

COVID-19 Vaccine Frequently Asked Questions

Record of changes:	1
About Vaccines	1
Vaccine Safety and Efficacy	2
COVID-19 Vaccine Planning and Distribution	4
Contraindications.....	6
Other.....	7

Record of changes:

12.23.2020 – added categories for ease of reading, added new questions (Contraindications), added dates to new and updated questions.

12.28.2020 – added new questions (vaccination in long-term care facilities, vaccination for those who live in Rhode Island for part of the year), updated questions.

About Vaccines

1. Will I get sick from the vaccine?

No. Vaccines do not cause disease. However, vaccines can cause your immune system to respond. This is a sign that the vaccine—and your body’s immune system—is working.

Based on information released about the Pfizer and Moderna vaccines, we expect people to have symptoms after vaccination. People may feel some soreness at the site of injection, some aches, and fatigue. These symptoms may be more noticeable than those that occur with a flu vaccine. This is completely normal and will clear up in a few days. *Response updated 12.28.2020*

2. What is an mRNA vaccine?

An mRNA vaccine is a vaccine that uses messenger ribonucleic acid (mRNA) to build a protein that will trigger an immune response. These vaccines give our cells instructions to make a harmless part of the COVID-19 virus—specifically, a protein on the virus’s surface. Once our cells receive these instructions, the mRNA breaks down and our cells get rid of it. Also, because the mRNA never enters the cell’s nucleus, mRNA is unable to interact with DNA in any way.

Our cells recognize the newly created protein as foreign. This triggers an immune response. In the process, our cells are learning how to protect against COVID-19 infection and provide immunity.



REOPENING RI

Vaccine Safety and Efficacy

3. How do vaccines get approved?

Vaccines go through three phases of clinical trial. Each phase tests for safety and effectiveness across an increasing number of test volunteers.

- In phase 1, potential vaccines are tested by approximately 20 to 100 people.
- In phase 2, the potential vaccines are tested by several hundred volunteers.
- In phase 3, vaccines are tested by thousands of volunteers.

The US Food and Drug Administration (FDA) will only approve a vaccine if it is safe, effective, and if its benefits outweigh its risks.

4. Will the vaccine be safe?

Safety is a top priority. COVID-19 vaccines have been tested in large clinical trials with people of different ages, races, and ethnicities to make sure they are safe. No steps involving safety have been skipped—COVID-19 vaccines are being held to the same standards as other vaccines to make sure they are safe. To ensure safety of vaccines in the United States, there is a rigorous vaccine development and approval process. Following approval of a vaccine, there are several systems in place to continue to ensure safety. Please see the answer above describing how vaccine safety is determined in the approval process.

5. What steps are taken to ensure safety after a vaccine is approved?

After a vaccine is approved and distributed, vaccine monitoring systems are used to watch for possible side effects. If an unexpected side effect is seen, experts study it to determine whether changes are needed in vaccine recommendations.

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program of the FDA and the CDC. VAERS collects and analyzes information from reports of adverse events (e.g., side effects) that occur after a vaccine has been approved and distributed. Anyone can submit a report to VAERS by going to this link: <https://vaers.hhs.gov/reportevent.html>. Vaccine Adverse Event Reporting Systems exist for the Department of Defense, the Department of Affairs, and the Indian Health Service.

There are several programs and initiatives, in addition to VAERS, that monitor vaccine safety. These include: CDC's Vaccine Safety Datalink and Clinical Immunization Safety Assessment Project, and FDA's Biologics Effectiveness and Safety System and Sentinel Initiative. More information about these different systems is available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>.

6. What is v-safe?

V-safe is a smartphone-based tool—developed by the CDC—that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through v-safe, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you and get more information. And v-safe will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's v-safe makes a difference—it helps keep COVID-19 vaccines safe. For more on v-safe, visit CDC's [site](#). *Response added 12.14.2020*



7. What is an Emergency Use Authorization?

Emergency Use Authorization (EUA) is an authority that allows the FDA to make certain medical products (e.g., vaccines, treatments) available during public health emergencies. It also can allow the use of medical products that have been approved, but for use in a different way than originally intended.

An EUA lasts for the length of an emergency. A regular FDA approval lasts forever, unless a safety or efficacy issue comes up that needs further review.

The [FDA has authorized COVID-19 vaccines made by Pfizer and Moderna for emergency use](#). Response updated 12.22.2020

8. What criteria are necessary to issue an EUA?

To issue an EUA, at minimum, the known and potential benefits of a drug, device, or test must outweigh the risks. In addition, the drug, device, or test must meet certain thresholds for safety and effectiveness, and people must be in urgent need of care.

9. How do we know that drugs, devices, or tests that have received EUAs are safe?

The FDA released [guidance](#) for vaccine manufacturers considering requests for an EUA. This guidance explains the criteria that need to be met before any vaccine for COVID-19 will receive an EUA. To meet criteria, manufacturers will use data from a Phase III clinical trial. The vaccine's potential and known benefits must outweigh the potential and known risks. In addition, the vaccine must be at least 50% effective and must meet certain safety standards among a sufficiently large group of volunteers. The FDA will also consult with an independent advisory committee before issuing an EUA for a COVID-19 vaccine.

