Tobacco Cessation

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A MESSAGE FROM U.S. SURGEON GENERAL JEROME ADAMS
DISCLOSURES

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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

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

- Cigarettes
- Smokeless tobacco (chew, oral snuff, dip)
- Snus
- Cigars, cigarillos, little cigars
- E-cigarettes, nicotine vapes
- Hookah (water pipe smoking)
- Heated Tobacco Products
- Nicotine Pouches
- Cloves, Kreteks
- Bidis
- Pipes
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.

13.7% of US adults are current smokers

15.6%
12.0%
CIGARETTE SMOKING PREVALENCE BY CENSUS TRACK

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

Smoking prevalence, %
- 8.8 - 10.8
- 11.0 - 12.8
- 13.2 - 14.8
- 15.0 - 17.1
- 17.4 - 19.4
- 20.0 - 23.6
- 24.2 - 29.3
- 29.7 - 35.4
- 38.2 - 49.1

Source: CDC / RWJF
Nearly 7 in 10 adults who smoke want to quit
Adults who currently use e-cigarettes as of 2018

- 18-24 YEARS OLD: 7.6%
- 25-44: 4.2%
- 45-66: 2.1%
- 65+: 0.8%

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

Source: 2018 National Health Interview Survey
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

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

- **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

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**Graph:**
- **27.5%** high school e-cigarette use
- **10.5%** middle school e-cigarette use
- **5.8%** high school cigarette use
- **2.3%** middle school cigarette use
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<tr>
<td>“JUUL”</td>
<td>148000*</td>
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</tbody>
</table>

*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)
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.

SOURCE: MAYO
NEUROCHEMICAL and RELATED EFFECTS of NICOTINE

- 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

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

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

• 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

• 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]
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
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
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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

- **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

1984
- Rx nicotine gum

1991
- Rx transdermal nicotine patch

1996
- Rx nicotine lozenge
- Rx nicotine nasal spray

1997
- OTC nicotine gum & patch

2002
- Rx varenicline

2006
- OTC nicotine gum & patch; Rx nicotine nasal spray
- Rx nicotine patch; Rx bupropion SR
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 wakening (< 30m)

combination NRT

Gum otc

Patches otc

Lozenge otc

Nasal spray

Inhaler

Nicotine mouth spray
NICOTINE "GUM"

- Chew slowly
- Chew again when peppery taste or tingle fades
- Park between cheek & gum
- Stop chewing at first sign of peppery taste or tingling sensation
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
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 $\rightarrow$ reduces smoking (CPD)
EAGLES Trial
N=8144

### Weeks 9–24

#### Comparison OR
- **V vs P**: 2.74
- **Bupr vs P**: 1.89
- **N vs P**: 1.81
- **V vs NRT**: 1.52
- **Bupr vs NRT**: 1.04
- **V vs Bupr**: 1.45

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### Comparison OR (95% CI)

#### Primary comparisons

- **Varenicline vs. placebo**
  - Non-Psych (N = 4028): 4.00 (3.20, 5.00)
  - Psych Cohort (N = 4116): 3.24 (2.56, 4.11)
  - Overall (N = 8144): 3.61 (3.07, 4.24)
- **Bupropion vs. placebo**
  - Non-Psych (N = 4028): 2.26 (1.80, 2.85)
  - Psych Cohort (N = 4116): 1.87 (1.46, 2.39)
  - Overall (N = 8144): 2.07 (1.75, 2.45)
- **NRT vs. placebo**
  - Non-Psych (N = 4028): 2.30 (1.83, 2.90)
  - Psych Cohort (N = 4116): 2.00 (1.56, 2.55)
  - Overall (N = 8144): 2.15 (1.82, 2.54)
- **Varenicline vs. NRT**
  - Non-Psych (N = 4028): 1.74 (1.43, 2.10)
  - Psych Cohort (N = 4116): 1.62 (1.32, 1.99)
  - Overall (N = 8144): 1.81 (1.49, 2.19)
- **Bupropion vs. NRT**
  - Non-Psych (N = 4028): 0.98 (0.80, 1.20)
  - Psych Cohort (N = 4116): 0.94 (0.75, 1.16)
  - Overall (N = 8144): 0.96 (0.83, 1.11)
- **Varenicline vs. bupropion**
  - Non-Psych (N = 4028): 1.77 (1.46, 2.14)
  - Psych Cohort (N = 4116): 1.49 (1.20, 1.85)
  - Overall (N = 8144): 1.45 (1.24, 1.70)
EAGLES: Primary NPS Composite Safety Endpoint

