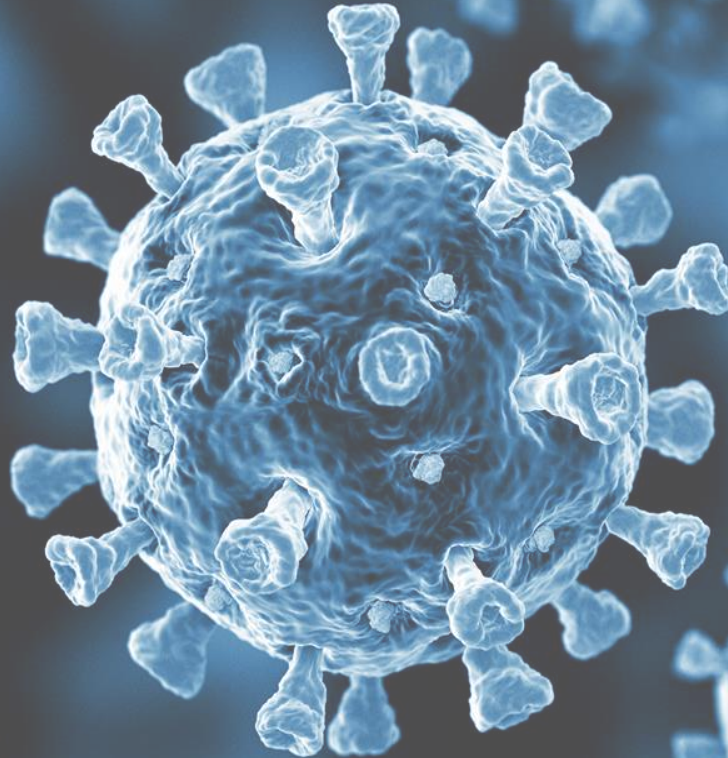# Ohio's COVID-19 Vaccine Program

A closer look at safety and effectiveness.

COVID-19 VACCINE SAFETY & EFFICACY

Overview:
➡ Fast facts about two authorized vaccine products.
➡ How the vaccines were developed so quickly.
➡ How mRNA vaccines work.
➡ How safe are the COVID-19 vaccines?
➡ Who should, shouldn't get the vaccine.
➡ Side effects, adverse reactions.

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Fast facts about first COVID-19 vaccines

Pfizer/BioNTech	Moderna
Two doses required, 21 days apart.	Two doses required, 28 days apart.
Full effectiveness reached one week after second shot.	Full effectiveness reached two weeks after second shot.
Efficacy: 95% effective in clinical trials.	Efficacy: 94% effective in clinical trials.
Stored at ultra-cold minus-70 degrees Celsius.	Stored frozen at minus-20 degrees Celsius.
Emergency use authorization granted on Dec. 11, 2020.	Emergency use authorization granted on Dec. 18, 2020.
Ages 16 and older.	Ages 18 and older.