Granting an EUA does not mean that vaccine clinical trials will stop. Data can continue to be collected through trials even if an EUA is granted.

For more on EUAs, visit: [Emergency Use Authorization](#) and [FAQs on Emergency Use Authorizations \(EUAs\) for Devices - COVID-19](#).

10. What happens after the FDA authorizes (through an EUA) or approves a vaccine?

After the FDA authorizes or approves a vaccine, there are more steps to ensure safety. The CDC's Advisory Committee on Immunization Practices (ACIP) will hold a public meeting and will review all available information from clinical trials. This includes the descriptions of who received each vaccine, how different groups of people responded to the vaccines, and any side effects experienced. The ACIP then votes on whether to recommend the vaccine and who should receive the vaccine.

Rhode Island has added an additional layer of approval. The COVID-19 Vaccine Subcommittee of Rhode Island's Vaccine Advisory Committee is a group of medical experts and community leaders who will also review the science.

REOPENING RI

11. Is the COVID-19 vaccine development and approval process different from a typical vaccine development and approval process?

The COVID-19 vaccines are being held to the same standards as other vaccines to make sure they are safe. No steps involving safety have been skipped.

There are some differences in other processes that may make the COVID-19 vaccine available much faster than a typical vaccine. Importantly, there has been much collaboration across the scientific community to develop a vaccine. This is a global pandemic. As a result, a lot of time and resources from across the globe have gone into developing several COVID-19 vaccines.

Further, researchers had a head start on vaccine development because of research already done on similar coronaviruses. This includes the viruses that caused Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Also, the government began producing doses of certain COVID-19 vaccines when they reached phase 3 trials. This way, when these vaccines were determined to be safe and effective, people could get them immediately.

12. How many COVID-19 vaccines are in trial?

There are many vaccines in various trial phases. However, not all of them will be approved or authorized for emergency use. It is possible that Rhode Island will receive several different approved COVID-19 vaccines. We may receive these vaccines at different times, depending on when they are approved.

13. How do we know who was included in trials? Was there enough testing done among people like me?

The COVID-19 vaccines that have been authorized were tested in large clinical trials with people of different ages, races, and ethnicities. Information about vaccine trial participants is being released by researchers. Based on recent [press releases](#), we know that the phase 3 trial of the Moderna vaccine includes 30,000 participants ages 18 and older. Nearly half (42%) of the study participants belong to high-risk groups. This means that they are older than 65 or have chronic conditions like diabetes, severe obesity, and cardiac disease. More than one third (37%) of study participants belong to communities of color. You can also find data on the diversity of participants in the [Pfizer vaccine clinical trial here](#).

COVID-19 Vaccine Planning and Distribution

14. When will a vaccine for COVID-19 be ready?

The US Food and Drug Administration authorized Pfizer's COVID-19 vaccine for emergency use on December 11 and Moderna's COVID-19 vaccine for emergency use on December 18. Rhode Island began vaccinating high-risk hospital workers the week of December 14. *Response updated 12.21.2020*
People can follow the progress of different vaccines at various vaccine tracker sites and applications, like the [New York Times Coronavirus Tracker](#) or [BioPharma Dive](#). *Response updated 12.14.2020*



REOPENING RI

15. Who will get the vaccine once it is available?

Rhode Island's initial supply of vaccine is limited. At first, vaccine will only be available for people most at risk for COVID-19. A special subcommittee of Rhode Island's Vaccine Advisory Committee [recommended](#) that high-risk healthcare workers be vaccinated against COVID-19 first. These vaccinations began on December 14. (For more information on doses administered, [see our data page.](#))

Rhode Island is using the National Academies of Science, Engineering, and Medicine framework, recommendations from CDC's Advisory Committee on Immunization Practices (ACIP), and input from its COVID-19 vaccine subcommittee to make decisions about how to distribute the vaccine in Rhode Island. The Rhode Island Department of Health (RIDOH) is considering multiple, complex factors as we prioritize groups to receive the COVID-19 vaccine. These factors include, but are not limited to, expert guidance, safety, and equity concerns. We are looking at recommendations from the CDC and FDA and considering high-risk populations while keeping Rhode Island's unique population needs in mind. We are planning to roll out vaccine in phases to more groups of people as more doses become available. You can learn more here: <https://health.ri.gov/covid/vaccine/> Response updated 12.17.2020

16. How is vaccination happening at long-term care facilities?

Vaccination of long-term care facility residents and staff is a top priority for our State. CDC has partnered with CVS and Walgreens to administer COVID-19 vaccines to residents and staff of long-term care facilities through a national program. The federal government has set the timeline for this program. Rhode Island has hit all major program milestones. Vaccination clinics began at nursing homes on December 28. CVS and Walgreens have committed to completing the first clinic for every enrolled nursing home in three weeks. Clinics for other long-term care facilities, such as assisted living facilities, group homes for individuals primarily older than 65, and elderly housing with residential services, will begin once all of the first clinics for nursing homes are complete.

