Key Messaging for the COVID-19 Vaccine

12/30/2020











Get the facts at ny.gov/vaccine







- and NYS Clinical Advisory Task Force
- Backed by clinical trial • data
- The vaccine cannot give • you COVID
- The best way to protect • yourself and others from COVID-19
- Our weapon to end the war

- Vaccine distribution will be fair and equitable
- NYS will reach out to • underserved communities
- Every New Yorker will be ٠ able to have access to vaccine at no cost



The COVID-19 vaccines are safe.

- The COVID-19 vaccines have gone through the same rigorous review that all vaccines must follow in the U.S. As of December 30, 2020, two vaccines have been approved by the FDA: the Pfizer/BioNTech vaccine and the Moderna vaccine.
- These approvals followed three rounds of clinical trials with thousands of participants with a diverse range of race, age and other demographics.
- In New York, the State's independent COVID-19 Clinical Advisory Task Force, made up of prominent health experts, also approved these COVID-19 vaccines as safe and effective.
- Additionally, even after a vaccine is approved, multiple safety systems at the FDA and the CDC constantly monitor for adverse events. If an adverse event is found, it is immediately investigated to determine if it poses a true health issue.



Approved by the FDA, the CDC, and New York State's independent Clinical Advisory Task Force.

- The FDA has a <u>rigorous process</u> that vaccine developers must go through before a vaccine can be approved
- New York State's independent <u>COVID-19 Clinical Advisory Task Force</u> is made up of renowned health and medical experts, and is chaired by Dr. Charles Rice, winner of the 2020 Nobel Prize in Medicine
- The Clinical Advisory Task Force reviews vaccine clinical data alongside the FDA so that they can provide a thorough review that does not delay the timeline



Clinical trials:

Phase 1 20-100 Healthy Volunteers



Researchers try to answer these questions:

- Is this vaccine safe?
- Are there any serious side effects?
- How does the vaccine dose relate to any side effects?
- Is the vaccine causing an immune response?

Phase 2 Several Hundred Volunteers



Researchers try to answer these questions:

- What are the most common short-term side effects?
- What's the body's immune response?
- Are there signs that the vaccine is protective?

Phase 3 1000+ Volunteers



Researchers try to answer these questions:

- How do disease rates compare between people who get the vaccine and those who do not?
- How well can the vaccine protect people from disease?

Phase 4 Vaccine is Approved



Researchers try to answer these questions:

 FDA approves a vaccine only if it's safe, effective, and benefits outweigh the risks.

 Researchers continue to collect data on the vaccine's long-term benefits and side effects.

Source: CDC



Pfizer/BioNTech clinical trial info:

- Phase 2/3 clinical trials had about 43,400 participants who participated at 152 clinical sites across the globe, 130 of which were in the United States.
- Half of participants received the vaccine, the other half received a placebo (assigned randomly)
- Demographics of participants:
 - 49% female, 51% male
 - 83% white
 - 9% Black or African American
 - 28% Hispanic or Latinx
 - 4.3% Asian
 - 0.5% Native American/Alaska Native

Source: <u>New England Journal of</u> <u>Medicine</u>



Pfizer/BioNTech clinical trial info: (cont.)

- 35% of participants were clinically obese
- 21% of participants had at least one coexisting condition
- The median age was 52 years old
- The age range of participants spanned from 16 to 91

The vaccine was found to be 95% effective at preventing COVID-19.

> Source: <u>New England Journal of</u> <u>Medicine</u>



Moderna clinical trial info:

- Phase 3 clinical trials had about 30,400 participants from the United States
- Half of participants received the vaccine, the other half received a placebo (assigned randomly)
- Demographics of participants:*
 - 48% female, 52% male
 - 79% white
 - 10% Black or African American
 - 21% Hispanic or Latinx
 - 5% Asian
 - 0.8% American Indian/Alaska Native

*Safety Set

Source: FDA Briefing Document



Moderna clinical trial info:

(cont.)

