COVID-19 VACCINE: WILL BE AVAILABLE IN JANUARY

ANSWERS TO YOUR QUESTIONS

COVID-19 VACCINE HESITATION IS REAL

Specific LTC staff concerns

- "being first", "being a Guinea pig"
- Vaccine "being rushed"
- Safety (side effects)
- Not being represented in the vaccine trials

Other important factors

- How protective is the vaccine?
- How long does protection last?
- What is EUA (Emergency Use Authorization)?

WHY SHOULD I GET VACCINATED?

- Protect myself and my family
- Keep my residents safe
- Help stop spread in the community
- Set the example for others, including residents, families, co-workers, and the community-at-large

COMMON QUESTIONS WE WILL ADDRESS:

- How do we know the vaccine is effective and safe?
- Why should we trust the vaccine?
- Is there new technology being used and is that dangerous to me?
- What is an EUA and what does that mean for me?
- When and how long will I be protected?
- Will I still need to wear a mask?
- What are the expected side effects?
- What if I've already had COVID-19?
- Where should I look to get accurate information?

THE FIRST TWO COVID-19 VACCINES

Both are mRNA vaccines

- Pfizer (BNT162b2)
- Moderna (mRNA-1273)

They Do <u>NOT</u> contain COVID-19 virus

mRNA COVID-19 Vaccines

- mRNA technology is new in vaccine production but is already being used in cancer treatment. It has been studied for more than ten years.
- COVID-19 mRNA vaccines give instructions for our cells to make **a harmless piece** that looks like the "spike protein." The spike protein is found on the surface of the COVID-19 virus.
- Our bodies recognize that this protein should not be there, so they build antibodies that will remember how to fight the virus that causes COVID-19 if we are infected in the future.

Can mRNA vaccine give me COVID-19? NO
Can mRNA vaccine change my DNA? NO

WHO WAS INCLUDED IN THE COVID-19 VACCINE TRIALS?

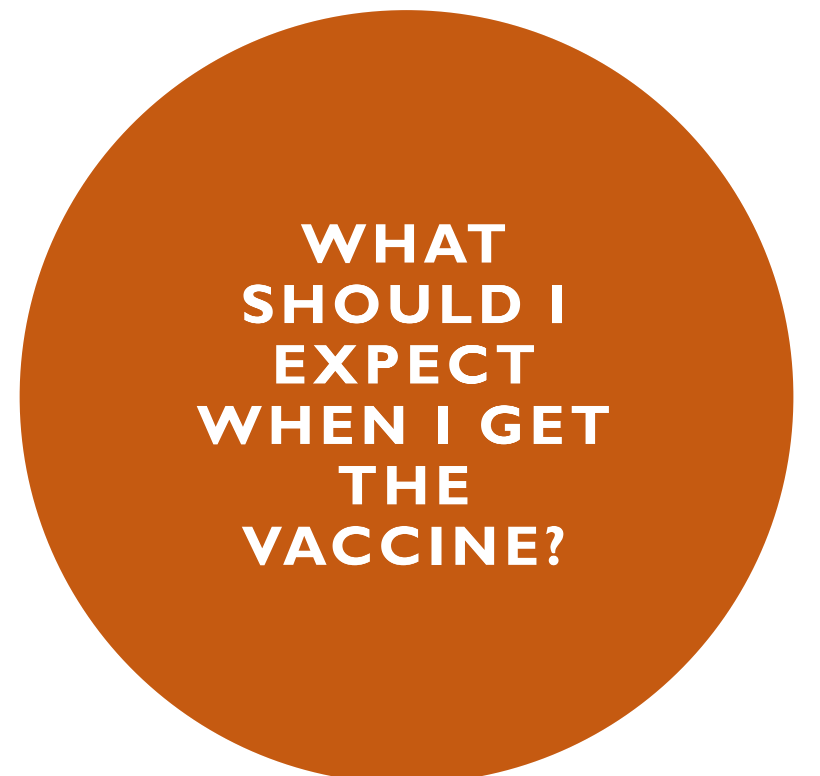
	Pfizer (BNT162b2)	Moderna (mRNA-1273)
Number of people enrolled	**Over 40,000**	**Over 25,000**
Race and ethnicity of participants	Total 30% racially diverse 10% black, 13% Hispanic	37% racially diverse 10% black, 20% Hispanic/Latino
Older adults	45% were 56-85 years	23% were >65 years

