New and Emerging Tobacco Products and Counseling Patients in a New Tobacco Landscape

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Why should dental providers care about tobacco?

- Tobacco is the single leading cause of preventable death in the United States
- Tobacco use ***kills over 35,000 Californians*** each year - more than any other state
- Tobacco use worsens nearly every dental/oral condition that dental providers manage
- Dental providers are well positioned to help prevent tobacco use and promote tobacco cessation. You can make a difference!

New tobacco products are catching the public's eye

Relatively new tobacco products such as snus, tobacco waterpipes (hookah), and electronic cigarettes (e-cigarettes) are rising in popularity. The tables below review common tobacco products and their potential health effects. The remainder of this handout includes practical resources for helping patients quit.

Traditional tobacco products on the market

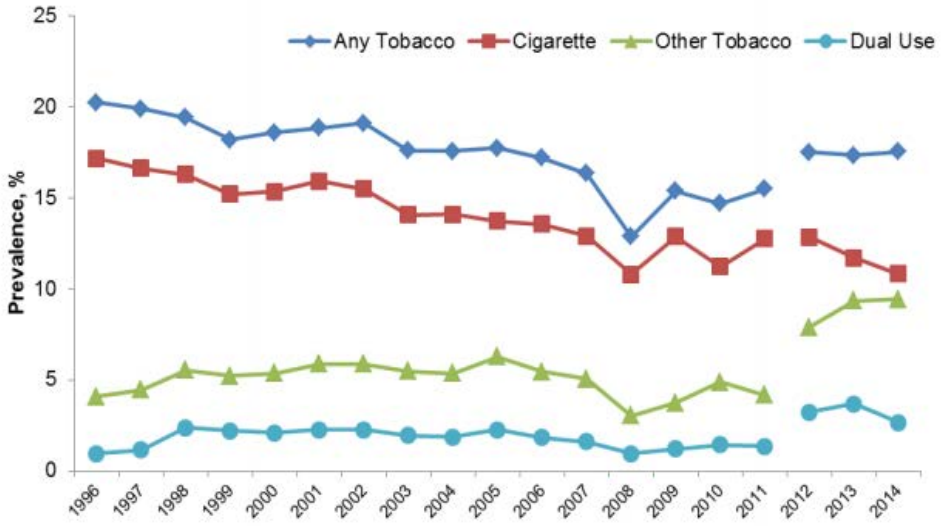
Tobacco Product	What is it?	Is it safe?
Cigarettes	**Cigarettes** consist of finely chopped tobacco leaves rolled in a paper wrapper.	– Smoking exposes users to nicotine, carcinogens such as tobacco specific nitrosamines (TSNAs), and other toxic chemicals – Cigarette use negatively affects every organ in the body and is associated with increased risks of: ***Oral diseases/conditions***: Oral and pharyngeal cancers, oral mucosal lesions (e.g., oral leukoplakia, nicotine stomatitis), periodontal disease, impaired healing after periodontal treatment, gingival recession, and tooth staining ***Systemic diseases/conditions***: Cardiovascular disease, stroke, COPD, increased risk of cancers, birth-related complications, craniofacial defects in infants and more
Cigars (including cigarillos & little cigars)	**Cigars** are tightly rolled tobacco bundles wrapped in a tobacco leaf or manufactured tobacco wrapper.	– Cigar smoke contains the same toxic and carcinogenic compounds as cigarettes including, TSNAs, nitrogen oxides, ammonia, nicotine, carbon monoxide and tar – Cigar smoking is associated with: ***Oral diseases/conditions:*** Oral cancer, lip cancer and periodontal disease ***Systemic diseases/conditions:*** laryngeal, esophageal, pancreatic and lung cancer; coronary heart disease, aortic aneurysms and COPD
Dip or "snuff"	**Dip** (oral moist snuff) is finely ground tobacco, packaged loose or in tea bag-like sachets.	– Use of dip or chew is associated with increased risks of: ***Oral diseases/conditions:*** gingival keratosis, tooth discoloration, halitosis, erosion, gingival recession, alveolar bone damage, dental caries, tooth loss, oral lesions and oral and pharyngeal cancers ***Systemic diseases/conditions:*** pancreatic cancer, nicotine dependence, increased risk of initiating smoking among adolescents
Chewing tobacco	**Chewing tobacco** is coarsely shredded tobacco that is chewed or placed against the buccal mucosa.	

