LIMITED EVIDENCE OF A LINK BETWEEN ACETAMINOPHEN AND AUTISM OR ADHD

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Q. Is the use of acetaminophen during pregnancy linked to autism or ADHD? A: There...

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 \mathbf{x} Q. Is the use of acetaminophen during pregnancy linked to autism or ADHD?

A: There is currently no strong evidence that acetaminophen use during pregnancy causes autism or ADHD in children. Expert groups continue to recommend use of the drug during pregnancy when necessary and in consultation with a doctor.

FULL QUESTION

Does Tylenol have links to Autism?

Is Tylenol a threat for pregnant people and tied to asd and adhd?

FULL ANSWER

Readers have asked whether Tylenol (acetaminophen) is connected to autism or ADHD, also known as attention-deficit/hyperactivity disorder. One person forwarded a sponsored Facebook post from the page "Child Autism & ADHD from Tylenol during pregnancy" stating that "parents of children with autism or ADHD whose mother took Tylenol while pregnant may be eligible for legal compensation." The page continues to run similar <u>advertisements</u>, as do <u>various</u> other <u>pages</u>. Parents have <u>filed</u> <u>lawsuits</u> against retailers of acetaminophen, stating that their children developed autism or ADHD due to exposure to acetaminophen taken during pregnancy.



Some <u>studies</u> have indeed <u>shown a relationship</u> between acetaminophen taken during pregnancy and autism or ADHD in children, but <u>they do not demonstrate</u> that the <u>acetaminophen use</u> caused the elevated rates of autism and ADHD, researchers say. For example, a pregnant person who takes acetaminophen may have a child with ADHD or autism because of other factors, such as genetics.

Experts agree that acetaminophen has a role in pregnancy but that it should be used only when necessary and in consultation with a doctor. Avoiding use of acetaminophen for fever or pain during pregnancy <u>may have negative consequences</u>. For instance, an uncontrolled fever in early pregnancy can harm brain development.

A Food and Drug Administration spokesperson told us via email that the available evidence is "too limited to make any recommendations based on these studies at this time."

The American College of Obstetricians and Gynecologists said in a 2021 <u>statement</u> that studies "show no clear evidence that proves a direct relationship between the prudent use of acetaminophen during any trimester and fetal developmental issues." An ACOG representative told us that the statement is the most up-to-date communication on the topic. And a 2017 Society for Maternal-Fetal Medicine <u>statement</u>, which a representative also confirmed to be the most up-to-date document, found the evidence on a causal link between acetaminophen and neurobehavioral disorders to be "inconclusive."

Studies of Acetaminophen During Pregnancy Have Weaknesses

Acetaminophen, called <u>paracetamol</u> outside the U.S., is used <u>widely</u> during pregnancy to treat pain and fever. It is <u>an ingredient</u> in many over-the-counter and prescription medications, including Tylenol, DayQuil, NyQuil, Excedrin, Sudafed, Mucinex, Midol, oxycodone, Vicodin and others.

As we said, some studies have found that women who reported using acetaminophen during pregnancy were more likely than those who didn't to have children who later developed autism or ADHD. A 2018 <u>paper</u> published in the American Journal of Epidemiology that aimed to comprehensively analyze data from multiple studies, for example, found a 34% and 19% higher risk of ADHD and autism, respectively, in children whose mothers took acetaminophen in pregnancy compared with those whose mothers did not.



But this doesn't necessarily mean acetaminophen is to blame for the conditions. These studies were <u>observational</u>, meaning that researchers simply noted levels of acetaminophen exposure, generally based on <u>reports</u> from the parents in the studies. Randomized controlled trials — in which one group receives a medication or treatment and another group receives a placebo or standard care — are the gold standard for determining whether a causal relationship exists.

It is possible that people who take more acetaminophen are more likely to have characteristics that predispose them to have a child with autism or ADHD — including the <u>illnesses</u> or other health conditions that might have prompted a pregnant person to take acetaminophen in the first place.

The authors of the 2018 study recognized this issue, writing that the results "should be interpreted with caution given that the available evidence consists of observational studies and is susceptible to several potential sources of bias."

<u>Sura Alwan</u>, a birth defects epidemiologist and co-director of the <u>Teratogen Information System</u> at the University of Washington, told us in an email that genetic factors might also help explain the results, adding that not all studies have found an association between prenatal acetaminophen and neurodevelopmental outcomes like autism and ADHD.

In any case, she said, the studies "do not necessarily imply a causal link, which means that there isn't enough evidence to say that taking acetaminophen causes those behavioral or cognitive concerns."

Some researchers do think the associations are worrisome enough to caution women taking acetaminophen during pregnancy. In 2021, an international group of scientists, clinicians, and public health professionals published what they called a "consensus statement" in Nature Reviews Endocrinology, which <u>made news</u> for calling for "precautionary action" based on data indicating acetaminophen might alter fetal development, with an increasing <u>impact</u> with increasing <u>duration</u> of exposure.

"We recognize that limited medical alternatives exist to treat pain and fever; however, we believe the combined weight of animal and human scientific evidence is strong enough for pregnant women to be cautioned by health professionals against its indiscriminate use, both as a single ingredient and in combination with other medications," the researchers wrote.

The statement proved controversial, however, with other groups of scientists pushing back to <u>add</u> <u>context</u> and <u>explain</u> why acetaminophen might not have <u>caused</u> the links seen in the studies.

