# Coronavirus Vaccines Show Promise in Early Studies

Four vaccine candidates produced antibody and T-cell immune responses in the first stages of human clinical trials.

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Four experimental coronavirus vaccines—from the United States, the United Kingdom, China and Germany—were found to stimulate both antibody production and T-cell immune responses in early studies, according to recent reports.

Experts caution that it is too soon to say if these vaccine candidates will produce long-lasting immunity in the real world. Some recent studies suggest that antibodies against the new coronavirus, officially known as SARS-CoV-2, may not last very long. But the early findings show that COVID-19 vaccine research appears to be on the right track.

Speaking at the International AIDS Conference (AIDS 2020) and the American Association for Cancer Research COVID-19 and Cancer virtual meeting this month, National Institute of Allergy and Infectious Diseases (NIAID) director Anthony Fauci, MD, predicted that at least one vaccine could be available by the end of 2020 or the beginning of 2021, beating the projection of 12 to 18 months he made earlier in the pandemic.

In a Congressional hearing on July 21, executives from leading companies in the vaccine development race gave similar timelines—but vowed not to cut corners on safety to speed up the process.

Fauci said he was “cautiously optimistic” that effective coronavirus vaccines could be developed, noting that the chances are improved by “taking multiple shots on goal.”

## Moderna mRNA Vaccine

One of the first out of the gate is an investigational vaccine called mRNA-1273, jointly developed by researchers at NIAID and the Cambridge-based biotechnology company Moderna.

This vaccine platform inserts messenger RNA (mRNA) from viruses into a nanoparticle delivery system. The mRNA-1273 vaccine includes genetic sequences for the SARS-CoV-2 spike protein,

which the virus uses to bind to human cells. It causes human cells to express the spike protein, triggering an immune response. Scientists were already working on an investigational vaccine targeting the spike on the MERS coronavirus, so they were able to quickly modify it to target SARS-CoV-2. However, no mRNA vaccines have yet been approved for any infectious disease.

The mRNA-1273 vaccine was studied in a Phase I clinical trial that enrolled 45 people in Seattle and Atlanta. Half were men, most were white, and the median age was 33. The study initially enrolled people ages 18 to 55, but it was modified to include older individuals.

Participants received two shots of one of three different doses of the vaccine (25, 100 or 250 micrograms) administered via intramuscular injection in the upper arm about a month apart.

Moderna announced preliminary results from the study in a press release in May. A report in the July 14 edition of The New England Journal of Medicine offered more complete data.

Fewer than half of the participants produced neutralizing antibodies after the first shot, but everyone did so after the second dose, Lisa Jackson, MD, of Kaiser Permanente in Seattle, and colleagues reported. Those who received the two higher doses had greater antibody responses. Antibody levels in the blood were similar to those seen in people who have recovered from COVID-19, and laboratory tests showed that these antibodies neutralized the virus as well as those from recovered patients. What's more, the vaccine also stimulated T-cell immune responses. Participants will be followed for a year to see how these responses last.

The vaccine was generally safe and well tolerated but adverse effects were common. Most participants experienced side effects—especially after the second dose—that included fatigue, chills, headache, muscle aches and pain at the injection site, mostly mild to moderate. People receiving the highest dose experienced more severe adverse events.

The vaccine will now be tested in a larger placebo-controlled Phase III trial (ClinicalTrials.gov number NCT04470427) that starts this month. It aims to enroll 30,000 participants at study sites across the United States. They will receive two injections of the 100 mcg vaccine dose, deemed to offer the best balance of efficacy and tolerability.

Oxford-Astra Zeneca Vaccine

A second promising vaccine is being developed by researchers at the University of Oxford in collaboration with AstraZeneca.

This vaccine, dubbed AZD1222 or ChAdOx1 nCoV-19, uses a weakened chimpanzee adenovirus—similar to viruses that cause the common cold—as a vector to deliver genes encoding the SARS-CoV-2 spike protein.

The vaccine was studied in a Phase I/II trial that enrolled 1,077 participants ages 18 to 55 at five centers in the United Kingdom. About half were men, most were white, and the average age was 35.

The study volunteers were randomly assigned to receive a single dose of AZD1222 via intramuscular injection or a meningococcal vaccine as a control. A small subgroup of 10 people received a second booster dose of AZD1222 about a month after the first shot.

Interim results were published in the July 20 edition of The Lancet.

