

NEW YORK NURSING HOMES AND THE COVID-19 VACCINE

GET THE FACTS

December 16th | 1:00PM – 3:00PM

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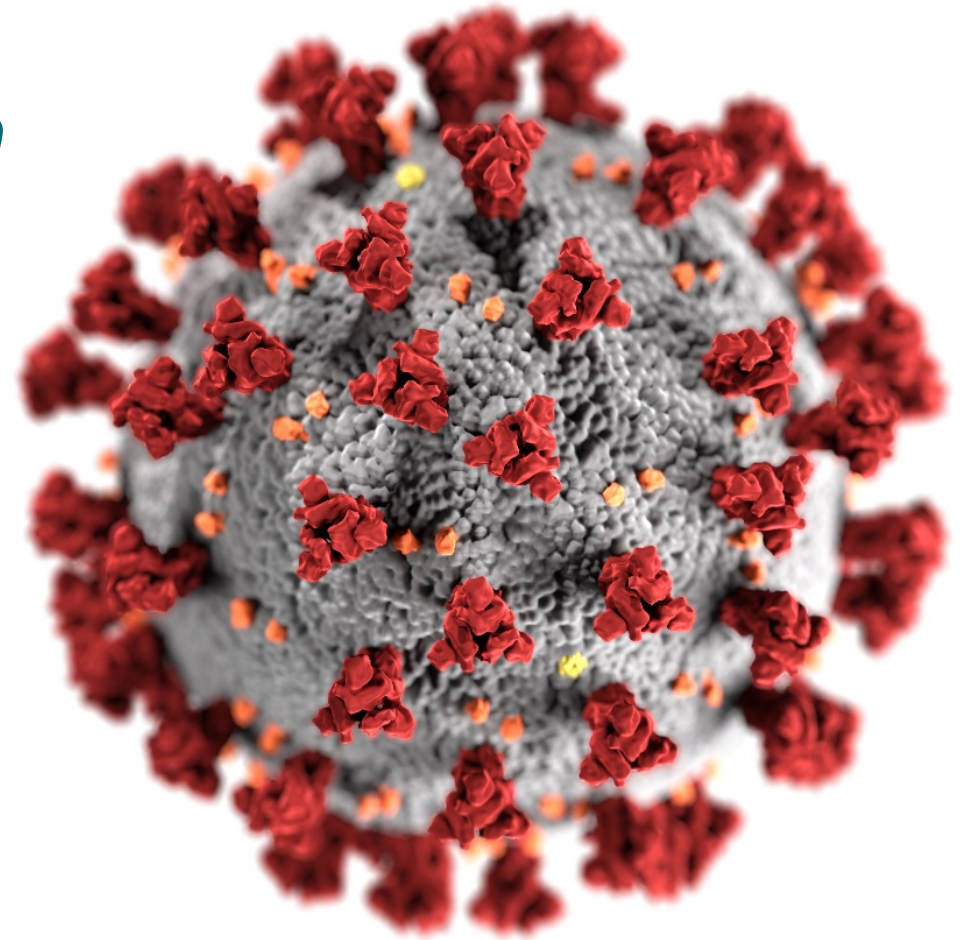


Dr. Nimalie Stone, MD, MS

**Team Lead, Long-term Care Response
Centers for Disease Control (CDC)
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COVID-19 Vaccine Information for Long-term Care

Nimalie D. Stone, MD, MS
Long-term Care Team Lead
Prevention and Response Branch
Dec. 2020



