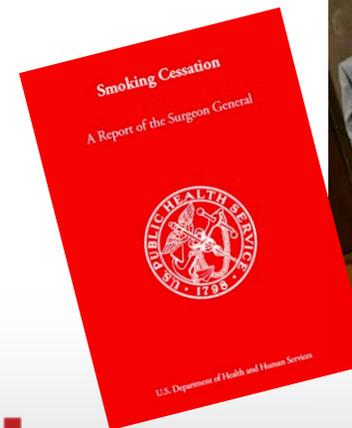


DC | HEALTH

Tobacco Cessation

Judith J. Prochaska, PhD, MPH
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Stanford University

A MESSAGE FROM U.S. SURGEON GENERAL JEROME ADAMS



DISCLOSURES

Current Funding: NHLBI R01HL117736; NCI R01CA204356, R01CA217165 and P01CA225597; NCI Moonshot Suppl P30CA124435; NIDA UHAG052168, R34DA046008, R21DA042222, and R44DA04871

Consulting: Consultant to pharmaceutical (Pfizer, Achieve Life Sciences) and technology companies (Carrot) focused on helping people quit smoking; expert witness for plaintiff counsel in litigation against the tobacco companies

Learning Objectives

Describe	evolution of the tobacco product landscape;
Discuss	fundamentals of tobacco use, health effects, and nicotine addiction;
Understand	combined behavioral & pharmacological treatment best practices;
Describe	newer strategies with cessation medications & behavioral treatments;
Discuss	brief motivational approaches for client engagement & referral;
Summarize	key conclusions of 2020 Surgeon General Report on Smoking Cessation;
Identify	gaps in the treatment literature and future directions.

Overview



Epidemiology: nicotine product landscape, use patterns, addiction and health harms



Counseling: modalities for delivery of behavioral counseling (e.g., quitlines, web, text, app interventions)



Pharmacotherapy: new approaches to medications (e.g., combination medications, pre-loading)

Overview



Epidemiology: nicotine product landscape, use patterns, addiction and health harms



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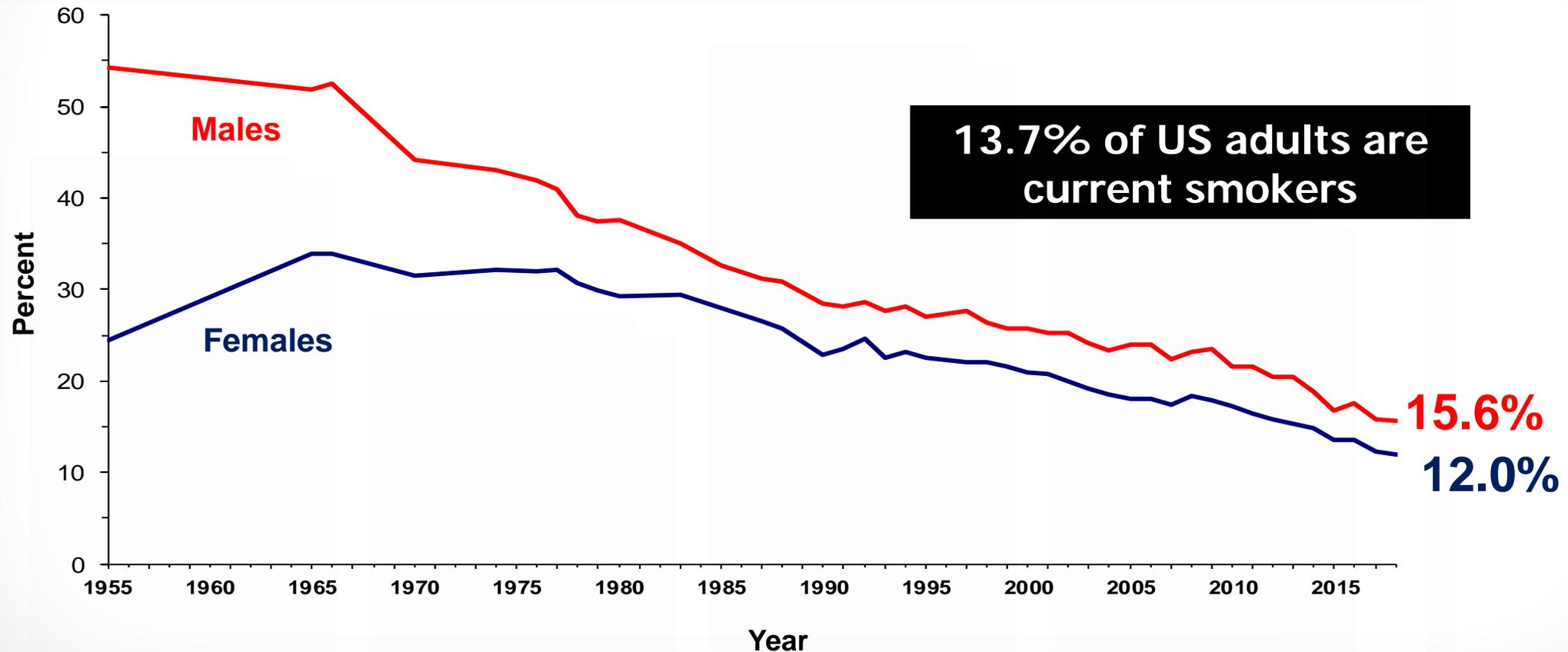
E-CIGARETTE EVOLUTION



FORMS of TOBACCO: SUMMARY

- A variety of tobacco products exist.
- For US adults, cigarettes are, by far, the most common form of tobacco.
- All forms of tobacco are harmful.
- The safety/efficacy of e-cigarettes is not established.
- E-cigarettes have increased in their efficiency of nicotine delivery.
- Clinical attention to all forms of tobacco is needed.

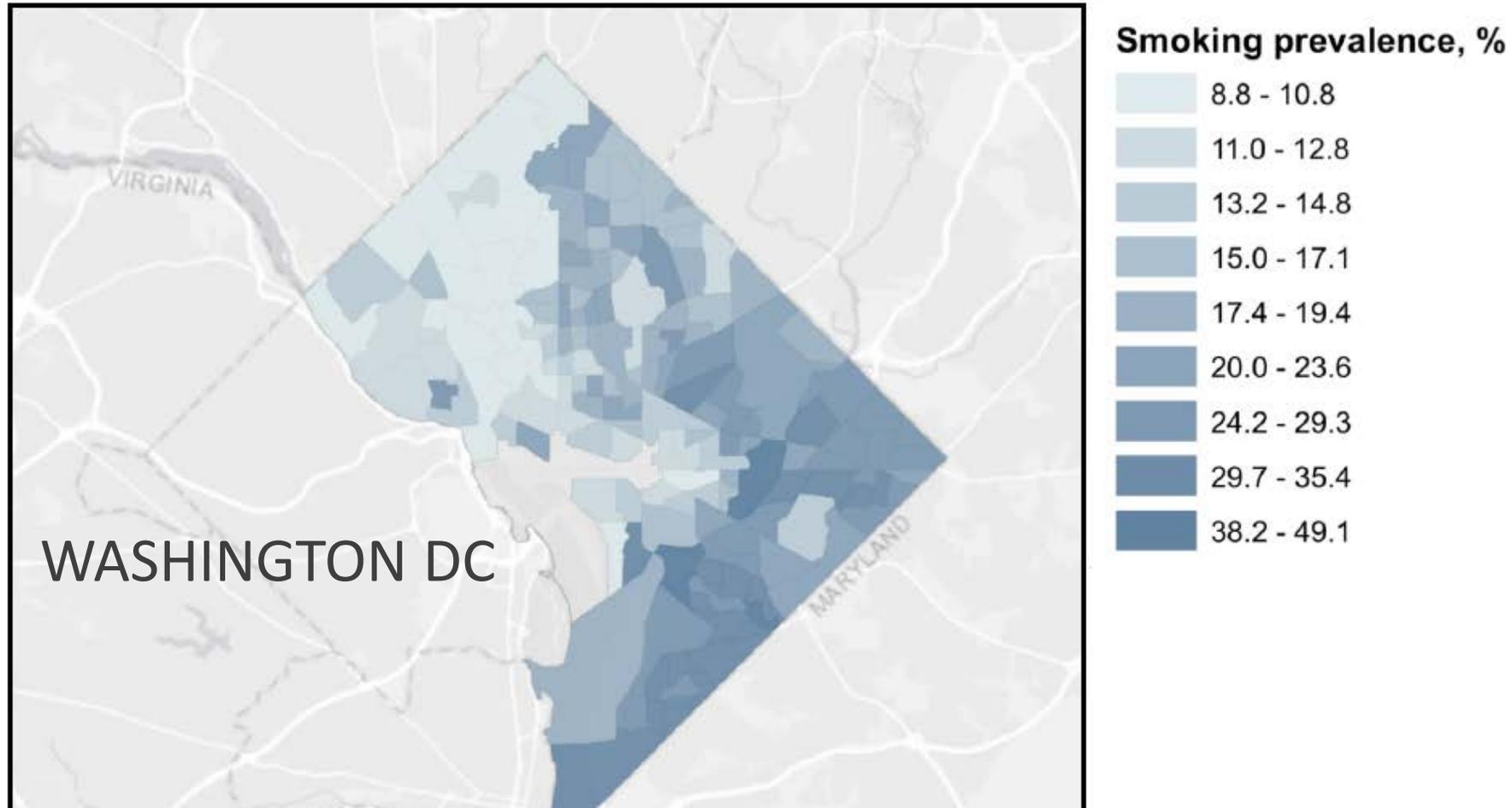
US ADULT SMOKING, by SEX: 1955–2018



Graph provided by the Centers for Disease Control and Prevention. 1955 Current Population Survey; 1965–2018 NHIS. Estimates since 1992 include some-day smoking.

CIGARETTE SMOKING PREVALENCE BY CENSUS TRACT

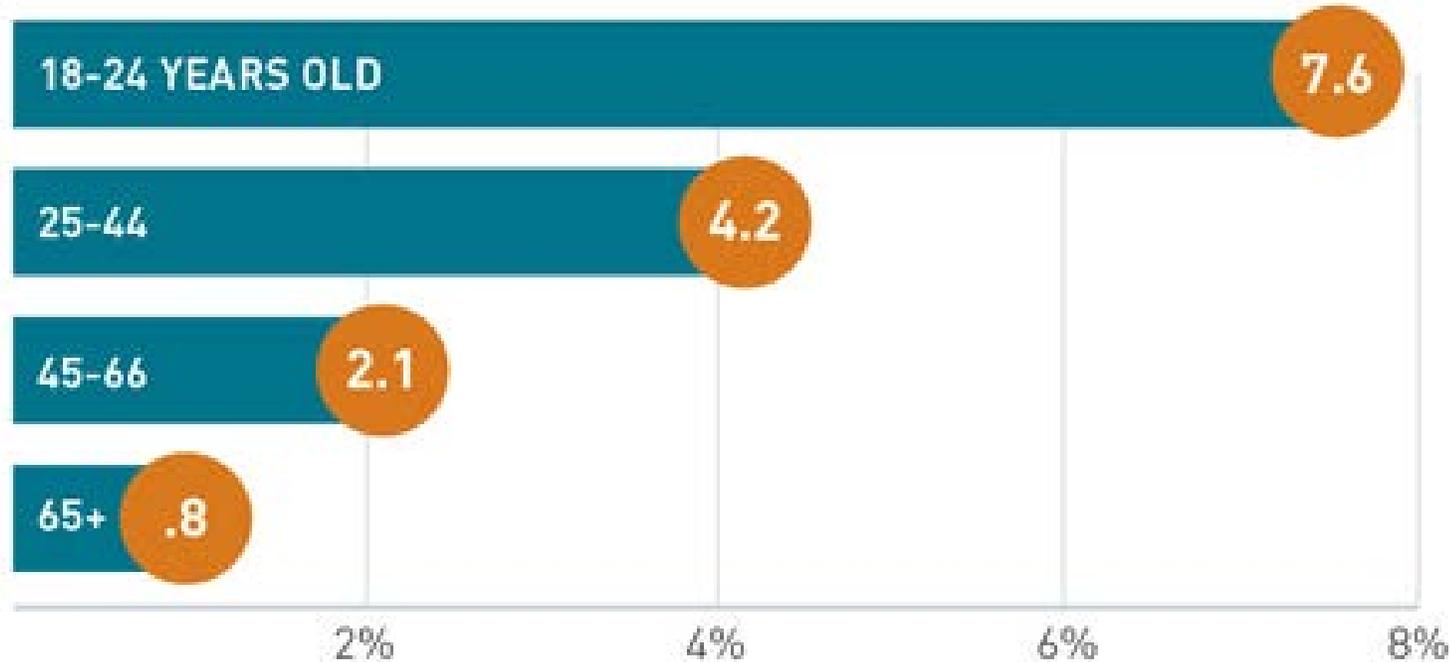
C) Current smoking among adults aged ≥ 18 years by census tract, Washington, DC, 2014, Gini = 0.23