A single dose of the vaccine produced "robust" immune responses in all evaluated participants. Most people (91%) showed neutralizing antibody responses against SAR-CoV-2 activity a month after the single shot, as did all of those who received a booster dose. Here, too, neutralizing antibody levels were similar to those seen in recovered COVID-19 patients.

"We saw the strongest immune response in participants who received two doses of the vaccine, indicating that this might be a good strategy for vaccination," lead study author Andrew Pollard, PhD, of the University of Oxford, said in an AstraZeneca press release.

In addition, all participants showed T-cell responses that peaked on day 14 post-vaccination and were maintained for the two months of follow-up so far in the ongoing trial.

"The immune system has two ways of finding and attacking pathogens—antibody and T cell responses," Pollard explained in a Lancet press release. "This vaccine is intended to induce both, so it can attack the virus when it's circulating in the body, as well as attacking infected cells. We hope this means the immune system will remember the virus, so that our vaccine will protect people for an extended period. However, we need more research before we can confirm the vaccine effectively protects against SARS-CoV-2 infection, and for how long any protection lasts."

This vaccine was also generally safe, but a majority of participants reported mild to moderate side effects including fatigue, headache, fever, chills, muscle aches and pain at the injection site. With this vaccine, adverse events were less common after the second dose. Side effects were reduced by administering acetaminophen in advance.

The Oxford-Astra Zeneca vaccine is now being tested in Phase II/III trials in the United Kingdom, Brazil and South Africa, and one is due to start in the United States. The company indicated that future studies would evaluate whether two shots of the vaccine generates stronger immune responses than one.

CanSino Vaccine

A third vaccine candidate, also employing an adenovirus delivery vector, is being developed by the Chinese biotech company CanSino Biologics.

This vaccine, dubbed Ad5-nCoV, uses a weakened form of the common cold virus adenovirus 5 (Ad5) to carry genetic instructions that enable cells to express the SARS-C0V-2 spike protein. One concern with this type of vaccine is that many people have pre-existing immunity to this adenovirus, so it will not work as well as a vaccine vector—a problem the Oxford-AstraZeneca vaccine avoids by using a chimpanzee version.

Results from a Phase I trial were published in The Lancet in May, with more extensive Phase II data reported in the July 20 edition.

The Phase II trial enrolled 508 participants ages 18 to 60 at a single center in Wuhan, China. Half were men and the average age was about 40; just 13% were 65 or older. About half had high-level pre-existing immunity to Ad5.

Participants were randomly assigned to receive a single intramuscular shot of a high or low dose of the vaccine or a placebo injection.

A month after vaccination, nearly all participants showed some type of immune response to the vaccine, either antibodies or T-cell responses, Wei Chen, PhD, of the Beijing Institute of Biotechnology, and colleagues reported.

While most participants produced binding antibodies within a month, the proportion who produced neutralizing antibodies was lower: 59% in the high-dose vaccine group and 47% in the low-dose group. People age 55 or older did not respond as well and, as expected, individuals with pre-existing Ad5 immunity—which is more common in older people—were less likely to develop strong neutralizing antibody responses to the vaccine.

However, 90% of participants in the high-dose vaccine group and 88% in the low-dose group developed T-cell responses to SARS-CoV-2, and these responses occurred in those with or without pre-existing Ad5 immunity.

This vaccine was also generally safe, and most side effects were mild to moderate, including fever, fatigue, headache and injection site pain. About 9% of those taking the high dose experienced severe adverse events (most often fever) compared with 1% in the low-dose group and 2% in the placebo group.

A Phase III trial of the CanSino vaccine is now underway in the United Arab Emirates. Up to 15,000 participants ages 18 to 60 will receive two doses spaced three weeks apart. China has already approved the vaccine for use by members of its military.

Pfizer-BioNTech Vaccine

Pfizer and the German company BioNTech are also developing a vaccine using the mRNA nanoparticle approach. Although results have not yet been published in a peer-reviewed medical journal, the companies announced preliminary findings in a preprint and press release early this month.

Four versions of the vaccine are being evaluated in Phase I/II trials, one of which will be selected for further evaluation. The companies announced early findings for the most advanced candidate, known as BNT162b1, which encodes an optimized SARS-CoV-2 receptor binding domain antigen.

One analysis included 45 participants ages 18 to 55 in the United States. About half were men, most were white and the median age was 35.

