

Kicking Butts: Smoking Cessation Counseling & Medications

Matt Perez, MD

Objectives for Learning Outcomes:

1. Utilize effective strategies to approach tobacco use.
2. Counsel patients on current evidence regarding smoking cessation medications.
3. Discuss clinical use of Varenicline, Bupropion & nicotine replacement.




Kicking Butts

Smoking Cessation Counseling & Medications


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Learning Objectives



- Utilize effective strategies to approach tobacco use
- Review current evidence smoking cessation medications
- Discuss clinical use of:
 - Varenicline
 - Bupropion
 - Nicotine replacement

Take Home Points



- Recommend patients quit smoking
- Prescribe more varenicline
- Combine Bupropion & nicotine patches
- *Cut down to quit* is effective
- Be optimistic about quitting

COPD exacerbation follow up



- Breathing better now
- Still Smoking
 - 1 pack/day x 30 years
- **What do you say about smoking?**

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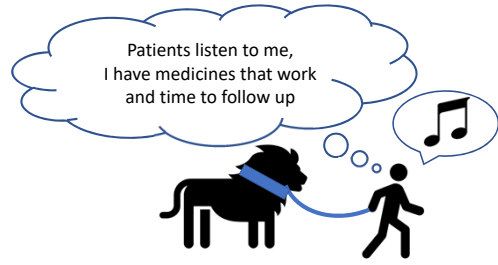
Talking about smoking



Provider

Photographer: Jachandran Samanth

Talking about Smoking Should feel like this



Patients listen to me,
I have medicines that work
and time to follow up

Patient Letter

Hi Dr. Matt

I am doing super good, the medication is just amazing!

I thought I would never quit smoking. Thanks Dr. Perez for insisting over and over for me to quit.

I'm in shock for all the progress I have made.

...I have had no side effects, I feel overall much better.

... I'm down to 2 cigarettes a day. I know for sure I will be smoke free 100% with your help, the medicine and my will.

Thanks again for taking care of my health

The 5 As of Smoking Cessation



Ask everyone about smoking

Advise to Quit



Assess Readiness to Quit



Assist In Quit Attempt



Arrange Follow Up

Source 5As:
<https://www.ahrq.gov/prevention/guidelines/tobacco/5as.html>
Source photos, Bottom 8 NHS Publication No. SMA12-50697CQ

The 5 A's for Tobacco Cessation

- **Ask** each patient about tobacco use
- **Advise** those who use tobacco to quit
 - Brief Intervention
- **Assess** willingness for quit attempt
 - Motivational interviewing
- **Assist** patient in their quit attempt
 - Quit line, phone apps
 - Tobacco replacement, bupropion, varenicline
- **Arrange** follow up visits

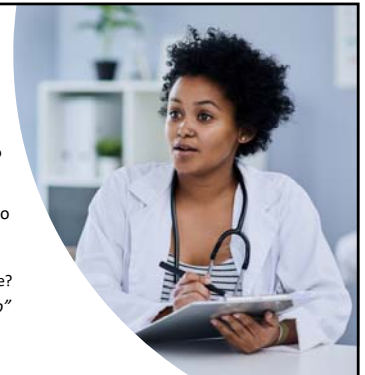
Washington State Department of Health
Tobacco and Vapor Product Prevention & Control Program
The 5 A's for Tobacco Cessation, in (Clinical) Practice

Source <https://www.ahrq.gov/prevention/guidelines/tobacco/5as.html>

Ask each patient about tobacco use

Do you smoke or use tobacco?

- In a typical week, how much alcohol do you drink?
- Do you use any other drugs?
 - Like cocaine, heroin, meth, oxycodone?
- "If I don't ask everyone, I can't say I do"



istockphoto

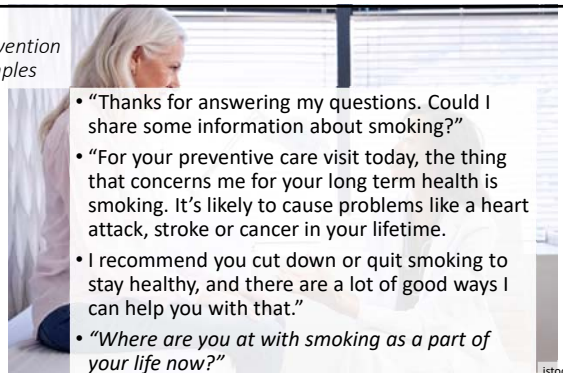
Advise those who use tobacco to quit

Brief Intervention

- Ask for Permission
- Give a Clear Recommendation
- Convey Empathy
- Assess Stage of Change

Brief Intervention Examples

- "Thanks for answering my questions. Could I share some information about smoking?"
- "For your preventive care visit today, the thing that concerns me for your long term health is smoking. It's likely to cause problems like a heart attack, stroke or cancer in your lifetime.
- I recommend you cut down or quit smoking to stay healthy, and there are a lot of good ways I can help you with that."
- "Where are you at with smoking as a part of your life now?"



