What more can we do to help all clients recover from tobacco use challenges?

Tobacco Treatment Training Program, LifeLong Medical Care

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Disclosures

- I, Cathy McDonald, MD, do not have any financial relationship with any ineligible company as defined by ACCME.
- I, Tara Leiker, Ph.D, do not have any financial relationship with any ineligible company as defined by ACCME.
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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.

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Who's in the room?

Please put your **position** (e.g., psychiatrist, primary care MD, counselor, nurse, activity specialist, or other category) and the **agency you work** at in the chat!

Behavioral Health Should Take the Lead

High prevalence of tobacco use disorders

Knowledge about addictive disorders

Longer and more treatment sessions

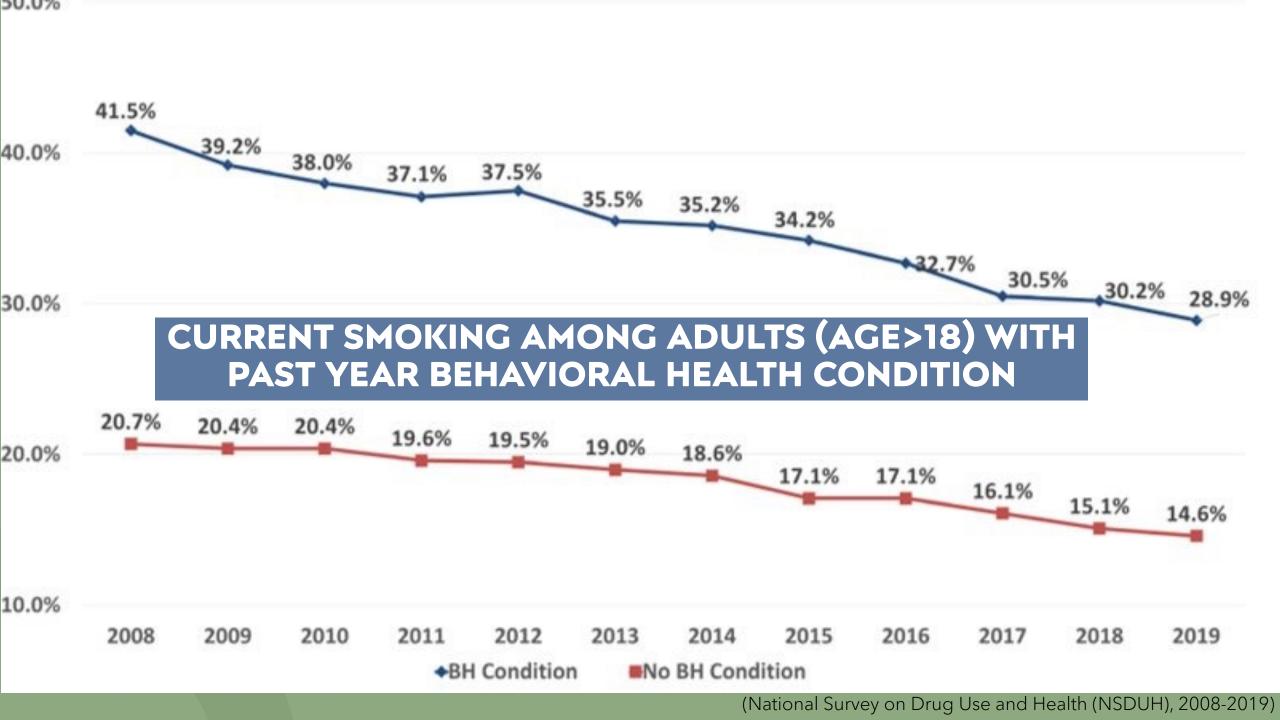
Experts in psychosocial treatment

All providers are encouraged to step up, work in teams with support staff and collaborate when indicated. McFall 2010 - significant increase 7 day PP abstinence in veterans with PTSD getting integrated tobacco treatment compared to referral rx by TTS.

The Cornerstone of Effective Tobacco Treatment is a Tobacco-Free Agency

Is your agency taking steps to support tobacco recovery?

- Does every client have a tobacco use history and offered tobacco treatment if a tobacco user?
- o Are clients able to enter your agency without walking through a cloud of smoke?
- Are there outdoor gathering areas free of tobacco smoke to support those clients who are in tobacco recovery?



Changes in Smoking Rates and Cigarette Sales in California

Category	2016	2021	Percent change
Serious psychological distress likely	26.1%	9.5%%	-63.6%
Serious psychological distress unlikely	11.3%	5.8%	-48.7%

- Smoking rates among adults > or = to 18 per California Health Interview Survey
- Following California's flavored tobacco ban in December 2022, total cigarette pack sales decreased by 16.0% (49.9 million packs) during January-October 2023, compared to the same period in 2022.

Tobacco Treatment is NEEDED in SUD/MH Populations

FACTS

- People with severe mental health needs die 10-25 years sooner than the general population.
- Half of all people in substance use recovery die of tobacco-related diseases.
- Studies show that less than half of people in MH or SUD treatment are offered tobacco treatment services/support.

National BH Smoking Rate Breakdowns

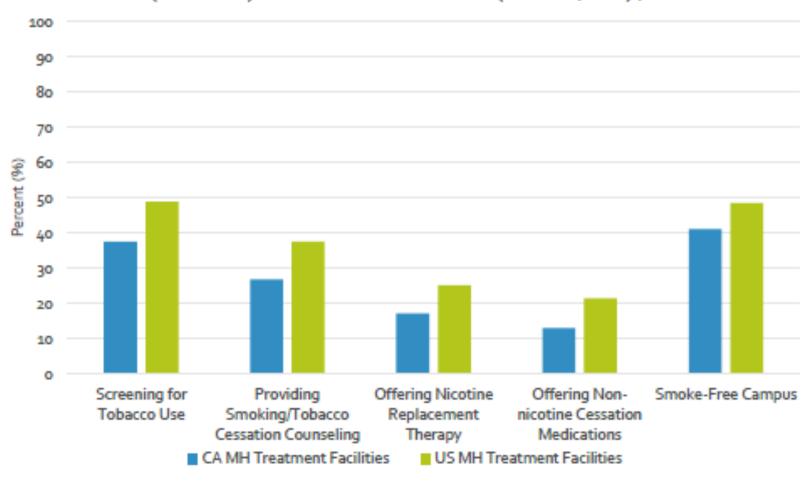
Population	Smoking Rate
Alcohol Use	56.1% (past mo.); 43.5% (lifetime) 1
Drug Addictions*	67.9% (past mo.); 49% (lifetime) 1
Individuals receiving substance abuse treatment	77%4
Opioid-dependent individuals	92%5
Schizophrenia	70-85%²
Anxiety	54.6% (past mo.); 46% (lifetime)1
PTSD	44.6% (past mo.); 45.3% (lifetime) 1
ADHD	41-42% (adults) 1; 19-46% (adolescents) 3
Bipolar Disorder	60-70%5

Brooner et al: Arch Gen Psychiatry, 1997;54:71-80.

