

# COVID-19 Vaccine

Julianne Nesbit, Health Commissioner

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**Clermont County**  
**Public Health**  
Prevent. Promote. Protect.

# How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

## PHASE 1



**20-100  
healthy volunteers**



- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

## PHASE 2



**several hundred  
volunteers**

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

## PHASE 3



**hundreds or thousands  
of volunteers**

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

**FDA licenses the vaccine only if:**

- It's safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.



Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

The FDA inspects manufacturing facilities regularly to ensure quality and safety.



**FOR MORE INFORMATION, VISIT [HTTPS://WWW.FDA.GOV/CBER](https://www.fda.gov/cber)**



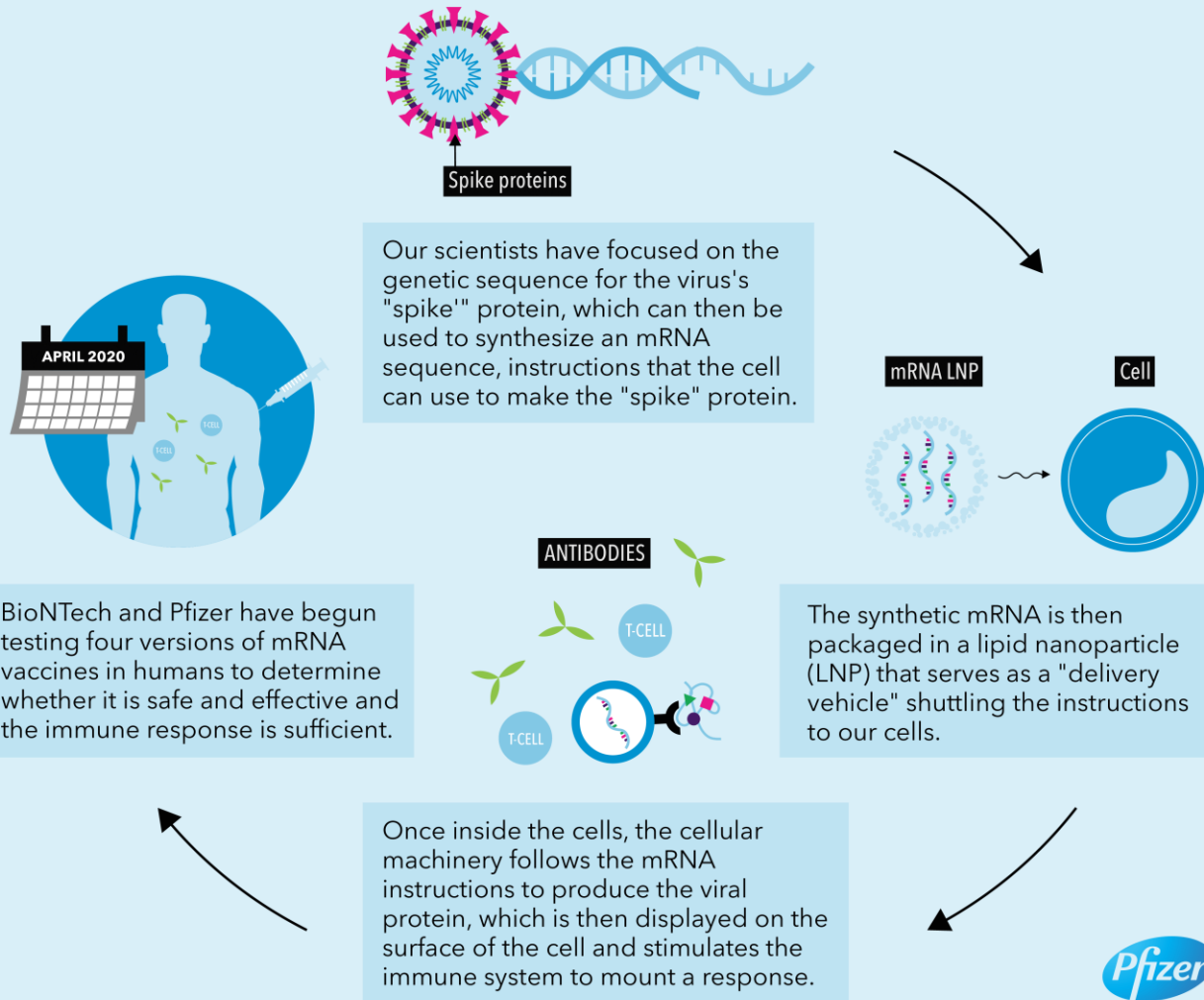
# Vaccine

- Currently Two Types (messenger RNA)
  - Pfizer–
    - Requires ultra cold storage
    - Two doses 21 days apart
    - Intramuscular injection
  - Moderna–
    - Requires standard freezer shipping, shelf stable 30 days under refrigeration.
    - Two doses 28 days apart
    - Intramuscular injection
  - Two more products expected in early 2021, AstraZeneca and Johnson and Johnson
- All vaccines are 100% voluntary



# UNDERSTANDING mRNA VACCINES

To build an mRNA vaccine, scientists only need access to the genetic sequence of SARS-CoV-2, and not the actual virus.



