



Smoking and Tobacco Use

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Disclosure

- None



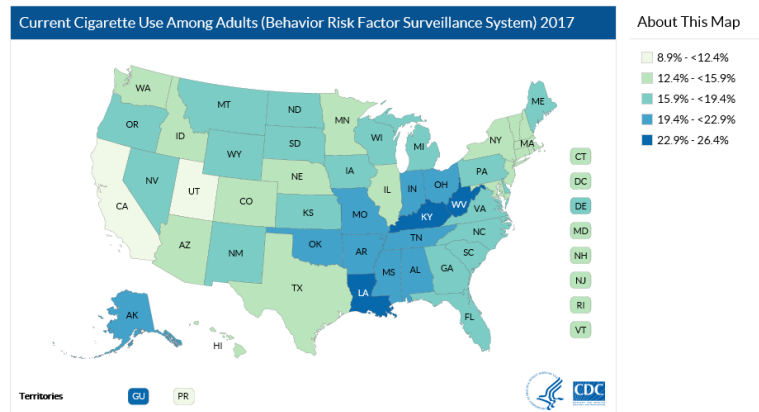
Objectives

1. Describe disease burden of tobacco use in people with HIV
2. Assess the drivers of tobacco use
3. Use evidence-based treatment for tobacco use in people with HIV



