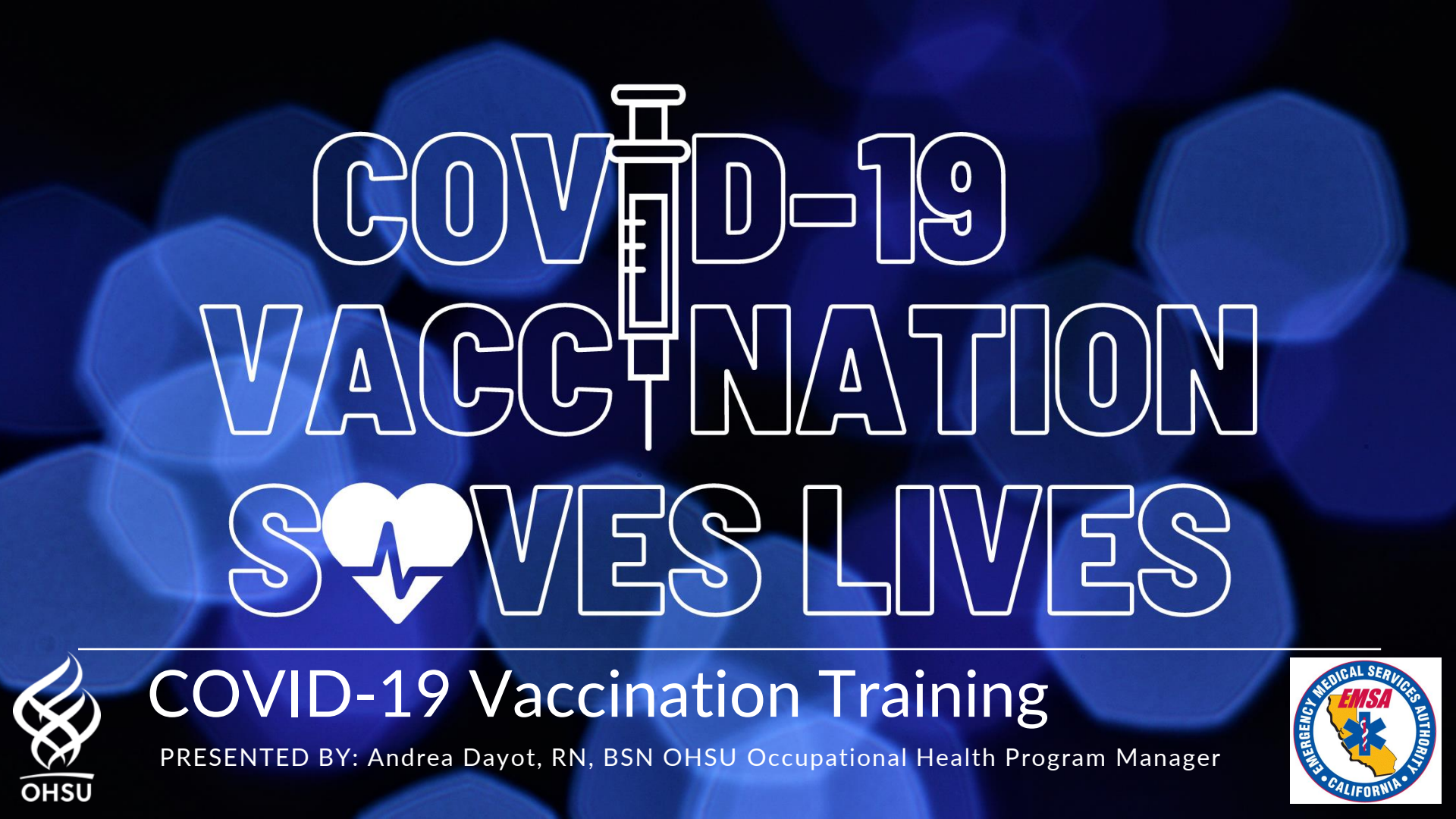


COVID-19 Vaccination Training

PRESENTED BY: Andrea Dayot, RN, BSN OHSU Occupational Health Program Manager

OHSU

EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA
CALIFORNIA

COVID-19 Vaccination Program Objectives

Most crucial mass immunization program in recent history.

- Ensure safety and effectiveness of vaccines
- Reduce incidence of serious illnesses and deaths
- Minimize disruption to society and economy
- Maintain healthcare capacity
- Ensure equity in vaccine allocation and distribution

Training and Education is Critical

ALL HCP should receive comprehensive, competency-based training BEFORE administering vaccines.

- Prevent errors, injuries, adverse events
- Preserve and maximize a precious, life-saving resource
- Prevent compromising vaccine efficacy
- Prevent loss of confidence in the vaccine, in our care and practice

Become a COVID-19 Immunizer

As a COVID-19 Immunizer, you will:

- Contribute to an important public health cause
- Make a global impact
- Be part of the solution
- Save lives

Timelines

In December 2020, the Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to 2 COVID-19 vaccines in the US.

