

Massachusetts Nursing Homes and the COVID-19 Vaccine: Get the Facts

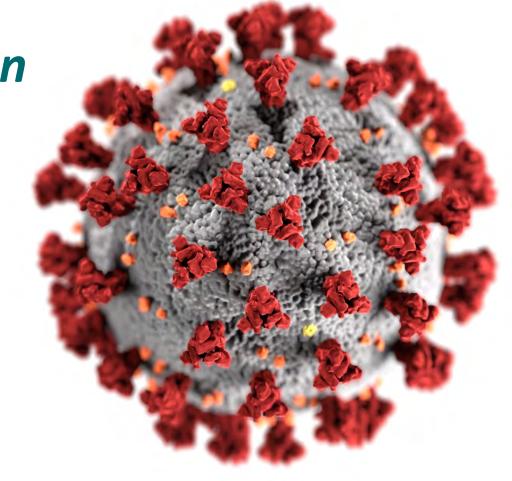
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COVID-19 Vaccine Information for Long-term Care

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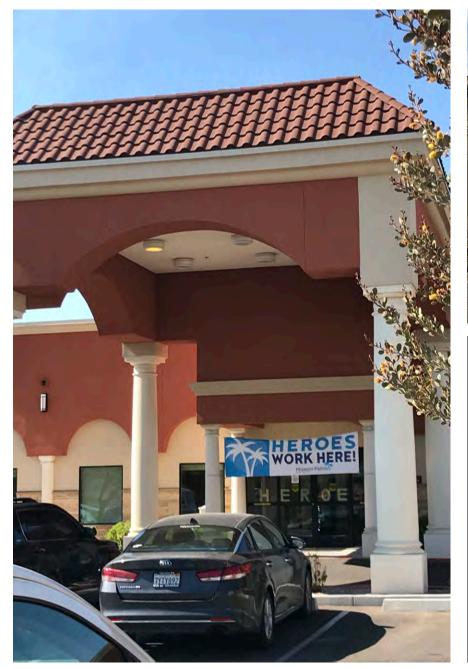


cdc.gov/coronavirus

## **Speaker Disclosures**

- No disclosures to report
- The content of this presentation reflects my opinion and does not necessarily reflect the official position of the CDC









Thanks to the essential caregiving teams supporting residents and families!

### What we know about COVID-19

- Infection with SARS-CoV-2, the virus that causes COVID-19, can result in a range of illnesses, from mild symptoms to severe illness and death.
- We don't know how SARS-CoV-2 will affect each person.
- Some people are more likely than others to become severely ill, such as older adults (65+ years) or people with certain medical conditions.

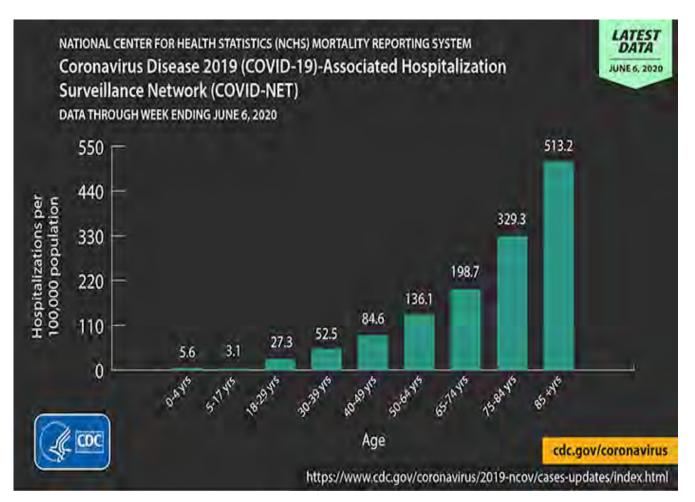


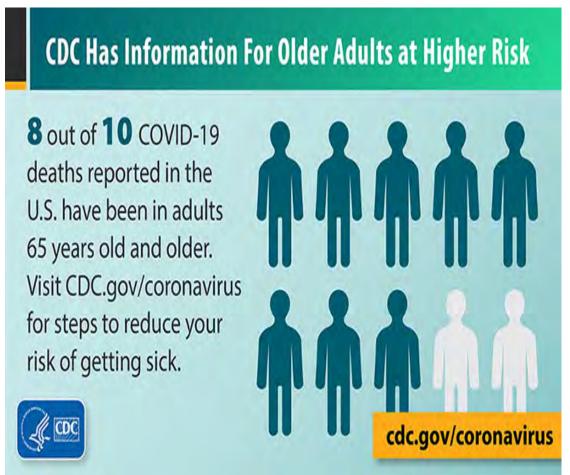






### **COVID-19 and Older Adults**





## **COVID-19 Impact in U.S. Nursing Homes: May-Nov 2020**

**Resident and Staff Cases and Deaths** 

322,690





https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg

1,162

## Healthcare personnel: A priority for COVID-19 vaccination

- On the front lines and at risk of exposure
- Can potentially transmit the virus that causes COVID-19 to residents, their families, and their communities
- Can positively influence vaccination decisions of peers, residents, friends, and family
- Healthcare personnel = paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials – not exclusive to medical personnel, includes administration, support staff, etc.





