J&J COVID-19 Vaccine Is 72% Effective After a Single Dose in U.S. Study

Another vaccine, from Novavax, was 89% effective in a U.K. trial, but both were less potent against the South African coronavirus mutation.

January 29, 2021 By Liz Highleyman

Two new COVID-19 vaccines may soon join the armamentarium against COVID-19, which should substantially increase the total supply and speed up the ongoing vaccine rollout in the United States and worldwide.

A single-shot vaccine from Johnson & Johnson (J&J) reduced the risk of COVID-19 by 66% overall in Phase III trials, the company announced on January 29. Another vaccine, from Novavax, was 89% effective in a trial in the United Kingdom, according to the company. But the efficacy of both vaccines dropped off in South Africa, where a new, more transmissible coronavirus variant is circulating.

Although not as highly effective as the Pfizer/BioNTech and Moderna mRNA vaccines—95% and 94%, respectively—the J&J and Novavax vaccines could still be potent weapons against COVID-19. The J&J vaccine requires only a single injection, doubling the number of people who can be vaccinated with a given supply. Both vaccines can be stored in a standard refrigerator and are easier to transport and distribute than the more fragile mRNA vaccines, which must be kept at super-cold temperatures.

The J&J vaccine uses a weakened human adenovirus—similar to viruses that cause the common cold—as a vector to deliver genes encoding the SARS-CoV-2 spike protein. (The company's Ebola virus vaccine uses the same AdVac technology, which is also being studied for HIV.) A vaccine from AstraZeneca and the University of Oxford, already approved in the U.K. and several other countries, uses a chimpanzee adenovirus vector. The Pfizer/BioNTech and Moderna mRNA vaccines deliver genetic blueprints for the spike protein encased in fat bubbles, turning human cells into factories to produce the protein. The Novavax vaccine directly injects an engineered version of the spike protein produced in insect cells.

With all the vaccines, the immune system recognizes and produces antibodies against the spike protein, which the virus uses to enter human cells. Although levels of antibodies in the blood normally wane over time, antibody-producing memory B cells remain behind, primed to restart production if the coronavirus is encountered again. Long-lived T cells also play a role in immunity.

But the whole process can be stymied if the spike protein mutates so much that it no longer resembles the one the vaccines were designed to target.

J&J Vaccine

The J&J vaccine (dubbed Ad.26.COV2.S or JNJ-78436725), developed by Janssen Pharmaceuticals, was evaluated in the Phase III ENSEMBLE trial, which enrolled more about 44,000 adults in six Central and South American countries, South Africa and the United States.

Across the U.S. sites, 74% of participants were white, 15% were Latino, 13% were Black, 6% were Asian and 1% were Native American. One in four had underlying health conditions associated with higher COVID-19 risk, including obesity (29%), hypertension (10%), diabetes (7%) and HIV (3%).

The participants were randomly assigned to receive a single injection of the vaccine or a placebo.

An interim analysis showed that the vaccine was 66% effective overall at preventing moderate and severe COVID-19 at 28 days after the single dose. What's more, it demonstrated protection for people of all ages—including older people who tend to have weaker immune responses—all racial/ethnic groups and people with comorbdities.

However, the effectiveness differed by region. The vaccine showed 72% effectiveness in the United States and 66% effectiveness in Latin America, but this fell to 57% in South Africa, where a new, more transmissible variant dubbed B.1.351 is predominant.

Across regions, the vaccine was 85% effective at preventing severe COVID-19, defined as severe systemic illness, respiratory failure, shock, organ failure, intensive care unit admission or death. No one in the vaccine group was hospitalized after 28 days post-vaccination. Moreover, immunity appeared to improve over time, with no new cases of severe disease occurring after 49 days post-vaccination. No COVID-19 deaths occurred in the vaccine group while five were reported in the placebo group.

"Eighty-five percent efficacy in preventing severe COVID-19 disease and prevention of COVID-19-related medical interventions will potentially protect hundreds of millions of people from serious and fatal outcomes of COVID-19," J&J chief scientific officer Paul Stoffels, MD, said in a press release. "It also offers the hope of helping ease the huge burden placed on healthcare systems and communities."

The results from this trial are not directly comparable with those of the Pfizer/BioNTech and Moderna studies, which had as their endpoint the prevention of symptomatic COVID-19 of any severity, including mild disease. And these vaccines completed their Phase III trials before resistant coronavirus variants were widespread.

Speaking at a media briefing about the J&J results, National Institutes of Allergy and Infectious Diseases director Anthony Fauci, MD, noted that if the first two vaccines had not shown better than 90% effectiveness, "one would have said this was an absolutely spectacular result." In fact, the FDA originally set a threshold of just 50% effectiveness for COVID-19 vaccines.

As with the other vaccines, it is not yet known whether the J&J vaccine will prevent asymptomatic infection or coronavirus transmission.

The J&J vaccine was well tolerated with no significant safety concerns, according to the company. It appears to be less reactogenic than the Pfizer/BioNTech and Moderna vaccines, meaning less likely to cause side effects such as chills, muscle aches and other flu-like symptoms. No cases of anaphylaxis were reported.

J&J is also currently evaluating two doses of the vaccine spaced about two months apart in the ENSEMBLE 2 trial to see whether a double-dose regimen will boost effectiveness.

Novavax Vaccine

On January 28, Novavax released interim findings from a Phase III trial in the United Kingdom and a Phase IIb study in South Africa that are evaluating its NVX-CoV2373 vaccine. A Phase III trial in the United States and Mexico is currently enrolling.

The U.K. trial enrolled more than 15,000 adults (ages 18 or older), including 27% over age 65. None tested positive for SARS-CoV-2 antibodies at study entry. The South African trial enrolled about 4,400 participants, 6% of whom were living with HIV. About a third tested positive for SARS-CoV-2 antibodies, presumably against the original variant.

