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Problems continue with inappropriate prescription of antipsychotic drugs

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Low-dose, antipsychotic medications are continuing to be widely prescribed, a new analysis suggests, even though it's likely many of the prescriptions are for conditions where there's weak evidence of their effectiveness and serious risks remain.

The problem is less severe than it used to be, due to changes in marketing of the drugs, researchers said. A $520 million settlement against the manufacturer of the medication of largest concern, quetiapine, reduced "off-label" promotion of the drug for conditions not approved by the FDA, and may have led to declines in this type of sub-therapeutic use.

However, an analysis of Medicaid patients from 2004-08 shows that many of these powerful medications – which are meant to be used for severe mental illness such as schizophrenia and bipolar disorder – are still being prescribed at lower doses, possibly for conditions such as anxiety, attention deficit disorder and even insomnia.

The findings were made by researchers from Oregon State University, Oregon Health and *Science* University, the University of Colorado and Dartmouth Institute for Health Policy and Clinical Practice. They were published in *Pharmacoepidemiology and Drug Safety*, in work supported by the National Institutes of Health.

"The reduction in low-dose prescribing suggests there has been a decline in off-label use of quetiapine, but it's still a problem that people should

be aware of," said Daniel Hartung, an associate professor in the OSU College of Pharmacy.

"In far too many cases, these drugs are being prescribed for conditions in which there's less-clear evidence of efficacy and safety," Hartung said. "Other medications are available that have been shown to work and usually cost less. And the side effects of these antipsychotic drugs include serious concerns such as increases in blood sugar, cholesterol, weight gain and an increased risk of diabetes."

The drugs at first were used mostly by psychiatrists treating serious mental illness, but in recent years have been much more widely administered by general practitioners. Too often that was done without careful screening of blood sugar and cholesterol, a past study found, since use of the drugs can increase the risk of diabetes in a patient population already more prone to that condition.

Quetiapine, sold under the trade name Seroquel, was one serious concern. It was promoted by its manufacturer for a range of uses not approved by the Food and Drug Administration, and widely prescribed at lower doses for dementia, post-traumatic stress, anxiety, attention deficit and insomnia. It and some other drugs have since gained approval for use in treatment-resistant depression, but in many cases the inappropriate prescription of these medications is continuing.

The investigation of this problem was prompted by state Medicaid agencies, researchers said, because of an explosion in the use of costly antipsychotic drugs from 1997 to 2007. During that period, the market more than quadrupled from $1.7 billion to $7.4 billion.

One estimate indicated that second-generation antipsychotic medications accounted for more than 16 percent of total Medicaid pharmacy spending.At least five state Medicaid programs are exploring policy

options to curtail the use of sub-therapeutic doses of quetiapine, the researchers said in their report.

States concerned about these issues may wish to first evaluate policies that restrict potentially safer options, such as other drugs that could be used off-label as a sedative, the scientists recommended. This might avoid driving physicians toward prescribing the antipsychotic medications.

"These issues have been reported nationally and policy discussions have taken place," Hartung said. "But changes in the prescribing practices of the medical profession are sometimes slow to come."

Provided by Oregon State University