As part of this program, which is free of charge to facilities, the pharmacies will schedule and coordinate on-site clinics with each facility, order vaccines and supplies (e.g., syringes, needles, personal protective equipment), ensure vaccines are appropriately stored and handled, administer vaccine to all residents and any staff not already vaccinated, report required vaccination data, and ensure their vaccination and administrative staff entering long-term care facilities meet federal COVID-19 testing requirements. This partnership will help us get vaccines quickly, efficiently, safely, and equitably to all Rhode Island long-term care facilities. It will also help ensure the highest level of training and support for all facilities receiving vaccine. Response added 12.28.2020

17. How can I sign up for vaccination? Is there a priority list?

RIDOH will share information on its vaccine web page, through social media, and through media, community partners, employers, and other groups as decisions about who can get vaccinated in each phase of Rhode Island's COVID-19 vaccination program are made. We will also describe how different groups can get vaccinated. (Please note: there is no "priority list" or "waiting list" that people can join to get vaccinated.) RIDOH will engage additional stakeholders and partners in the planning process as we learn more about the availability of vaccine during each phase of the program. For the most up-to-date information, visit C19vaccineRI.org. Response updated 12.17.2020, 12.28.2020



18. Is there a cost or co-pay to get vaccinated?

According to the CDC, at this time, it is expected that the COVID-19 vaccine will be free to everyone. Those who administer vaccines may charge insurance companies, but not the person being vaccinated, a fee for providing a shot to someone. There will be no cost or co-pay for anyone getting vaccinated for COVID-19. In addition, people without health insurance will be able to get the COVID-19 vaccine at no cost.

19. Will there be multiple doses of the vaccine?

This depends on which vaccines are authorized for use. Both the Pfizer and Moderna vaccines—the first vaccines to request emergency use authorization—require two doses. The Pfizer vaccine requires a second dose 21 days after the first dose and the Moderna vaccine requires a second dose 28 days after the first dose.

20. How will I know when to get a second dose?

We are looking into several different methods to help people remember which vaccines they received and to notify people when they need to get their second dose. Those who receive the vaccine will also receive a vaccination card that states when they received the vaccine and which vaccine they received. It's a good idea to take a picture of this card with your phone so that you can keep your own record. You will learn more about how to get a second dose when you receive your first dose of vaccine.

21. If I am a resident of RI in the summer but another state in the winter, where do I get the vaccine?

You will need to receive both doses in the same state. This is because the second dose will be shipped automatically to the healthcare provider or location that provided the first dose. It is possible that there will be some flexibility on location within provider networks. For more information, please call your provider.
Response added 12.28.2020

Contraindications

22. Can I get vaccinated if I have allergies?

People with a history of severe allergic reaction (e.g., anaphylaxis) to other vaccines (i.e., not Pfizer-BioNTech vaccine) or to an injectable medication should assess their risks with a primary care provider. However, they can be vaccinated. Often, after vaccination, people are asked to wait for 15 minutes to be observed for potential side effects. People with a history of severe allergic reactions should be prepared for a 30-minute observation period.

Individuals with a history of other allergies (e.g., to food, pets, insects, environmental allergies) or a family history of anaphylaxis should be vaccinated.

People with a history of severe allergic reactions (e.g., anaphylaxis) to any component of the Pfizer-BioNTech or Moderna COVID-19 vaccines should not be vaccinated. *Response added 12.17.2020*

23. Can I receive the COVID-19 vaccine if I am pregnant or breastfeeding?

Pregnant and breastfeeding women in high-risk groups should be offered the vaccine, with the opportunity to discuss with their healthcare providers. Note: Routine testing for pregnancy prior to receiving COVID-19 vaccine is not recommended. *Response added 12.17.2020*

24. Should I get the COVID-19 vaccine if I already had COVID-19?

People who have tested positive for SARS-CoV-2 (the virus that causes COVID-19) should wait to receive the COVID-19 vaccine until they have recovered from illness and until after they have completed their isolation. *Response added 12.17.2020*

25. Should I get the COVID-19 vaccine if I received monoclonal antibody treatment?

The CDC advises waiting 90 days after monoclonal antibody or convalescent plasma treatment before receiving COVID-19 vaccine. *Response added 12.17.2020*

26. Should I get the COVID-19 vaccine if I was just received a different vaccine (e.g., Shingrix)?

People who have received any other vaccine within the past 14 days should wait until 14 days have passed to receive the COVID-19 vaccine. *Response added 12.17.2020*

Other

27. What can we do while we wait for a vaccine?

There are prevention measures that we know work. While waiting for a vaccine, please continue to wear a mask, wash your hands, watch your distance, and stay home if you're feeling sick or if you have symptoms of COVID-19.

It is important to continue these practices even after you receive the vaccine. We are still learning about how effective the vaccines are and for how long they are effective.

28. Where can I learn more?

For answers to additional frequently asked questions about COVID-19 vaccine, visit: [Frequently Asked Questions about COVID-19 Vaccination](#).