

TOBACCO TREATMENT PHARMACOLOGY

**DR. SAMI LUBEGA
MARCH 2024**



**OUR
PROGRAM**

The Tobacco Treatment Training Program helps behavioral health providers in Alameda County improve their tobacco use interventions

Contracted with Alameda County Behavioral Health Care Services (ACBH) to support ACBH-funded substance use disorder and mental health treatment providers

Provide free training and technical assistance to healthcare staff and leadership

Program Manager – Tara Leiker, PhD
Program Coordinator – Sophia Artis

HOUSEKEEPING



Upon joining, all participants will be automatically muted. Participants are encouraged to turn their cameras on.



Please change your Zoom name to your first and last name and your organization/agency (e.g., "Jane Doe, LifeLong Medical Care").



This webinar is being recorded. The link to the recording will be shared after the training, along with a PDF of the slides.



Please use the Zoom Chat to ask questions. We will address questions during the Q&A period at the end of the training.



**CONTINUING
EDUCATION
REMINDERS**

This brown bag is eligible for **one (1.0) hour of continuing education credit** for LMFT's, LCSW's, LPCC's, LEP's, and SUD Counseling Staff as required by the California Board of Behavioral Sciences and by the **California** Consortium of Addiction Programs and Professionals (CCAPP).

To receive CE credit, attendees must be **present for the entirety of the training** and **complete the post-test**, which will be provided after the Q&A section.

Attendees who do not qualify for CE credit are eligible to receive a course completion certificate, also conditional on completion of the post-test.

WHAT IS THE BEST TREATMENT FOR TOBACCO DEPENDENCE?



Self quitting (aka Cold Turkey): 5%



Physician Advice: 10%



Group or Individual Counseling: 20%



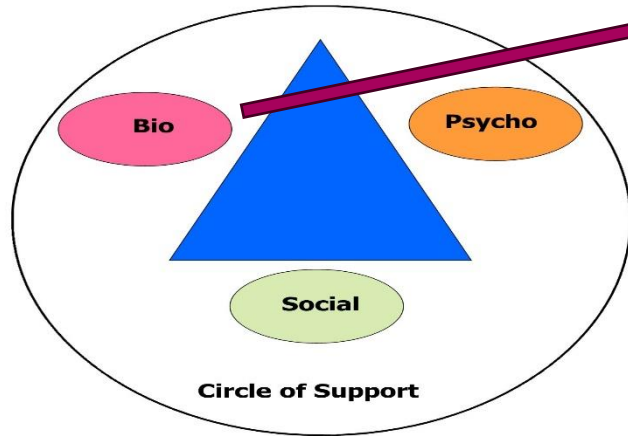
Medication: 20%



Combination **medication + counseling**: 35-40%

TREATING TOBACCO USE

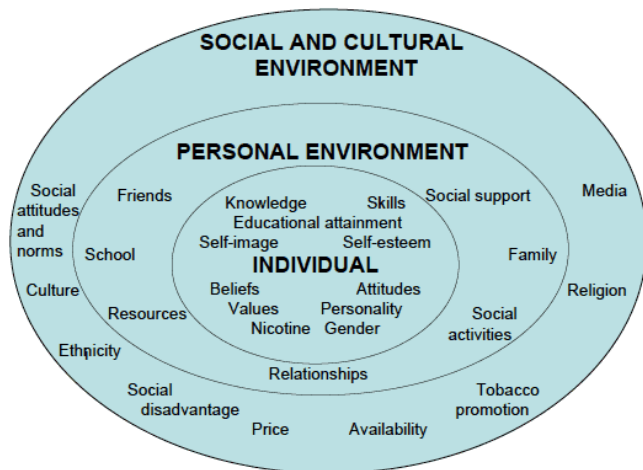
**Addiction Triangle
Biopsychosocial**



Medication +

Behavioral support

- Integrated Counseling
- Support Groups
- Quitline Referral
- Peer-to-Peer Interventions



COUNSELING



MEDICATIONS



Kick It: Quit Smoking | Vaping App

Free, customizable quit plan, progress tracker, and craving help to quit smoking or vaping. Access clinically proven behavior change strategies -- kick tobacco & nicotine for good.

[Find out More](#)

Quitting Cigarettes

Smoking is a habit that often fills a need, so you may have mixed feelings about quitting. Whether you've tried many times to quit or you're just thinking about it for the first time, we'll help you build a plan that will work for your life.

Quitting Vapes

Quitting vapes can be hard. You can be physically addicted to nicotine and emotionally tied to the device. For young people, there can also be social pressure to vape. We help people of all ages overcome their specific challenges.

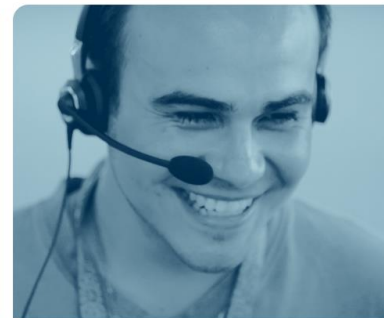
Quitting Smokeless Tobacco

Using smokeless tobacco can lead to high levels of nicotine dependence, making it very hard to quit. Whatever product you use, we can help you make a quit plan to take back control and say goodbye to smokeless tobacco for good.



1. Connect with a Coach

[Call](#), [Chat](#) or [Complete our web form](#). We'll ask you a few questions about your situation. What you share will be private.