Thomson D. Berk M. Dodd S. et al. Tobacco Use in Bipolar Disorder. Clin Psychophormoco Neurosci 2015;13(1):1-11.

*Includes all substance use disorders outlined in DSM-III-R

Tobacco Cessation Interventions and Smoke-Free Policies in Mental Health Treatment Facilities – CA (N=877) vs. United States (N=12,136), 2016



MISCONCEPTIONS vs. REALITY

Smoking helps people manage stress

Smoking helps manage mental health symptoms

Quitting Smoking will jeopardize sobriety or treatment outcomes

Smoking is a low priority problem

- People are as motivated to quit as people who smoke without a mental illness.
- People are able to quit, especially when offered proven treatments.
- Quitting improves psychological well-being-when treated for T with SUD clients are 25%> SUD free.

(Pagano et al., 2016; Prochaska et al. 2004)

Improved Mental Health with Quitting Smoking

Table 1| Effect of smoking cessation on mental health. Sensitivity analysis after removal of studies of low quality (medium-low scores on Newcastle-Ottawa scale)

			Standardised mean difference (95% CI)		
Outcome	No of studies included	No of studies excluded	Effect estimate	Original effect estimate	
Anxiety	4	0	-0.37 (-0.70 to -0.03)	-0.37 (-0.70 to -0.03)	
Depression	9	1	-0.29 (-0.42 to -0.15)	-0.25 (-0.37 to -0.12)	
Mixed anxiety and depression	4	1	-0.36 (-0.58 to -0.14)	-0.31 (-0.47 to -0.14)	
Psychological quality of life	4	4	0.17 (-0.02 to 0.35)	0.22 (0.09 to 0.36)	
Positive affect	1	2	0.68 (0.24 to 1.12)	0.40 (0.09 to 0.71)	
Stress	2	1	-0.23 (-0.39 to -0.07)	-0.27 (-0.40 to -0.13)	

Meta Analysis of 26 studies, including 6 studies in those with psychiatric conditions

That is not all-

- More financially stable
- More likely to get jobs
- More housing options

Benefits of Starting a Tobacco Recovery Journey – over time - for People in Mental Health Recovery

RELATIONSHIPS and SOCIALIZING

At first it may seem like starting a tobacco recovery journey is interfering with your personal relationships. Over time things that may change:

Relationships are often better – People are often more available because they are not focused on the next cigarette.

Clothes and hair and body smell better – Family and friends are more likely to hug and kiss you.

SELF ESTEEM

- People usually feel better about themselves because they have conquered something very challenging in the recovery process.
- People generally feel proud that they were able to recover from tobacco use.
- Friends and family often offer lots of praise for recovering which is heartwarming.

The industry provided free samples to MH hospitals, and they fought against smoking bans in mental health units of hospitals successfully.

This is a social justice issue.



The 5A's

A strategy to guide providers in addressing the problem

- Ask
- Advise
- Assess
- Assist
- Arrange

Alternatives: AAR (Ask, Advise, and Refer or Ask, Assess, and Refer if ready)

Tobacco Cessation Tool-the Ask

Pharmaceutical Company Smoking Cessation Pilot

		STATEMENT WILL AND
History: Tobacco Usage	_	
Smoking status: Current some day smoker		
Tobacco use: yes, cigarette	Passive Smoke Exposure: Positive SHS	Panel Control: 🕣 Toggle 🕒 🐔 Cycle 🕩
Advise to QUIT		\odot
Assist Quit Attempt (Medications)		\odot
Arrange Follow Up - Referrals		\odot
		Generate Document

*Note the alert for SHS (secondhand smoke exposure). This is critical in the patients you deal with.

Tobacco Use History from Clinicians Gateway

Assessment Psychiatric Mental Health

USE (if	None/		Mild Moderate Problem Problem		ln Baanina	Client-Perceived Problem?		
known)	Dellies	Exposure	riobieili	riobieiii	riobieiii	recovery	Yes	No

Progress Note Med Staff

	1			2		-
Smoking Status	O Never sm O Heavy tob	oker OSn pacco smok Brief Smoking	moker, curre er O Light g Cessation	ent status u t tobacco si Counseling	nknown @ moker Provide	er O Former smoker Unknown if ever smoked d Referral to Smoking Cessation cribe)

- These activities might seem inconsistent when administered in a setting where people are smoking or smelling of smoke.
- Tobacco free policies are recommended by ACBH, and certain standards are required. If you need assistance with policy at an agency you work with, please contact the staff of the Tobacco Treatment Training Program.
- The most recent version of ACBH's Tobacco Policy can be found at https://bhcsproviders.acgov.org/providers/PP/1901-1- 1%20Provider%20Tobacco%20Policies%20&%20Consumer%20Treatment%20P&P.pdf

ADVISE to quit

Identify the behavioral change required and suggest that the client make that change, e.g., recommend the person with tobacco use challenges considers stopping.

CLEAR: "Quitting tobacco can decrease your anxiety and I recommend it."

PERSONALIZED: "Can help you need less medicine for your mental health challenges because the smoke makes your body need more medicine."

Personalized MH: "Quitting tobacco can help improve your mood over time"

ASSESS readiness to quit

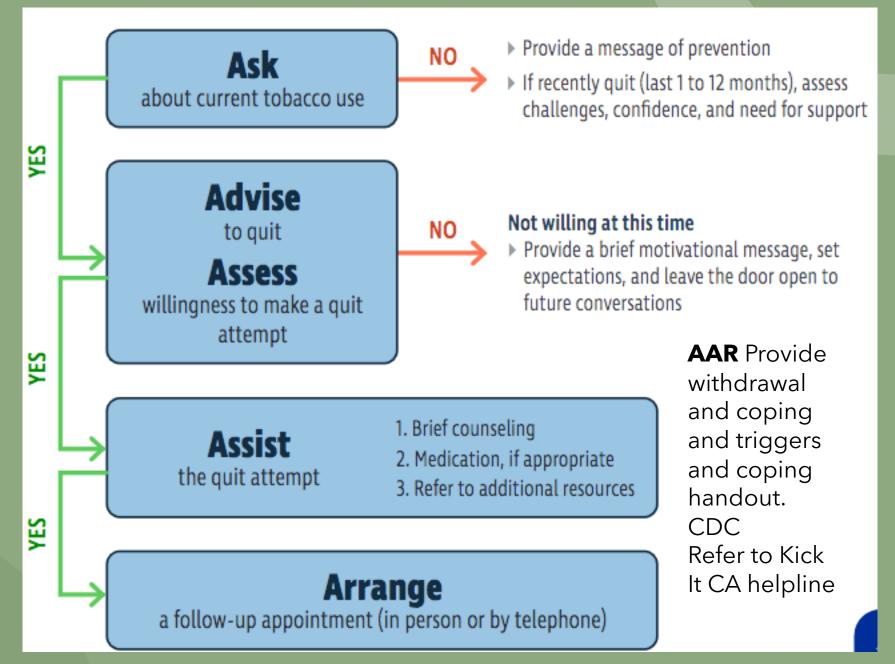
Determine the stage of change the client is in, e.g., is the person with tobacco challenges prepared to attempt to stop?