Nearly 7 in 10 adults who smoke want to quit



Adults who currently use e-cigarettes as of 2018



Source: 2018 National Health Interview Survey



2017 NHIS US Adults: Current Ecig Use by Race

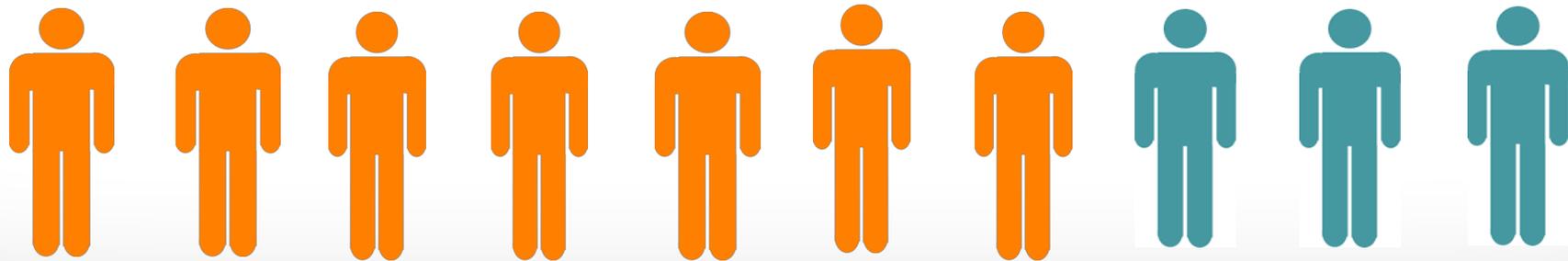
6% Multi-racial
3% non-Hispanic White
2% non-Hispanic Black
2% Hispanic
1% non-Hispanic Asian

Q: True or False?

Most adults who smoke do not want to quit

A: False

Nearly 70% of adults who smoke report wanting to quit.

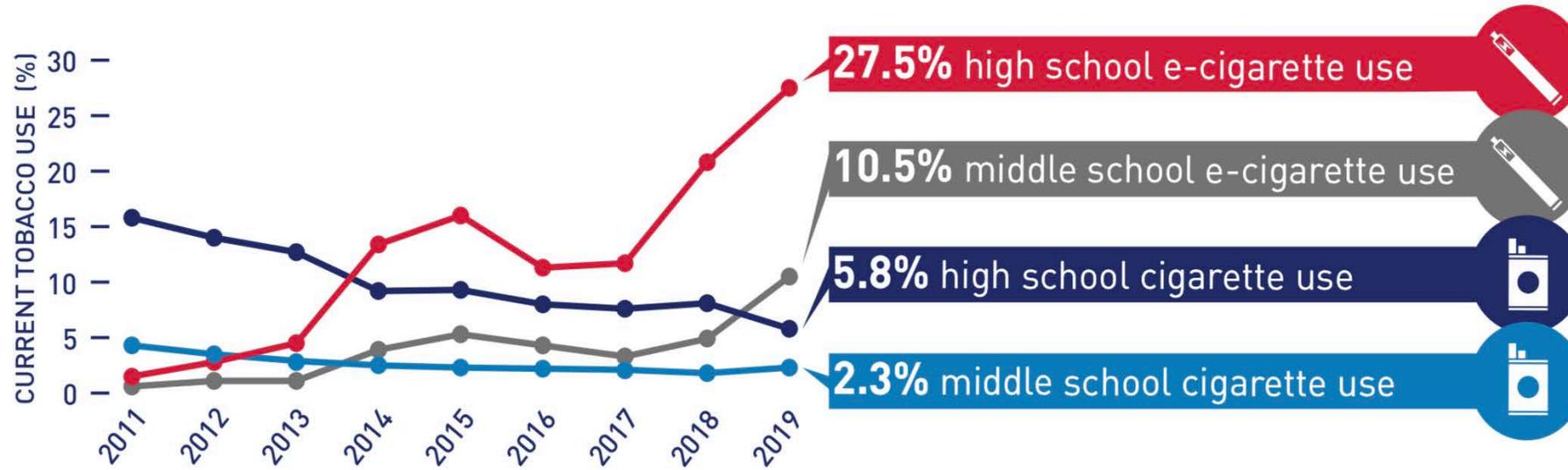


Youth Tobacco Use Patterns NYTS 2019

OVER 5 Million
youth are currently using e-cigarettes

MORE THAN **3.6 M** 2018
MORE THAN **5 M** 2019

Current e-cigarette use has **INCREASED DRAMATICALLY**, while current cigarette use has dropped, **UNDERMINING PROGRESS** toward reducing overall tobacco use



MAJORITY of the current e-cigarette users reported **JUUL** as their usual brand

- 2019 Monitoring the Future study, 1 in 9 HS seniors (11.7%) vaped nicotine nearly daily
- NHIS 2018: 3.2% of adults currently used e-cigs every day or some days



<u>YouTube Search Terms</u>	<u># of Videos</u>
<i>"JUUL at School"</i>	15500
<i>"JUUL in school bathroom"</i>	1040
<i>"JUUL in class"</i>	6840
<i>"JUUL at camp"</i>	2480
<i>"Hiding JUUL in school"</i>	2030
<i>"Hiding JUUL at home"</i>	1230
<i>"Hiding JUUL from teacher"</i>	531
<i>"Hiding JUUL from parents"</i>	1990
<i>"JUUL school suspension"</i>	758
<i>"JUUL in a Sharpie"</i>	451
<i>"JUUL flavors"</i>	6510
<i>"JUUL"</i>	148000*

*57 videos have >100,000 views



FDA E cig Flavor Restriction

- Prohibits the sale of flavored cartridge-based e-cigs, other than menthol or tobacco flavor
- As of Feb 6, 2020, many flavored e-liquid pods, including Juul and Juul-compatible products, are no longer sold legally in US
- The guidance does not:
 - Restrict all flavors
 - Address concept flavors
 - Include all e-cigs (tanks/mods, closed systems)
 - Apply to other tobacco products (e.g., cigars, cigarillos, hookah)



WARNING: This product contains nicotine. Nicotine is an addictive chemical.

A Powerful Delivery System

Inhaling tobacco smoke delivers large amounts of nicotine to the brain quickly — in less than 10 seconds.



In the brain, nicotine fits perfectly into receptors on the surface of specific brain cells.

Creating an Addiction

Nicotine does not last very long in the brain. When it leaves the receptors, *withdrawal* symptoms occur until the brain cells receive more nicotine.

Changing the Brain

The large amount of nicotine delivered by a cigarette causes an *increase* in the number of receptors.

A Rush of Relief

By binding to the receptors, nicotine activates the brain cells to release “feel good” chemicals.

NEUROCHEMICAL and RELATED EFFECTS of NICOTINE

N
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- ➔ Dopamine Pleasure, reward
- ➔ Norepinephrine Arousal, appetite suppression
- ➔ Acetylcholine Arousal, cognitive enhancement
- ➔ Glutamate Learning, memory enhancement
- ➔ β -Endorphin Reduction of anxiety and tension
- ➔ GABA Reduction of anxiety and tension
- ➔ Serotonin Mood modulation, appetite suppression

NICOTINE WITHDRAWAL EFFECTS:

- Dysphoric or depressed mood
- Insomnia and fatigue
- Irritability / frustration / anger
- Anxiety or nervousness
- Difficulty concentrating
- Increased appetite / weight gain
- Restlessness and impatience
- Cravings

What is Addiction?



“Compulsive drug use, without medical purpose, in the face of negative consequences”

National Institute on Drug Abuse

2020 ICD-10-CM DIAGNOSIS CODES:

- Z72.0 Tobacco Use (non-dependent)
- F17.2 Nicotine Dependence (specify product type)
 - F17.29-, Nicotine dependence, other tobacco products
 - E-cigs are non-combustible tobacco products
- Z87.891 History of Tobacco Dependence
- Z77.22 Exposure to "Environmental Tobacco Smoke"



NICOTINE ADDICTION: SUMMARY

- The speed at which a drug hits the brain impacts its addiction potential.
- Tobacco products are effective delivery systems for the drug nicotine.
- Nicotine activates the dopamine reward pathway in the brain.
- Nicotine addiction is a chronic condition with a biological basis.
- With chronic drug use, the brain becomes chemically altered—transforming a drug user into a drug addict.

HEALTH CONSEQUENCES of SMOKING

- Cancers

- Bladder/kidney/ureter
- Blood (acute myeloid leukemia)
- Cervix
- Colon/rectum
- Esophagus/stomach
- Liver
- Lung
- Oropharynx/larynx
- Pancreatic

- Pulmonary diseases

- Asthma
- COPD
- Pneumonia/tuberculosis
- Chronic respiratory symptoms

- Cardiovascular diseases

- Aortic aneurysm
- Coronary heart disease
- Cerebrovascular disease
- Peripheral vascular disease

- Reproductive effects

- Reduced fertility in women
- Poor pregnancy outcomes (e.g., congenital defects, low birth weight, preterm delivery)
- Infant mortality

- Other: cataract, diabetes (type 2), erectile dysfunction, impaired immune function, osteoporosis, periodontitis, postoperative complications, rheumatoid arthritis

U.S. Department of Health and Human Services (USDHHS). (2014).
The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.

SMOKING EPIDEMIOLOGY & HARMS

About **34 million** U.S. adults currently smoke cigarettes.



▶ Smoking is the leading cause of preventable disease and death in the United States

▶ **480,000** Americans die from smoking each year, accounting for nearly 1 in 5 deaths



▶ **16 million** Americans live with a smoking-related disease

▶ Smoking-related death and disease cost the United States over **\$300 billion** each year



E-cig Aerosol may Contain:

- Nicotine (even if marketed as 0% nicotine)
- Ultrafine particles that can be inhaled deep into the lungs
- Flavoring such as diacetyl, a chemical linked to a serious lung dz
- Volatile organic compounds (VOCs)
- Cancer-causing chemicals
- Heavy metals such as nickel, tin, and lead

* At lower levels than in
combusted tobacco smoke



Primary humectants are propylene glycol and glycerol (aka vegetable glycerin)

E-cigarette or Vaping use-Associated Lung Injury (EVALI)

- **Clinical Presentation**

- Respiratory symptoms (e.g., cough, chest pain, SOB)
- GI symptoms (e.g., abdominal pain, nausea, vomiting, diarrhea)
- Nonspecific constitutional symptoms (e.g., fever, chills, weight loss)
- Reduced blood oxygen levels and elevated white blood cell counts
- Injuries resembled “exposures to toxic chemical fumes, poisonous gases and toxic agents” (Mayo)
- ❖ A diagnosis of exclusion

- **Patient Recommendations:**

- Do not use THC-containing vaping products, particularly from informal sources (e.g., friends, family, in-person or online sellers)
- Vitamin E acetate should not be added to vaping products



Reporting EVALI Cases

- CDC encourages clinicians to continue to report possible EVALI cases to their local or state health department for further investigation
- If EVALI suspected, collect a detailed history of:
 - Substances used
 - Sources of products
 - Duration and frequency of use
 - Devices used and how used

EVALI Confirmed Case Criteria

Using an e-cigarette (“vaping”) or dabbing* in 90 days prior to symptom onset

AND

Pulmonary infiltrate, such as opacities, on plain film chest radiograph or ground-glass opacities on chest CT

AND

Absence of pulmonary infection on initial work-up. *Minimum criteria* are:

