BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

Pfizer/BioNtech vaccine data indicates 100 percent reduction in SARS-CoV-2 among US children ages 12-15. Will it save any lives? Almost certainly.

The US Food and Drug Administration extended the Emergency Use Authorization for the Pfizer/BioNtech vaccine to adolescents ages 12-15 on Monday. The FDA <u>published data</u> on the safety and efficacy of the mRNA-based vaccine, which has been administered to millions of adults in 93 countries without any major safety concerns so far.

The short of it is that the vaccine performed well, according to data that followed the outcomes of adolescents who received either the vaccine or a placebo. There were 16 cases of covid-19 among adolescents who received placebo and *zero* among those who received the Pfizer/BioNtech vaccine. We do not know how serious the cases in the placebo group were.

But first and foremost, this was a safety assessment. Over half of the adolescents who received the vaccine experienced headache or fatigue after the first dose and nearly 2/3 of recipients had these symptoms after the second dose. As with the adults, a lower but still impressive number of people who received a placebo shot also reported these symptoms (around 35-40 percent). Interestingly, the number of subjects with these symptoms was *lower* after the second placebo dose, implying that psychological effects of were higher after the first sham shot than the second. In fact, rates of most side effects were higher after subjects got their second "real" dose, while almost all of those same side effects went down the second time among those getting placebo. (As a sidebar, I add that the human mind is never ceases to amaze). The rate of severe symptoms was generally under 1 percent, though for a few systemic reactions like headache, up to 2 percent reported a "severe" instance, and 2.3 percent reported fevers as high as 102-104F (38.9C-40.0C).

But what about "serious adverse events," define as death, a life-threatening adverse event, hospitalization (or prolonging of an existing hospitalization), disruption of the ability to conduct normal life functions, or any "important medical event"? In the place group 0.1 percent of the 1,100 subjects (or around 1 person) reported such an occurrence, compared to 0.4 percent (4 people) in the vaccine group. We were not given granular details on these 5 events, but it's more likely that the events were of the milder nature of these "severe adverse events" (i.e. prolongation of existing hospitalization as opposed to death), both by virtue of the odds of death in general being low, and the absolute scandal that it would be if 4 deaths out of 1,100 kids in the vaccine arm were not mentioned to the FDA. The FDA document states that there were "no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine."

Meanwhile, antibody levels taken one month after the second dose were excellent among 12-15-year old subjects included in the dataset. In fact, the levels were more robust than those seen among 16-25-year old test subjects from previous studies.

So far, in the US, 282 children ages 0-17 have died from covid-19. If the vaccines are 95-100 percent effective in reducing deaths among this group, as they appear to be in younger adults, the new data mean that vaccinating kids could save hundreds if not thousands of pediatric lives in the United States in the coming months. Just how many remains unknown. However, we can make some <u>educated guesses</u>. If it is the case that 50 percent of US children have already been infected with SARS-CoV-2, then fully vaccinating the entire pediatric population would

effectively safe 282 pediatric lives (since half remain unexposed and we assume that the mortality rate would apply if the kids were not vaccinated). If merely 20 percent of US children have been exposed (which is possible, given school closures), vaccines would be poised to save over 1,100 more lives of US children. These numbers, of course, do not take into account the suffering related to far higher rates of hospitalization and other complications such as the multisystem inflammatory syndromes in covid-19 (MISC), which according to the US Centers for Disease Control and Prevention has affected over 3,000 US children as of April 2021.

Pediatric vaccinations appear safe in the short-term. Assuming this continues to be the case in the longer run, vaccinating kids will remain an important tool in ending the covid-19 pandemic.

—Jeremy Samuel Faust MD MS

POLICY BRIEFING

Unemployment benefit restrictions return as many states struggle to fill open jobs.

Following last week's surprisingly disappointing unemployment numbers, several states have taken steps to reimpose limitations on unemployment benefits that were temporarily removed due to the coronavirus pandemic. Only a few states have announced that they will stop receiving federal aid to provide \$300 in supplemental income weekly to those enrolled in unemployment benefit programs, but many others have already begun requiring beneficiaries to be actively searching for work to receive the benefits. Although details and timing of these changes are varied, they are happening in both red and blue states.

Critics of the recent moves argue that a myriad of problems exposed by the pandemic remain, resulting in fewer workers seeking the jobs that are available. One example they point to is the large number of women who are still responsible for childcare. Many of the high skill positions which were eliminated by the economic downturn still have not returned, leaving those workers torn between waiting for their old careers to come back or accepting new jobs, often with significantly lower wages. Furthermore, employers and staffing companies are concerned that they may not be able to fill a large number of seasonal positions including those at hotels and restaurants before the summer months. *The Associated Press*.

—Jordan M. Warchol, MD, MPH

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