- **Notes**: Courtesy of Dr. Anuj Mehta, Data is accurate as of 11/18/2020. More information is constantly becoming available. Sub-group comparisons (e.g. comparisons about efficacy between races or age groups) may be less accurate due to smaller numbers. Sub-group numbers for the Pfizer vaccine are given for US participants with international percentages in parentheses.
- https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine
- https://www.pfizer.com/science/coronavirus/vaccine
- https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy
- https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf

HOW EFFECTIVE ARE THE COVID-19 VACCINES?

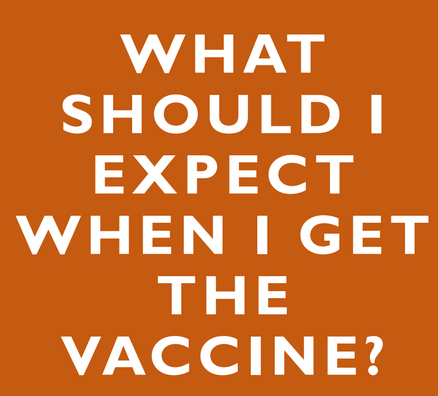
	Pfizer (BNT162b2)	**Moderna (mRNA-1273)**
Efficacy Overall	95% protection from having an infection	94.1% protection from having an infection

Similar efficacy with different race, ethnicity and age



THE VACCINE CANNOT GIVE YOU COVID-19!

- Up to 1 in 10 people will have short-term discomfort: fatigue, headache, muscle pain, chills, fever and pain at injection site after vaccination
- These reactions will last for 24-48 hours and are typically more pronounced after the second dose
- Side effects mean your body is doing its job and making antibodies (IT IS A GOOD THING)
- These side effects are normal, common and expected



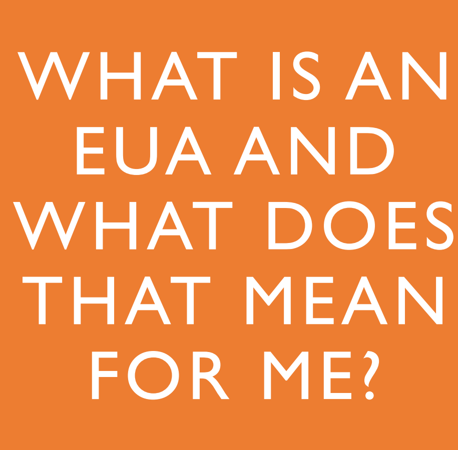
- **YOU MUST GET THE SECOND DOSE** because the vaccine will not protect you if only get one dose
- It is important to get the **SAME VACCINE** as the first dose

ARE THE COVID-19 VACCINES SAFE?

- Safety is the most important priority in vaccine approval
- Most side effects occur within 6 weeks of vaccination. To be more cautious, the FDA (Food and Drug Administration) requires 8 weeks of safety monitoring of the COVID-19 vaccines
- Monitoring for safety will continue as the vaccine is distributed to the public
- To assess safety FDA typically advises that a minimum of 3,000 participants are included in the trial. The current COVID-19 vaccine trials include 30,000 to 50,000 participants

WHY SHOULD WE TRUST THE COVID-19 VACCINE?

- The FDA is using the same strict standards that it has for decades
- No steps are "skipped"
- Two **independent advisory committees** are reviewing the results. Members and experts of these committees have no conflict of interest and are not associated with any vaccine manufacturers
  1. The Vaccine and Related Biological Products Advisory Committee (VRBPAC) that advises the FDA
  2. The Advisory Committee on Immunization Practices (ACIP) that advises the CDC



- **An Emergency Use Authorization (EUA)** for a vaccine is based on the need to use a vaccine quickly to save lives during a public health emergency
- EUA is a shorter process **but <u>no steps are skipped</u> in the safety evaluation process**
- The FDA will assess if the vaccine known and potential benefits outweigh the known and potential risks
- Two separate advisory boards (VRBPAC and ACIP) will also review the data and make recommendations
- **An EUA does NOT imply that the authorization was done too quickly or that the vaccine is not safe**

HOW WAS THE VACCINE DEVELOPED SO QUICKLY?

