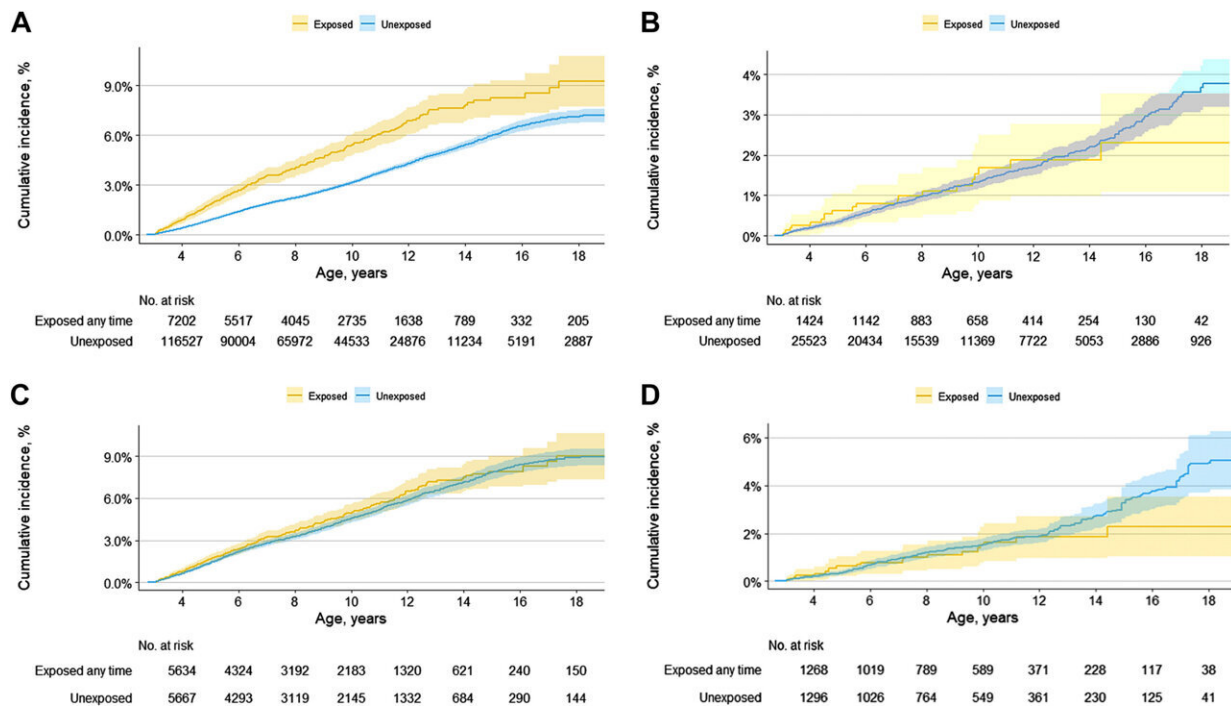


Study eases concern at antipsychotics use in pregnancy

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Crude and propensity score-weighted cumulative incidence (with 95% confidence intervals) for composite neurodevelopmental outcome from age 3–19 years in children of mothers with psychiatric disorders born between 2000 and 2020 by prenatal antipsychotic exposure. A) Crude cumulative incidence (with 95% confidence intervals) in combined cohort (Finland, Iceland, Norway, Sweden) B) Crude cumulative incidence (with 95% confidence intervals) in Denmark C) Propensity score-weighted cumulative incidence (with 95% confidence intervals) in combined cohort (Finland, Iceland, Norway, Sweden) D) Propensity score-weighted cumulative incidence (with 95% confidence intervals) in Denmark. ^aAdjusted for birth year, sex of child, child’s country of birth, maternal birth country, age, parity, education, cohabitation status, BMI &

smoking in early pregnancy, use of other medications during pregnancy, or known/suspected teratogens and comorbidity prior to pregnancy using propensity score overlap weights. Credit: *eClinicalMedicine* (2024). DOI: 10.1016/j.eclinm.2024.102531

Antipsychotics—a branch of medication designed to treat schizophrenia and bipolar disorder—are important tools for mental health care management. They work by blocking the effect of dopamine, which can help reduce psychotic symptoms such as hallucinations or delusions.

These versatile medications are also widely used for other mental health conditions and developmental disorders, like anxiety, depression, [autism spectrum disorder](#), and insomnia.

However, many women and pregnant people using these medications may feel concerned about the potential risks they pose to their unborn babies.

A new international study led by UNSW Sydney, published in [eClinicalMedicine](#), tracked the long-term risk of a child developing neurodevelopmental disorders and learning difficulties after being exposed to antipsychotics in the womb.

The findings show there's little to no increased risk of exposure leading to intellectual disability, poor academic performance in math and language, or learning, speech, and language disorders.