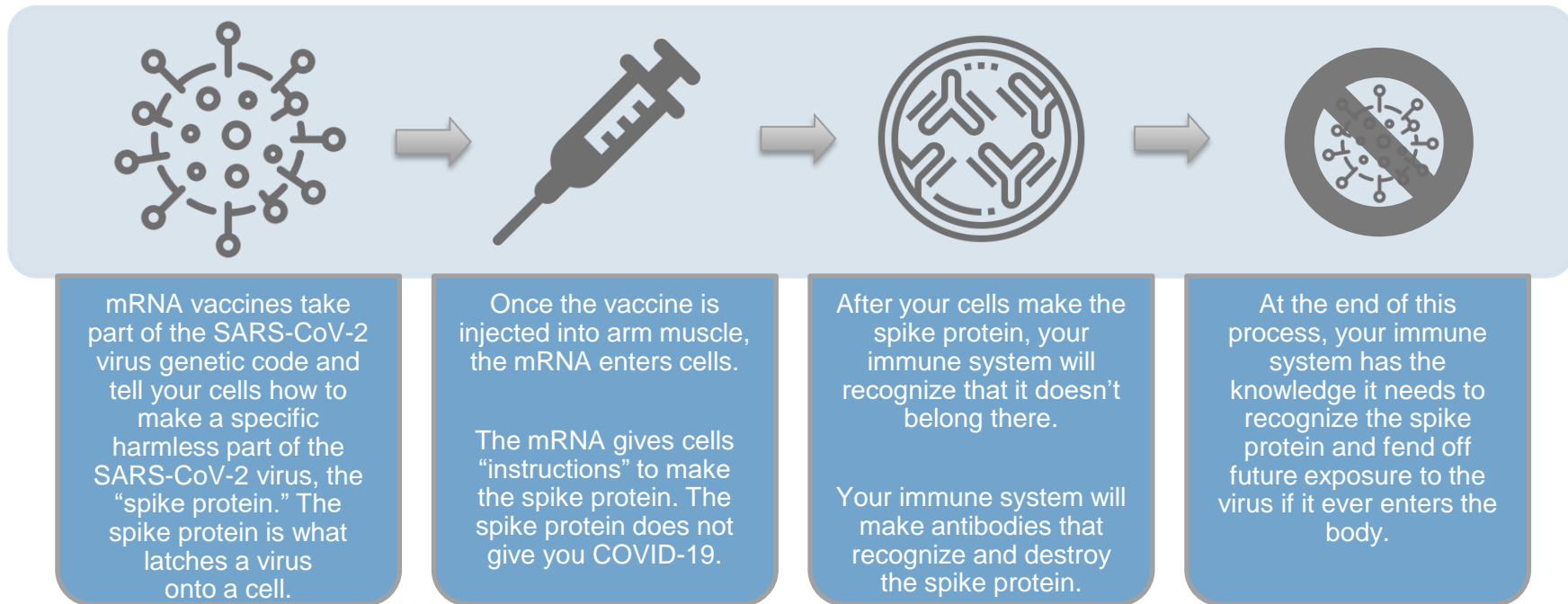# How was the COVID-19 vaccine developed so quickly?

No shortcuts

- In the past, vaccines have taken many years to develop.
- The process for COVID-19 vaccines has been quicker for many reasons.
- No steps were skipped, but researchers did conduct some stages of the process simultaneously. This included concurrent trial phases, and condensed timelines that eliminated long waiting periods.

mRNA

- Researchers have been studying messenger RNA (mRNA), used by the Pfizer and Moderna vaccines, for decades.
- Early-stage clinical trials using mRNA vaccines occurred for influenza, Zika, rabies, and other viruses.
- Because COVID-19 comes from a family of viruses, including the SARS coronavirus of 2002 and the MERS coronavirus of 2012, scientists had already researched how coronaviruses behaved and had begun development on a similar vaccine.

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How do mRNA vaccines work?

Messenger RNA vaccines give the immune system genetic instructions to recognize the COVID-19 virus.

mRNA vaccines take part of the SARS-CoV-2 virus genetic code and tell your cells how to make a specific harmless part of the SARS-CoV-2 virus, the "spike protein." The spike protein is what latches a virus onto a cell.

Once the vaccine is injected into arm muscle, the mRNA enters cells.

The mRNA gives cells "instructions" to make the spike protein. The spike protein does not give you COVID-19.

After your cells make the spike protein, your immune system will recognize that it doesn't belong there.

Your immune system will make antibodies that recognize and destroy the spike protein.

At the end of this process, your immune system has the knowledge it needs to recognize the spike protein and fend off future exposure to the virus if it ever enters the body.

How safe are the COVID-19 vaccines?

Safety has been a top priority throughout the vaccine development and approval process. It continues to be a top priority through continuous safety monitoring measures.

Rigorous testing

- The COVID-19 vaccine development process involved several steps comparable with those used to develop other vaccines, such as the flu vaccine.
- Clinical trials study the safety and effectiveness of a vaccine in thousands of study participants.
- No serious safety concerns emerged during the clinical trials.