1. A negative respiratory viral panel

AND

2. A negative influenza PCR or rapid test, if local epidemiology supports influenza testing

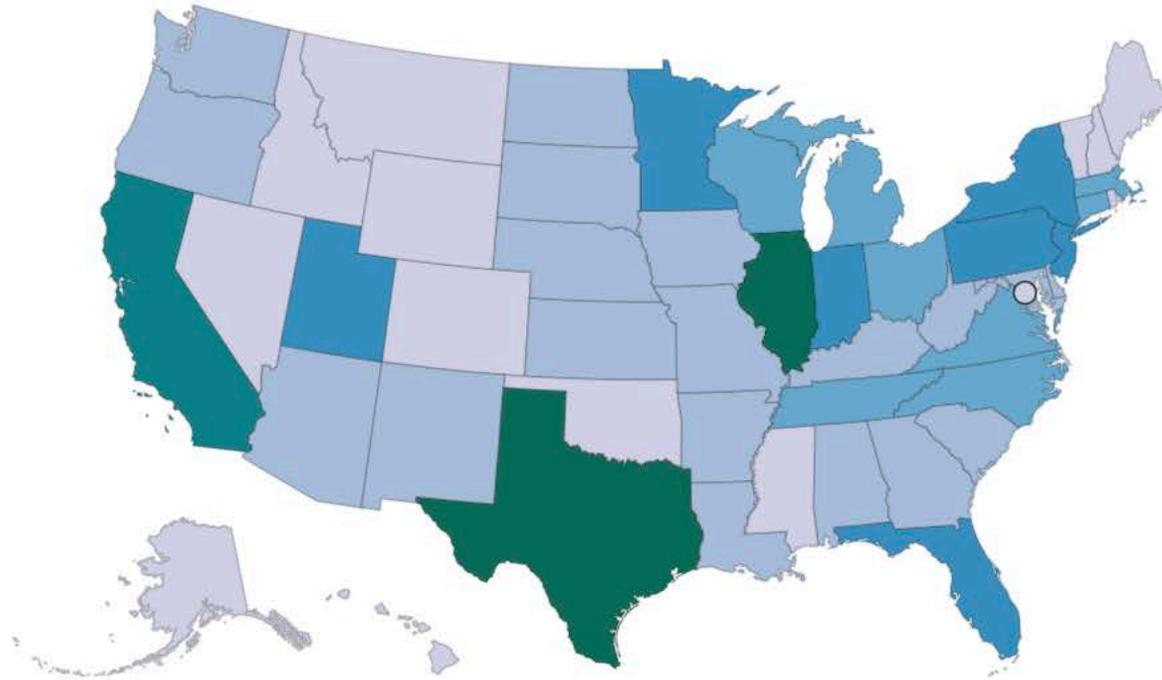
AND

3. All other clinically-indicated respiratory infectious disease testing (e.g., urine Antigen for *Streptococcus pneumoniae* and *Legionella*, sputum culture if productive cough, bronchoalveolar lavage (BAL) culture if done, blood culture, HIV-related opportunistic respiratory infections if appropriate) are negative

AND

No evidence in medical record of alternative plausible diagnoses (e.g., cardiac, rheumatologic, or neoplastic process).

Number of Hospitalized EVALI Cases or Deaths Reported to CDC as of January 14, 2020



Territories

- AS
- GU
- MH
- FM
- PW
- PR
- VI

Legend

Number of hospitalized EVALI cases or deaths per state

- 0 cases
- 1-9 cases
- 10-49 cases
- 50-99 cases
- 100-149 cases
- 150-199 cases
- 200-249 cases



USE & HARMS: SUMMARY

- Fewer than 1 in 7 US adults are current smokers
- Smoking prevalence varies by sociodemographic characteristics
- Nearly half a million U.S. deaths are attributable to smoking annually
- Smoking costs the U.S. an estimated \$300 billion annually
- E-cigarettes are a diverse product group and their health harms are still being determined

Overview



Epidemiology: nicotine product landscape, use patterns, addiction and health harms



Counseling: modalities for delivery of behavioral counseling (e.g., quitlines, web, text, app interventions)



Pharmacotherapy: new approaches to medications (e.g., combination medications, pre-loading)

Counseling



7 in 10 tobacco users see a healthcare provider in a given year



Treating tobacco is relevant to all areas of medicine



USPSTF: “**Grade A**” recommendation for clinician-delivered brief tobacco treatment



Counseling by nonphysician health providers also increases quit rates

National Cancer Institute's 5 As

1

ASK all patients
about use of all
forms of tobacco

2

ADVISE
tobacco users to
quit

3

ASSESS patient
readiness to quit

4

ASSIST in the
quit attempt with
counseling,
medications, &
referrals

5

ARRANGE
follow-up

ASK – ADVISE – REFER

Tobacco Quitline: 1-800-QUIT-NOW

1

ASK about tobacco
use

2

ADVISE tobacco
users to quit, and
then...

3

REFER patients to
an outside entity
for assistance and
follow-up

Q: True or False?

Healthcare professional advice to quit is not an effective smoking cessation intervention.



A: False

Even brief advice from a healthcare professional can increase quit attempts and quit success.

Only 57% of adults who smoke reported receiving such advice from a healthcare professional in the last year.

INTENSIVE COUNSELING

- **Recommended in clinical practice guidelines**
 - Format: in person, individually, in groups
 - Settings: clinical, behavioral, workplace, community
 - Frameworks: cognitive-behavioral, motivational, mindfulness
- Systematic review 49 RCTS, 19,000 participants:
 - Intensive counseling only (without medications) more effective than minimal contact (i.e., brief advice + self-help materials)
 - **Greater effects when combined with cessation medications**



COUNSELING: SUMMARY

- Routinely identify tobacco users (ASK)
- Strongly ADVISE patients to quit
- ASSESS readiness to quit at each contact
- Tailor intervention messages (ASSIST)
 - Be a good listener
 - Minimal intervention in absence of time for more intensive intervention
- ARRANGE follow-up
 - Use the referral process, if needed

Tobacco Quitlines

Take Control

1-800-QUIT-NOW

Call. It's free. It works.

1-800-784-8669

For details on your state services, go to: <http://map.naquitline.org>

- Toll-free national portal
 - Links to state quitline by area code
- Trained counselors providing:
 - information, self-help materials
 - individual counseling
 - local referrals
 - may provide free cessation meds
- Effectiveness well demonstrated
- Reach ~1% of smokers annually

Internet Interventions

smokefree.gov

Quit Smoking **TODAY!**
we can help

Get started...

- Use the Step-by-Step Quit Guide
- Talk to an Expert
- Find Tools to Help You Quit
- Learn About Topics Related to Quitting

Take our monthly quiz!

Send a Smokefree e-card

Interested in being part of a research study?

Go mobile!

- Increasing sophistication + interaction
- Best Practices: **Individual tailoring**
- **Smokefree.gov**
 - Evidence-based, tailored to readiness to quit
 - Assistance via IM + phone (1-877-44U-QUIT)
 - SmokefreeTXT + Smokefree smartphone
- Tailored versions for veterans, women, teens, Spanish-speaking, and older adults
- Relative to quitlines:
 - 27 Xs greater reach [annually, 11 M vs 400K]
 - at a lower cost per quit [\$291 vs \$900]

Smokefree.gov



2014 search: 546 quit smoking apps in the Apple Store and on Google Play

3.2 M downloads US + 20 M global

Broad reach and high scalability

2015 review of 225 Android quit smoking apps:
Most provide simplistic tools (e.g., calculators + trackers);

Use of tailoring limited, although positively related to app popularity and user ratings of quality

Evaluation of intervention effects on quitting smoking is sorely needed

[MyQuit Coach](#) | [Cessation Nation](#) | [QuitNow!](#) | [Smoke Free](#) | [Kwit](#) |
[Get Rich or Die Smoking](#) | [SmokeFree](#) | [Quit Tracker](#) | [EasyQuit](#) |
[Stop Smoking in 2 Hours](#) | [My Last Cigarette](#) | [Quit It Lite](#)

Social Media

- 72% of US adults use social media
 - 80% are seeking health information
 - Most access the sites daily
- Efforts to **sustain engagement** are key and can be challenging
- Preliminary evidence of good acceptability and efficacy



MONETARY INCENTIVES



- Reward **outcome** (i.e., abstinence) or **participation** (i.e., engagement)
- Meta-analysis, 33 trials:
 - increased abstinence persisted after incentives ceased
- Incentives: \$0 (self-deposits) to \$45 -- \$1185, no clear difference by level
- Conditional (i.e., \$ for abstinence) outperformed nonconditional \$
- Smokers w/ substance use problems = similar outcomes
- Pregnant smokers > 2-fold greater abstinence thru 24 wks postpartum

Overview



Epidemiology: nicotine product landscape, use patterns, addiction and health harms

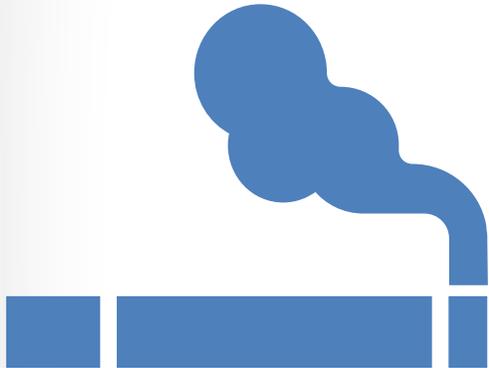


Counseling: modalities for delivery of behavioral counseling (e.g., quitlines, web, text, app interventions)



Pharmacotherapy: new approaches to medications (e.g., combination medications, pre-loading)

Cessation Medications



1. Reduce Nicotine withdrawal symptoms
2. Reduce rewarding effects of nicotine from smoking by blocking or desensitizing nicotine receptors

NEUROCHEMICAL and RELATED EFFECTS of NICOTINE

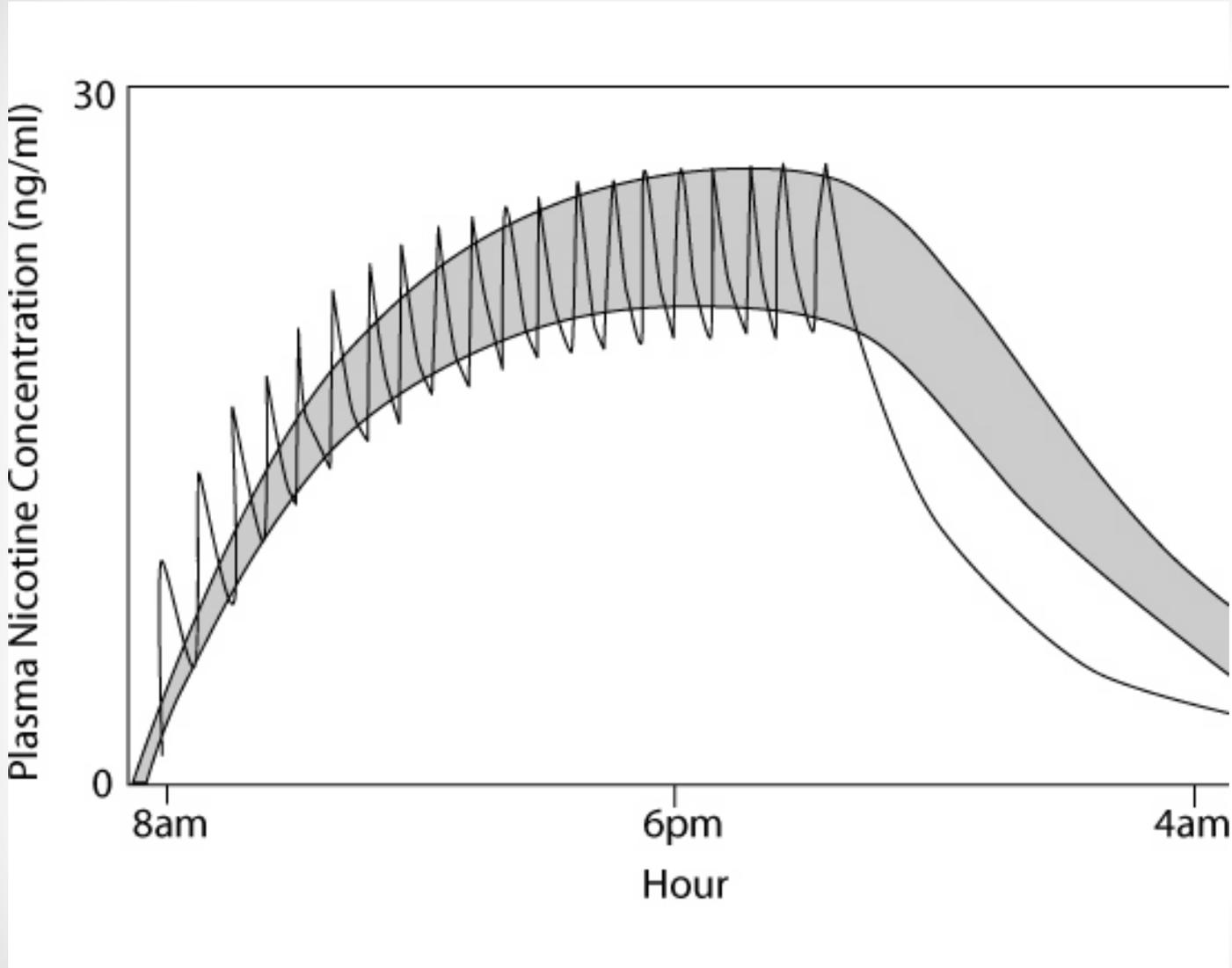
N
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- Dopamine Pleasure, reward
- Norepinephrine Arousal, appetite suppression
- Acetylcholine Arousal, cognitive enhancement
- Glutamate Learning, memory enhancement
- β -Endorphin Reduction of anxiety and tension
- GABA Reduction of anxiety and tension
- Serotonin Mood modulation, appetite suppression