New and emerging tobacco products on the market

Tobacco Product	What is it?	Is it safe?
Snus	**Snus** is a new smokeless tobacco product in the US, modeled after Swedish snus. It is finely ground tobacco contained in sachets and used like dip. It's marketed under major cigarette brands.	– Data regarding the health effects of snus are currently inconclusive – Snus products may contain lower TSNA levels than conventional ST products, but TSNA levels vary across brands – Snus products also contain high nicotine levels, increasing addiction risk
Hookah (Tobacco waterpipe)	**Tobacco waterpipes** often consist of a head, body, water bowl, and one or more hoses with individual mouthpieces. Tobacco is placed in the head and heated using charcoal.	– Hookah use has negative health effects, similar to cigarettes – Hookah smoke contains high toxic compound levels, including heavy metals, TSNAs, and carbon monoxide, as well as nicotine – Research suggests that one hookah smoking session can expose users to smoke at levels equivalent to 100 cigarettes due to the length of time and second hand smoke exposure during the smoking session
Electronic cigarettes (E-cigarettes)	**E-cigarettes**, also termed e-cigs or vape pens, are electronic nicotine delivery systems that heat and convert a liquid mixture (e-liquid) into an aerosol (commonly termed vapor). E-cigarettes vary in design, including disposable or rechargeable forms.	– The long-term oral and systemic health effects of e-cigarettes are currently unknown – E-cigarettes are currently federally unregulated in the US – E-cigarette aerosols have been shown to contain nicotine, ultrafine particles, and other toxic compounds such as acetaldehyde, acrolein, and toluene, although at significantly lower levels than cigarettes – To date, few studies have reported the oral health effects of e-cigarettes. However, due to the nicotine level in most e-cigarette products, it is possible that e-cigarettes may adversely affect oral tissues and immune response – *There is insufficient evidence to support the use of e-cigarettes as a tobacco cessation aid*

Modified from: 1.) US DHHS. "The health consequences of smoking—50 years of progress: A report of the surgeon general." *Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health* 17 (2014) and 2.) Winn, Deborah M. "Tobacco use and oral disease." *Journal of Dental Education* 65.4 (2001): 306-312.

California adult tobacco use, 1996-2014



California has the second-lowest prevalence of adult cigarette smoking among all US states. However, in recent years, the emergence in popularity of other tobacco and nicotine products, such as cigars and e-cigarettes, has led to an overall *increase* in the percentage of Californians who use at least one form of tobacco.

California Tobacco Facts and Figures. California Tobacco Control Program California Department of Public Health. Available from: www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/FactsandFigures/2016FactsFiguresWeb.pdf

Provider Interventions

The **5 A's Approach** is the evidence-based framework and gold standard used by health professionals for tobacco use intervention.

The Five A's Approach to Tobacco Cessation	
Approach	**Suggested Actions and/or Language**
ASK: Ask about tobacco use at every visit Tobacco use status (current, former, never) Amount used (daily/weekly) Document patient response	"Do you ever smoke or use any type of tobacco product?" "How often do you use [tobacco product]?" "I take time to ask all of our clients about tobacco use because it is important."
ADVISE: Advise users to quit Give clear, non-judgmental, strong, personalized advice to quit. Connect advice with oral findings	"There have been some tissue changes in your mouth, and your gum health is getting worse since your last visit. Your use of [tobacco product] is affecting your health." "The best thing that I can do for you today to protect your current and future health is to advise you to stop using [tobacco product]."
ASSESS: Assess their willingness to quit Is the tobacco user willing to make a quit attempt at this time?	"Would you like to try to quit tobacco in the next month/year?" "On a scale of 0-10 (0 being not at all important and 10 being very important), how important is it for you to quit using [tobacco product]?" "What would it take for you to give quitting a try?"
ASSIST: Assist with a quit plan Work with the patient on a quit plan: – Set a quit date within two weeks – Review past quit attempts – Avoid other tobacco users & alcohol – Tell family and friends – Remove tobacco from home, work, & car – Recommend or prescribe pharmacotherapy	*For patients who are ready to quit:* "Would you like to create a quit plan with me today?" *For patients who are not ready to quit:* Provide a brief intervention or motivational interview using MI strategies (pages 4 & 5) and the 5 R's approach (page 4).
ARRANGE: Arrange follow-up contact Document in their chart and schedule a follow-up appointment to review progress and provide additional tobacco cessation counseling.	*For patients not ready to quit:* "If it is okay with you, I'd like to check in with you at your next appointment to see where you are in your decision making." *For patients who are ready to quit:* "If it's okay with you, I'd like to schedule a follow-up appointment or phone call to discuss your progress." "You can call 1-800-QUIT-NOW for free telephone support." (Refer)

