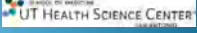


Tobacco Use and Dependence Guideline Update

2011 Annual South Texas Oral Health Network Summer Meeting
August 5th, 2011

Carlos Roberto Jaén, MD, PhD, FAAFP
Vice Chair of The Guideline Panel
Professor and Chair Family and Community Medicine
Professor of Epidemiology and Biostatistics
Adjunct Professor of Public Health, UT School of Public Health

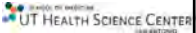


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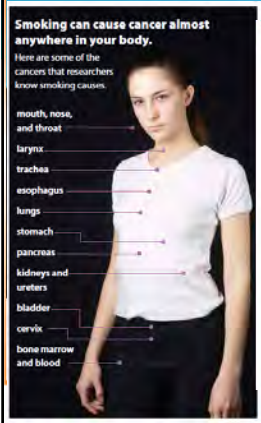
Objectives

- Review oral health effects of cigarette use
- Describe the 10 key recommendations from the most recent update of the smoking cessation guideline
- Identify strategies to increase demand for tobacco use and dependence
- Describe local opportunities for engaging in local tobacco control efforts



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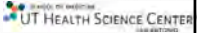
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Smoking can cause cancer almost anywhere in your body.
Here are some of the cancers that researchers know smoking causes.

... what it means to YOU

Within 5 years of quitting, your chance of cancer of the mouth, throat, esophagus, and bladder is cut in half. If nobody smoked, 1 of every 3 cancer deaths in the United States would not happen.

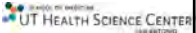
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Dentists' attitudes


- 46% of the dentists reported they know how to assess patients for tobacco use
- 58% felt that it was important/very important as part of their role to intervene with patients' tobacco use
- 26% felt well-prepared
- 18% felt effective in intervening.

Prakash et al., Dentists' tobacco control attitudes, behaviors and barriers, APHA Meeting Presentation 2009.

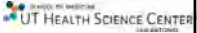


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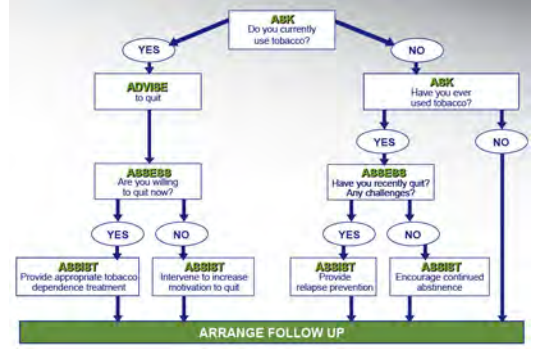
Tobacco use causes certain types of cancers, and contributes to the development and progression of periodontal disease. Over its course, the patient will experience oral symptoms ranging from bad breath to significant pain, swelling, and ultimately loss of teeth.



5

5

The "5 A's" Model for Treating Tobacco Use and Dependence - 2008




6

6

Dentists and the 5 A's

- 'often or almost always':
 - 74% asked patients about tobacco use
 - 78% advised patients to quit
 - 19% assessed readiness to quit
 - 39% assisted patients with quitting
 - 4% arranged follow-up
 - 38% received any formal training in cessation counseling

Prakash et al., Dentists' tobacco control attitudes, behaviors and barriers, APHA Meeting Presentation 2009.




7

Barriers among dentists

- Strong barriers to providing tobacco use cessation services were
 - patient resistance (65%)
 - lack of insurance reimbursement (56%)
 - not knowing where to refer for care (49%)
 - and lack of time (32%).


Prakash et al., Dentists' tobacco control attitudes, behaviors and barriers, APHA Meeting Presentation 2009.



8


Wisdom and experience shared

- What barriers do you experience in your office when trying to intervene on your patients who use tobacco?
- What changes have worked well in your office to help your patients who smoke get better dental health outcomes?




