Overview of COVID-19 vaccination

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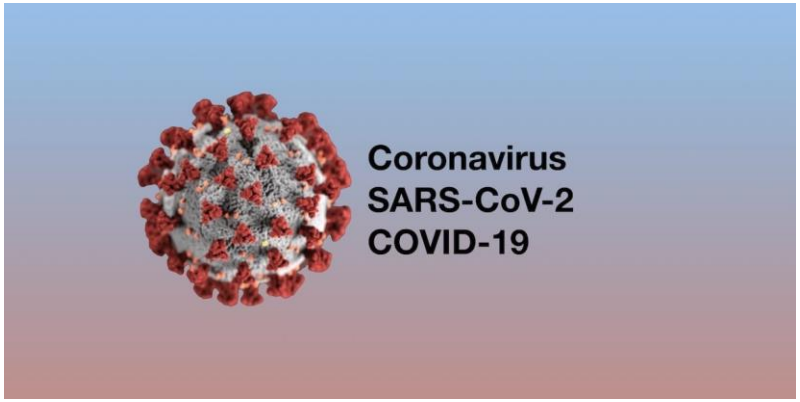
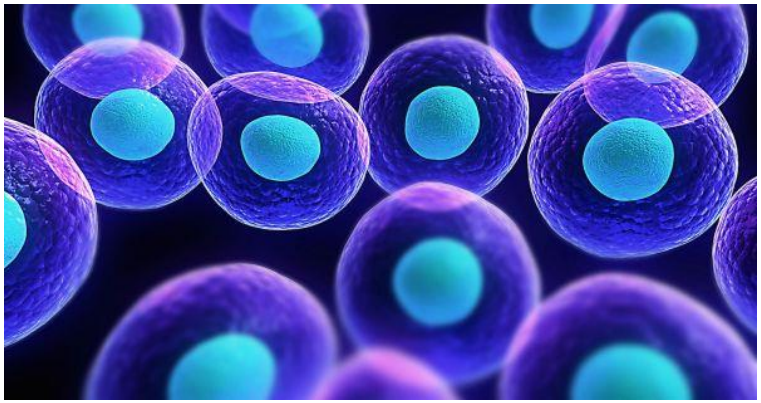
Immune system vaccine basics

- SARS-CoV-2(COVID-19) respiratory virus contains 25 major proteins
- The main target for vaccine induced immune response is the glycoprotein spike



Immune response-immune memory

- Three main cell types:
- 1) antibody (attacks virus outside the cell). Made by B cells
- 2) CD4 helper T cells (attacks virus inside the cell)
- 3) CD8 killer T cells (attack virus inside the cell)



Natural immunity after COVID-19 infection

- How long does natural immunity last after infection?
- We don't know for sure, but……
- It looks like about 95% of infected people still have immune memory at 6-8 months

MRNA vaccines are new!

- New vaccine technology
- MRNA codes for a single spike protein
- No live virus, no deactivated virus

- The MRNA is carried into our cells and codes for the spike protein.
- Our cells then produce it, so the immune system recognizes it on the COVID-19 virus if we are infected
- Takes place in the cytoplasm
- Creates antibodies and T-cell response

MRNA vaccines

- A brief, temporary message that expires quickly
- Does not alter DNA

MRNA vaccines

- The MRNA is carried into our cells by lipid nanoparticles
- Mostly taken up by muscle cells
- Also by a few specialized immune cells

- Often, adjuvants used to get vaccines into cells and convey “severity” to the immune system
- No adjuvants or preservatives in Pfizer-BioNTech or Moderna vaccines

Virus mutation

- Can viruses mutate to make vaccines less effective?
- Absolutely, but it is highly variable
- Influenza mutates easily and often
- Measles, polio, and Hep B for example basically have not mutated
- Yet to be seen what will happen with COVID-19

MRNA vaccines

- MRNA vaccine technology will not work for all viruses, but is highly likely to be used for other viruses in the future
- Other COVID-19 vaccines in development use a viral vector, not MRNA (Astrazeneca, Johnson & Johnson)