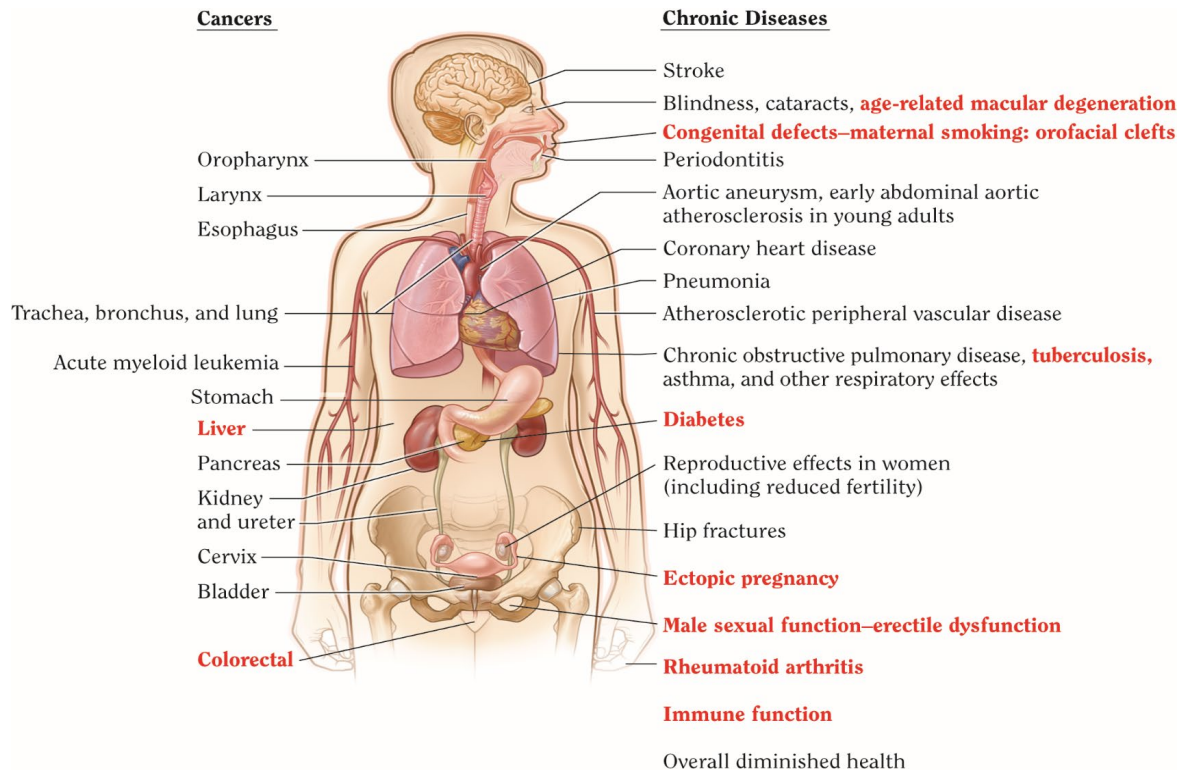
Smoking in the US

- 13.7% percent of US population smoked in 2018
- 33.6% of adults with HIV smoked in 2014
- Cigarette smoking is the leading cause of preventable death in the US
- Cigarette smoking is the main contributor of preventable death in people whose HIV is effectively treated
- >480,000 deaths every year from smoking
- Tobacco smoke contains over 7,000 chemicals and about 70 cause cancer
- 68% of adult cigarette smokers reported wanting to quit smoking in 2015





Health Consequences of Smoking





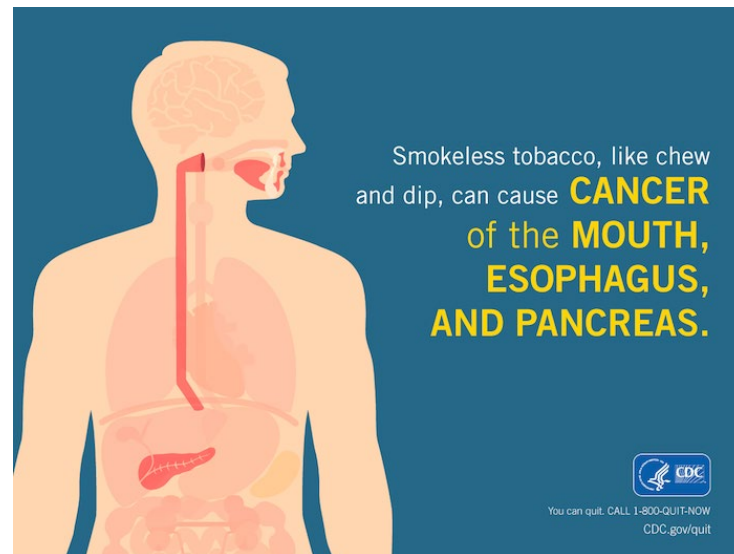
Health Benefits of Quitting Smoking Over Time

Time after quitting	Health benefits
Minutes	Heart rate drops
24 hours	Nicotine level in the blood drops to zero
Several days	Carbon monoxide level in the blood drops to level of someone who does not smoke
1 to 12 months	Coughing and shortness of breath decrease
1 to 2 years	Risk of heart attack drops sharply
3 to 6 years	Added risk of coronary heart disease drops by half
5 to 10 years	Added risk of cancers of the mouth, throat, and voice box drops by half Risk of stroke decreases
10 years	Added risk of lung cancer drops by half after 10-15 years Risk of cancers of the bladder, esophagus, and kidney decreases
15 years	Risk of coronary heart disease drops to close to that of someone who does not smoke
20 years	Risk of cancers of the mouth, throat, and voice box as well as pancreas drops to close to that of someone who does not smoke



Smokeless Tobacco and Cigars

- Smokeless tobacco increases risk of death from heart disease and stroke
- Cigar smoking is associated with lung, esophagus, larynx, and oral cavity cancers
- Heavy cigar smoking increases risk of coronary heart disease and emphysema





People Living with HIV who Smoke

- Smoking rates are 2-3 x that of the general population
- Mortality rates are higher among smokers compared with non-smokers
- A study from Denmark showed people who smoked lost more years from smoking than HIV (12.3 years lost with smoking vs 5.1 years lost associated with HIV status)
- Patients that quit smoking have a 40% lower risk of death



People Living with HIV who Smoke

- More likely than non-smokers with HIV to develop:
 - Cancer
 - Bacterial pneumonia
 - Pneumocystis pneumonia
 - COPD
 - Heart disease
- 70% of MI in PLHIV are due to smoking
- 27% of cancers in PLHIV are due to smoking



Lung Cancer: People Living with HIV who Smoke

- Leading cause of mortality from non-AIDs-defining complication is lung cancer
 - Onset 25 to 30 years earlier than general population with lower exposure to cigarette smoke
 - Lung cancer risk 3 x higher in HIV than non-HIV infected populations