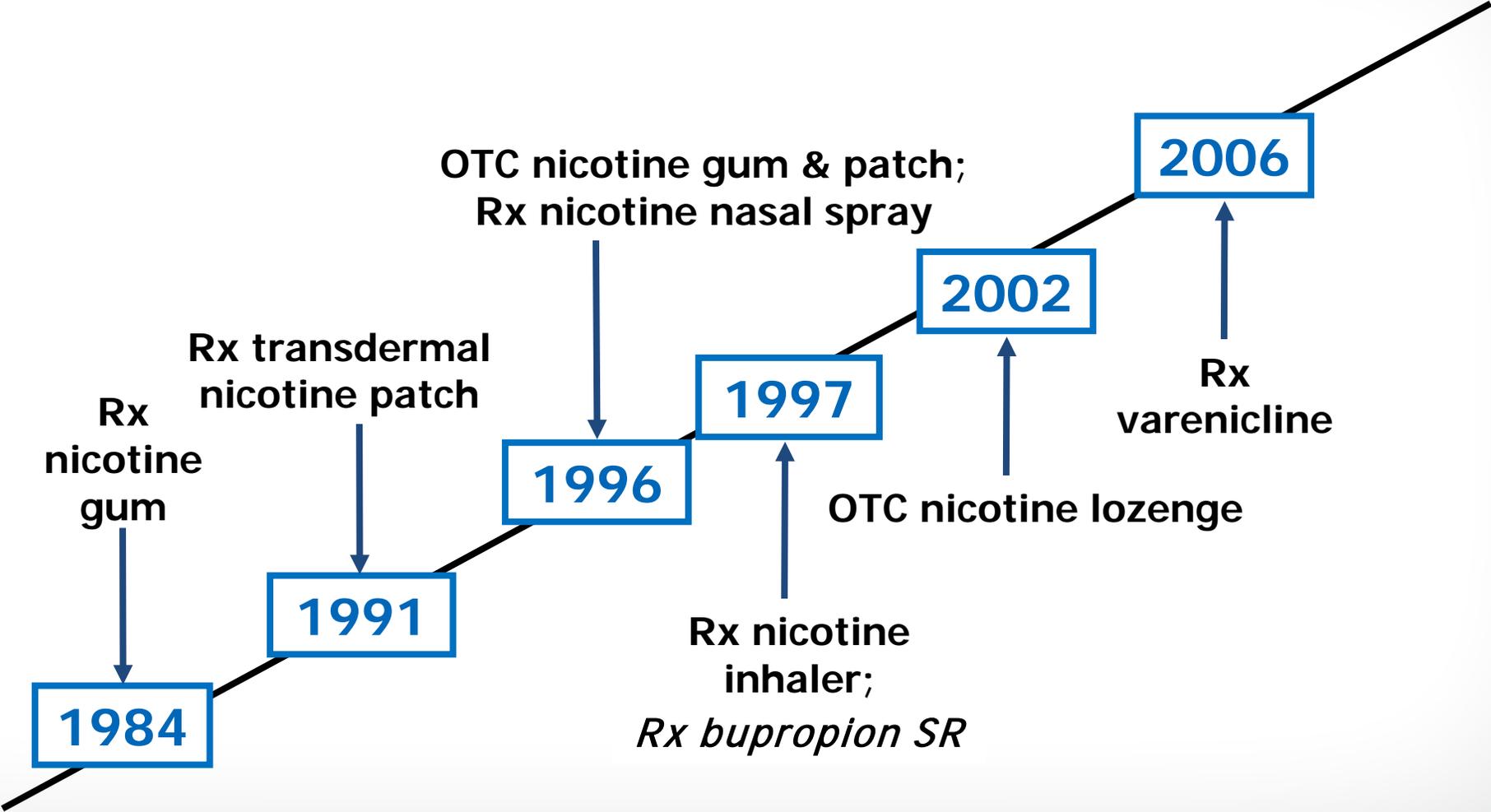
NICOTINE WITHDRAWAL EFFECTS

- Dysphoric or depressed mood
- Insomnia and fatigue
- Irritability / frustration / anger
- Anxiety or nervousness
- Difficulty concentrating
- Increased appetite / weight gain
- Restlessness and impatience
- Cravings

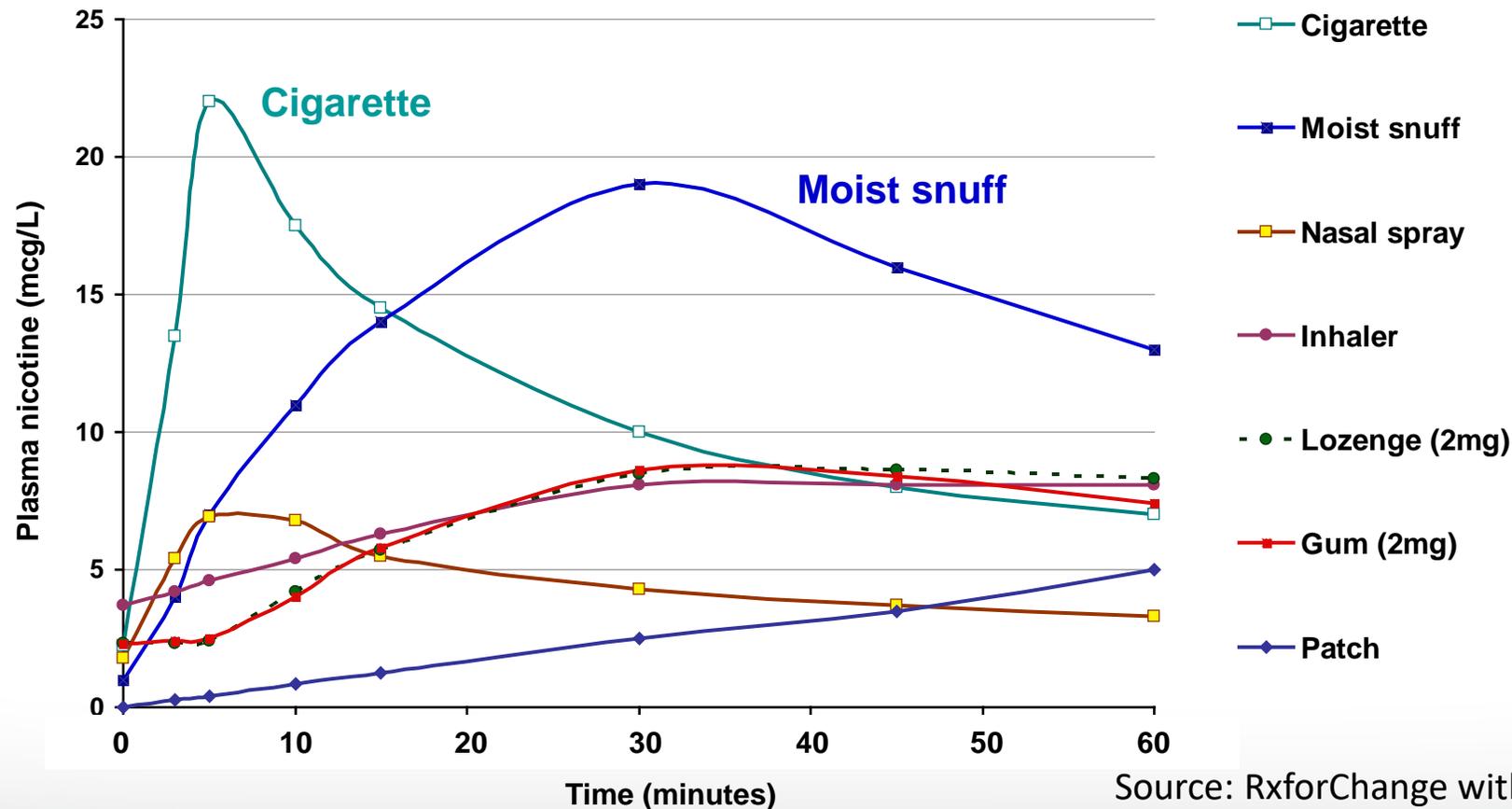
NICOTINE ADDICTION CYCLE



FDA APPROVALS: SMOKING CESSATION



PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS



Source: RxforChange with data from Fant et al., 1999; Schneider et al., 2001; Choi et al., 2003

Nicotine Replacement Therapies (NRT)

approx. 1 cig = 1 mg

time to first cigarette upon waking ($\leq 30m$)

combination NRT

Gum ^{otc}

Patches ^{otc}

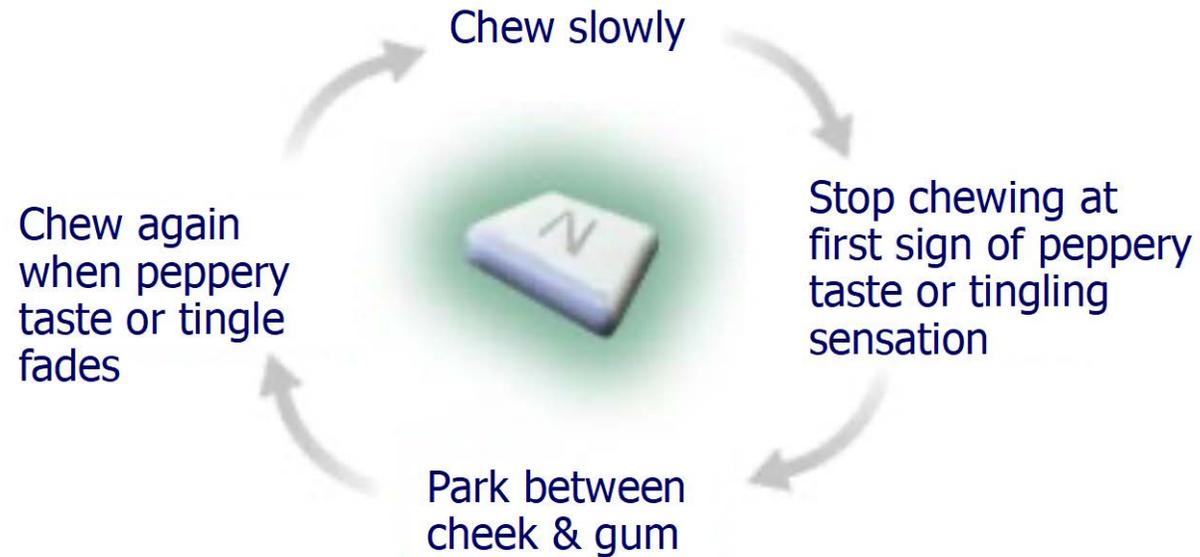
Lozenge ^{otc}

Nasal spray

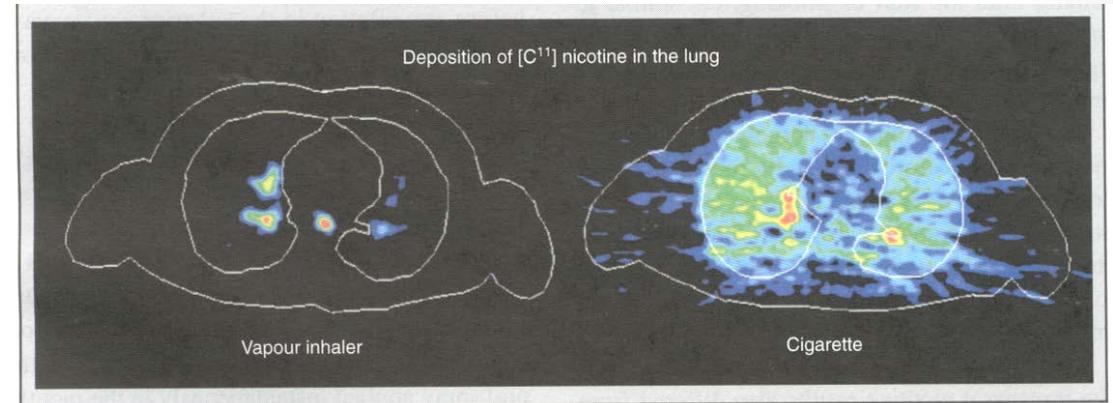
Inhaler

Nicotine mouth spray

NICOTINE "GUM"



NICOTINE “INHALER”



Q: What two items inform dosing of nicotine replacement therapy?