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





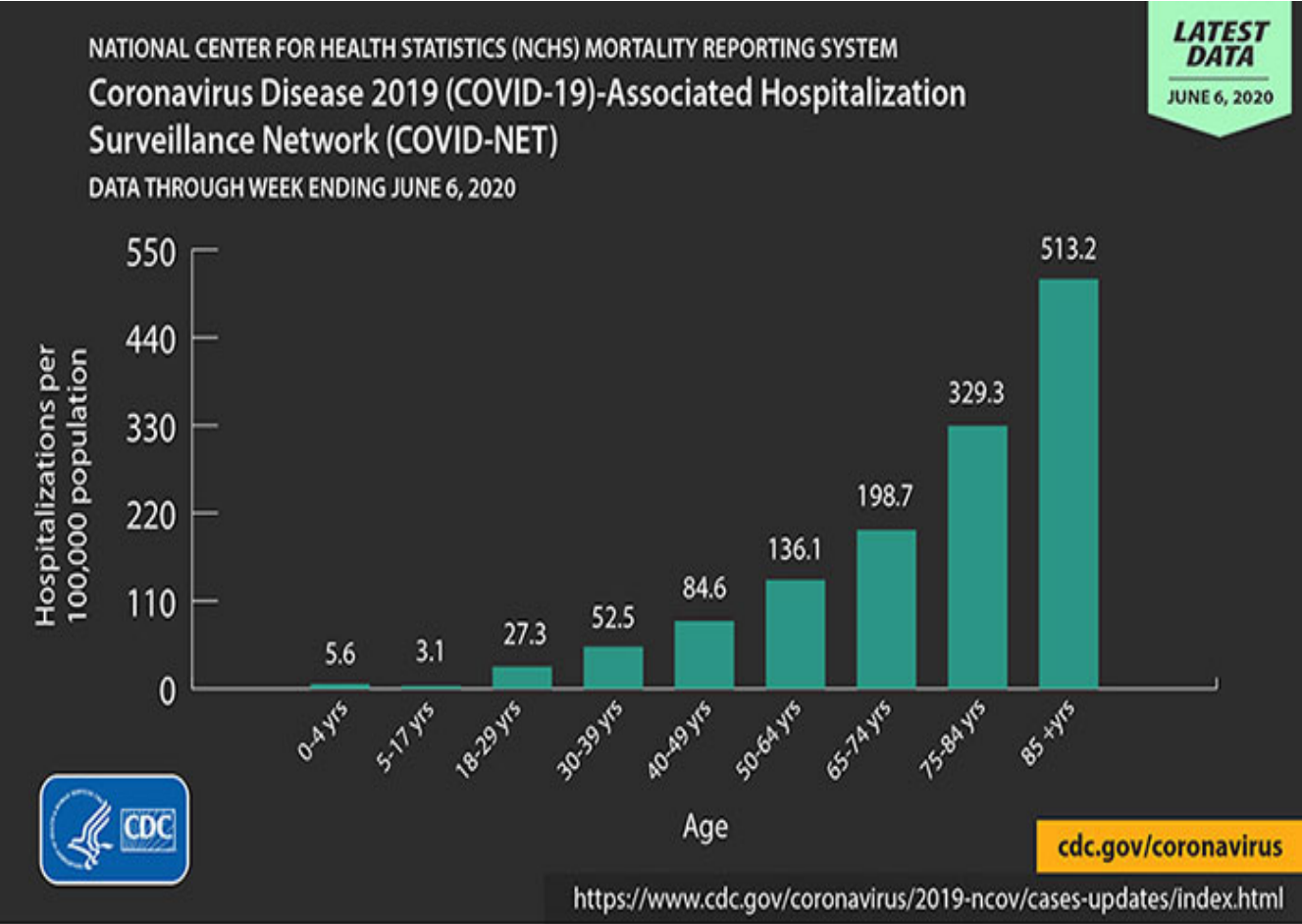
Thanks to the essential caregiving teams supporting residents and families!

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



CDC Has Information For Older Adults at Higher Risk

8 out of **10** COVID-19 deaths reported in the U.S. have been in adults 65 years old and older.

Visit [CDC.gov/coronavirus](https://www.cdc.gov/coronavirus) for steps to reduce your risk of getting sick.