Participants were randomly assigned to receive one of three doses (10, 30 or 100 mcg) of the BNT162b1 vaccine or a placebo, given as an initial injection followed by a booster shot three weeks later. However, the booster shot at the highest dose was not administered due to side effects.

A week after receiving the second injection, all 24 participants who received the 10 mcg or 30 mcg dose developed neutralizing antibodies against SARS-CoV-2, according to the press release. The booster shot was needed to produce good responses; people who received two injections of the low and intermediate doses reached higher antibody levels than those who got a single shot of the high dose. Neutralizing antibody levels were about two to three times higher than those seen in recovered COVID-19 patients.

A second preprint described results from a separate Phase I/II trial that included 60 participants in Germany who received two injections of BNT162b1 at three dose levels (10, 30 or 50 mcg). According to that report, the vaccine also produced high-level CD4 (helper) and CD8 (killer) T-cell responses. Specifically, 94% of participants developed CD4 T-cell responses against the SARS-CoV-2 receptor binding domain, and 81% had vaccine-induced CD8 T-cell responses, most of which were strong.

This vaccine, too, was safe and generally well tolerated. In the U.S. study, side effects, including fatigue, headache, fever, chills and injection site reactions, were mostly mild to moderate and occurred more often after the second dose. About 8% of participants who received the 10 mcg dose and 75% of those who received the 30 mcg dose developed fever after the second injection. In the German study, participants experienced a transient increase in the inflammatory biomarker C-reactive protein and a temporary reduction in lymphocyte counts, which the authors attributed to redistribution of these cells into tissues.

Pfizer and BioNTech will test the selected vaccine candidate, dubbed BNT162b2, in a large global Phase IIb/III trial that aims to enroll 30,000 volunteers. The study, which starts this month, will have 39 sites in the United States.

“If the ongoing studies are successful and the vaccine candidate receives regulatory approval, the companies expect to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.2 billion doses by the end of 2021,” the press release states. The companies subsequently announced they had reached production agreements with both the United Kingdom and the United States.

## Vaccine Challenges

Together, late-stage trials of the Moderna, Oxford-AstraZeneca, Pfizer-BioNTech and other vaccines in the pipeline are expected to require at least 100,000 participants. Another two dozen or so vaccine candidates are in human studies. At one point, this looked like a potential barrier as COVID-19 outbreaks appeared to be contained in many countries, but it may be less so as cases continue to rise in the United States.

It will be important for future studies to include more racially and ethnically diverse participants as well as older people, who are at greatest risk for severe COVID-19 but may be slower to develop immune responses to a vaccine.

The National Institutes of Health recently launched a new clinical trials network called the COVID-19 Prevention Network (CoVPN) to conduct studies of vaccines and monoclonal antibodies. Those interested in participating can fill out a questionnaire to join the CoVPN Volunteer Screening Registry.

As noted, none of these vaccines have been tested long-term, so it remains to be seen how long antibodies might last in the body or remain active against the virus. But the generation of T-cell responses is promising, as these could persist even if antibody levels wane over time.

While the unprecedented speed of COVID-19 vaccine development is impressive, it is important not to cut corners when it comes to evaluating safety.

“The safety signals from these two important trials are reassuring. But when things are urgent, we must proceed cautiously,” Naor Bar-Zeev, PhD, and William Moss, MD, MPH, of the International Vaccine Access Center at Johns Hopkins Bloomberg School of Public Health, wrote in a commentary accompanying the Lancet reports. “The success of COVID-19 vaccines hinges on community trust in vaccine sciences, which requires comprehensive and transparent evaluation of risk and honest communication of potential harms.”

If one or more of the vaccines prove safe and effective in larger studies, producing enough for worldwide distribution will be a challenge—especially if they require more than one dose. Companies are already gearing up production even as late-stage testing is still underway so vaccines will be ready for quick deployment if their early promise is confirmed.

Finally, vaccine pricing and availability remains a closely watched issue, with many scientists and advocates demanding that vaccines and treatments for COVID-19 be made available to all who need them worldwide. And until supplies are ramped up, they say, vaccines should be allocated based on greatest risk of exposure or greatest vulnerability to severe disease, not based on ability to pay or the country in which they were developed.

In the words of Bill Gates at the COVID-19 Conference that wrapped up AIDS 2020, “If we just let drugs and vaccines go to the highest bidder instead of to the people and the places where they are most needed, we’ll have a longer, more unjust, deadlier pandemic.”

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