In both studies, participants were randomly assigned to receive two doses of the vaccine or a placebo, spaced three weeks apart. The study assessed the occurrence of symptomatic COVID-19 of any severity—the same endpoint as the Pfizer/BioNTech and Moderna trials.

In the U.K. study, the vaccine was 89% effective at preventing symptomatic COVID-19 seven days after the second dose. Of the 62 cases reported, only six (none severe) occurred in the vaccine arm compared with 56 (one severe) in the placebo arm. Based on a preliminary analysis, Novavax said the vaccine was 96% effective against the original SARS-CoV-2 variant, but still retained high effectiveness—86%—against a variant first identified in the U.K. in December, named B.1.1.7.

However, the efficacy again dropped off in South Africa. In that study, the reported effectiveness was 60% among HIV-negative people, but it fell to just 49% when study participants with HIV were included, indicating that HIV-positive people had a weaker response. In this study, 15 COVID-19 cases (none severe) were reported in the vaccine group compared with 29 cases (one severe) in the placebo group. Most cases analyzed involved the B.1.351 variant.

“These data suggest that prior infection with COVID-19 may not completely protect against subsequent infection by the South Africa escape variant, however, vaccination with NVX-CoV2373 provided significant protection,” according to a Novavax press release. The company said it is working on a modified vaccine targeting the new variant, which could also serve as a booster shot for those who have received the current one.

In these studies, too, the vaccine was safe and well tolerated, with adverse events being

infrequent and balanced between the vaccine and placebo groups, according to Novavax.

Am often asked about different vaccines and their efficacy

Each trials tracks, reports efficacy differently

Currently, we have preliminary results for Novavax and J&J

But what numbers matter? What should you look for?

Here's one set of data to track. In a simple table pic.twitter.com/9m2OBgqcla

— Ashish K. Jha, MD, MPH (@ashishkjha) February 1, 2021

Merck Vaccines Abandoned

In more disappointing news, Merck announced on January 25 that it plans to halt development of two COVID-19 vaccine candidates after seeing inadequate immune responses in a Phase I trial. The company said it would focus instead on COVID-19 treatments.

These vaccines, dubbed V590 and V591, used a vesicular stomatitis virus vector that can replicate in the body, which researchers hoped would lead to longer lasting immunity. However, both vaccines produced lower antibody levels than those seen in people who recover from natural SARS-CoV-2 infection. COVID-19 vaccines from other companies produce antibody levels similar to or several times higher than those resulting from natural infection.

The International AIDS Vaccine Initiative (IAVI) will further study one of the vaccines to determine whether a different administration route—possibly oral or intranasal—might work better, STAT reported. But the setback could make it more difficult to conduct placebo-controlled clinical trials once other highly effective vaccines are authorized.

Vaccine Rollout

Speeding up the vaccine rollout is especially urgent given the emergence of more transmissible SARS-CoV-2 variants, which have mutated spike protein that enable them to more readily enter human cells.

The U.K. variant has been reported in the United States and dozens of other countries. The South African variant was recently detected in South Carolina. And a new strain first identified in Brazil has been found in Minnesota.

The Pfizer/BioNTech and Moderna vaccines still work well against the U.K. variant, but they appear to be slightly less effective against the South African strain, according to preliminary laboratory results.

Modern vaccine platforms can be modified quickly to target new viral variants by substituting or adding the mutated spike proteins. Vaccine manufacturers are now rushing to develop broader-spectrum vaccines, as well as booster shots for those already vaccinated. The testing process will be shorter compared with initial development, but manufacturing the modified vaccines will take time.

FDA authorization of the J&J vaccine is expected in early February. The U.S. has purchased 100 million doses, to be delivered by the end of June. The company said it could produce up to 1 billion doses this year, which—given its one-shot regimen, lower cost and easier storage—could substantially aid the global vaccine rollout.

Increasing the total vaccine supply and distributing it as fast as possible—while maintaining precautions such as wearing masks and social distancing in the meantime—is of critical importance, because the longer the virus is able to circulate in an unprotected population, the greater the odds that new and perhaps more resistant, transmissible or deadly mutations will evolve. A growing number of experts are urging that vulnerable people be given a single dose as soon as possible, delaying the second until supplies are more robust.

Debate over 2nd dose continues – newest entry is @nytimes editorial that advocates for 1 dose now for hi-risk groups. Authors make the point that it’s not unusual to modify vaccination schedules based on

circumstances – which today is the need for speed.

https://t.co/fbE4917IRl

— Bob Wachter (@Bob_Wachter) January 29, 2021

President Joe Biden has set a goal of 100 million vaccine doses to be administered during his first 100 days in office. His vaccination plan calls for mass vaccine centers supported by the federal government, as well as using pharmacies, community clinics and mobile vaccination units to reach underserved populations.

As of late January, around 30 million doses had been administered in the United States, according to Bloomberg's vaccine tracker. The U.S. population is about 331 million, and people need two doses of most vaccines.

Having different vaccines with varying degrees of effectiveness could complicate distribution and raise new concerns about equity, as people vie to get the ones that performed best in clinical trials. But less effective vaccines can still provide substantial individual protection and contribute to herd immunity. Experts stress that the most important thing right now is to get as many people as possible vaccinated as soon possible, and they urge everyone to accept whichever vaccine they're offered.

"The policy implications of having different vaccines with different levels of efficacy are huge," Carlos del Rio, MD, of Emory University School of Medicine in Atlanta, told STAT. "To deal with this pandemic and stop the spread, I think you use all the tools in the toolbox."

Click here for more news about COVID-19 vaccines.

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http://beta.docker.poz.com/article/jj-covid19-vaccine-72-effective-single-dose-us-study