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BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

Pfizer/BioNtech data from Israel. Four key takeaways including why the second dose matters.

The United States has administered the highest number of coronavirus vaccines. Israel had vaccinated the second highest percentage of its population, trailing only Seychelles, the nation located in the Somali Sea

[New data](#) in *The Lancet* out yesterday provides important updates and insights that go well beyond the usual expected results—i.e. that the Pfizer/BioNtech mRNA-based coronavirus vaccine works spectacularly well. Let’s look at four key points in this new study.

First, the data show that the “real world” data match the approximate findings of the data from the phase III clinical trials which first made headlines in November. The vaccine provides impressive protection against covid-19-related hospitalization and deaths across a wide spectrum of age groups. The news here is that the data remain impressive—with 97 percent reduction in hospitalizations—even in the face of SARS-CoV-2 variants. The B.1.1.7 variant (the so-called “UK Variant”) accounted for 94.5 percent of all infections. This is incredibly important news.

Second, the vaccine decreased both symptomatic infection (97 percent effective) and asymptomatic infection as well (91.5 percent effective). This means that the over 9 in 10 people who are vaccinated have *zero chance* of spreading the virus to others. Whether spread occurred from the few people who had “breakthrough infections” to other people remains unknown.

Third, the vaccine was effective across a wide array of ages. Some people mistakenly believe that covid-19 is harmless to adolescents and young adults. In Israel, 36 people aged 16-44 died of covid-19 during the 2.5 months that was studied. Every single one of those deaths occurred in unvaccinated individuals. Given that Israel’s population is approximately 36-times smaller than the United States, the equivalent number of deaths in the US would have recorded 1,300 deaths among persons age 16-44. This is a strong argument for vaccinating people in all approved age groups.

Lastly, the study provided granular data on the effectiveness of one dose. The researchers found that at day 21 (i.e. prior to a 2nd vaccination), the vaccine’s effectiveness was certainly notable but not nearly at its peak. At day 21, the effectiveness in protecting vaccine recipients from any-and-all infection was 57 percent; the effectiveness in protecting against asymptomatic infection was 49 percent. This implies that in that weeks leading up to the 2nd dose and after, an important fraction of people could still get the virus, some of whom were hospitalized and died. Again, it remains unknown whether these partially vaccinated individuals were able to spread the virus to others still. In addition, we do not know how long the first dose confers immunity. So while one dose is certainly a large improvement over zero doses, these data suggest that, at least for now, the second dose is important. That said, the researchers did not follow outcomes of the relatively few persons who never received a second dose, so we do not know whether the numbers would have improved to the levels seen two weeks after the second dose. What is known, is that the second dose of the Pfizer/BioNtech vaccine boosts antibody levels impressively, a finding which is thought to help protect against coronavirus variants slip out of the antibody-virus chokehold more easily.

—Jeremy Samuel Faust, MD MS

POLICY BRIEFING

Eli Lilly facing staff complaints at its drug manufacturing sites.

In the haste to beat back the ever-advancing covid-19 pandemic over the past year, scientists, researchers, and pharmaceutical companies have had to work at breakneck speed—occasionally to the detriment of quality. Examples of this came in the form of at least some less-than-high-quality journal articles, and some questionable manufacturing [practices](#) at the one of the facilities making the Johnson & Johnson vaccine. Now, Eli Lilly seems to be facing some similar challenges with respect to quality control.

[According to employees](#) at the company, a factory executive in Branchburg, New Jersey may have altered government-required documents in order to downplay quality control problems at the plant where Lilly's monoclonal antibody treatment, bamlanivimab, was being manufactured. Per *Reuters*, the internal complaint from early April asserts that the executive rewrote findings by Lilly's technical experts at the plant to make more favorable conclusions, which were then shared with the US Food and Drug Administration (FDA) as part of its investigation of the site.

The complaint was filed by more than 10 employees, including managers, who claimed they saw the findings before and after they were allegedly edited to paint a rosier view. A Lilly spokesman confirmed the employees' complaint and said that the company takes all reports of improper or inappropriate conduct seriously.

Separately in March, FDA inspectors identified numerous manufacturing lapses at another Lilly facility, in Indianapolis, with respect to substandard sanitation and quality control procedures of bottles of its covid-19 therapy and other drugs. The troubles at these factories, in addition to numerous internal complaints in recent years, deepen the challenges facing one of the nation's largest drug producers.

—Miranda Yaver, PhD

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