- A. Number of failed prior quit attempts
- B. Cigarettes per day
- C. Time to first cigarette upon wakening
- D. Number of withdrawal symptoms

Q: What two items inform dosing of nicotine replacement therapy?



A. Number of failed prior quit attempts

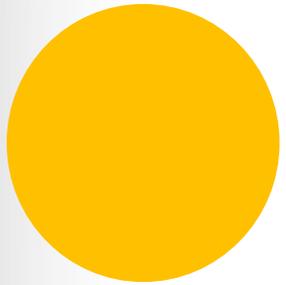
B. Cigarettes per day

C. Time to first cigarette upon wakening

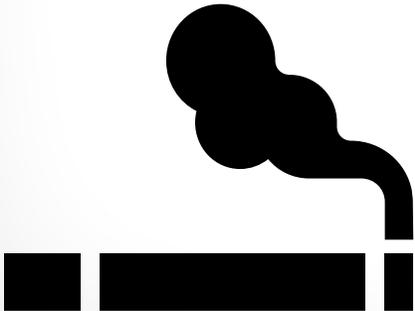
D. Number of withdrawal symptoms



Dosing of NRT



- Key indicators of addiction:
 - Time to first cigarette upon waking
 - Cigarettes per day
- Both are used to dose NRT
- Nicotine gum or lozenge:
 - 4 mg if smoke within 30 mins of waking
 - 2 mg if smoke after 30 mins of waking
- Nicotine patch:
 - Start with 21 mg patch if smoke >10 CPD
 - Start with 14 mg patch if smoke ≤ 10 CPD



Bupropion



Atypical antidepressant with dopaminergic + noradrenergic properties



Start 2 wks before quit date

Primary active chemical is hydroxybupropion, which takes 7 days to reach steady state



Can be used in combination with NRT

Varenicline



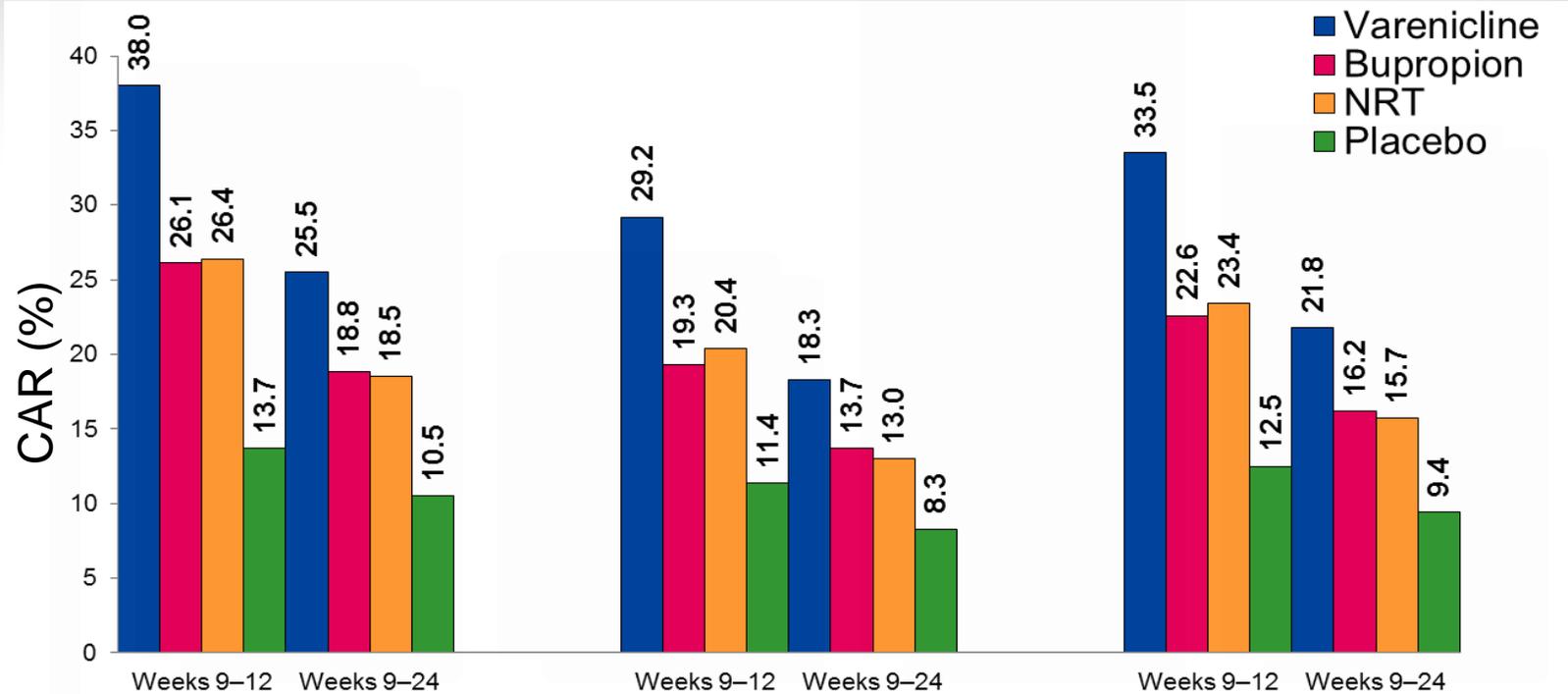
- Partial agonist at nicotinic $\alpha_4\beta_2$ receptor
 - $\alpha_4\beta_2$ the major receptor mediating nicotine addiction
 - activates (~50% of max. effect of nicotine) + blocks nicotine effects
 - reduces withdrawal symptoms, while reducing rewarding effects of nicotine from cigarette smoke
- Varenicline pre-smoking cessation → reduces smoking (CPD)

EAGLES Trial

N=8144

Weeks 9–24

Comparison	OR
V vs P	2.74
Bupr vs P	1.89
NRT vs P	1.81
V vs NRT	1.52
Bupr vs NRT	1.04
V vs Bupr	1.45



OR (95% CI)

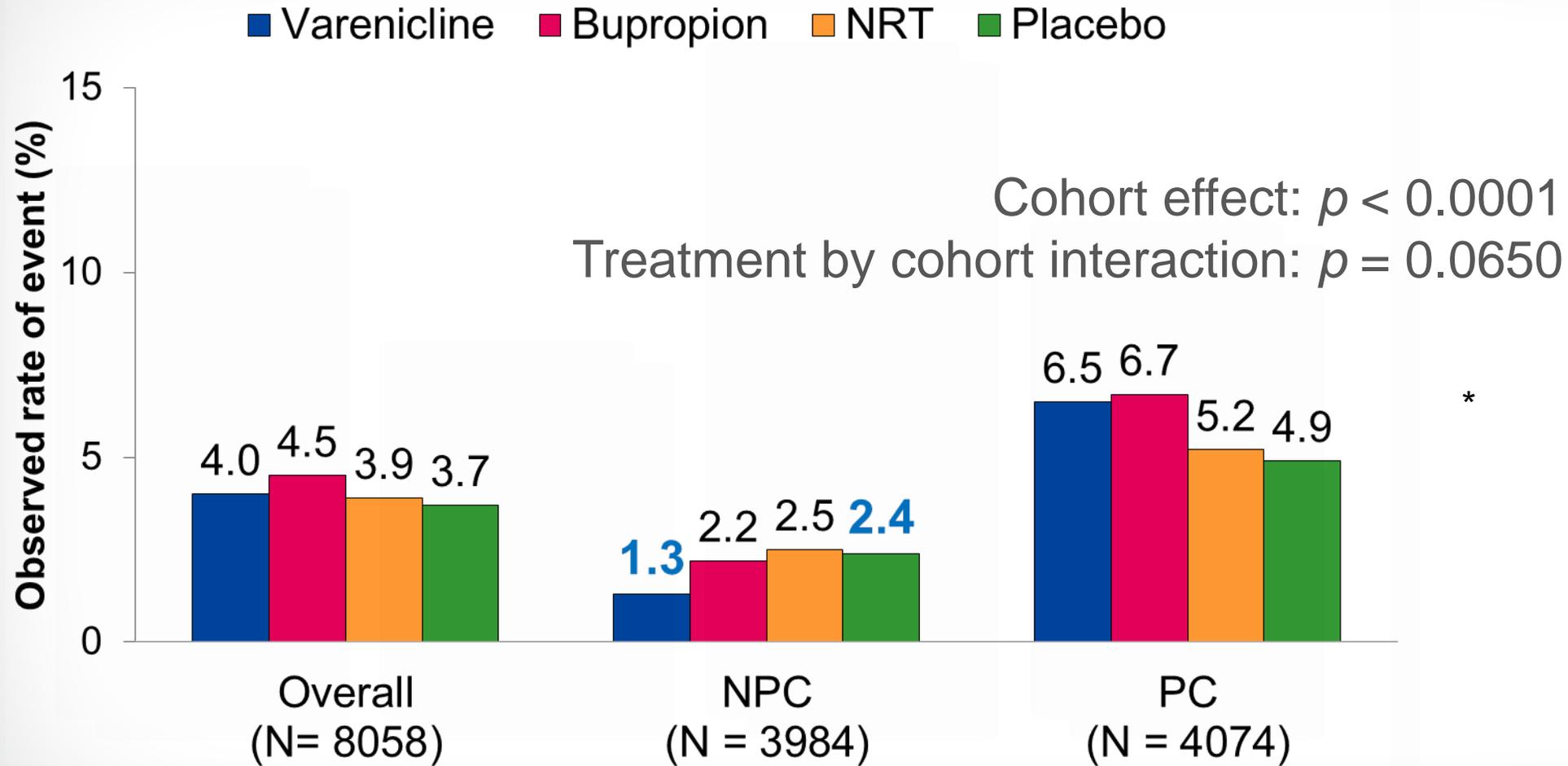
Primary comparisons

	Non-Psych (N = 4028)	Psych Cohort (N = 4116)	Overall (N = 8144)
Varenicline vs. placebo	4.00 (3.20, 5.00)	3.24 (2.56, 4.11)	3.61 (3.07, 4.24)
Bupropion vs. placebo	2.26 (1.80, 2.85)	1.87 (1.46, 2.39)	2.07 (1.75, 2.45)

Secondary comparisons

	Non-Psych (N = 4028)	Psych Cohort (N = 4116)	Overall (N = 8144)
NRT vs. placebo	2.30 (1.83, 2.90)	2.00 (1.56, 2.55)	2.15 (1.82, 2.54)
Varenicline vs. NRT	1.74 (1.43, 2.10)	1.62 (1.32, 1.99)	1.68 (1.46, 1.93)
Bupropion vs. NRT	0.98 (0.80, 1.20)	0.94 (0.75, 1.16)	0.96 (0.83, 1.11)
Varenicline vs. bupropion	1.77 (1.46, 2.14)	1.74 (1.41, 2.14)	1.75 (1.52, 2.01)

EAGLES: Primary NPS Composite Safety Endpoint



AEs reported during treatment and ≤ 30 days after last dose (All treated population).