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Brief
Intervention
Examples

- "Wow, it sounds like it's been really hard for you to breathe lately.
- I worry that smoking is making your asthma worse.
- I recommend you cut down or quit to help your lungs heal.
- *How important is changing smoking for you right now?"*

Brief
Intervention
Examples

- "That's great! Your blood pressure is well-controlled and the cholesterol medicine seems to be working well.
- The only thing I'd like to check in about is smoking...
- "Your 10 year risk of heart attack and stroke was 20%, and these medicines will help you lower your risk, and quitting smoking will reduce it even more.
- I recommend you quit smoking to have the best chance of avoiding a major cardiovascular event or cancer.
- *"What are your current thoughts on smoking? Is it something you're happy with right now or are you looking at cutting down or quitting?"*

Assess

willingness for
quit attempt



Precontemplative

Contemplative

Planning

Action

Assess willingness for quit attempt

Where are you at with smoking now?
Are you happy smoking as you are right now, or do you want to cut down or quit?



There are lots of effective ways I can help you cut down or quit, if you'd like to review them

Assess willingness for quit attempt

What do you like about smoking?

(Validate)

What do you *not* like so much about smoking?

(validate responses)

Help me understand – on one hand, you like ()
But on the other hand, _____ isn't working for you.
How do you make sense of that?

Example Conversation

Ask

- Do you smoke or use tobacco?
- How much and for how long?

Assess

- So where are you with smoking right now?
- Are you happy with smoking how you are right now, or do you want to cut down or quit?

Advise

- (Advise they cut down or quit)

Assess

- What do you like about smoking?
– "I'm so stressed at the end of the day. It helps me relax."
- Sure, everyone needs to relax (sincere validation)
- What else do you like about smoking?
- What do you *not like so much* about smoking?

Assist patient in their quit attempt

- Varenicline (Chantix)
- Nicotine replacement therapy
- Bupropion (Zyban, Wellbutrin)
- WA state Quit line or app

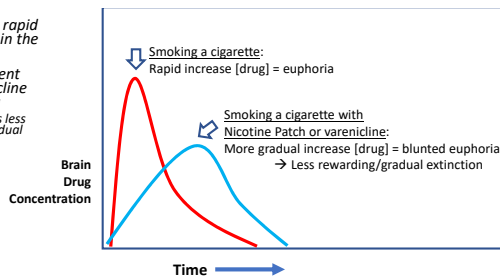
*In order of effectiveness as monotherapy

When to use Tobacco Cessation Medicines



Your Brain on Nicotine

- Rapid changes in drug concentration can produce euphoria
 - Examples: Opioids, nicotine, cocaine
- Smoking produces rapid increases nicotine in the brain
- Nicotine replacement products & varenicline blunt the euphoria
 - Smoking becomes less rewarding → gradual extinction



*conceptualization, not actual data

What are the Most Effective Treatments to Quit Smoking?

Best Monotherapy:
Varenicline

Most Effective:
Nicotine Patches plus Bupropion

Source: Tobacco Use and Dependence Guideline Panel May 2008. US Dept HHS
<https://www.ncbi.nlm.nih.gov/books/NBK63952/>

2008 meta-analysis Smoking cessation meds compared placebo at 6 months (n=83 studies)

Medication	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Placebo	80	1	13.8
Monotherapies			
Varenicline (2 mg/day)	5	3.1 (2.5–3.8)	33.2 (28.9–37.8)
High-Dose Nicotine Patch (> 25 mg) (These included both standard or long-term duration)	4	2.3 (1.7–3.0)	26.5 (21.3–32.5)
Long-Term Nicotine Gum (> 14 weeks)	6	2.2 (1.5–3.2)	26.1 (19.7–33.6)
Varenicline (1 mg/day)	3	2.1 (1.5–3.0)	25.4 (19.6–32.2)
Bupropion SR	26	2.0 (1.8–2.2)	24.2 (22.2–26.4)
Nicotine Patch (6–14 weeks)	32	1.9 (1.7–2.2)	23.4 (21.3–25.8)
Long-Term Nicotine Patch (> 14 weeks)	10	1.9 (1.7–2.3)	23.7 (21.0–26.6)
Nortriptyline	5	1.8 (1.3–2.6)	22.5 (16.8–29.4)
Nicotine Gum (6–14 weeks)	15	1.5 (1.2–1.7)	19.0 (16.5–21.9)

Go to www.surgeongeneral.gov/tobacco/gdinrefs.htm for the articles used in this meta-analysis

2008 meta-analysis Combination therapies

Medication	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
★ Patch (long-term; > 14 weeks) + ad lib NRT (gum or spray) ★	3	3.6 (2.5–5.2)	36.5 (28.6–45.3) ★
★ Patch + Bupropion SR ★	3	2.5 (1.9–3.4)	28.9 (23.5–35.1) ★
Patch + Nortriptyline	2	2.3 (1.3–4.2)	27.3 (17.2–40.4)
Patch + Inhaler	2	2.2 (1.3–3.6)	25.8 (17.4–36.5)
Patch + Second generation antidepressants (paroxetine, venlafaxine)	3	2.0 (1.2–3.4)	24.3 (16.1–35.0)