## Four phases of clinical trials to evaluate vaccine safety and efficacy



- · 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.
- FDA's Emergency Use
   Authorization is a
   process that helps
   facilitate the
   availability and use of
   medicines and vaccines
- COVID-19 vaccines are being held to the same safety standards as all vaccines.



Source: https://covid19community.nih.gov/resources/understanding-clinical-trials

# **COVID-19 vaccines and FDA Emergency Use Authorizations** (EUAs)

- Current vaccines requesting Emergency Use Authorizations (EUAs) from the FDA:
  - Pfizer/BioNTech (BNT162b2): 2 doses given at least 21 days apart
    - 95% effective (manufacturer data)
    - EUA issued on Dec 13, 2020 for use in persons ≥16 years
  - Moderna (mRNA-1273): 2 doses given at least 28 days apart
    - 94.5% effective (manufacturer data)
- Both vaccines were tested in tens of thousands of adults from diverse backgrounds, including older adults and communities of color.
- Clinical trial data show that both vaccines are safe and effective at preventing COVID-19.

Sources: <a href="https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine-https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy.">https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy.</a>

## What are messenger RNA (mRNA) vaccines?

- Carry genetic material that teaches our cells how to make a harmless piece of "spike protein," which is found on the surface of the SARS-CoV-2 virus.
  - Genetic material from the vaccine is destroyed by our cells once copies of the spike protein are made and it is no longer needed.
- Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies. This produces antibodies to protect us from getting infected if the SARS-CoV-2 virus enters our bodies.
- Do not affect our DNA; mRNA does not enter the cell nucleus.
- Cannot give someone COVID-19.
- Use technology that is new but not unknown. mRNA vaccines have been studied for influenza, Zika, rabies, and cytomegalovirus (CMV).



### **About these COVID-19 mRNA vaccines**

- These mRNA vaccines are expected to produce side effects after vaccination, especially after the 2nd dose.
- Side effects may include:
  - fever
  - headache
  - muscle aches
- No significant safety concerns were identified in the clinical trials.
- At least 8 weeks of safety data were gathered in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination.



Source: <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html">https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html</a>

## The COVID-19 mRNA vaccines will not give you COVID-19

- **None** of the COVID-19 vaccines in use or under development use the live virus that causes COVID-19.
- People can experience normal side effects, such as fever, after vaccination.
   These side effects are signs that the body is building immunity.
- It takes a few weeks for the body to build immunity after vaccination.
  - A person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection.
- We don't know yet how long protection from vaccines might last

## How was the vaccine development timeline accelerated while ensuring safety?

- Researchers used existing networks to conduct COVID-19 vaccine trials.
- Manufacturing began while clinical trials are still underway. Normally, manufacturing doesn't begin until after completion of the trials.
- mRNA vaccines are faster to produce than traditional vaccines.
- FDA and CDC are prioritizing review and authorization of COVID-19 vaccines.

## Safety of COVID-19 vaccines is a top priority.

COVID-19 vaccines are being held to the same safety standards as all vaccines.



#### **Before authorization**

- FDA carefully reviews all safety data from clinical trials.
- ACIP reviews all safety data before recommending use.



After vaccine authorization

 FDA and CDC closely monitor vaccine safety and side effects.

## Monitoring vaccine safety is a regular, ongoing part of vaccine development.

- **Existing** systems and data sources are used to monitor safety of vaccines after they are authorized or licensed, such as:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Clinical Immunization Safety Assessment (CISA)
  - Biologics Effectiveness and Safety System (BEST)
- New systems are being developed to monitor vaccine safety, such as v-safe:
  - Active surveillance that uses text messaging to initiate web-based survey monitoring
  - Any clinically important events reported by a participant would be sent to VAERS for follow-up



## **Vaccine Safety Monitoring Resources**





Vaccine Adverse Event Reporting System

co-managed by CDC and FDA

vaers.hhs.gov





#### What is v-safe?

V-safe is a smartphone-based tool 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 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.

#### How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

#### How long do v-safe check-ins last?

During the first week after you get your vaccine, v-safe will send you a text message each day to ask how you are doing. Then you

V-safe
after vaccination
health checker

Use your smartphone
to tell CDC about
any side effects after
getting the COVID-19
vaccine. You'll also get
reminders if you need a
second vaccine dose.