- Dec 11th: Pfizer/BioNTech's COVID-19 vaccine
  - Dec 13th: Use in persons ≥16 years of age
- Dec 18th: Moderna's COVID-19 vaccine indicated for persons ≥18 years of age

As of December 28th, 3 vaccines are in Phase 3 clinical trials

- AstraZeneca's, Janssen's, Novavax's COVID-19 vaccine

Emergency Use Authorization (EUA)

Allows access to critical medical products during a public health emergency. An EUA is different from licensure/approval.

Criteria for an EUA to be issued:

- Used for a serious or life-threatening disease or condition
- May be effective based on scientific evidence
- Known and potential benefits outweigh risks
- There is no adequate FDA-approved alternative available

EUA Considerations for Vaccine Providers

Scope of authorized use will be specified in an EUA Fact Sheet for HCP.

Use Requirements:

- Provide the EUA Fact Sheet for Recipients (hard copy or electronic)
  Report vaccine administration data to CDC
- Report administration errors and adverse events to VAERS

Pfizer's Fact Sheets:

EUA Fact Sheet for Vaccine Providers

EUA Fact Sheet for Recipients and Caregivers

Moderna's Fact Sheets:

EUA Fact Sheet for Vaccine Providers

EUA Fact Sheet for Recipients and Caregiver

Benefits of Getting a COVID-19 Vaccine

- Help decrease your risk of getting COVID-19
- Prevent serious illness if you do end up with COVID-19
- May also protect people around you
- Develop immunity without risks of infection
- An important tool to help stop the pandemic

Stopping a pandemic requires all the tools we have available. Masking, physical distancing, hand hygiene must continue until we reach community immunity

Vaccine Types

Viral vector (e.g. AstraZeneca and Johnson & Johnson)

Uses an inactivated viral vector to induce production of immunogenic SARS-CoV2 spike protein

Protein-based (e.g. Novavax, Sanofi and GlaxoSmithKline)

Virus protein packaged into a nanoparticle is delivered into cells with an adjuvant to enhance immune response

Messenger Ribonucleic Acid (mRNA) (e.g. Pfizer/BioNtech and Moderna)

Encodes virus protein. When inserted into cells, induces production of harmless but immunogenic SARS CoV-2 spike protein

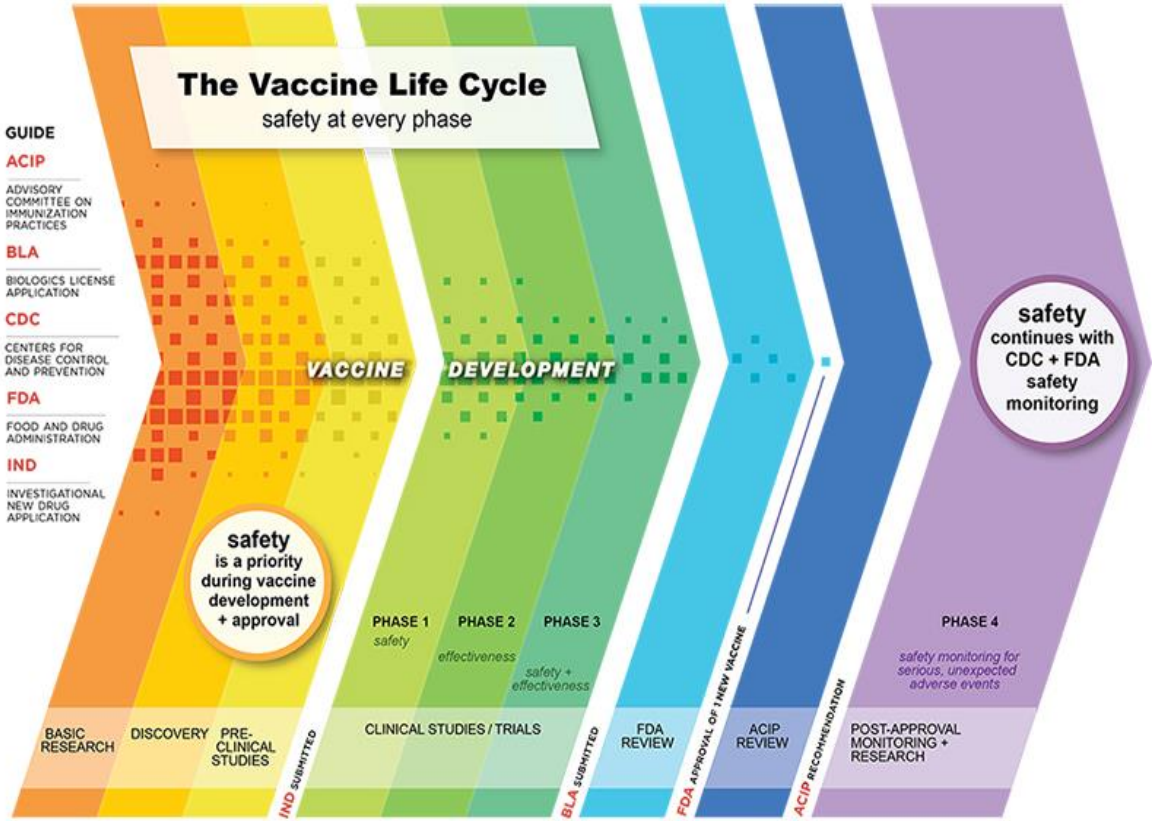
- Adjuvant: Substance used to enhance immune responses
- Vector: Weakened virus used as a carrier to deliver immune-stimulating material

mRNA Vaccines

Contains instructions for building a harmless coronavirus protein known as “spike” which then gets released into the body and triggers an immune response without causing infection.