[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

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

Resident and Staff Cases and Deaths

TOTAL RESIDENT COVID-19 CONFIRMED CASES

377,510

TOTAL RESIDENT COVID-19 DEATHS

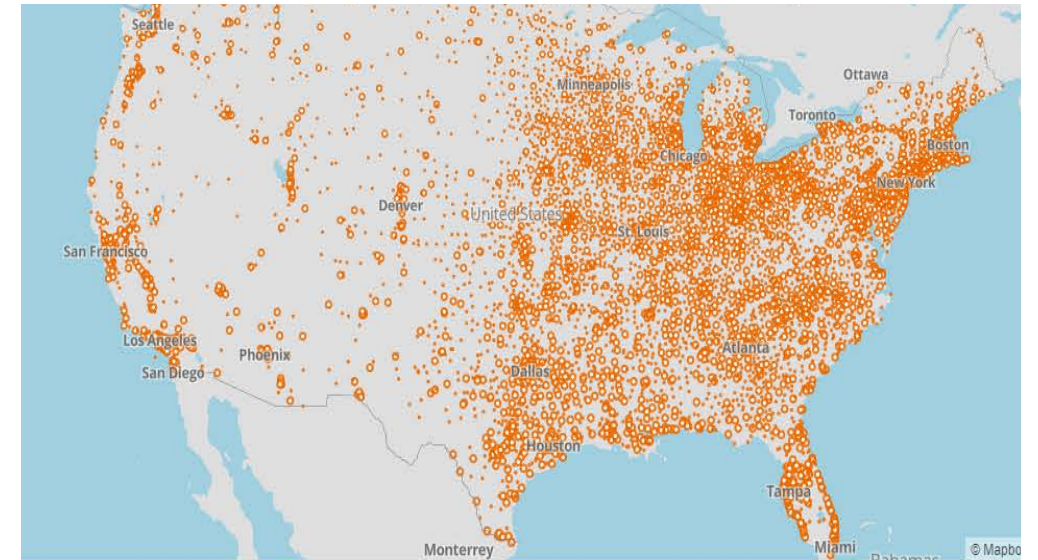
76,542

TOTAL STAFF COVID-19 CONFIRMED CASES

322,690

TOTAL STAFF COVID-19 DEATHS

1,162



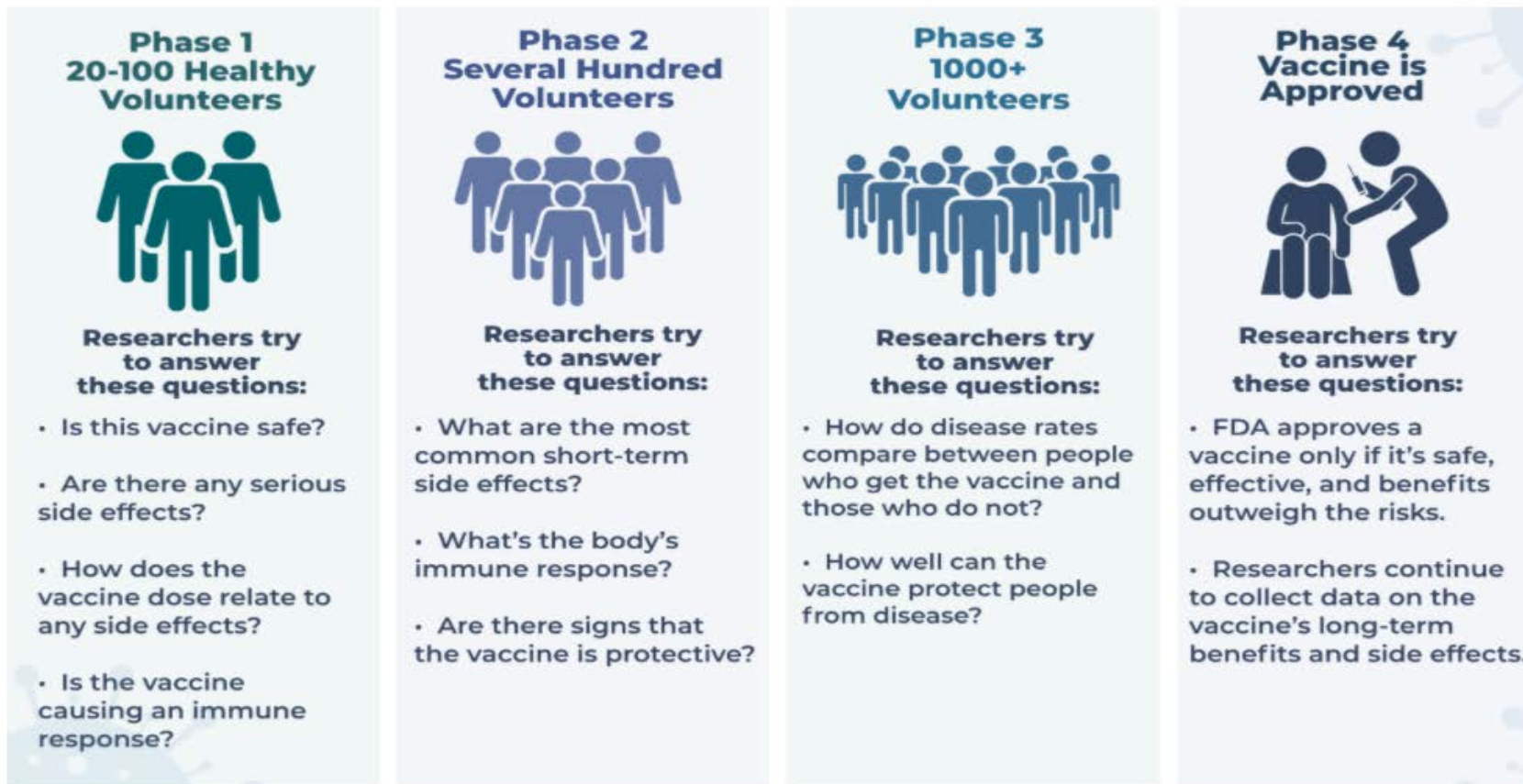
<https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg>

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



- 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: <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>

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).



Sources: College of Physicians of Philadelphia. What is an mRNA vaccine? <https://historyofvaccines.blog/2020/07/29/what-is-an-mrna-vaccine/>
JAMA. COVID-19 and mRNA Vaccines—First Large Test for a New Approach. <https://jamanetwork.com/journals/jama/fullarticle/2770485>

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.



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.

*For more information, visit the COVID-19 Prevention Network:

www.coronaviruspreventionnetwork.org/about-covpn

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



VAERS

Vaccine Adverse Event Reporting System

co-managed by
CDC and FDA

vaers.hhs.gov

The screenshot shows the VAERS website with a navigation bar and a main content area. The navigation bar includes links for 'About VAERS', 'Report an Adverse Event', 'VAERS Data', 'Resources', and 'Submit Follow-Up Information'. The main content area features a large image of a family looking at a laptop, with the text 'What is VAERS?' below it. To the left of the image, there are instructions in English and Spanish for reporting an adverse event, including a note about seeking immediate assistance for medical emergencies.

The graphic features three icons: a bandage, a smartphone, and a thumbs up. The text reads: 'Get vaccinated. Get your smartphone. Get started with v-safe.' Below this, it explains 'What is v-safe?' as a smartphone-based tool for health check-ins. It also includes sections for 'How can I participate?' and 'How long do v-safe check-ins last?'. A purple box on the right contains the text: '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.' The v-safe logo is prominently displayed.