For busy clinicians who may not have time to provide in-depth cessation services, there is an alternative approach to the 5 A's called **Ask-Advise-Refer**. This is a simplified version that allows clinicians to Ask, Advise and Refer patients to a quitline or cessation services that will Assess, Assist, and Arrange follow-up. ***This shortened approach takes less than 3 minutes!***

Ask-Advise-Refer Approach to Tobacco Cessation*	
Approach	**Suggested Actions and/or Language**
ASK: Ask about tobacco use Tobacco use status should be updated for all patients on a regular basis Understand tobacco habits (type of product, dose, frequency, duration of use)	"Do you ever smoke or use other types of tobacco or nicotine, such as e-cigarettes?" "I take time to ask all of my patients about tobacco use—because it's important." "Condition X often is caused or worsened by smoking. Do you, or does someone in your household smoke?"
ADVISE: Advise tobacco users to quit Message should be clear, strong, and personalized	"It's important that you quit as soon as possible, and I can help you." "Occasional or light smoking is still harmful." "Quitting is the most important thing you can do to protect your health now and in the future."
REFER: Refer tobacco users to cessation services Refer to CA Smoker's Helpline, Peer-to-peer counselor, and/or other program	"Let me put you in contact with a local cessation program that can offer you assistance as your get ready to quit." "You can call 1-800-QUIT-NOW any time for free telephone support while you are quitting. Can I sign you up with the helpline today?"

Stead LF, Buitrago D, Preciado N, Sanchez G, Hartmann-Boyce J, Lancaster T. Physician advice for smoking cessation. Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD000165; Treating Tobacco Use and Dependence: 2008 Update. June 2015. Agency for Healthcare Research and Quality, Rockville, MD.

The **5 R's Approach** is intended to increase the *motivation* to quit among patients who are not yet ready to make a quit attempt.

The Five R's Approach to Tobacco Cessation*	
Approach	**Suggested Actions and/or Language**
RELEVANCE Encourage patient to indicate why quitting is personally relevant	"Why is quitting tobacco personally relevant to you?"
RISKS Ask the patient to identify potential negative consequences of tobacco use	"What do you think are the negative consequences of tobacco use?"
REWARDS Ask the patient to identify potential benefits of stopping	"What do you think are the benefits of quitting tobacco?"
ROADBLOCKS Ask the patient to identify barriers or impediments to quitting	"What do you think are the barriers preventing you from quitting tobacco?" "Can you think of any ways to circumvent these barriers?"
REPETITION The motivational intervention should be repeated every time an unmotivated patient has an interaction with a clinician. Tobacco users who have failed in previous quit attempts should be encouraged to continue trying to quit.	"Most people make repeated quit attempts before they are successful." "Would it be OK with you if we revisit this conversation at your next visit?"

*Modified from American Dental Association (ADA), www.ada.org/goto/quitsmoking; and U.S. Public Health Service, Clinical Practice Guideline: Treating TobaccoUse and Dependence, www.surgeongeneral.gov/tobacco/

Motivational Interviewing (MI) Strategies

MI is a collaborative, goal-oriented communication style designed to strengthen a person's own motivation and commitment to change. The spirit of MI incorporates four key elements: **partnership** (not confrontation), **acceptance** (not judgement), **compassion** (not in difference) and **evocation** (not advice). The following MI strategies can be used to assist providers in helping patients explore and enhance their motivation to quit using tobacco.

Patient-Centered Communication Methods (O-A-R-S)	
Approach	**Suggested Actions and/or Language**
Open-ended questions *Patient benefits* • Allows patient to express him or herself • The patient verbalizes what is important to them *Provider benefits* • Learn more about the patient • Sets a positive tone for the session	"How would you do that?" "What do you see being your biggest challenge?" "Can you tell me more about that?" "What are your thoughts about quitting smoking? "What do you know about the health consequences of smokeless tobacco use?" "What worries you about your cigarette use?"
Affirmations Statements of appreciation to nurture strengths Strategically designed to anchor clients in their strengths, values, and resources despite difficulties/challenges Authentic observations about the person; Focused on non-problem areas; Focused on behaviors vs. attitudes/goals	*Patient:* "I tried sixteen times to stop smoking." *Provider:* "Wow, you've already showed your commitment to trying to stop smoking several times. That's great! More importantly, you're willing to try again."
Reflections *Reflections from the provider convey:* • That they are interested • That it's important to understand the patient • The they want to hear more • What the patient says is important	*Patient:* "I'm afraid that my daughter is going to smoke because she sees me smoke." *Provider reflection:* "You're worried about how the things that you do like smoking, might impact your daughter."
Summaries Reflecting elements that will aid the patient in moving forward Selective judgement on what to include and exclude Can be used to gather more information Can be used to move into a new direction Can be used to link both sides of ambivalence	"So, it sounds like on one hand you love smoking and it helps relax you, but on the other hand it is starting to affect your health and you would like to quit." "What I hear you saying is that it is very important for you to quit, but you are worried that you may not have the tools to be successful. What worries you the most about quitting? (Open-ended question)"

Miller, W. R., & Rollnick, S. (2012). Motivational interviewing: Helping people change. Guilford press.

