Brian Hurley, M.D., M.B.A., DFASAM Medical Director, Substance Abuse Prevention and Control County of Los Angeles Department of Public Health

> Medications for Smoking Treatment







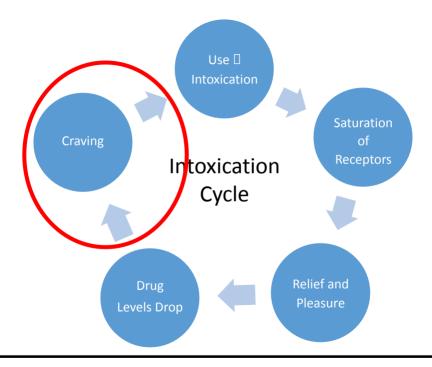


Brian Hurley, M.D., M.B.A., DFASAM

No disclosures



https://www.guitplan.com/assets/documents/guitguide-english.pdf



Providers Have the Opportunity to Ask and Act

- •70% of tobacco users want to quit
- Without assistance only 5% are able to quit
- Most tobacco users try to quit on their own;

more than 95% relapse

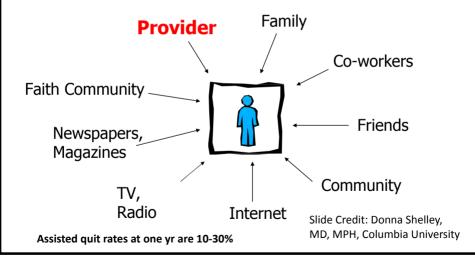
• Physicians using evidence-based programs can more than double the quit rates

Ending the Tobacco Problem: A Blueprint for the Nation. PHS Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update

Slide Credit: American Academy of Family Physicians

ROLE OF THE HEALTH CARE TEAM

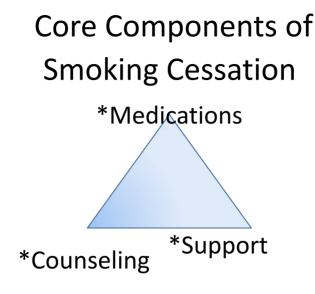
Multiple Influences on a Tobacco User



Tobacco Cessation Strategies

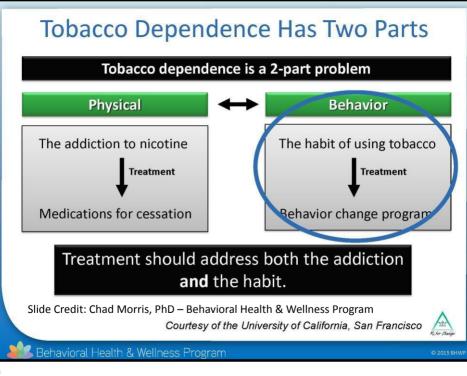
Slide Credit: Chad Morris, PhD – Behavioral Health & Wellness Program





*When appropriate

Source: https://www.samhsa.gov/treatment



Behavior Change Interventions

- Screening, Assessment, Intervention, & Referral
- Cognitive-Behavioral Therapy
- Physician Advice
- Individual counseling
 - > 4 sessions
 - > 10 minutes
- Psycho-educational groups
- Peer support
- Age-tailored self-help materials
- Referral to quitlines





Slide Credit: Chad Morris, PhD – Behavioral Health & Wellness Program

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https://www.nobutts.org



You Can Quit Smoking. We Can Help!

We offer free telephone counseling, self-help materials, and online help in six languages to help you quit smoking. Call **1-800-NO-BUTTS** (1-800-662-8887) for more information.

Learn More





Medications for tebacce use diserder*

Nicotine replacement

Bupropion

Varenicline

*paired with psychosocial support interventions when needed

Slide credit: Hilary Connery, M.D.