Lung Cancer

- National Lung Screening Trial (2011) findings: Annual CT screening results in a 15-20% reduction in lung cancer mortality compared to chest x-ray
- Shared decision making: Choice to be screened or not be screened (risks vs benefits)





Screening Recommendations – 2020 Guidelines

National Comprehensive Cancer Network

Criteria 1	Criteria 2
Ages 55-77	Ages 50 or older
30 pack-year smoking history	20 pack-year smoking history
Current smokers or have quit less than 15 years ago	Have at least one additional risk factor: lung disease history, exposure to radon, asbestos, or other carcinogen; personal history of smoking-related cancer; family history of lung cancer

Effective Tobacco Use Treatment



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What Improves Outcomes?

- Evaluation
- Medications
- Behavioral Treatment
- Follow up



The 5 As: Evidence-Based, Brief Counseling Intervention

- **ASK** about tobacco
- **ADVISE** them to stop all tobacco use
- **ASSESS** interest /motivation to make a change
- **ASSIST** with counseling / medications
- **ARRANGE** to follow-up during subsequent visits



The 5 As: Evidence-Based, Brief Counseling Intervention

- **ASK** about tobacco
 - Ask in a judgment free way
 - Instead of asking “Are you a smoker?” Or “You don’t smoke, do you?”
 - Ask “Have you ever smoked cigarettes or used other tobacco products? How much and how often can also be included in this section.
- **ADVISE** them to stop all tobacco use
 - Brief specific advice from a provider is shown to be very effective
 - “Quitting smoking is one of the best things that you can do to prevent having another stroke.”



The 5 As: Evidence-Based, Brief Counseling Intervention

- **ASSESS** interest /motivation to make a change
 - Instead of asking “Are you ready to quit?”
 - Ask open-ended questions – “I’d like to hear your thoughts about tobacco use.”
- **ASSIST** with counseling / medications
 - This is not dependent on readiness to quit but rather willingness to take the first steps
- **ARRANGE** to follow-up during subsequent visits
 - Referral, schedule a visit, email, phone calls



Assessment

- What are the major challenges my patient will face in quitting and staying abstinent?
- What are the major motivations and strengths my patient brings to this quit attempt?

CHALLENGES	MOTIVATORS
Why the patient smokes, what the patient likes, what he/she enjoys about smoking	Why the patient wants/needs to quit, what he/she doesn't like about smoking
What makes it difficult to stop; triggers, fears, causes of relapse of quit in past	What being tobacco free would be like



Predictors of Relapse

- Other people using tobacco in the home, neighborhood, community, social circles
- Negative affect
- High levels of stress
- Concern about weight gain
- Postpartum
- Psychiatric comorbidities
- Alcohol and drug use
- Low self-efficacy
- Low SES
- Poor health literacy
- High nicotine dependence
- Genetic predisposition



Assessment

- Can occur before and during visit
- Using assessment answers to improve motivation

How long, how much, what type and brand?

Where and with whom do you smoke?

How many times have you tried to quit in the past?

How long were you able to quit in the past?

What have you used to quit in the past?

What led to relapse?



Two Drivers of Smoking

1. **Nicotine Withdrawal** - nicotine half-life is 2 hours.

Treatment: Medications (reduce withdrawal)

2. **Triggers “Cues”** – routines, places, emotions, smells, alcohol, thoughts.