The **Elicit-Provide-Elicit model** is a brief MI intervention promoted by the Mayo Clinic for tobacco cessation and is based on the dental provider's ability to elicit the patient's perspective, provide information about tobacco products and cessation strategies, and elicit a patient's thoughts about the information shared and their ideas about next steps.

Elicit-Provide-Elicit Model for Brief Interventions	
Approach	**Appropriate/Inappropriate Language**
Elicit Ask what the patient knows or would like to know	"What do you know about the health effects of second hand smoke?" (A) "What worries you about your cigarette use?" (A)
Provide Information in a neutral and non-judgmental fashion	"Research suggests that…" (A) "What we know is…" (A) **INSTEAD OF…** "You're putting your family at risk every time you smoke in your house or car." (I)
Elicit Elicit the patient's interpretation Avoid sentences with "I" or "you"	"What does this mean to you?" (A) **INSTEAD OF…** "It's obvious from this information that you need to quit smoking today." (I)

The following conversation is an example of how a clinician might incorporate these MI strategies when discussing the use of e-cigarettes as a cessation aid with their patient.

Electronic Cigarette - Example Conversation

1 **Patient (P):** "I plan to start using an electronic cigarette to stop smoking."

2 **Clinician (C):** "It sounds like you would like to make an effort to stop smoking (Reflection). What makes quitting important to you right now?" (Open-ended question)

3 *Opportunity to discuss importance and motivation*

4 **C:** "What do you know about electronic cigarettes?" (Elicit)

5 *Listen for motivations for use (hand/mouth substitute, curiosity, etc.); Assess for gaps in patient's knowledge. Integrate use of OARS.*

6 **C:** "Would it be alright if I shared some information about what health experts know about e-cigarettes? (Asking permission) While it is certainly becoming more popular as an alternative to smoking for some folks, there is currently no evidence to show e-cigarettes are either safe to use or effective to help people stop smoking. Until further research is done, it is something we do not recommend to our patients. (Provide) I'm wondering what this means to you?" (Elicit)

7 **P:** "Well I just know that I need something to hold in my hand because the habit is harder to break than the cravings."

8 **C:** "Changing behaviors will be an important part of a quit plan for you. (Reflection) Are you aware of the medications that are available to help people stop smoking?" (Elicit)

9 **P:** "I've heard about the patch and the gum, but that's about it."

10 **C:** "Many people find medications helpful in managing cravings and breaking habits while quitting smoking. For people who like something to hold in their hand, the nicotine inhaler can be an option. (Provide) Would it be okay if I shared some information about the FDA-approved medication options?" (Ask Permission)

Mayo Clinic Nicotine Dependence Center Education Program. Rochester, MN.

Things Heard at the Dental Office

“Wouldn’t it be better for me to stick to teeth and let the medical doctors handle tobacco cessation?”

- Dental professionals can be just as effective as physicians in helping patients quit
- Tobacco prevention and cessation are central to the dental profession and a standard of care
- Tobacco use negatively affects nearly every aspect of oral health, from gingivitis to implants
- Research shows that dental patients *expect* their dental provider to ask about tobacco use
- Patients report greater satisfaction when dental providers engage in tobacco cessation

“I don’t have patients who smoke. This doesn’t affect my practice.”

- Wonderful! But keep in mind…
- Many people who smoke cigarettes occasionally do not consider themselves to be “smokers”
- Patients use many other tobacco products, such as cigars, dip/chew, e-cigarettes, and hookah
- If you only ask “do you smoke?” you may miss a substantial amount of tobacco use in your practice

“What should I tell my patients about vaping?”

- E-cigarettes and vaping are not harmless
- E-cigarette users are exposed to nicotine, heavy metals, and respiratory irritants
- However, e-cigarettes *are* likely to be less harmful than smoking cigarettes
- If a patient is motivated to quit smoking by trying e-cigarettes, encourage their quit attempt! Use MI to understand their motivation to use e-cigarettes as opposed to other safer options.
- Remember, e-cigarettes *are not* approved as tobacco cessation aids, and the little evidence that suggests they are safe or effective for quitting smoking is mixed
- The long-term goal for any patient looking to quit tobacco use should be to live completely nicotine or tobacco free

"What about marijuana?"

