COVID-19 Vaccine Q&A

The COVID-19 pandemic has been a stressful and often frightening time for many people, including those working on the frontlines. The new COVID-19 vaccine is a much anticipated and exciting next step in our fight against COVID-19. It is natural, as with any new medication or treatment, that people have questions about it. In the age of social media, it is easy for misinformation to spread quickly, and we want you to have your questions answered accurately and honestly. Here are some common questions about the COVID-19 vaccine and answers from Wellforce's Infectious Disease experts:

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Vaccine Basics

1. How does the COVID-19 vaccine work?

In the mRNA vaccine, the active ingredient (the mRNA) has instructions for the cell on how to make a piece of the "spike protein" that is unique to the virus that causes COVID-19. Since only part of the protein is made, it does not do any harm to the person vaccinated. The piece of the "spike protein" prompts the immune system to produce antibodies and activate the T cells, a part of the immune system that focuses on recognizing, attacking and remembering foreign particles, to destroy infected cells. If the patient later then encounters coronavirus, the antibodies and T cells are awakened to fight the virus.

2. Are the FDA-authorized COVID-19 vaccines safe?

These vaccines underwent a rigorous review by the FDA, not much different than the usual FDA approval process. During a public health crisis, the FDA can grant an Emergency Use Authorization (EUA) for treatments such as vaccines. This means that the vaccines met safety and efficacy standards (based on the currently available data from the clinical trials with more than 35,000 participants) and it was felt the clear benefits of the vaccines outweighed the possible risks associated with them.

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3. But these vaccines were developed so quickly, are we sure they are safe?

The vaccines have gone through the normal rigorous clinical trial process with added layers of safety, including use of external data monitoring committees, full data analysis by the FDA, external review by the FDA Advisory Committee (VRBPAC) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP). The data we have seen is very reassuring. Neither Moderna nor Pfizer have reported any widespread or permanent serious adverse effects to vaccine recipients compared to placebo in their respective clinical trials.

The FDA issued Emergency Use Authorization for the Pfizer vaccine on December 11, 2020 and for the Moderna vaccine on December 18, 2020.

While we don't have as much long-term safety data as we would like, many participants have been followed for several months now. It is known from other vaccines that adverse events will almost always be seen within a couple of weeks after vaccination.

4. Can I get COVID-19 disease from the vaccine?

No. You cannot develop COVID-19 disease from the vaccine. Nor can you have a false positive PCR or antigen test.

5. What are the side effects of the COVID-19 vaccine?

The most commonly reported side effects are soreness at the site of the injection as well as non-localized symptoms, including fatigue, body aches, chills or fevers. Side effects were most common after the second dose of the vaccine, and more likely to be experienced by younger participants in the trial. These symptoms go away within a few days after receiving the vaccine. These side effects are normal and tell us that the body is building protection against the virus. (There are NO respiratory symptoms reported after these vaccines: No cough, sore throat, shortness of breath, loss of smell or taste. If you have these symptoms, consult your health care provider.)

6. Do you need to take a test before receiving the vaccine?

No. Because it is safe to receive the vaccine even if you have active or recent COVID-19, you do not need to take a test before vaccination. However, if you know that you have active COVID-19, we ask that you delay your vaccination until you are released from isolation, so that you don't expose others during the vaccination process. It will not impair the effectiveness of the vaccine to delay by a few days or even a few weeks.

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7. If someone had COVID, when should they get the vaccine?

If you have COVID, we simply ask that you delay your vaccination until you are released from isolation, so that you are no longer contagious to others.

8. I had a known close contact with a COVID-19 positive individual within the last 14 days. Can I receive the vaccine if I provide a negative COVID-19 test? Alternately, how long should I wait after such an exposure before I can receive the vaccine?

It's very important you follow public heath guidance provided for quarantine. Once released from quarantine, it is fine to undergo vaccination. Since hospital employees are permitted to work even after an exposure, if you work at a hospital you may receive your vaccination at the hospital despite a recent exposure. You do not need to have a negative Covid test to be vaccinated but you may need a negative test to be released from quarantine or to return to work. Check with your manager.

9. Will people who have had the vaccine and become infected with COVID become less ill with COVID? If so, will this reduce the number of people that had COVID and now struggle with long-hauler post-COVID syndrome?