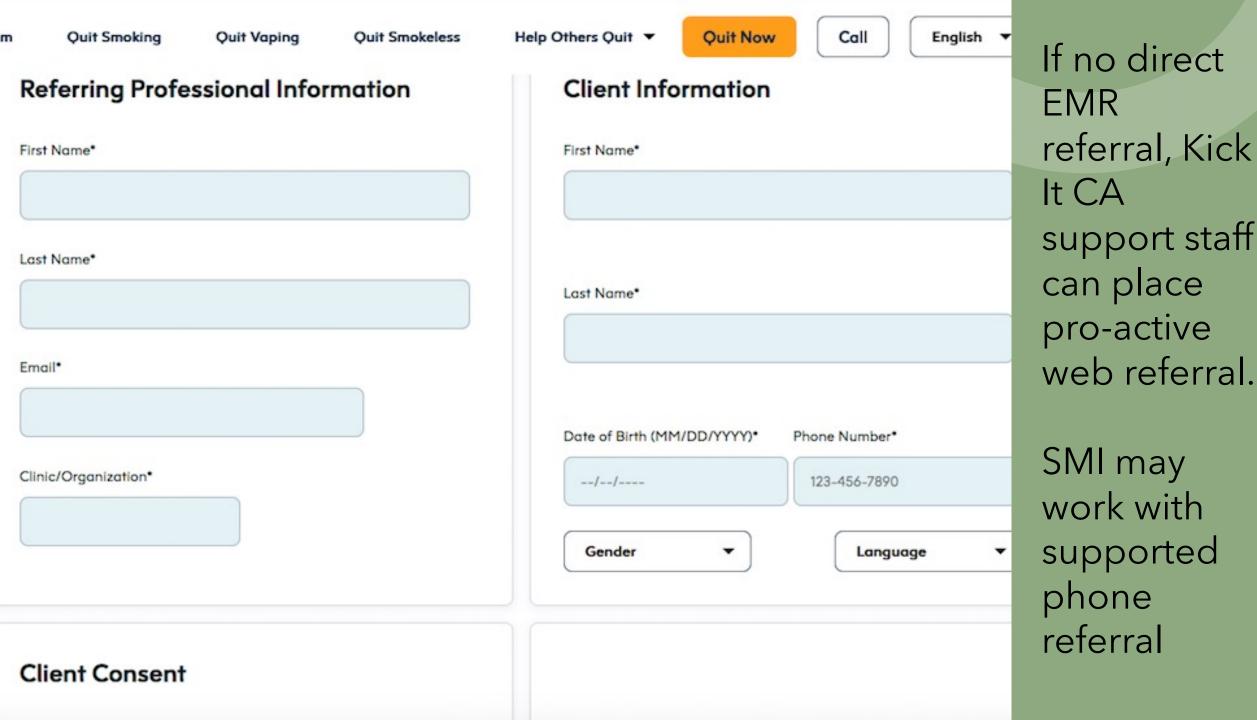
"What are your thoughts about quitting?"

"Do you think you want to quit eventually?"

"What do you think it would take for you to be ready?"

Importance/Confidence Scale





ASSIST to quit/reduce/Counseling

Assistance needs to be appropriate to the stage the client is in, e.g., use counseling, training, or pharmacotherapy to help them quit. Counseling alone not sufficient for patients with schizophrenia/schizoaffective disorder.

Practical Counseling

- Problem Solving and Skills Training
- Build on past smoking change experiences
- Recognize danger situations
- Develop coping skills
- Education about starting meds and cutting down +/to quit later

Social Support

- Encourage the patient in a change attempt
- Communicate caring and concern
- Encourage the patient to discuss their change attempt with loved ones

Consider agency staff leading: "Learning About Healthy Living, https://rwjms.rutgers.edu/images/Departments/Psychiatry/Addiction%20Psychiatry/2012lahl.pdf

ASSIST and ARRANGE follow-up

Assistance needs to be appropriate to the stage the client is in, e.g., use counseling, training, or pharmacotherapy to help them quit.

If Ready, Start Quit Plan

- Start meds Quit date TBA?
- Who can help you?
- What are your triggers?
- Skills and behaviors you can use?
- How will you prepare?

Areas to Follow-Up:

- Medication:
 - Pharmacy issues
 - Quit date
 - Complications
 - Not taking them correctly
- Support staff Referral
- Ongoing follow up Counseling
- Letting the PCP know
- Support through slips/relapses

The Five A's of Tobacco Treatment

	Cardiology	Family Med	Internist	Pulmonologist	Psychiatrist
Ask	97.3	95.2	95.9	100	81.7
Advise	98.6	93.8	98.2	99.4	78.7
Assess	88.4	87.0	92.9	97.7	73.6
Assist	22.4	27.9	33.3	44	15.9
Arrange	17%	16.4	29.0	28.0	26.4

- Survey of 1058 physicians 6 different specialties no psych (Schaer et al., 2021)
 - o Response was always or some of the time I ask, advise etc.
- Psychiatrist data same survey 1 year later (Young et al. 2022)
 - 141 psychiatrists
 - o Mean 56 y.o. 66% White
 - Non-white psych assess willing
 - o 57% vs. 37% p=.036
 - Assist 29% vs. 11% p=.014

Psychiatrists' perceptions of treatment options as very or somewhat effective

Survey of 141 Psychiatrists

Medication	% Psych Perceived Very or Somewhat Effective
Varenicline	89.7%
Patch	77.5%
Bupropion	73.5%
Gum	70.5%
Lozenge	60.3%
Inhaler	57.1%
Spray	52.3%