Thorough evaluation

- The FDA uses rigorous standards to evaluate trial data to ensure that a vaccine is safe and effective and the benefits outweigh the risks.
- After an FDA decision, the CDC also reviews available data before making final recommendations for vaccine use.

Ongoing safety monitoring

- The CDC and other federal partners continue to monitor the new vaccines for any serious side effects, using many vaccine safety monitoring systems.
- This continued monitoring could reveal side effects that may not have been observed in clinical trials.

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1. COVID-19 vaccines are safe and effective. COVID-19 vaccines currently available in the U.S. were rigorously tested and are more than 94% effective.

2. You can't get COVID-19 from a COVID-19 vaccine. The vaccines do not contain a live virus, meaning they can't give you COVID-19 or cause a positive COVID-19 viral test.

3. COVID-19 vaccine trials were among the largest in history. A typical vaccine study has about 5,000 participants – the Moderna COVID-19 trial had more than 30,000 participants, and the Pfizer-BioNTech study had more than 43,000.

4. COVID-19 vaccines have not been linked to infertility or miscarriage. There is no evidence that COVID-19 vaccines cause infertility or increase the risk of miscarriage.

5. No serious safety concerns were observed in clinical trials. The most common side effects, much like other vaccines, are fatigue, headache, soreness or redness at the injection site, and muscle or joint pain.

6. COVID-19 vaccines will not change your DNA or alter your genetic makeup. It isn't possible for mRNA to alter or modify a person's genetic makeup.

7. Vaccine injections do NOT contain microchips or tracking devices. Vaccines do not contain microchips, nanochips, RFID trackers, or devices that would track or control your body in any way.

8. Vaccines do not cause autism. Studies conducted across the globe continue to show that there is no connection between autism and vaccines.

Are the vaccines safe for everyone?

Diversity in race in <u>clinical trials</u>

- Clinical trials that studied the vaccine's effectiveness and safety included a diverse cross-section of people.
- In the Moderna study, 37% of the participants were from communities of color, which is similar to the diversity of the U.S. at large.
- Approximately 42% of participants in Pfizer BioNTech's worldwide clinical trials come from communities of color.

Diversity in age, health conditions in <u>clinical trials</u>

- Clinical trials included participants older than age 65 (23% of Moderna participants, 21% of Pfizer-BioNTech participants).
- Also included were people with high-risk chronic diseases that put them at increased risk of severe COVID-19 (42% of Moderna participants, 46% of Pfizer-BioNTech participants).

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Who should, shouldn't get the vaccine

Do not administer to patients who:

- Currently have COVID-19.
- Have a history of severe or immediate reactions to vaccines, injectable therapy, or any ingredients in the COVID-19 vaccines.
- People who have had an allergic reaction to polyethylene glycol (PEG) or polysorbate.

Vaccine is NOT contraindicated for:

- People who are immunocompromised.
- People who are pregnant or breastfeeding.
- These individuals are urged to consult with their healthcare provider to discuss further before vaccination.
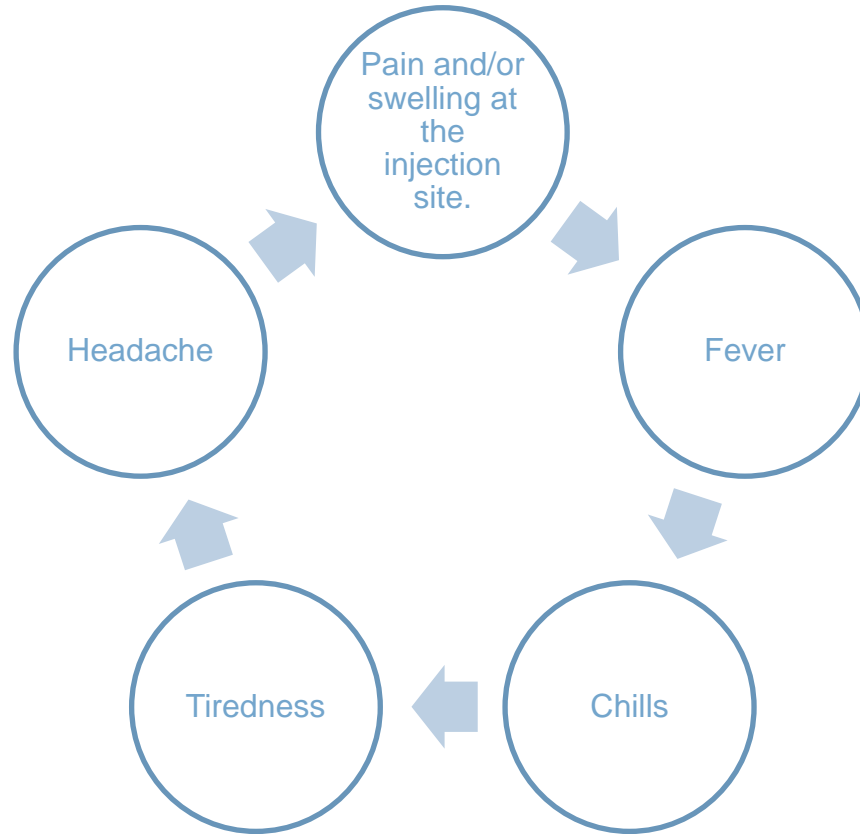
Source: CDC

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Which types of allergies are a concern?

Allergy history	CDC recommendation
People with a history of severe allergic reactions not related to vaccines or medications (food, pet, venom, environmental, or latex).	☑ Yes, get vaccinated.
People with a history of allergies to oral medications or a family history of severe allergic reactions.	☑ Yes, get vaccinated.
People who have had an immediate allergic reaction – even if not severe – to vaccine or injectable therapy for another disease.	⚠ Talk to their doctor first.
People who have had an immediate allergic reaction – even if it was not severe – to any ingredient in an mRNA COVID-19 vaccine or polysorbate.	✕ Do not get one of the available mRNA COVID-19 vaccines.
People who had an immediate allergic reaction after getting the first dose of an mRNA COVID-19 vaccine.	✕ Do not get the second dose.

SOURCE: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html

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Common side effects from the vaccine

Pain and/or swelling at the injection site.

Fever

Chills

Tiredness

Headache

Vaccine safety monitoring systems

Monitoring vaccine safety is critical to ensure that the benefits of COVID-19 vaccines continue to outweigh the risks for people who are vaccinated.

CDC and FDA: Vaccine Adverse Event Reporting System

The national system that collects reports of post-vaccination adverse effects from healthcare professionals, vaccine manufacturers, and the public.

CDC: V-safe

A new smartphone-based, post-vaccination health checker for people who receive COVID-19 vaccines.

CDC: National Healthcare Safety Network

An acute care and long-term care facility monitoring system reporting to VAERS.

CDC: Vaccine Safety Datalink

A network of nine U.S. integrated healthcare organizations that conducts active surveillance and research.

CDC: Clinical Immunization Safety Assessment Project

A collaboration between CDC and seven medical research centers to provide expert consultation on individual cases and conduct clinical research studies about vaccine safety.

FDA: Other large insurer/payer databases

A system of administrative and claims-based data for surveillance and research.

FDA and the Centers for Medicare & Medicaid Services

Medicare data — A claims-based system for active surveillance and research.

FDA: Biologics Effectiveness and Safety System

A system of electronic health record, administrative, and claims-based data for active surveillance and research.

FDA: Sentinel Initiative

An additional system of electronic health record, administrative, and claims-based data for active surveillance and research.

