Novavax and Vaccine Efficacy

By Chuck Dinerstein, MD, MBA — February 2, 2021

Our first two vaccines have greater than 90% efficacy; Novavax reports 89.3%, Johnson and Johnson’s reports 66%. Should we care? What do those numbers mean to you and me when we worry about the protection the vaccine affords us?

Novavax

Quick note, the data has only been provided as a press release; the FDA documents are pending.

Novavax is unlike the two current vaccines. It features a COVID-19 spike protein (the portion of the virus attaching to the cell) made by recombinant technology in insect cells. In contrast, the two mRNA vaccines use your cell's manufacturing system to make the spike protein. Novavax’s vaccine also involves an “adjuvant,” a molecule that enhances the immune response and is a common feature in other vaccines. Like the other two vaccines, it requires two doses, three weeks apart; but doesn’t need those supercold temperatures and cold chain logistics.

The phase 3 trial, conducted in the UK, involved 15,000 adults, of which 27% were over 65. There were 62 cases of PCR-proven COVID-19, 56 in the placebo group, 6 in the vaccinated – that is the source of the 89.3% efficacy. Sixty-one cases developed mild or moderate symptoms; only one in the placebo group was severe. What is more important to note is that patients had to have
symptoms to be identified. We have no idea how many were asymptotically infected. B.1.1.7, also known as the UK variant, was found in half of those PCR proven cases; while the vaccine was more effective against COVID-19, the original at 95%, the efficacy against the variant was 85%.

The more controversial data was found in a phase 2b trial of Novavax in South Africa. A 2b trial is meant to determine optimum doses and intervals. It precedes a full out phase 3 study. The trial was smaller, involving 4,000 individuals. There were 29 cases in the placebo arm, 15 in the vaccination arm – as in the other study, only one individual had a severe disease course, and they were in the placebo arm. As a result, overall efficacy was 60%. But the study comes with some crucial caveats.

First, about a third of the participants had already been exposed to COVID-19 based upon their pre-vaccination testing. Second, the troubling South African variant was in wide circulation at that time. The results do not include those that were serologically positive before vaccination. Then there is this:

“In the South Africa Phase 2b clinical trial, 60% efficacy (95% CI: 19.9 – 80.1) for the prevention of mild, moderate and severe COVID-19 disease was observed in the 94% of the study population that was HIV-negative.”

That last clause caught my eye, HIV negative – why mention HIV? For two good reasons.

- When including HIV positive individuals, the efficacy of the vaccine drops to 49%.
- South Africa has the highest prevalence of HIV in the world, roughly 20% of its population. For comparison, the prevalence in the US is in the range of 0.01 to 0.03%.

Vaccines will work differently on differing populations, for reasons we may ill understand, at this point. Undoubtedly, some genetic influences, possibly gender differences, and Novavax’s data show other chronic infectious diseases can play a role.

You have to understand who is being tested and judge the results based on how well you are reflected in that group.

**Vaccination for COVID-19 is not a magic bullet**

The vaccines do not prevent all COVID-19 infections, but they significantly lessen the consequences. As with many medical care advances in the last few decades, and HIV is a great example, we can convert a lethal disease into a smoldering, chronic illness. Given the alternative, to simply accept COVID-19’s case fatality rate and that of its variants, chronic illness or a transient infection is a bargain. That is how we have been treating seasonal flu; we convert it into a more benign disease. As with these studies of COVID-19 vaccines, we do not test everyone to identify the asymptomatic – we have little idea of how many individuals with seasonal flu vaccinations become infected. We only see the symptomatic. (By the way, the cases of seasonal flu [3] are way down this year.)
As with other COVID-related medical issues, we know very little about how vaccines alter our day-to-day immune response. We know that they are very effective in eliminating the disease, as measured by symptoms, and in lessening the disease as measured by outcomes. Any of these vaccines will do the trick right now. There should be no fighting about which is best and which one goes in your arm.

Source URL: https://www.acsh.org/news/2021/02/02/novavax-and-vaccine-efficacy-15311

Links