[Vaers.hhs.gov](http://vaers.hhs.gov)

[V-safe After Vaccination Health Checker | CDC](#)

Key facts about COVID-19 vaccination



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*

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines/vaccine-myths.html>



*<https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

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

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search COVID-19
[Advanced Search](#) 

Coronavirus Disease 2019 (COVID-19)



Your Health ▾ Community, Work & School ▾ Healthcare Workers & Labs ▾ Health Depts ▾ Cases & Data ▾ More ▾

Your Health

Things You Need to Know

Symptoms +





Testing +


Vaccines -

- 8 Things to Know
- About COVID-19 Vaccines +
- Facts about COVID-19 Vaccines
- How CDC is Making Vaccine Recommendations
- Ensuring the Safety of Vaccines
- Ensuring COVID-19 Vaccines Work

YOUR HEALTH

Vaccines

Updated Nov. 20, 2020 Languages ▾ Print    



Safety Is a Top Priority
The U.S. vaccine safety system ensures that all vaccines are as safe as possible. [Learn more.](#)

<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/2019-ncov/vaccines/expect.html>
- Toolkit For Medical Centers, Clinics and Clinicians
 - <https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>
- *More toolkits coming soon!*
 - *Long-term care facilities*
 - *Health departments*
 - *Community-based organizations*
 - *Employers of essential workers*



Why Get Vaccinated?

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.



Building Vaccine Confidence in Health Systems and Clinics

Tips for Immunization Coordinators

Developed by:
CDC COVID-19 Response
Vaccine Task Force
December 2020



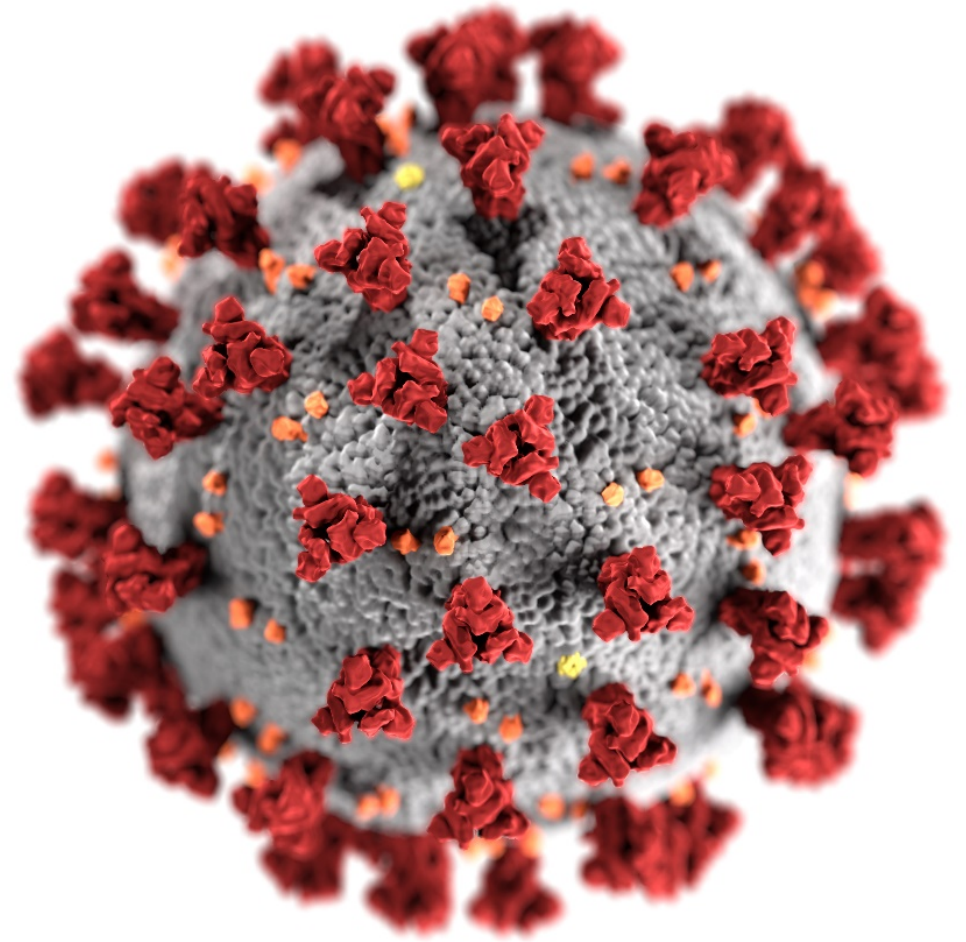
www.cdc.gov/coronavirus/vaccines



<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.





Loretta A. Santilli, MPH

Director

Office of Public Health Practice,
New York State Department of Health



**Department
of Health**

COVID-19 Vaccine

What Nursing Home Workers Need to Know

Presentation to 1199SEIU – December 16, 2020

Loretta A. Santilli, MPH

Director, Office of Public Health Practice
New York State Department of Health

Welcome & Overview

The New York State COVID-19 Vaccination Program was developed to ensure the distribution and administration of a safe and effective COVID-19 vaccine to all residents of New York State who wish to receive it. The program was designed to provide flexibility based on the many unknowns at the time.

Today's objective: provide a high level overview of the vaccination plan as we prepare to vaccinate approximate 90,000 nursing home residents and more than 131,000 nursing home employees.

CDC COVID-19 Prioritization

ACIP Phase 1a Prioritization Recommendations

- The CDC's Advisory Committee on Immunization Practices (ACIP) voted on December 1, 2020 to recommend that when a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) healthcare personnel* and 2) residents of long-term care facilities**

*The ACIP defined healthcare personnel as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials.