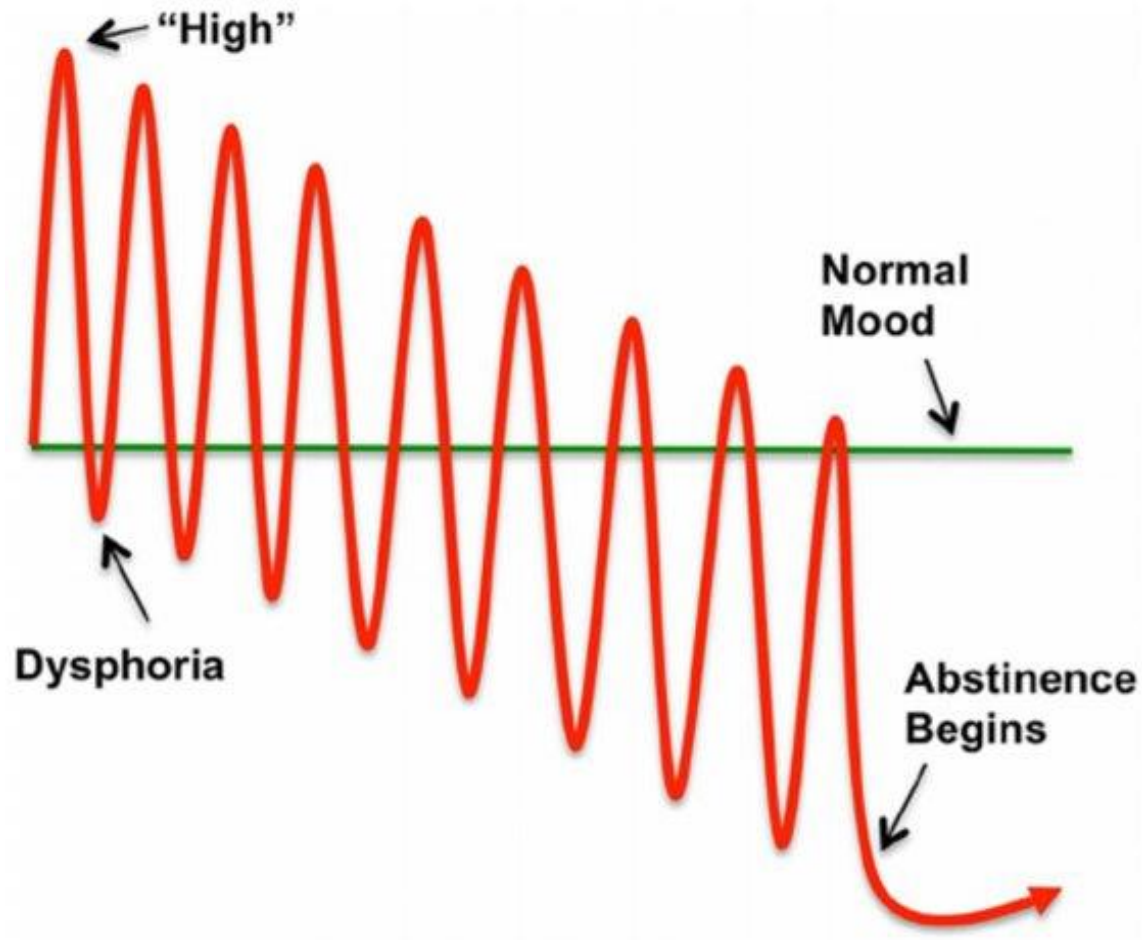
2. Create a Quit Plan

A Quit Coach will work with you to craft a personal Quit Plan using proven strategies. [Listen to a planning call](#).



3. Quit for Good

A Quit Coach will check in with you at key points, to help you stay motivated and increase your chances of kicking nicotine.



WITHDRAWAL DYSPHORIA



WHY MEDICATION?

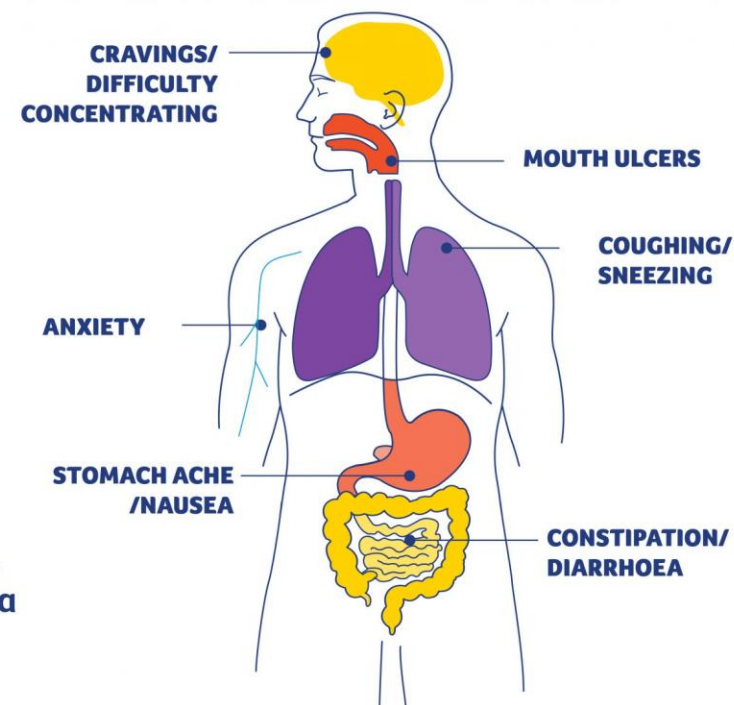
- Anxiety 87%
- Irritability 80%
- Lack of concentration 73%
- Restlessness 71%
- Craving 62%
- Digestive problems 33%
- Headaches 24%
- Drowsiness 22%
- Others including :
coughing, dizziness depression, tightness in chest, hunger

Symptoms of nicotine withdrawal:

- urges to smoke or cravings
- restlessness or difficulty concentrating
- difficulty sleeping
- irritability or anger
- anxiety or a low mood

Less common nicotine withdrawal symptoms:

- cold symptoms such as coughing, sore throat and sneezing
- constipation, diarrhoea, stomach aches or nausea
- dizziness or feeling light-headed
- mouth ulcers



PHARMACOTHERAPY FOR NICOTINE DEPENDENCE

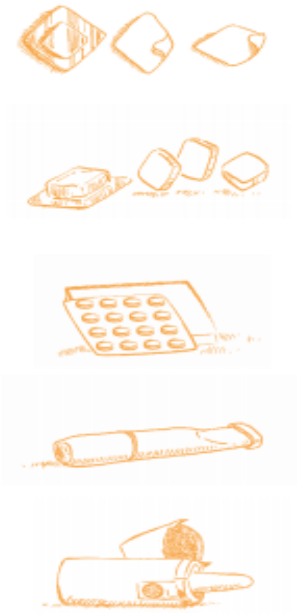
- Strongly recommended as first line for smoking cessation
- Exceptions:
 - Light/non-daily smoking (<5 cig per day)
 - Pregnant/breastfeeding* → can consider NRT, avoid oral agents
 - Smokeless tobacco use* → not well studied, but no contraindication
 - Adolescents* → AAP recommends off-label use for mod-severe dependence (vaping)

**Official recommendation for other groups is counseling with careful consideration of pharmacotherapy*

FDA- APPROVED QUIT AIDS

Quit aids are tools that make it easier to quit smoking. The FDA has approved two types: NRT (nicotine replacement therapy) & non-nicotine pills. Both of these cut withdrawal symptoms, like cravings and irritability.

NRT



Nicotine Patch

- Worn on the skin like a Band-Aid®
- Gives nicotine to the body through the skin
- Can get over-the-counter

Nicotine Gum

- Chewed and “parked” between the cheek and gums
- Gives nicotine to the body through the lining of the mouth
- Can get over-the-counter

Nicotine Lozenge

- Looks like hard candy and dissolves in the mouth
- Gives nicotine to the body through the lining of the mouth
- Can get over-the-counter

Nicotine Inhaler

- Users puff on it and get hits of nicotine vapor
- Requires a prescription

Nicotine Nasal Spray

- A pump bottle that contains nicotine
- The tip of the bottle is put into the nose and sprayed
- Requires a prescription

Non-nicotine Pills



Zyban (bupropion)

- Does not have nicotine
- Also sold as Wellbutrin SR® (an anti-depressant)
- Requires a prescription

Chantix (varenicline)

- Does not have nicotine
- Cuts cravings by tricking the body to feel like it is getting nicotine
- Blocks the pleasure of smoking
- Requires a prescription

Smoking Cessation Medication Prescribing Chart

(See reverse for instructions and FAQs)

When a person stops smoking, you may need to adjust dosage of medications that interact with tobacco smoke. Visit www.nysmokefree.com/CME for further guidance.