Treatment: Behavioral Treatment: (Motivational Interviewing / Cognitive Skills – Triggers / Mindfulness)



Withdrawal and the Stages of Recovery

- **Withdrawal Symptoms:** Feeling irritable, angry, anxious, having trouble thinking, craving tobacco products, feeling hungrier than usual
- Urges typically last under 5 minutes but can be prolonged
- Withdrawal lasts for **2-3 weeks** and is highly correlated with relapse
- Frequent urges and emotion dysregulation can continue for **3-6 months**
- We now prescribe medications for 12 weeks (3 months)
- At 3 months we reassess and extend to 6 months if needed



Interventions in People Living with HIV

- Cioe published a literature review looking at 10 studies in 2013
 - Pharmacologic and behavioral approaches
 - Sample sizes were frequently small and the effects not of sustained over time
 - Emotional distress was a barrier to success
 - Adherence to pharmacologic therapy often declined over time and may have contributed to low cessation rates



Interventions in People Living with HIV

- Cioe published a literature review looking at 10 studies in 2013
 - Cell phone-delivered intensive counseling with NRT was shown to have a significant effect on outcomes when compared to usual care
 - Need for the development and implementation of effective interventions tailored to this population

Medication Management



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Standard of Care Treatment

- **Medication management and behavioral treatment**
- **First Line Medications:** Varenicline or combination nicotine replacement therapy
- **What about quitting “Cold Turkey”?**
 - Abrupt quitting with no counseling or medications has a 3-5% success rate
 - High likelihood of relapse



Sustained Release Medications

- **Nicotine Patch** nicotine is a full agonist at alpha-4, beta-2 nicotinic receptor.
- **Varenicline** partial agonist/antagonist at alpha-4, beta-2, full agonist at alpha-7 nicotinic receptors.
- **Bupropion** increases dopamine and norepinephrine levels (but not serotonin)





Management of Urges – Immediate Release Medications

- **Nicotine Gum**
- **Nicotine Lozenge**
- **Nicotine Nasal Spray**
- **Nicotine Inhaler**

- These medications provide urge relief when urges occur. They can be used “prophylactically”
- Do not act as rapidly as cigarettes, but provide a soft “spike” of nicotine
- Standard of Care: Sustained release + immediate release medications together



Nicotine Patch

- Patch sticks to the skin with adhesive. Nicotine is absorbed through the skin enters the body – slowly.
- Provides nicotine over a 24-hour period
- Strongest urges are often when a person first wakes up, so keep it on at night if possible



Nicotine Patch

- Side Effects:
 - 19.5% experience skin irritations but only 7% discontinue due to this
- Contraindication:
 - Adhesive allergy 0.3% of the population
- Tell patients their skin will turn red under the patch
- Change patch site daily
- Keep the patch on for 24 hours and remove it



Patch Side Effects

About 4% of patients stop the nicotine patch due to side effects

Other Common Side Effects:

1. Too much nicotine (8%): nausea, palpitations, hiccups, dizziness.
2. Not enough nicotine (5%): HA, anxiety, depression, urges, withdrawal
3. Insomnia (11%): Stop patch at night



Nicotine Patch Dosing

- *Transdermal patch*: Topical: **Note**: Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced).
- Patients smoking >10 cigarettes/day: Begin with step 1 (21 mg/day) for 6 weeks, **followed by** step 2 (14 mg/day) for 2 weeks; **finish with** step 3 (7 mg/day) for 2 weeks
- Patients smoking ≤ 10 cigarettes/day: Begin with step 2 (14 mg/day) for 6 weeks, **followed by** step 3 (7 mg/day) for 2 weeks

Nicotine Gum + Lozenges

- Lowest side effect profile
- Use with long acting medication
- Use alone if side effects to other medications

Gum/Lozenge Side Effects

Nausea: 16-17%

Headache: 9-10%

Mouth Soreness: 5.4%





Nicotine Gum + Lozenges

- **How to use:**
 - Nicotine causes a tingly sensation
 - Gum: Chew and park between cheek and gum
 - Do not use gum in a patient with dentures
 - Lozenge: Suck on like a normal lozenge
 - Lozenge take 20-30 minutes to dissolve
 - Miniature lozenges take 10 minutes to dissolve
 - Do not chew or swallow lozenges
 - Use during an urge
 - Leave 15 minute window before and after eating / drinking



