

Unintended danger from antidepressant warnings

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Fluoxetine (Prozac). Image: Wikimedia Commons

Researchers have found that U.S. Food and Drug Administration warnings about a potential danger for young people taking antidepressants may have backfired, causing an increase in suicide attempts by teens and young adults.

The 2003 warnings drew intense and possibly exaggerated media coverage that led to a sudden, steep decline in the number of prescriptions for antidepressants. In a study published in *BMJ*, researchers at Harvard Medical School's Department of Population Medicine and the Harvard Pilgrim Health Care Institute report that in the year following the warnings, when antidepressant prescriptions fell by more than a fifth among [young people](#), there was a relative increase of 21.7 percent in suicide attempts by overdose with [psychotropic drugs](#),

and 33.7 percent among young adults.

"This study is a one of the first to directly measure a health outcome driven by the interaction of public policy and mass media," said Christine Lu, HMS instructor in population medicine at Harvard Pilgrim Health Care Institute and lead author of the study. "The FDA, the media and physicians need to find better ways to work together to ensure that patients get the medication that they need, while still being protected from potential risks."

"This is an extraordinarily difficult public health problem, and if we don't get it right, it can backfire in serious ways," said co-author Stephen Soumerai, HMS professor of population medicine at Harvard Pilgrim Health Care Institute.

In 2003, an analysis that combed through all the existing clinical trials noted that approximately 1 percent of adolescents and young adults taking antidepressants experienced an increase in thinking about suicide.

The original warning, which was heavily publicized in news reports, mentioned only this potential risk of antidepressants to patients without noting the potential risk of under-treatment of depression.

These well-intended safety warnings became frightening alarms to clinicians, parents and young people, the researchers note, with many prominent media outlets warning that these drugs raised the risk of suicide. However, the FDA-cited studies showed only an increase in the risk of suicidal thoughts, not in attempted or completed suicide. In fact, as more young people were prescribed antidepressants in the years before the warning was issued, suicide attempts by young people were stable, the researchers said.

The FDA later revised the warning to recommend that physicians

consider both the risk of prescribing the medication and the risk of not prescribing the medication, monitoring patients for thoughts of suicide and treating them as needed.

"These drugs can save lives," Soumerai said. "The media concentrated more on the relatively small risk than on the significant upside."

The risks cited by the FDA were about 1 percent of those treated, but antidepressant use dropped suddenly by about a relative 20 percent, unintentionally leaving many depressed young people without appropriate treatment, which likely drove the accompanying hospital and emergency department admissions for suicide attempts, he said.

The researchers analyzed claims data for the years 2000 to 2010 from 11 health plans in the U.S. Mental Health Research Network, using a "virtual data warehouse" with anonymous patient data organized to facilitate sharing and data comparison between health systems. The study cohorts included 1.1 million adolescents, 1.4 million [young adults](#) and 5 million adults.

The researchers used overdose with psychotropic drugs as a conservative measure of suicide attempts. Completed suicides are very rare, so the researchers were not surprised to find no change in their 7.5 million patient sample.

The researchers noted that [suicide attempts](#) with drug overdose are very serious, resulting in long-term hospitalization and significant disruption to the lives of patients and their families.

"We need to do a better job of understanding and communicating the risks of taking—and not taking—medications," Lu said.

Provided by Harvard Medical School

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