

BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

The pandemic's effect on preterm birth rates. What you've heard may be wrong.

Since the 1800s, pediatricians have [speculated](#) about the causes of preterm birth with little concrete evidence or answers. Now, new data in light of the covid-19 pandemic has sparked a renewed conversation. Recently, officials from [Denmark](#), [Ireland](#) and the [Netherlands](#) have reported decreased rates of preterm birth during the pandemic. Researchers have speculated that things like physical distancing and improved hand hygiene decreased exposure to viruses and bacteria for pregnant women. However, a full understanding remains elusive. To make matters muddier, new data gathered in Philadelphia, seems to contradict these findings.

A recent [JAMA](#) article assessed new preterm birth data from Philadelphia gathered from two large delivery hospitals, defining the premature birth as birth of an infant at less than 37 weeks of pregnancy. The researchers divided births into spontaneous and “medically indicated preterm birth” (i.e. induced or c-section). They also measured the rate of stillbirths. Given the relative diversity of Philadelphia (particularly in comparison to the aforementioned European countries), the new data with respect to race and ethnicity are of particular interest.

In total, there were nearly 3,000 premature births between March and June of 2020, approximately the same number during those months in both 2018 and 2019. Researchers found no significant difference overall in preterm births or stillbirths. The one notable exception was that non-Hispanic White women had a decreased rate of spontaneous preterm births.

Unfortunately, there are far too many variables to make heads or tails of this outcome, especially when compared to the European data. As such, the authors offer differences in population heterogeneity, stay-at-home policies, social stressors, and healthcare access as possible explanations. Hopefully there will be follow up to the Philadelphia and European studies, but until then, it remains important to remember that there should be no stigmatization of women and families regarding preterm birth. Doctors and scientists still have few answers, and it would not be productive to believe women have the ability to control prematurity. Perhaps in the future we will have more answers to this centuries old question. —*Joanna Parga-Belinkie, MD*

Your pediatrician doesn't want covid-19 to make you forget about other vaccines.

With all the hype surrounding the forthcoming covid-19 vaccines, it can be easy to forget that there have been plenty of feared viruses and bacteria over the years, which we have managed to largely suppress with modern science and medicine. Particularly in the pediatric community, one of the more feared infectious is *Haemophilus influenzae*, specifically type b, known as *Hib*. In children under 5 years old, *Hib* is known to be a leading cause of meningitis, a particularly dangerous of spinal cord and/or brain infection.

Over the years, millions of American children have been [vaccinated](#) against *Hib* and rates of the disease have plummeted. The *Hib* vaccine is safe and effective, but horrifyingly, it's also becoming increasingly underutilized. A pediatrician's worst nightmare is that a forgotten disease like *Hib* will make a resurgence in communities who are forgoing their routine vaccinations out of fear. Many Americans are fearful of taking their child to the doctor because covid-19 might be in the waiting room. But the reality is that many of the diseases we routinely vaccinate against are far more deadly to children than covid-19 is. Unfortunately, pediatricians have noticed that they are administering far fewer vaccines in 2020, as reported in a new [JAMA Pediatrics](#) paper.

In this study, researchers pulled data from the Colorado Immunization Information System, in which the vast majority of state healthcare providers log vaccine administrations. The investigators studied a period from January 5, 2020 to May 2, 2020 to assess the effect of the pandemic on vaccine administration. (Social distancing guidelines went into effect on March 15 in Colorado). They found that by the middle of March, immunization rates had plummeted in children age 0 to 17. In the most critical vaccination window of 0 to 2 years (when infants get multiple doses of the *Hib* vaccine), rates fell by 31 percent.

There is no doubt that this is happening in other states across the country. It would be devastating if one of the many secondary harms of covid-19 became an epidemic of vaccine preventable disease in the United States. Because of this, pediatrician offices are taking full [precautions](#) to make office visits safe. Yes, the covid-19 vaccine will be an important step towards a healthier and safer America, but the vaccines we routinely administer are arguably just as important, safe and effective. And they're not just for children—get your flu shot this year and any others you may be due to receive.

—Joanna Parga-Belinkie, MD

POLICY BRIEFING

FDA set to make EUA recommendation for Pfizer/BioNTech vaccine today.

In the wake of multiple countries including the U.K. and [Canada](#) approving the covid-19 vaccine manufactured by Pfizer and BioNTech, Americans await the Food and Drug Administration's (FDA) final determination regarding Emergency Use Authorization (EUA). The EUA request was sent on November 20, and the FDA's vaccine advisory committee will meet today to make its final recommendation. Ahead of its meeting, the FDA released its [analysis](#) on Tuesday, suggesting that the EUA would be forthcoming.

In its analysis, the FDA discusses the ongoing safety and efficacy data being collected as part of the phase 3 randomized double-blinded and placebo-controlled trial. Thus far, the data from ~36,000 participants randomized to receive either a two-part vaccine or placebo, has suggested a 95 percent efficacy in preventing covid-19. Plus, the vaccine has been shown to decrease severe illnesses and reduce rates of symptomatic disease even after just one dose.

Furthermore, they remarked that the safety profile of the vaccine suggests, “no specific safety concerns identified that would preclude issuance of an EUA.” The most common adverse reactions reported were injection site reactions, fatigue, headache, muscle pain, chills, joint pain and fever. Severe adverse reactions were recorded in 0 to 4.6% of participants, and were more common after the second dose. Serious adverse reactions were noted to be less than 0.5%.

Today's meeting will be an open forum, during which the FDA will ask its committee to recommend whether they think the potential benefits of the vaccine outweigh its risks based on the available scientific evidence and suggest possible follow up studies. Of note, their recommendations will be made only for Americans ages 16 and older.

Though safety and efficacy data will be collected for many months to come, it is clear that this and the other

candidates, such as those from Moderna and AstraZeneca, boast strong safety and efficacy profiles. While we may yet learn of rare complications resulting from the new mRNA technology used by Pfizer and Moderna, we also know that the possibility of covid-19 infection leading to death is at least an order of magnitude greater than the flu and countless recovered patients are still suffering from [long term](#) symptoms. *Various.* —Fred Milgrim, MD

Kimi Chernoby, MD, JD, Policy Section Founder, Joshua Niforatos, MD Research Section Editor, Frederick Milgrim, MD, Editor-at-Large, Barb Cunningham, Copy-editor, Anna Fang, Week-in-Review. Megan Davis, social media. Kane Elfman PhD, Publishing and Design. Jeremy Samuel Faust MD MS, Editor-in-Chief. <http://www.brief19.com/> Twitter: [@brief_19_submissions@brief19.com](https://twitter.com/brief_19_submissions). 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.