Smoking Cessation

A Report of the Surgeon General

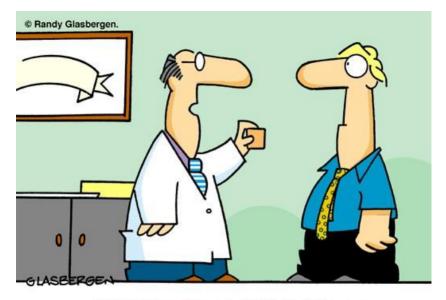


U.S. Department of Health and Human Services

PHARMACOLOGIC PRODUCT GUIDE: FDA-Approved Medications for Smoking Cessation

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS						VARENICLINE
GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	BUPROPION SR	VAKENIGLINE
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 Poc Metered spray 10 mg/mL nicotine solution	Nicotrol Inhaler ^e Rx 10 mg cartridge delivers 4 mg inhaled vapor	Zyban', Generic flx 150 mg sustained-release tablet	Chantix ² Rx 0.5 mg, 1 mg tablet
Recent (C 2 evel), myocandial distances assession and hybrid and hybrid Softonic or wearbing angles pectris Strengenermiddad pint disease Programs/ and transitioning Addiscretis (-10 year)	Pleased (c 2 eresks) myocardial description - Sortexe underlying amhyo pectors Pregamery ¹ and breastfleeding - Addecounts (<3 years)	- Riseard (i c 2 weeks) myocardial - Manness underking antipatiness - Sorress underking antipatiness portoris - Pregrancy ² and basadiesdang - Addeconts (<18 years)	Plenet (1: 2: weeks) myocardial Manchin Sorsen underlying antyfathises Sorsen underlying antyfathises Sorsen underlying antyfathises disordering characteristic disordering characteristic disordering characteristic disordering characteristic Sorsen statube antwork disorder Physiany ⁴ and threstflerding Addescentis (~18 years)	Plevent (c) 2: wesks) myocardial Manchin Screen underhing antyletines: Screen underhing antyletines: Screen underhing antyletines: Screen underhing antyletines: Pleventreparagent antyletines: Pleventreparag	Constraint threap with metadom/ included Include in the lawer has above thread in length of the lawer Include in any other than the lawer Instrument of the lawer has a lawer has a lawer Instrument of the lawer has a lawer has a lawer Instrument of the lawer has a lawer has a lawer Instrument of the lawer has a lawer has a lawer Instrument of the lawer has a lawer has a lawer Instrument of the lawer has a lawer has a lawer Instrument of the lawer has a lawer has a lawer has a lawer Instrument of the lawer has a lawer has a lawer has a lawer Instrument of the lawer has a lawer	Severe read impairment (does adjustment in accessary) = Proparacy ² and Sexatelecting and Sexatelecting International Control (Control (Control) International Control) International Control (Control) International Co
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https://www.aafp.org/dam/AAFP/documents/patient_care/tobacco/pharmacologic-guide.pdf



"I'm prescribing a patch to help you quit smoking. Wear it over your mouth."

Slide credit: Hilary Connery, M.D.

Factors to Consider When Choosing a Medication Strategy

- □ Patient preference
- Clinician familiarity with the medications
- □ Contraindications for selected patients
- Previous patient experiences with a specific agent (positive or negative)
- Patient characteristics (concern about weight gain, history of depression)

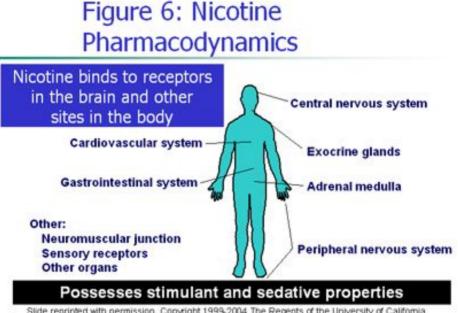
NRT patch

- 7-21 mg available
- Produces steady nicotine levels which reduces cravings and withdrawal symptoms
- Take off at night (nightmares), skin irritation
- Have gum by bedside for early awakenings and before shower, put patch on after shower
- Easily comes off with sweat have pts prepared with surgical tape and spare patches
- Combine with gum/lozenge for breakthrough cravings (<u>recommended</u>)

Slide credit: Hilary Connery, M.D.

