Reducing off-label use of antipsychotic medications may save money

May 15 2012

Reducing the non-FDA-approved use of antipsychotic drugs may be a way to save money while having little effect on patient care, according to a Penn State College of Medicine study.

Researchers say that 57.6 percent of patients prescribed antipsychotic medications in data from 2003 did not have schizophrenia or bipolar disorder, the conditions for which the drugs were approved for use. Use of medication for treatments that is not FDA-approved is called off-label use.

"Given healthcare reform and widespread crisis in state revenues, state Medicaid programs will be under pressure to serve larger patient populations, increasing their fiscal stress," said Douglass L. Leslie, Ph.D., professor of public health sciences. "Medicaid prescription drug programs covered 75 percent of all antipsychotic prescription medications in the United States in 2002. Reducing off-label antipsychotic use may generate savings with little impact on patient outcomes."

Researchers looked at data for 42 states from 2003, the latest data available at the time of analysis, from the Centers for Medicare & Medicaid Services. They report their results in a recent issue of *American Journal of Managed Care*. Patients in a Medicaid fee-for-service plan for the entire year were chosen using de-identified patient information that could not be traced to the individuals. The researchers chose patients without a diagnosis of either schizophrenia or bipolar

disorder during 2003 who received an antipsychotic medication.

During 2003, 372,038 patients received an antipsychotic medication. Of these patients, 214,113, or 57.6 percent, did not have a diagnosis of schizophrenia or bipolar disorder. Diagnoses included other mental disorders: 35 percent, minor depression -- 25.4 percent, major depression -- 23.2 percent, no mental disorder -- 18.8 percent, conduct disorder -- 18.8 percent, and anxiety disorder -- 16.2 percent.

"A high rate of off-label antipsychotic use would not necessarily be of concern if there were scientific evidence supporting the effectiveness of these medications for conditions other than schizophrenia and bipolar disorder," Leslie said.

Off-label use is supported in the medical community, with the American Academy of Neurology endorsing the use of quinine for treatment-resistant leg cramps, for example. Since 2003, some of the antipsychotic medications have been approved by the FDA for the treatment of other conditions, including irritability in autism and treatment-resistant depression. However, at the time the data were collected they were considered off-label.

The rate of off-label use of antipsychotics is high compared to other medications. Other studies have shown off-label medication use includes cardiovascular drugs: 46 percent, anticonvulsants -- 46 percent, and antiasthmatics -- 42 percent.

"Antipsychotics were the highest selling medication class at $14.6 billion in 2009," Leslie said. "Medicaid bears a significant proportion of these costs. Hence, off-label use may be responsible for a considerable portion of state Medicaid budgets, with little or no documented clinical benefit and a substantial risk of adverse effects. Off-label use may be an area of potential savings with little impact on patient outcomes."

The newest antipsychotic drugs can cost up to $10 per day at doses recommended for patients with schizophrenia.

According to the researchers, more research is needed to determine if off-label use of antipsychotic medications yields substantial clinical benefit and to identify how doctors decide to prescribe these drugs for non-FDA approved conditions.

Reasons why drugs may be prescribed off-label include a lack of research results showing the drug's effectiveness in certain patients or for other conditions, or that the drugs may be used as a last resort for those patients who have not responded to other treatments. Further research is needed on the decision-making process of doctors to prescribe off-label.

"Where there is limited evidence of clinical benefit, greater caution should probably be used before prescribing these drugs off-label because they can have hazardous side effects," Leslie said.

Provided by Pennsylvania State University