9

2008 Clinical Practice Update



- Tobacco dependence is a chronic disease
- Tobacco users need to be identified in the practice
- Treatments work for a wide range of populations
- Brief treatment is effective
- Counseling works, more is better
- Medications work, consider them in every attempt
- Counseling + medication, better than either alone
- Telephone quitlines are effective
- Motivational interventions increase attempts to quit
- Treatments are clinically effective and cost-effective

Fiore MC, Jaén CR, Baker TB, et al. Treating tobacco use and dependence clinical practice guideline, 2008 update. Rockville MD: USDHHS, 2008.



10

Sponsors

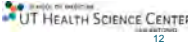
- Agency for Healthcare Research and Quality
- National Cancer Institute
- National Heart, Lung & Blood Institute,
- National Institute on Drug Abuse
- Centers for Disease Control and Prevention
- The Robert Wood Johnson Foundation
- American Legacy Foundation
- University of Wisconsin-Center for Tobacco Research and Intervention



11

#6 Key Recommendation

- There are numerous effective medications for tobacco dependence and clinicians should encourage their use by all patients attempting to quit smoking, except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents). (SOE=A)
- Clinicians should also consider the use of certain combinations of medications identified as effective in this Guideline. (SOE=A)



12

#6 Key Recommendation

- Seven first-line medications reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine lozenge
 - Nicotine nasal spray
 - Nicotine patch
 - Varenicline

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Medication Mega-meta-analysis

- Combined all medications, long-term medication use and medication combinations
- 83 RCTs
- Both placebo and patch used as reference group
- Yielded relative efficacy

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14

Medication Combinations

Medication	Number of arms	Estimated odds ratio (95% C. I.)	Estimated abstinence rate (95% C. I.)
Placebo	80	1.0	13.8
Patch (> 14 weeks) + ad lib NRT (gum or spray)	3	3.6 (2.5, 5.2)	36.5 (28.6, 45.3)
Patch + Bupropion SR	3	2.5 (1.9, 3.4)	28.9 (23.5, 35.1)
Patch + Nortriptyline	2	2.3 (1.3, 4.2)	27.3 (17.2, 40.4)
Patch + Inhaler	2	2.2 (1.3, 3.6)	25.8 (17.4, 36.5)
Patch + Second generation antidepressants	3	2.0 (1.2, 3.4)	24.3 (16.1, 35.0)

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Long-term Medications

Medication	Number of arms	Estimated odds ratio (95% C. I.)	Estimated abstinence rate (95% C. I.)
Placebo	80	1.0	13.8
Long-Term Nicotine Gum (> 14 weeks)	6	2.2 (1.5, 3.2)	26.1 (19.7, 33.6)
Nicotine Patch (6-14 weeks)	32	1.9 (1.7, 2.2)	23.4 (21.3, 25.8)
Long-Term Nicotine Patch (> 14 weeks)	10	1.9 (1.7, 2.3)	23.7 (21.0, 26.6)
Nicotine Gum (6-14 weeks)	15	1.5 (1.2, 1.7)	19.0 (16.5, 21.9)

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Relative Efficacy

Medication	Number of arms	Estimated odds ratio (95% C. I.)
Nicotine Patch (reference group)	32	1.0
Varenicline (2 mg/day)	5	1.6 (1.3, 2.0)
Patch (long-term; >14 weeks) + NRT (gum or spray)	3	1.9 (1.3, 2.7)
Patch + Bupropion SR	3	1.3 (1.0, 1.8)

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#7 Key Recommendation

- Counseling and medication are effective when used by themselves for treating tobacco dependence. However, the combination of counseling and medication is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication. (SOE=A)

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18

Combinations: Medication and Counseling

Effectiveness of and estimated abstinence rates for the combination of counseling and medication versus medication alone (n = 18 studies)

Treatment	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Medication alone	8	1.0	21.7
Medication and counseling	39	1.4 (1.2, 1.6)	27.6 (25.0, 30.3)

19

Combinations: Medication and Counseling

Effectiveness of and estimated abstinence rates for the combination of counseling and medication versus counseling alone (n = 9 studies)

Treatment	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Counseling alone	11	1.0	14.6
Medication and counseling	13	1.7 (1.3, 2.1)	22.1 (18.1, 26.8)

20

#8 Key Recommendation

- Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, clinicians and healthcare delivery systems should both ensure patient access to quitlines and promote quitline use. (SOE=A)

21

Advantages of quitlines

- Accessibility
- Appeal to those who are uncomfortable in a group setting
- Smokers more likely to use a quitline than face-to-face program
- No cost to patient
- Easy intervention for healthcare professionals
- It only takes 30 seconds to refer a patient to a toll-free tobacco-cessation quitline.
- Quitlines are staffed by trained cessation experts who tailor a plan and advice for each caller.
- Calling a quitline can double a smoker's chance of successfully quitting.