# ACIP PROPOSED PHASE 1 VACCINATION GROUPS

	<b>Phase 1c</b> Adults with high-risk medical conditions Adults aged 65+ years
	<b>Phase 1b</b> Essential workers <i>(E.g., education sector, food and agriculture, utilities, police, firefighters, corrections officers, transportation)</i>
<b>Phase 1a</b> Healthcare personnel Long-term care facility residents	



# Are the COVID-19 Vaccine Safe?

- The development process involved several steps comparable to other vaccines such as the flu or measles
- The U.S. Food and Drug Administration (FDA), have ensured that vaccine is thoroughly evaluated.
- Evidence shows that COVID-19 vaccines are safe and work to prevent COVID-19
- Of the first two vaccines to be granted FDA emergency use authorization, the Pfizer vaccine is 95% effective, and the Moderna vaccine is 94% effective
- The technology used in mRNA vaccines has been studied for decades



# Was the process rushed?

- There have been no shortcuts in the vaccine development process.
- The process was quicker as a result of efforts to run concurrent trial phases
- Researchers have been studying mRNA for decades, and early-stage clinical trials using mRNA vaccines have been carried out for influenza, Zika, and rabies
- Recent technological advancements in RNA biology and chemistry, have allowed these COVID-19 vaccines using mRNA to be developed as safe and effective vaccines.



# Will it alter my DNA?

- mRNA, is not able to alter a person's genetic makeup
- The mRNA from the vaccine never enters the nucleus of the cell, where your DNA is kept
- The mRNA can be described as instructions for your body on how to make a harmless piece of "spike protein" to allow our immune systems to recognize the protein doesn't belong there and begin building an immune response and making antibodies
- COVID-19 vaccines work with the body's natural defenses to safely develop immunity to the virus, giving your cells a blueprint of how to make antibodies





# Can you get COVID-19 from the vaccine?

- None of the vaccines approved or in development in the US use live virus that causes COVID-19
- It takes a few weeks for the body to build immunity after vaccination, and some vaccines require two doses.
- That means it is possible that a person could be infected with the virus that causes COVID-19 just before, or just after, getting the vaccination and become sick, since it takes the vaccine time to provide protection.



# What are the side effects?

- The goal of these vaccines is to teach our immune systems to recognize and fight the virus that causes COVID-19
- Sometimes this process can cause side effects, such as fatigue, headache, soreness or redness at the injection site, and muscle or joint pain
- These symptoms are normal and are a sign that the body is building immunity
- Anaphylactic reactions



# Who should not get the vaccine?

- Severe allergic reaction to any ingredient of this vaccine or severe allergic reaction after a previous dose of COVID-19 vaccine
- Tested + for COVID-19 in last 14 days
- Been in close contact with anyone who tested + in last 14 days
- If you have symptoms of COVID-19
- If you had another vaccine in the last 14 days
- If you received monoclonal antibodies or convalescent plasma in the last 90 days



# Should I get the vaccine if I have already had COVID-19?

- We do not know how long someone is protected from getting sick again after recovering from COVID-19
- Due to the severe health risks associated with COVID-19, and because re-infection with COVID-19 is possible, people are encouraged to get a vaccine even if they have been sick with the virus before
- The immunity someone gains from having an infection, called natural immunity, varies from person to person.



# Will I test positive for COVID-19 if I get vaccinated?

- Current vaccines won't cause you to test positive on viral tests, which see if you have a current infection.
- If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests.
- Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus.



# Should I get the vaccine if I am pregnant or breastfeeding?

- People who are pregnant may choose to be vaccinated.
- The American College of Obstetricians and Gynecologists' (ACOG) recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on priority groups.
- The vaccines currently have not been tested in pregnant or breastfeeding women. Therefore, there is no safety data specific to use in pregnancy.



# More information

- CDC <https://www.cdc.gov/vaccines/covid-19/index.html>
- Ohio <https://coronavirus.ohio.gov/wps/portal/gov/covid-19/covid-19-vaccination-program>
- FDA <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>
- Pfizer Fact Sheet for Recipients and Caregivers <https://www.fda.gov/media/144414/download>
- Moderna Fact Sheet for Recipients and Caregivers <https://www.fda.gov/media/144638/download>
- [www.ccphohio.org](http://www.ccphohio.org)



Questions?