Medication*	Suggested Regimen	Precautions	Contraindications	Potential Adverse Effects	
Nicotine Replacement Therapy (NRT)	Patch[†] Long acting NRT	<ul style="list-style-type: none"> ≤10 cig/d, start with 14 mg/qd x 6 weeks, followed by 7 mg/qd x 2 weeks >10 cig/d, start with 21 mg/qd x 6 weeks, followed by 14 mg/qd x 2 weeks, followed by 7 mg/qd x 2 weeks 	<ul style="list-style-type: none"> ■ Pregnancy Class D[‡] ■ Uncontrolled hypertension ■ TMJ disease, dental work, dentures (gum) ■ Skin disorders (patch) ■ MRI (patch) ■ Allergy to adhesive tape (patch) ■ Stomach ulcer (gum, lozenge, nasal spray, inhaler) ■ Sodium-restricted diet (gum, lozenge, nasal spray) ■ Reactive airway disease (inhaler, nasal spray) ■ Sinusitis, rhinitis (nasal spray) ■ Advise starting with the highest-dose patch available except for patients weighing less than 100 lbs 	<ul style="list-style-type: none"> ■ Heart attack within 2 weeks ■ Serious cardiac arrhythmia ■ Unstable angina 	<ul style="list-style-type: none"> ■ Symptoms of too much nicotine, like nausea, headache, dizziness, fast heartbeat ■ Jaw pain, dry mouth (gum) ■ Hiccups, heartburn (gum, lozenge) ■ Skin irritation, insomnia (patch) ■ Mouth and throat irritation (inhaler) ■ Bronchospasm (nasal spray, inhaler) ■ Nasal irritation, tearing, sneezing (nasal spray)
	Gum[†] Short acting NRT	<ul style="list-style-type: none"> 1st cig >30 mins after awakening, 2 mg/hr 1st cig ≤30 mins after awakening, 4 mg/hr (both up to 24 pcs/day) 			
	Lozenge[†] Short acting NRT	<ul style="list-style-type: none"> 1st cig >30 mins after awakening, 2 mg/hr 1st cig ≤30 mins after awakening, 4 mg/hr (both up to 20 pcs/day) 			
	Nasal spray Short acting NRT	1–2 sprays/hr, as needed (max 40/d up to 3 mos)			
	Inhaler Short acting NRT	Frequent continuous puffing for up to 20 mins at a time every hour, as needed (6–16 cartridges/d up to 6 months)			
The nicotine patch can be combined with a short acting NRT.					
Bupropion SR (Zyban[®], Wellbutrin[®])	<ul style="list-style-type: none"> Days 1–3: 150 mg po qd Day 4 to 7–12 weeks (or end of treatment): 150 mg po bid Can be maintained up to 6 months (24 weeks) Can be combined with NRT 	<ul style="list-style-type: none"> ■ Pregnancy Class C[‡] ■ Uncontrolled hypertension ■ Severe cirrhosis – dose adjustment required ■ Mild-mod hepatic & mod-severe renal impairment – consider dose adjustment 	<ul style="list-style-type: none"> ■ MAO inhibitor in past 14 days ■ Seizure disorder, bulimia/anorexia ■ Abrupt discontinuation of ethanol or sedatives 	<ul style="list-style-type: none"> ■ Insomnia, dry mouth, headaches, pruritis, pharyngitis, tachycardia, seizures, neuropsychiatric effects and suicide risk <p><small>As of December 16, 2016, the FDA removed the Boxed Warning for this medication. https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm</small></p>	
Varenicline (Chantix[®])	<ul style="list-style-type: none"> Starting month pack: (start 1 week before quit date[§]) 0.5 mg po qd x 3 days; THEN 0.5 mg po bid x 4 days; THEN 1 mg po bid x 3 weeks Continuing month pack: Week 5 to 12 (or end of treatment): 1 mg po bid Can be maintained up to 6 months (24 weeks) CANNOT be combined with NRT 	<ul style="list-style-type: none"> ■ Pregnancy Class C[‡] ■ Seizure disorder ■ CrCl <30 or dialysis – dose adjustment required ■ May increase risk of CV events in patients with CVD ■ Operate heavy machinery ■ May lower alcohol tolerance 	<ul style="list-style-type: none"> ■ Known history of serious hypersensitivity or skin reactions to varenicline 	<ul style="list-style-type: none"> ■ Nausea, insomnia, abnormal dreams, constipation, neuropsychiatric effects, seizures, suicide risk and cardiovascular events <p><small>As of December 16, 2016, the FDA removed the Boxed Warning for this medication. https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm</small></p>	

*Consult the plan administrator or formulary to see the current medications covered – a list of all Medicaid Managed Care formularies can be found on pubic.nysdoh.suny.edu. New York State Medicaid Fee for Service covers all medications. Uninsured patients or those with gaps in coverage may want to consider New York City's official prescription discount card, BigAppleRx, which provides savings even on OTC medications (with a prescription).

[†] In 2013, the FDA did not identify any safety risks associated with longer-term use of OTC NRT products. Tailor to patient's needs if longer duration is necessary. Modifications to Labeling of NRT Products for OTC Human Use, 78 Fed. Reg. 19718 (proposed 4/13/2013).

[‡] May consider if counseling alone is ineffective, the patient is highly motivated to quit, and the risk/benefit has been carefully assessed with patient.

[§] Alternative regimen for varenicline is to instruct patient to take 1 mg bid then select target quit date between Days 8 and 35 of treatment.

Note: Zyban[®] and Wellbutrin[®] are registered trademarks of GlaxoSmithKline. Chantix[®] is a registered trademark of Pfizer, Inc. The use of brand names does not imply endorsement of any product by the New York City Department of Health and Mental Hygiene. Please consult prescribing information for complete usage and safety information.



PHARMACOLOGIC METHODS: FIRST-LINE THERAPIES

Three general classes of FDA-approved drugs for smoking cessation:

- Nicotine replacement therapy (NRT)
 - Nicotine gum, lozenge, patch, nasal spray, inhaler
- Psychotropics
 - Sustained-release bupropion
- Partial nicotinic receptor agonist
 - Varenicline



PHARMACOLOGIC METHODS: FIRST-LINE THERAPIES

Nicotine gum

- Nicorette (OTC)
- Generic nicotine gum (OTC)

Nicotine lozenge

- Commit (OTC)
- Generic nicotine lozenge (OTC)

Transdermal nicotine patch

- NicoDerm CQ (OTC)
- Generic nicotine patches (OTC, Rx)

Nicotine nasal spray

- Nicotrol NS (Rx)

Nicotine oral inhaler

- Nicotrol (Rx)

Bupropion SR tablets

- ~~Zyban (Rx)~~
- Generic (Rx)

Varenicline tablets

- Chantix (Rx)