"The findings are really reassuring for both women managing these psychiatric conditions during pregnancy and their providers," says Dr. Claudia Bruno, a pharmacoepidemiologist based at UNSW's School of Population Health and lead author of the study.

"There's no increased risk when taking the [medication](#) during pregnancy, not only for the specific neurodevelopmental disorders that we looked at but also ADHD and autism as shown in our team's previous studies."

This research is the most comprehensive study on antipsychotics and neurodevelopmental outcomes to date: it pulls together nationwide data from Denmark, Finland, Iceland, Norway, and Sweden into a large sample size of 213,302 children born to mothers with a diagnosed psychiatric condition, 5.5 percent (11,626) of which were prenatally exposed to antipsychotics.

These five Nordic countries all have similar health and education systems and keep detailed data on birth records, filled prescriptions, and diagnoses from inpatient and outpatient specialist care, as well as antenatal care. The researchers teamed these data with results from the children's first standardized national school test (similar to Australia's NAPLAN tests), which happens between the ages of 8–10.

"It's reassuring that everything points to the same 'no major indication' of increased risks overall," says Scientia Associate Professor Helga Zoega, senior author of the study and pharmacoepidemiologist, also based at UNSW's School of Population Health.

"The study builds on our team's previous work that looked at birth outcomes, including serious congenital malformations, where we've seen similar null results."

"I think it's important to get excited about null results because this is essential information for the management of serious mental health conditions in pregnancy. It's as equally important as finding an increased risk of outcomes."

A gap that big health data is trying to fix

While this study is part of a growing body of research about medication safety in pregnancy, there's still a lot left in this field to discover, says A/Prof. Zoega.

"This is a hugely understudied area," she says. "Unfortunately, we know way too little about medication safety during pregnancy."

One of the reasons so little is known about medicines and pregnancy is that it's simply not feasible—or in many cases, ethical—to conduct randomized [clinical trials](#) on [pregnant women](#). The potential risks of testing or withholding treatment to the unborn child and mother or pregnant person is often too great.

That's where harnessing big data can step in—although the research isn't as simple as looking at the raw data alone.

For example, women treated with antipsychotics during pregnancy were more likely to smoke, have higher BMIs, lower education levels, to be older (35 years or more) and use other medications during pregnancy compared to women who didn't take antipsychotics during pregnancy—all of which are risk factors that can potentially impact birth outcomes.

These circumstances—called 'confounding factors'—are accounted for in observational research using careful study design and complex adjusted risk models to make sure the results show the impact of the medication alone.

"These types of studies are methodologically tricky and can take a long time to do," says A/Prof. Zoega. "This study has been in the making for almost 10 years now."

"We already know these women are dealing with psychiatric conditions,

and by genetic default, their children would be more likely to have psychiatric or neurodevelopmental outcomes. But we're focused on the risks and benefits of the medication treatment in pregnancy, so we use methods to make the comparison groups as similar as possible."

The researchers also strengthened their findings by slicing up the data to take a closer look at whether individual medications, trimesters of exposure, and siblings carried higher risk levels.

While one antipsychotic, chlorpromazine, showed potential increased links to language and speech delays, these findings were based on small sample sizes of 8-15 children, so more research is needed to investigate this potential link.

Other than this anomaly, the results supported the finding that there was little to no increased risk of children prenatally exposed to antipsychotics developing [neurodevelopmental disorders](#) or learning difficulties.

Looking ahead

Dr. Bruno is currently involved in two related studies on prenatal medication use and pregnancy outcomes. One explores if there is a relationship between the use of antiseizure medications during pregnancy and a child's school performance, and the other examines whether taking ADHD medication use and discontinuation during pregnancy on child health outcomes.

But she sees many avenues for future research to build on this work, including harnessing more Australian big health data.

"There's so much to learn about medication safety in pregnancy," says Dr. Bruno. "These women are typically excluded from clinical trials, so there's a real lack of data or evidence.

"While these results are highly generalizable to women in Australia, we now have real-world linked Australian data that can start contributing to large-scale international studies like this one, which we're very excited for."

A/Prof. Zoega co-leads an international research collaboration called International Pregnancy Drug Safety Study (InPreSS), which investigates the safety of medication in pregnancy. She says there's plenty to do in this space.

"Antipsychotics are only one class of medications, and we already know that up to 80 percent of women use at least one prescription medicine during pregnancy. Most often, there's little or no guidance on safety."

"There are so many unanswered questions that there's enough for a lifetime of research."

More information: Claudia Bruno et al, Antipsychotic use during pregnancy and risk of specific neurodevelopmental disorders and learning difficulties in children: a multinational cohort study, *eClinicalMedicine* (2024). [DOI: 10.1016/j.eclinm.2024.102531](https://doi.org/10.1016/j.eclinm.2024.102531)

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