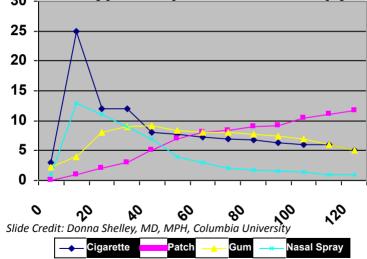
NRT gum or lozenge

- 2 4 mg; replacement boxes cheaper than starter kits
- "chew and park" method nicotine absorbed through cheek mucosa –"peppery" taste
- Some peak effects but less than inhaled
- Lozenges also available OTC in 2-4 mg
- Inhalers and nasal spray prescription only, disadvantages are more adverse events with spray and failure to break behavioral cues with inhaler. Anticipated to be covered by Medi-Cal, but not currently on formulary for DHS/DMH.



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Plasma nicotine levels after a cigarette vs. different types of pharmacotherapy

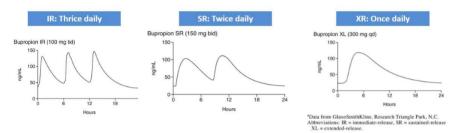


Bupropion XL (Zyban, Wellbutrin)

- Also an antidepressant, improves probability of quit success, may reduce weight gain
- Contraindicated in those with seizure disorder or predisposition to seizures (active bulimia nervosa) and also with bipolar I disorder patients
- Begin 1- 2 weeks before quit date: 150 mg daily x 3 days, then increase as tolerated to 300mg daily
- Warn about "jitters," insomnia, dry mouth
- Maintenance efficacious as maintenance medication for 6 months post-cessation
- Can combine with NRT safely

Evins AE et al. (2007) J Clin Psychopharmacol. 27(4):380-6

Bupropion formulations: IR, SR and XR



Fava M, et al. 15 years of clinical experience with bupropion HCl: from bupropion to bupropion SR to bupropion XL. Primary care companion to the Journal of clinical psychiatry. 2005;7(3):106-13. O PSYCHOPHARMACOLOGY

Bupropion Pharmacokinetics

- The parent drug has a half-life of 8 to 10 hours and is transformed to three active metabolites:
- – Hydroxybupropion, which is the major metabolite
 - Threohydrobupropion
 - Erythrohydrobupropion
- These metabolites all have half-lives of around 24 hours or more and accumulate to a greater extent than the parent drug.
- CYP 2B6 is responsible for the conversion of bupropion to hydroxybupropion . The mechanisms responsible for the conversion of bupropion to its other two major

Fava M, et al. 15 years of clinical experience with bupropion HCI: from bupropion to bupropion SR to bupropion XL. Primary care companion to the Journal of clinical psychiatry. 2005;7(3):106-13.

PSYCHOPHARMACOLOGY INSTITUTE

https://psychopharmacologyinstitute.com/antidepressants/bupropionpsychopharmacology/

Bupropion Cautions

Precautions

- Concomitant therapy with medications/conditions known to lower the seizure threshold
- Hepatic impairment
- Pregnancy and breastfeeding
- Adolescents (<18 years)
- Treatment-emergent neuropsychiatric symptoms (BOXED WARNING REMOVED 12/2016)

Contraindications

- Seizure disorder
- Concomitant bupropion (e.g., Wellbutrin) therapy
- Current or prior diagnosis of bulimia or anorexia nervosa
- Simultaneous abrupt discontinuation of alcohol or sedatives like benzodiazepines
- MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors

Vareniciline (Chantix)

- Partial agonist at the $\alpha 4\beta 2$ nicotinic cholinergic receptors
- Provides mild activation while <u>blocking nicotine</u> from being able to activate receptor
- Abrupt discontinuation can result in mild withdrawal syndrome
- Most effective cessation agent when used as monotherapy
- Begin 1 week before quit date: Days 1 – 3: 0.5 mg once daily
 - Days 4 7: 0.5 mg twice daily