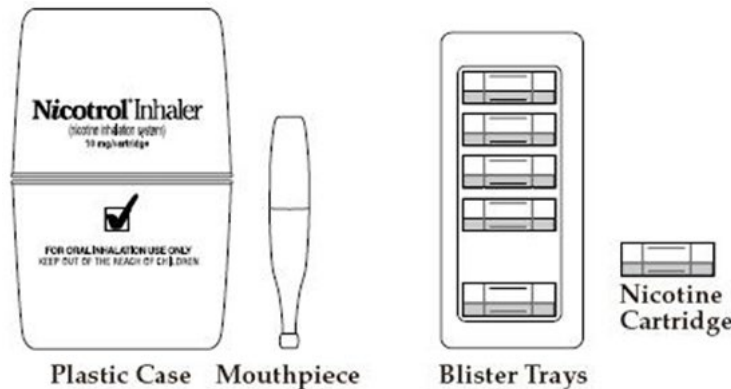
Nicotine Gum + Lozenges Dosing

- First cigarette within 30 minutes of waking: 4 mg strength
- First cigarette after 30 minutes of waking: 2 mg strength
- Maximum: 20 lozenges per day or 24 pieces of gum per day
- 12-week protocol:
 - Weeks 1-6: one lozenge or gum every 1-2 hours
 - Weeks 7-9: one lozenge or gum every 2-4 hours
 - Weeks 10-12: one lozenge or gum every 4-8 hours
 - Duration of therapy = 12 weeks



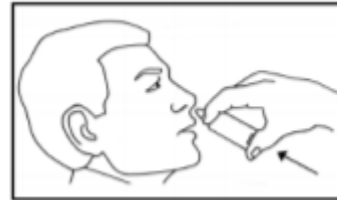
Nicotine Inhaler

- The inhaler creates a large particle aerosol absorbed in the mouth and the upper airways
- Requires multiple small puffs to get sufficient nicotine to match cigarettes
- Side Effects:
 - Throat irritations: 15-50%
 - Coughing: 16-40%
 - Headache, nausea, indigestion: <20%



Nicotine Nasal Spray

- Rapid administration
- Used in combination with patch
- Not recommended for patients with:
 - Chronic nasal disorders
 - Reactive airway disease
- Side Effects:
 - Nasal irritation: 94%
 - Headache: 18%





Varenicline

- Binds to nicotine receptors for 12 hours
- Competitive inhibition - Varenicline competes with nicotine
- Mildly stimulates receptor
- Smoking is no longer as satisfying
- Keeps a lapse from turning into a relapse





Varenicline

- **Contraindications:**
 - Severe renal impairment
 - Pregnant or breastfeeding
 - <18 years old
- **Side Effects:**
 - Nausea: 17-44%
 - Insomnia: 5.1-42.9%
 - Abnormal dreams: 5.6-37.2%
 - In individuals with pre-existing psychiatric conditions there is numeric but non-significant increase in mood related symptoms



Varenicline: Suicidality and Cardiac Events

N = 25,000 VA patients – Varenicline vs. NRT – no increase in psychiatric or cardiovascular events

N = 270,000 in UK – Varenicline vs. NRT – no increase in depression or self-harm, or CV events



EAGLES TRIAL

8144 participants: 4028 to the non-psychiatric cohort; 4116 to the psychiatric cohort

Assessed for moderate and severe neuropsychiatric adverse events.

Non-psychiatric cohort:

13 (1.3%) of 990 participants varenicline group

22 (2.2%) of 989 in the bupropion group

25 (2.5%) of 1006 in the nicotine patch group

24 (2.4%) of 999 in the placebo group

Abstinence rates vs. placebo:

Varenicline OR = 3.61

Nicotine Patch OR = 1.68

Bupropion OR = 1.75

Psychiatric cohort:

67 (6.5%) of 1026 participants in the varenicline group

68 (6.7%) of 1017 in the bupropion group

53 (5.2%) of 1016 in the nicotine patch group

50 (4.9%) of 1015 in the placebo group

Differences were non-significant



FDA Removes Black Box Warning For Chantix

12-16-2016: “As a result of our review of the large clinical trial, we are removing the Boxed Warning, FDA’s most prominent warning, for serious mental health side effects from the Chantix drug label.”