Yes. Based on the clinical trial data we can expect that if people who have been vaccinated do acquire COVID-19 infection it will be less severe. The prevalence of post-COVID-19 long-hauler symptoms has not been reported in the clinical trials.

10. Do I need to receive both doses of the vaccine to be effective?

Yes. The vaccines have only been studied for efficacy after two doses. The Pfizer vaccines should be given as two doses 21 days apart and the Moderna vaccine as two doses 28 days apart. It is important to stick to your scheduled appointments for each vaccine dose. The efficacy of one dose has not been fully studied.

If I test positive for COVID-19 between dose 1 and dose 2, should I still get dose 2?

Yes. We simply ask that you delay your vaccination until you are released from isolation, so that you are no longer contagious to others. Please schedule dose 2 for as soon as possible after your release from isolation.

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11. Do I have to get the same vaccine (Moderna or Pfizer) for both doses?

Yes. Whichever vaccine you received for your first dose, you must receive the same brand of vaccine for your second dose. It is also important to stick to your scheduled appointments for each vaccine dose.

12. When will we know if the vaccines protect people from spreading the virus?

So far, studies show that the vaccines prevent COVID-19 illness. The Moderna trial data show a hint of decreasing asymptomatic infection, but we need more data. For this reason, even after vaccination everyone should continue to wear masks, social distance and follow CDC guidelines until we have more information.

13. How long does it take after receiving the vaccine for my body to create an immune response?

After receiving the vaccine, it can take up to 2 weeks for the body to create an immune response. Therefore, you will be maximally protected about 2 weeks after the second dose. It is important to continue to wear a mask and practice social distancing, even if you have received the vaccine.

14. How long does vaccine protection last?

We are still awaiting data on the duration of immunity following vaccination.

15. Is the vaccine really helpful? I heard that you can develop immunity by getting COVID-19, so why do I need to get my immunity through a vaccine?

While some patients with COVID-19 have mild disease, others can become seriously ill. Those who develop mild disease may unknowingly pass it to someone who will develop severe disease. To date, COVID-19 has been responsible for more than 300,000 deaths in the United States. There may be some partial protection after infection, but there have been enough documented cases of re-infection, that we can infer protection after infection is not nearly 100%. Vaccine is the safest choice for developing immunity.

Pfizer vs. Moderna

16. What is the difference between the Pfizer and Moderna vaccines?

The Pfizer and Moderna vaccines are very similar mRNA with similarly high levels of effectiveness and safety. Unlike other vaccines, neither of these vaccines use any actual virus particles. Both involve receiving two doses of the vaccine, either three weeks (Pfizer) or four weeks (Moderna) apart. There is no clear reason to prefer one over the other.

17. Do both brands of vaccine carry the same precaution/allergy statements?

Yes. Both are contraindicated in persons with history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine (see Q18 for list of vaccine components), in persons with a history of immediate allergic reaction to any mRNA vaccine, and in history of immediate allergic reaction to polysorbate. If you have had an immediate allergic reaction to polyethylene glycol (PEG, a component of the vaccines) or polysorbate (chemically related to PEG), the CDC recommends an evaluation by an allergist/immunologist to determine if you can receive the vaccine safely. CDC considers a history of immediate allergic reaction to another vaccine or injectable therapy, or a history of anaphylaxis due to any cause to be a precaution but not a contraindication to vaccination. People who have these reactions should be observed for 30 minutes (rather than 15) after each dose of vaccine. For more information, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

People with allergies to any of the following MAY receive these vaccines without any special precautions:

- Eggs, gelatin, other foods, latex, pets, bee or wasp stings, or seasonal allergies (hay fever etc).
- ORAL medications

18. What are the ingredients in the vaccine so I can determine if I have any known allergies?

The **Pfizer BioNTech COVID-19 vaccine** includes the following ingredients:

- mRNA,
- lipids (
  - (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315),
  - 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) ,
  - 1,2-Distearoyl-sn-glycero-3- phosphocholine
  - cholesterol)
- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

The **Moderna COVID-19 vccine** includes the following ingredients:

- mRNA
- lipids
  - SM-102, polyethylene (PEG) 2000-DMG,
  - 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
  - cholesterol),

- tromethamine (Tris buffer), sodium acetate, sucrose (sugar).