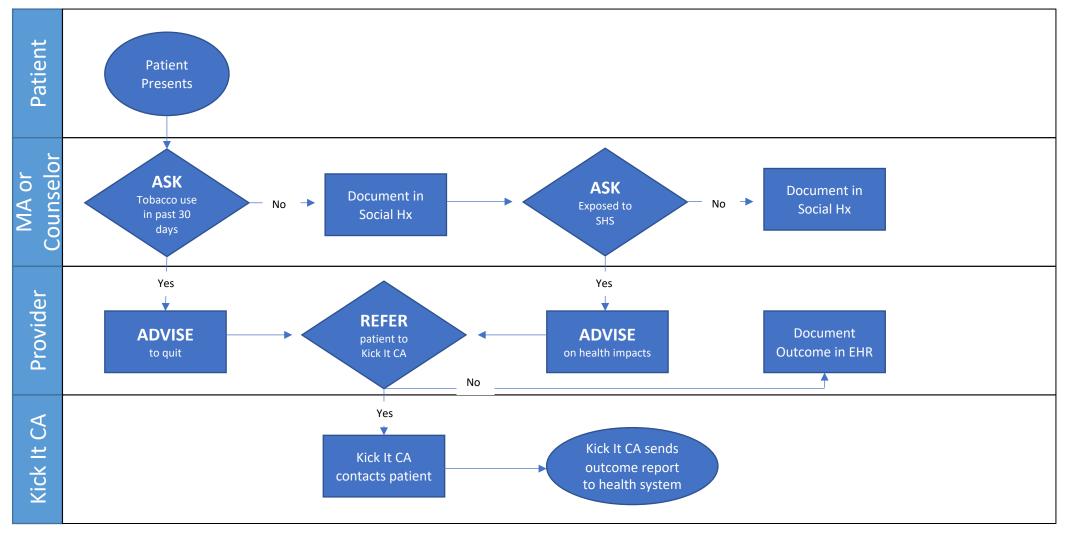
PATIENT with SCHIZOPHRENIA Pharmacy-based Intervention

From Rx for Change, https://rxforchange.ucsf.edu/ View at: https://www.youtube.com/watch?v=o8F3GJxJgtk

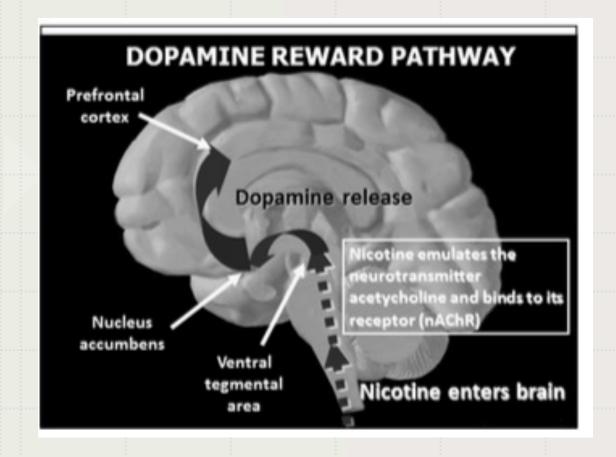
Observations or Questions?



One example of workflow: Swimlane Flowchart - Key is sharing responsibility



This flowchart is organized by who is responsible for each step in the process. This flowchart shows the referral process made to **Kick It California**, formerly known as the California Smokers' Helpline



In 7 seconds, nicotine from a cigarette reaches the brain and triggers the release of dopamine in the nucleus accumbens.

E-cigarettes' pharmacokinetics are similar.

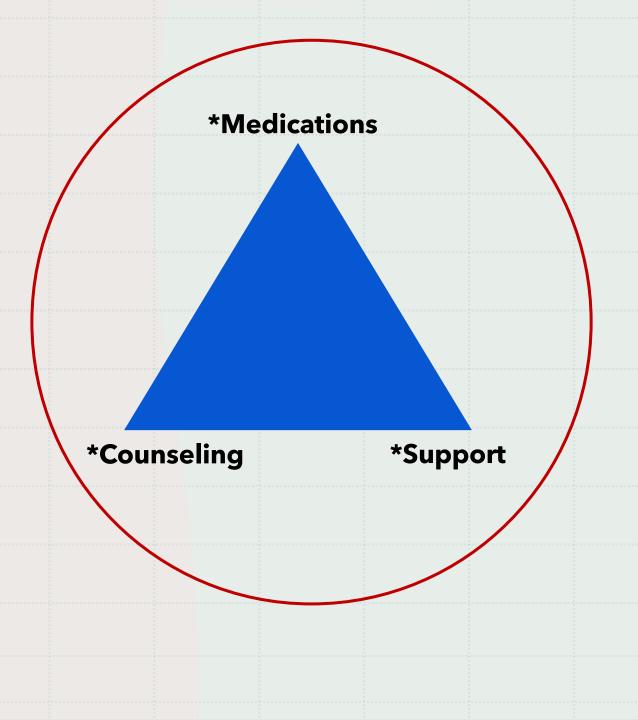
Vicious cycle: 1 cigarette leads to dopamine release, tolerance develops, and individual experiences powerful physiologic withdrawal when they don't have a cigarette, so they keep needing more.

Core Components of Tobacco Treatment:

Evidence-Based Treatment is Medication plus Counseling

Evidence-based treatment is the combination of medication and counseling.

Patients with Serious Mental Health
Conditions and/or other substance
addictions do best with medication +
counseling, not just counseling. Kick it
California can do a counseling session if
client is willing.



Barriers to Intervention By Providers, per Dr. Evins in a National Association of Mental Illness (NAMI) Blog

- 11/19 /20 (timed with Great American Smoke Out)
- Barriers to intervention include preconceptions that:
 - Medicines dangerous for schizophrenic patients/those with SMI
 - o Patients aren't interested or able to quit
 - Medicine won't work in them (actually 6x more successful with meds)
 - Will worsen psych symptoms not true
 - OR waiting for patient to ask
- **Implicit Bias** 57 primary care providers (62% male) (43 no response biased participants)
 - o Associate tobacco users as guilty compared to those with hypertension
 - The greatest difference: treating people who smoke frustrates me p<.0.001 Help investment was found to be negatively correlated with emotional response <0.002
 - Very small exploratory study with no measure of clinician behavior

Pharmacotherapy

Behavioral health clients with TUD:

- > Most will need medication to quit
- May need higher doses, longer duration of treatment, a nd combination of medications
- Like other clients, most will need multiple attempts be supportive and keep your expectations realistic

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.