OTC = over-the-counter / no prescription needed

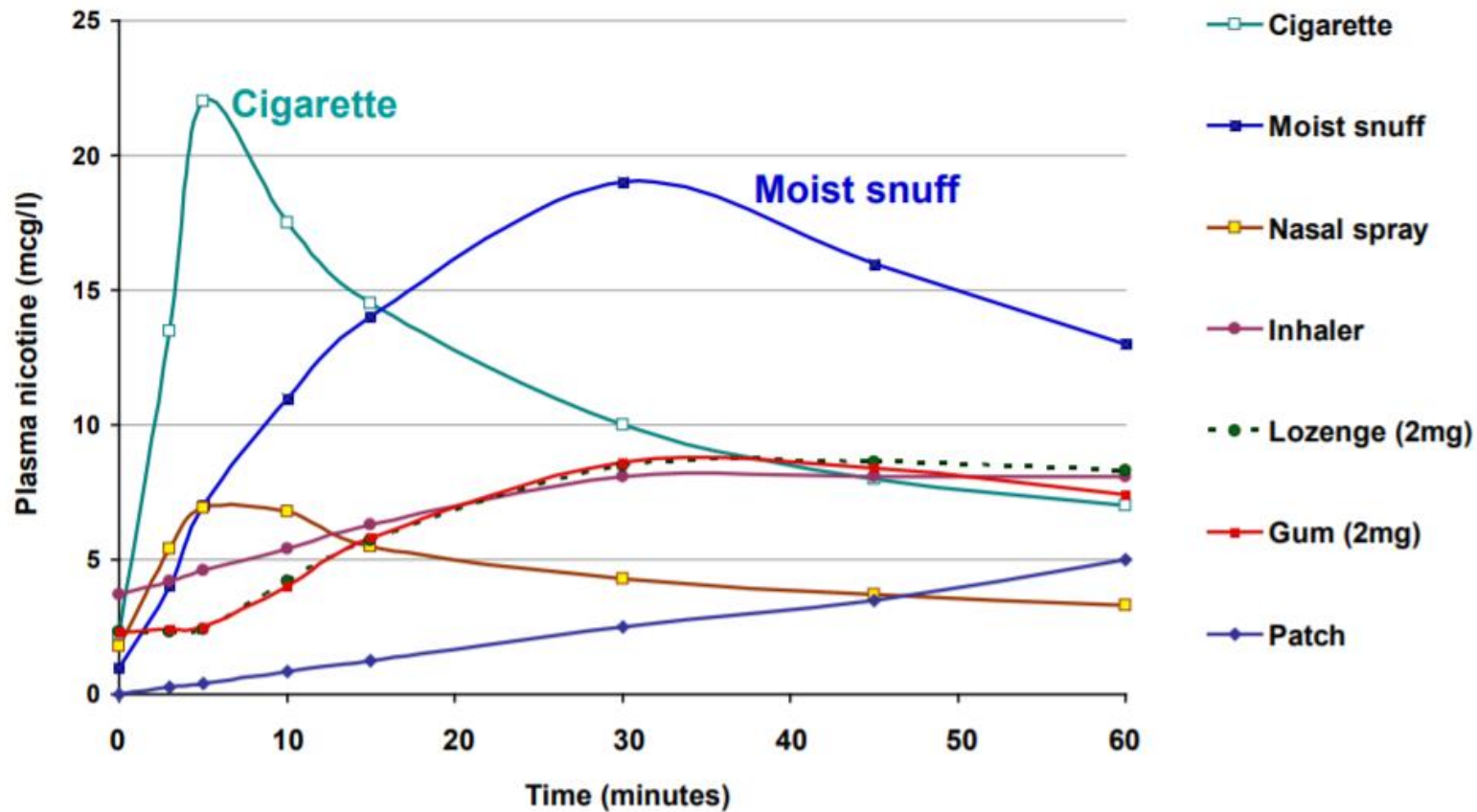
These are the only medications approved by the Food and Drug Administration (FDA) for smoking cessation.

NICOTINE REPLACEMENT THERAPY: MECHANISM OF ACTION

- Provides 'medicinal' or 'clean' nicotine
- Reduces withdrawal symptoms and craving
- May provide some positive effects of nicotine:
 - Desirable mood
 - Improved attention
- Replaces oral/handling aspects of habit

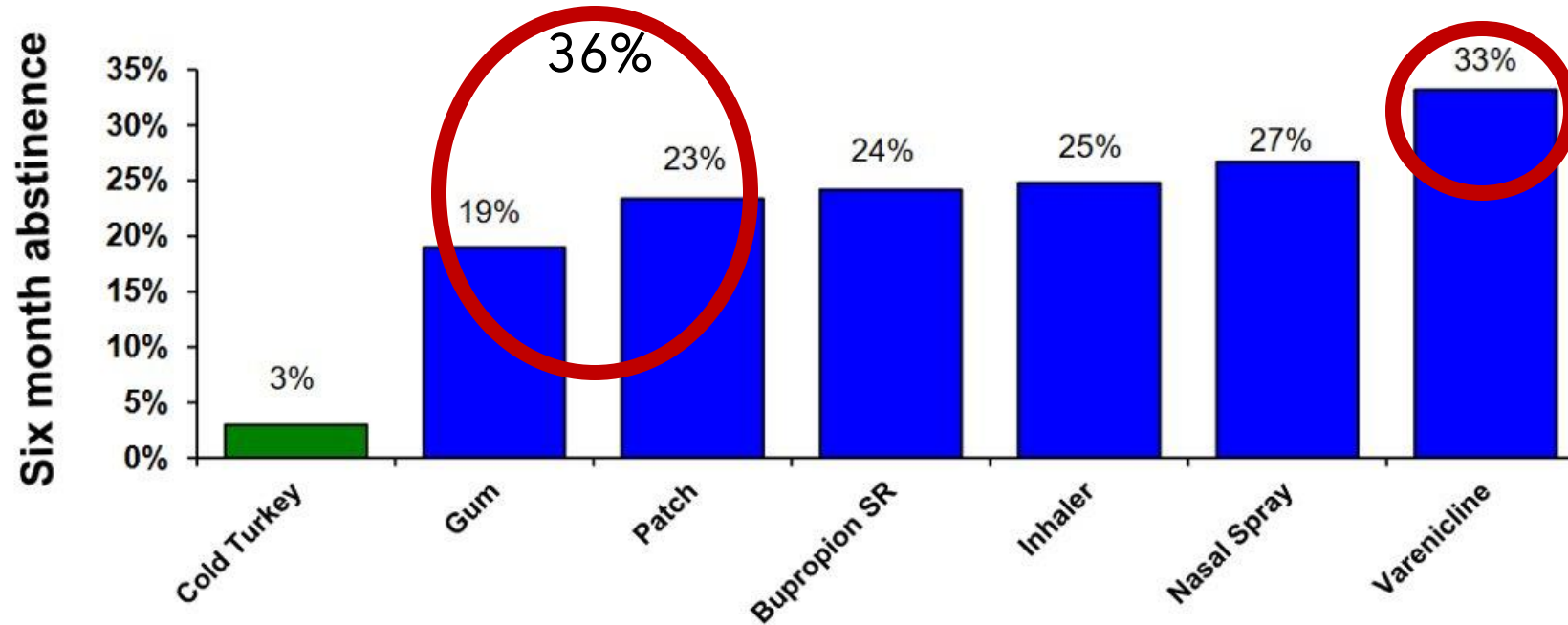


PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS



WHICH MEDICATION WORKS THE BEST FOR TOBACCO TREATMENT?

Whichever one a person is willing to take.



