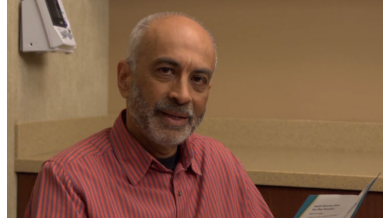




PUTTING IT ALL TOGETHER: PATIENT ENCOUNTERS



PATIENT ENCOUNTER #1



“But I’ve tried everything. None of these quit smoking medicines *ever* work for me!”



PATIENTS WHO HAVE RELAPSED AFTER USING MEDICATIONS

▪ Step 1: Ask

“What medications have you tried in the past?”

- “Tell me how you used them.”

“Did you receive any professional advice or enroll in a quitting support program?”

- IF YES: “Tell me what you liked, or didn’t like, about it.”
- IF NO: “What are your thoughts about enrolling in a formal quitting program this time?”



PATIENTS WHO HAVE RELAPSED AFTER USING MEDICATIONS

▪ Step 2: Advise

“The best way to quit is to combine a smoking cessation medication with a support program.”

For patients who are willing to use medication(s):

- Conduct a tobacco use history; determine viable treatment options
- Consider patient preferences, insurance coverage, and cost



PATIENTS WHO HAVE RELAPSED AFTER USING MEDICATIONS

▪ Step 2: Advise (cont’d) and Assist

- Patients with previous failed quit attempts using medication(s) for cessation

– Prior medication used incorrectly:

- Carefully review usage instructions / emphasize adherence (daily / duration)

– Prior medication used correctly, well-tolerated, appeared to have been effective:

- Consider repeating same medication in combination with an enhanced behavioral support program



PATIENTS WHO HAVE RELAPSED AFTER USING MEDICATIONS

▪ Step 2: Advise and assist (cont’d)

- Prior medication used correctly but did not control withdrawal symptoms, or patient prefers a different medication:

- Review alternative options
- Emphasize importance of the behavioral aspects of quitting
- Promote adherence (daily use and full duration of therapy)

Rx||CHANGE “Drugs don’t work...
 ...in patients who don’t take them.”



C. Everett Koop, MD
 U.S. Surgeon General, 1982-1989


Medication adherence should be addressed at each encounter.

Rx||CHANGE The 5 A’s

- ASK
- ADVISE
- ASSESS
- ASSIST
- ARRANGE

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update Clinical Practice Guideline*. Rockville, MD: USDHHS, PHS, May 2008.

Rx||CHANGE PATIENT ENCOUNTER #2



“I don’t understand...how will a quitline help me to stop smoking? How does it work?”

Rx||CHANGE WHAT ARE TOBACCO QUITLINES?


- Tobacco cessation counseling program, provided at no cost via telephone
- Up to 4–6 personalized sessions (varies by state)
- Staffed by highly trained specialists
- Some state quitlines offer pharmacotherapy at no cost (or reduced cost)
- 28.1% success rate for patients who use the quitline and a medication for cessation (vs 12.7% for quitline use alone)*

Quitlines have broad reach and are recommended as an effective strategy in the Clinical Practice Guideline.

*Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update Clinical Practice Guideline*. Rockville, MD: USDHHS, PHS, May 2008.

Rx||CHANGE WHEN a PATIENT CALLS the QUITLINE

- Caller is routed to language-appropriate staff
- Brief Questionnaire
 - Contact and demographic information
 - Smoking behavior
- Choice of services
 - Individualized telephone counseling
 - Quitting literature mailed within 24 hrs
 - Referral to local programs, as appropriate



The Tobacco Quitline is a formal cessation program, with multiple sessions. It is NOT a crisis hotline.

Rx||CHANGE BRIEF COUNSELING: ASK, ADVISE, REFER

- ASK → about tobacco USE
- ADVISE → tobacco users to QUIT
- REFER → to other resources

Patient receives assistance from other resources, with follow-up counseling arranged

- ASSIST
- ARRANGE



MAKE a COMMITMENT...

Address tobacco use

with all patients.

At a minimum,

make a commitment to incorporate brief tobacco interventions as part of routine patient care.

Ask, Advise, and Refer.



PATIENT ENCOUNTER #3

- **Your health screening intake form for Greg** reveals that he is a 54 yo male with controlled HTN, hyperlipidemia, depression, chronic rhinitis
- **Current medications:**
 - Valsartan 80mg QAM for HTN
 - Atorvastatin 40mg QAM for hyperlipidemia
 - Bupropion XL 300mg QAM for depression
 - Fluticasone (50mcg/spray), 1 spray in each nostril QAM for rhinitis



KEY CONSIDERATIONS FOR GREG

- **Tobacco use history:**
 - Current use: 25 cigarettes/day x 25 years
 - No other forms of tobacco or vaping
 - Smokes within 20 min of waking
 - Previous quit attempts: “many” (cold turkey, gum, patch)
 - Longest duration tobacco-free: 2 weeks (patch)
 - Last quit attempt, 10 months ago (patch only)
 - Reasons for relapse: withdrawal, other smokers



KEY CONSIDERATIONS FOR GREG (cont'd)

- **Key issues for upcoming quit attempt:**
 - Reasons, motivation for wanting to quit: worsening CVD
 - Father died young, of an acute MI
 - Caffeine: 2 cups of coffee in the morning; 1 cola with lunch and dinner
- **Importance, Readiness, and Confidence ratings:**
 - Importance of quitting: 10
 - Readiness to quit: 10
 - Confidence for quitting: 9



SCREENING CONSIDERATIONS: HIGH-RISK PATIENTS

- **Cardiovascular disease with:**
 - Myocardial infarction in past 2 weeks
 - History of arrhythmias or irregular heartbeat
 - Unstable angina or chest pain with strenuous activity
- History of mental health disorder(s) AND is perceived to not be stable
- Pregnant or planning to become pregnant (N/A)

If YES – Consult with or refer Greg to a primary care provider, psychiatrist, or other provider, as appropriate.