ı	/ledication*	Suggested Regimen	Precautions	Contraindications	Potential Adverse Effects	
Nicotine Replacement Therapy (NRT)	Patch [†] Long acting NRT	≤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	 Pregnancy Class D[‡] Uncontrolled hypertension TMJ disease, dental work, dentures (gum) Skin disorders (patch) MRI (patch) 	 Heart attack within 2 weeks Serious cardiac arrhythmia Unstable angina 	 Symptoms of too much nicotine, like nausea, headache, dizziness, fast heartbeat Jaw pain, dry mouth (gum) Hiccups, heartburn (gum, 	
	Gum [†] Short acting NRT	1st cig >30 mins after awakening, 2 mg/hr 1st cig ≤30 mins after awakening, 4 mg/hr (both up to 24 pcs/day)	 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 indicated (CM) 		 Allergy to adhesive tape (patch) Stomach ulcer (gum, lozenge, nasal spray, inhaler) Skin irritation Mouth and (inhaler) 	 Skin irritation, insomnia (patch) Mouth and throat irritation (inhaler)
	Lozenge† Short acting NRT Mini-lozenge (CM)	1st cig >30 mins after awakening, 2 mg/hr 1st cig ≤30 mins after awakening, 4 mg/hr (both up to 20 pcs/day)			 Bronchospasm (nasal spray, inhaler) Nasal irritation, tearing, 	
	Nasal spray Short acting NRT	1–2 sprays/hr, as needed (max 40/d up to 3 mos)			sneezing (nasal spray)	
	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 nicotir	ne patch can be combined with a short acting N			
(2	upropion SR Zyban®, /ellbutrin®)	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	 Pregnancy Class C‡ Uncontrolled hypertension Severe cirrhosis – dose adjustment required Mild-mod hepatic & mod-severe renal impairment – consider dose adjustment 	 MAO inhibitor in past 14 days Seizure disorder, bulimia/anorexia Abrupt discontinuation of ethanol or sedatives 	■ Insomnia, dry mouth, headaches, pruritis, pharyngitis, tachycardia, seizures, neuropsychiatric effects and suicide risk As of December 16, 2016, the FDA removed the Boxed Warning for this medication. https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm	
	arenicline Chantix®)	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 CAN be combined with NRT (CM)	 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 	 Known history of serious hypersensitivity or skin reactions to varenicline 	■ Nausea, insomnia, abnormal dreams, constipation, neuropsychiatric effects, seizures, suicide risk and cardiovascular events As of December 16, 2016, the FDA removed the Boxed Warning for this medication. https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm	

Initiating Pharmacologic Treatment in Tobacco-Dependent Adults: An Official American Thoracic Society Clinical Practice Guideline: Executive Summary Frank T. Leone*, Yuqing Zhang*, Sarah Evers-Casey, A. Eden Evins, et al.

THIS OFFICIAL CLINICAL PRACTICE GUIDELINE WAS APPROVED BY THE AMERICAN THORACIC SOCIETY, MAY 2020

5 Strong Recommendations

- 1. Using varenicline rather than a nicotine patch
- 2. Using varenicline rather than bupropion,
- 3. Using varenicline rather than a nicotine patch in adults with a comorbid psychiatric condition
- 4. initiating varenicline in adults even if they are unready to quit
- 5. Using controller therapy for an extended treatment duration greater than 12 weeks.

Conditional recommendations

- 1. Combining a nicotine patch with varenicline rather than using varenicline alone
- 2. using varenicline rather than electronic cigarettes.

Smoking effects medication & impacts psychiatric care

Psychotropic Drug levels decreased by smoking* not complete list:

- > Antidepressants: Amitryptyline, Nortriptyline, Imipramine, Clomipramine, Fluvoxamine, Trazodone, Duloxetine, Mirtazapine,
- Antipsychotics: Fluphenazine, Haloperidol, Olanzapine, Clozapine, Chlorpromazine (Williams & Hughes 03) also Asenapine + other benzodiazepines (different mechanism)
- Melatonin and Alprazolam
- Similar effect on caffeine
- Methadone

Clients who smoke get lower blood levels of these medications than those who do not due to CYP1A1, CYP1A2, CYP2E1 and UGT enzymes

Enzyme activity caused not by nicotine but by (PAHs) hydrocarbons in the smoke

This effect takes about 3 weeks to show up after they stop smoking- then the dose generally needs to be lowered so clients are not "sedated"

NICOTINE WITHDRAWAL EFFECTS

- Irritability/frustration/anger
- Anxiety
- Difficulty concentrating
- Restlessness/impatience
- Depressed mood/depression
- Insomnia
- Impaired performance
- Increased appetite/weight gain
- Cravings

Most symptoms manifest within the first 1-2 days, peak within the first week, and subside within 2-4 weeks.



Other effects include coughing, dizziness, depression, tightness in chest, and hunger

How successful are people at quitting after 6 months? - medication only - NOT SMI

- Self quitting: 5% Physician Advice: 10%
- **Placebo**: 13.8%
- Nicotine patch: 6-14 weeks 23.4%
- **Bupropion/Zyban**: 24.2%
- Patch + Paroxetine/Paxil or Venlafaxin/Effexor: 24.3%
- Patch + Bupropion/Zyban: 28.9%
- Varenicline/Chantix: 33.2%
- Nicotine patch >14 weeks + gum or spray: 36.5%

Nicotine Replacement Therapy OR Varenicline: Rationale for Use

- Reduces physical withdrawal from nicotine-help client understand how withdrawal causes cravings
- Eliminates the immediate, reinforcing effects of nicotine that is rapidly absorbed via tobacco smoke
- Allows patient to focus on behavioral and psychological aspects of tobacco cessation

•

These products double or triple quit rates.

NRT generally does not cause addiction due to slow absorption

5 Types of Nicotine Replacement



LOZENGE





PATCH





NASAL SPRAY

Patch - Dosing Guideline

Remember tobacco math: 20 cigarettes in a pack, 1 mg nicotine per cigarette or

Vaping: Go by mgs of nicotine in a cartridge and how long it takes for the client to vape the entirety of the cartridge

PATCH

21 mg, 14 mg or 7 mg

Dose: 1 pa

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

Taper dose after 4-6 weeks

Short-Acting Nicotine Gum

- Gum comes in 2mg and 4 mg
- 4mg for more addicted- those who smoke within 30 minutes of awakening
- Comes in plain and flavors- most prefer mint or fruit but must be on scrip
- Must use chew and park method or does not work/upsets stomach
- Challenging for those with dentures, braces, or missing teeth
- If used alone without patch typically used on a schedule
- Can be used in combo with nicotine patch, typically when the client is having breakthrough cravings