NICOTINE PATCH



PATCH - DOSING GUIDELINE

PATCH	
21 mg, 14 mg or 7 mg	
Dose:	1 patch every 24 hrs
Start:	21 mg patch if \geq 10 cig/day 14 mg patch if $<$ 10 cig/day
Duration:	~8 weeks to up to 6 months



TRANSDERMAL NICOTINE PATCH

Available: 21 mg, 14 mg, 7 mg

Pros:

- Once-daily dosing
- Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours

Cons:

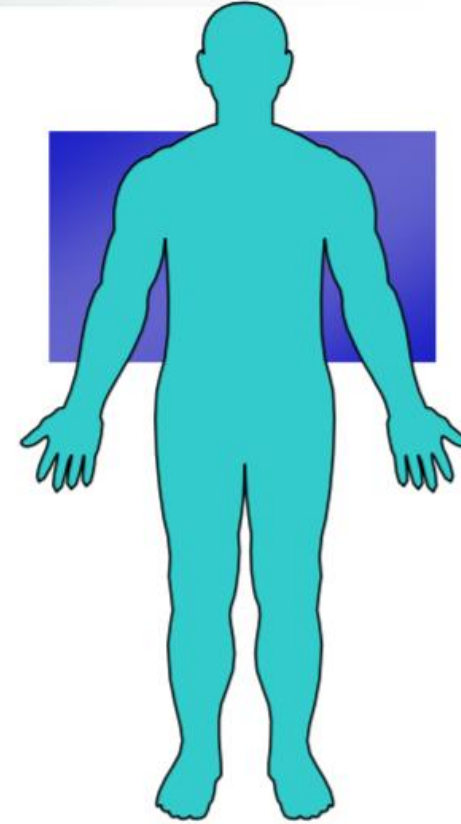
- Cannot be titrated to acutely manage withdrawal symptoms
- Not recommended for use with dermatologic conditions





TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE

- Choose an area of skin on the upper body or upper outer part of the arm
- Make sure skin is clean, dry, hairless, and not irritated
- Apply patch to different area each day
- Do not leave patch on skin for more than 24 hours—doing so may lead to skin irritation
- Do not use same area again for at least 1 week





TRANSDERMAL NICOTINE PATCH: ADDITIONAL PATIENT EDUCATION

- Water will not harm the nicotine patch if it is applied correctly; patients may bathe, swim, shower, or exercise while wearing the patch
- Do *not* cut patches to adjust dose
 - Nicotine may evaporate from cut edges
 - Patch may be less effective
- Keep new and used patches out of the reach of children and pets
- Remove patch before MRI procedures





TRANSDERMAL NICOTINE PATCH: ADD' L PATIENT EDUCATION (cont' d)

- Side effects to expect in first hour:
 - Mild itching
 - Burning
 - Tingling
- Additional possible side effects:
 - Vivid dreams or sleep disturbances
 - Headache

NICOTINE GUM





NICOTINE GUM and LOZENGE

Available: 2 mg, 4 mg; various flavors

Pros:

- Oral substitute for tobacco
- Can be titrated to manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges

Cons:

- Need for frequent dosing can compromise adherence
- Might be problematic with significant dental work
- Proper chewing technique is necessary for gum
- Gum chewing might not be acceptable/desirable



GUM - DOSING GUIDELINE

GUM	
2 mg or 4 mg	
Dose:	1 piece every 1-2 hrs
Start:	2mg if > 30 min to first cig 4 mg if \leq 30 min to first cig
Max:	24 pieces/day
Duration:	Up to 6 months



NICOTINE GUM/LOZENGE: DOSING

Dosage is based on the “time to first cigarette” (TTFC) as an indicator of nicotine dependence

Use the 2 mg strength:

If you smoke your first cigarette more than 30 minutes after waking

Use the 4 mg strength:

If you smoke your first cigarette of the day within 30 minutes of waking



GUM "CHEW AND PARK METHOD"

- ▶ Chew slowly until "peppery" taste emerges
- ▶ Then "park" gum between cheek and gums
- ▶ Slowly and intermittently "chew and park" for 30 minutes

**PROPER CHEWING TECHNIQUE IS
CRITICAL!**

Avoid acidic foods and beverages while
chewing the gum

Different flavors available

NICOTINE LOZENGE



Mini lozenge - dissolves 3
times faster

LOZENGES - INSTRUCTIONS

- ▶ Allow to dissolve slowly
- ▶ Do not bite or chew
- ▶ “Park” between cheek and gum, and move around with tongue periodically

Avoid acidic foods and beverages while using the lozenge

FDA CONSUMER UPDATE: NRT OTC LABELING

Drug Facts Labeling (2013)	Current Labels
<p><i>Warnings</i></p>	
<p>Do not use</p> <ul style="list-style-type: none"> • If you continue to smoke, chew tobacco, use snuff, or use [a different NRT product] or other nicotine containing products 	<p>None. The “Do not use” statement has been deleted</p>
<p><i>Directions</i></p>	
<ul style="list-style-type: none"> • Stop smoking completely when you begin using the [NRT product] • It is important to complete treatment. Stop using [the NRT product] at the end of [a specified number of weeks]. If you still feel the need to use [the NRT product], talk to your doctor 	<ul style="list-style-type: none"> • Begin using [the NRT product] on your quit day • It is important to complete treatment. If you feel you need to use [the NRT product] for longer period to keep from smoking, talk to your health care provider

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm345087.htm>

<https://www.federalregister.gov/documents/2013/04/02/2013-07528/modifications-to-labeling-of-nicotine-replacement-therapy-products-for-over-the-counter-human-use>

FDA CONSUMER UPDATE: NRT OTC LABELING

- These recommendations now:
 - Allow potential for use of more than one form of NRT
 - Eliminate the precaution about smoking while using NRT
 - Note that use longer than 12 weeks is safe in most cases



NICOTINE NASAL SPRAY

Available: 10ml bottle; 0.5 mg per spray

Pros:

- Can be titrated to rapidly manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges

Cons:

- Need for frequent dosing can compromise adherence
- Nasal administration; nasal irritation often problematic
- Not recommended for use with chronic nasal disorders or severe reactive airway disease





NICOTINE NASAL SPRAY: DIRECTIONS for USE (cont' d)

- Prime the pump (before first use)
 - Re-prime (1-2 sprays) if not used for 24 hours
- Blow nose (if not clear)
- Tilt head back slightly and insert tip of bottle into nostril as far as comfortable
- Breathe through mouth, and spray once in each nostril
- Do not sniff or inhale while spraying
- Avoid contact with skin, eyes, and mouth





NICOTINE NASAL SPRAY: ADDITIONAL PATIENT EDUCATION

- What to expect (first week):
 - Hot peppery feeling in back of throat or nose
 - Sneezing
 - Coughing
 - Watery eyes
 - Runny nose
- Side effects should lessen over a few days
 - Regular use during the first week will help in development of tolerance to the irritant effects of the spray
- If side effects do not decrease after a week, contact health care provider



NICOTINE ORAL INHALER

Available: 10mg cartridge delivers 4mg inhaled vapor for absorption across buccal mucosa

Pros:

- 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



Cons:

- Need for frequent dosing can compromise adherence
- Cartridges might be less effective in cold environments ($\leq 60^{\circ}\text{F}$)



NICOTINE INHALER: DIRECTIONS for USE (cont' d)

- Press nicotine cartridge firmly into bottom of mouthpiece until it pops down into place
- Line up the markings on the mouthpiece again and push the two pieces back together so they fit tightly
- Twist top to misalign marks and secure unit





NICOTINE INHALER: DIRECTIONS for USE (cont' d)

- During inhalation, nicotine is vaporized and absorbed across oropharyngeal mucosa
- Inhale into back of throat or puff in short breaths
- Nicotine in cartridges is depleted after about 20 minutes of active puffing
 - Cartridge does *not* have to be used all at once—try different schedules (e.g., 5 minutes at a time) to find what works best
 - Open cartridge retains potency for 24 hours
- Mouthpiece is reusable; clean regularly with mild detergent

PRECAUTIONS : NRT

- Immediate post-heart attack period
- Uncontrolled cardiac arrhythmias
- Severe or worsening angina

NON-NRT FIRST LINE TREATMENT:

BUPROPION AND VARENICLINE



BUPROPION SR



- ▶ Former brand name: Zyban
- ▶ Currently available as Wellbutrin SR or bupropion SR





BUPROPION SR

Available: 150 mg tablets

Pros:

- Twice-daily dosing
- Might be beneficial in patients with depression
- Can be used in combination with NRT

Cons:

- Seizure risk is increased
- Several contraindications and precautions
- Patients must be monitored for potential neuropsychiatric symptoms





BUPROPION SR: DOSING

To ensure that therapeutic plasma levels of the drug are achieved, patients should begin therapy 1 to 2 weeks PRIOR to their quit date.