Day 8 – End of treatment: 1 mg BID

• 12-24 weeks; nausea, insomnia, HA

Varenicline Precautions

- Severe renal impairment (dosage adjustment is necessary)
- Pregnancy and breastfeeding
- Adolescents (<18 years)
- Treatment-emergent neuropsychiatric symptoms (BOXED WARNING REMOVED 12/2016)

Varenicline Side Effects

- Nausea
- Sleep disturbances (insomnia, abnormal/vivid dreams)
- Headache
- Flatulence
- Constipation
- Taste alteration
- Neuropsychiatric symptoms (rare)

Varenicline Cardiovascular Risk

- Meta-analysis of 14 double-blind randomized controlled trials, n=8216. (Singh et al 2011)
 - Varenicline was associated with an increased risk of serious adverse cardiovascular events compared to placebo (1.06% vs 0.82%). OR: 1.72.
 - Too few deaths to compare mortality
- Meta-analysis of 22 double-blind randomized controlled trials, n=9232. (Prochaska and Hilton 2012)
 - Varenicline was associated with an increased risk of serious adverse cardiovascular events compared to placebo (0.63% vs 0.47%).
 - Neither clinically or statically significant
- Cohort study: Denmark 2007-2010, n=17,926 (Svanstrom et al 2012)
 - 57 major cardiovascular events (6.9 cases per 1000 person years)
 - vs 60 events in patients treated with bupropion
 - Acute coronary syndrome, ischemic stroke and cardiovascular death.
 - Varenicline was not associated with increased risk of major cardiovascular events in patients with or without a history of cardiovascular disease

www.fda.gov/safetv,

Varenicline Psychiatric

- Perfective trials have not reported increased incidence of psychiatric adverse events other than sleep disturbance.
 - However, Smokers with major mental illness have been excluded from <u>most</u> large prospective trials to date
 - **[12-16-2016]** Based on a U.S. Food and Drug Administration (FDA) review of a large clinical trial that we required the drug companies to conduct,¹ we have determined the risk of serious side effects on mood, behavior, or thinking with the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion)^{*} is **lower than previously suspected**.

The risk of these mental health side effects is **still present**, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past.

However, most people who had these side effects **did not have serious consequences** such as hospitalization. <u>The results of the trial confirm that the</u> <u>benefits of stopping smoking outweigh the risks of these medicines</u>.

Keating and Lyseng-Williamson 2010, Yousefi et al 2011, Ahmed 2011, MacSuibhne et al 2010, Pachas et al 2012, Knibbs and Tsoi 2011, Forcen et al 2012, Tonstad et al 2010, Cahill et al 2009, Moore et al 2010, Garza et al 2011, Bolliger et al 2011, Els et al 2011, Cerimele and Durango 2012, - Home / Drugs / Drug Safety and Availability / FDA Updates and Press Announcements on Nitrosamine in Vasenicline (Chantist

FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)

f Share ♥ Twent in Linkedin S Email ↔ Enint

Drug Safety and Availability	9/17/2021: UPDATE - Pfizer again expands voluntary Chantix recall	Content current as of:
Information about	Update [9/17/2021] FDA is alerting patients and health care professionals that Pfizer is	09/17/2021
Nitrosamine Impurities in	expanding its voluntary recall to include all lots of varenicline (Chantix) 0.5 mg and 1 mg	Regulated Product(s)
Medications	tablets. Pfizer is recalling these lots due to the presence of unacceptable N-nitroso-	Drugs
	varenicline levels.	Topic(s)
Drug Alerts and Statements	10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Safety - Issues, Errors, an
	To lessen the impact to patients from a drug shortage due to this ongoing recall, FDA will	Problems
Medication Guides	not object to certain manufacturers distributing varenicline tablets containing N-nitroso- varenicline above FDA's acceptable intake limit of 37 ng per day but below the interim	
	acceptable intake limit of 185 ng per day until the impurity can be eliminated or reduced	
Drug Safety Communications	to acceptable levels.	