Ingredients

- Pfizer-BioNTech:
- 1) MRNA
- 2) 4 Lipid nanoparticles
- 3) 4 salts
- 4) Sucrose (protects the vaccine during freezing)

- Must be stored frozen at ultra-low temperature between -112 to -76 degrees F to protect MRNA

- Moderna:
- 1) MRNA
- 2) 3 Lipid nanoparticles
- 3) Tromethamine / Tromethamine hydrochloride / acetic acid / sodium acetate (PH buffers)
- 4) Sucrose

- Stored frozen between -13 to 5 degrees F long term, but can be stored refrigerated (36-46 degrees F) up to 30 days

Vaccine immunity

- How long will COVID 19 vaccine immunity last?
- We don’t know yet

- It might be the same as natural immunity, much longer than natural immunity, or shorter than natural immunity

So how did we get here so quickly?

- No vaccines in human history had ever been developed and implemented in less than a calendar year until now
- Most vaccines take more than 10 years to develop and put to use

Normal process

- Phase 1 trial
- Phase 2 trial
- Phase 3 trial
- Approval
- Large scale manufacturing

- For past vaccines, followed sequentially in order

Operation Warp Speed

- Partnership between Government and private industry
- US government spent $10 billion
- DoD, HHS, CDC, NIH, BARDA
- Absolutely no corners were cut in the approval process
- Up front funding was key

Operation Warp Speed

- Funding allowed phased trials to run contiguously instead of sequentially
- Also allowed for manufacturing of large quantities during development in anticipation of approval
- Normally, these massive financial risks could not be taken
- Pfizer and Moderna have received EUA, 3 other vaccines in phase 3 trials as of late 2020
- Pfizer-BioNTech was the first to market but took no government funding other than purchase orders for the vaccine

EUA: Emergency Use Authorization

- FDA can grant EUA when there is a public health crisis, and something is developed that has no already approved counterpart
- Pfizer-BioNTech: EUA issued 12-11-2020 for age 16 and older
- Moderna: issued 12-18-2020 for age 18 and older

Trial Participants

- Pfizer-BioNTech
  - 21,720 vaccine
  - 21,728 placebo
- Moderna
  - 15,419 people received at least one vaccine dose (15,179 received both doses)
  - 15,163 placebo

Effectivity

- Both vaccines approximately 95% effective, and 90% (Pfizer-Biontech) to nearly 100% (Moderna) effective at preventing severe disease
- Extremely high efficacy

So who should / should not get vaccinated?

- No if severely allergic to any ingredients
- No if severe allergic reaction to first dose
- Pregnancy / breast feeding unknown

- If already had COVID-19 infection, should still get vaccinated, but can wait a while

- Need studies now on children under 16 / 18

- It is an individual and personal decision, but these vaccines appear to be particularly safe