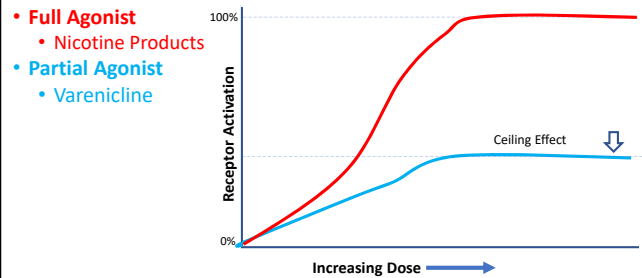
Go to www.surgeongeneral.gov/tobacco/gdinrefs.htm for the articles used in this meta-analysis

Varenicline is a Nicotine Receptor Partial Agonist

- Twice daily oral medication
- FDA approved 12-week course
 - Longer courses are more effective (24 weeks or longer)
- Prescribe starting pack varenicline first month
 - 0.5mg QD x 3 days, 0.5mg BID x 4 days
 - then 1mg BID x 3 weeks
- Continuing month pack = 1mg x 8 weeks
- May need maintenance treatment up to 6 months

Source: Tobacco Use and Dependence Guideline Panel May 2008. US Dept HHS
<https://www.ncbi.nlm.nih.gov/books/NBK63952/>

Nicotine Receptor Activity by dose



That sounds great **BUT**

“Why should I use medicines to quit?”

Smoking Cessation Medicines:

- Prevent Withdrawal
- Reduce Cravings
- Make Smoking Less Enjoyable

And double or triple your chances of successfully cutting down or quitting



Wiki commons Photo

I'd love to quit **BUT**

“I don't want to take meds to quit smoking because...”

- I'm depressed enough as it is
- I don't want to think about suicide
- I've attempted suicide before
- I have bipolar, schizophrenia, depression and my psychiatrist says I can't take them

What are the psychiatric risks of smoking cessation medicines?



Wiki commons Photo

EAGLES Smoking Cessation Study

Evaluating Adverse Events in a Global Smoking Cessation Study

- 12 week Randomized, double-blind, triple dummy, placebo and active NRT controlled trial
 - Nicotine Patch Taper
 - Varenicline BID
 - Bupropion 150mg BID
- 12 weeks of follow up
 - weekly brief counseling
- **N = 4092**
 - Primary psychotic (n = 390)
 - Anxiety (n = 792)
 - Mood disorder (n = 2910)

50% on psych meds,
 33% lifetime suicidal ideation,
 12% suicidal behavior

Evins et al. Neuropsychiatric Safety and Efficacy of Varenicline, Bupropion, and Nicotine Patch in Smokers With Psychotic, Anxiety, and Mood Disorders in the EAGLES Trial (J Clin Psychopharmacol 2019;39: 108–116)

EAGLES study was funded by Pfizer & Glaxo (GSK)

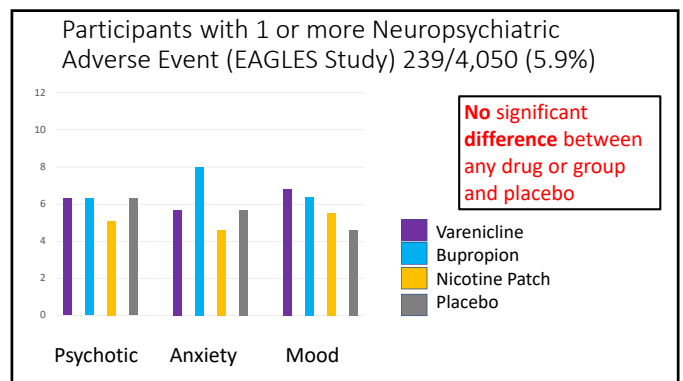
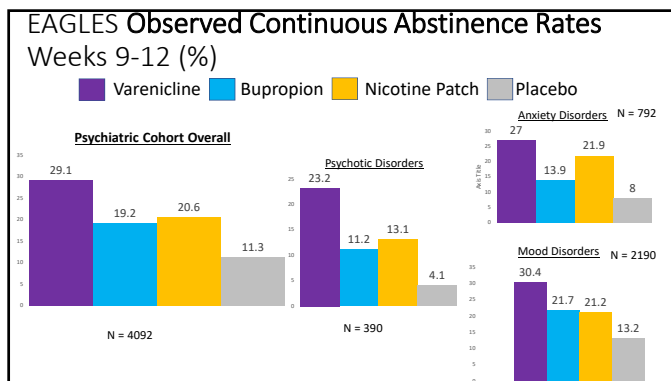
EAGLES Study Primary End-Points

- Weeks 9-12 continuous abstinence rates
- incidence of prespecified moderate and severe neuropsychiatric adverse events (NPSAEs):

- | | | |
|--------------------|----------------------|---------------------|
| • anxiety | • hallucinations | • suicidal ideation |
| • depression | • homicidal ideation | • suicidal behavior |
| • feeling abnormal | • mania | • completed suicide |
| • hostility | • panic | |
| • agitation | • paranoia | |
| • aggression | • psychosis | |
| • delusions | | |

Evins et al. Neuropsychiatric Safety and Efficacy of Varenicline, Bupropion, and Nicotine Patch in Smokers With Psychotic, Anxiety, and Mood Disorders in the EAGLES Trial (J Clin Psychopharmacol 2019;39: 108–116)

EAGLES study was funded by Pfizer & Glaxo (GSK)



Varenicline & Neuropsych Adverse Events Systematic Review and Meta-analysis

- 39 RCTs (10,761 participants)
- Non-industry sponsored study
 - Reviewed both industry & non-industry funded studies
- No increased risk** (compared to placebo)
 - Suicide/attempted suicide
 - Suicidal ideation
 - Depression
 - Irritability or aggression
 - Death
- Increased risk of
 - Sleep disorders, insomnia, abnormal dreams, fatigue

Risk of Neuropsychiatric adverse events associated with varenicline: systematic Review and meta-analysis. Thomas et al, BMJ 2015

FDA Removes Varenicline Black Box Warning

[12-16-2016]
 "...we are removing the Boxed Warning... for serious mental health side effects from the Chantix drug label... and Zyban label.