The FDA has approved the first generic version of varenicline. Developed by Par Pharmaceutical, which is part of Endo International, the generic varenicline tablet was approved August 11, 2021.

FDA will not object to certain manufacturers distributing varenicline tablets with below the interim acceptable nitrosamine intake limit

http://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-pressannouncements-nitrosamine-varenicline-chantix

During Pregnancy

- Psychotherapy remains first-line
- No evidence of perinatal harms related to NRT use among pregnant women, although studies examining rare harms are limited
- Conventional wisdom is that NRT is safer than smoking.

Patnode, C. D., Henderson, J. T., Thompson, J. H., Senger, C. A., Fortmann, S. P., & Whitlock, E. P. (2015). Behavioral Counseling and Pharmacotherapy Interventions for Tobacco Cessation in Adults, Including Pregnant Women: A Review of Reviews for the US Preventive Services Task Force Interventions for Smoking Cessation. *Annals of internal medicine*, *163*(8), 608-621.

During Pregnancy

- The metabolism nicotine is increased in pregnancy and NRT can become less effective at standard doses.
- Varenicline and bupropion metabolism is not affected

Coleman, T., Chamberlain, C., Davey, M. A., Cooper, S. E., & Leonardi-Bee, J. (2012). Pharmacological interventions for promoting smoking cessation during pregnancy. *Cochrane Database Syst Rev, 9*(9).

During Pregnancy

• There are insufficient data to support the use of varenicline and/or bupropion for smoking cessation during pregnancy

Patnode, C. D., Henderson, J. T., Thompson, J. H., Senger, C. A., Fortmann, S. P., & Whitlock, E. P. (2015). Behavioral Counseling and Pharmacotherapy Interventions for Tobacco Cessation in Adults, Including Pregnant Women: A Review of Reviews for the US Preventive Services Task Force Interventions for Smoking Cessation. *Annals of internal medicine*, *163*(8), 608-621.

After Pregnancy

- The use of **nicotine replacement therapy** while **breastfeeding** is safer than continuing smoking as it reduces infant exposure to cigarette smoke
- Lactated nicotine is ~50 times less than maternal exposure

Dempsey DA, Benowitz NL. Risks and benefits of nicotine to aid smoking cessation in pregnancy. Drug Saf 2001;24(4):277-322.

After Pregnancy

- Bupropion & metabolites are present in small quantities in the breast milk of lactating women.
- Unknown whether varenicline is secreted in human breast milk

Haas, J. S., Kaplan, C. P., Barenboim, D., Jacob, P. I. I. I., & Benowitz, N. L. (2004). Bupropion in breast milk: an exposure assessment for potential treatment to prevent post-partum tobacco use. *Tobacco control*, *13*(1), 52-56.

Pang, E., & Stern, M. (2014). Providing support to patients who wish to quit smoking. *Prescriber*, 25(7), 22-26.

Patients With Mental Illness

- Most will need medication
- May need <u>higher doses</u>, <u>longer duration of</u> <u>treatment</u> and <u>combination of medications</u>
- Patients with bipolar disorder should only receive bupropion if on mood stabilizer
- Each agent is effective for those with schizophrenia

PHS Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update Signal Behavioral Health Network and the Colorado State Tobacco Education & Prevention Partnership (STEPP). Smoking Cessation for Persons with Mental Illness: A Tookit for Health Providers: 2009

Smoking and psychotropics

• Polycyclic aromatic hydrocarbons induce hepatic enzymes to increase metabolism of many categories of medication, including antipsychotics, antidepressants and anxiolytics

Desai, Seabolt and Jann. 2001 CNS Drugs, 15, 469-494.

