

The Nicotine Challenger

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This issue: Reaching Out

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A View From The Director

by Jonathan Foulds, PhD

How can we make tobacco treatment available to more smokers?

Although the US Public Health Service Clinical Practice Guideline for the Treatment of Tobacco Use and Dependence recommends that physicians ask all patients about their tobacco use, and all smokers be offered an approved medication to help them quit, this is clearly not happening¹. An analysis of the 2001-2 national Ambulatory Care Survey² found that tobacco counseling occurred in 22.5% of visits by tobacco users, and cessation medications were prescribed on only 2.4% of occasions (with the odds being 15 times higher if the patient requested it). These rates are no higher than were found in this survey in 1991. A different study involving direct observation of physician encounters with patients³ found that of 244 smokers identified, physicians provided assistance with smoking cessation for 38% (range among practices = 0%-100%). Bupropion and nicotine replacement therapies were discussed with smokers in 31% and 17% of encounters, respectively. Numerous other studies have documented poor adherence of physicians to the basic recommendations in the 1996 and 2000 Tobacco Treatment Guidelines¹ regarding the "5 As" (Ask, Advise, Assess, Assist, Arrange), with particularly low rates of "assisting" on use of medications and "arranging" follow-ups.⁴⁻⁶ This partly relates to lack of familiarity with the Guideline,⁷ but time constraints and the perception that smokers are unreceptive to counseling were the two most common barriers cited by both physicians and office managers in one study⁸. Thorndike et al⁹ reported that there has been a small increase in physicians' rates of patients' smoking status identification and a small decrease in rates of counseling smokers over the decade 1993-2003. This lack of progress may reflect barriers in the US health care environment, including limited physician time to provide counseling.

A National Commission on Prevention Priorities, led by former US Surgeon General Dr David Satcher, ranked 25 preventive healthcare interventions for their population impact and cost-effectiveness¹⁰. Three interventions achieved the top ranking on both of these measures (total score=10): daily aspirin for people over 40, childhood immunizations, and brief counseling and pharmacotherapy for tobacco use. Of all the interventions evaluated, the tobacco intervention was estimated to have by far the biggest impact on Quality-Adjusted Life Years saved if widely implemented (1.3 million annually). Under-treatment of tobacco dependence therefore represents a major failure in the US healthcare system. So what are the causes and potential remedies? Here are my thoughts:

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CHANTIX: MIRACLE PILL OR DANGEROUS DRUG?

by Michael B. Steinberg, MD MPH
Medical Director and Associate Professor

The answer is **neither**...

Chantix (varenicline) is the latest FDA approved medication to be used for treating tobacco dependence. In the clinical trials to date and in early anecdotal reports from tobacco treatment clinicians, Chantix is performing very well as an effective aid to help smokers quit. Here at the Tobacco Dependence Clinic, we are prescribing Chantix quite actively, and have found it to be a very useful, effective, and well-tolerated medication both for smokers who have never used pharmacotherapy and those who have battled tobacco dependence with other medications in the past. Despite these results, smokers (and providers) need to be continually reminded that this is not a "magic-bullet" and that all pharmacological agents perform better when made part of a comprehensive tobacco dependence treatment plan.



Recently, widely broadcasted case reports have aroused concern over the safety of Chantix, but the forces at play here are complex:

- In the few thousands of subjects enrolled in Pfizer's published clinical trials, there did not seem to be concerning reports of erratic behavior, depression, or suicidal ideation
- It should be noted that in these early trials (as customary for many initial trials), subjects were screened out for many psychiatric and medical illnesses
- The current market of Chantix is estimated around 3,000,000 users, much greater numbers than were able to be studied in clinical trials
- It stands to reason that now that the medication is out in the general public, previous rare effects might present themselves more commonly (this is why post-marketing surveillance is so important)
- The reports of erratic behavior in the media are not clearly linked solely to the use of this medication, because there are often several factors in play. For example, stopping smoking

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The **Tobacco Dependence Program** is dedicated to reducing the harm to health caused by tobacco use. We do this through education, treatment, research and advocacy.

The **Tobacco Dependence Program**, UMDNJ-School of Public Health, helps programs, organizations and clinicians deal with tobacco issues and nicotine dependence.

Products and services include:

- ◆ consultation
- ◆ education and training
- ◆ policy & program development
- ◆ treatment planning
- ◆ staff recovery workshops
- ◆ tobacco dependence treatment



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can, on its own, influence mood. Additionally, other substance use, such as alcohol, may have been involved in some of these case reports.

- However, desire of the general media climate (i.e., TV, newspaper, magazine) to sell a story, combined with easy access to (often times unreliable) internet information sources, can cause an increase in the perceived risk of a side-effect to a level much higher than the actual risk.

So what should a prudent clinician do?

My opinion is that we need to take these recent reports in their proper context. We should continue to practice close, appropriate monitoring, and not panic. After all, Chantix remains an important part of the pharmacologic arsenal for tobacco dependence treatment. It is a proven effective medication and has good trial safety data for up to 1 year of use. The few case reports seem to be isolated instances of erratic behavior, depression, etc., and have involved other factors (e.g., history of mental illness, alcohol use). In addition, quitting smoking has its own set of withdrawal symptoms that can affect mood and behavior. The reasonable response to this is to:

1. Continue to use this effective medication in our general population of smokers
2. Monitor patients on Chantix for mood changes, erratic behavior, or other side effects (as would be part of good clinical practice), and report instances as appropriate.
3. Allow the FDA to explore these reports with due scientific rigor
4. Let the evidence inform the process - do not abandon an effective and life-saving treatment solely due to media reports.
5. Have an open dialogue with patients regarding their individual choice of medication

As dedicated clinicians, we aim to improve the lives and well being of those we are privileged to care for, and we must let the evidence guide us in safely and effectively achieving this goal.