MEDICATION SELECTION FOR GREG

- **Key considerations for medication selection:**
 - Previous failed quit attempts with monotherapy (patch, gum)
 - Did not like chewing the gum
 - Challenges adhering with complex regimens
 - Taking bupropion XL 300mg daily for depression x 18 mo
 - Concerned about side effects of varenicline
 - Chronic rhinitis



DRUG INTERACTION: TOBACCO SMOKE and CAFFEINE

- Assess caffeine intake from all sources
- Caffeine levels increase ~56% upon quitting
- Challenges:
 - Nicotine withdrawal effects may be enhanced by increased caffeine levels
 - Insomnia can be due to ↑ caffeine levels or a side effect of a smoking cessation drug (e.g., 24-hr nicotine patch, bupropion SR, varenicline)
- Recommendations:
 - Decrease caffeine intake when quitting
 - Stop consumption by early afternoon for individuals with a typical bedtime



COMBINATION NRT

Combination NRT

- Long-acting formulation (patch)
 - Produces relatively constant levels of nicotine
- PLUS**
- Short-acting formulation (gum, inhaler, lozenge, nasal spray)
 - Allows for acute dose titration as needed for nicotine withdrawal symptoms

Combination therapy increases dosing flexibility and overall plasma nicotine concentration.



GREG'S QUESTION



"Chantix... isn't that the drug with all the horrible side effects?"



Articles

Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial

Robert M. Anthenelli, Neal J. Benowitz, Robert West, Lisa St Aubin, Thomas Muller, David Lawrence, John Archer, Cristina Bus, Arik Kishin, Aileen Gato

Summary

Background Substantial concerns have been raised about the neuropsychiatric safety of the smoking cessation medications varenicline and bupropion. Their efficacy relative to nicotine patch largely relies on indirect comparisons, and there is limited information on safety and efficacy in smokers with psychiatric disorders. We compared the relative neuropsychiatric safety risk and efficacy of varenicline and bupropion with nicotine patch and placebo in smokers with and without psychiatric disorders.

Methods We did a randomised, double-blind, triple-blinded, placebo-controlled and active-controlled (nicotine patch: 21 mg per day with taper) trial of varenicline (1 mg twice a day) and bupropion (150 mg twice a day) for 12 weeks with 12-week non-treatment follow-up done at 140 centres (clinical trial centres, academic centres, and outpatient clinics) in 16 countries between Nov 30, 2011, and Jan 11, 2015. Participants were matched-to-quit smokers with and without psychiatric disorders who received brief cessation counselling at each visit. Randomization

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FDA U.S. FOOD & DRUG ADMINISTRATION

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Drug Safety and Availability

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FDA Drug Safety Communication: FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings

This is an update to the Drug Safety Communication issued on March 9, 2015.

Safety Announcement

(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, we have determined that 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. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medicines.

As a result of our review of the large clinical trial, we are removing the boxed warning, FDA's most prominent warning, for serious mental health side effects from the Chantix drug label. The language describing the serious mental health side effects from Chantix during smoking are also to be removed from the boxed warning in the Zyban label. We are also updating the existing warning section in both labels that describes the side effects on mood, behavior, or thinking to exclude the results from the clinical trial. This



GREG at 14-DAY FOLLOW-UP



"I've been having a hard time sleeping – do you think that's the Chantix?"

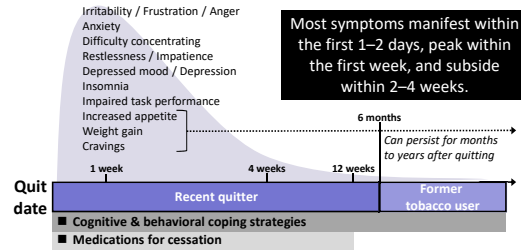


Which of the following might be contributing to Greg's insomnia?

- A. Bupropion XL – unlikely, he has been on this medication for 18 months
- B. Varenicline – possible, insomnia occurs in 13% of patients
- C. Drug interaction between tobacco smoke and caffeine – likely, if he is still consuming caffeine
- D. Nicotine withdrawal symptoms – can cause insomnia (see graph)



NICOTINE WITHDRAWAL SYMPTOMS: Time Course* and Management



*Timeline aspect of the figure is not according to scale.

Data from Hughes. (2007). *Nicotine Tob Res* 9:315–327.



CESSATION APPROACHES for ENDS LIMITED EVIDENCE to GUIDE TREATMENT

- Behavioral counseling
- Pharmacotherapy
 - Nicotine replacement therapy
 - If patient has switched from smoking to vaping: start with pre-vaping # cigarettes/day and TTFC to guide initial dosing
 - If user has only vaped nicotine: Estimate nicotine intake
 - ≥20 mg/day, start with 21 mg patch
 - <20 mg/day, start with 14 mg patch
 - Add short-acting NRT for break-through
 - Early follow-up to assess response and adjust dosing as needed
 - Varenicline or Bupropion SR

Therapeutic Research Center. (2019). Help patients break the e-cigarette habit. *Pharmacists Letter* (December).



SUMMARY

- There are two parts to smoking and there are two parts to quitting.
- The 5 A's is an appropriate framework for comprehensive tobacco cessation counseling.
- In the absence of time or expertise...
 - Ask about tobacco use
 - Advise patients to quit
 - Refer patients to the tobacco quitline or other resources for assistance and follow-up