Because allergies vary from person to person, there is not one ingredient that has been identified as the cause for the reported allergic reactions associated with the vaccine.

- Because of its similarity to the vaccine ingredient polyethylene glycol, which is an ingredient in both vaccines, people who are allergic to polysorbate should not receive these vaccines. A person who had a past history of an immediate allergic reaction to polyethylene glycol or polysorbate should be evaluated by an allergist/immunologist to determine if they can receive the vaccine safely.

19. If we have both vaccines, would employees be able to choose Moderna vs. Pfizer?

Data show no difference in safety of efficacy between the Moderna and Pfizer vaccines. We recommend you receive the vaccine you are offered.

20. One report said that Pfizer vaccine is only 74.4 percent effective in Asians while the Moderna one is 100 percent effective. Are we considering this when we vaccinate our colleagues?

Both the Pfizer and Moderna vaccines demonstrated efficacy in diverse populations, including Asian individuals. Some groups were small and it is important not to over-interpret subgroup analysis. We recommend and are confident in the safety and efficacy of both the Pfizer and Moderna vaccines.

21. I'm most concerned about any long-term effects of either vaccine for myself and my family. We just don't know about long-term effects, right?

The vaccines have gone through the normal clinical trial process with added layers of safety, including use of external data monitoring committees, full data analysis by the FDA, external review by the FDA Advisory Committee and the CDC ACIP. The safety data we have seen are very reassuring. Neither Moderna nor Pfizer have reported any widespread or permanent serious effects to the vaccine recipients compared to placebo in the respective clinical trial.

The FDA issued emergency use authorization for the Pfizer vaccine on December 11, 2020 and the Moderna vaccine on December 18,2020. This was following a thorough safety review by the FDA and an external expert advisory panel. While we don't have as much long-term safety data as we would like, many participants have been followed for several months now. **It is known from other vaccines that adverse events will almost always be seen within a couple of weeks after vaccination**.

22. I will not be available for my second dose of the Pfizer vaccine on day 21. Should I still receive my first dose today? Can I receive my second dose of Pfizer vaccine early or late?

No. Because the clinical trials achieved approximately 95% efficacy for both vaccines using a strict schedule, we strongly advise you to return for your second dose of vaccine on day 21 for the Pfizer vaccine and day 28 for the Moderna vaccine. We cannot assure the same level of protection if you deviate from that schedule. It is important that you keep the appointment and arrive on time to ensure that we will see you promptly. If you can't keep your appointment, please let us know by email at vaccine@tuftsmedicalcenter.org.

23. Do we have any information on the efficacy of the vaccine on the new variant strain from Great Britain?

The new variant from the UK has a modification in the spike protein and it is hypothesized that this mutation could make it adhere to the ACE2 receptors in the cells of the respiratory lining more easily and thus it could be more infectious, although this has not been proven. The science suggests that both vaccines – Moderna and Pfizer - should work just as well on this new variant.

Vaccine Use in Special Populations

24. Can I get the COVID-19 vaccine if I have an immunocompromising condition (such as HIV, cancer, organ or bone marrow transplant, etc.?)

Yes. Data are not currently available to determine vaccine efficacy in people who have an immunocompromising condition such as HIV, have undergone transplantation, have other immunocompromising conditions or are taking immunosuppressive medication. However, this group of people might be at increased risk for severe COVID-19 disease. Therefore, immunocompromised individuals can still receive COVID-19 vaccination. Immunocompromised persons, including individuals receiving immunosuppressant therapy, might have a diminished immune response to the COVID-19 vaccines. We do not expect a difference in safety. All people who are vaccinated should continue to follow all current guidance to protect themselves against COVID-19 such as wearing masks, practicing social distancing and frequent hand hygiene, and speak with their doctor for specific guidance. For more information, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

25. Can I get the COVID-19 vaccine if I have an autoimmune disease or if I am on biologic medications?

Yes. Patients who have underlying autoimmune disease or are on biologics may still receive COVID-19 vaccination. Data area not currently available to determine vaccine efficacy in these groups but we would not expect a difference in safety. These patients may have a diminished immune response to the vaccines. People who are vaccinated should continue to follow all current guidance to protect themselves against COVID-19 and speak with their doctor for specific guidance. For more information, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