(the FDA) confirmed that Chantix, Zyban, and nicotine replacement patches were all more effective...than placebo.

...(medicines) help people quit smoking regardless of whether or not they had a history of mental illness"

<https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm>
<https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-revises-description-mental-health-side-effects-stop-smoking>

Nicotine Patches

"Put one on when you get up and remove at bedtime.

Smoke as much as you want with the patch on.

It will help you smoke less over time and feel normal"

<https://commons.wikimedia.org/wiki/File:Nicoderm.JPG>

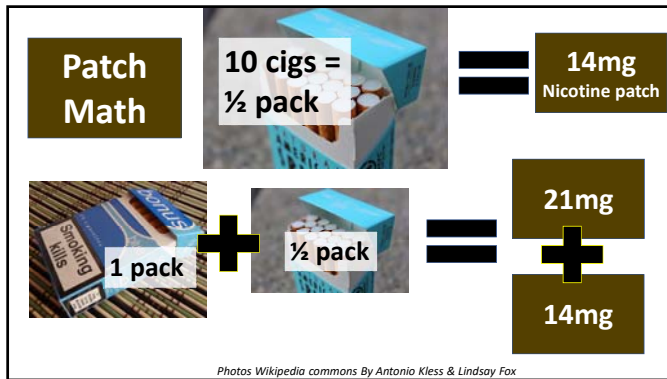
Patch Math!

1mg = 20 cigarettes

20mg = 20 cigarettes

21mg Nicotine patch

Photo Wikipedia commons By Antonio Klers



FDA Approved Dosing Nicotine Patches & Bupropion

• Nicotine Patches → *stop cigarette use at tx onset*

- >10 cigarette/day habit
 - 21mg patch QD x 6 weeks, then
 - 14mg patch QD x 2 weeks, then
 - 7mg patch QD x 2 weeks
- 6-10 cigarette/day habit
 - Apply 14mg patch QD x 6 weeks, then
 - 7mg patch QD x 2 weeks

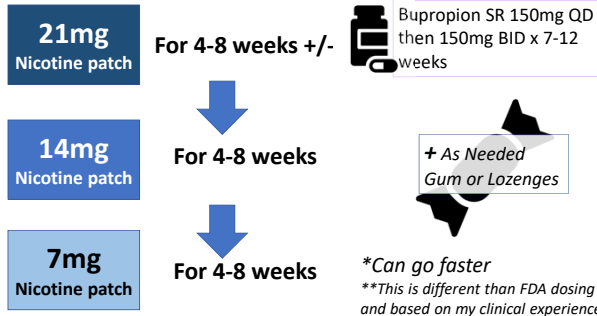
*Both FDA Approved
up to 6 months!*

• Bupropion 12 hour ER 150mg tabs

- 150mg PO QD x 3 days then 150mg PO BID x 7-12 weeks
 - Stop smoking after 5-7 days of tx

*Bupropion 12 vs 24 hr
extended release?*

My Suggested Patch Dosing for 1ppd**



What if they haven't quit smoking by the end of my prescription?

- Prescribe for longer!
- Extended therapy works
 - >12 weeks of varenicline
 - >14 weeks Nicotine patches
 - FDA Approved 6 months

Source: Tobacco Use and Dependence Guideline Panel May 2008. US Dept HHS
<https://www.ncbi.nlm.nih.gov/books/NBK63952/>

Sources supporting Extended Use Tobacco Dependence Meds

- Tobacco Use and Dependence Guideline Panel May 2008. US Dept HHS <https://www.ncbi.nlm.nih.gov/books/NBK63952/>
- Fiore et al., 2008. PHS Guideline
- Schnoll et al., 2015
- Evins, 2014
- Pachas et al., 2012

I'd love to quit **BUT**

"I was still smoking so I didn't use the patches... I didn't think it would be safe"

**What are the risks of smoking
WITH
Nicotine Replacement medicines?**

Wiki commons Photo

Smoking with Nicotine Replacement?

• Benefits of NRT + smoking exceed low risk of harm

- NRT is safe even with a high-dose patch or combination of NRT and concurrent smoking
- RCTs have not shown an association between nicotine patch therapy and acute cardiovascular events

Sharma et al., Curr Cardiol Rep (2015) 17:554

https://pubmed.ncbi.nlm.nih.gov/258792112_Cardiovascular_Adverse_Events_Associated_with_Nicotine_Cessation_Pharmacotherapies

NRT = nicotine replacement therapy
Wiki commons photo

Why Smoke with Nicotine Replacement?