22

Pro-active Quitlines

Effectiveness of and estimated abstinence rates for quitline counseling compared to minimal interventions, self-help or no counseling (n = 9 studies)

Intervention	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Minimal or no counseling or self-help	11	1.0	8.5
Quitline counseling	11	1.6 (1.4, 1.8)	12.7 (11.3, 14.2)

23

Pro-active Quitlines


Effectiveness of and estimated abstinence rates for quitline counseling and medication compared to medication alone (n = 6 studies)

Intervention	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Medication alone	6	1.0	23.2
Medication and quitline counseling	6	1.3 (1.1, 1.6)	28.1 (24.5, 32.0)

24

#9 Key Recommendation

- If a tobacco user is currently unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be effective in increasing future quit attempts. (SOE=B)



25

Motivational Interviewing (MI)

- The four general principles that underlie MI are:
 - Express empathy
 - Develop discrepancy
 - Roll with resistance
 - Support self-efficacy




26


5386 Woods and Jain / Am J Prev Med 2010;38(3):S385-S392

Table 1. Recommendations to increase patient demand for tobacco treatments


Recommendation	Design principle	Target
1. Reframe the definition of success.	Lower the bar Make it tangible	Patients and clinicians
2. Portray proven treatments as the best care.	Make it look and feel good	Patients and clinicians
3. Redesign the SA's of tobacco intervention.	Lower the bar Facilitate transitions	Clinicians and healthcare system administrators
4. Be ready and deliver the right treatment at the right time.	Integrate with their lives Connect the dots	Clinicians
5. Move tobacco from the social history to the problem list.	Connect the dots Facilitate transitions	Clinicians
6. Use words as therapy and language that makes sense.	Make it look and feel good	Clinicians
7. Fit tobacco treatment into clinical team workflows.	Foster community Facilitate transitions	Healthcare teams
8. Embed tobacco treatment into health information technology.	Connect the dots Lower the bar	Clinicians and healthcare system administrators
9. Make every encounter an opportunity to intervene.	Connect the dots Make progress tangible	Clinicians and healthcare system administrators
10. End social disparities for tobacco users.	Foster community	Healthcare teams and healthcare system administrators



27



- Grant from Texas Dept. of State Health Services
- Community-based coalition
- Comprehensive tobacco prevention and control program
- Data-driven program, evidence-based interventions



28



TPCC

Clear the Air

ENVision
Healthier Environment... Healthier You

How was this toolkit designed?

Background Information

Want to help your patients quit?

Solutions and Resources

Environmental Initiative



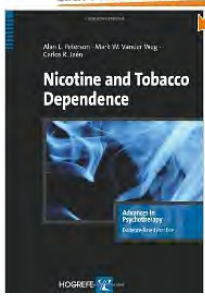
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- Nicotine and Tobacco Dependence


Resources for Practice

"A handy compendium of everything a clinician needs to know to assess the degree of tobacco dependence and to decide on the appropriate treatment. Every practice should have this book."

Steven A. Schroeder, MD,
Distinguished Professor of Health and Health Care, Department of Medicine, Director, Smoking Cessation Leadership Center, University of California, San Francisco, CA



Click to LOOK INSIDE!



30

... what it means to YOU

Smoking around others increases their risk for heart attack and death. By not smoking, you help protect your family, friends, and coworkers.

A public smoking ban drastically cut heart attacks.

Publics, Colorado banned smoking in work places and all public areas in July 2003. The number of people hospitalized for heart attacks dropped 41 percent in 3 years.