Initial treatment

- 150 mg po q AM for 3 days

Then...

- 150 mg po bid for 7–12 weeks
- Doses must be administered at least 8 hours apart
- Tapering not necessary when discontinuing therapy

BUPROPION SR: DOSING

BUPROPION SR

May be combined with nicotine replacement

150 mg tablets

Dose:
(begin 1-2 weeks
before quit date)

150 mg once per day (days 1-3)

150 mg twice per day (day 4+)

Max:

300 mg/day

Duration:

12 weeks*

* If quit at 12 wks, consider 12 more weeks of drug

BUPROPION SR: MECHANISM OF ACTION

- Mechanism of action for tobacco cessation:
unknown
 - Weak inhibitor of uptake of dopamine (DA) and norepinephrine (NE)
 - Benefit likely related to the reduction in NE and DA during withdrawal
 - PET scans show that brain areas known to be involved in drug craving do NOT activate in response to cigarette-related cues when in the presence of bupropion*

PRECAUTIONS: BUPROPION SR

- **History of seizure or condition that lowers seizure threshold**
 - History of anorexia or bulimia
 - Excessive or binge drinking
 - Medications associated with increased seizure risk
- **History of mania**
- Concomitant use of Wellbutrin/bupropion for another indication
- Liver disease and/or renal insufficiency
 - Consider reduced dose
- MAO inhibitor use within 14 days

DRUG INTERACTIONS- BUPROPION

- Levadopa
- MAO inhibitors
- Tricyclic antidepressants
- SSRIs (fluoxetine, paroxetine)
- Cimetidine (Tagamet)
- Ritonavir (HIV med)

LONG TERM BUPROPION FOR MAINTENANCE

- Conflicting evidence
- Bupropion 300 mg/day for up to 12 months for successful quitters
 - Effective at 12 months
 - No effect at 24 months
- Bupropion for 6 months for successful quitters who had used patch
 - Bupropion: 28% abstinent at 6 months
 - Placebo: 25% abstinent

VARENICLINE (CHANTIX)





VARENICLINE

Available: 0.5 and 1.0 mg tablets

Pros:

- Twice-daily dosing
- Offers a different mechanism of action

Cons:

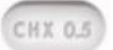
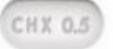
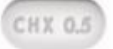
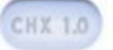
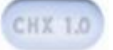
- Should be taken with food or full glass of water
- Patients must be monitored for potential neuropsychiatric symptoms





VARENICLINE: DOSING

Patients should begin therapy 1 week PRIOR to their quit date. The dose is gradually increased to minimize treatment-related nausea and insomnia.

Treatment Day	Dose
Day 1 to day 3	 0.5 mg qd
Day 4 to day 7	  0.5 mg bid
Day 8 to end of treatment*	  1 mg bid

Initial dose titration

* Up to 12 weeks

VARENICLINE: MECHANISM OF ACTION

- Varenicline acts as a partial agonist/antagonist on the nicotinic acetylcholine receptors :
 - Providing some nicotine effects to ease the withdrawal symptoms and
 - Blocking the effects of nicotine from cigarettes if they resume smoking

VARENICLINE: DOSING GUIDELINE

VARENICLINE (Chantix®)

0.5 mg, 1 mg tablets

Dose:
(begin 8 - 35 days
before quit date)

Starting Month Pak =
0.5 mg once per day (days 1-3)
0.5 mg twice per day (days 4-7)
1 mg twice per day (days 8+)
Continuing Month Pak =
1 mg twice per day

Max:

2mg/day

Duration:

12 weeks*

* If quit at 12 weeks, then 12 more weeks of therapy may be considered

SIDE EFFECTS OF VARENICLINE

- ▶ Most common side effect: **nausea**
- ▶ Other side effects include: headaches, abnormal dreams, constipation, insomnia, vomiting and flatulence
 - Some of the side effects like nausea and insomnia may improve with dose reduction
- ▶ Anyone experiencing worsening depression or suicidal thoughts should contact their doctor immediately

VARENICLINE: PRECAUTIONS

- ▶ Use lower dosage if kidney function is severely impaired
- ▶ An important study has shown NO increased risk for neuropsychiatric symptoms (Anthenelli, R et al, 2016)
- ▶ In 2016 FDA removed the black box warning
- ▶ As with any medication close medical supervision is recommended

For additional information go to this link

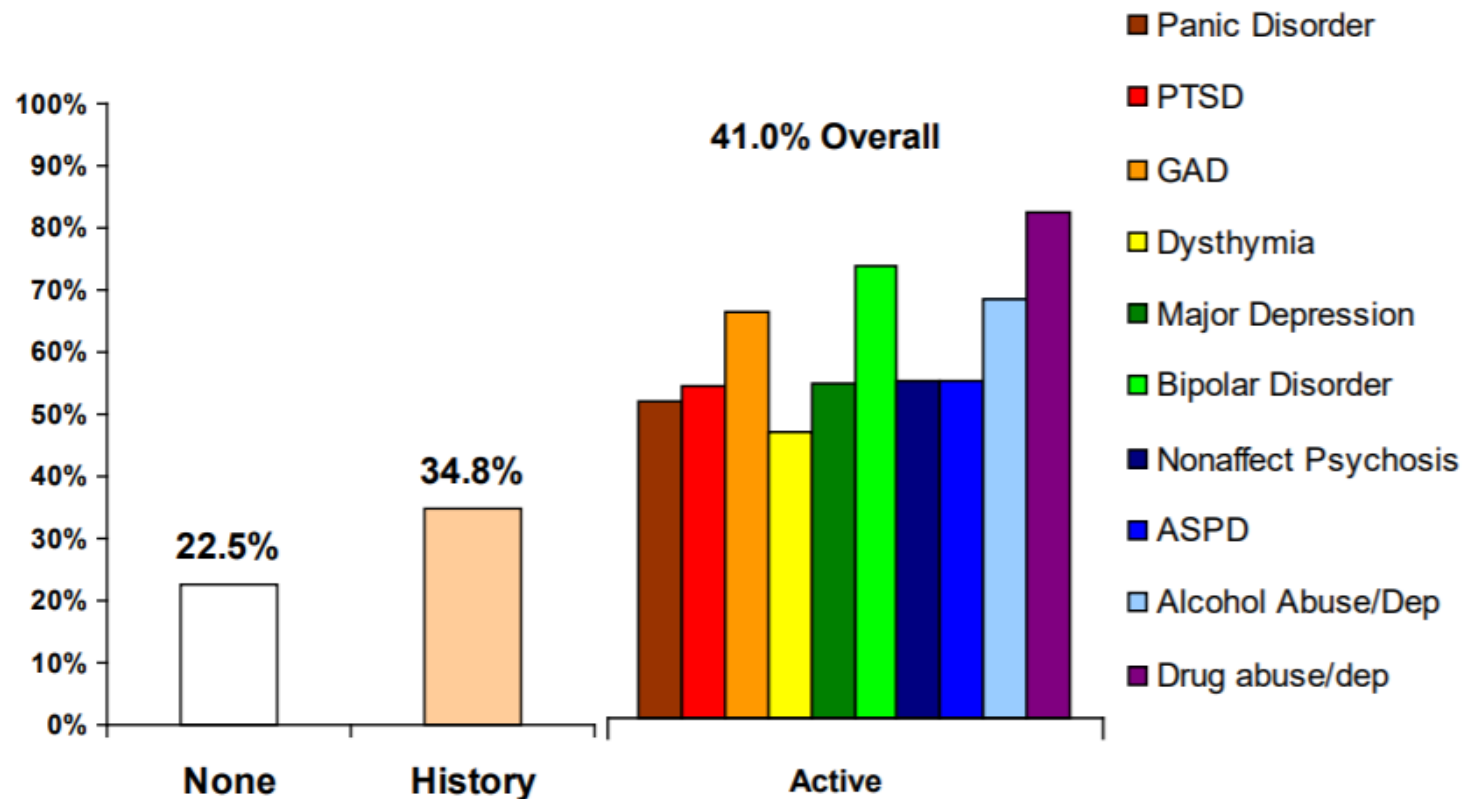
<https://www.chantix.com/getting-started-with-chantix/what-to-expect>