* 1 additional participant (PC/NRT group) +SI identified after clinical database lock and not included in the analysis



Varenicline Quit Approaches

FIXED QUIT approach

- Set quit date for 1 wk after starting varenicline
- Continue treatment for 12 wks

FLEXIBLE QUIT approach

- Start taking varenicline and pick a quit date between 8 to 35 days from treatment initiation
- Continue treatment for 12 wks

GRADUAL QUIT approach

- Start taking varenicline and reduce smoking by 50% within the first 4 wks, an additional 50% in the next 4 wks, and continue until complete abstinence by 12 wks



EVIDENCE-BASED PHARMACOTHERAPY

- **Most effective**
- **Combination NRT [patch + short acting]**
 - **Varenicline**
- **Second line**
- **Bupropion (+/- NRT)**
- **Single form NRT**
- **Other considerations**
- **Most effective with behavior therapy**
- **Extended pharmacotherapy – up to 1 year**
 - **Flexible quit date**



Q: What are the two most effective medication options for quitting smoking?

- A. varenicline
- B. bupropion
- C. nicotine inhaler
- D. combination nicotine replacement



Q; What are the two most effective medication options for quitting smoking?

A. varenicline

B. bupropion

C. nicotine inhaler

D. combination nicotine replacement



Varenicline is the best single form medication for quitting smoking. Combining a long- (patch) + short-acting form of NRT (lozenge, gum, inhaler, nasal spray) is just as effective in treating tobacco use.

While use of a single form of NRT also has evidence for supporting cessation, combined use is recommended to ensure sufficient dosing of nicotine replacement and to address break-through cravings.

Bupropion also has evidence for supporting cessation, but is less effective than varenicline and combination NRT.

Medications in Development



Golden chain/rain

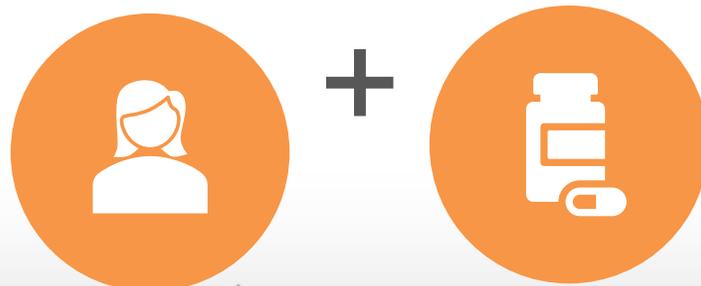
- Cytisine - alkaloid extracted from seeds of Cytisus laburnum
 - like varenicline, a partial agonist at the $\alpha_4\beta_2$ nAChR
 - significant effects relative to placebo
 - meta-analysis; RR, 1.74; 95% CI, 1.38 to 2.19)
 - superior to NRT in RCT, paired with behavioral support
- Tried + Ineffective:
 - mecamylamine, SSRIs, anxiolytics (benzodiazepines, buspirone), MAOIs (moclobemide, selegiline), modafenil, naltrexone, rimonabant, silver acetate, ondansetron, lobeline, nicotine vaccines, and Nicobrevin (quinine, methyl valerate, camphor, eucalyptus oil)

Q: True or False?

The combination of counseling and medication is more effective than either treatment alone.

A: True

While counseling and medication are each independently effective at increasing smoking cessation, the combination of the two is even more effective.



DC | **HEALTH**

What About E-cigs?



- e-cigs, e-hookah, mods, vape pens, vapes, tank systems, Juul, Suorin, Phix, Rubi, Vuse, electronic nicotine delivery systems (ENDS)

WHAT IS AN E-CIG?

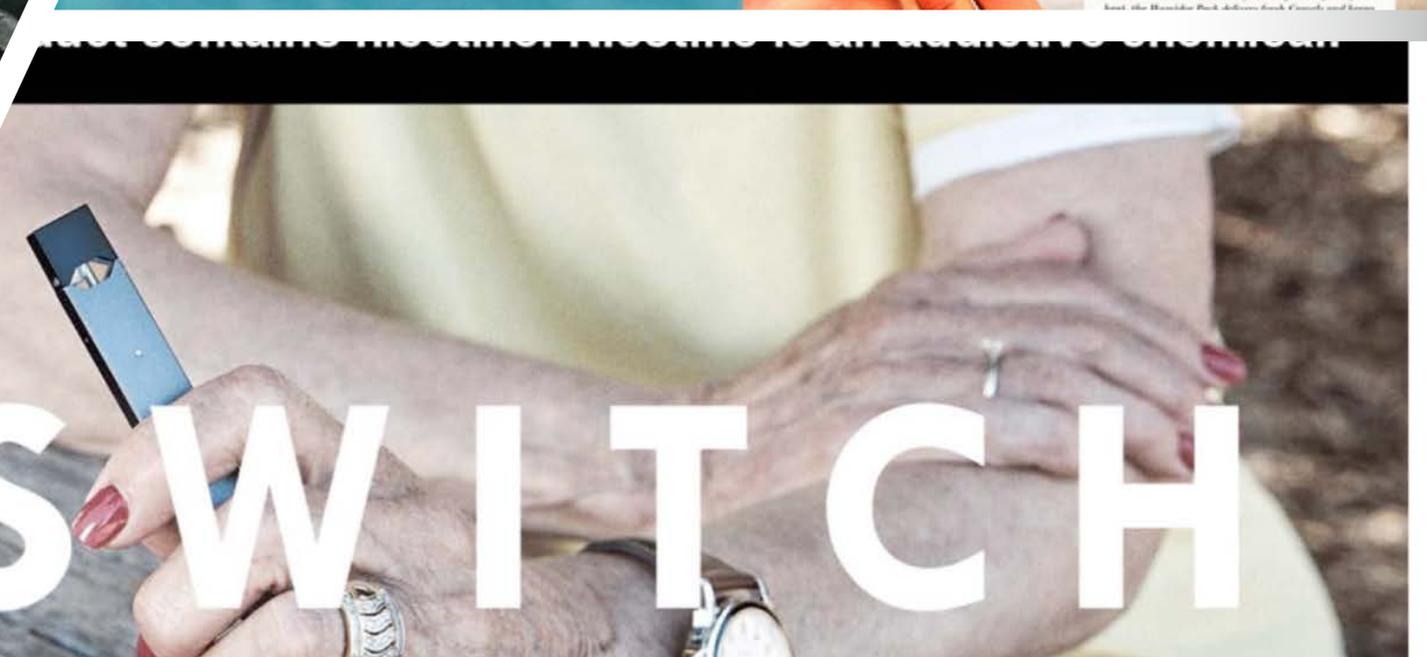


WHY QUIT? SWITCH TO BLU

blu is the smart choice for smokers wanting a change. Take back your freedom to smoke when and where you want without ash or smell. blu is everything you enjoy about smoking and nothing else. Nobody likes a quitter, so make the switch today.

Visit blucigs.com

MORE DOCTORS
RECOMMEND
blu
THAN USE TRADITIONAL
CIGARETTES



SWITCH

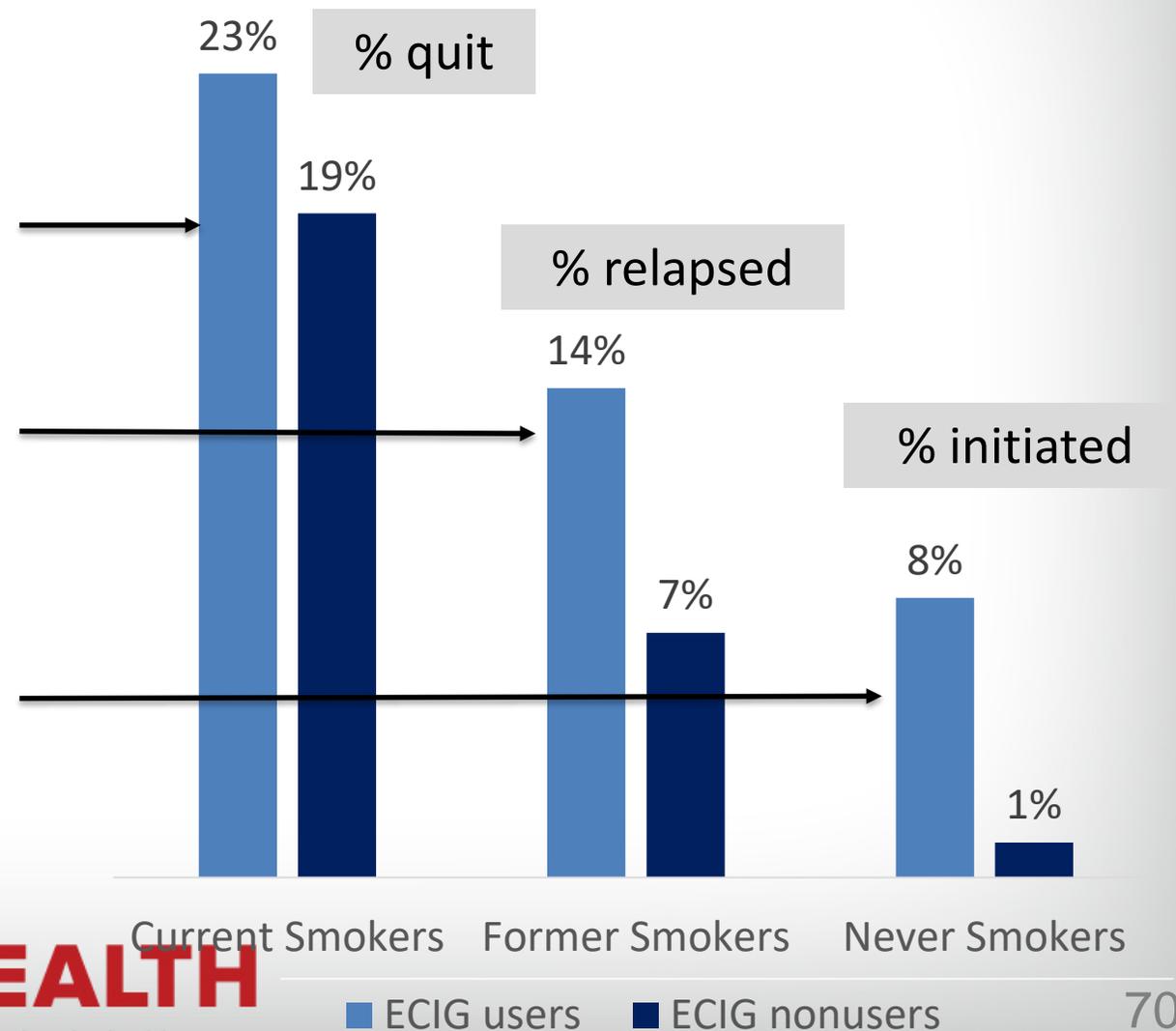
CHANGE in EHR DOCUMENTED SMOKING STATUS by ECIG USE, 2012-2015

- Kaiser Permanente Northern California patients aged 12+ with at least one instance of documented ECIG use from 2012-2015 (N=8,256)
- **AIM:** Examine change in smoking by ECIG use documented 12 mo prior
- Matched analyses comparing the subset of patients with documented ECIG use (N=7926) and without documented ECIG use (N=7926)
 - Matched on age, sex, race/ethnicity, and smoking status
 - Smoking status was 57% current smokers, 35% former, and 8% never-smokers

Young-Wolff KC, Klebaner D, Folck B, Fogelberg R, Prochaska JJ. (2018). Documentation of e-cigarette use and associations with smoking from 2012 to 2015 in an integrated healthcare delivery system. Preventive Medicine, 109, 113-118.