- 22% of participants had at least one high-risk condition
- 25% of participants were health care workers
- Median age of 52
- The age range of participants spanned from 18 to 95

The vaccine was found to be 94.5% effective at preventing COVID-19.

*Safety Set

Source: FDA Briefing Document



Distribution will be equitable.

- One of the key principles of New York's vaccination program is equity and fairness
- The federal government has agreed that it will not force New York State to provide any information that could be used to identify immigration status as part of the vaccination program.
- New York State will work closely with partners across the state who can assist in addressing health equity issues
- New York State recognizes that there is a long history of inequity and racism in health care (e.g. the Tuskegee experiment) that has led many to be understandably skeptical of government public health efforts
- New York will work to address the concerns of all communities



Main Reasons for Vaccine Hesitancy

- 1. "The vaccine could give me COVID."
- 2. "The vaccine was developed too fast."
- 3. "I'm worried about side effects."

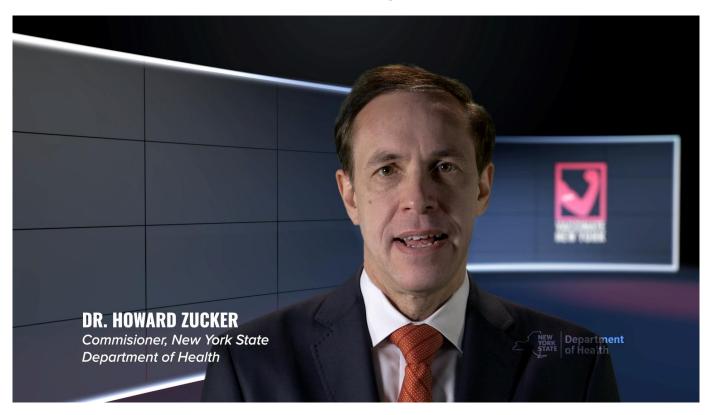


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The vaccine cannot give you COVID.



Click <u>here</u> for YouTube video.



The vaccine cannot give you COVID.

Facts about COVID-19 mRNA vaccines:

They cannot give someone COVID-19.

This is because mRNA vaccines do not use the live virus that causes COVID-19.

They do not affect or interact with our DNA in any way.

mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

Source: cdc.gov

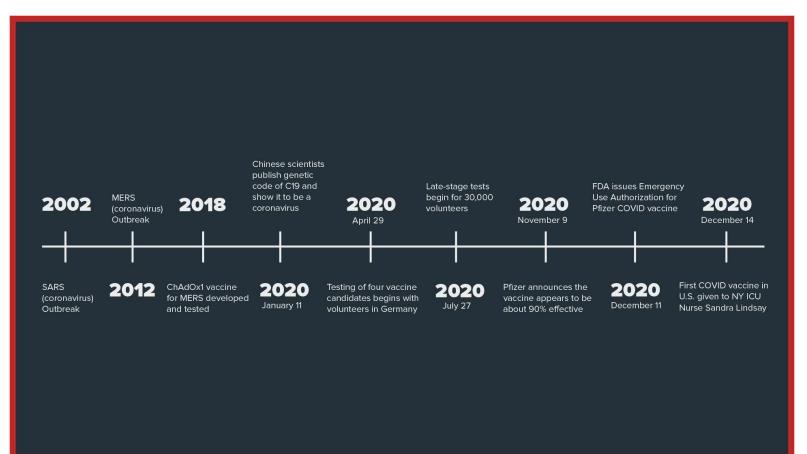


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Years of research are behind the vaccine.