- Legalization of recreational marijuana use in California reflects increasing social acceptance
- Like tobacco smoke, marijuana smoke contains numerous carcinogens. Whether tobacco or cannabis, lighting a plant on fire and breathing the smoke is not good for one’s health
- Studies suggest marijuana use can lead to problems with memory, impaired body movement, mood changes, lung infections, decreased fertility, *xerostomia, and periodontal disease*
- No need for stigma: dental providers can have fact-based patient discussions on cannabis

"Tobacco cessation takes too much time. I'm too busy. I don't get paid for it."

- Anyone on the dental team can help patients quit: just 3-5 minutes makes a difference
- Your dental practice can literally *save a life* in 3 minutes
- Are you a health care provider or do you just "stick to teeth"?

Tobacco Cessation Resources

For more information about tobacco products, current evidence-based tobacco cessation counseling recommendations, and strategies for implementing in-office tobacco education and cessation counseling, we recommend the following FREE resources:

Provider

- **CDC Tips from Former Smokers®:**
  - Link: https://www.cdc.gov/tobacco/campaign/tips/partners/health/dental/index.html
  - Patient fact sheets, posters, provider resources, etc.
- **California Smokers'™ Helpline:**
  - Link: https://www.cdc.gov/tobacco/campaign/tips/partners/health/index.html
  - Free materials, toolkits, training, etc.
- **American Dental Association (ADA):**
  - Link: https://www.ada.org/en/member-center/oral-health-topics/smoking-and-tobacco-cessation
  - Patient and provider resources, brochures, etc.
- ***Rx for Change:***
  - Link: rxforchange.ucsf.edu
  - Comprehensive tobacco cessation training program for health professionals
- ***Clinical Practice Guidelines:***
  - Fiore, MC et al. (2008). ***Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline***. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service.
  - Link: http://bphc.hrsa.gov/buckets/treatingtobacco.pdf

Patient

- **Websites:**
  - Department of Health and Human Services: www.BeTobaccoFree.gov
  - National Cancer Institute: www.smokefree.gov
  - The California Smokers'™ Helpline: www.nobutts.org
  - My Last Dip: www.mylastdip.com
  - American Cancer Society: www.cancer.org
  - American Heart Association: www.heart.org
  - American Lung Association: www.lungusa.org
  - Become an Ex: www.becomeanex.com
  - Nicotine Anonymous: www.nicotine-anonymous.org
  - QuitNet: www.quitnet.com
- **Community-based or local cessation resources (e.g. support groups, on-site counseling, etc.)**
  - Find local programs in your county: http://www.nobutts.org/county-listing
- **Free telephone-based quitlines:**
  - 1-800-QUIT-NOW (US)
  - 1-800-NO-BUTTS (CA)
- **Text messaging programs:**
  - NCI's Smokefree TXT: Text QUIT to 47848
  - NCI's dipfree TXT: Register at teen.smokefree.gov/tools-tips/text-programs/quit-for-good/dipfreetxt
  - The California Smokers'™ Helpline: Register at forms-nobutts.org/texting
- **Smartphone applications**
  - NCI QuitGuide (Adults) and QuitSTART (Teens): smokefree.gov/apps

The 5As Flowchart:

A systematic approach to a brief patient conversation

Ask about tobacco use at every visit, for every patient. This is your chance to change a life.

ASK Do you use tobacco?

Respond firmly but without judgment. "The best health advice I can give my patients is to quit using tobacco."

Yes

ADVISE tobacco users to quit

ASSESS willingness to quit within the next 30 days

Yes

Provide medications, counseling, cessation aids, referral to quitline or local services

ASSIST with the quit plan

ARRANGE for follow-up and continued support

Don't leave the patient to do it alone: follow-up!

No

5Rs

- Relevance
- Risks
- Rewards
- Roadblocks
- Repetition

The 5Rs can be motivating for patients in "pre-contemplation" or "contemplation" stages: not ready to quit, but open to non-judgmental, empathetic communication

THE key decision point: For the patient ready to make a quit attempt, provide resources. For the patient *not* ready to quit, don't force it. Use the 5Rs and be ready to help at the next visit

No

Great! If the patient does say no, ask about past use. Did this patient recently quit? Is there risk of relapse or initiation?

Have you ever used tobacco?

Yes

Support continued abstinence; re-evaluate next visit

Affirm the decision to quit and congratulate cessation success. Make sure recent quitters have the support they need to stay tobacco free.

