Ready to Quit? The Risks and Rewards of a Potent Smoking-Cessation Drug

May 28, 2008 By David Evans

Recent reports say Chantix, the powerful smoking-cessation drug from Pfizer, may have problematic side effects. Given the efficacy of the drug, however, and the dangers of smoking, Chantix could still be a prescription for success. The key for people living with HIV: Knowing the drug's potential risks and monitoring its effect on your body while taking it.

Chantix (veranicline) is a successful stop-smoking aid—according to claims made in television advertisements by its manufacturer, Pfizer. But a report released last week by the Institute for Safe Medication Practices (ISMP), a nonprofit organization that educates consumers about medicinal products, reveals that the U.S. Food and Drug Administration (FDA) has received many safety warnings regarding Chantix over the past year.

The reports detail accidents and falls, vision problems and heart rhythm disturbances among people using the drug. The news follows another set of reports detailing psychiatric symptoms—including such marked behavioral changes as agitation, depressed mood, and suicidal thoughts and actions—that caused Pfizer to issue a warning letter about Chantix earlier this year. The Federal Aviation Administration (FAA) considered the new side effects so serious that it now bars airline pilots from using the medication. Trucking regulators joined the FAA this week, banning Chantix use among its drivers.

So what do these reports mean for HIV-positive wannabe ex-smokers? Gary Blick, MD, a Connecticut HIV specialist with nearly two decades of experience, feels that the FAA's response is reasonable but says his experience with Chantix in his HIV-positive patients has been almost universally good. "Chantix, for me, has been really the first drug where our patients have been successful [at quitting smoking] the majority of the time," says Dr. Blick.

And that's a message he hopes that other physicians treating HIV-positive patients embrace. "It's such an important thing to talk to our patients about quitting smoking," Blick says, "since I think we're going to be seeing a lot of cardiovascular disease in our HIV-positive patients. In fact, I think we're already starting to see it."

Lirio Covey, PhD, associate professor of clinical psychology at Columbia University and a lead researcher on two of the Pfizer-sponsored Chantix studies, says that it's difficult to put the safety warnings into proper context, as all of the Chantix studies conducted so far excluded people who

had other underlying health problems, including HIV. But she adds, “Studies are being carried out to test whether the [incidents leading to the warnings] are really [because of] side effects of Chantix or coming from some other cause.”

Perhaps the best thing smokers looking to quit can do is learn and weigh the potential risks and benefits of the various smoking-cessation aids available and make an educated decision in consultation with their health care provider. While Chantix’s critics may caution people about its use, no one would argue that continuing to smoke is a good idea.

Quitting Smoking 101

Anyone who has ever tried to quit smoking is all too familiar with the withdrawal symptoms: irritability, restlessness, anxiety, difficulty concentrating, increased hunger, insomnia and a sometimes overwhelming craving for tobacco. Our closest friends and loved ones learn to walk on tiptoes around us in the early days of a quit attempt.

According to a survey of HIV-positive New Yorkers over the age of 50, conducted in 2006 by the AIDS Community Research Initiative of America (ACRIA), plenty of people with HIV are likely familiar with the power of nicotine addiction. ACRIA found that 84 percent of the people surveyed had a history of smoking and 57 percent continued to smoke. Covey says that she’s also familiar with research showing that people living with HIV are much more likely to be smokers than the general public is.

This is a serious and growing concern, says Blick. Smoking tobacco has been linked to lung cancer, emphysema, strokes and heart attacks, and all of these ailments are more common as people age. Combination antiretroviral (ARV) treatment has been a blessing, in the sense that so many more people with HIV are surviving into older age. It also means, however, that a growing number of people with HIV will find themselves at increased risk for these diseases.

What’s more, research shows that quitting cold turkey rarely works. In most studies, fewer than 5 percent of people who quit on their own are still smoke-free one year later. The only way to increase the odds of success, according to science, is to take advantage of the various support programs and quit-smoking aids available, and the data show that Chantix may be the most successful.