How to report adverse events

Adverse events that occur in a recipient after receipt of COVID-19 vaccine should be reported to the **Vaccine Adverse Events Reporting System (VAERS).**
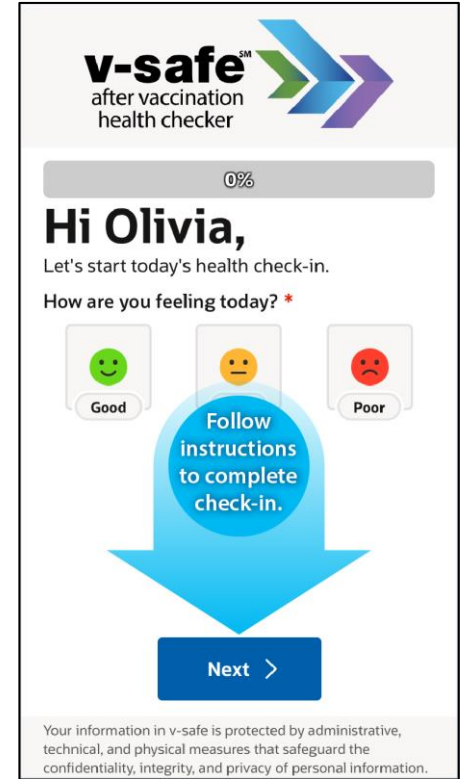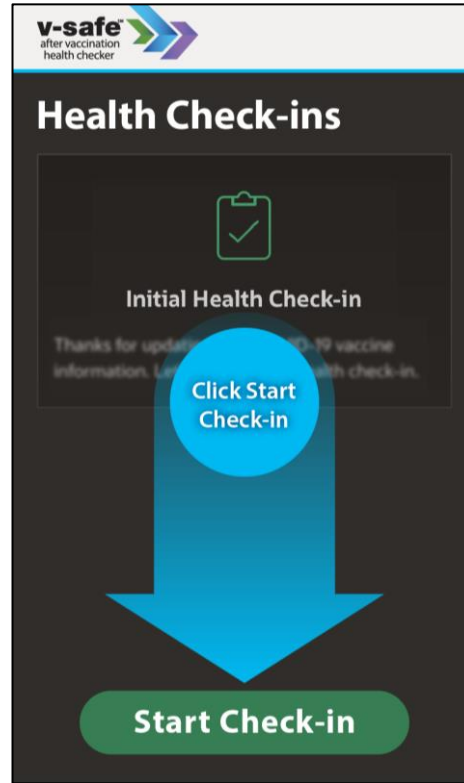
An "adverse event" is any health problem that happens after a vaccination that <u>may or may not be caused by a vaccine</u>. VAERS cannot determine if a vaccine caused an adverse event, but it can determine if further investigation is needed.

Healthcare providers are required by law to report:

- Vaccine administration errors.
- Serious adverse events that occur within a specified time period following vaccination, whether or not it is clear that a vaccine caused the adverse event.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.
- Report via https://vaers.hhs.gov/reportevent.html.
- Additional details are available by calling 800-822-7967 or at https://vaers.hhs.gov/faq.html.

CDC offers v-safe health checker

- **V-safe** is a smartphone-based tool that vaccine recipients can opt to use. It uses text messaging and web surveys to provide personalized health check-ins after a COVID-19 vaccination.

- Patients can tell the CDC if they 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.

- **V-safe** also will remind patients to get the second COVID-19 vaccine dose when it is due.

Vaccine communications toolkit

http://bit.ly/OHVaccineToolkit

- ODH offers a COVID-19 Vaccine Communications Toolkit featuring talking points, language tips, graphics, FAQs, myths vs. facts, social media language, and trusted resources to help partners better communicate about the vaccine.

- Language translations are now available.

- We ask for your support by using it to communicate with members of your community.

Q&A: Your questions about Ohio's vaccine plan

Resources	Contact us
Visit our COVID-19 information hub for vaccine information and resources for providers and consumers. **coronavirus.ohio.gov/vaccine**	Do you have COVID-19 questions? • Contact our Call Center at 1-833-4-ASK-ODH (1-833-427-5634).

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