VARENICLINE AND BUPROPION: UPDATE

- 2009: FDA enhanced warnings and precautions for Varenicline and Bupropion
 - Response to post marketing reports
 - Changes included possibility of serious neuropsychiatric symptoms (changes in behavior, agitation, depressed mood, and suicidal ideation and behavior)
- 2016: The FDA REMOVED the above Black Box warning
 - Based on the outcomes of the EAGLES (Evaluating Adverse Events in a Global Smoking Cessation Study)
 - The study also showed superior efficacy of varenicline compared to bupropion or NRT

Psychiatric and Substance Use Disorders

SMOKING PREVALENCE by PSYCHIATRIC DIAGNOSIS



Free cigarette give-aways for psychiatric patients

RJR

Interoffice Memorandum

Subject: Gratis Request
Operation Santa Claus

Date: November 16, 1984

To: Peter Allan

From: Miriam G. Adams



OK (PS) 11-20

Attached is a request for cigarettes for Operation Santa Claus. This is an event we have made donation to over the years, and last year we donated 60 cartons.

This is for a worthwhile cause but would have to be charged to CPR as RJRT does not have sufficient budget.

Your comments would be appreciated.

**Operation Santa Claus
60 cartons of cigarettes**

to the Forsyth County Residents of
John Umstead & Murdoch Center

Corporate Public Relations

MGA:bkm

Attachment



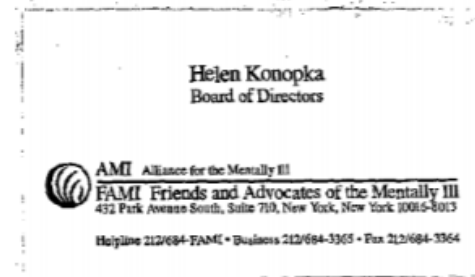
HOSPITAL SMOKING BAN EXEMPTION for MENTAL HEALTH

THE WALL STREET JOURNAL TUESDAY, OCTOBER 11, 1994

Mental Patients Fight to Smoke When They Are in the Hospital

"It's one of the very very few pleasures that schizophrenics and people with major depression have," says Helen Konopka, a 71-year-old retired New York teacher who organized a tidal wave of letters and petitions to the Joint Commission. She says

Ms. Konopka's crusade is backed by the National Alliance for the Mentally Ill, an influential advocacy group of patients and their families. The group says it hasn't had any contact with the tobacco industry.



*Philip Morris:
FAMI is fighting the City, HHC
and Bellevue Hospital bureaucracy.
The patients on the psychiatric inpatient
units, emergency unit and admissions
units need a discrete smoking area and
not be forced to go Cold Spring.
Helen Konopka*

The New York Times

SUNDAY, FEBRUARY 19, 1995

JCAHO ultimately “yielded to massive pressure from mental patients and their families, relaxing a policy that called on hospitals to ban smoking.”

This is a social justice issue.

BIG TOBACCO IS TARGETING PEOPLE THEY SEE AS VULNERABLE.

People suffering from mental illnesses.
People struggling to make ends meet.

People we know. People we care about. People like us.

Big Tobacco has gone after them,
From price fixing to faux-science,
Treating them unfairly in the name of profit.

That's not a coincidence.
It's exploitation.



TOBACCO & BH DISORDERS

- Leading cause of death in people with mental health disorders
 - Major contributor to 25-year mortality gap
- Leading cause of death among people in recovery: up to 50% of deaths
- Smoking cessation in depression, PTSD, schizophrenia tx:
 - No worsening in clinical symptoms
 - More likely to achieve cessation at 9 months
 - Often associated with reduction in psychiatric med doses
- When SUD treatment is combined with tobacco treatment, risk of relapse to drugs decreases 25% one year later



Provider Beliefs about Tobacco and BH

- Tobacco is necessary self-medication
- BH consumers are not interested in quitting
- They are unable to quit
- Quitting worsens recovery
- Smoking is a low priority problem
- **THESE ARE MYTHS**



MOOD DISORDERS

- ▶ Bupropion or nortriptyline started prior to quitting (along with NRT) may help with cravings, depressive symptoms in highly dependent
- ▶ Bupropion may be most useful for those with past history of depression
- ▶ Psychosocial mood management important component of treatment

ANXIETY DISORDERS

- Less data is available
- Stable NRT blood levels throughout the day reduce fluctuations in nicotine which may feel like anxiety
- Use caution if considering bupropion

SCHIZOPHRENIA

- RCTs have found **varenicline** to be more effective than placebo
- Bupropion associated with stable symptoms, increased quit rates but **high relapse** rates after treatment discontinuation in this population
- Combination **bupropion plus NRT** may be superior
- This group is usually highly dependent
 - NRT may need higher doses and for longer duration.

SOME COMMON DRUGS THAT MAY REQUIRE DOSE REDUCTION DURING SMOKING CESSATION

- Methadone
- Many psychoactive drugs:
 - Benzodiazepines (Valium, Ativan, etc.)
 - Clozapine
 - Haloperidol (Haldol)
 - Imipramine (Tofranil)
 - Fluvoxamine (Luvox)
- Propranolol (Inderal)
- Caffeine
- Warfarin
- Insulin

WEIGHT GAIN AND SMOKING CESSATION

- Nicotine gum and nicotine lozenge may delay weight gain
- Long term bupropion may reduce weight gain

EVIDENCE-BASED PHARMACOTHERAPY FOR TOBACCO TREATMENT

- ▶ What evidence from randomized controlled trials (RCTs) provides and doesn't provide:
 - A rationale for following explicit guidelines when the evidence is strong
 - Flexibility to make choices when appropriate
 - An opening for informed clinical judgments when the evidence is limited

EFFECTIVENESS OF FIRST LINE MEDICATIONS: NRT

Results from meta-analyses

Medication(s)	OR	95% CI
Patch vs. placebo	1.91	1.71-2.14
Gum vs. placebo	1.68	1.51-1.88
Combo NRT vs. placebo	2.73	2.07-3.65
Bupropion vs. placebo	1.85	1.6-2.1
Varenicline vs. placebo	2.89	2.4-3.48
Bupropion vs. NRT patch	0.97	0.83-1.13
Varenicline vs. NRT patch	1.51	1.22-1.87
Varenicline vs. combo NRT	1.06	0.75-1.48