26. Can I get the COVID-19 vaccine if I have severe allergies to other vaccines or injectable medications?

Yes. The Centers for Disease Control considers a history of severe allergic reaction (e.g., anaphylaxis and or required EpiPen and/or hospitalization) to any other vaccine or injectable therapy (e.g., intramuscular intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination. People who have had anaphylactic reactions to any substance should be observed for 30 minutes (rather than the usual 15) after each dose of vaccine.

Allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, environmental or latex allergies; oral medications [including the oral equivalents of injectable medications] are not a contraindication or precaution to vaccination with mRNA COVID-19 vaccines. For more information, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

27. Can I get the COVID-19 vaccine if I am pregnant?

Yes. Because of the risks of severe COVID-19 in pregnant women, The Society for Maternal-Fetal Medicine and The American College of Obstetricians and Gynecologists strongly recommends that pregnant individuals have access to COVID-19 vaccines and that each person have a discussion with their healthcare professional about their own personal choice.

The Pfizer and Moderna vaccines were not tested in pregnant women, so there are no clear recommendations for vaccination in pregnancy. This is the usual process for studying a new drug and is not due to any particular concern with this vaccine. We do not have data on whether the vaccine works as well in pregnancy as it did in non-pregnant individuals. We do not have data on whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.

That being said, pregnant women who get COVID-19 are five times more likely to end up in the intensive care unit (ICU) or on a ventilator than women with Covid-19 who are not pregnant. Additionally, preterm birth may be more common for pregnant women with severe COVID. For a detailed decision-making tool, click here. We encourage pregnant women to discuss Covid vaccine decisions with their health care providers.

28. Does the COVID vaccine have any effect on fertility?

No. There is no evidence or scientific concern that the vaccine could impact fertility.

29. Can I receive the vaccine if I am breastfeeding?

Yes. The Society for Maternal-Fetal Medicine reports that there is no reason to believe that the vaccine affects the safety of breastmilk. When we have an infection or get a vaccine, our bodies make antibodies to fight the infection. Antibodies formed from vaccines given during pregnancy do pass into the breastmilk and then to the baby to help prevent infections. Since the vaccine does not contain the virus, there is no risk of breastmilk containing the virus. For a detailed decision-making tool, click here.

30. Is there any contraindication with my oral medications (anti-anxiety/ depression/ home medications and antibiotics)?

No. At this time, there are no known reactions or interactions between oral medications and the Covid-19 vaccines.

31. Can I get the COVID 19 vaccine if I had treatments for Covid-19 such as monoclonal COVID 19 antibody and/or convalescent plasma? How about remdesivir, hydroxychloroquine or other medications.

Yes. There are no data on the safety or efficacy of mRNA COVID-19 vaccines in people who have received monoclonal antibodies or convalescent plasma to treat COVID-19. Because these products might affect the efficacy of the vaccine, it is recommended that you wait 90 days after last receiving them before being vaccinated. For more information, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html**. Most other Covid-19 antiviral treatments should not affect the effectiveness of Covid-19 vaccines. Consult your prescribing health care provider.**

32. Can I get the COVID-19 vaccine if I have Hepatitis B?

Yes

33. Can I get the COVID-19 vaccine if I have Hepatitis C?

Yes

34. Can you discuss concerns associated with taking the vaccine for people that take anti-coagulants (blood thinners?) I have seen internet chat about this.

The only risk known to be associated with blood thinners is the small risk of bleeding at the injection site. However, this is not a contraindication to receiving the vaccine.

35. I have heard that some people who received either the Pfizer or Moderna Covid vaccine developed Bell's palsy afterward. Should I be concerned?

Bell's palsy is a rare weakness of the muscles on one side of the face which often occurs spontaneously and is usually temporary. This condition occurred in a few people who received

Covid vaccine during clinical trials. This is about the same number of people who would be expected to develop Bell's palsy in the general population who have not received the vaccine. Therefore, at this time, there does not appear to be a relationship between receiving the vaccine and the subsequent development of Bell's palsy. A group of experts from the American Academy of Otolaryngology advised that people should not be discouraged from receiving this critical vaccine due to a concern about developing Bell's palsy. People who have a history of Bell's palsy should discuss the risk with their doctor.