Major reasons we were able to get these vaccines developed more quickly than usual include :

- Global effort with the world's leading scientists focused on a single task
- Nearly unlimited resources (money, knowledge, manpower, technology)
- A large pool of diverse adult volunteer trial participants

WHEN AND HOW LONG WILL I BE PROTECTED BY THE COVID-19 VACCINE?

- Most of the vaccines are **2 doses**, 3-4 weeks apart
- Protection occurs **1-2 weeks after the second dose**
- We will most likely not know how long the vaccine will be protective once we receive it. We will know more as more time passes in the current research
- May need to have vaccine shots for COVID-19 on a regular basis (like the flu shot)

WILL I STILL NEED TO WEAR A MASK?

YES !

Similar to other vaccines, a large number of people in the community will need to get vaccinated before transmission drops enough to stop the use of masks

SPECIAL CIRCUMSTANCE

WHAT IF I ALREADY HAD COVID-19?

- It is safe to get the COVID-19 vaccine even if you have had COVID-19
- Even if you have had COVID-19, it is important to get vaccinated. It could give you longer or better protection against the disease
- Even if you have positive antibodies, you should get the COVID-19 vaccine

WHERE SHOULD I LOOK TO GET ACCURATE INFORMATION?

It is important to get information from reliable sources (CDC, AMDA, medical directors, providers) **Social media is full of misinformation and opinions based on that misinformation**

Here are some link to information:

- CDC: https://www.cdc.gov/vaccines/hcp/covid-conversations/answering-questions.html
- CDC: About COVID-19 vaccines: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines.html
- CDC: Provider Resources for COVID-19 Vaccine Conversations with Patients and Answering Patients' Questions: https://www.cdc.gov/vaccines/hcp/covid-conversations/

VACCINES ARE THE ONLY WAY TO CONTROL THE COVID-19 PANDEMIC

- Everyone has to do their part and get vaccinated to get back to a normal life

ECHRS QUESTIONS??

- **Will ECHRS employees and residents be required to get the vaccination?**
  - No one will be required to get the vaccination. Vaccination is strongly encouraged to protect ourselves and the residents. Please consider it!
- **How will employees/residents get the vaccination?**
  - ECHRS has partnered with Omnicare/CVS Pharmacy for administration of the vaccine. Omnicare is stating that the dates for the clinic will tentatively be January 4th and January 25th, 2021 and will come to ECHRS to assist with the administration. As soon as the dates are finalized, we will share with all staff. Information is changing frequently, so stay tuned.
- **Will employees have to sign anything?**
  - Yes. Omnicare has provided a required Consent Form. You will need to complete 2 consent forms, one for each dose (each time it is administered).
- **Will employees pay for the vaccination?**
  - No. The vaccination is being provided free of charge. Omnicare is asking for a photo copy of all employees health insurance card. Omnicare will bill employees insurance for administration. Bring your health insurance card to the clinic on testing day.

ECHRS QUESTIONS??

- **Which vaccine will I receive, Pfizer or Moderna?**
  - Omnicare initially indicated that the Pfizer vaccine would be used; however, we received notification today that it might be Moderna. We are posting fact sheets for both vaccines for your review.
- **What do I do if I want to receive the COVID-19 vaccination?**
  - If you would like to receive the COVID-19 vaccination, you must complete a consent form and submit it to HR. Forms will be located in the breakroom, on each unit in the Clinical Mentor office, with your supervisor, and HR.
  - You will be responsible for receiving your second dose, as you will not be vaccinated without receiving the second does.
  - CDC asks that you enroll in a smartphone-based tool called, V-Safe. You will receive health check-ins after you receive a COVID-19 vaccination through text messages from the CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 months). V-Safe will remind you to get your second COVID-19 vaccine dose, which is VERY important.
- **What do I do if I have any of the symptoms after receiving the vaccine?**
  - The CDC has published a document to provide guidance regarding what signs are likely to be from COVID-19 vaccination and would allow you to work: fever, fatigue, headache, chills, myalgia, arthralgia (joint pain).
  - HCP's who meet the following criteria may be considered to work without viral testing:
    - Feel well enough to work, and
    - Are afebrile (no fever within the last 24 hours of shift without fever reducing medication), and
    - Signs and symptoms are limited only to those outline above following vaccination.