"In my opinion, the level of evidence out there is poor, and I do not believe that there is any causal or any other association between at least short-term use of acetaminophen during pregnancy and ensuing increased risk of childhood ADHD or ASD ," <u>Dr. Per Damkier</u>, a professor and clinical pharmacologist at Odense University Hospital and University of Southern Denmark, told us in an interview. Damkier was one of the scientists who pushed back at the consensus statement.

Multiple factors contribute to <u>autism</u> and <u>ADHD</u>. These conditions "are variable in clinical presentation, very difficult to assess and associate with a single causal factor," Alwan said.

Damkier emphasized that many studies do not adequately take into account whether the parents had ADHD or autism, which run in families. He pointed to one <u>study</u> that suggested accounting for ADHD in parents likely weakens the relationship between this disorder and acetaminophen.

Many studies also rely on questionnaires filled out by parents, Damkier said. These may identify children at increased risk of ADHD or autism but do not replace an official diagnosis.

Finally, Damkier said that even if you accepted the analyses in the studies showing increased risk as

valid, "which you should not," the risk levels — typically 20% to 30% increased risk during childhood — represent a "weak association," especially since there is typically a fair to moderate degree of uncertainty surrounding the numbers.

A Closer Look at Cord Blood

A 2019 JAMA Psychiatry <u>study</u>, which is <u>cited</u> in <u>legal advertisements</u>, did not rely on self-reported data, instead looking at concentrations of broken down acetaminophen components in blood collected at Boston Medical Center from umbilical cords at birth and stored for future study.

The children with acetaminophen exposure in the top third — meaning the highest concentrations of the drug components in cord blood — had 2.86 times higher odds of an ADHD diagnosis and 3.62 times higher odds of an autism diagnosis compared with children with exposure in the bottom third. "Our findings support previous studies regarding the association between prenatal and perinatal acetaminophen exposure and childhood neurodevelopmental risk and warrant additional investigations," the authors wrote.

The authors themselves noted some limitations of the paper at the time of publication. The cord blood measurements did not give a sense of acetaminophen exposure throughout pregnancy, instead showing recent use by people who had just given birth. Further, "caution is needed to apply our findings to other populations with different characteristics," they wrote. Finally, one author pointed out in a <u>press release</u> that the study does not show that Tylenol causes ADHD or autism.

Damkier and <u>others</u> said that some observations and the characteristics of the children in the study appeared unusual, making it hard to draw general conclusions. Every cord blood sample showed acetaminophen exposure, he noted, and there were extremely high rates of ADHD and autism among the children. The study also lacked information on the mothers' use of drugs or history of psychiatric disease.

Acetaminophen Treats Pain and Fever During Pregnancy

Expert groups said that acetaminophen can have benefits for pregnant people experiencing pain or fever, and there may not be good alternatives. The ACOG <u>statement</u> reads: "ACOG and obstetrician-gynecologists across the country have always identified acetaminophen as one of the only safe pain relievers for pregnant individuals during pregnancy."

Nonsteroidal anti-inflammatory drugs, such as ibuprofen and aspirin, can <u>have risks</u> during pregnancy. Taking these drugs during later portions of pregnancy can lead to <u>problems</u> including <u>insufficient amniotic fluid volume</u> and premature closing of a major blood vessel in the fetus. Opioids can also <u>harm the fetus</u> and lead to withdrawal at birth, as well as pose risks for the mother.

Avoiding acetaminophen could have consequences for both mother and child. Fever early in pregnancy can lead to defects in the neural tube affecting the formation of the brain or spinal cord, Alwan said, noting that it is "critically important to treat fever in pregnancy."

The Society for Maternal-Fetal Medicine <u>statement</u> calls acetaminophen "a reasonable and appropriate medication choice for the treatment of pain and/or fever during pregnancy."

The authors of the 2021 Nature Reviews Endocrinology statement suggested doing more research into acetaminophen during pregnancy and cautioned women to "forego APAP unless its use is medically indicated; consult with a physician or pharmacist if they are uncertain whether use is indicated and before using on a long-term basis; and minimize exposure by using the lowest effective dose for the shortest possible time."

This advice is in line with longstanding recommendations for pregnant people. "ACOG's clinical guidance remains the same and physicians should not change clinical practice until definitive prospective research is done. Most importantly, patients should not be frightened away from the many benefits of acetaminophen. However, as always, any medication taken during pregnancy should be used only as needed, in moderation, and after the pregnant patient has consulted with their doctor," the ACOG statement said.

"It is important for pregnant women and all women of reproductive age who may become pregnant to always consult their health care provider to find the best treatment option for pain or fever in pregnancy, which may be taking the recommended dose of acetaminophen and making sure to stay well hydrated and getting lots of rest," Alwan said. People with questions about medications during pregnancy or breastfeeding can contact organizations like <u>MotherToBaby</u>, she added.

An FDA spokesperson told us in an email: "The FDA is aware of and understands the concerns arising from reports questioning the safety of prescription and over-the-counter (OTC) pain medicines when used during pregnancy. As a result, we evaluated research studies on acetaminophen published in the medical literature and determined that they are too limited to make any recommendations based on these studies at this time. Because of this uncertainty, the use of pain medicines during pregnancy should be carefully considered. We urge pregnant persons to always discuss all medicines with their health care professionals before using them. Acetaminophen labels contain the following information regarding pregnancy: 'If pregnant or breast feeding, ask a health professional before use.' The FDA continues to review the published literature and to monitor the potential impacts of acetaminophen."

The spokesperson concluded by sharing a link to a 2015 <u>Drug Safety Communication</u> describing an FDA review of the risks of pain medicine during pregnancy. The document noted that severe and persistent pain, when not treated effectively, can lead to depression, anxiety and high blood pressure for the pregnant individual.

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