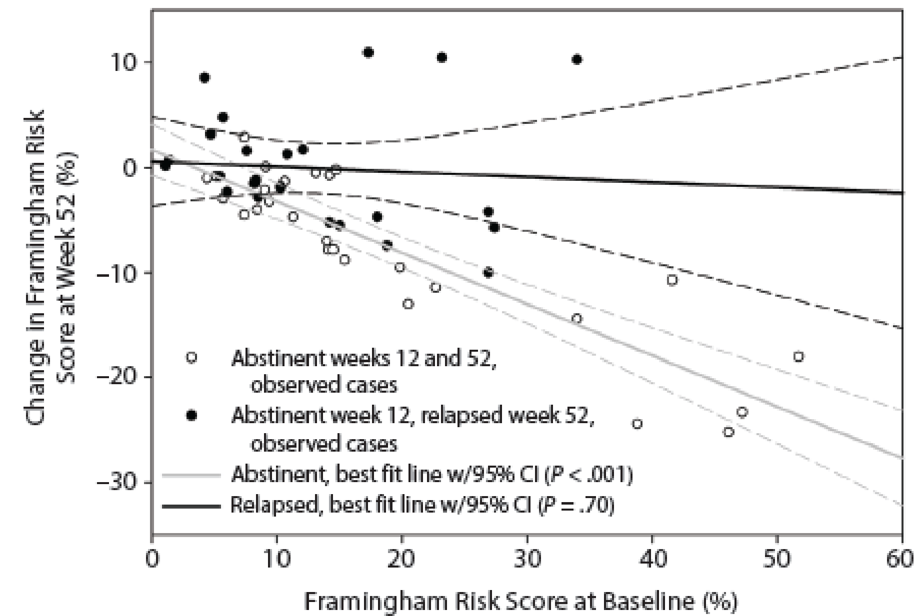




Thorndike, *J Clin Psych.* 2016.

Change in weight and Framingham risk score by smokers who remained quit vs. those who relapsed over 1 year





Those who were abstinent gained > 4 kg at 52 wks

Thorndike, *J Clin Psych.* 2016.

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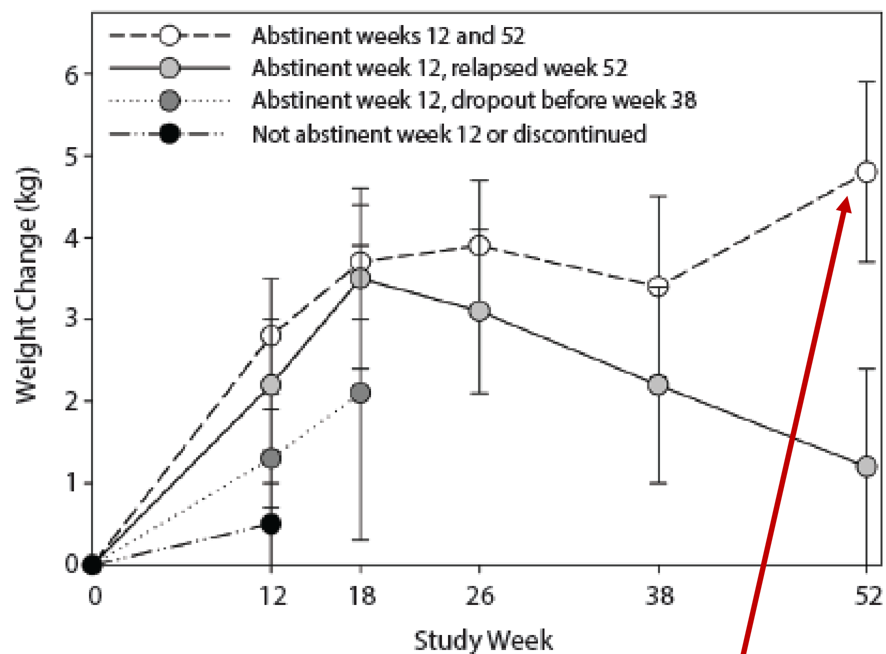

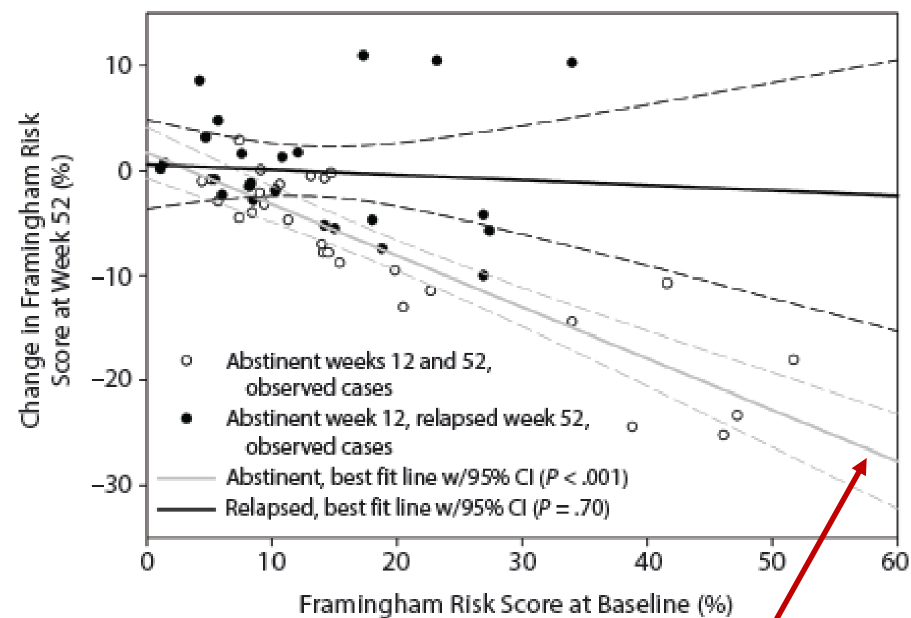

Those who were abstinent gained > 4 kg at 52 wks

Those who were abstinent reduced their FRS by > 20% at 52 wks

Thorndike, *J Clin Psych.* 2016.

Conclusions: *Good News and Bad News*

Let’s start with the Bad News first. . .

- **Smoking and SMI**
  - Despite an all-time low in smoking in the US, people with SMI have a prevalence similar to overall smoking rates in the1960’s
  - Enormous mortality gap due to CVD and other smoking-related diseases.

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  - Enormous mortality gap due to CVD and other smoking-related diseases.
- **E-cigarettes**
  - Just when teen tobacco use started decreasing, unprecedented rapid rise in use of e-cigarettes in 2018
  - “JUUL phenomenon” will lead to increase in nicotine dependence
  - Clinicians have little guidance about treating chronic e-cig use
  - Research is needed to determine effective strategies for quitting

. . . But end with the Good News!

- **Smoking and SMI**
  - Smoking medications are safe and effective
  - Black box warnings have been removed from varenicline and bupropion
  - Flexible and gradual quit strategies provide quitting options for smokers willing to start a medication

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  - Smoking medications are safe and effective
  - Black box warnings have been removed from varenicline and bupropion
  - Flexible and gradual quit strategies provide quitting options for smokers willing to start a medication
- **E-cigarettes**
  - FDA is taking strong action to keep e-cigs away from kids
  - New evidence that e-cigs may help some adult smokers quit
  - The ACC has published the first guidelines for talking about e-cigs with patients; it is likely that other groups will follow

Thank you!