Short-Acting Nicotine Lozenge

- Lozenge comes in 2 mg and 4 mg-* also mini lozenge
 2mg and 4 mg dissolves 3 x faster
- 4 mg for clients with high levels of addiction = those who smoke within 30 minutes of awakening
- Lozenge comes in plain and flavors most clients prefer mint or fruit, but must be on script
- *Use "suck and park" method
- Gum and Lozenge typically used for 2-6 months- gradually stepping down from patch and g/l to g/l alone



R. for Change COMBINATION PHARMACOTHERAPY

Regimens with enough evidence to be 'recommended' first-line

Combination NRT

Long-acting formulation (patch)

Produces relatively constant levels of nicotine

PLUS

Short-acting formulation (gum, inhaler, nasal spray)

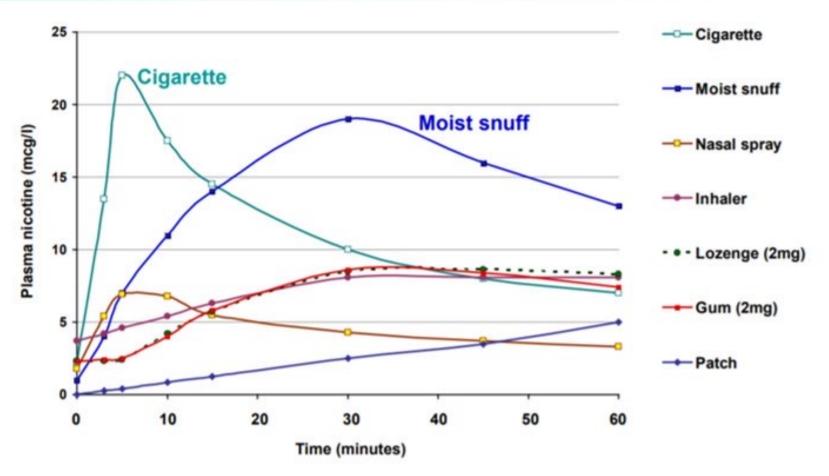
 Allows for acute dose titration as needed for nicotine withdrawal symptoms

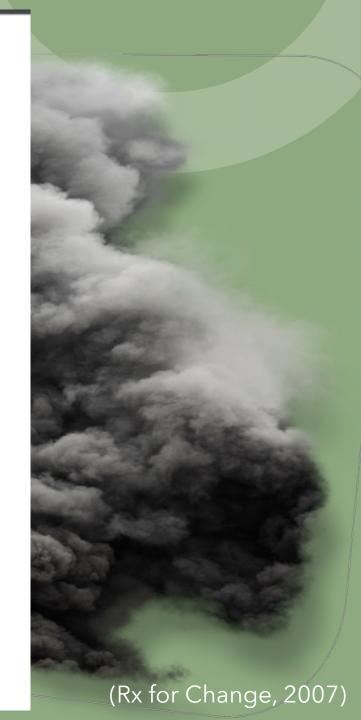
Bupropion SR + Nicotine Patch

*ALSO- Varenicline + Nicotine Patch



PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS





Reduce to Quit Strategy

- For patients who aren't ready to quit but are willing to use nicotine replacement to reduce their smoking.
- Prescribe patch in usual dosing for the # cigarettes smoked. Follow up closely WILL decrease cigs & increase quit rate.

Other Short-Acting Nicotine Replacement Therapies

Prescription only -Harder to get because they may require prior authorization request (PAR)

NicotineInhaler

Nicotine Nasal Spray



Inhaler - hand to mouth - conspicuous - suck to back of throat - lots of sucking to get proper dose

Nasal Spray - fast acting - more addictive potential - very uncomfortable first doses due to coughing and sneezing - supervise first dose in session - improves overtime - do not inhale the spray

Avoid/exercise caution with significant reactive airway disease

Medication as a Relapse Prevention Tool

- > Carry gum or lozenge, for the first 6-12 months after quit for serious urges
- Pair with other relapse prevention tools, like phone calls, avoiding risky situations, positive self-talk etc.
- Emerging use of NRT for reduce to quit will smoke less if use it
- Practice quits-
- Reframe attempt when smoked less cigarettes or quit for a day or 2 or more as success!! Explore the cause, congratulate the success and do motivational interviewing and encourage another attempt as soon as possible
- *********Success in smoke-free housing-Using gum, lozenge or patch inside- help clients have safe smoke-free home/apt; lay foundation for future tobacco recovery-Similar in crisis settings

Non-NRT Tobacco Treatment Medications

Both started 1 week before quitting - one standard dose adjusted for side effects as needed

Bupropion Contraindications:

Allergy to bup, Seizures, MAO inhibitors, linezolid, methylene blue, severe depression/mood disorders, suicidality, active alcoholism or eating disorder Caution re: serious skin reaction (1-4%)



Likely works by decreasing breakdown of dopamine

Varenicline Contraindications:

severe psychiatric conditions, suicidality, seizures, erythema multiforme or Stevens Johnson syndrome. Monitor if renal disease.

Relative Contraindication: Severe GI conditions





Works by partially blocking nicotine receptors and partially stimulating nicotine receptors (Advise to take with a full meal and a glass of water)

How does bupropion/Wellbutrin work?

- It is not NRT
- · It probably increases dopamine by decreasing dopamine breakdown
- Antidepressant not used as such; can help a depressed person who smokes cigarettes
- Started a week before quitting
- 150 mg qd x 3 days, 150 mg bid x 4 days then stop tobacco
- Continue med at 150 mg bid x 3 months
- Can be used in combination with nicotine patch
- Bupropion +/- patch recommended in 2010 PORT

Varenicline/Chantix

- · First ever non-nicotine medication designed for smoking cessation
- · Alpha 4 Beta 2 partial agonist
- Blocking effect competitive agonist makes nicotine less effective
- 0.5 mg qd x 3; 0.5 mg bid x 4 (white 0.5 mg pills); 1mg bid x 3 months (blue pills); consider second dose earlier (5pm) if sleep disturbance/bad dreams
- Begin the week before quit date (OK to take for 35 days before quitting (now up to 3 months before quitting (Ebbert et al. 2015))
- Black box warning removed (caution with severe depression & suicidality or unstable psych status)
- For general population varenicline may be extended an additional 3 months if successful. (Those who continue experience 30% less relapse at 12 months)
- Schizophrenic patients who continue varenicline for 1 year had quit rates of 60% at 52 weeks; 45% at 64 wks; and 30% at 76 wks
- Cytisinicline (Cytisine) will be an alternative once approved for use by FDA (Rigotti et al. 2023)

Nicotine patch + Varenicline: a promising new treatment (Subjects no MH)

- > 15 mg nic patch 16 hr/day x 7 days
- Patch plus varenicline x 7 days then stop smoking
- Continue combination for 13 weeks + 9 tenminute counseling sessions
- > (increase in SE in intervention
 - V + Nic vs. V + Placebo not statistically significant)

