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Deborah Brauser has disclosed no relevant financial relationships.



### From Medscape Medical News

## Psychotropic Medications Linked to Serious Adverse Drug Reactions in Children

Deborah Brauser

July 2, 2010 — Psychotropic medications are associated with adverse drug reactions (ADRs), many of which are serious, in children younger than 17 years, according to a new database study from Danish researchers.

Results also showed that all but one of the psychotropic-related ADRs for children between the ages of birth and 2 years were serious, including birth defects such as neonatal withdrawal syndrome, ventricular septal defects, and premature labor.

These findings were "probably due to the mothers' intake of psychotropic medicine, primarily antidepressants and antipsychotics, during pregnancy," write the study authors.

For the overall patient population, the largest share of reported ADRs came from psychostimulants (42%), followed by antidepressants (31%) and antipsychotics (24.5%).

"The high number of serious ADRs reported for psychotropic medicines in the pediatric population should be a concern for health care professionals and physicians," the study authors write.

In addition, "clinicians must be aware of the risks for the unborn child if they treat pregnant women with [these drugs]," coinvestigator Ebba Hansen, MSc, professor of social pharmacy and director for the FKL-Research Center for Quality in Medicine Use at the University of Copenhagen, Denmark, told *Medscape Medical News*.

She noted that many of the general practitioners interviewed for this study "thought that SSRI [selective serotonin reuptake inhibitor] antidepressants are harmless. Therefore, we recommend that treatment of pregnant women with psychotropic drugs should be an issue for specialists only."

The study is published online in *BMC Research Notes*.

### ADR Evidence Lacking

Although regulatory authorities have issued warnings about risks associated with the use of psychotropics in pediatric patients, "little evidence has been reported about the ADRs of these medicines in practice," write the study authors.

"Overall, we have very little information about [ADRs] in children, and especially in infants, as vulnerable groups are excluded from the clinical trials that document a medication's efficacy and safety before licensing and marketing," said Professor Hansen.

For this study, her team evaluated 4500 ADRs in children listed in the national Danish ADR database between 1998 and 2007.

"Spontaneous ADR reporting [is] an important contributor to knowledge about safety of medicines," the study authors write. They note that spontaneous reports are "the main source for information about new and previous unknown ADRs."

### **Serious ADRs Found**

Results showed that 429 of the ADRs reported during the study period were for psychotropic medications. Of these, 241 (56%) were deemed serious.

A total of 50% of the psychotropic ADRs reported were for adolescents between the ages of 11 and 17 years (n = 214), of which 45% were serious. Almost 19% were for children between the ages of birth and 2 years (n = 80).

In addition, 39% of the overall psychotropic-related ADRs were from the "nervous and psychiatric disorders" categories. When looking at sex, 59% of the total ADRs reported were for boys.

A total of 79 of the 80 ADRs associated with psychotropics in the children younger than 2 years were serious, and 2 of these were fatal (one was associated with citalopram due to chorioamnionitis and the other with fluoxetine due to persistent fetal circulation).

Finally, 40% of all psychotropic ADRs were associated with the psychostimulants methylphenidate and atomoxetine, whereas 59% of the ADRs reported for antipsychotics were associated with ziprasidone, olanzapine, and risperidone. A total of 61% of the total ADRs reported for antidepressants were with sertraline and citalopram.

When asked about her team's upcoming plans for further research, Professor Hansen reported that 2 studies on ADRs in children associated with vaccines and use of antibiotics have recently been completed — and that both articles are currently pending review. In addition, a new study on ADRs in children treated with psychostimulants is "in the pipeline."

"An interesting idea for study would also be to follow up on the children who were attacked by ADRs [in this study] and see if there are any long-term effects, such as cognitive disturbances," she added.

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

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