257 heart attacks per 100,000 (January 2003 - June 2005)

187 heart attacks per 100,000 (July 2005 - December 2006)

152 heart attacks per 100,000 (January 2007 - June 2008)

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31

Think, pair and share

- Is there a change you can make in your office that can make a difference in how you approach patients who use tobacco?
- What one strategy can you incorporate next week in your office to improve the dental health of your patients who use tobacco?

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32


Summary

- Tobacco use is an important cause of oral disease
- There is evidence for effective treatments for tobacco use and dependence treatment
- Identify strategies to increase demand for tobacco use and dependence
- There are resources and local opportunities available for you to engage in tobacco control

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33

2008 Clinical Practice Update



- Tobacco dependence is a chronic disease
- Tobacco users need to be identified in the practice
- Treatments work for a wide range of populations
- Brief treatment is effective
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Fiore MC, Jaén CR, Baker TB, et al. Treating tobacco use and dependence clinical practice guideline, 2008 update. Rockville MD: USDHHS, 2008.

34

Supplemental Slides: Medications that work

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35

Pharmacologic Methods: First-line Therapies

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

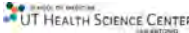
- Nicotine replacement therapy (NRT)
 - nicotine gum, patch, lozenge, nasal spray, inhaler
- Partial nicotine receptor agonist
 - varenicline
- Psychotropics
 - Sustained-release bupropion

Currently, no medications have an FDA indication for use in spit tobacco cessation.

36

Nicotine Gum

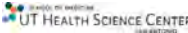
<p>Advantages</p> <ul style="list-style-type: none"> ■ Gum use may satisfy oral cravings. ■ Gum use may delay weight gain. ■ Patients can titrate therapy to manage withdrawal symptoms. 	<p>Disadvantages</p> <ul style="list-style-type: none"> ■ Gum may not be socially acceptable. ■ Gum is difficult to use with dentures. ■ Patients must use proper chewing technique to minimize adverse effects.
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37

Transdermal Nicotine Patch

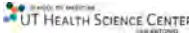
<p>Advantages</p> <ul style="list-style-type: none"> ■ The patch provides consistent nicotine levels. ■ Three strengths: 7,14,21 mg ■ The patch is easy to use and conceal. ■ Fewer compliance issues are associated with the patch. 	<p>Disadvantages</p> <ul style="list-style-type: none"> ■ Patients cannot titrate the dose. ■ Allergic reactions to adhesive may occur. ■ 16-hr patch may lead to morning nicotine cravings. ■ Patients with dermatologic conditions should not use.
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38

Nicotine Lozenge

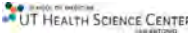
<p>Advantages</p> <ul style="list-style-type: none"> ■ Lozenge use may satisfy oral cravings. ■ The lozenge is easy to use and conceal. ■ Patients can titrate therapy to manage withdrawal symptoms. 	<p>Disadvantages</p> <ul style="list-style-type: none"> ■ Gastrointestinal side effects (nausea, hiccups, and heartburn) may be bothersome.
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39

Nicotine Nasal Spray

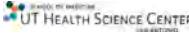
<p>Advantages</p> <ul style="list-style-type: none"> ■ Patients can easily titrate therapy to rapidly manage withdrawal symptoms. 	<p>Disadvantages</p> <ul style="list-style-type: none"> ■ Nasal/throat irritation ■ Dependence can result. ■ Patients must wait 5 minutes before driving or operating heavy machinery. ■ Patients with chronic nasal disorders or severe reactive airway disease should not use the spray.
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40

Nicotine Inhaler


<p>Advantages</p> <ul style="list-style-type: none"> ■ Patients can easily titrate therapy to manage withdrawal symptoms. ■ The inhaler mimics hand-to-mouth ritual of smoking. 	<p>Disadvantages</p> <ul style="list-style-type: none"> ■ Initial throat or mouth irritation. ■ Can't store cartridges in very warm conditions or use in very cold conditions. ■ Patients with underlying bronchospastic disease must use with caution.
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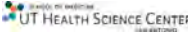


41

BUPROPION SR: Mechanism of Action

- Atypical antidepressant thought to affect levels of various brain neurotransmitters
 - Dopamine
 - Norepinephrine
- Clinical effects
 - ↓ craving for cigarettes
 - ↓ symptoms of nicotine withdrawal





42

BUPROPION SR: Dosing

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

Initial treatment

- 150 mg po q AM x 3 days

Then...