Facts about mRNA vaccines:

- mRNA vaccines have been studied before for flu, Zika, rabies, and cytomegalovirus (CMV)
- Research into mRNA vaccines began in 1989 and the first mRNA vaccines were developed in the 1990s
- As soon as the necessary information about the virus that causes COVID-19 was available, scientists began designing the mRNA instructions for cells to build the unique spike protein into an mRNA vaccine
- mRNA vaccines are being held to the same <u>rigorous safety and effectiveness</u> <u>standards</u> as all other types of vaccines in the United States

Source: cdc.gov



REUTERS

With Wuhan virus genetic code in hand, scientists begin work on a vaccine

By Julie Steenhuysen, Kate Kelland

JANUARY 24, 2020

ScienceDaily

Whole genome of novel coronavirus, 2019-nCoV, sequenced

Institut Pasteur | January 31, 2020

- The genetic code of the virus (2019-nCoV) was first published in January 2020 by Chinese scientists, who made the research public to the global scientific community
- French scientists also sequenced the entire genome of the virus in January 2020
- This meant scientists around the world could almost immediately begin developing a vaccine for the virus



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No serious side effects of the vaccine have been observed in clinical trials.



It is normal for your body to have an immune response after being vaccinated.

This is a sign that the vaccine is working.





"Immune Response"



Distribution?

The CDC's Advisory Committee on Immunization Practices calls for:

Phase 1a:

- High-risk hospital workers (emergency room workers, ICU staff & Pulmonary Department staff)
- Nursing home residents and staff
- Federally Qualified Health Care Center employees
- EMS workers
- Coroners, medical examiners and certain funeral workers
- Staff and residents at OPWDD, OMH and OASAS facilities
- Urgent Care Center employees
- Individuals administering COVID-19 vaccines, including local health department staff

Phase 1b:

• Essential workers and adults in the general public aged 75+

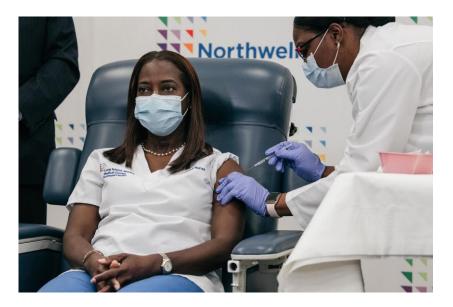
Updated information will be available at <u>ny.gov/vaccine</u>



Distribution?

Phase 1a has begun.

Phase 1b is not expected to begin until around the end of January.



Updated information will be available at <u>ny.gov/vaccine</u>



Don't throw out your mask yet.

- COVID-19 vaccines are just one of many important tools to help us stop this pandemic.
- It's important for everyone to continue using all the tools we have to combat COVID as the vaccine becomes more available over time.
- Wear a mask, social distance, avoid gatherings and wash your hands frequently. Taking these steps will still be a great way to protect yourself and others.



Join the conversation on social media:

#VaccinateNY



Thank you.



Additional resources:

- NYS COVID-19 vaccine website: <u>www.ny.gov/vaccine</u>
- NYS Department of Health Frequently Asked Questions: https://covid19vaccine.health.ny.gov/frequently-asked-questions
- CDC's Frequently Asked Questions: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html</u>
- CDC webpage on ensuring COVID-19 vaccine safety: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html
- CDC's "8 Things to Know about the U.S. COVID-19 Vaccination Program": https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html
- CDC explainer on mRNA vaccines: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html</u>
- CDC guide with key facts on COVID-19 vaccines: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits/facts.html</u>
- CDC guide explaining how COVID-19 vaccines work: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html</u>
- CDC guide explaining the benefits of the COVID-19 vaccine: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html</u>
- FDA webpage explaining the vaccine development process:
- <u>https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101</u>
- General vaccine safety information from the CDC: <u>https://www.cdc.gov/vaccinesafety/index.html</u>
- Explanation of the FDA's Emergency Use Authorization: <u>https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained</u>
- Video explainer of the FDA's Emergency Use Authorization: <u>https://www.youtube.com/watch?v=iGkwaESsGBQ</u>
- CDC communications toolkit for medical centers, clinics and clinicians: <u>https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html</u>

