

Monitoring of high-risk medications unchanged despite FDA warnings

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A new study concludes that many doctors appear to have largely ignored a Food and Drug Administration warning to screen users of new antipsychotic drugs for high blood sugar and cholesterol, which poses risks to their health and raises questions about the efficacy of warning protocols in general.

The research analyzed about 109,000 Medicaid patients taking "second generation" antipsychotic drugs, which can cause increases in blood sugar, cholesterol and significant weight gain, as well as other symptoms - significantly raising the risk of diabetes. It was done by health researchers from Oregon, Colorado, Georgia and Missouri, and just published in the [Archives of General Psychiatry](#).

It found that most doctors never changed their level of baseline screening for blood sugar and cholesterol, despite a warning in 2003 from the FDA and two other organizations that these antipsychotic drugs could raise the risk of diabetes in a patient population that already was at higher risk for this disease.

"The existing baseline screening and ongoing monitoring of [glucose](#) and lipid levels in these patients was already pretty low, and the FDA warning really had no impact in changing that," said Daniel Hartung, an assistant professor of pharmacy instruction in the College of Pharmacy at Oregon State University.

"The side effects that can be caused by these new types of antipsychotic

medications, some of which were first approved in the 1990s, are not trivial," Hartung said. "Increases in blood sugar, cholesterol and body weight can lead to diabetes in some cases, and this patient group already has a problem with diabetes that's almost twice that of the general population."

By 2003, Hartung said, enough evidence of these problems had accumulated that the FDA, along with the American Diabetes Association and the American Psychiatric Association, issued formal statements and warnings about the issue, and recommended baseline metabolic testing and ongoing monitoring for anyone beginning these medications.

In this study group - that examined more than 100,000 patients in California, Missouri and Oregon - it never happened.

There were no significant changes in the level of baseline testing for blood sugar and cholesterol. There was some movement toward one drug that posed less metabolic risk, the study found, but much of that could have been caused by the elimination in California, around the same time, of required prior authorization for that drug.

Second-generation antipsychotic drugs, such as olanzapine, aripiprazole and others, are very powerful medications and were originally developed for treatment of schizophrenia, Hartung said. They were largely prescribed at first only by psychiatrists, but their use has now expanded widely into treatment for problems such as bipolar disorder and less serious mental health problems such as depression, and they are often administered by general practitioners.

The study noted that individuals with serious mental illness often have a higher risk of diabetes and cardiovascular disease, and as such are already a vulnerable population. Since the new drugs can significantly

increase those risks, monitoring blood sugar and cholesterol is very important, experts say.

"Part of the problem may be that simply sending doctors a letter about these issues, which come up every now and then with medications, is just not getting the job done," Hartung said. "With this group of medications, at least, it clearly wasn't effective, and it does raise questions about whether new approaches are needed. Part of the problem may also be people moving from one doctor to another, and inaccurate assumptions about testing being made."

"Also, changes in behavior are always slow," he said.

Anyone taking these medications, Hartung said, may wish to discuss with their physicians what type of metabolic screening they've had, and consider glucose and lipid testing if it has not already been done. If there are problems with [high blood sugar](#), [cholesterol](#) or body weight, it may need to be considered by the physician in choosing the best treatment, he said.

Provided by Oregon State University

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