ECHRS QUESTIONS??

- **Where do I go to receive the vaccine?**
  - You will come to the Great Room in the front of the long-term care building. We will announce when the clinic is set up and ready for use. See attached map.

Clear Form

COVID Vaccine Intake Consent Form

CVS pharmacy

Clinic Information

Clinic ID | Clinic Name | Telephone | Store Number

Address | City | State | Zip

Patient Information

Last Name | First Name | Date of Birth | Gender

Address | City | State | Zip | SSN* (or driver's license)

Primary Care Provider (PCP) Name | PCP Phone Number | PCP Fax Number

PCP Address | City | State | Zip

SSN and state of residence, or state identification/driver's license is needed to verify patient eligibility. If a SSN and state of residence, or state identification/driver's license is not submitted, you will need to attest that you attempted to capture this information before submitting a claim and the patient did not have this information at the time of service, or that you did not have direct contact with the patient and thus did not have an opportunity to attempt to capture this information. Claims submitted without a SSN and state of residence, or state identification/driver's license may take longer to verify for patient eligibility.

If you are part of a Senior Facility clinic, are you a resident ○ or an employee/staff ○ ?

If someone else manages health decisions on behalf of the resident, please provide the following:

Caregiver or Financially Responsible Party Name | Relationship | Phone Number

Insurance Information: Fill in all that apply

Prescription Insurance:

○ Patient is primary card holder (check box if yes)

Pharmacy Insurance Provider | ID # | GRP ID | BIN | PCN

Medicare Fields: (Note: COVID Vaccine will be billed at Part B through your Medicare provider)

○ Yes ○ No

Is the patient age 65 or older or is the patient Medicare Eligible? | Medicare Part A/B ID Number (MBI)

Medical Insurance:

Medical Insurance Provider | ID # | GRP ID | ○ Yes ○ No Is the patient the Primary Cardholder?

If you are uninsured, please read the below statement and check the box for acknowledgement:

○ I do not have medical insurance, Medicare, Medicaid or any commercial or government-funded health benefit plan I acknowledge that I must answer this question truthfully in order to have the cost of my test covered by the U.S. Department of Health and Human Services (HHS) Uninsured Program. If I have active insurance that I fail to provide, I may be charged in full for the vaccine.

COVID-19 Screening Questions

	YES	NO	DON'T KNOW
1. In the past two weeks, have you tested positive for COVID-19 or are you currently being monitored for COVID-19?	○	○	○
2. In the past two weeks, have you had contact with anyone who tested positive for COVID-19?	○	○	○
3. Do you currently or have you in the past 14 days, had a fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, nausea, vomiting, or diarrhea?	○	○	○

To be filled out by the Immunizer: Patient Temperature: | Date:

If patient answers yes to any of these questions or patient's bodily temperature is 100°F or greater, please inform them that they should not receive the vaccine at this time, instruct them to contact their primary care provider for next steps and that the facility coordinator will be notified.