Vaers.hhs.gov

V-safe After Vaccination Health Checker | CDC

## **Key facts about COVID-19 vaccination**



https://www.cdc.gov/coronavirus/2019 -ncov/vaccines/about-vaccines/vaccinemyths.html COVID-19 vaccines can not give you COVID-19

People who have already gotten sick with COVID-19 may still benefit from getting vaccinated

Getting vaccinated can help prevent getting sick with COVID-19

COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests\*



## Vaccination is one measure to help stop the pandemic

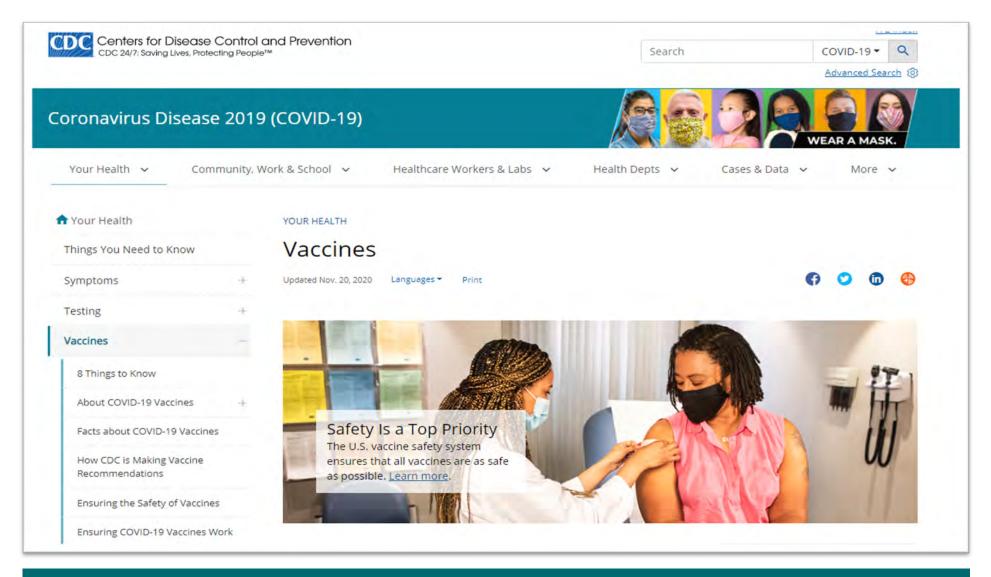
- While COVID-19 mRNA vaccines appear to be highly effective, additional preventive tools remain important to limit the spread of COVID-19.
- The combination of getting vaccinated and continuing to follow CDC infection prevention and control recommendations offers the best protection from COVID-19.
  - Cover your nose and mouth with a mask.
  - Maintain social distancing.
  - Performing hand hygiene
  - Use of personal protective equipment
  - Clean and disinfect shared surfaces.

# Vaccination protects yourself, your family, friends, co-workers, residents, and community

- You are all role models in your community
  - Choose to get vaccinated yourself when it is available to you.
- Participate in v-safe and help CDC monitor for any health effects after vaccination.
- Share your experience with coworkers, friends, and family.
- Know the basics about the COVID-19 vaccine.
   Help answer questions from your family and friends.
- Visibly show you received a vaccine, such as by wearing a sticker or button.



### **COVID-19 Vaccine information**



https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

### **COVID-19 Vaccine Communication Resources**

- HCP: Preparing to Provide COVID-19 Vaccines
  - https://www.cdc.gov/vaccines/covid-19/hcp/index.html
- What to Expect at Your Appointment to Get Vaccinated
  - https://www.cdc.gov/coronavirus/2019ncov/vaccines/expect.html
- Toolkit For Medical Centers, Clinics and Clinicians
  - https://www.cdc.gov/vaccines/covid-19/health-systemscommunication-toolkit.html
- More toolkits coming soon!
  - Long-term care facilities
  - Health departments
  - Community-based organizations
  - Employers of essential workers





To Protect Yourself, Your Coworkers, Your Patients, Your Family, and Your Community

- Building defenses against COVID-19 in this facility and in your community is a team effort. And **you** are a key part of that defense.
- Getting the COVID-19 vaccine adds one more layer of protection for you, your coworkers, patients, and family.



Here are ways you can **build people's confidence** in the new COVID-19 vaccines in your facility, your community, and at home:

- Get vaccinated and enroll in the v-safe text messaging program to help CDC monitor vaccine safety.
- Tell others why you are getting vaccinated and encourage them to get vaccinated.
- Learn how to have conversations about COVID-19 vaccine with coworkers, family, and friends.



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www.cdc.gov/coronavirus/vaccines







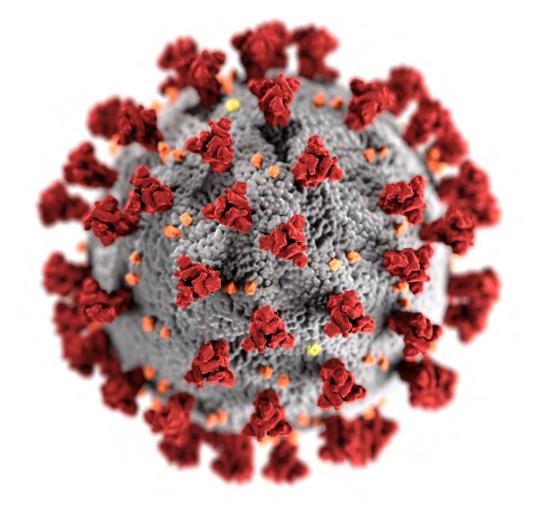


https://www.cdc.gov/vaccines/covid-19/index.html

## Thank you!

For more information, contact CDC 1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 www.cdc.gov



The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