Smoking and psychotropics

P450 1A2 isoenzyme particularly affected: amitriptyline haloperidol clomipramine perphenazine imipramine chlorpromazine duloxetine fluphenazine mirtazapine ropinirole ALL clozapine methylxanthines olanzapine ziprasidone

<u>http://www.psychresidentonline.com/CYP450 drug</u> <u>interactions.htm – Accessed 9/10/11 at 12:00pm</u>

Medication interactions with smoking and smoking cessation



- Smoking interacts with both psychiatric and non-psychiatric medications commonly used by people with mental illness.
- Medication levels can vary if someone starts or stops smoking, or if they change how much they smoke.
- Some people may need dose adjustment when quitting or reducing smoking or when resuming smoking following abstinence.
- Interactions are caused by components of tobacco smoke not nicotine and nicotine replacement therapy will not affect changes in medication levels caused by smoking cessation.
- Interactions are often the result of tobacco smoke inducing cytochrome P450 enzymes in the liver, affecting absorption, distribution, metabolism or elimination of the medication.

The table on the following pages summarises possible interactions between common medications and smoking or smoking cessation as described in guidance developed by the former Hunter New England Area Health Service, Mersey Care NHS Trust, UK and Regents University, California.

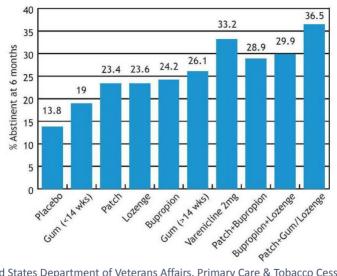
https://www.health.nsw.gov.au/tobacco/publications/tool-14-medication-intera.pdf

Quitting in Rehab?

- Stopping smoking during first year of substance use treatment predicted alcohol and drug treatment outcomes:
 - 1 year: 14.1% smokers stopped, 10.7% of the non-smokers started.
 - Smokers who stopped were more likely in remission from SUD, OR 2.4 (year 1 data).

Tsoh, et al. Drug and alcohol dependence 114.2 (2011): 110-118.

FIGURE 1. EFFICACY OF MEDICATIONS FOR SMOKING CESSATION^{6,9,12-1}



United States Department of Veterans Affairs. Primary Care & Tobacco Cessation Handbook. Washington, DC : U.S. Department of Veterans Affairs, Veterans Health Administration, 2014. Retrieved from https://pulsearch.princeton.edu/catalog/9567271 - Accessed 12/1/2015.

Recommended Medication Strategy

Non-Daily tobacco product user - offer prn nicotine replacement therapy

If 2 or fewer cigarettes or equivalents during a typical smoking	If 3 or more cigarettes or equivalents during a typical smoking
episode:	episode:
□ Nicotine Gum or Lozenge 2mg, take up to 5x/d prn smoking urge	□ Nicotine Gum or Lozenge 4mg, take up to 5x/d prn smoking urge

Smoking 1/4 ppd (corresponds to 8 or fewer nicotine cigarettes or equivalents daily):

Start with:	Combine with:	If patient interested in an additional agent that can		
Start with.	combine with:	help treat depression and mitigate weight gain, add:		
Nicotine Patch 7mg / 24 hour, apply to	Nicotine Gum or Lozenge 2mg, take up to	□Bupropion XL 150mg daily for three days,		
bare skin in the morning and take off at	5x/d prn smoking urge	then 300mg daily thereafter		
bedtime				
Or if the patient has not responded to or tolerated nicotine patches in the past, or declines nicotine patches:				
□Varenicline 1mg, take ½ tab daily x3d, then	Nicotine Gum or Lozenge 2mg, take up to	□Bupropion XL 150mg daily for three days,		
½ tab BID x4d, then 1 tab BID thereafter	5x/d prn smoking urge	then 300mg daily thereafter		

Recommended Medication

Smok grape graph sponds to 9-15 nicotine cigarettes or equivalents daily):

07		If patient interested in an additional agent that can		
Start with:	Combine with:	help treat depression and mitigate weight gain, add:		
Nicotine Patch 14mg / 24 hour, apply to	Nicotine Gum or Lozenge 2mg or 4mg	□Bupropion XL 150mg daily for three days,		
bare skin in the morning and take off at	take up to 5x/d prn smoking urge	then 300mg daily thereafter		
bedtime				
Or if the patient has not responded to or tolerated nicotine patches in the past, or declines nicotine patches:				
□Varenicline 1mg, take ½ tab daily x3d, then	Nicotine Gum or Lozenge 2mg or 4mg	□Bupropion XL 150mg daily for three days,		
½ tab BID x4d, then 1 tab BID thereafter	take up to 5x/d prn smoking urge	then 300mg daily thereafter		

