

<u>BRIEF19</u>

A daily review of covid-19 research and policy

RESEARCH BRIEFING

Coronavirus vaccines for kids: are we throwing away their shot?

With a slew of reassuring data, vaccine rollouts now firmly underway, and President Biden promising that there will be sufficient shots <u>available</u> for every US adult by this coming May, it seems that the waiting and wondering for most adults may be coming to an end. And yet, for pregnant women and children, the fact remains that no studies have adequately assessed the safety and efficacy for these populations for any of the three vaccines currently authorized for use in the US. Earlier this month, an article in the medical journal <u>*Pediatrics*</u> put forth recommendations from the American Academy of Pediatrics (AAP) for when and how to start enrolling children in the coronavirus vaccine trials.

While the risks of enrolling children in clinical trials is not an easy choice for parents to make, the authors of the paper weighed the decision between exposing kids to unnecessary risk around covid-19 against ensuring that the same children are not missing out on the likely substantial benefits offered by vaccines. Highlighted in the paper is the fact that more children are becoming infected with covid-19 now than at any time during the pandemic; in November, it was reported that 11.5 percent of cases were in minors, and while a majority of the documented cases have been asymptomatic or have been mildly symptomatic, a handful can develop severe illnesses. These devastating outcomes, including those caused by the after effects of a <u>rare but</u> harmful condition known as Multisystem Inflammatory Syndrome in Children (MIS-C), are well worth preventing, especially if the vaccines are as safe as they are in adults.

The AAP has consistently advocated for including children in vaccine research, and the organization continues to do so in this paper. Of course, as the writers acknowledge, one of the most difficult aspects of enrolling children in vaccine trials is that they are often unable to consent for themselves and therefore are reliant on their parents' providing consent for them.

But the recommendations boil down to this: the AAP feels that the benefits of enrolling children in vaccines trials outweigh the risks. Vaccinating our youth would be a way to help reopen schools and daycare centers, address education gaps that have widened during the use of virtual learning, and help to address social, emotional and mental health issues that have come to the forefront during the pandemic. The key to making this recommendation from the AAP's perspective was noting the robust safety profile that has been recorded for the various vaccines tested in adults. Drawing on this, researchers are first expanding studies to adolescents, and will add younger children in the future.

Ultimately, children are a large part of our society, and their health, wellness and immunity have an important impact on everyone. Not only would enrolling kids in these trials be a service to themselves, society would benefit as a whole. Kids could be a major piece of the puzzle in ending this pandemic once and for all.

—Joanna Parga-Belinkie, MD

POLICY BRIEFING

FDA rejects ivermectin, despite growing interest in some corners of the internet.

Throughout the pandemic, various treatments and preventives have floated into the public consciousness as possible covid-19 treatments based on their efficacy against other, unrelated conditions or based on studies done on cells in laboratories. One drug that has gained popular

footing is called ivermectin, an anti-parasitic drug. A recent <u>JAMA</u> article (covered in <u>Brief19</u>) provides background on this growing interest, as a result of the drug's efficacy against the virus in animal and *in vitro* models.

The US Food and Drug Administration (FDA) has now <u>updated</u> its information page on ivermectin, stating that the drug is only approved to treat two conditions caused by parasitic worms in humans, as well as multiple parasitic infections in animals. Further, the agency specifies that ivermectin is not considered a true antiviral therapy. The biggest point that the FDA emphasizes is that formulations for animals are different than those for humans, and individuals should under no circumstances take medication compounded for a different species. *Various*.

—Brief19 Policy Team

Kimi Chernoby, MD, JD, Policy Section Founder, Joshua Niforatos, MD Research Section Editor, Frederick Milgrim, MD, Editor-at-Large, Joshua Lesko, MD Lead Policy Analysist, Barb Cunningham, Copy-editor, Benjy Renton, Thread-of-the-Week, Anna Fang, Week-in-Review. Megan Davis, social media. Kane Elfman PhD, Publishing and Design. Jeremy Samuel Faust MD MS, Editor-in-Chief. <u>http://www.brief19.com/</u> Twitter: <u>@brief 19</u> submissions@brief19.com. Brief19 is a daily executive summary of covid-19-related medical research, news, and public policy. It was founded and created by frontline emergency medicine physicians with expertise in medical research critique, health and public policy.