No

For patients who do not use tobacco, provide affirmation and encouragement. Remind youth of the benefits of never starting.

CALIFORNIA SMOKERS' HELPLINE
1-800-NO-BUTTS

HELP YOUR PATIENTS QUIT SMOKING
A GUIDE FOR HEALTH PROFESSIONALS
(Cut out then fold this pocket guide along the dashed lines.)

CALIFORNIA SMOKERS' HELPLINE 1-800-NO-BUTTS

1

YOU ARE KEY TO YOUR PATIENTS' SUCCESS!

Remember, every quit attempt brings a smoker closer to quitting for good.

YOU succeed every time you encourage a smoker to quit.

2

ASK

Every patient at every visit:

"Do you use any form of tobacco?"

3

ADVISE

Tobacco users to quit.

Your advice **doubles the chance** that your patients will make a quit attempt.*

* Monogr Natl Cancer Inst 5, 1-22. NIH Publication No. 94-3693

4

REFER

Your patients to 1-800-NO-BUTTS.

LET THEM KNOW:

"You can double your chances of quitting successfully by calling **1-800-NO-BUTTS.**"*

* Zhu S-H., Anderson CM, Tedeschi G., et al. Evidence of real world effectiveness of a telephone quitline for smokers. N Engl J Med 2002; 347: 1087-93

5

1-800-NO-BUTTS

Operated by Moores UCSD Cancer Center

FREE Cessation Services Include:

- **Self-help materials**
- **Referral to local services**
- **Telephone counseling**
  - Up to 6 one-on-one counseling sessions to help patients create a plan and stick to it.
  - Specialized services available for teens, tobacco chewers, and pregnant smokers.

6

All services are FREE

English
1-800-NO-BUTTS
(1-800-662-8887)

Spanish
1-800-45-NO-FUME
(1-800-456-6386)

Mandarin & Cantonese
1-800-838-8917

Korean
1-800-556-5564

Vietnamese
1-800-778-8440

Chewing Tobacco
1-800-844-CHEW
(1-800-844-2439)

TDD: Deaf or Hard of Hearing
1-800-933-4TDD
(1-800-933-4833)

Hours of Operation
Monday–Friday: 7am – 9pm
Saturday and Sunday: 9am – 5pm

ORDER FREE PATIENT MATERIALS AT WWW.NOBUTTS.ORG

7 **Suggestions for Clinical Use of Pharmacotherapies for Smoking Cessation** (The information contained within this table is not comprehensive) 8

PHARMACOTHERAPY	SIDE EFFECTS	DOSAGE	DURATION	PRODUCT NAME & AVAILABILTIY
Nicotine Patch	Local skin reaction; Insomnia	21 mg/24 hours 14 mg/24 hours 7 mg/24 hours	4-6 weeks then 2 weeks then 2 weeks	Nicoderm CQ (OTC) Generic (Rx & OTC)
Nicotine Gum	Mouth soreness; Dyspepsia	1-24 cigs/day-2 mg gum. (To start: every 1-2 hrs,up to 24 pcs/day) 25+ cigs/day-4 mg gum. (To start: every 1-2 hrs,up to 24 pcs/day)	Up to 12 weeks	Nicorette, Generic (OTC) Original & various flavors
Nicotine Nasal Spray	Nasal irritation	8-40 doses/day. (To start: every 1-2 hrs)	3-6 months	Nicotrol NS (Rx)
Nicotine Inhaler	Local irritation of mouth and throat	6-16 cartridges/day. (To start: every 1-2 hrs)	Up to 6 months	Nicotrol Inhaler (Rx)
Nicotine Lozenge	Mouth soreness; Local irritation of throat; Hiccups	2 mg or 4 mg. (To start: every 1-2 hrs, up to 20 pcs/day)	12 weeks	Commit, Generic (OTC)
Bupropion SR** (Precautions/contraindications include history of seizure and eating disorder)	Insomnia; Dry mouth	150 mg every morning for 3 days, then 150 mg twice daily. (Begin treatment 1-2 weeks pre-quit)	7-12 weeks; Maint. up to 6 months	Zyban, Generic (Rx)
Varenicline*** (Precautions/contraindications include pregnant or breastfeeding women, children under 18, history of kidney problems)	Nausea; Headache; Insomnia; Flatulence; Vomiting	0.5 mg once a day for 1-3 days, then 0.5 mg twice daily (1 in am, 1 in pm) for 4-7 days. On day 8 through completion, 1 mg twice daily. (Begin treatment 1 week pre-quit)	12 weeks; Maint. option: add'l 12 weeks	Chantix (Rx)

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PHARMACOTHERAPY
for Smoking Cessation

How Nicotine Creates Dependence[1]

- When cigarette smoke is inhaled, nicotine reaches the brain quickly and binds with nicotinic receptors.
- At the receptor sites, nicotine stimulates the release of "feel good" chemicals such as dopamine, acetylcholine, norepinephrine, serotonin, and beta endorphin.
- Through chronic smoking the brain makes more nicotinic receptors and becomes accustomed to a certain level of chemical stimulation from nicotine.
- Quitting smoking leaves the brain wanting nicotine and causes withdrawal symptoms.

