

Innappropriate drug prescriptions wasting millions, raising health risks

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A recent study in Oregon suggests that drugs designed for treating the most severe mental illnesses are often prescribed at inappropriately low doses and at considerable expense, for use in conditions where their benefit has not been established.

In this case, prescription drugs that might cost as much as \$20 to \$25 a day were being widely used to treat problems for which they were not FDA-approved. Some of those problems could have been addressed with generic medications costing \$1 a day, with better results and less risk of serious side effects.

This is a reflection of widespread use of medications for "off-label" uses that have not been carefully considered or approved by the Food and Drug Administration, researchers said, some of which are unnecessarily raising medical costs and reducing the effectiveness of health care.

The research was done by scientists in the College of Pharmacy at Oregon State University, the Department of Psychiatry at Columbia University, and Oregon Health and Science University. It was published in the *Journal of Clinical Psychiatry*, and funded by the National Institutes of Health.

"It's legal for a physician to prescribe a medication for something other than its FDA-approved uses, and based on good studies or clinical judgment it may be justified," said Daniel Hartung, an assistant professor of pharmacy practice at OSU. "However, the approved uses

are usually a pretty good proxy for real, proven effectiveness. And if in fact drugs are being used inappropriately, it not only can be very expensive but also pose an unnecessary health risk."

Both of those problems were found in this study.

In this case, the health conditions of 830 Oregon Medicaid patients were examined - all of whom had been given one of the newer antipsychotic medications approved only for some of the most severe forms of mental illness, such as schizophrenia or bipolar disorder. However, the researchers found that the vast majority of the people receiving one of these drugs did not have schizophrenia or bipolar disorder, the underlying mental health conditions for which the drugs had been approved.

Most people who received these "atypical antipsychotic" drugs, which are very powerful and have potentially severe side effects, had less serious mental health concerns such as depression, anxiety, post-traumatic stress disorder - or no psychiatric disorder other than insomnia.

The newer antipsychotic drugs can cause side effects such as neuromuscular rigidity, increased risk of stroke, heart arrhythmias, moderate-to-severe weight gain, and worsening glucose control that leads to increased risk of diabetes. The drugs may be necessary for patients with major mental health problems such as schizophrenia, Hartung said, but have not been demonstrated to be effective for most of their off-label uses, such as depression or agitation in persons suffering from dementia.

The prescriptions, he said, were also often given at lower doses and for shorter time periods than anything that has been shown to be therapeutic.

And the concerns involve many types of practitioners, the study found - the medications were prescribed by primary care physicians and nurse practitioners and, to a lesser extent, psychiatrists and psychiatric nurse practitioners.

"Some drug companies have been accused of encouraging and expanding the off-label use of drugs, and that may be where part of this misinformation is coming from," Hartung said. "That is an illegal practice, and some companies have been successfully sued on that basis. Regardless of what's causing this, it's a serious concern, both for ensuring resources are used judiciously and protecting health care quality."

These issues should be more carefully explored, the researchers said in their study. They are particularly relevant to Medicaid programs, in which use of antipsychotic medications is surging. In 2002 these drugs constituted more than 7 percent of the expenditures for all Medicaid programs nationally. In Oregon, the medications represented nearly 30 percent of all outpatient fee-for-service drug expenditures in 2006.

During 2006, the study found, the Oregon Medicaid program spent about \$2.5 million for chronic, subtherapeutic use of a single antipsychotic drug in adult patients.

Based on this, the researchers concluded that "a statewide initiative to provide guidance regarding the administration of antipsychotic medication could be beneficial."

The study was done in Oregon, Hartung said, but is probably a reflection of trends across the nation.

The researchers wrote in their report that "states wishing to reduce costs and improve the quality of use for atypical antipsychotic medications

should examine prescribing patterns to ensure that these drugs are prescribed within acceptable practice limits, and are not used for off-label uses when other approaches may be more appropriate and less expensive."

Source: Oregon State University

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