- Harm reduction
- Makes Smoking less reinforcing
- Continuing patch increases chance quitting
- Withdrawing treatment is punishing failure

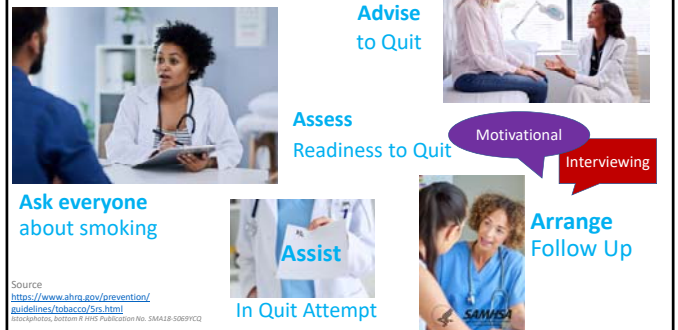
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• How do I tell people to use nicotine gum?

- It's not bubblegum.
 - Chew until it tingles then stop, put wad by gums, and rechew when tingling fades, move wad to gums again
 - Each piece lasts ~30 minutes
- Chew 1 piece of gum (4 mg) as needed every 1-2 hours
- **Nicotine lozenges** just slowly dissolve in the mouth without chewing
 - Do you smoke your first cigarette **within 30 minutes** of waking up?
 - Yes = 4mg lozenge
 - No = 2mg lozenge



The 5 As of Smoking Cessation



Arrange Follow Up

MI principle: optimism about capacity for change, self efficacy

Wow!
Why did you so well?

Why didn't you quit yet?

- Ask questions so they answer about with positive traits about themselves
 - How have you had great adherence?
 - Why is it easier than you thought?
 - How have you already quit smoking?
 - You've cut down to ¼ pack already?

Patients Not Ready To Quit Now (The "5 R's")

- **Relevance** - why quitting is personally relevant
- **Risks** - identify potential negative consequences
- **Rewards** –potential benefits of quitting?
- **Roadblocks** – What would make it hard to quit?
- **Repetition** – Repeat it every visit
 - Remind them it takes most people make multiple attempts to quit

Internet Citation: Patients Not Ready To Make A Quit Attempt Now (The "5 R's"). Content last reviewed December 2012. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/prevention/guidelines/tobacco/5rs.html>

Sample 5 Rs

- *Why would you want to quit tobacco some day?*
- *What health problems do you worry about getting from smoking? I.e. cancer, heart attack, stroke, gum disease, COPD. Correct misinformation & educate as appropriate.*
- *What do you think would be different if you quit smoking? (breathing, money, dental health, smell/taste etc)*
- *What would make it hard for you to cut down or quit smoking? What roadblocks do you see? What would you miss?*
- *It's easy to get discouraged. Most people make several quit attempts before they're successful. I'm optimistic we can come up with a good plan when you're ready to cut down or quit.*

5Rs Goal: Develop Discrepancy

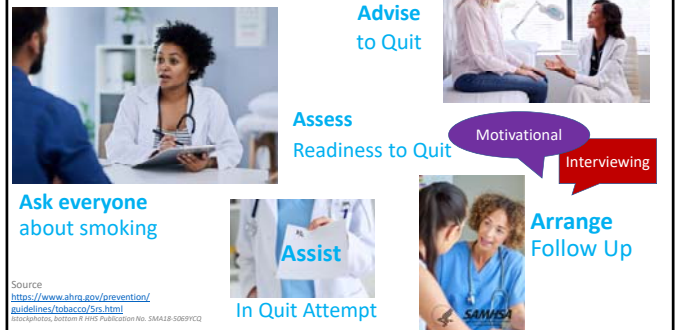
- Benefits of Status Quo
- Benefits of changing



Roll with Resistance

- Smoking's not that bad for me in the grand scheme of things
 - When changing behavior is hard, it's easier to change our attitudes
- Smoking is the only vice I have left
 - Acknowledge progress they've made (stop IVU, depression, DM etc)
 - Bring back to health goals
- I've tried before and always went back to smoking
 - Quitting is really hard. It often takes multiple attempts... what's different now?
- It's not a good time for me. I'm too stressed now
 - Totally. It takes effort to quit. What about cutting down with medicines?
- I roll my own, vape, chew etc "that's safer than smoking"
 - (address misconceptions)

The 5 As of Smoking Cession



Thank you for Kicking Butts

- Recommend quitting
- Consider varenicline
- Combine bupropion & NRT
- *Cut down to quit*
- Be optimistic

Matt Perez, MD

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Supplement:
External Smoking Cessation Resources

Sample 5 As

- **Ask** • *Do you smoke or use tobacco?*
- **Advise** • *I worry your (health problem) will worsen with smoking. I recommend you quit smoking*
- **Assess** • *How important is it for you to cut down or quit smoking now?*
- **Assist** • *There are lots of good medicines that help people quit successfully without feeling sick like cold turkey. Would you like to hear more?*
- **Arrange** • *Let's follow up in 4 weeks to check in on nicotine patch & the new bupropion medicine. I think these will help you smoke less*

Patients Not Ready To Quit Now (The "5 R's")