Immunization Screening Questions

	YES	NO	DON'T KNOW
1. Are you sick today? (For example: a cold, fever or acute illness)	○	○	○
2. Do you have allergies or reactions to any foods, medications, vaccines or latex? (For example: eggs, gelatin, neomycin, thimerosal, etc.)	○	○	○
3. Have you ever had a serious reaction after receiving a vaccination? Do you have a history of fainting, particularly with vaccines? Has any physician or other healthcare professional ever cautioned or warned you about receiving certain vaccines or receiving vaccines outside of a medical setting?	○	○	○

Last Name	First Name	Date of Birth

Immunization Screening Questions (continued)

		YES	NO	DON'T KNOW
4.	Have you had a seizure or a brain or other nervous system problem or Guillain Barre?	○	○	○
5.	Do you take anticoagulation medication? For example: warfarin, Coumadin or other blood thinner.	○	○	○
6.	Do you have a long-term health problem such as heart disease, lung disease, liver disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia or other blood disorder?	○	○	○
7.	Do you have cancer, leukemia, HIV/AIDS, rheumatoid arthritis, ankylosing spondylitis, Crohn's disease or any other immune system problem?	○	○	○
8.	Do you have a weakened immune system or in past 3 months, taken medications that weaken it such as cortisone, prednisone, other steroids, anticancer drugs, or radiation treatments?	○	○	○
9.	During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	○	○	○
10.	For women, are you pregnant or is there a chance you could become pregnant during the next month?	○	○	○
11.	Have you received any vaccinations or TB skin test in the past 4 weeks?	○	○	○

CONSENT FOR SERVICES: I have been provided with the Vaccine Information Sheet(s) corresponding to the vaccine(s) that I am receiving. I have read the information provided about the vaccine I am to receive. I have had the chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of vaccination and I voluntarily assume full responsibility for any reactions that may result. I understand that I should remain in the vaccine administration area for 15 minutes after the vaccination to be monitored for any potential adverse reactions. I understand if I experience side effects that I should do the following: call pharmacy, contact doctor, call 911.I request that the vaccine be given to me or to the person named above for whom I am authorized to make this request. State of Georgia only: I verify a pharmacist asked for my health history and whether I have had a physical exam within the past year. Health care providers did not identify condition(s) that would mean I should not receive vaccine(s).

AUTHORIZATION TO REQUEST PAYMENT: I do hereby authorize CVS Pharmacy® ("CVS®") to release information and request payment. I certify that the information given by me in applying for payment under Medicare or Medicaid is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

DISCLOSURE OF RECORDS: I understand that CVS® may be required to or may voluntarily disclose my health information to the physician responsible for this protocol of specific health information of people vaccinated at CVS (if applicable), my Primary Care Physician (if I have one), my insurance plan, health systems and hospitals, and/or state or federal registries, for purposes of treatment, payment or other health care operations (such as administration or quality assurance). I also understand that CVS will use and disclose my health information as set forth in the CVS Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy). State of California only: I agree to have CAIR share my immunization data with Health Care Providers, agencies or schools. Vaccine Clinics: If I am receiving a vaccine through a vaccine clinic, I understand that my name, vaccine appointment date and time will be provided to the clinic coordinator.

X ______________________________ ____________

Signature of patient to receive vaccine or person authorized to make the request — Date

Vaccine Administration Information for Immunizer/Pharmacist use only

Administration Date	Vaccine	VIS Date	Manufacturer
			○ L ○ R

Lot #	Exp. Date	Route	Site	Volume (mL)

Administering Immunizer Name & Title	Administering Immunizer Signature

To be filled out by immunizer, as required for state immunization registry reporting. Only for states listed.

MS: Check all fields for patients 18 years of age and younger

OK: Check Race and Ethnicity for all patients. Select Next of Kin for patients 18 years of age and younger.

Race: ○ 1 - American Indian or Alaska Native ○ 2 - Asian ○ 3 - Native Hawaiian/Other Pacific Islander ○ 4 - Black or African American ○ 5 - White ○ 6 - Other Race

Ethnicity: ○ 1 - Hispanic ○ 2 - Not Hispanic or Latino ○ 3 - Unknown

Next of Kin (18 or younger)

Name	Phone Number	Relationship

Address

State of NJ only

Prescriber Name	Prescriber Address

For CA, MA, MT, NJ, NM, NY, TX (For CA, this indicator means the registry will not share with Universities, Schools or other agencies)

Registry Sharing Indicator: ○ Yes ○ No

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VACCINE CLINIC MAP