- New but not unknown
- Studied for more than a decade and rigorously tested for safety
- Does not use inactivated or live virus
- Does not affect a person’s DNA
- Cell breaks down and gets rid of the mRNA soon after it is finished using the instructions

Vaccine Safety



Vaccine Efficacy and Immunity

FDA requires vaccines to be >50% effective

- Pfizer:
  - 52% effective after 1st dose
  - 95% effective after 2nd dose
  - Equally effective regardless of age, race, ethnicity, weight or sex
- Moderna:
  - 94.5% effective after 2nd dose; 100% against serious disease
- Generally, it takes a week or two for immunity to develop post vaccination
- Since we do not yet know how long immunity after infection lasts, immunity following vaccination will also have to be determined

Vaccine Efficacy and Immunity

Phase 3 Clinical Trials

Typical size: Hundreds to thousands of volunteers

COVID Vaccine Trials: Many of the COVID-19 vaccine trials are much larger than a typical phase 3 clinical trial

Pfizer had 44, 000 participants

- 162 cases of symptomatic disease in placebo; 8 in vaccine group
- 10 cases of severe disease; 9 in placebo, 1 in vaccine

Moderna had 30, 000 participants

- 90 cases of symptomatic disease in placebo; 5 in vaccine group
- 11 cases of severe COVID all in placebo group

Possible Side Effects

- Anticipated, self-limiting, benign
- Sign that the immune system is being primed

Systemic symptoms more common after **second** dose

Data from published Phase I/II trials

Moderna[1] Adults 18–55 years of age

100µg	Post-dose 1			Post-dose 2		
N=15	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Fever	—	—	—	5 (33%)	1 (7%)	—
Headache	4 (27%)	—	—	5 (33%)	4 (27%)	—
Myalgia	1 (7%)	—	—	2 (13%)	6 (40%)	—

Pfizer[2]

30µg	Post-dose 1			Post-dose 2		
N=12	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Fever	1 (8%)	1 (8%)	—	—	2 (17%)	—
Headache	3 (25%)	1 (8%)	2 (17%)	6 (50%)	2 (17%)	—
Myalgia	1 (8%)	1 (8%)	1 (8%)	4 (33%)	3 (25%)	—

[1]Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.
[2]Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.

Managing Side Effects

Usually last 24-48 hrs and resolve on their own.

- For local reactions or fever, may take OTC meds
- Rest and hydrate. No strenuous activity/exercise for a few hours
- Reduce soreness by moving arm throughout the day
- Apply cold packs to site 15-20 mins, initially for 24 hours
- Plan for possible absenteeism due to side effects

*Routine prophylaxis is not recommended at this time, due to lack of information on impact of use on vaccine-induced antibody responses

Vaccine Information

COVID-19 Vaccine	Pfizer	Moderna
Age indication	16 yrs and older	18 yrs and older
Dose	0.3 ml	0.5 ml
Route & Site	IM, deltoid muscle	IM, deltoid muscle
Schedule	2 dose (0, 21 days) *4-day grace period (17-21 days)	2 dose (0, 28 days) *4-day grace period (24-28 days)
Presentation	Multi-dose vial 5-6 doses of 0.3 ml per vial	Multi-dose vial 10 doses of 0.5 ml per vial
Diluent	1.8 ml of 0.9 % sodium chloride (normal saline)	None

*COVID-19 vaccines will NOT be interchangeable
*Second doses should be administered as close to the recommended interval as possible
*Do not use the grace period to schedule appointments for the second dose