- **Relevance** - why quitting is personally relevant
- **Risks** - identify potential negative consequences
- **Rewards** –potential benefits of quitting?
- **Roadblocks** – What would make it hard to quit?
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Sample 5 Rs

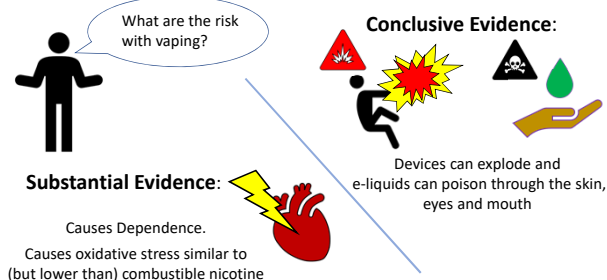
- *Why would you want to quit tobacco some day?*
- *What health problems do you worry about getting from smoking? ie cancer, heart attack, stroke, gum disease, COPD. Correct misinformation & educate as appropriate.*
- *What do you think would be different if you quit smoking? (breathing, money, dental health, smell/taste etc)*
- *What would make it hard for you to cut down or quit smoking? What roadblocks do you see? What would you miss?*
- *It's easy to get discouraged. Most people make several quit attempts before they're successful. I'm optimistic we can come up with a good plan when you're ready to cut down or quit.*

Vaping? "like smoking only with your heart"

- **Similar problems but less severe** than smoking in short term
- **Long term Evidence and consequences unknown**
 - Though mechanisms for long-term harm are present in e-cigarettes
 - such as the presence of chemicals that can damage DNA
- **Conclusive evidence that:**
 - Electronic nicotine delivery devices can explode, causing burns and other injuries.
 - Exposure to e-liquids through skin, eyes and mouth can result in poisoning.
- **Substantial evidence that e-cigarette use:**
 - Can result in symptoms of dependence
 - Increases heart rate
 - Causes dysfunction in endothelial cells like smoking and cardiovascular disease
 - Causes oxidative stress
 - which is linked to many inflammatory diseases
 - Though levels are lower than combustible tobacco.

Source: National Academies of Sciences, Engineering and Medicine (NASEM) 2018 report Public Health Consequences of E-Cigarettes Short and Long-term Health Effects of E-Cigarettes
Further reading: <https://www.doh.wa.gov/YouandYourFamily/Tobacco/VaporProducts/HealthandSafety>

Summary of NASEM 2018 Vaping Report



Source: National Academies of Sciences, Engineering and Medicine (NASEM) 2018 report Public Health Consequences of E-Cigarettes Short and Long-term Health Effects of E-Cigarettes
Further reading: <https://www.doh.wa.gov/YouandYourFamily/Tobacco/VaporProducts/HealthandSafety>



How Can I Help People Quit Smoking?

- **Ask** each patient about tobacco use
- **Advise** those who use tobacco to quit
- **Assess** willingness for quit attempt
- **Assist** patient in their quit attempt
- **Arrange** follow up visits

Do you smoke or use tobacco?

*I worry your (health problem) will worsen with smoking.
I recommend you quit smoking*

How important is it for you to cut down or quit smoking now?

There are lots of good medicines that help people quit successfully without feeling sick like cold turkey. Would you like to hear more?

Let's follow up in 4 weeks to check in on nicotine patch & the new bupropion medicine. I think these will help you smoke less

How do I engage Patients Not Ready To Make A Quit Attempt Now?

1. **Relevance** - Encourage the patient to indicate why quitting is personally relevant.
2. **Risks** - Ask the patient to identify potential negative consequences of tobacco use.
3. **Rewards** - Ask the patient to identify potential benefits of stopping tobacco use.
4. **Roadblocks** - Ask the patient to identify barriers or impediments to quitting.
5. **Repetition** - The motivational intervention should be repeated every time an unmotivated patient has an interaction with a clinician. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.

Source <https://www.ahrq.gov/prevention/guidelines/tobacco/5rs.html>

Why would you want to quit tobacco some day?

What health problems do you worry about getting from smoking? I.e cancer, heart attack, stroke, gum disease, COPD. Correct misinformation & educate as appropriate.

What do you think would be different if you quit smoking? (breathing, money, dental health, smell/taste etc)

What would make it hard for you to cut down or quit smoking? What roadblocks do you see?

It's easy to get discouraged. Most people make several quit attempts before they're successful. I'm optimistic we can come up with a good plan when you're ready to cut down or quit.

What Resources can I share to help people quit tobacco?

WASHINGTON STATE TOBACCO QUITLINE

1-800-QUIT-NOW

1-800-784-8669 | quitline.com

Quit Line (also Spanish): free telephone sessions (~5), covered insurance or grant, some access nicotine replacement products

Patient Handout to Quit Smoking (also Spanish)

<https://www.ahrq.gov/prevention/guidelines/tobacco/clinicians/tearsheets/tearsheet.html>

2Morrow Free Phone App to quit smoking

www.doh.wa.gov/quit <https://www.2morrowinc.com/smoking-cessation/>





Medicines Help More People Quit Smoking

What are the most effective treatments to quit smoking?

