

Pfizer and Moderna SARS CoV-2 Vaccines Frequently Asked Questions – January 7, 2021 1439

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What is mRNA and why hasn't it been used in previous vaccines?

Messenger RNA (mRNA) is a genetic coding material that is translated by cells into a protein. mRNA is very unstable and easily broken down by the human body, which makes it challenging to study. Recent technological advancements have mitigated these challenges and improved the stability, safety and effectiveness of mRNA vaccines. Both the Pfizer and Moderna vaccines use mRNA that encodes the spike protein from SARS CoV-2, which is the main protein the immune system uses to respond to the virus.

How large were the Pfizer and Moderna clinical trials?

At least 73,000 (43,000 for Pfizer and 30,000 for Moderna) people participated in the clinical trials, both of which were double blinded randomized placebo-controlled trials. Half the participants in each trial received vaccine and the other half received placebo, which is saline solution in both trials. About 10% of participants in both trials were Black and 20-25% identified as Hispanic or LatinX. Both trials included large numbers of participants with medical co-morbidities and age >65.

How effective is this vaccine?

Note that the question of effectiveness can only be answered through studies after the vaccine is distributed.

Efficacy rates are determined through clinical trials. In the clinical trials conducted to support emergency use authorization (EUA), over 36,000 individuals received both injections of the vaccine. There were nine COVID-19 cases among participants who received both injections of the Pfizer vaccine and 11 cases among those who received the Moderna vaccine. The Pfizer placebo group reported 169 cases. Moderna's placebo group reported 185.

The Pfizer vaccine demonstrated >90% efficacy across all age, gender and race groups, including obese participants and those with medical co-morbidities. The exception was for Asians, where efficacy was 75%. Researchers don't know why the vaccine appears less efficacious in this group and it will require further study before any definitive conclusions can be made. The vaccine efficacy was 82% after only one dose; however, the vast majority of participants received two doses; so, it is difficult to draw firm conclusions about the efficacy of only one dose.

The Moderna vaccine demonstrated >90% efficacy except in persons >65; for that group, the vaccine, where the efficacy was 86%. Overall, the Moderna vaccine demonstrated >90% efficacy for participants receiving one or two doses, but like the Pfizer vaccine, the vast majority of participants received both doses and thus no firm conclusions can be drawn about the efficacy of only one dose.

How many injections are required?

Both vaccines require two injections. The Pfizer vaccine requires injections be spaced 21 days apart. Moderna calls for 28 days between doses. Although trial data from both vaccines suggests some efficacy

after one dose, this has not been evaluated in clinical trials. It is very important to administer two injections from the same manufacturer for maximum efficacy; both FDA and the vaccine manufacturers stress the importance of receiving both injections of the same vaccine – either both Pfizer or both Moderna. If the second dose is missed, it should be administered at the earliest opportunity. There is no need to repeat the initial dose.

How does the efficacy of the COVID-19 vaccines compare to current vaccines used in clinical practice?

In terms of efficacy, and based on clinical trial data to date, the COVID-19 vaccines compare favorably to other vaccines. For example, measles vaccine is ~99% effective, polio ~99%, shingles ~92%, and the annual influenza vaccine is typically between 40-60% effective.

Did any clinical trial participants, vaccinated or placebo, develop a severe COVID-19 infection?

Yes. In the clinical trials conducted so far, Pfizer reported 10 cases in the placebo group and one in the vaccine group. Moderna reported 30 cases in the placebo group and zero in the vaccine group. Although the total number of cases of severe COVID-19 is small, the data suggest the vaccines may protect against severe disease. Further study is needed before definitive conclusions can be made.

Were persons with a previous history of COVID-19 included in the trials?

Yes. Although the number of participants with a previous COVID-19 infection was small, data suggest that this group would benefit from vaccination. The Advisory Council on Immunization Practices (ACIP) also recommends anyone with a previous history of asymptomatic or symptomatic COVID-19 infection receive the vaccination. ACIP recommends persons wait until quarantine period has ended to avoid potentially exposing those administering vaccination. ACIP also states that persons with a history of COVID-19 may also choose to wait 90 days from diagnosis as current research indicates immunity from natural infection lasts at least 90 days.