Nicotine Patch + Varenicline - Promising New Treatment

Cont Abstinent 24 WEEKS

V + Nic 55.4%

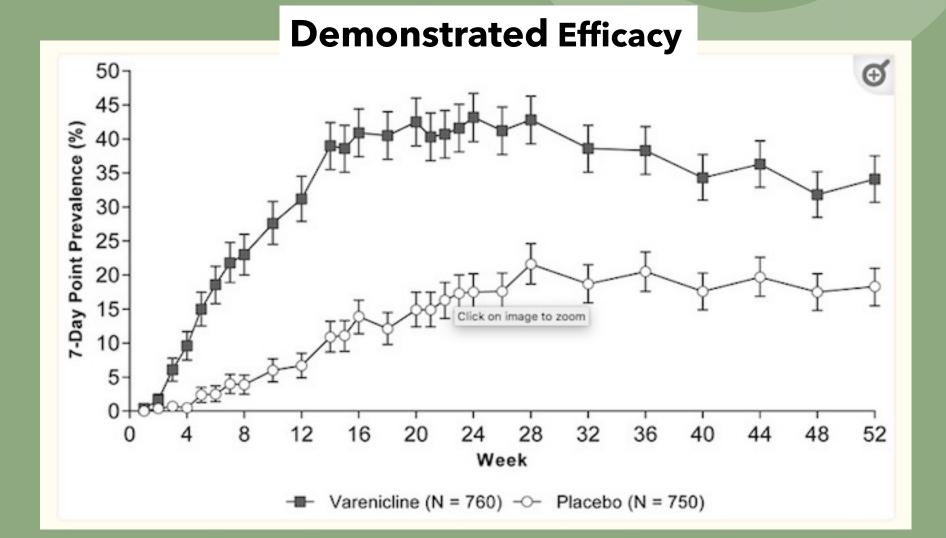
Cont Abstinence 24 WEEKS

49 %

V + 40% 32.6% Placebo

Recently researched treatment - "reduce to quit" with varenicline

Subjects: wanted to quit next 3 months Excluded psychiatric diagnoses-last 12 months SUD



FDA ordered Evaluating Adverse Events in a Global Smoking Cessation Study EAGLES

It was a randomized, double -blind, active & placebo controlled trial in those who smoke with psychiatric disorders (4074) and without (3984) in NPSAE analysis. (C-SSRS)

12 weeksrx +30d	Varenicline 1026	Bupropion 1017	Nic Patch 1016	Placebo 1015
SB	0	1 (<1%)	0	2(<1%)
SI	27 (3%)	15 (1%)	20 (2%)	25 (2%)
SB	1 (<1%)	0	1 (<1%)	1(<1%)
SI last 8 wks.	14 (2%)	4 (<1%)	9 (1%)	11(1%)
Events	Varenicline	Bupropion	Nicotine patch	Placebo
Agitation	2.4%	2.9%	2.1%	2.2%
Aggression	1.4%	0.9%	0.7%	0.8%
Panic	0.7%	1.6%	1.3%	0.7%
Serious AE	0.6%	0.5%	0.3%	0.3%
Results in end rx	1.6%	1.5%	1.2%	1.5%
Got Intervention	0.7%	1.2%	0.7%	1.1%
NPSAE both grps	4.0% 80/2016	4.5% 90/2006	3.9% 78/2022	3.7% 74/2014

Serious adverse events: Varenicline SI 2, depression 1, aud hallucinations 1, worse bipolar I 1, anxiety + self injurious behavior 1(6); Bupropion SB + schizoaffective disorder 1, worse bipolar I 2, Bipolar II 1, emotional disorder + neuropsych symptoms 1,(5); Patch anxiety 2, depression 1, (3); Placebo SB 1, SI 1, aggression 1. (3). Interventions included psychotropic meds, psychotherapy, counseling and admission to hospital.

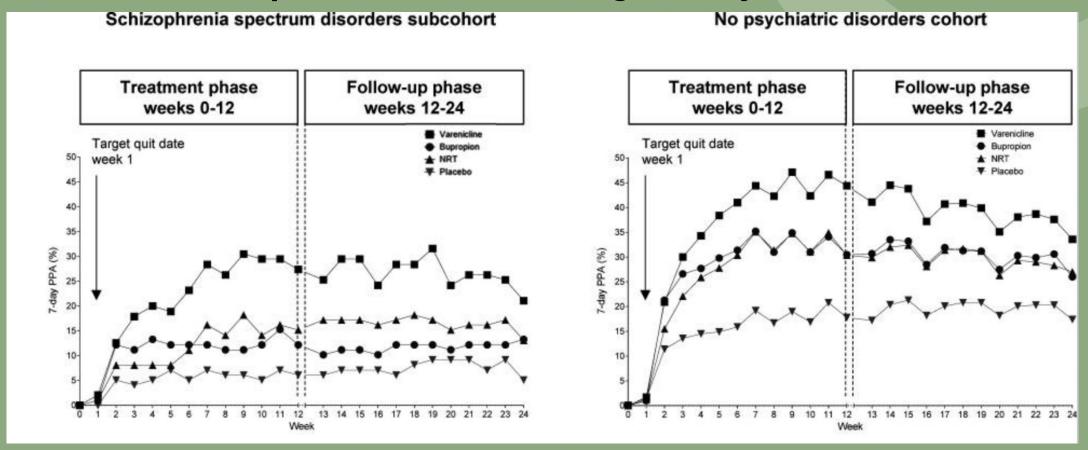
Continuous abstinence in psychiatric cohort

All Abstinent	Varenicline	Bupropion	Nicotine Patch	Placebo
Wks 9-16	29.2%	19.3%	20.4%	11.4%
Wks 16-24	18.3%	13.7%	13.0%	8.3%

Cather's recommendations to optimize treatment of tobacco in Schizophrenia - many are relevant for those who use tobacco and have mental health challenges

- Varenicline is safer than initially suspected less likely to be prescribed
- Bupropion is equally safe <u>not as effective</u> but recommended in 2010 PORT
- Safety and efficacy of Varenicline in people with schizophrenia conditions documented in 390 patients with schizophrenia or schizoaffective disorder in the Eagles study that removed black box/varenicline and bupropion (FDA stated trial confirmed benefits of quitting outweighed the risks of varenicline. Study results were obtained with frequent contact including cessation counseling as well as follow up for side effects and or neuropsychiatric adverse events).
- Neuropsychiatric SE was 6.3 % in varenicline, bupropion and placebo groups and 5.1% in patch alone - only one was sleep disturbance (Very low compared to early death rates due to smoking in SMI)
- Quit rates schizophrenic group of Eagles: 23.2% V; 11.2% B;13.1% NP; 4.1% P
- Probably need Pharmacotherapy to stop tobacco
- Low quit rates may reflect smoking in social environment
- Rapid relapse less with (maintenance) pharma (Evins et al., 2014)
- Consider (V or B) for month before cut down/quit/separate symptoms med vs abstain
 V = varenicline B = bupropion NP = nicotine patch P = placebo