Smoking 1 ppd (corresponds to 16-20 nicotine cigarettes or equivalents daily):

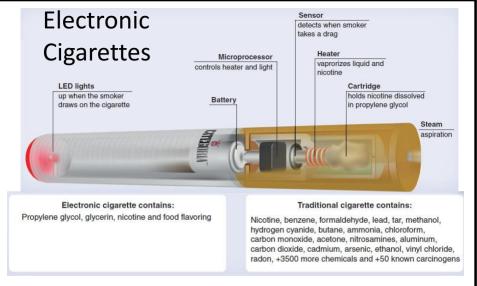
Start with:	Combine with:	If patient interested in an additional agent that can help treat depression and mitigate weight gain, add:		
Nicotine Patch 21mg / 24 hour, apply to	Nicotine Gum or Lozenge 4mg take up to	□Bupropion XL 150mg daily for three days,		
bare skin in the morning and take off at	5x/d prn smoking urge	then 300mg daily thereafter		
bedtime				
Or if the patient has not responded to or tolerated nicotine patches in the past, or declines nicotine patches:				
□Varenicline 1mg, take ½ tab daily x3d, then	Nicotine Gum or Lozenge 4mg take up to	□Bupropion XL 150mg daily for three days,		
½ tab BID x4d, then 1 tab BID thereafter	5x/d prn smoking urge	then 300mg daily thereafter		

• Smoking >1 ppd (corresponds >20 nicotine cigarettes or equivalents daily): □ If the patient is taking nicotine patches, should prescribe additional patches for tobacco product users who use greater than 1 ppd or the equivalent in tobacco products to match or exceed their daily tobacco consumption. There are no dose adjustments for varenicline or bupropion for heavy tobacco product users – dose as 1ppd smoker.

MB: Smoking Cessation Treatment

• Would you recommend MB use vaping / e-Cigarettes as a tool to quit?





The American Cancer Society is awaiting further research on this topic, and has not taken a position on whether electronic cigarettes should be banned from the US market. -cancer.org, Last Revised: 09/09/2013

Caponnetto et al 2012,

THE LANCET Respiratory Medicine



Volume 4, Issue 2, February 2016, Pages 116-128

Articles

E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis Sara Kalkhoran MD ^a, Prof Stanton A Glantz PhD ^{a, b} A ^{SS}

E-cigarettes are associated with significantly less quitting among smokers.

Kalkhoran, S., & Glantz, S. A. (2016). E-cigarettes and smoking cessation in realworld and clinical settings: a systematic review and meta-analysis. *The Lancet Respiratory Medicine*, 4(2), 116-128.

Resources: DO's and DON'Ts

- <u>www.smokefree.gov</u>
- <u>http://www.nicotine-anonymous.org/</u>
- <u>http://smokingcessationleadership.ucsf.edu/Behavioral</u> <u>Health.htm</u>
- DON'T recommend:
- "light" cigarettes or "natural" cigarettes
- Smokeless tobacco (carcinogenic, just as addictive)
- SNUS: harm reduction vs. marketing for nicotine addiction?
 - PLoS Med. 2007 Jul;4(7):e185.
- E-cigarettes: antifreeze, expensive, not proven safe or effective Int J Gen Med. 2011 Feb 1;4:115-20.

PERSISTENCE

THANK YOU!

Questions?

<u>bhurley@ucla.edu</u>

Interested in more? Come to:

•ASAM Annual Meeting • CSAM Annual Meeting • AAAP Annual Meeting

(Florida in April 2022!) (San Diego in Summer 2022!) (Virtual! Dec 2021)

http://csam-asam.org

http://www.asam.org http://www.aaap.org