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## Authors and Disclosures

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## From Medscape Medical News Unsupported Antipsychotic Use in Children Widespread



Pam Harrison

February 24, 2010 — A significant proportion of children younger than 18 years in at least 1 state Medicaid population received a second-generation antipsychotic for conditions that have no published evidence supporting their use.

Prathamesh Pathak, MS, BPharm, currently with Health Economics and Outcomes Research, IMS Health, Falls Church, Virginia, and colleagues found that the number of children younger than 18 years in a state Medicaid database who were newly treated with a second-generation antipsychotic doubled between 2001 and 2005. They also found that among new users, 41.3% had no diagnosis for which treatment was supported by a published study. The highest level of non-evidence-based use was with aripiprazole at 77.1%.

"These results add to the evidence that treatment of children with second-generation antipsychotic medications increased dramatically in the early years of this new century," the study authors write. However, they add that "further studies are needed to determine whether this trend is evident in other pediatric populations, especially among children not enrolled in Medicaid."

### **Medicaid Claims**

For the analysis, the study authors retrospectively examined Medicaid claims between January 2000 and December 2006 for children younger than 18 years who had received a second-generation antipsychotic. The final sample included 11,700 children.

"The primary measure of interest was the proportion [of children] for whom use of the antipsychotic was based on evidence," the investigators write. Evidence-based use was defined as any use of an antipsychotic for any diagnosis that was supported by clinical trial findings published before the end of 2005.

Analyses showed that risperidone was given as the initial therapy in 51.2% of the children. "The agent least used for initial treatment was ziprasidone (2.5%)," the study authors write. Interestingly, they note that 5% of the sample received more than 1 second-generation antipsychotic on their index date."

The most common conditions identified for which children received a second-generation antipsychotic were attention-deficit/hyperactivity disorder (ADHD), followed by depression, conduct disorder, oppositional defiant disorder, and adjustment reactions. At the time, the use of risperidone was well supported by evidence for the treatment of conduct disorder, developmental disorders, pervasive developmental disorders, and psychoses, whereas plausible evidence for its use was found for the treatment of mania and bipolar disorders; among children treated with risperidone, 64.1% of the use was based on strong evidence.

For olanzapine, there was also strong evidence supporting its use for the treatment of psychoses and plausible evidence for the treatment of mania and bipolar disorders, whereas for quetiapine, strong evidence supported its use in mania and bipolar disorders.

In contrast, neither strong nor plausible evidence was found for the use of aripiprazole or ziprasidone to treat any condition.

**Table. Evidence for Use of Second-Generation Antipsychotics to Treat Disorders in Pediatric Medicaid Recipients**

Level of Evidence	Aripiprazole, %	Olanzapine, %	Quetiapine, %	Risperidone, %	Ziprasidone, %
Strong		10.8	21.6	64.2	
Plausible		16.2		3.6	
Weak	22.9	29.1	45.9	1.7	56.9
None	77.1	43.9	32.6	30.6	43.1

**Particular Interest**

According to the study, the growth in the use of aripiprazole in this particular pediatric cohort is of "particular interest." Introduced in 2002, the number of new pediatric users of aripiprazole increased by 338% between 2003 and 2004 and by 368% between 2003 and 2005.

The study authors also say it was "notable" that in 2005 the proportion of children (8.2%) who received aripiprazole as initial therapy, for which there is no good evidence to support its use, was almost equal to the proportion of children who received initial therapy with risperidone at 9.8%, for which there is good evidence.

"Clearly, behavioural problems, including oppositional and conduct disorders and hyperkinetic-hyperactivity symptoms, were frequently seen among the children treated with second-generation antipsychotics," the investigators write.

They add that "if the primary off-label uses for these medications are for children with behavioural problems, there is an obvious and urgent need to compare the safety and effectiveness of these agents and of other treatment approaches that are effective in modifying children's behaviours."

**Big Debate**

Noting that there is currently a big debate on whether antipsychotics are used both judiciously and for the correct indications for children and adolescents, Christoph Correll, MD, Albert Einstein College of Medicine, New York City, felt that one of the main problems with the study is that it only covers antipsychotic prescribing in children and adolescents from 2001 up to the end of 2005, when the evidence base for judging the appropriateness of antipsychotic use in children was much slimmer than it is today.

Indeed, several atypicals, including aripiprazole, have since been approved by the Food and Drug Administration (FDA) for a number of conditions, including schizophrenia, bipolar disorder, and autism, "so the evidence base for atypical antipsychotic effectiveness in youth for these conditions is now there," Dr. Correll told *Medscape Psychiatry*.

However, he added, that the study "makes it sound as if the sole use of such medications without FDA approval at that time invalidates their potential usefulness for a number of major psychiatric conditions in youth."

Dr. Correll also stressed that giving a child a diagnosis of ADHD, for example, by no means rules out the fact that many children with ADHD may also have aggressive and disruptive behaviors and/or disorders that can interfere with developmental milestones and overall functioning.

"In general, symptoms need to be distressing or interfere with functionality before prescribers reach for psychotropic medications, but we do treat symptoms more than diagnoses," he said.

"I'm not saying that all of these patients should be getting an antipsychotic as first-line treatment; they need to be very carefully diagnosed and receive initial or additional psychosocial interventions where possible, but this is not always feasible, as these young patients are often more complicated than they appear, and I think the authors should be far more cautious about the conclusions they derive from this type of claims database," Dr. Correll added.

*The study authors have disclosed no relevant financial relationships.*

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