Using Varenicline in PLHIV – Lancet HIV 2018

- 248 patients: 123 in the varenicline group and 125 in the placebo group
- Varenicline or placebo twice daily for 12 weeks plus face to face counselling
- Immunovirological markers of HIV control and clinical HIV progression were not affected over the trial
- No increased psychiatric or cardiovascular events in Varenicline group compared to placebo group
- Abstinent Rates at 48 weeks:
 - Varenicline: 18 (15%) of 123 patients
 - Placebo: 8 (6%) of 124 patients in the placebo group
 - Abstinence more common when the counselor was the ID specialist rather than the tobaccologist
- Conclusion:
 - Varenicline with tailored counseling is an effective smoking cessation treatment



Bupropion

- Developed as an anti-depressant. Still widely used for this.
- Increases dopamine and norepinephrine levels (not serotonin)
- Reduces feelings of anhedonia (inability to feel satisfaction/reward) and concentration difficulties (alertness) that are major symptoms of withdrawal
- It is a good choice for smokers with untreated mild depression
- Good choice for smokers who gain weight - Norepinephrine is an appetite suppressant
- Affordable
- Least effective monotherapy



Bupropion Contraindications

Contraindications:

- At risk for a seizure
- Hepatic Impairment
- Pregnancy*
- <18 years old*

Lowers seizure threshold:

- Prior seizure
- Head injury
- Stroke
- Brain tumor
- Bulimia/anorexia
- On MAO inhibitors in last 14 days
- On seizure meds
- Alcohol abuse/dependence
- Acute discontinuation of alcohol / benzodiazepines

* Would recommend getting a specialist involved in these cases



Bupropion Side Effects

- **Side Effects:**
 - Insomnia
 - Dry Mouth
 - Constipation, Nausea, Vomiting
 - Headache
 - Agitation
- **Dosing:**
 - Bupropion SR



Antiretrovirals that induce CYP2B6 activity (Bupropion Metabolism)

- Efavirenze: Bupropion - AUC decreased 55%
- Ritonavir: Bupropion - AUC decreased 40-67%
- Monitor of decreased bupropion efficacy



Cochrane Systematic Review – Medications

- NRT and Bupropion: For every 10 people who quit with placebo about 18 could be expected to quit with NRT or Bupropion
- Varenicline: For every 10 people who quit with placebo about 28 could be expected to quit with Varenicline
- Combination use of NRT is as effective as varenicline



Making a Plan



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Planning: Behavioral Strategy

- Identifying treatment based on the patient's needs, willingness to engage, and the availability
- Setting a Quit Day and preparing (“clean up”)
- Identifying triggers and cues
- Identifying social support





Planning: Behavioral Strategy

- What if someone is not ready to quit but is willing to cut down?
 - Motivational interviewing
 - Make a reduction plan
 - Do not keep cigarettes next to self
 - Stop smoking in certain locations
 - Identify and address triggers
 - Address tobacco use at every visit
- What if others in the household smoke?



Follow-Up

- Most effective: Once per week for 4-8 weeks
- Beneficial regardless of patient's abstinence status
- Confirm patient is using medications for full 12 weeks



Relapse

- Relapse is normal
- 6-7 attempts before abstinence achieved
 - Slip: 1 to a couple of cigarettes
 - Lapse: regular use over several weeks/month
 - Relapse: return to previous level of use



After a Lapse/Relapse

- Reassess changes in self-efficacy / confidence
- Normalize
- Affirm initial success
- Review what worked and what didn't
- Any benefits to being tobacco free?
- “Practice quitting”
- Address embarrassment / shame



What Improves Outcomes?

- Evaluation
- Medications
- Behavioral Treatment
- Follow up



Resources for Patients

Smoking Cessation Programs with your Health Department or Health System

State Quitline



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- Evidence-based telephone tobacco treatment service
- Available free in all 50 states
- Accessible 24 hours a day, 7 days a week
- English, Spanish and translation service
- Fax referral



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Questions?



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Pfizer or GlaxoSmithKline Medication Information

- Nicotine Nasal Spray:
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- Chantix: <http://labeling.pfizer.com/ShowLabeling.aspx?id=557>
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Image Citation

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