COVID-19 Vaccine Frequently Asked Questions

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

We do not know for sure when a COVID-19 vaccine will be available in the United States. However, we are tracking the progress of the various COVID-19 vaccines being tested in vaccine trials. We are also preparing to distribute vaccine in Rhode Island once a vaccine is approved.

2. 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.

3. Will the vaccine be safe?

Safety is a top priority. 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.

4. 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.

5. 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.

It is possible that the FDA will issue an EUA for a COVID-19 vaccine.

6. 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.

7. 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.

8. 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 will also review the scientific data to ensure that Rhode Island is confident in the federal recommendations.

9. 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.

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 a vaccine.

Further, researchers had a head start on vaccine development because of research already done on similar coronaviruses. This includes the viruses that caused the Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). In addition, the government has decided to start producing doses of certain COVID-19 vaccines already in phase 3 trials. This way, if these vaccines are determined to be safe and effective, people can get them immediately.

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

There are many vaccines in various trial phases. However, not all of them will be approved. 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.

11. 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.

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

We expect to receive limited initial supplies of vaccine. At first, vaccine will likely only be available for people most at risk for COVID-19. We will be transparent about how these decisions are made. A special subcommittee of Rhode Island's Vaccine Advisory Committee will also advise on how to prioritize distribution of vaccine. With this subcommittee, we are using the National Academies of Science, Engineering, and Medicine framework. When CDC's Advisory Committee on Immunization Practices (ACIP) recommendations become available, we will incorporate them into our approach. Our goal is to make sure this is done equitably, in a way that protects the State as a whole. We are planning to roll out vaccine in phases to more groups of people as more doses become available. You can learn more about the COVID-19 Vaccine Subcommittee and our vaccination plan here: https://health.ri.gov/covid/vaccine/

13. What is Rhode Island doing to plan for a vaccine?

Rhode Island has been planning for how to distribute a COVID-19 vaccine for several months now. On October 16, we submitted an interim, draft vaccination plan to CDC. We will add more information and may change the plan as we learn more. You can learn more about our vaccination plan here: https://health.ri.gov/covid/vaccine/

14. How much will it cost to get vaccinated?

According to the CDC, at this time, it is expected that the vaccine will be free. Those who administer vaccines may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the person receiving vaccine. However, they may not seek any reimbursement, including through balance billing, from the person receiving vaccine. In addition, people without health insurance will be able to get the COVID-19 vaccine at no cost.

15. Will there be multiple doses of the vaccine?

This depends on which vaccines are approved. Some of these vaccines will likely have two doses.

16. Where can I learn more?

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