**The ACIP defined long-term care facility residents as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

Overview of CDC Pharmacy Partnership Program

Pharmacy Partnership for LTCF Program

- CDC contracted with CVS and Walgreens (and a few other pharmacies) to administer COVID-19 vaccine in long-term care facilities (LTCFs) nationwide
- Involves end-to-end management of COVID-19 vaccination process for LTCFs
- On-site vaccinations for all residents and staff not already vaccinated
- Fulfillment of reporting requirements

Federal LTCF Program in NYS

- Nearly 100% of skilled nursing facilities/nursing homes enrolled in the Federal program!
- On Friday, December 4, 2020 NYS officially requested activation of the Federal program as of the first available date – December 21, 2020.
- NYS authorized the transfer of the necessary doses of Pfizer vaccine to the pharmacies to implement the program.

Key Points for Staff

- Vaccine has been shown to be 95% effective in preventing SARS-CoV-2 infection in clinical trial participants.
 - There was no difference based on age, gender, race, and ethnicity.
- Participation is voluntary
- Two doses of the same vaccine are required to build immunity
- You must plan to return to the same place where you received your first dose for your second dose.

Safety and Side Effects

- To date, NO serious safety concerns observed
- YOU CANNOT GET COVID FROM THE VACCINE!
- Most “adverse events” were mild to moderate and resolved in 1-2 days
 - Pain, Fever, Chills, Fatigue, Headache
- This means your immune system is working!

Vaccination at Nursing Homes

The Pharmacy Partner will make 3 visits to the facility:

- Visit 1: Administer 1st dose to group 1
- Visit 2: Administer 2nd dose to group 1
Administer 1st dose to group 2
- Visit 3: Administer 2nd dose to group 2
- Group 1 = all residents present, clinically eligible and consented PLUS approximately 1/3 of staff
- Group 2 = new residents, returning residents that were not on site visit 1, newly eligible/consented that were not as of visit 1

Who gets vaccinated first?

- Considerations:
 - Any staff (not only clinicians) who work in an area where transmission is higher (ex. unit where aerosolizing procedures are performed)
 - Paid and unpaid persons who have the potential for direct or indirect exposure to patients or infectious materials
 - Exposure to the public occurs in an uncontrolled way (reception areas, cafeterias etc.)
 - Staff who routinely touch shared surfaces or common items
 - Do not vaccinate more than one-third of the staff on a particular ward, unit or floor to mitigate potential staff absenteeism issues

What about the other 2/3 of staff?

- Approximately 2/3 of staff will not be vaccinated at the time the residents are.
- It is our intent that ALL staff who wish to be vaccinated will be provided the opportunity to do so within 30 days.
- Options for these staff vaccinations may include:
 - Enrolling the NH as a COVID-19 vaccine provider with NYS so they may receive and administer their own supply of vaccine.
 - Staff may be vaccinated at a regional health care hub partner site or another regional vaccination network provider
 - NYSDOH may arrange with the local health department to vaccinate on-site at the facility
 - NYSDOH may arrange with a pharmacy provider (enrolled in the NYS COVID-19 Vaccination Program) to vaccinate on-site at the facility
 - NYSDOH may also open commercial pharmacy sites as potential administration sites for staff.

Timeline of COVID-19 Vaccine Related Events

- **Friday, November 20, 2020:** Pfizer files EUA package to the FDA
- **Monday, November 30, 2020:** Moderna files EUA package to the FDA.
- **Thursday, December 10, 2020:** Public meeting of the VRBPAC regarding Pfizer's EUA submission – VRBPAC concluded that based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 vaccine outweigh its risks for use in individuals 16 years of age and older.
- **Friday, December 11, 2020:** FDA Emergency use Authorization (EUA) granted
- **Saturday, December 12, 2020:** Advisory Committee on Immunization Practices (ACIP) clinical use recommendations on Pfizer's vaccine released
- **Monday, December 14, 2020:** First deliveries of COVID-19 vaccine rec'd by NYS hospitals
- **Thursday, December 17, 2020:** Public meeting of the VRBPAC regarding Moderna's EUA submission
- **Friday, December 18 – Monday, December 22, 2020:** Window for FDA EUA authorization and ACIP recommendations on Moderna's vaccine
- **Monday, December 21, 2020** Anticipated first NH based vaccination clinic

Questions?

IF YOU HAVE A QUESTION FOR A PANELIST

use "Q&A" or "Raise Hand"



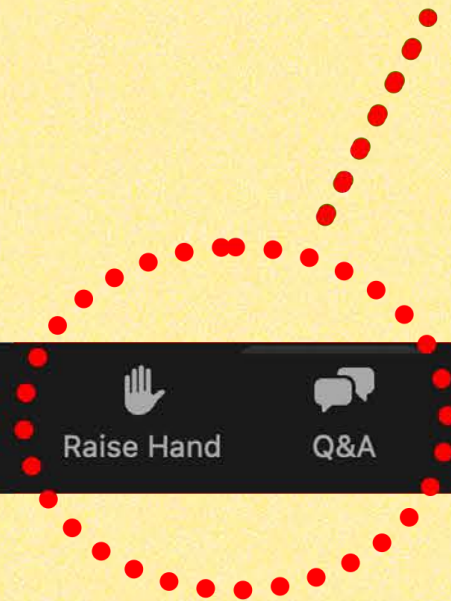
Chat



Raise Hand



Q&A





FREE ONLINE TRAININGS FOR HOME CARE & NURSING HOME WORKERS

Stipends* (pre-paid debit cards) available for the following courses



To get started, visit LTVWIO.ORG on your computer, phone or tablet
Technical Support: (800) 516 - 9693

*\$25 stipend (pre-paid debit card) per course. Courses must be completed on your own time by January 31st, 2021. Payment of stipends subject to availability of funding and verification of eligibility.