- 150 mg po bid
- Duration, 7–12 weeks

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BUPROPION SR

Advantages

- Easy to use.
- Bupropion SR can be used with NRT.
- Might be beneficial for patients with depression.

Disadvantages

- Seizure risk is increased.
- Bupropion SR should be avoided or used with caution in patients with:
 - History of seizures or cranial trauma
 - Anorexia or bulimia nervosa
 - Medications that lower seizure threshold
 - Severe hepatic cirrhosis
 - Concurrent use of any form of Wellbutrin, or any MAO inhibitor in preceding 14 days
 - Patients undergoing abrupt discontinuation of alcohol or sedatives

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Varenicline

Effectiveness and abstinence rates for various medications and medication combinations compared to placebo at 6-months post-quit (n = 86 studies)

Medication	Number of arms	Estimated odds ratio (95% C. I.)	Estimated abstinence rate (95% C. I.)
Placebo	80	1.0	13.8
Varenicline (2 mg/day)	5	3.1 (2.5, 3.8)	33.2 (28.9, 37.8)
Varenicline (1 mg/day)	3	2.1 (1.5, 3.0)	25.4 (19.6, 32.2)

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VARENICLINE: Mechanism of Action

- Binds with high affinity and selectivity at $\alpha_4\beta_2$ neuronal nicotinic acetylcholine receptors
 - Stimulates low-level agonist activity
 - Competitively inhibits binding of nicotine
- Clinical effects
 - ↓ symptoms of nicotine withdrawal
 - Blocks dopaminergic stimulation responsible for reinforcement & reward associated with smoking

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VARENICLINE: Dosing

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

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

Initial dose titration

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47

VARENICLINE: Adverse Effects

Common side effects ($\geq 5\%$ and twice the rate observed in placebo-treated patients) include:

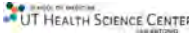
- Nausea (30%)
- Sleep disturbances (insomnia 18%, abnormal dreams 13%)
- Constipation (8%)
- Flatulence (6%)
- Vomiting (5%)

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VARENICLINE:

<h3>ADVANTAGES</h3> <ul style="list-style-type: none"> Varenicline is an oral formulation with twice-a-day dosing Varenicline offers a new mechanism of action for persons who previously failed using other medications 	<h3>DISADVANTAGES</h3> <ul style="list-style-type: none"> May induce nausea in up to one third of patients Avoid in chronic renal failure Post-marketing surveillance data just emerging New warning about rare but important psychiatric symptoms; hard to distinguish from nicotine withdrawal
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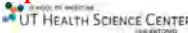
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Varenicline: FDA warning

- In February 2008, the FDA added a warning regarding the use of varenicline. Specifically, it noted that depressed mood, agitation, changes in behavior, suicidal ideation, and suicide have been reported in patients attempting to quit smoking while using varenicline. The FDA recommends that patients should tell their health care provider about any history of psychiatric illness prior to starting this medication, and clinicians should monitor patients for changes in mood and behavior when prescribing this medication.

SCREEN and MONITOR for psychiatric problems

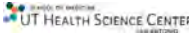
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Varenicline: FDA Warning CV Risk

On July 22, 2011 the FDA announced results of a trial that showed efficacy for varenicline among patients with stable cardiovascular disease. This trial also demonstrated that varenicline may be associated with a small, increased risk of certain cardiovascular adverse events in these patients. The absolute risk of cardiovascular adverse events with varenicline, in relation to its efficacy, is small.

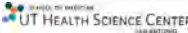
Always weigh the potential benefits against its potential risks when deciding to use varenicline in patients with cardiovascular disease.

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51

Patients with mental illness

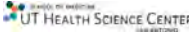
- Most will need medication
- Patients with bipolar disorder or eating disorders should not receive bupropion
- Patch is effective for those with schizophrenia
- Varenicline safety not yet established

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52

Patients with mental illness

- Quitting can increase the effect of some psychiatric medications Dose adjustments may be needed
- Check for relapse to mental illness with changes in smoking status

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53