CHANGE in SMOKING STATUS at 12-MO by ECIG USE

- Among **current smokers**, documented ECIG users had increased odds of quitting smoking
 - OR=1.26, 95% CI=1.13-1.40, p<0.001
- Among **former smokers**, ECIG users had increased odds of relapsing to smoking
 - OR=1.79, 95% CI=1.45-2.21, p<0.001
- Among **never-smokers**, ECIG users had elevated odds of becoming a smoker
 - OR=8.17, 95% CI=3.50-19.1, p<0.001



Hajek et al. 2019 NEJM

Among participants with 1-year abstinence:
80% in ECIG group vs. 9% in NRT group
still using the assigned products @ 52 wks



18% ECIG vs. 10% NRT quit smoking at 52 wks

Table 2. Abstinence Rates at Different Time Points and Smoking Reduction at 52 Weeks.*

Outcome	E-Cigarettes (N=438)	Nicotine Replacement (N=446)	Primary Analysis: Relative Risk (95% CI)†	Sensitivity Analysis: Adjusted Relative Risk (95% CI)
Primary outcome: abstinence at 52 wk — no. (%)	79 (18.0)	44 (9.9)	1.83 (1.30–2.58)	1.75 (1.24–2.46)‡
Secondary outcomes				
Abstinence between wk 26 and wk 52 — no. (%)	93 (21.2)	53 (11.9)	1.79 (1.32–2.44)	1.82 (1.34–2.47)§
Abstinence at 4 wk after target quit date — no. (%)	192 (43.8)	134 (30.0)	1.45 (1.22–1.74)	1.43 (1.20–1.71)¶
Abstinence at 26 wk after target quit date — no. (%)	155 (35.4)	112 (25.1)	1.40 (1.14–1.72)	1.36 (1.15–1.67)‡
Carbon monoxide–validated reduction in smoking of ≥50% in participants without abstinence between wk 26 and wk 52 — no./total no. (%)	44/345 (12.8)	29/393 (7.4)	1.75 (1.12–2.72)	1.73 (1.11–2.69)

* Abstinence at 52 weeks was defined as a self-report of smoking no more than five cigarettes from 2 weeks after the target quit date, validated biochemically by an expired carbon monoxide level of less than 8 ppm at 52 weeks. Abstinence between week 26 and week 52 was defined as a self-report of smoking no more than five cigarettes between week 26 and week 52, plus an expired carbon monoxide level of less than 8 ppm at 52 weeks. Abstinence at 4 weeks was defined as a self-report of no smoking from 2 weeks after the target quit date, plus an expired carbon monoxide level of less than 8 ppm at 4 weeks. Abstinence at 26 weeks was defined as a self-report of smoking no more than five cigarettes from 2 weeks after the target quit date to 26 weeks; there was no validation by expired carbon monoxide level.

† The analysis was adjusted for trial center only.

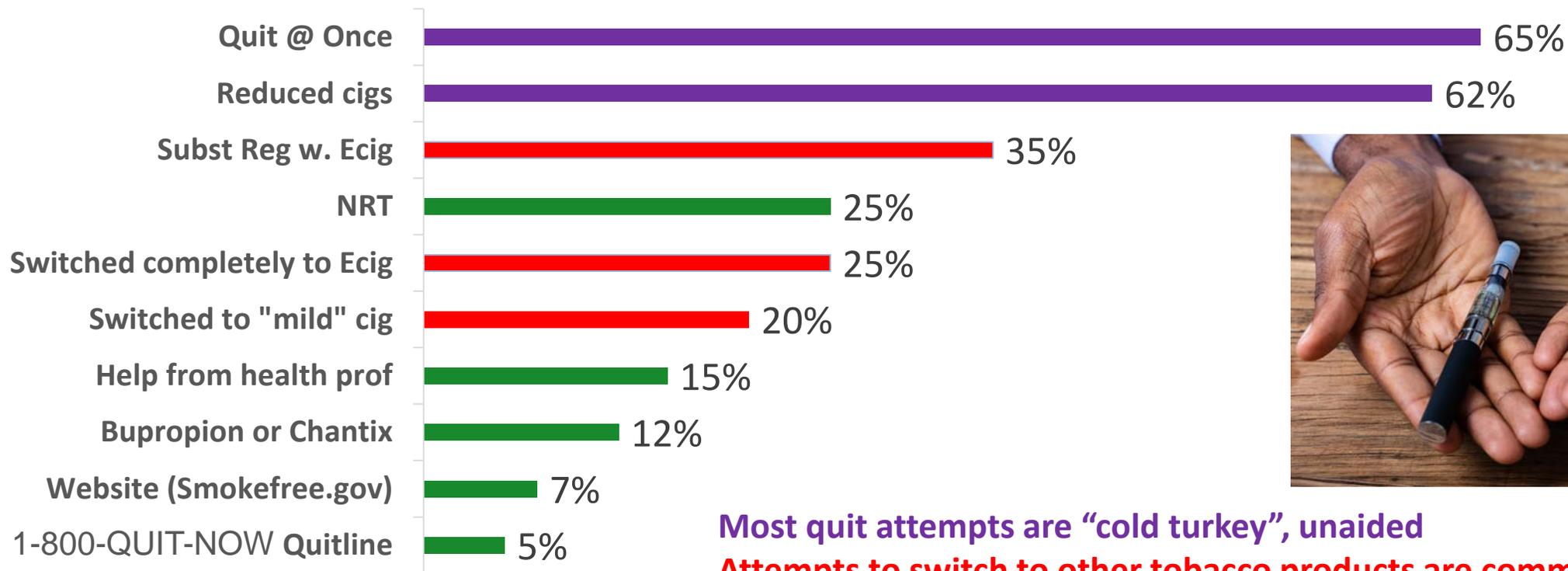
‡ The analysis was adjusted for trial center, marital status, age at smoking initiation, and score on the Fagerström Test for Cigarette Dependence.

§ The analysis was adjusted for trial center, age, score on the Fagerström Test for Cigarette Dependence, and age at smoking initiation.

¶ The analysis was adjusted for trial center, education level, partner who smokes (yes or no), and score on the Fagerström Test for Cigarette Dependence.

|| The analysis was adjusted for trial center, sex, age, and partner who smokes (yes or no).

US Adult Smokers' Quit Methods, 2014–16 (n=15,943)



Most quit attempts are “cold turkey”, unaided
Attempts to switch to other tobacco products are common
Few use evidence-based treatments

Less than 4% of smokers in a given year succeed in remaining abstinent

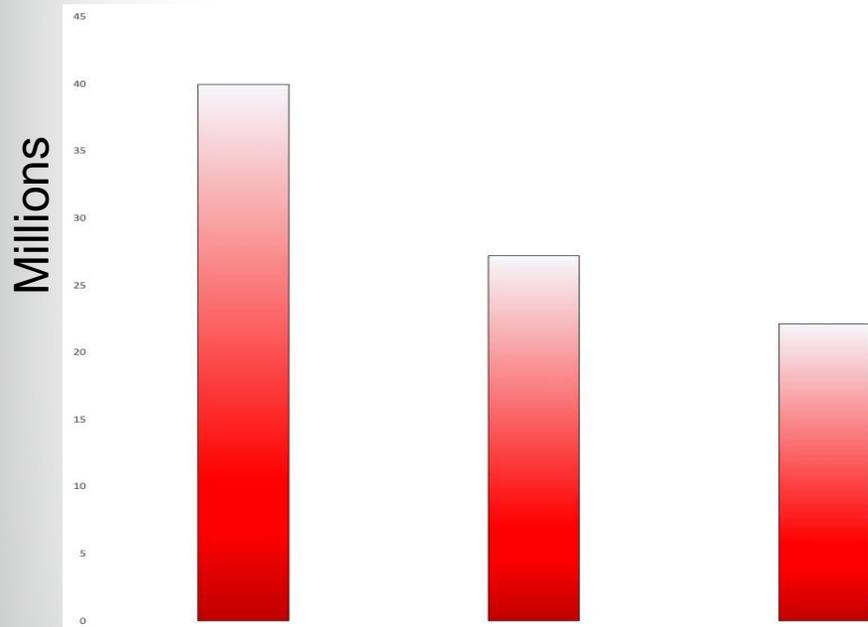
34 Million
US Adult Smokers

68%
23 Million
want to quit

55%
19 Million quit
for ≥ 24 hrs

7%
2 Million quit
6 mos out

< 4%
1.4 Million
succeed



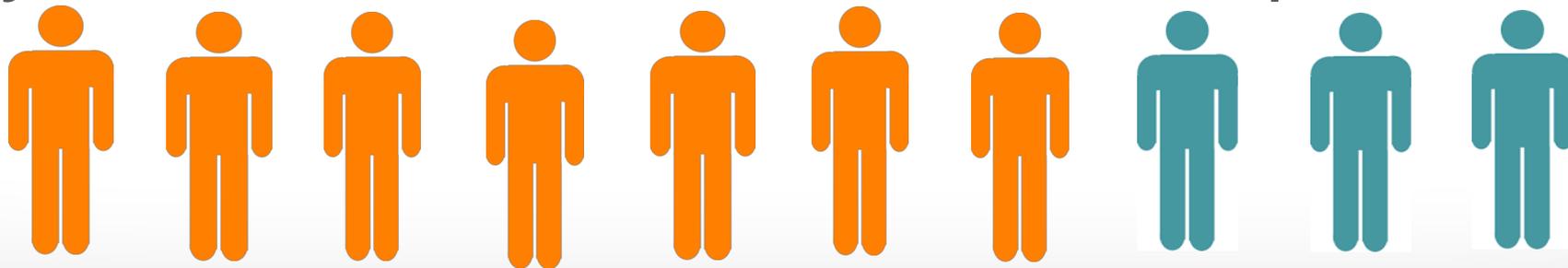
Every day: >3000 12- to-17-year olds smoke their first cigarette and >2000 become new daily smokers

Q: True or False?

Most adults who try to quit smoking report using evidence-based treatment to do so

A: False

Nearly 7 in 10 adults who try to quit smoking did not use any evidence-based treatment in their quit attempt.





Original article

Adolescents' E-Cigarette Use: Increases in Frequency, Dependence, and Nicotine Exposure Over 12 Months

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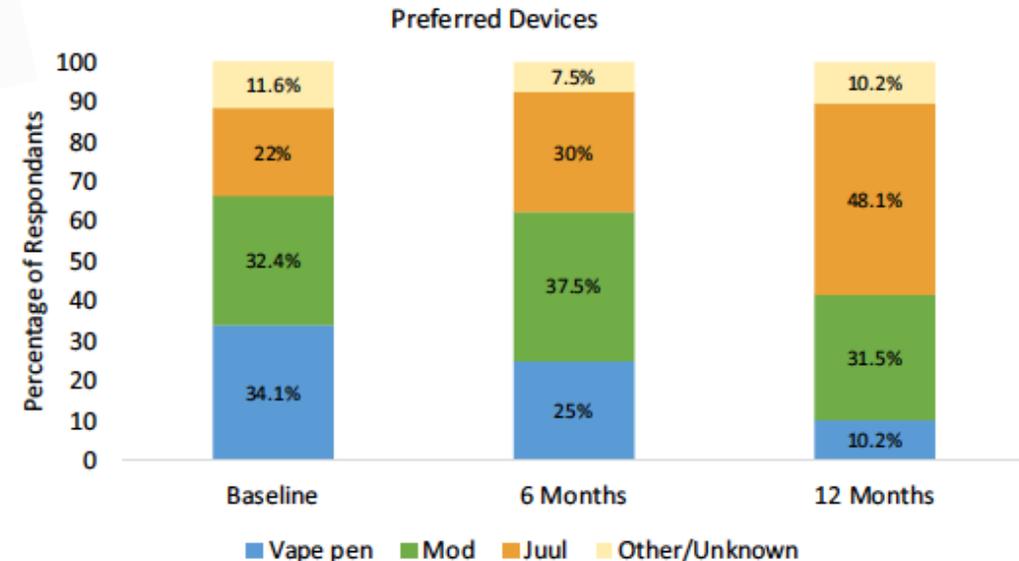


- **N=173 adolescents** using an ECIG at least once in the prior 30 days and 10+ lifetime uses
- 75% male, age M=16.6 yrs (SD=1.2, R: 13-18), 55% Wh
- At 12-month follow-up, **80% continued to use ECIGs**
- **Daily use** increased from 14.5% at baseline, to 18% at 6-month follow-up, and **30% at 12-months**

Table 1
Frequency, dependence, and cotinine levels at each time point

	Baseline, N = 173	6 mo, N = 120	12 mo, N = 127
Frequency in days/month, M (SD)	15.4 (9.8)	15.0 (11.3)	19.6 (9.7)
Daily use, n (%)	25 (14.5)	21 (18.1)	31 (29.8)
ECDI dependence score, M (SD)	3.4 (3.9)	4.5 (4.4)	5.1 (4.6)
No dependence, n (%)	108 (62.4)	61 (52.6)	47 (45.6)
Low dependence, n (%)	42 (24.3)	34 (29.3)	32 (31.1)
Medium dependence, n (%)	17 (9.8)	12 (10.3)	15 (14.6)
High dependence, n (%)	6 (3.5)	9 (7.8)	9 (8.7)
Cotinine in ng/ml, median (IQR)	2.1 (35.2)	9.1 (85.4)	10.8 (79.6)

ECDI = Electronic Cigarette Dependence Index; IQR = interquartile range; SD = standard deviation.



5A_s for e-cigarettes

ASK | ADVISE | ASSESS | ASSIST | ARRANGE

Do you use any e-cigarette or tobacco products?