Dr. Martin Grossman, MD

Chief Medical Officer
Citadel Care Centers

THE END OF COVID-19: VACCINATION AND THE LAST MILE

**MARTIN A. GROSSMAN, MD
CHIEF MEDICAL OFFICER
CITADEL CARE CENTERS**

VACCINE HESITATION

- **MOST IMPORTANT FACTORS FOR ACCEPTANCE (KREPS ET AL JAMA 2020;3(10):E2025594)**
 - **EFFICACY**
 - **DURATION OF PROTECTION**
 - **LOWER INCIDENCE OF MAJOR SIDE EFFECTS**
- **OTHER FACTORS**
 - **EMERGENCY USE AUTHORIZATION**
 - **DEVELOPMENT OUTSIDE THE USA**
- **SPECIFIC CONCERNS OF LTC STAFF**
 - **BEING FIRST**
 - **SAFETY**
 - **NOT BEING REPRESENTED IN VACCINE TRIALS**

EMERGENCY USE AUTHORIZATION

- **HERCULEAN EFFORT IN DEVELOPMENT BY GOVERNMENT AND ACADEMIA**
- **FDA USED THE SAME STANDARDS THAT IT HAS USED FOR DECADES**
- **NO STEPS WERE SKIPPED IN THE APPROVAL PROCESS**
- **30,000-50,000 INDIVIDUALS WERE STUDIED**
- **95% EFFECTIVE IN PREVENTING COVID INFECTION**
- **SAFETY PROFILE COMPARABLE TO OTHER VACCINES ON THE MARKET**
- **VOLUNTARY**

TRUST

NURSES CONSISTENTLY ON TOP 25 YEARS

84% VERY HIGH/HIGH

99% VERY HIGH/HIGH AND AVERAGE

MEDICAL DOCTORS

67% VERY HIGH/HIGH

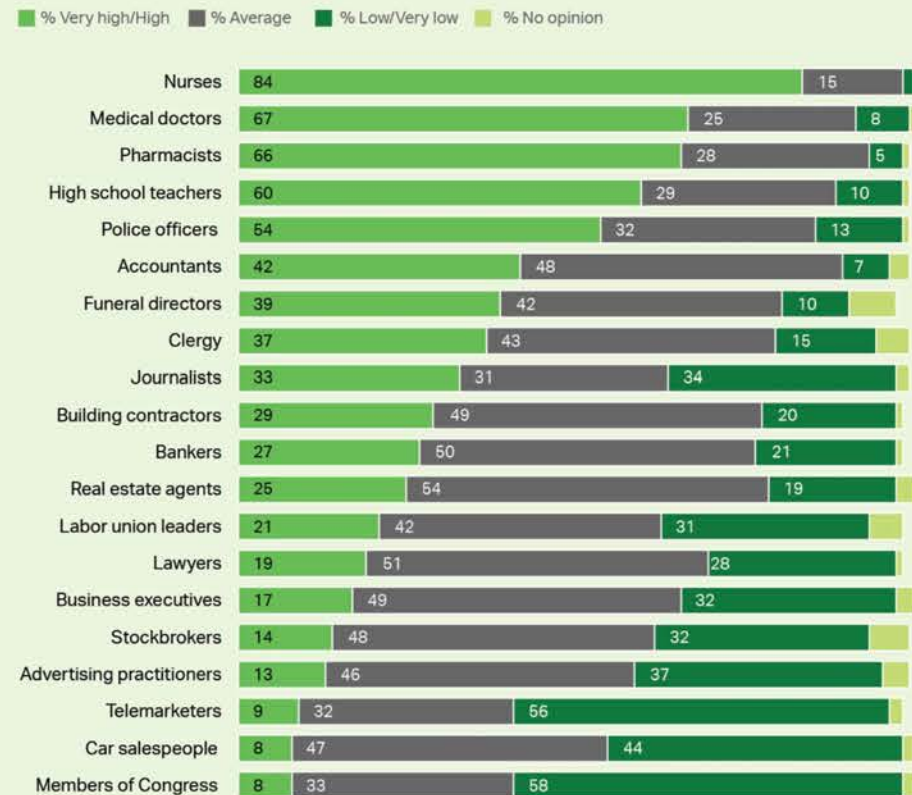
89% VERY HIGH/HIGH AND AVERAGE

PHARMACISTS

66% VERY HIGH/HIGH

96% VERY HIGH/HIGH AND AVERAGE

Please tell me how you would rate the honesty and ethical standards of people in these different fields -- very high, high, average, low or very low?



