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HEALTH | ESSAY

Does Tylenol Cause Autism? Here's How We Could Find Out

In the absence of randomized trials on the effects of acetaminophen, researchers need to use 'natural experiments' to develop better guidance for patients.

By Christopher M. Worsham and Anupam B. Jena

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PHOTO: ELIZABETH COETZEE/WSJ

In the fall of 1982, Extra-Strength Tylenol capsules containing the toxin potassium cyanide were found to be responsible for multiple deaths in the Chicago area. Local police drove through neighborhoods, issuing warnings over loudspeakers: “Do not take Tylenol until further notice.” The FDA would go on to advise the entire country to stop taking Extra Strength Tylenol, and Johnson & Johnson withdrew Tylenol capsules from the market. Investigations would ultimately reveal that the poisonings were the result not of manufacturing contamination but of tampering by an individual whose identity remains unknown to this day.

If you were pregnant in the fall of 1982 and developed a toothache or a fever, would you have taken the Tylenol sitting in your medicine cabinet? Perhaps—but you were

probably much less likely to take it than you would have been in the summer of 1982, before the poisonings occurred.

Last week, the Trump administration announced that the FDA will be issuing warnings that “the use of acetaminophen [the active ingredient in Tylenol] by pregnant women may be associated with an increased risk of neurological conditions such as autism and ADHD in children.” The president himself offered medical advice: “If you’re pregnant, don’t take Tylenol, and don’t give it to the baby after the baby is born.”

Physician groups have made it clear that the highest quality evidence available suggests acetaminophen is safe during pregnancy, and that there are risks to leaving pain and fevers untreated or treated by other drugs. But some pregnant mothers will likely heed the administration’s advice and, as in 1982, be less likely to take acetaminophen than they otherwise would have been.

Though some studies cited by the administration have found correlations between acetaminophen use during pregnancy and the childhood development of neurodevelopmental disorders like autism and ADHD, these studies lack the most important feature of high quality research: randomization. Without randomization, it’s difficult to establish that acetaminophen use during pregnancy causes childhood autism or ADHD.

After all, it might be that mothers of children with higher genetic or other risk for autism are simply more likely to take acetaminophen. Mothers who are more likely to take acetaminophen may also be more likely to bring their child in to be evaluated for a neurodevelopmental disorder. The reason a pregnant mother took acetaminophen in the first place—for example, a viral illness causing fevers—could also increase the rate of these disorders. The inability to account for these confounding factors is why correlation does not equal causation.

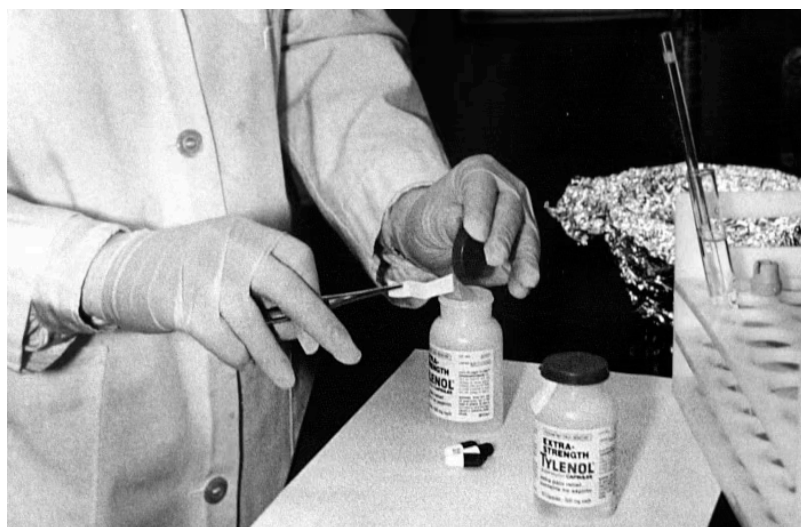
FDA commissioner Marty Makary, in his notice to physicians, said as much: “To be clear, while an association between acetaminophen and autism has been described in many studies, a causal relationship has not been established and there are contrary studies in the scientific literature.”

This recent public health announcement is, in part, the result of a much broader problem with public health and medical research. In the absence of randomized control trials, the void is often filled with studies that repeatedly establish correlations while doing little to address questions of causation.

Randomized trials are the gold standard in such research, but they can be costly and time consuming. By contrast, natural experiments—situations where otherwise similar individuals are exposed, by chance, to different treatments—are a cheaper tool that can be used to study hard-to-answer questions. But they require ingenuity, as hard problems often do.

So what about the hypothesis that Tylenol use during pregnancy causes neurodevelopmental disorders in children? Randomized controlled trials are one way to prove whether this is true. If we really want to know what happens when pregnant mothers with fevers take acetaminophen, we have to compare them to a similar group of mothers with fevers who are randomly selected not to take acetaminophen. Trials like this aren't easy to do, in part because studies of pregnant patients have unique ethical considerations.

But there may be other approaches, if we're willing to search for them. For instance, both the 1982 Tylenol murders and the Trump administration's recent announcement provide us with a natural experiment, wherein a randomly timed factor—like national panic over a contaminated drug supply or new warnings issued by the federal government—could influence pregnant women's decisions to take acetaminophen.



Bottles of Extra-Strength Tylenol are tested for cyanide after poisoned capsules killed seven people in Chicago in October 1982. PHOTO: JOHN SWART/ASSOCIATED PRESS

In 1982, mothers who were at critical stages of pregnancy in the fall would have been less likely to take acetaminophen compared with mothers who reached that same stage of pregnancy earlier that year. The reduction in acetaminophen use may also have been greater in Chicago, where the deaths occurred, compared with other large cities. If acetaminophen causes neurodevelopmental disorders, we should expect to

see a lower rate of these disorders among kids who were in utero just after Tylenol was removed from pharmacy shelves.

A similar analysis, based on likely changes in acetaminophen use brought on by the new announcement, could be conducted several years from now. Such study designs could also measure the potential harms of untreated pain and fevers among pregnant mothers.

Alternatively, one could look at children born just before or after 1960, when acetaminophen first became available as an over-the-counter drug that didn't require a prescription and was likely used more often by pregnant mothers.

Another idea would be to take advantage of a common practice in medicine: treatment cutoffs. A fever is traditionally defined as 100.4 degrees Fahrenheit, meaning that pregnant women with a temperature of 100.2 may be less likely to take acetaminophen—even though they have essentially the same temperature. That small difference in temperature would serve to effectively randomize pregnant women into groups receiving acetaminophen or not. If acetaminophen caused neurodevelopmental disorders, we would expect to see a lower rate in children of mothers whose temperature was 100.2 (versus 100.4) when they were sick during pregnancy.

The best evidence to date suggests that acetaminophen use during pregnancy does not cause autism or ADHD. If it does, the current studies certainly don't prove it. Advising pregnant women to forego medication for pain and fevers could potentially be harmful.

Studying such difficult questions requires creative and rigorous solutions, which is what today's patients, facing so much confusing advice about this common drug, deserve.

Christopher M. Worsham is a critical care physician and professor at Harvard Medical School. Anupam B. Jena is an economist, physician and professor at Harvard Medical School. They are the authors of "Random Acts of Medicine: The Hidden Forces That Sway Doctors, Impact Patients, and Shape Our Health" and the Random Acts of Medicine Substack.

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