CIGARETTES E-CIGARETTES BOTH NEITHER

Evidence Gaps

Treatment underutilization

GAP: Limited clinical integration

Evidence largely for adults

GAP: Youth cessation

Evidence largely for daily smoking

GAP: Nondaily smokers

Evidence largely for cigarettes

GAP: Other tobacco products and dual users

Conclusions



Treating tobacco use is relevant to all areas of medicine



Medications work alone and are maximized when paired with counseling



USPSTF: **“Grade A”** recommendation for treating tobacco use



Mobile health solutions extend reach and have demonstrated efficacy

DC | HEALTH

Patient cases - Tobacco Cessation

Estela Lajthia, PharmD
Clinical Assistant Professor of Pharmacy Practice
Howard University College of Pharmacy

LETS PRACTICE!!

- Objectives
 - Identify possible barriers and solutions using a patient centered approach
 - Apply the main concepts and approaches of tobacco cessation

CASE 1

- T.A. is a 49 year old male with a history of smoking since the age of 22. He presents today to clinic seeking assistance with smoking cessation.
- Past medical history: type 2 diabetes x7 years, hyperlipidemia x8 years, hypertension x8 years and coronary artery disease (s/p an MI)
- Family history: father died of prostate cancer; mother has heart disease and type 2 diabetes. No siblings.
- Social history: works as a mailman; sedentary lifestyle; drinks a six pack of beer 3-4 times a week; divorced; smokes 10 - 15 cigarettes a day, cut down after his MI 5 years ago; admits to poor adherence because he is “on too many pills”.

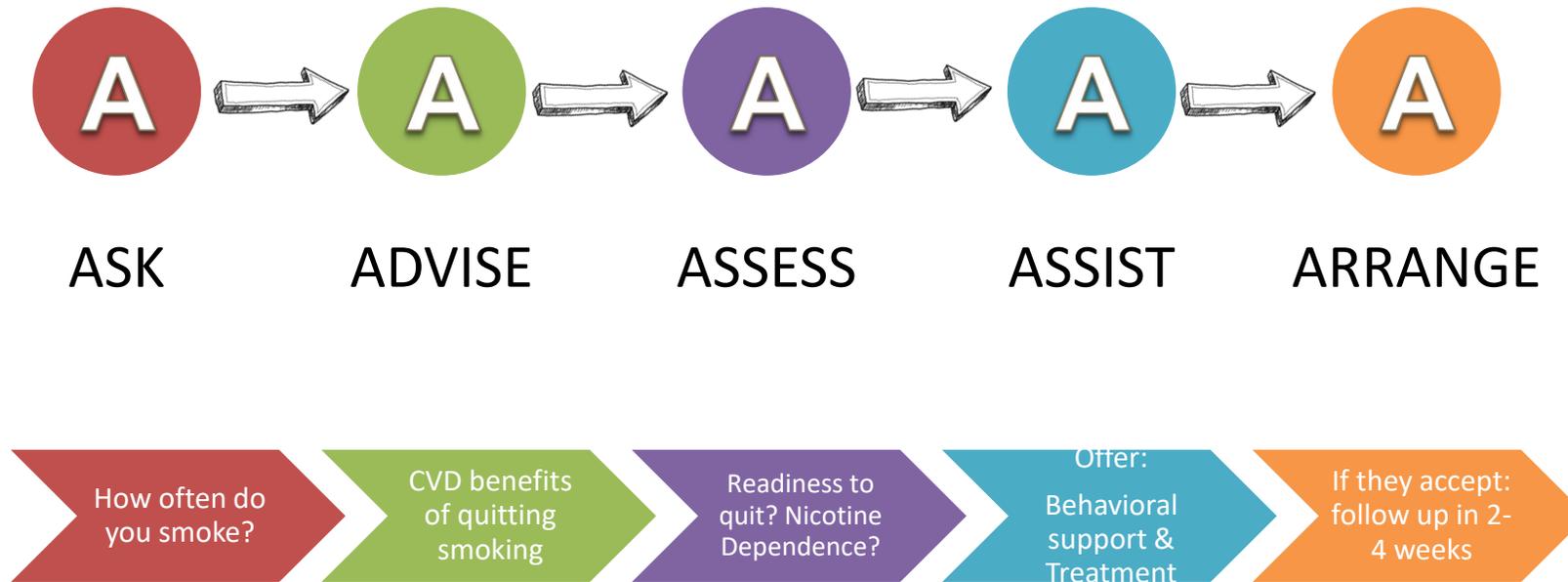
CASE 1 – CLINICAL PRESENTATION

- Vital signs: BP 130/78 mmHg; HR 78bpm; **BMI 34.2**

Laboratory findings	
HbA1c 8.7%	TC 159 mg/dL
HDL 39 mg/dL	TG 181 mg/dL
LDL-C 84 mg/dL	eGFR 86 mL/min/1.73m ²
Na 140 mEq/L	Cl 104 mEq/L
CO2 21mEq/L	BUN 13 mg/dL
K 4.2 mEq/L	SCr 1.02 mg/dL
AST 36 U/L	ALT 21 U/L

Medication list
Lisinopril – HCTZ 20-12.5mg daily
Metoprolol 50mg twice a day
Amlodipine 10mg daily
Aspirin 81mg daily
Atorvastatin 40mg daily
Metformin 1000mg twice daily
Sitagliptin 100mg daily
Lantus 34 units daily

APPROACH



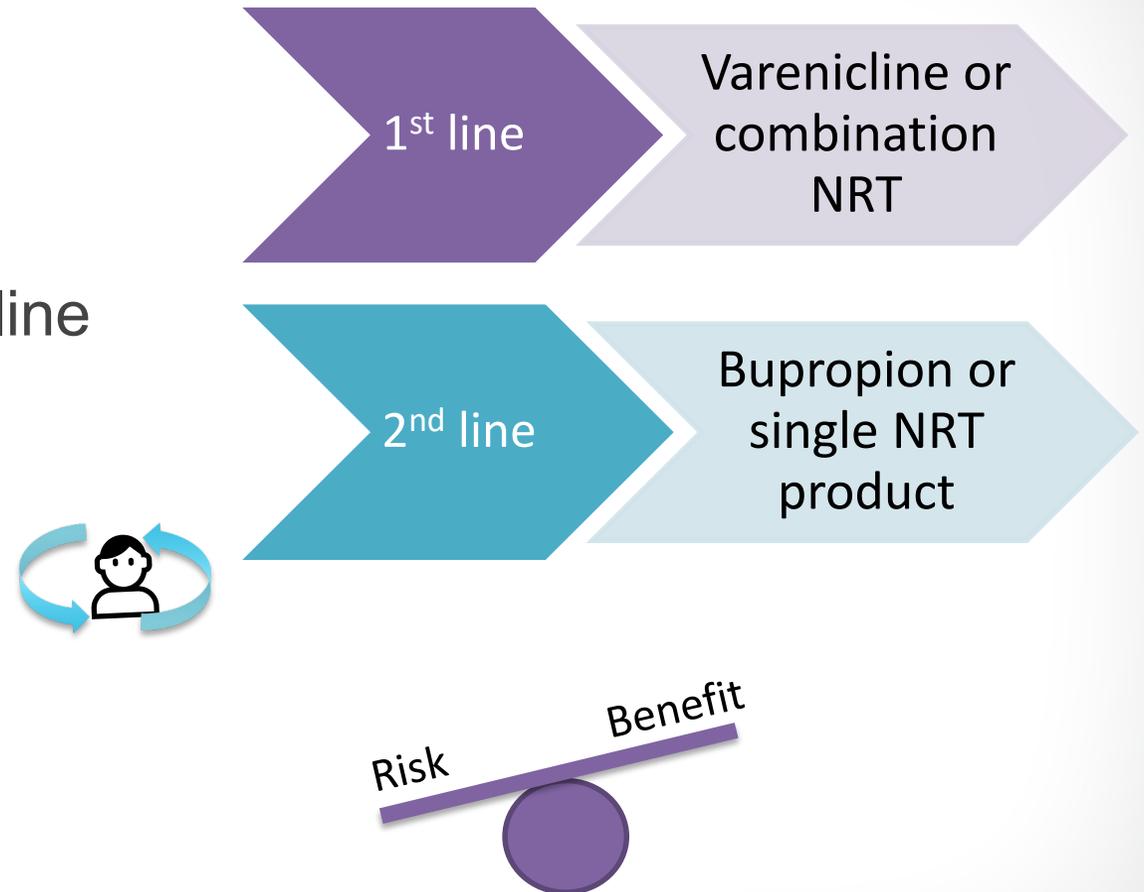
CASE 1

- **Ask** → T.A. smokes daily
- **Advise** → CVD risks
 - Extensive history of CVD
 - Motivational interviewing
 - “Quitting now is the best way to avoid another heart attack”
- **Assess** → Readiness? Smoking index?
 - How many cigarettes do you smoke?
 - 0: <10
 - **1: 11-20**
 - 2: 21-30
 - 3: >30
 - How soon after waking up do you smoke your first cigarette of the day?
 - 0: after 60 mins
 - 1: 31 – 60mins
 - 2: 6-30 mins
 - **3: within 5 mins**
 - Score: 0-2 (low); **3-4 (moderate)**; 5-6 (high)
 - T.A. has moderate nicotine dependence

CASE 1 - PLAN

Assist

- Behavioral support
- Pharmacotherapy
 - NRT vs. Bupropion vs. Varenicline
 - Medication adherence?
 - Drug - Drug interactions
 - Check!
 - Drug - Disease interactions
 - Side effects
 - Bupropion – weight gain
 - Education on nicotine withdrawal



CASE 1 - PLAN

- **Arrange**
 - If patient accepts follow up via phone or office visit in 2-4 weeks
 - Monitor treatment response, adherence, and adverse events
 - If patient declines continue to engage and ask them to quit at every visit
- **Document!!!!**
 - **E- prescribe**



CASE 2

- S.B. is 54 year old AA female with hypertension x11 years, hyperlipidemia x8 years, arthritis x5 years presents to your clinic for routine visit.
- Family history: father has hypertension and heart disease, mother died of breast cancer 5 years ago.
- She started smoking at the age of 25. About 7 years ago she was able to quit “cold turkey” and was smoke free for 2 years. Unfortunately, she lost her mother in 2015 and relapsed. She started smoking again to deal with the stress. Currently smokes one pack a day, not ready to quit at this time.
- Social history: drinks alcohol socially; married with two children; denies use of illicit drugs; recently lost her job.

CASE 2 – CLINICAL PRESENTATION

- Vitals from the visit: BP 142/82 mmHg; HR 87 bpm; BMI 29.5

Laboratory findings	
TC 159 mg/dL	TG 181 mg/dL
HDL 39 mg/dL	LDL-C 84 mg/dL

Medication list
Losartan 20mg daily
Rosuvastatin 5 mg daily
Amlodipine 5 mg daily
Naproxen 220mg daily as needed

APPROACH



CASE 2 - PLAN



- **Ask**

- Smokes daily
- Not ready to quit due to current stress

- **Advise** → risk factors

- Personalized motivational interviewing
 - ASCVD 10 year risk calculator (<http://tools.acc.org/ASCVD-Risk-Estimator-Plus>)
 - Current risk 14.3%
 - If quits risk ↓ 7.5%



- **Refer**

- 1-800-QUIT-NOW
- Web, text, app interventions.
- DC Tobacco Free Coalition
 - QuitNow.net/dc
 - (800)-QUIT-NOW
 - 202-333-4488 (Spanish speaking)
 - Free patches and lozenges for all DC residents**

CASE 3

- E.P is a 31 year old male who used to smoke cigarettes socially on weekends while in college. Later on he switched to e-cigarettes thinking it was a “better choice”. Now, five years later he thinks he is addicted to e-cigarettes and wants to quit.
- Past medical history: not significant
- Family history: mother has Crohn’s disease; father has hypertension and vitamin D deficiency.
- Social history: consumes 4-5 drinks on weekends; occasional use of marijuana; single; works as an accountant.

APPROACH



CASE 3 - PLAN

- **Ask**
- **Advise**
 - E- cigarettes contain additional chemicals to nicotine (risk?)
 - E- cigarettes vs. combustible cigarettes
 - No long term data
- **Assess** → how often and for how long?
- **Assist**
 - Behavioral
 - Make a plan to taper down
 - Set goals!
 - Pharmacotherapy
 - NRT off label
- **Arrange**