36. If an employee is a verified non responder to the Hepatitis B vaccine, is there any evidence that they would be a non-responder to the Covid vaccine?

No. We have no data to tell us whether a non-responder to the Hepatitis B vaccine will be a non-responder to the COVID-19 vaccines. For Hepatitis B, post-vaccination antibody levels can be used to determine immunity, whereas there is no such antibody test for COVID-19. However, based on the clinical trials, we expect a 95% efficacy rate.

Post-Vaccine Info

37. What medications can I take for injection site pain, headache, or achiness after I receive the vaccine?

Take acetaminophen or ibuprofen as needed for fever, aches, or headache after vaccination.

38. I have been feeling a lot of fatigue with the vaccine. It has been five days now. Does anyone else feel like this?

Up to 68 percent of vaccine recipients reported fatigue in the clinical trials. Most reports of fatigue last 1-3 days following the vaccine but some were reported to last a bit longer.

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39. I had a reaction after the vaccine that a health care professional said was not allergic in nature (such as flushing, fainting, rapid heart rate, elevated blood pressure). Should I get the second dose?

Yes. It is safe to get the second dose if you had a **non**-allergic reaction after the first dose.

40. What is the risk of Guillain-Barre syndrome after the mRNA vaccine?

Neither COVID-19 disease nor the COVID-19 vaccines have been associated with Guillain-Barre Syndrome at a rate that is higher than the baseline population rate of this condition.

41. If I feel sick after receiving the vaccine, do I stay home?

If you have any of the following symptoms, you should stay out of work and call the number for your organization listed below.

- Fever of 100.4°F (38°C) or higher
- Fever, chills, fatigue, muscle pain, headache and/or pain in the joints **AND** close contact with a confirmed case of COVID-19 in the 14 days before the symptoms started
- Fever, chills, fatigue, muscle pain, headache and/or pain in the joints **lasting more than 3 days**
- Symptoms that are NOT likely due to vaccination and could indicate COVID-19 or another infection are:
    - Cough, sore throat, shortness of breath, loss of taste or smell and/or runny nose

Contact numbers:

- Tufts Medical Center: Call Vaccination Symptom Hotline Guidance and FAQ line at 617-636-4400, operational 24/7.

42. Are we allowed to travel internationally after receiving the vaccine?

There are no differences in travel guidelines or restrictions based on vaccine status. Please check the latest travel guidelines from the state.

43. When do you think the staff infection numbers will decline due to the vaccination?

We hope that staff COVID infection numbers will decrease soon and encourage everyone to mask whenever in the presence of people with whom you don't live, maintain at least 6 feet of physical distance from others, follow hygiene protocols and not come to work when ill. Estimates are that 60-70% of the population will need to be immune following vaccination or infection to reach herd immunity when the SARS CoV-2 virus will stop spreading.

44. Do you think quarantine requirements will be changing based on vaccination status?

At this time, the CDC and MA DPH recommend quarantine for all close contacts, defined as exposure within 6 feet of a confirmed or clinically diagnosed COVID-19 case for at least 15 minutes (cumulative over 24 hours) while the case was symptomatic or within the 48 hours before symptom onset (outside of a health care setting, PPE is not taken into consideration) or direct contact with infectious secretions of a confirmed or clinically diagnosed COVID-19 case (e.g., being coughed on) while not wearing recommended PPE. Vaccine status does not change the requirements at this time. It is possible that this will change at a future time.

45. Is there a way to measure individual immune response after getting vaccinated?

No. There is no clinically relevant way to measure immune response. The vaccine induces both antibody and T-cell responses. The currently available antibody tests do not measure protection against Covid-19.

46. How is herd immunity determined? Is there a test positivity rate or some other metric that would determine herd immunity?

Current estimates are that we need to get 60 to 70 percent of the population immune to the virus through a combination of vaccination and infection before we can reach herd immunity. How close we are to herd immunity will be difficult to measure because we do not yet know how long immunity lasts from natural disease or vaccination. We can expect to see deaths decrease first before the infection rates decrease.