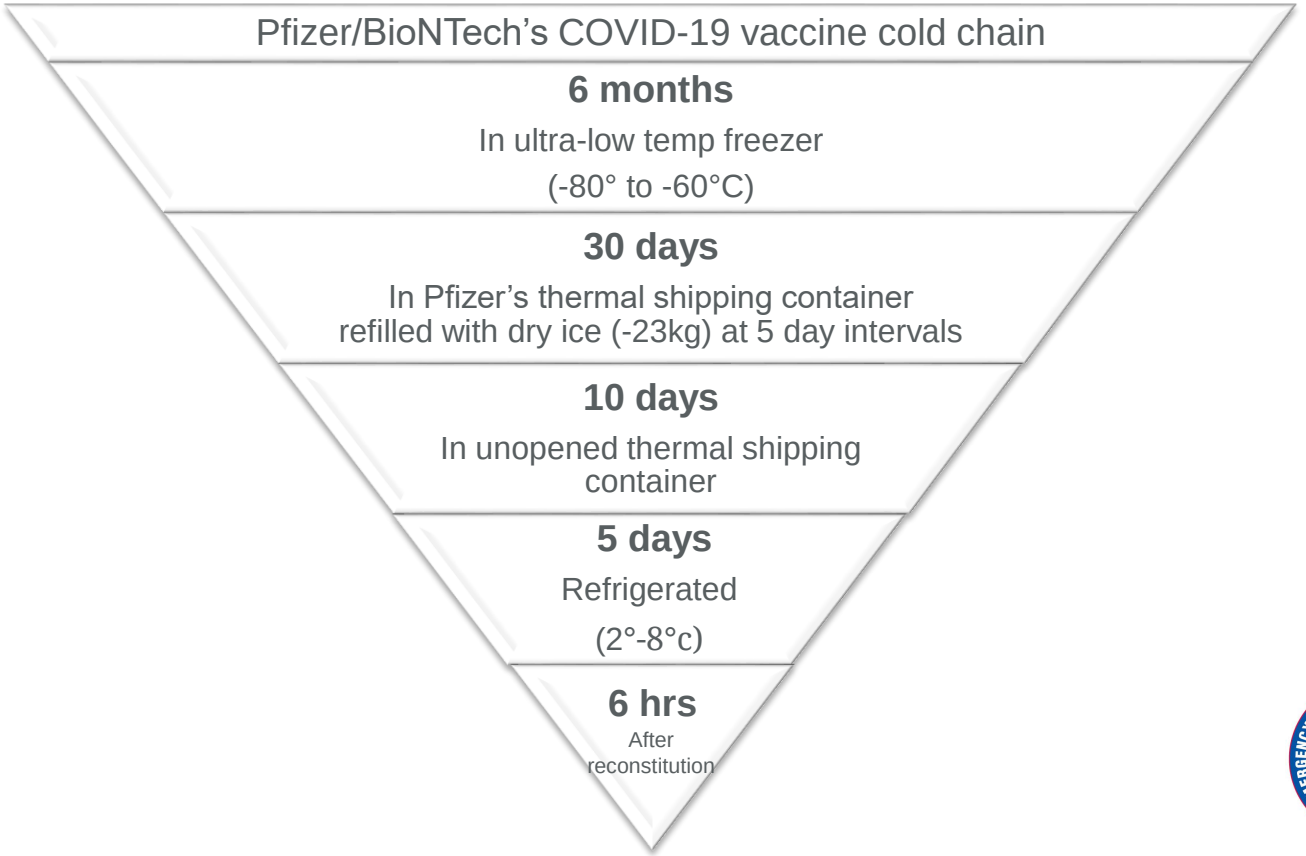
Vaccine Ingredients

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

* Neither vaccine contain eggs, gelatin, latex, or preservatives

Storage and Handling

"To protect our vaccine recipients we must protect our vaccine supply"



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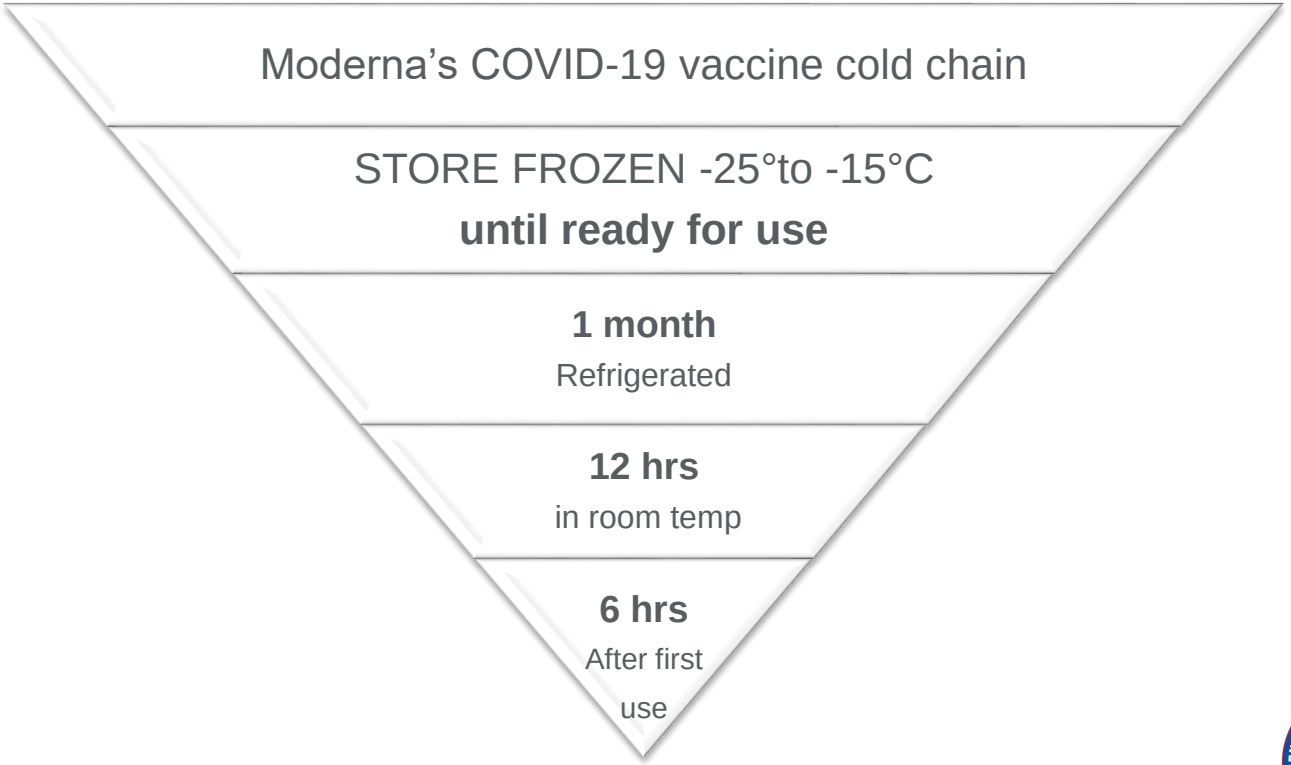