How Pharmacotherapy Helps Tobacco Users Quit

- Pharmacotherapy helps reduce withdrawal symptoms in two main ways:
  - Nicotine Replacement Therapy (NRT) delivers nicotine to the brain from a less harmful source.
  - Prescription Drugs stimulate "feel good" chemicals in the brain without nicotine.
- These pharmacological tools are designed to reduce withdrawal symptoms, freeing the smoker to focus on the behavioral aspects of quitting.

Recommendations

- All FDA-approved pharmacological quitting aids can improve the odds of success and should be covered by health plans and hospital formularies.
- When feasible, quitting aids should be combined with behavioral counseling to further improve the odds of successful quitting. Combined use of quitting aids can also be considered.
- Factors to consider when helping a patient select a quitting aid include contraindications, insurance coverage, previous use of quitting aids, and current patient preference. The last of these should be weighed heavily, since patients who obtain the quitting aid they want are more likely to use it.
- While the clinical guidelines for tobacco cessation[2] recommend pharmacotherapy for everyone trying to quit, it is also possible to quit successfully without quitting aids. Patients who do not have access to them or who do not wish to use them should still be encouraged to make a quit attempt.

CALIFORNIA SMOKERS' HELPLINE
1-800-NO-BUTTS
Moores UCSD Cancer Center, 9500 Gilman Drive, #0905, La Jolla CA 92093-0905, T: 858-300-1010, F: 858-300-1099, www.NoButts.org
This material made possible by funds received from the California Department of Public Health and from First 5 California.

PHARMACOLOGIC PRODUCT GUIDE: FDA-Approved Medications for Smoking Cessation

	NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS					BUPROPION SR	VARENICLINE
	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER		
PRODUCT	**Nicorette,[1] ZONNIC,[2] Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette Lozenge,[1]** **Nicorette Mini Lozenge,[1] Generic** OTC 2 mg, 4 mg; cherry, mint	**NicoDerm CQ,[1] Generic** OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hr release)	**Nicotrol NS[3]** Rx Metered spray 10 mg/mL aqueous solution	**Nicotrol Inhaler[3]** Rx 10 mg cartridge delivers 4 mg inhaled vapor	**Zyban[1], Generic** Rx 150 mg sustained-release tablet	**Chantix[3]** Rx 0.5 mg, 1 mg tablet
PRECAUTIONS	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Temporomandibular joint disease • Pregnancy[4] and breastfeeding • Adolescents (<18 years)	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Pregnancy[4] and breastfeeding • Adolescents (<18 years)	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Pregnancy[4] (Rx formulations, category D) and breastfeeding • Adolescents (<18 years)	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) • Severe reactive airway disease • Pregnancy[4] (category D) and breastfeeding • Adolescents (<18 years)	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Bronchospastic disease • Pregnancy[4] (category D) and breastfeeding • Adolescents (<18 years)	• Concomitant therapy with medications/conditions known to lower the seizure threshold • Hepatic impairment • Pregnancy[4] (category C) and breastfeeding • Adolescents (<18 years) • Treatment-emergent neuropsychiatric symptoms[5]: **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/benzodiazepines • MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors	• Severe renal impairment (dosage adjustment is necessary) • Pregnancy[4] (category C) and breastfeeding • Adolescents (<18 years) • Treatment-emergent neuropsychiatric symptoms[5]: **BOXED WARNING REMOVED 12/2016**
DOSING	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours • Maximum, 24 pieces/day • Chew each piece slowly • Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) • Resume chewing when tingle fades • Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) • Park in different areas of mouth • No food or beverages 15 minutes before or during use • Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours • Maximum, 20 lozenges/day • Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) • Nicotine release may cause a warm, tingling sensation • Do not chew or swallow • Occasionally rotate to different areas of the mouth • No food or beverages 15 minutes before or during use • Duration: up to 12 weeks	≥10 cigarettes/day: 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks ≤10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks • Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week • May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) • Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa • Maximum – 5 doses/hour or – 40 doses/day • For best results, initially use at least 8 doses/day • Do not sniff, swallow, or inhale through the nose as the spray is being administered • Duration: 3–6 months	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours • Best effects with continuous puffing for 20 minutes • Initially use at least 6 cartridges/day • Nicotine in cartridge is depleted after 20 minutes of active puffing • Inhale into back of throat or puff in short breaths • Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe • Open cartridge retains potency for 24 hours • No food or beverages 15 minutes before or during use • Duration: 3–6 months	150 mg po q AM x 3 days, then 150 mg po bid • Do not exceed 300 mg/day • Begin therapy 1–2 weeks **prior** to quit date • Allow at least 8 hours between doses • Avoid bedtime dosing to minimize insomnia • Dose tapering is not necessary • Duration: 7–12 weeks, with maintenance up to 6 months in selected patients	Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid • Begin therapy 1 week **prior** to quit date • Take dose after eating and with a full glass of water • Dose tapering is not necessary • Dosing adjustment is necessary for patients with severe renal impairment • Duration: 12 weeks; an additional 12-week course may be used in selected patients • May initiate up to 35 days before target quit date OR may reduce smoking over a 12-week period of treatment prior to quitting and continue treatment for an additional 12 weeks

	NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS					BUPROPION SR	VARENICLINE
	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER		
ADVERSE EFFECTS	• Mouth/jaw soreness • Hiccups • Dyspepsia • Hypersalivation • Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	• Nausea • Hiccups • Cough • Heartburn • Headache • Flatulence • Insomnia	• Local skin reactions (erythema, pruritus, burning) • Headache • Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	• Nasal and/or throat irritation (hot, peppery, or burning sensation) • Rhinitis • Tearing • Sneezing • Cough • Headache	• Mouth and/or throat irritation • Cough • Headache • Rhinitis • Dyspepsia • Hiccups	• Insomnia • Dry mouth • Nervousness/difficulty concentrating • Nausea • Dizziness • Constipation • Rash • Seizures (risk is 0.1%) • Neuropsychiatric symptoms (rare; see PRECAUTIONS)	• Nausea • Sleep disturbances (insomnia, abnormal/vivid dreams) • Constipation • Flatulence • Vomiting • Neuropsychiatric symptoms (rare; see PRECAUTIONS)
ADVANTAGES	• Might serve as an oral substitute for tobacco • Might delay weight gain • Can be titrated to manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges	• Might serve as an oral substitute for tobacco • Might delay weight gain • Can be titrated to manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges	• Once-daily dosing associated with fewer adherence problems • Of all NRT products, its use is least obvious to others • Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours	• Can be titrated to rapidly manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges	• Might serve as an oral substitute for tobacco • Can be titrated to manage withdrawal symptoms • Mimics hand-to-mouth ritual of smoking • Can be used in combination with other agents to manage situational urges	• Twice-daily oral dosing is simple and associated with fewer adherence problems • Might delay weight gain • Might be beneficial in patients with depression • Can be used in combination with NRT agents	• Twice-daily oral dosing is simple and associated with fewer adherence problems • Offers a different mechanism of action for patients who have failed other agents
DISADVANTAGES	• Need for frequent dosing can compromise adherence • Might be problematic for patients with significant dental work • Proper chewing technique is necessary for effectiveness and to minimize adverse effects • Gum chewing might not be acceptable or desirable for some patients	• Need for frequent dosing can compromise adherence • Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	• When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms • Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	• Need for frequent dosing can compromise adherence • Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic • Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	• Need for frequent dosing can compromise adherence • Cartridges might be less effective in cold environments (≤60°F)	• Seizure risk is increased • Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) • Patients should be monitored for potential neuropsychiatric symptoms[5] (see PRECAUTIONS)	• Should be taken with food or a full glass of water to reduce the incidence of nausea • Patients should be monitored for potential neuropsychiatric symptoms[5] (see PRECAUTIONS)
COST/DAY[6]	2 mg or 4 mg: $1.90–$3.70 (9 pieces)	2 mg or 4 mg: $3.36–$3.78 (9 pieces)	$1.52–$3.48 (1 patch)	$6.67 (8 doses)	$11.35 (6 cartridges)	$2.58–$7.87 (2 tablets)	$11.86 (2 tablets)

[1] Marketed by GlaxoSmithKline.

[2] Marketed by Niconovum USA (a subsidiary of Reynolds American, Inc.)

[3] Marketed by Pfizer.

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

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

[6] Wholesale acquisition cost from Red Book Online. Thomson Reuters, December 2016.

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

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

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