Should persons be tested for current or past history of COVID-19 infection before being vaccinated?

No, ACIP does NOT recommend viral or serologic testing for the purpose of deciding whether to administer the vaccine.

What impact have the vaccines had on the severity of COVID-19 illness and mortality?

They are likely to have a positive impact on both, but these questions can only be answered with further data gathered after a large-scale roll out of the vaccines. For example, although the effectiveness of influenza vaccination varies year to year, studies have shown that influenza vaccination decreases the severity of illness and overall influenza mortality.

Can this vaccine be used in pregnancy?

Pregnant women were NOT included in the vaccine trials and therefore the safety and efficacy of the vaccines administered during pregnancy are unknown at this point. However, the Moderna trial identified seven vaccine recipients who become pregnant during the course of the trial; as of December 17, 2020, all those pregnancies have continued without incident. Pregnancy increases the risk for severe COVID-19 disease. ACIP, the American College of Obstetricians and Gynecologists (ACOG) and the Society of Maternal Fetal Medicine (SMFM) all recommend pregnant health care workers be offered COVID-19

vaccines. They all suggest the pregnant health care worker and health care provider engage in shared decision-making regarding receipt of the vaccine.

Can breast feeding women receive this vaccine?

Breastfeeding women were not included in the trials. However, breastfeeding is NOT a contraindication to receiving any other vaccination such as influenza, tDAP, hepatitis B, etc. ACIP, ACOG and SMFM all recommend that breastfeeding health care workers be vaccinated if they desire.

Can the vaccine be administered to children?

The clinical trials did not include minors. At this time, the Pfizer vaccine is NOT recommended for anyone under the age of 16 and the Moderna vaccine is NOT recommended for anyone under the age of 18.

Should immunocompromised persons receive the COVID-19 vaccination?

The number of immunocompromised participants (including HIV) in the trials was small, therefore data do not establish safety and efficacy in this population. ACIP recommends persons with immunocompromising conditions or on immunosuppressive medications receive COVID-19 vaccination unless otherwise contraindicated. They should be counseled that they may have a suboptimal immune response to vaccination.

Should persons with known current active COVID-19 infection be vaccinated?

Vaccination should be deferred at least until recovery from acute illness (if person had symptoms) and criteria have been met to discontinue isolation.

How long will immunity from this vaccination last?

We don't know. This question will be answered by ongoing clinical trials and observational studies once widespread vaccination occurs.

What were the most common adverse events?

The most common adverse events were predictable and included injection site reaction/pain, fatigue, headache, body aches, low grade fevers and chills. These side effects are very similar to those seen in previous vaccine trials and with current vaccines in clinical use. Both the Pfizer and Moderna trials indicated that these adverse events were more common after the second injection and that they typically resolve within 1-2 days.

Did anyone in the trials have allergic reactions?

Yes, 0.63% of the vaccine group in the Pfizer trial had allergic reactions. None of them were considered serious, nor were any fatal. There were no reports of allergic reactions during the Moderna trial. Severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer or Moderna COVID19 vaccine is a contraindication to vaccination.

Due to recent reports of anaphylactic allergic reactions outside clinical trials, ACIP recommends persons who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) should NOT receive the Pfizer or Moderna vaccine at this time. The American College of Allergy, Asthma and Immunology (ACAAI) recommends anyone with a known history of severe allergic reaction to polyethylene glycol should not receive either vaccine, but that previous allergic reaction to another vaccine is not a contraindication. ACAAI notes that persons with common allergies to medications,

foods, inhalants, insects and latex are, based on the clinical trial data available to date, NO MORE likely than the general public to have an allergic reaction to either vaccine.

Were there any major adverse events during the clinical trials?

Six deaths occurred in the Pfizer trial and one in the Moderna trial. All were determined to be unrelated to vaccine. In addition, 12 cases of appendicitis occurred in the Pfizer trial, also considered to be unrelated to vaccination.

Does the vaccine cause Bell's palsy?

In the Pfizer clinical trial, there were four cases of Bell's palsy in the vaccine group and none in the placebo group, but that number of cases is not above normal. There were also four cases of Bell's palsy in the Moderna trial, three in the vaccine group and one in the placebo group. There is no known or expected causal relationship between these vaccines and Bell's palsy, according to the CDC, but it will continue surveillance.

