

Infants exposed to certain biologics during pregnancy can safely receive rotavirus vaccine, finds study

November 27 2023



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A study by University of Calgary researchers and the Canadian Immunization Research Network may prompt a change to vaccination

guidelines for infants. Researchers investigated how the immune systems of babies exposed to biologic agent medications during pregnancy are affected.

Biologic agents or biologics are commonly used in the treatment of autoimmune conditions, such as Crohn's disease and rheumatoid arthritis. People with these types of diseases who become pregnant are generally encouraged to continue biologic therapy throughout pregnancy, helping to prevent disease flares or other complications. In the past, it hasn't been well understood how biologics affect the developing immune system of a fetus, including the potential impacts into childhood.

"The present recommendations were not supported by evidence and from an infectious disease and vaccinology perspective, we knew it didn't make a lot of sense to keep the rotavirus [vaccine](#) away from this population," says Dr. Cora Constantinescu, MD, Calgary principal investigator.

Currently, the guidelines state that live vaccines for these infants should be avoided in the first six months of life which, according to the Canadian immunization schedule, excludes these babies from receiving the rotavirus vaccine. Rotavirus—a cause of severe diarrhea and dehydration in infants and [young children](#)—can pose a serious risk for babies in the first few years of life. After six months, it is too late for administration of this vaccine, leaving these young children susceptible to severe infection.

We don't want to leave these babies unprotected

In 2017, physicians at the Alberta Children's Hospital began assessing such infants to determine if they could safely receive the rotavirus vaccine, performing the most in-depth immunological assessment of these babies compared to what had been previously reported in the

literature. They expanded their clinical work into a study, focusing on the most common biologics (mainly anti-TNF alpha agents) used for pregnant people with autoimmune diseases and making case-by-case recommendations for vaccination.

"We performed an in-depth analysis of the different components of these babies' immune systems, which is one of the strengths of this study," says Dr. Luis Murguia-Favela, MD, pediatric immunologist at the Alberta Children's Hospital and co-author on the paper. "We found that all infants had normal immunological development, with no evidence that prenatal exposure to biologics caused changes in the immune systems of these babies."

Once infants were cleared, the team liaised with the Calgary Zone Public Health Provincial Immunization Program to arrange for the rotavirus vaccine to be given, as per the recommended schedule for each infant.

"We have the perfect setup and have built outstanding relationships in Calgary: a fantastic and well-supported outpatient pediatric infectious diseases clinic, an incredible and very engaged immunology team and state-of-the-art immunology lab, a trusted relationship with our adult colleagues and their expertise, such as Dr. Cynthia Seow, MD, from gastroenterology who looked after the pregnant adult counterparts," says Constantinescu. "And of course, the Calgary Zone Public Health Provincial Immunization Program who trusted our protocol and expertise to go ahead and safely vaccinate these babies."

Hope that the research will change guidelines

Via the Canadian Special Immunization Clinic (SIC) Network, this approach took on a national collaboration and grew in scale. A total of 191 infants were referred to one of six sites across Canada, representing the largest cohort of infants exposed to biologics during pregnancy to

date. All [infants](#) enrolled in the study were followed closely to monitor outcomes following rotavirus vaccination. The findings were [published](#) in *The Lancet Child & Adolescent Health*.

"Experts across Canada came together based on the science to determine the best clinical care for these babies," says Dr. Karina Top, MD, national principal investigator who led the SIC Network at Dalhousie University and has since relocated to the University of Alberta as a pediatric infectious disease professor. "This is a great example of physicians working across specialties and provinces on a common goal: to improve care for our patients. The success of this project also speaks to the trust that these parents and families have in us."

"Calgary was truly the 'epicenter' for this ongoing collaboration. We are hopeful that this work will change guidelines so that these babies can proceed with rotavirus vaccine safely as part of their routine infant immunization series, without the need for specialized assessments," says Constantinescu. "We hope to be able to offer the [rotavirus vaccine](#) to these families so their babies have the same level of protection as the next baby, and we now know that we can do that safely."

More information: Tiffany Fitzpatrick et al, Immunological effects and safety of live rotavirus vaccination after antenatal exposure to immunomodulatory biologic agents: a prospective cohort study from the Canadian Immunization Research Network, *The Lancet Child & Adolescent Health* (2023). [DOI: 10.1016/S2352-4642\(23\)00136-0](https://doi.org/10.1016/S2352-4642(23)00136-0)

Provided by University of Calgary

Citation: Infants exposed to certain biologics during pregnancy can safely receive rotavirus vaccine, finds study (2023, November 27) retrieved 29 April 2024 from

<https://medicalxpress.com/news/2023-11-infants-exposed-biologics-pregnancy-safely.html>

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