

## A roadmap for critical COVID-19 research in children

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Increasing reports of severe COVID-19 illness in children—coupled



with the fact that little is known about how and why the disease may behave differently in this younger population—demand that a set of critical steps be taken now to ensure children get the attention they need, according to an article just published in *Pediatric Research*.

The article, authored by research experts from I-ACT for Children and other leading pediatric researchers, outlines a roadmap for better understanding the disease in children and ensuring that potential treatments and vaccines are developed for children with the same level of urgency given to adults.

"Although the volume and severity of COVID-19 illness in adults has been greater, we cannot afford scientific unknowns for children, especially with mounting reports of severe illness in children.," said Gary Noel, M.D., the study's lead author and I-ACT for Children's Chief Medical Officer. "Studying the infection in children now could lead to valuable information that helps us successfully treat COVID-19 and prevent its further spread."

In early April, the CDC calculated that in the United States, about 1.7% (2,572 of 149,082 for which age was reported) of COVID-19 cases had occurred in children (

The authors outline five key areas of pediatric research that require urgent action:

1. Understanding how COVID-19 infection develops and progresses in children and the impact of a mother's infection during pregnancy on her newborn.

The early suggestion that children are at lower risk of severe disease from COVID-19 infection remains unexplained and has not been confirmed; research aimed at defining the pathophysiology and course of



the disease in children is essential for developing the <u>best treatment</u> and prevention strategies to address children's medical needs. This should receive the highest priority in the clinical research community.

2. Ensuring the availability of widespread, rapid point-of-care diagnostic testing to assess prevalence, inform prevention strategies.

Identifying infected children more extensively and more rapidly can help define the role children may be playing in spreading the infection, as well as help researchers understand the course of the disease in these children. The authors suggest that limited availability of testing has likely resulted in a significant underestimation of the number of infected children.

3. Conducting widespread antibody testing of children as a marker for susceptibility.

Defining the role specific antibodies play in determining immunity to COVID-19 infection is needed not only to advance vaccine strategies, but also to better understand the extent to which infants and children have responded to these infections, and therefore may be protected from new infections.

4. Establishing a dedicated framework for testing the safety and efficacy of new COVID-19 treatments in children.

As treatments are being developed and tested in adults, including pediatricians in that study planning can help ensure the collection of data that can be used to inform and accelerate pediatric studies, through use of extrapolation and other innovative research methods. Studies of investigational agents in children should begin as soon as deemed ethically appropriate based on risk and benefit assessment.



5. Evaluating vaccines and other preventive measures for children.

As with new treatments, early preparation for inclusion of children in trials of new vaccines and other preventive agents is important—and these trials should not be delayed once careful risk-benefit assessment justifies such inclusion. It is already clear that the risk for serious disease exists, and that the family impact of infection/disease in children can be significant.

"While it appears so far that children represent a small proportion of the total population with serious COVID-19 <u>disease</u>, this should not mean that we are left without the information we need to make well-informed decisions about using new therapies in children who are critically ill," said Edward Connor, M.D., M.B.E., Founder and Chairman of I-ACT for Children and the article's senior author. "We must collaborate to ensure pediatric needs aren't pushed to the edge of the radar."

Drug development in pediatrics has been slow and inefficient for decades. Half the medicines prescribed for children have never been proven effective for them. I-ACT for Children was created to level the playing field by championing and participating in the research needed to ensure children have the same access as adults to effective medicines.

I-ACT for Children has created a public-private pediatric research network that is specifically designed to advance product development in <a href="mailto:children">children</a>. It collaborates with similar organizations in Europe, Canada and Japan to provide a global research framework.

**More information:** Gary J. Noel et al. Key clinical research priorities for the pediatric community during the COVID-19 pandemic, *Pediatric Research* (2020). DOI: 10.1038/s41390-020-0962-y



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