Cohort effect: $p < 0.0001$
Treatment by cohort interaction: $p = 0.0650$

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

- **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.
What About E-cigs?

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

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

• Kaiser Permanante 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

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

Young-Wolff et al. 2018 Prev Med
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.*

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

* 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.
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
5A<sub>s</sub> for e-cigarettes

Do you use any e-cigarette or tobacco products?
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
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

<table>
<thead>
<tr>
<th>Laboratory findings</th>
<th>Medication list</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c 8.7%</td>
<td>Lisinopril – HCTZ 20-12.5mg daily</td>
</tr>
<tr>
<td>HDL 39 mg/dL</td>
<td>Metoprolol 50mg twice a day</td>
</tr>
<tr>
<td>LDL-C 84 mg/dL</td>
<td>Amlodipine 10mg daily</td>
</tr>
<tr>
<td>eGFR 86 mL/min/1.73m²</td>
<td>Aspirin 81mg daily</td>
</tr>
<tr>
<td>Na 140 mEq/L</td>
<td>Atorvastatin 40mg daily</td>
</tr>
<tr>
<td>Cl 104 mEq/L</td>
<td>Metformin 1000mg twice daily</td>
</tr>
<tr>
<td>CO2 21mEq/L</td>
<td>Sitagliptin 100mg daily</td>
</tr>
<tr>
<td>BUN 13 mg/dL</td>
<td>Lantus 34 units daily</td>
</tr>
<tr>
<td>K 4.2 mEq/L</td>
<td></td>
</tr>
<tr>
<td>SCr 1.02 mg/dL</td>
<td></td>
</tr>
<tr>
<td>AST 36 U/L</td>
<td></td>
</tr>
<tr>
<td>ALT 21 U/L</td>
<td></td>
</tr>
</tbody>
</table>
How often do you smoke?

CVD benefits of quitting smoking

Readiness to quit? Nicotine Dependence?

Offer: Behavioral support & Treatment

If they accept: follow up in 2-4 weeks
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

1st line
- Varenicline or combination NRT

2nd line
- Bupropion or single NRT product

J Am Coll Cardiol. 2018 Dec, 72 (25) 3332-3365
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

<table>
<thead>
<tr>
<th>Laboratory findings</th>
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</tr>
</thead>
<tbody>
<tr>
<td>TC 159 mg/dL</td>
<td>Losartan 20mg daily</td>
</tr>
<tr>
<td>TG 181 mg/dL</td>
<td>Rosuvastatin 5 mg daily</td>
</tr>
<tr>
<td>HDL 39 mg/dL</td>
<td>Amlodipine 5 mg daily</td>
</tr>
<tr>
<td>LDL-C 84 mg/dL</td>
<td>Naproxen 220mg daily as needed</td>
</tr>
</tbody>
</table>
APPROACH

ASK
How often do you smoke?

ADVISE
Explain the benefits of quitting

REFER
Refer
CASE 2 - PLAN

• **Ask**
  – Smokes daily
  – Not ready to quit due to current stress

• **Advise** → risk factors
  – Personalized motivational interviewing
      – 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](http://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

ASK

Risks of e-cigarettes.

Readiness to quit?

Offer: Behavioral support

If they accept: follow up in 2-4 weeks

ASSIST

How often are you smoking?
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

DC HEALTH