Data related to schizophrenic subset of the Eagles study



- 390 patients with schizophrenia spectrum disorder were compared to 4028 no psych
- Patients were randomly assigned to varenicline (n=95) 22CPD, bupropion, nicotine patch or placebo
- Graphs show continuous abstinence varenicline was superior to bupropion, patch and placebo all schizophrenia spectrum disorder subjects had score <5 on CGIS (Clinical Global Impression Scale). Controls had no axis 1 diagnosis.
- Schizophrenic spectrum group NPSAE were estimated at 6% in V, 6% with B, 5% with NP and 6% with P. NO
 EFFECTS ON SI OR SB. Serious adverse events 2% V, 1%B, 2% NP, 2%P- In spectrum group NPSAE was 5%
 compared to those without spectrum NPSAE was 1%. (Comparable in mood & anxiety disorders- Evins et al., 2019)
- 1/3 of the NPSAEs took place during partial or complete abstinence (Evins et al., 2014)

Cather's recommendations to optimize treatment of tobacco in Schizophrenia cont.

- Have someone check cigarettes per day (cpd) med tolerability, and psych symptoms weekly to monitor for need to adjust psych med (by other staff).
- The more people try to quit and experience this cycle the more likely to be successful

What about behavioral therapy?

- Much variability- no clear answers
- Cather's groups peer support, repeated keys ie. refusing offered cigs + 1shared quit day-
- included successful peer experienced with meds + counseling.
 Set positive expectancy. Peers also gave testimonials re: finances, health and less pressure to quit
 (Cather et al., 2017)

Efficacy in Studies of Maintenance Varenicline

Evins et al. studied 247 recruited those with schizophrenia or bipolar from community health centers 2008-2012-Treated group for 12 weeks those successful divided to V or P monitored to 76 wks. Stop med 52 wk

- 203 qualified rx'd 12 weeks standard dose Varenicline (V) or Placebo (P) in randomized, double blind, placebo controlled 12 trial
- 87 had 2 weeks abstinent at 12 weeks and got maintenance 1 mg V bid or P 61/87 70% completed the maintenance received - randomized to 40 weeks (7 V and 19 P dropped out)
- 24/40 60% V had CO verified 7day PPA (point prevalence abstinence) 52wks OR 6.2 p<.001
- 9/47 19% P had CO verified 7-day PPA
- 18/40 45% V had CO verified 7-day PPA at 64 wks OR 4.6 p= .004
- 7/47 15% P had CO verified 7-day PPA
- $12/40\ 30\%\ V\ had\ self\ report\ 7-day\ PPA\ at\ 76\ wks\ OR\ 3.4\ p=.03$
- 5/47 11% P had self report 7-day PPA
- (5 psych hospitalizations among placebo and 2 among intervention)

Efficacy in Studies of Maintenance Varenicline cont.

What about serious adverse events?

- 2 in V and 2 in P groups had medical hospitalizations that seemed unrelated to study
- 2 in V and 5 in P had psych hospitalizations (8/11 continued after hospitalization)
- CBT weekly x1 month, biweekly x 2 months and then monthly -15 sessions in 40 wks
- There was 50% relapse in the placebo group by 35 days after active rx
- About 1/3 extended varenicline group relapsed after CBT went to monthly meetings
- Lots of support needed

The two most effective FDA approved tobacco treatment medication regimes (to be used with counseling, ideally)

- Varenicline alone
- Nicotine patch combined with short acting gum or lozenge
- If available, can combine with short acting inhaler or nasal spray

Duration: 3-6-12 months -sometimes years. Encourage clients to adhere to treatment and complete it.

The most effective medication plan is the one the client can get and will use

This may be impacted by many factors, including past experiences with meds

Medication for Adolescents and Other Special Populations

- If an **adolescent** is smoking or vaping non-stop, NRT likely helpful. Will need to be prescribed by doc if under 18, consistent with American Academy of Pediatrics (AAP) practices.
- Replacement is **not recommended** for someone who vapes a little bit off-and-on but will help quickly for vaping non-stop.
- Bupropion is not approved for tobacco treatment in children and teens
- Varenicline not approved for 16 and under
- · Should be available <u>confidentially</u> through sensitive services Medi-Cal
- Pregnancy no meds preferred; if meds necessary, consult OB- best may be short acting nicotine not continuous nicotine
- Light smokers seems meds are likely helpful if needed
 - Caucasian light smokers (primarily non-Hispanic white) twice as successful with varenicline as with placebo (Ebbert et al., 2016) Excluded those with mental health challenges.
 - Cox et al., 2022 demonstrated with a large group of African American heavy and light smokers that Varenicline was 2x better than placebo in light smokers and 3x better in moderate to heavy smokers

Smoke Free Homes trial - in Permanent Supportive Housing

Smoke-free home intervention

Residents

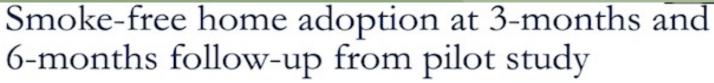
- 1-on-1 counseling
- Information on secondhand smoke, thirdhand smoke, & ecigs
- Impact on family and pets
- Personal expenditure exercise
- Smoke-free home pledge
- How to adopt a smoke-free home

Staff

- Group training
- Information on nicotine addiction
- Delivering 2As and R and 5As cessation counseling
- Local cessation resources
- Counseling on how to help residents adopt a smoke-free home

Data about Smoke Free Homes

- Participants lived in permanent supportive housing in SF and Oakland
- Benefits of smoke free homes: Smoke free social network; harder to smoke on demand; reduce frequency of smoking before quit; challenges to favorite cigarettes (after dinner); decrease smoking and relapse; increased successful recovery in combination with meds and counseling.





Summary

- Reviewed the extraordinary need for behavioral health clients to achieve tobacco recovery.
- Reviewed the 5 A's of tobacco treatment and ways to accomplish them using EHR and team work
- Discussed the possible treatments including reduce to quit and maintenance treatment for this highly addicted population and the evidence for superiority of varenicline
- Presented relatively low rates of NPSAE
- Discussed the critical importance of helping these individuals to have access to more smoke free housing.

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