Varenicline (Chantix) is the best single treatment (for 12-24 weeks)

Nicotine Patches plus Bupropion is the most effective treatment (7-12 weeks or longer)

Source: Tobacco Use and Dependence Guideline Panel May 2008. US Dept HHS <https://www.ncbi.nlm.nih.gov/books/NBK63952/>

How do I dose nicotine patches? *Nicotine replacement therapy = NRT*

1 cigarette = 1mg nicotine. Use dosage Nicotine patch > cigarettes/day.

For example, 0.5 pack/day = 10 cigs = 14mg patch. 1.5 packs/day = 30 cigs = 21 + 7mg patches

How do I tell people to use nicotine gum? It's not bubblegum. Chew until it tingles then stop, put wad by gums, and rechew when tingling fades, move wad to gums again. Each piece lasts ~30 minutes.

Nicotine lozenges just slowly dissolve in the mouth without chewing.

What if they haven't quit smoking by the end of my prescription?

Prescribe for longer! Extended therapy works. If they haven't quit by 12th week of varenicline or 14th nicotine patches, prescribe another round. More people will quit if continued for longer!

Do they have to quit completely before starting? What if they only want to cut down?

No. Cutting down without a desire to fully quit using meds is safe & effective. NRT & varenicline make smoking less enjoyable (blocking euphoria of nicotine) so many people will gradually reduce smoking over time.

Is it safe to smoke with nicotine patches on?

Yes, NRT & Smoking is low risk and benefits outweigh harms (no add'l cardiovascular events).

Sharma et al., Curr Cardiology Reports (Review) 2015

Are tobacco cessation meds safe with a psychiatric illness like bipolar or suicidal history?

Yes. Tobacco Cessation Meds are Safe, even in psychiatric illness! EAGLES 2018 Study showed no difference in neuropsychiatric adverse events from varenicline, bupropion, NRT & Placebo in psychotic, anxiety and mood disordered patients. Blackbox warning for varenicline & suicidality was removed by FDA b/c inaccurate.

Can people with schizophrenia really quit smoking?

Yes. EAGLES study 2018 showed high Continuous Abstinence Rates (CAR) at 9-12 weeks (20-30%!) in people with serious chronic mental illness like schizophrenia & bipolar when cessation medicines were used.

- **Varenicline**: 0.5mg QD x 3 days then 0.5mg BID x 4 days, then 1mg BID x 11 weeks
- *Continuing varenicline an additional 12 weeks helps more people quit if they haven't by week 12*
- **Nicotine patch and bupropion SR** 150mg BID x 7-12 weeks. Start bupropion 150mg QD x3days then BID. 21mg patch put on in morning & remove at Bedtime x4 weeks then decrease to 14mg in 2-4 weeks then 7mg x 2-4weeks. May extend duration if needed
- **Nicotine patch plus PRN NRT**: 21mg morning to bedtime x2-4 weeks then 14mg x2-4 weeks then 7mg x2-4 weeks then off, plus nicotine gum or lozenge PRN cravings



PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS FOR SMOKING CESSATION

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS						BUPROPION SR	VARENICLINE
PRODUCT	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	Zyban ¹ , Generic Rx 150 mg sustained-release tablet	Chantix ² Rx 0.5 mg, 1 mg tablet
	Nicorette ¹ , Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint	Nicorette ¹ , Generic Nicorette ¹ Mini OTC 2 mg, 4 mg; cherry, mint	NicoDerm CQ ¹ , Generic OTC (NicoDerm CQ, generic) 7 mg, 14 mg, 21 mg (24-hr release)	Nicotrol NS ² Rx Metered spray 10 mg/mL nicotine solution	Nicotrol Inhaler ² Rx 10 mg cartridge delivers 4 mg inhaled vapor		
PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Concomitant therapy with medications/conditions known to lower the seizure threshold Hepatic impairment Pregnancy³ and breastfeeding Adolescents (<18 years) Treatment-emergent neuropsychiatric symptoms⁴ <p>BOXED WARNING REMOVED 12/2016</p> <p>Contraindications:</p> <ul style="list-style-type: none"> Seizure disorder Concomitant bupropion (e.g., Wellbutrin) therapy Current or prior diagnosis of bulimia or anorexia nervosa Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors 	<ul style="list-style-type: none"> Severe renal impairment (dosage adjustment is necessary) Pregnancy³ and breastfeeding Adolescents (<18 years) Treatment-emergent neuropsychiatric symptoms⁴ <p>BOXED WARNING REMOVED 12/2016</p>
DOSING	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours</p> <p>Weeks 7–9: 1 piece q 2–4 hours</p> <p>Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day Allow to dissolve slowly (20–30 minutes for standard) Nicotine release may cause a warm, tingling sensation Do not chew or swallow Occasionally rotate to different areas of the mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>>10 cigarettes/day: 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p>≤ 10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> Maximum <ul style="list-style-type: none"> 5 doses/hour or 40 doses/day For best results, initially use at least 8 doses/day Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3 months 	<p>6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe Open cartridge retains potency for 24 hours No food or beverages 15 minutes before or during use Duration: 3–6 months 	<p>150 mg po q AM x 3 days, then 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Begin therapy 1–2 weeks prior to quit date Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Dose tapering is not necessary Duration: 7–12 weeks, with maintenance up to 6 months in selected patients 	<p>Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid</p> <ul style="list-style-type: none"> Begin therapy 1 week prior to quit date Take dose after eating and with a full glass of water Dose tapering is not necessary Dosing adjustment is necessary for patients with severe renal impairment Duration: 12 weeks; an additional 12-week course may be used in selected patients May initiate up to 35 days before target quit date OR may reduce smoking over a 12-week period of treatment prior to quitting and continue treatment for an additional 12 weeks

	NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS					BUPROPION SR	VARENICLINE
	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER		
ADVERSE EFFECTS	<ul style="list-style-type: none"> ■ Mouth and throat irritation ■ Jaw muscle soreness ■ Hiccups ■ GI complaints (dyspepsia, nausea) ■ May stick to dental work <p>■ Adverse effects more commonly experienced when chewing the lozenge or using incorrect gum chewing technique (due to rapid nicotine release):</p> <ul style="list-style-type: none"> – Lightheadedness/dizziness – Nausea/vomiting – Hiccups – Mouth and throat irritation 	<ul style="list-style-type: none"> ■ Mouth and throat irritation ■ Hiccups ■ GI complaints (dyspepsia, nausea) 	<ul style="list-style-type: none"> ■ Local skin reactions (erythema, pruritus, burning) ■ Sleep disturbances (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ■ Nasal and/or throat irritation (hot, peppery, or burning sensation) ■ Ocular irritation/tearing ■ Sneezing ■ Cough 	<ul style="list-style-type: none"> ■ Mouth and/or throat irritation ■ Cough ■ Hiccups ■ GI complaints (dyspepsia, nausea) 	<ul style="list-style-type: none"> ■ Insomnia ■ Dry mouth ■ Nausea ■ Anxiety/difficulty concentrating ■ Constipation ■ Tremor ■ Rash ■ Seizures (risk is 0.1%) ■ Neuropsychiatric symptoms (rare; see PRECAUTIONS) 	<ul style="list-style-type: none"> ■ Nausea ■ Sleep disturbances (insomnia, abnormal/vivid dreams) ■ Headache ■ Flatulence ■ Constipation ■ Taste alteration ■ Neuropsychiatric symptoms (rare; see PRECAUTIONS)
ADVANTAGES	<ul style="list-style-type: none"> ■ Might serve as an oral substitute for tobacco ■ Might delay weight gain ■ Can be titrated to manage withdrawal symptoms ■ Can be used in combination with other agents to manage situational urges ■ Relatively inexpensive 	<ul style="list-style-type: none"> ■ Might serve as an oral substitute for tobacco ■ Might delay weight gain ■ Can be titrated to manage withdrawal symptoms ■ Can be used in combination with other agents to manage situational urges ■ Relatively inexpensive 	<ul style="list-style-type: none"> ■ Once-daily dosing associated with fewer adherence problems ■ Of all NRT products, its use is least obvious to others ■ Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours ■ Relatively inexpensive 	<ul style="list-style-type: none"> ■ Can be titrated to rapidly manage withdrawal symptoms ■ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ■ Might serve as an oral substitute for tobacco ■ Can be titrated to manage withdrawal symptoms ■ Mimics hand-to-mouth ritual of smoking ■ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ■ Twice-daily oral dosing is simple and associated with fewer adherence problems ■ Might delay weight gain ■ Might be beneficial in patients with depression ■ Can be used in combination with NRT agents ■ Relatively inexpensive (generic formulations) 	<ul style="list-style-type: none"> ■ Twice-daily oral dosing is simple and associated with fewer adherence problems ■ Offers a different mechanism of action for patients who have failed other agents ■ Most effective cessation agent when used as monotherapy
DISADVANTAGES	<ul style="list-style-type: none"> ■ Need for frequent dosing can compromise adherence ■ Might be problematic for patients with significant dental work ■ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ■ Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> ■ Need for frequent dosing can compromise adherence ■ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ■ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ■ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis) 	<ul style="list-style-type: none"> ■ Need for frequent dosing can compromise adherence ■ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ■ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease ■ Cost of treatment 	<ul style="list-style-type: none"> ■ Need for frequent dosing can compromise adherence ■ Cartridges might be less effective in cold environments ($\leq 60^{\circ}\text{F}$) ■ Cost of treatment 	<ul style="list-style-type: none"> ■ Seizure risk is increased ■ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) ■ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS) 	<ul style="list-style-type: none"> ■ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS) ■ Cost of treatment
COST/DAY ⁵	2 mg or 4 mg: \$1.90–\$3.60 (9 pieces)	2 mg or 4 mg: \$3.33–\$3.60 (9 pieces)	\$1.52–\$2.90 (1 patch)	\$8.72 (8 doses)	\$14.88 (6 cartridges)	\$2.58–\$8.25 (2 tablets)	\$15.14 (2 tablets)

¹ Marketed by GlaxoSmithKline.

² Marketed by Pfizer.

³ The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

⁴ In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a health care provider immediately if they experience agitation, depressed mood, or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 2016.

⁵ Approximate cost based on the recommended initial dosing for each agent and the wholesale acquisition cost from Red Book Online. Thomson Reuters, December 2018.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (nonprescription product); Rx, prescription product.

For complete prescribing information and a comprehensive listing of warnings and precautions, please refer to the manufacturers' package inserts.

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