Storage and Handling

"To protect our vaccine recipients we must protect our vaccine supply"

Pfizer/BioNTech

Thaw before use:

- Thaw for 30 minutes at room temp before dilution
  - Once thawed at room temp, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C–8°C
- Can't be re-frozen

Moderna

Thaw before use:

- Thaw in refrigerated conditions between 2°C to 8°C for 2 hours
- Let vial stand at room temperature for 15 minutes before administering
- Alternatively, thaw at room temperature between 20°C to 25°C for 1 hour
- Can't be re-frozen

Vaccine Preparation

It is critical to prepare the vaccine correctly to:

- Maintain the integrity and efficacy of the vaccine
- Protect against contamination
- Limit risk of adverse events
- Prevent waste of precious resource: If we err on preparation we waste 5-10 doses of vaccine

Vaccine Reconstitution

Process of mixing lyophilized (freeze-dried) vaccine with a diluent

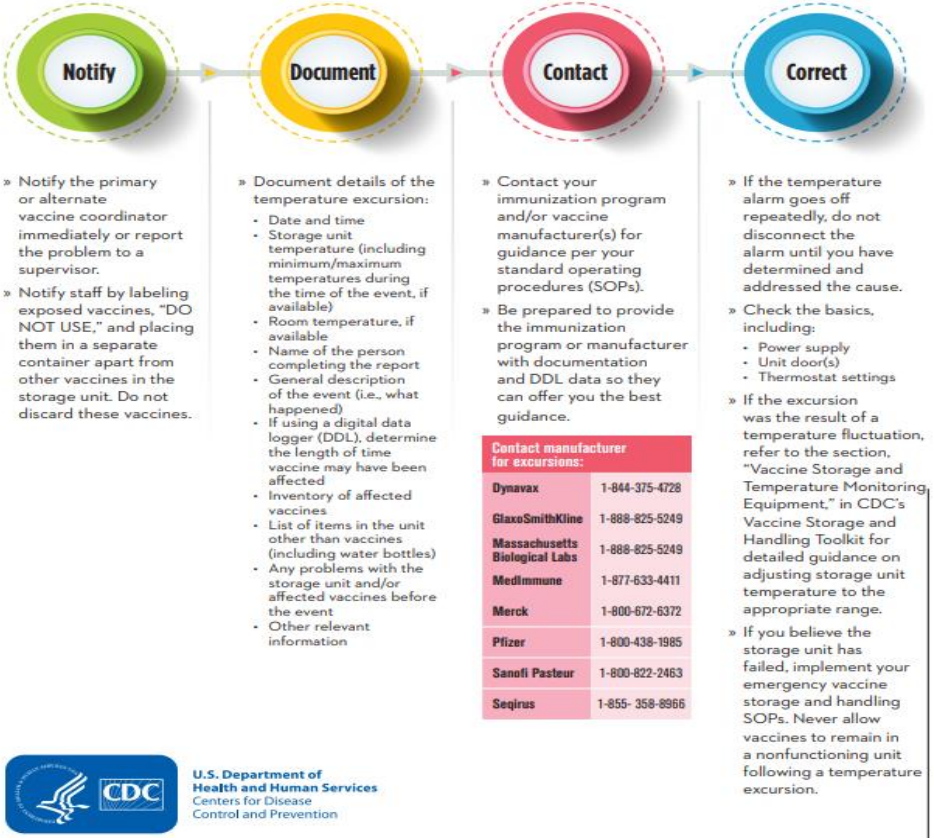
Basic steps:

1. Remove protective caps and wipe each stopper with an alcohol swab
2. Insert needle of syringe into diluent vial and withdraw 1.8 ml of diluent
3. Inject diluent into lyophilized vaccine vial
4. Invert the vial 10 times gently to mix (**do not shake**)
5. Check the appearance of the reconstituted vaccine **(should be off-white with no visible particulates)** for any discoloration/particulate matter or obvious lack of resuspension*

* If appearance of vaccine is not acceptable, do not use vial, note lot number and report immediately