GALLUP, DEC. 3-12, 2018

EMPOWERMENT

LEADERSHIP BUY IN AND PROMOTION

CHIEF NURSING OFFICER/DIRECTOR OF NURSING

CHIEF MEDICAL OFFICER/MEDICAL DIRECTOR

GOVERNING BODY/ADMINISTRATION

FRONT LINE STAFF AS ADVOCATES FOR VACCINATION

CNA STAFF

RN AND LPN STAFF

PRIMARY CARE PHYSICIANS

PHARMACISTS

PREPARATION FOR VACCINATION

- DESIGNATE VACCINE COORDINATOR(S) AND VERIFY CONTACT INFORMATION IN THE FACILITY AND AFTER HOURS
- SEND LETTER TO PATIENTS, SURROGATES AND STAFF WITH REGARD TO VACCINE
 - SAMPLE LETTER FROM AMDA CAN BE PROVIDED
 - SHOULD BE SIGNED BY CMO/MEDICAL DIRECTOR AND CNO/DIRECTOR OF NURSING
- IDENTIFY VACCINE CANDIDATES
 - AVOID IN SEVERE ALLERGIES AND ANAPHYLAXIS
 - AVOID IN CURRENT COVID INFECTION
 - SHOULD BE ADMINISTERED REGARDLESS OF RESOLVED COVID WITH OR WITHOUT ANTIBODIES
- DETERMINE DECISION MAKING CAPACITY OF THE PATIENTS

PREPARATION FOR VACCINATION

- DEVELOP AND IMPLEMENT POLICY AND PROCEDURE FOR:
 - PATIENTS
 - STAFF
- MANDATORY EDUCATION OF MEDICAL AND NURSING PERSONNEL (WEBEX AND RECORDED)
 - CONSENT FORMS WITH SIGNATURE
 - INDICATIONS AND EXCLUSIONS FOR VACCINATION
 - NECESSITY FOR REPEAT DOSE IN 21 DAYS (PFIZER) OR 28 DAYS (MODERNA)
 - POST VACCINE MONITORING PARAMETERS ESTABLISHED IN POLICY
 - ADVERSE REACTIONS
 - REPORTING AND DOCUMENTATION
 - TO MEDICAL PRACTITIONERS
 - TO NURSING ADMINISTRATION

PREPARATION FOR VACCINATION

- DEVELOP STAFF CONTINGENCY FOR POST VACCINATION SICK TIME
 - STAGGER STAFF VACCINATION ESPECIALLY BY DISCIPLINE
 - NO MORE THAN 1/3 OF STAFF SHOULD BE VACCINATED IN ONE DAY
- ANTICIPATE HOW MANY VACCINES WILL BE NEEDED FOR PATIENTS AND STAFF

VACCINE DAY

- **POST VACCINE MONITORING SPACE: FOR 15-30 MINUTES**
- **SET UP AN EMERGENCY BOX IN THE CLINIC AREA**
- **FOR BEDBOUND/ROOM BOUND PATIENTS**
 - **WILL PHARMACY VACCINATORS GO FROM ROOM TO ROOM?**
 - **STAFF TO ACCOMPANY VACCINATOR DURING VACCINATION**
 - **WHO WILL MONITOR THE PATIENTS IN THE ROOM POST VACCINATION?**

VACCINE DAY

- VACCINE CANDIDATES SHOULD BE ASKED ABOUT THE FOLLOWING HISTORY
 - ANY ALLERGIES
 - PRESENCE OF FEVER
 - PRESENCE OF BLEEDING DISORDER
 - TAKING BLOOD THINNING MEDICATIONS
 - CONDITION CAUSING IMMUNOCOMPROMISE
 - MEDICATIONS CAUSING IMMUNOCOMPROMISE
 - ARE PREGNANT OT PLANNING PREGNANCY
 - BREASTFEEDING
 - HAVE RECEIVED ANOTHER COVID VACCINE
 - THE VACCINES ARE NOT INTERCHANGEABLE
 - MUST BE 16 YEARS OF AGE OR OLDER

VACCINE-SIDE EFFECTS

Pfizer-BioNTech COVID-19 Vaccine
VRBPAC Briefing Document

Table 19. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1-month After Dose 2, Phase 2/3 Safety Population*, 16 Years of Age and Older

System Organ Class Preferred Term	BNT162b2 N=18801 n (%)	Placebo N=18785 n (%)	Total N=37586 n (%)
General disorders and administration site conditions	3521 (18.7)	737 (3.9)	4258 (11.3)
Injection site pain	2125 (11.3)	286 (1.5)	2411 (6.4)
Fatigue	1029 (5.5)	260 (1.4)	1289 (3.4)
Pyrexia	1146 (6.1)	61 (0.3)	1207 (3.2)
Chills	999 (5.3)	87 (0.5)	1086 (2.9)
Pain	455 (2.4)	36 (0.2)	491 (1.3)
Musculoskeletal and connective tissue disorders	1387 (7.4)	401 (2.1)	1788 (4.8)
Myalgia	909 (4.8)	126 (0.7)	1035 (2.8)
Arthralgia	212 (1.1)	82 (0.4)	294 (0.8)
Nervous system disorders	1158 (6.2)	460 (2.4)	1618 (4.3)
Headache	973 (5.2)	304 (1.6)	1277 (3.4)
Gastrointestinal disorders	565 (3.0)	368 (2.0)	933 (2.5)
Diarrhoea	194 (1.0)	149 (0.8)	343 (0.9)
Nausea	216 (1.1)	63 (0.3)	279 (0.7)

Source: FDA analysis.