Are adverse events going to be monitored going forward?

Yes. The EUAs issued by FDA mandate Pfizer and Moderna submit monthly safety reports and conduct post-authorization studies on adverse effects, deaths, hospitalizations and cases of COVID-19 in vaccine recipients and clinical trial participants. Any adverse event possibly caused by this vaccine must be reported to the Vaccine Adverse Events Reporting System (VAERS). CDC also is encouraging vaccine recipients to enroll in a new text messaging program for health care workers called "v-Safe" to monitor for adverse events.

Will masking, social distancing and other safety measures still be required going forward?

Yes. At this time, we do not know the impact vaccination will have on transmission of the virus. This will only be answered with studies after widespread vaccine rollout. Safety measures, including mandatory masking, social distancing, and pre-procedure COVID-19 testing will still be required until more information is available.

Do I still need to wear full PPE when taking care of COVID-19 patients?

Yes. Despite being vaccinated, ALL employees doing direct patient care for COVID-19 patients will still be required to wear ALL required PPE, including N95 respirators.

Are there other SARS CoV-2 vaccines in development?

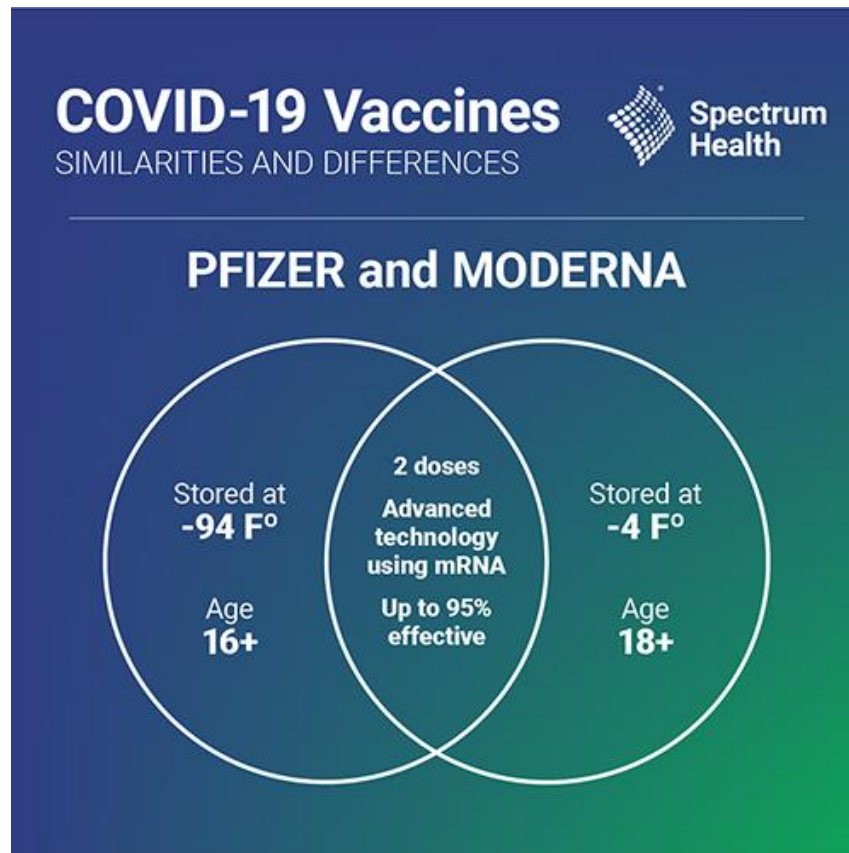
Yes, there are many other vaccines in late-stage clinical trials or getting ready to start clinical trials.

For further information, please visit:

- Centers for Disease Control and Prevention
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>
- U.S Food and Drug Administration
<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>
- State of Michigan
https://www.michigan.gov/coronavirus/0,9753,7-406-98178_103214---,00.html
- Vaccinate West Michigan
<http://vaccinatewestmi.com>
- American College of Obstetricians and Gynecologists

<https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19>

- American College of Allergy, Asthma and Immunology
<https://acaai.org/covid-19-asthma-and-allergies>
- Society for Maternal Fetal Medicine
<https://www.smfm.org/covid19>



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