*Pfizer: https://www.cvdvaccine-us.com/images/pdf/How-To-Prepare-and-Administer-the-Vac Poster.pdf

Managing Temperature Excursions



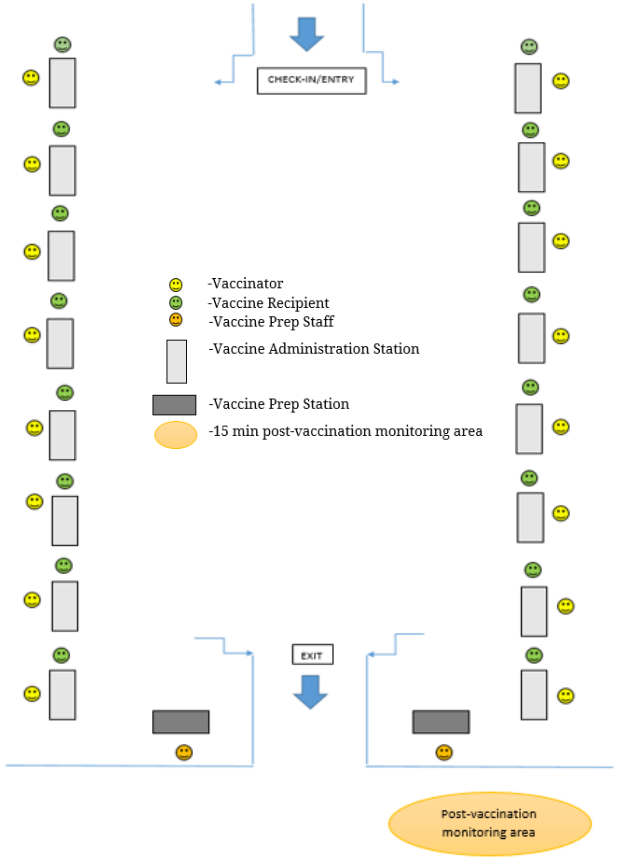
https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temperature-excursion-508.pdf

Contraindications and Precautions to mRNA COVID-19 Vaccine

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15-minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, injectable therapies, or polysorbate, such as: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies **ACTIONS** • 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) • 15-minute observation period: All other persons	**ALLERGIES** • History of any immediate allergic reaction‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines† or polysorbate, as these are contraindicated) **ACTIONS:** • Risk assessment • Consider deferral of vaccination and/or referral to allergist-immunologist • 30-minute observation period if vaccinated	**ALLERGIES** History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components • Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components† (including polyethylene glycol)# • Immediate allergic reaction of any severity to polysorbate^# **ACTIONS** • Do not vaccinate# • Consider referral to allergist-immunologist

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Mass Immunization Clinic Flow



COVID-19 Precautions during an Immunization Clinic:

- COVID symptom screening
- One way entry and exit
- Physical distancing and signage
- One vaccinator and vaccine recipient per 6 ft. table
- PPE will be required for vaccinator and vaccine recipients
- Hand hygiene and infection control supplies will be available
- Vaccines will be prepared using aseptic technique
- Cleaning and Disinfection

Mass Immunization Clinic Flow

5 Key Components:

1. Check-in (1-2 mins)
2. Screening/Assessment (1-2 mins)
3. Vaccination and Documentation (2-5 mins)
4. Monitoring (15 or 30 mins)
5. Check-out (<1 min)

*Vaccine reconstitution and prep is a separate process.

Ensures integrity of vaccine and limits errors that result in wasted doses

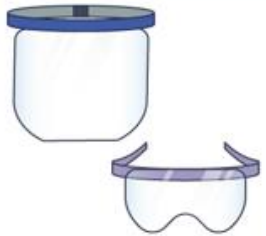
Personal Protective Equipment

National Center for Immunization and Respiratory Diseases

Vaccine Administration: COVID-19 Personal Protective Equipment

Face mask

- **Recommended:** All healthcare providers (N95 masks not recommended)



Eye protection

- **Recommended:** Areas of moderate/substantial community transmission
- **Optional:** Areas of minimal/ no community transmission unless otherwise indicated as a part of standard precautions

Gloves

- **Recommended:** Intranasal or oral vaccines
- **Optional:** Intramuscular or subcutaneous vaccines

08/23/20

www.cdc.gov/vaccines/pandemic-guidance/index.html

Vaccine Administration Equipment and Supplies

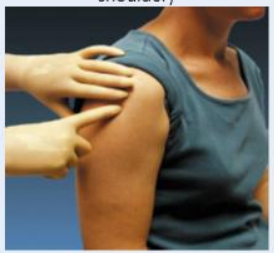
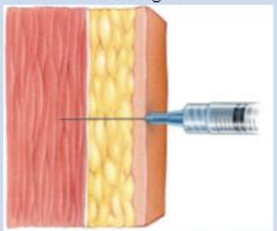
Ancillary supply kits will also be delivered separately and include:

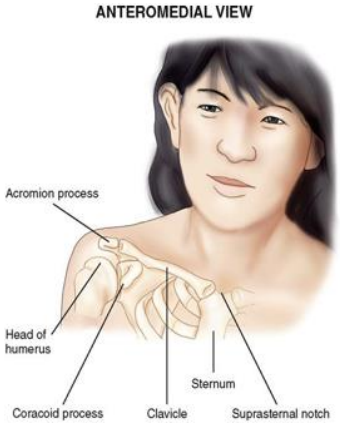
- Sterile diluent: 0.9% sodium chloride (normal saline, preservative-free)
- Mixing needles and syringes
- Administration needles and syringes
  - 25-gauge, 1" (if vaccination indicated for pediatric population)
  - 22–25-gauge, 1–1.5" (adult)
- Sterile alcohol preparation pads
- PPE (surgical masks and face shields for staff)
- COVID-19 vaccination record cards
- Needle gauge and length chart detailing the appropriate length/gauge for injections based on route, age (children), gender, and weight (adults)

Each ancillary kit includes enough supplies for 1 tray of vaccine.

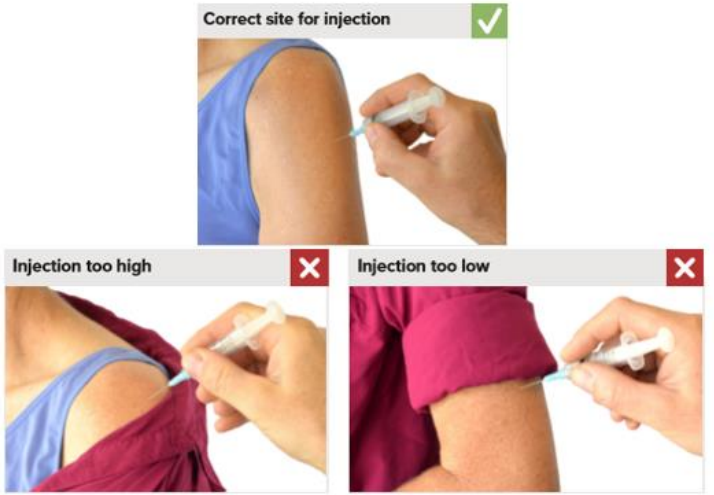
Not included: Puncture-resistant, biohazard containers, gloves, and bandages

Intramuscular Injection Technique

Route	Intramuscular (IM)
Site	Deltoid muscle (upper arm)
Landmark	2-3 fingerbreadths directly below acromion process (bony tip of shoulder) 
Angle of insertion	90° angle  Hold skin taut. Do not bunch!
Needle size	22 to 25 gauge and 1–1½" inch long



Needle Size Recommendations		
MALE	FEMALE	NEEDLE SIZE
Adults ≥ age 18 yrs.		
Less than 130 Lbs	Less than 130 Lbs	5/8- 1 inch
130- 150 Lbs	130-150 Lbs	1 inch
153-260 Lbs	153- 200 Lbs	1- 1.5 inches
260 + Lbs	200 + Lbs	1.5 inches



Giving a vaccine too high= can damage the bursa or other structures

Giving a vaccine too low= can damage the radial nerve where it winds around the humurus

Always measure!

*Consequences of Inadvertently giving an IM vaccine in the subcutaneous tissue vs the muscle:

- Impairs the immune response to vaccine
- Increases risk of adverse effects

Intramuscular Injection Technique

Prevent Shoulder Injury Related to Vaccine Administration (SIRVA)

- A debilitating injury to the musculoskeletal structures of the shoulder (bursa, joint space)
- Caused by incorrect injection technique (too high)
- Pain w/n 48 hrs unrelieved by OTC meds, limited range of motion can persist months-years
- 30% of cases will need surgery
- SIRVA is 100% preventable!

Vaccine Administration Procedure (Pfizer or Moderna)

Patient Education and Screening:
o Greet patient, introduce self, and verify correct patient using at least two identifiers (name, DOB/age); Pfizer is indicated for those ≥16 yrs; Moderna is indicated for those ≥18 yrs
o Explain what vaccine will be given (Pfizer or Moderna COVID-19 vaccine) and which type of injection will be done (IM)
o Verify patient received an Emergency Use Authorization (EUA) Fact Sheet (Pfizer or Moderna) electronically and had time to read it. If not, provide the patient a physical copy
o Screen for contraindications and precautions to vaccination (refer to Triage of persons presenting for mRNA COVID-19 vaccination below)
o Educate patient on what to expect after vaccination (possible side effects, interventions, and when to report side effects)
o Educate on need to come back for 2nd dose of vaccine (same product as 1st dose, 21 days later for Pfizer; 28 days later for Moderna)
Vaccine Preparation:
o Perform hand hygiene
o Verify the final dosing volume on prepared syringe (0.3 ml for Pfizer; 0.5 ml for Moderna), liquid should be white to off-white, there should be no particulates or discoloration observed
Vaccine Administration:
o Gather appropriate supplies for administration (vaccine prepared in a syringe, band aid, cotton ball, alcohol pad)
o Position patient and self ergonomically. Have patient relax arm on their lap. Position yourself parallel to the patients arm to align your back
o Have patient expose their entire preferred arm by rolling sleeve up to shoulder
o Locate acromion process (bony tip of shoulder)
o Measure 2-3 fingerbreadths directly below the acromion process
o Clean site with an alcohol wipe using circular motion from center to a 2"-3"circle. Allow to dry
o Stabilize patient's arm with the non-dominant hand (Hold skin taut, do not bunch), hold the needle an inch from the skin, and insert needle all the way in quickly at a 90 degree angle
o Inject vaccine using steady pressure, making sure full dose is administered, before withdrawing the needle quickly at the same angle
o Immediately activate safety device and dispose syringe in a sharps container
o Have patient apply gentle pressure to the injection site for several seconds with a dry cotton ball, if needed
o Apply band aid to injection site
o Perform hand hygiene
Documentation:
o Document immunization details on patient's record, provide a copy of immunization and 2nd dose reminder

