

Chantix unsuitable for first-line smoking cessation use

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The poor safety profile of the smoking-cessation drug varenicline (Chantix) makes it unsuitable for first-line use, according to a study published in the Nov. 2 edition of the journal *PLoS One*, an online publication of the Public Library of Science.

Varenicline, which already carries a "black box warning" from the U.S. [Food and Drug Administration](#) (FDA), showed a substantially increased risk of reported depression or suicidal behavior compared to other smoking-cessation treatments, according to researchers at Wake Forest Baptist Medical Center, the Institute for Safe Medication Practices, Harvard Medical School and Johns Hopkins University School of Medicine.

The researchers found that 90 percent of all reported suicides related to smoking-cessation drugs since 1998 implicated varenicline, even though it was on the market only four years in the nearly 13-year study period. They also found that varenicline was eight times more likely to result in a reported case of suicidal behavior or depression than nicotine replacement products.

"Our study contradicts the implications of a recent review by the FDA showing no difference in psychiatric hospitalizations between varenicline and nicotine replacement patches," said Curt D. Furberg, M.D., Ph.D., professor of Public Health Sciences at Wake Forest Baptist, co-author of the study and a nationally recognized leader in drug safety research. "The FDA hospitalization studies were flawed because

they could not capture most of the serious psychiatric side effects, including suicide, depression, aggression and assaults. These can be catastrophic events but do not normally result in hospitalization.

"We found that Chantix is associated with more suicidal behavior reports than any other smoking-cessation drug on the U.S. market. The risks simply outweigh the benefits."

In this study, the team of scientists analyzed 3,249 case reports of serious injury included in the FDA's Adverse Event Reporting System from 1998 through September 2010 for self-injurious behavior or depression linked to varenicline, bupropion (Zyban™), an antidepressant approved for smoking cessation, and nicotine replacement products. They identified 2,925 (90 percent) cases of suicidal behavior or depression for varenicline, 229 (7 percent) for bupropion, and 95 (3 percent) cases for nicotine replacement products.

Furburg said that although a growing body of research from multiple sources establishes that varenicline substantially increases the risk of psychiatric side effects, it remains uncertain how frequently these events occur.

"While suicidal behavior or depression appear to be prominent side effects of varenicline, they are by no means the only safety issues," said Thomas J. Moore, senior scientist at the Institute for Safe Medication Practices and lead author of the study. "Varenicline has been associated with aggression and violence in three studies and carries a warning about this behavior. Its effects on vision, cognition and motor control and other risks have led to its being banned for airline pilots, air traffic controllers, military pilots and missile crews, and restricted for truck drivers."

Varenicline also is associated with an increase in the risk of serious cardiovascular events, as reported in the July 4, 2011, issue of the

Canadian Medical Association Journal by Furberg and scientists at Wake Forest Baptist, Johns Hopkins University School of Medicine and the University of East Anglia in the United Kingdom.

"We strongly recommend that the FDA should revise the 'black box warning' to say what this study and the FDA's own data show – that varenicline has higher risks for [suicidal behavior](#) and depression than other [smoking-cessation](#) treatments," Furberg said.

"We agree with the recommendations of the U.S. Veterans Administration (VA) that varenicline should be prescribed only after failure of [nicotine replacement](#), bupropion or a combination," he added. "The VA also recommends a mental status examination to assess risk of suicidal or violent behavior prior to prescribing varenicline."

Tobacco use is responsible for one in five deaths in the United States each year and adds \$193 billion to health care costs. It is among the most treatment-resistant forms of drug dependency, with 36 percent of the nation's smokers attempting to quit each year but only 3 percent succeeding for six months or more, according to the Department of Health and Human Services.

Provided by Wake Forest Baptist Medical Center

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