“Chantix,” says Covey, “is the first designer drug for smokers in the sense that its development was based on how tobacco interacts with the brain.”

Chantix binds to the same receptors in the brain as nicotine. Not only does this reduce the craving for nicotine, but it prevents someone using the drug from experiencing a rush from smoking a cigarette. Patients are treated with Chantix for 12 weeks and start taking the drug approximately one week before their quit date. For those who have successfully stopped smoking at the end of 12 weeks, an additional 12 weeks of Chantix therapy is recommended to further increase the likelihood of long-term abstinence.

The Pfizer advertisements heavily promote the results of two clinical trials demonstrating that 44 percent of Chantix users were smoke-free 12 weeks after quitting, compared with 30 percent of those using Zyban, an antidepressant also approved to aid smoking cessation, and 18 percent of those who received a placebo. A year after entering the study, quit rates dropped in all three groups—22 percent of people taking Chantix, compared with 16 percent using Zyban and 10 percent using placebo, were still smoke-free.

Blick's experience with his patients has been even more positive. "My only patients who've not been successful are those who've failed to take it twice a day, either because of [lack of] motivation or because of the side effects."

Charles Skiba, DO, of the Pacific Oaks Medical Group in Beverly Hills, California, says his HIV-positive patients have also had good luck with Chantix. "I've had patients who've tried the gum and other products, and who were really skeptical at first, but they were amazed at how much Chantix reduced their cravings."

Growing Concerns

The first sign of trouble for Chantix, however, came on January 17, 2008, when Pfizer issued a warning letter to physicians, indicating that it had received reports of neuropsychiatric symptoms in people taking Chantix, such as the aforementioned marked behavioral changes, agitation, depressed mood, and suicidal thoughts and behavior.

Part of the problem, according to Covey, is that the rules of the Chantix clinical trials were such that anyone with a history of mental illness was excluded from the trials. Now that the product is approved, she says, it is being used in everybody, regardless of his or her mental health history. Though new trials that will compare Chantix to other products in people with histories of psychiatric problems are in the works, it is not yet possible to conclude that Chantix therapy increases the risk of these problems—or worsens psychiatric problems in those who already have them. Covey notes, however, that simply quitting smoking can inspire many of these same symptoms, especially in people with mental health problems.

Blick says it's important to talk about the side effects with patients and has been successful in helping many people through them. He says that the side effects that have been most troublesome for his patients are what he calls, "emotional disturbances." He says he warns all his patients who try Chantix that they "may get a little more emotional, a little more depressed, [and have] vivid dreams."

"What I do is tell them to call me immediately if they experience [those symptoms]," he says. When people do have these side effects, Blick says, "I usually end up taking them off the Chantix and then medicating them using a serotonin reuptake inhibitor and then restarting the Chantix. I've been successful doing that."

Last week, the ISMP released the results of its study, listing additional problems associated with

smoking-cessation therapy using Chantix, including accidental injury, vision disturbances and heart rhythm disturbances.

The ISMP report says that no other FDA-approved drug received even close to the same number of safety reports—Chantix, the ISMP says, was written up a total of 988 times. Blick says, “The [FAA’s action] is entirely reasonable. I wouldn’t want the pilot of my airplane to be on a new drug that we don’t know everything about.” He also says, however, that he hasn’t seen the majority of the new side effects outlined in the ISMP report.

Skiba agrees, asking, “The FDA requires you to list every side effect that occurs, but how are you supposed to determine in every case, whether or not it was the drug that caused it?”

For anyone considering using Chantix to help break the cigarette habit, Covey suggests “careful monitoring” by health care providers. “[Providers] can’t just write a prescription and say, ‘hello and goodbye.’ It’s a [powerful] drug and has effects on the brain.”

To get more information and support for quitting smoking in your area call 800.QUIT.NOW. Smoking-cessation experts at the Mayo Clinic also recommend the websites becomeanex.org, quitnet.com and naquitline.org.

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