PHARMACOTHERAPY OPTIONS

- Monotherapy

- Varenicline is superior

- Combination therapy

- Patch + short-acting NRT
- Bupropion + NRT (patch, gum, lozenge, etc.)
- Varenicline + NRT or Bupropion
 - *Controversial*
 - *Limit to smokers with high addiction levels*

SELECTING PHARMACOTHERAPY: THE SCIENCE AND THE ART

• The Science:

- Studies to date suggest nearly equivalent effectiveness of all first line medications
- Studies needed to directly compare effectiveness

▶ The Art:

- Using detailed knowledge of basic pharmacology, clinical studies, and patient factors to choose the optimum medication

GENTLE QUITTING

A PARADIGM SHIFT

- REDUCE TO QUIT
 - Using NRT for ≥ 6 months while cutting down
- SLIPS DURING NRT
 - Continuing NRT increases successful quitting
- PRE-TREATMENT
 - NRT or varenicline to reduce use and increase quit attempts

*“SOMETIMES SERIOUS
ADDICTION NEEDS TO
BE COAXED DOWN THE
STAIRS”*

*Dr. David Abrams, Director of Shroeder Institute for Tobacco
Research and Policy Studies*

GENTLE QUITTING APPROACHES

- **Non-NRT Alternative options with evidence:**
 - Medication Preloading: Pills 6 weeks to 6 months before set quit date
 - Reduce to Quit: Pills + Setting goal to reduce total # cigs by 50%
 - Continuing meds until no longer interested in cigs (12 weeks - 6+ months)
- **NRT: Intro to Nicotine Replacement Therapy:** "Quit for a day" or "Situational Quitting"
 - No tobacco at work
 - Stop for weekend with family
 - NRT while hospitalized
 - World No Tobacco Day (May)/ Great American Smoke-out (Nov)

Electronic Nicotine Delivery Devices

A generational look at the evolution of electronic nicotine delivery devices.

CIG-A-LIKES

Cig-a-likes first entered the market in 2007. These products mimic the size and shape of a tobacco cigarette and the nicotine solution is sold in pre-filled cartridges. Very often they are also disposable.



Blu Vuse Njoy

E-LIQUID

E-liquid is the flavored liquid that is used in e-cigarettes. Sometimes referred to as e-juice or vape juice, e-liquid is often available in a range of nicotine strengths and flavors.



VAPE PENS

Vape pens are larger than cig-a-likes and often have the appearance of an ink pen. These devices reach higher temperatures, can have batteries or be rechargeable, and have a refillable cartridge that the user fills with a nicotine or THC solution.



MODS & TANKS

Mods and tanks are the largest devices. They have a big battery to create more aerosol which allows the user to inhale greater amounts of nicotine and chemicals at a faster rate. The devices have a refillable tank for a nicotine solution.



POD SYSTEMS

Pod-based systems are typically smaller and can often look like a USB. Pods consist of two parts: a battery and a pod filled with a nicotine solution that connects to it. The pods can be refillable or purchased pre-filled.



Juul Suorin Drop Smok Novo Phix

DISPOSABLE POD DEVICES

Pod-based devices designed for single use. Devices come fully charged and pre-filled with nicotine solutions. When e-juice is gone, the device can be thrown away.



Puff Bar, Wave Bar, STIG

POD FLAVOR ADD-ONS

Pre-filled, no nicotine flavor attachments that can be used with multi-use and single use pod devices. Designed to add flavor to an assortment of vaping devices.



Puff Krush



info@cyanonline.org | (916) 339-3424 | www.cyanonline.org

© May 2020, California Youth Advocacy Network. This material was made possible by funds received from the California Department of Public Health, under contract #14-10013.

LEVEL OF DEPENDENCE: VAPING

- Hooked on Nicotine Checklist

The Hooked on Nicotine Checklist

The HONC is scored by tallying the number of yes responses, from 0-10. Any score greater than zero indicates that the smoker has lost some degree of autonomy over their smoking.

This indicates that nicotine addiction has begun.

	YES	NO
1) Have you ever tried to stop vaping, but couldn't?		
2) Do you vape <u>now</u> because it is really hard to quit?		
3) Have you ever felt like you were addicted to vaping?		
4) Do you ever have strong cravings to vape?		
5) Have you ever felt like you really needed to vape?		
6) Is it hard to keep from vaping in places where you are not supposed to, like school?		
When you tried to stop vaping...(or, when you haven't vaped for a while...)		
7) did you find it hard to concentrate because you couldn't vape?		
8) did you feel more irritable because you couldn't vape?		
9) did you feel a strong need or urge to vape?		
10) did you feel nervous, restless or anxious because you couldn't vape?		

- E-cig Dependence Scale for Adolescents

The Four-Item E-cigarette Dependence Scale for Assessing Adolescent E-cigarette Nicotine Dependence

	Never (0)	Rarely (1)	Sometimes (2)	Often (3)	Almost Always (4)
Instructions. Please respond to each question marking one box per row.					
I find myself reaching for my e-cigarette without thinking about it.					
I drop everything to go out and get e-cigarettes or e-juice.					
I vape more before going into a situation where vaping is not allowed.					
When I haven't been able to vape for a few hours, the craving gets intolerable.					

To score the measure, take the mean of the item scores.

https://downloads.aap.org/RCE/Factsheet_Supporting_Youth_Addicted_to_Nicotine.pdf_2019. https://f3d198cf-63bd-4a5a-8233-47d715075aa9.filesusr.com/ugd/08319b_3ca622a50f5c452a9d1aa0e43d065460.pdf 2019.

USING E-CIGS/VAPING FOR CESSATION

- Electronic nicotine delivery system (ENDS)
- Limited government oversight/regulation
 - Lack of quality assurance
 - Ingredient lists
- Brief FDA Regulation Timeline
 - 2016: Deeming rule extends FDA authority to ENDS and prohibits sale of ENDS products that were not commercially marketed as of 8/8/16
 - Manufacturers wanting to market any ENDS item are required to submit an application to the FDA that demonstrates that the product meets the applicable standard
 - February 2020: FDA will now no longer authorize or approve cartridge flavors other than menthol or tobacco

E-CIGARETTES/VAPING

- Systematic reviews
 - Quality of evidence considered 'low' to 'very low'
 - Highly variable methods and products amongst studies
 - Some evidence that ENDS better than placebo, and equal to nicotine replacement
 - Need for stronger studies, clearer protocols: some underway

E-CIGARETTES/VAPING

- Considerations
 - Appealing to smokers
 - Not FDA approved for cessation nor USPTF recommended
 - Carry risks
- Current Recommendations
 - Utilize first-line pharmacotherapy > ENDS products
 - If patient insists on trial of ENDS, caution regarding dual use
 - Monitor for ENDS dependence and respiratory/CV adverse effects

SUMMARY

- Ask EVERYONE about tobacco use, integrate counseling into medical, behavioral, and substance use care
- Varenicline and combination NRT have increasing evidence as strongest first line treatment, all show reasonable effectiveness
- Treat every quit attempt as a success!
- Advocate for policy changes that support vulnerable communities fight the influence of big tobacco
- Contact us for technical support, materials, and/or training

COUNSELING



MEDICATIONS