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Vaccine Distribution

47. What does the vaccination process look like?

When you receive your first dose you will be scheduled for a date/time to receive the second dose. Getting the vaccine, including registering, scheduling the second appointment, receiving the shot and being monitored for 15 minutes, takes approximately 20-30 minutes total (plan on hanging around an extra 15 minutes if you have a history of severe allergic reactions). Neither employees nor their health insurance will be billed for the vaccine.

Due to the potential side effects of the vaccine (including headache, fever, and injection site pain), we suggest employees consider scheduling a vaccination time when you have a day or two off after receiving the vaccine to monitor these symptoms. This is particularly important after the second dose. Those who are vaccinated will still be required to wear masks, socially distance and continue proper hand hygiene.

48. Who will receive the vaccine and when?

Wellforce is working across its system to ensure that the vaccine is distributed quickly, appropriately and equitably based on guidance from both the CDC and Massachusetts Department of Public Health. Employees in high-risk areas have begun to receive the vaccine at all Wellforce hospitals and Home Health Foundation. Appointments will be opened to others in the coming days and weeks. All patient facing employees will be vaccinated no later than the end of January.

The CDC Advisory Committee on Immunization Practices released these recommendations on December 22, 2020 to recommend the following prioritization:

Phase 1A: High-risk health care workers AND adults living in long-term care facilities.

Phase 1B: Essential workers, such as first responders; persons aged 75 years and older.

Phase 1C: Adults aged 65 and over; persons aged 16-64 years with high-risk medical conditions; essential workers not covered in Phase 1B.

Phase 2: All persons aged 16 years or older not previously recommended for vaccination.

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49. How will people in phase 1 B and C get the vaccine? For example, if our parents are over 80... Will it be available at CVS?

The planning for this is already underway. Partnerships with pharmacies are part of the plan. The first order of business is the vaccination of people in long-term care facilities. There is a lot going on at the state and federal level. At Tufts MC, we are also looking at how we will roll out the next phase of the vaccination process to the public.

48. Will Wellforce require employees to get a COVID-19 vaccine?

We will not require employees to receive a COVID-19 vaccine. However, the clinical leaders of Wellforce HIGHLY recommend that every health care worker who is identified as an appropriate candidate to receive the vaccine does so.

49. I need to receive other vaccinations. How should they be timed based on when I receive the COVID-19 vaccine?

Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the CDC states that the COVID-19 vaccine series should be administered alone, with a minimum of 14 days before or after administration of any other vaccines. However, if mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

50. Do I need to wear a mask and avoid close contact with others if I have received 2 doses of the vaccine?

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using **all the tools** available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others.

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FDA Process

51. What does the FDA approval/authorization process entail?

Pharmaceutical companies with a vaccine candidate conduct clinical trials with volunteers to test the safety and efficacy of the vaccine candidate. Both Pfizer and Moderna reached pre-specified endpoints in their Phase 3 vaccine trials and submitted requests for Emergency Use Authorization (EUA) of their respective COVID-19 vaccines. The FDA then conducted its own analysis of the companies' data.

The next step in the process is for the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) to hold a public, live-streamed hearing to discuss the safety and efficacy data associated with the Phase 3 clinical trial. This committee is made up of 17 external experts, including Tufts Children's Hospital Chief of Pediatric Infectious Disease Dr. Cody Meissner. Collectively, they made a recommendation to the FDA regarding issuing an EUA. VRBPAC voted to recommend authorization for both the Pfizer and Moderna vaccines, and the FDA agreed and issued an EUA for both.

52. What is the difference between FDA approval and and EUA?

The FDA provides independent scientific review of medical products like drugs and vaccines. In most cases, these medical products undergo a rigorous approval process that uses clinical data and other information to prove that the medical product is both safe and effective for the intended use and that it can be made according to federal quality standards. During public health crises like the COVID-19 pandemic, the FDA may grant an Emergency Use Authorization or EUA. This means that the vaccine meets safety and efficacy standards based on currently available data, and that data shows the benefits outweighing the risks. EUAs are effective until an emergency declaration ends. The rigorous review process is not very different from the traditional FDA approval process.