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

%; n/N. n = number of participants reporting at least 1 occurrence of the specified event.

of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.

* Participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

Pfizer-BioNTech COVID-19 Vaccine
VRBPAC Briefing Document

Table 21. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1 Month After Dose 2, Phase 2/3 Safety Population*, 65 Years and Older

System Organ Class Preferred Term	BNT162b2 (N=4058) n (%)	Placebo (N=4043) n (%)	Total (N=8101) n (%)
General disorders and administration site conditions	577 (14.2)	118 (2.9)	695 (8.6)
Injection site pain	361 (8.9)	39 (1.0)	400 (4.9)
Fatigue	175 (4.3)	44 (1.1)	219 (2.7)
Chills	143 (3.5)	19 (0.5)	162 (2.0)
Pyrexia	148 (3.6)	10 (0.2)	158 (2.0)
Pain	60 (1.5)	7 (0.2)	67 (0.8)
Musculoskeletal and connective tissue disorders	231 (5.7)	83 (2.1)	314 (3.9)
Myalgia	125 (3.1)	23 (0.6)	148 (1.8)
Arthralgia	42 (1.0)	21 (0.5)	63 (0.8)
Pain in extremity	33 (0.8)	10 (0.2)	43 (0.5)
Nervous system disorders	179 (4.4)	87 (2.2)	266 (3.3)
Headache	127 (3.1)	45 (1.1)	172 (2.1)
Gastrointestinal disorders	127 (3.1)	72 (1.8)	199 (2.5)
Diarrhea	49 (1.2)	26 (0.6)	75 (0.9)
Nausea	40 (1.0)	13 (0.3)	53 (0.7)

Source: FDA analysis.

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

%; n/N. n = number of participants reporting at least 1 occurrence of the specified event.

of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.

* Participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

VACCINATION DAY

- SEVERE SIDE EFFECTS ARE RARE; THEY MAY INCLUDE
 - DIFFICULTY BREATHING
 - SWELLING OF FACE AND THROAT
 - FAST HEARTBEAT
 - WHOLE BODY RASH
 - DIZZINESS AND WEAKNESS

POST VACCINATION

- **YOU CANNOT GET COVID-19 FROM THE VACCINE**
- **THE VACCINE DOES NOT CHANGE A PERSONS DNA**

POST VACCINATION-SIDE EFFECTS

- **REPORTING OF SIDE EFFECTS**
 - **FDA/CDC VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)**
 - **(800) 822-7967**
 - **[HTTPS://VAERS.HHS.GOV/REPORTEVENT.HTML](https://vaers.hhs.gov/reportevent.html)**
- **MONITORING**
 - **PRUDENT TO HAVE DAILY RN NOTES FOR 3 DAYS POST VACCINE**
 - **LOW THRESHOLD TO REACH OUT TO PRACTITIONERS CARING FOR PATIENTS ON CHANGES OF CONDITION**
- **DOCUMENT PATIENT SIDE EFFECTS IN MEDICAL RECORD**
- **STAFF SHOULD CONSULT WITH THEIR PERSONAL PHYSICIANS AND REPORT TO THEIR SUPERVISOR ANY SIDE EFFECTS**

POST VACCINATION-COVID TESTS

- **VIRAL TESTS**

- **PRIOR RECEIPT OF PFIZER VACCINE WILL NOT AFFECT THE RESULTS OF COVID PCR OR ANTIGEN TESTS**

- **ANTIBODY TESTS**

- **CURRENTLY AVAILABLE ANTIBODY TESTS FOR SARS-COV2 ASSESS IGM AND/OR IGG SPIKE OR NUCLEOCAPSIDE PROTEINS**
- **PRIZER COVID-19 VACCINE CONTAINS MRNA THAT ENCODES THE SPIKE PROTEIN; THIS A POSITIVE TEST FOR SPIKE PROTEINS IGM/IGG COULD INDICATE PRIOR INFECTION OR VACCINATION**
- **TO EVALUATE FOR EVIDENCE OF PRIOR INFECTION IN AN INDIVIDUAL WITH A HISTORY OF PFIZER COVID-19 VACCINE, A TEST SPECIFICALLY EVALUATING IGM/IGG TO THE NUCLEOCAPSID PROTEIN SHOULD BE USED**

POST VACCINATION

- **IMMUNITY IS ONLY ACHIEVED AFTER THE SECOND VACCINATION**
- **FACE MASKS AND SOCIAL DISTANCING WILL STILL BE REQUIRED FOR THE FORESEEABLE FUTURE**
- **AT THIS TIME IT IS UNKNOWN HOW LONG IMMUNITY IS CONFERRED FROM THE VACCINE**



Dr. Van H. Dunn, MD

Chief Medical Officer
1199SEIU Benefit and Pension Fund

Questions?

IF YOU HAVE A QUESTION FOR A PANELIST

use "Q&A" or "Raise Hand"



Chat



Raise Hand



Q&A