Documentation and Dose Reminders

- Document vaccine administration in their medical record systems within 24 hours
- Report administration data to the relevant system (i.e., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration
- MUST provide recipient an Immunization Record Card Make every attempt to schedule a recipient's second-dose appointment when they get their first dose
- Second dose must be from the same manufacturer

Management of Vasovagal Syncope

- Situational syncope is a type of vasovagal syncope which happens only during certain situations that affect the nervous system. Results in temporary loss of consciousness
  - Dehydration, hunger, low blood sugar
  - Intense emotional stress (fear, anxiety)
  - Pain
- Generally recover within a few minutes
- Watch for symptoms that precede fainting (pallor, lightheadedness, nausea, cold, clammy sweat, blurred vision)
- Prevent fall/injury
- Provide supportive care (cold compress, juice/candy, elevate legs)
- Provide wellness resources (peer support, counseling as needed)
- Observe for 15 minutes, patient should be seated or lying down
- Monitor vital signs

Management of Anaphylaxis in a COVID-19 Vaccination Site

Primary goal: Early recognition of anaphylaxis

If anaphylaxis is suspected, take the following steps:

- Rapidly assess airway, breathing, circulation, and mentation
- Call for emergency medical services/rapid response
- Place the patient in a supine position (face up), with feet elevated, unless upper airway obstruction is present or the patient is vomiting
- Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Recommended meds and supplies for management of anaphylaxis

The following emergency equipment should be immediately available to the clinical team assessing and managing anaphylaxis.

Should be available at all sites	If feasible, include at sites (not required)
Epinephrine prefilled syringe or autoinjector*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine)†	Oxygen
Blood pressure cuff	Bronchodilator (e.g., albuterol)
Stethoscope	H2 antihistamine (e.g., famotidine, cimetidine)
Timing device to assess pulse	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

*COVID-19 vaccination sites should have at least 3 doses of epinephrine on hand at any given time.
†Antihistamines may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.

Reporting Vaccine Adverse Events

HCPs are required to report the following to VAERS:

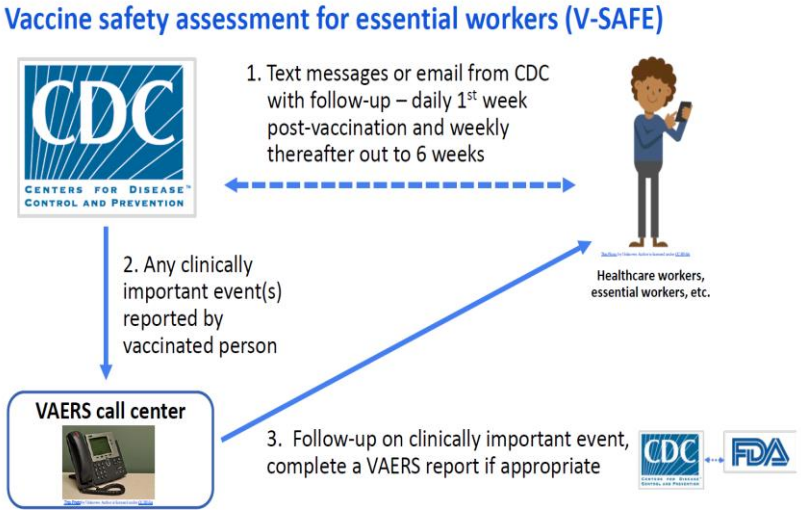
- Vaccine administration errors
- Serious AEs should be reported even if the cause is uncertain
- Hospitalization or death from COVID-19 disease in a vaccine recipient
- Multisystem Inflammatory Syndrome

There are two ways to file a VAERS report:

- Online — https://vaers.hhs.gov/esub/index.jsp
- PDF — https://vaers.hhs.gov/uploadFile/index.jsp

Reporting Vaccine Adverse Events for Recipients

- If symptoms do not resolve, are severe or getting worse, seek prompt medical evaluation
- Make sure you enroll in CDC's V-safe
  - Recipients sign up voluntarily
  - Available in 5 languages
  - Link provided by vaccine provider
  - V-Safe sign up instructions



EVERY SAFE AND EFFECTIVE VACCINATION IS A VICTORY

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