- Herd immunity requires approximately 70% vaccination in the population

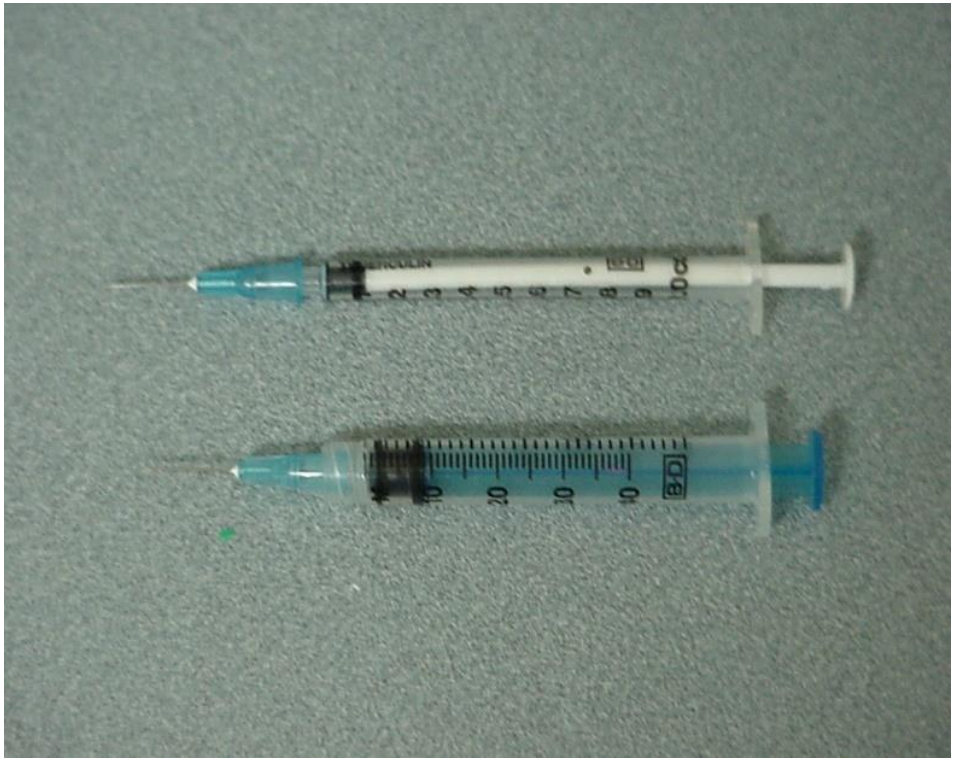
Vaccination priority

- CDC recommendations:

- Phase 1A: Health care personnel and residents of long-term care facilities
- Phase 1B: People 75 and older and front-line essential workers
- Phase 1C:People 65-74, people 16-64 with high-risk medical conditions, other non-front-line essential workers
- Phase 2: all others 16+

IM Administration technique

- So how are IM injections delivered?

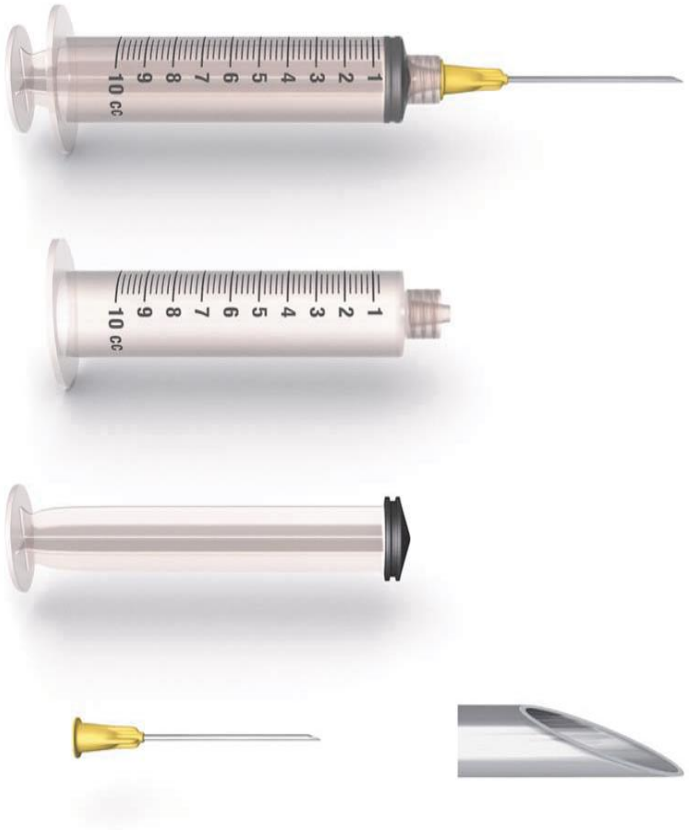


Syringe basics

- 1ml (TB): vaccines generally
- 3ML
- 5ML
- Larger (less common except for blood draws)

Needle basics

- Bevel (angled slice)
- Gauge: larger number = smaller needle
- 19, 23, 25, 27, 30, etc.
- May have second # indicating length (inches):27 ½ G



Needle gauges

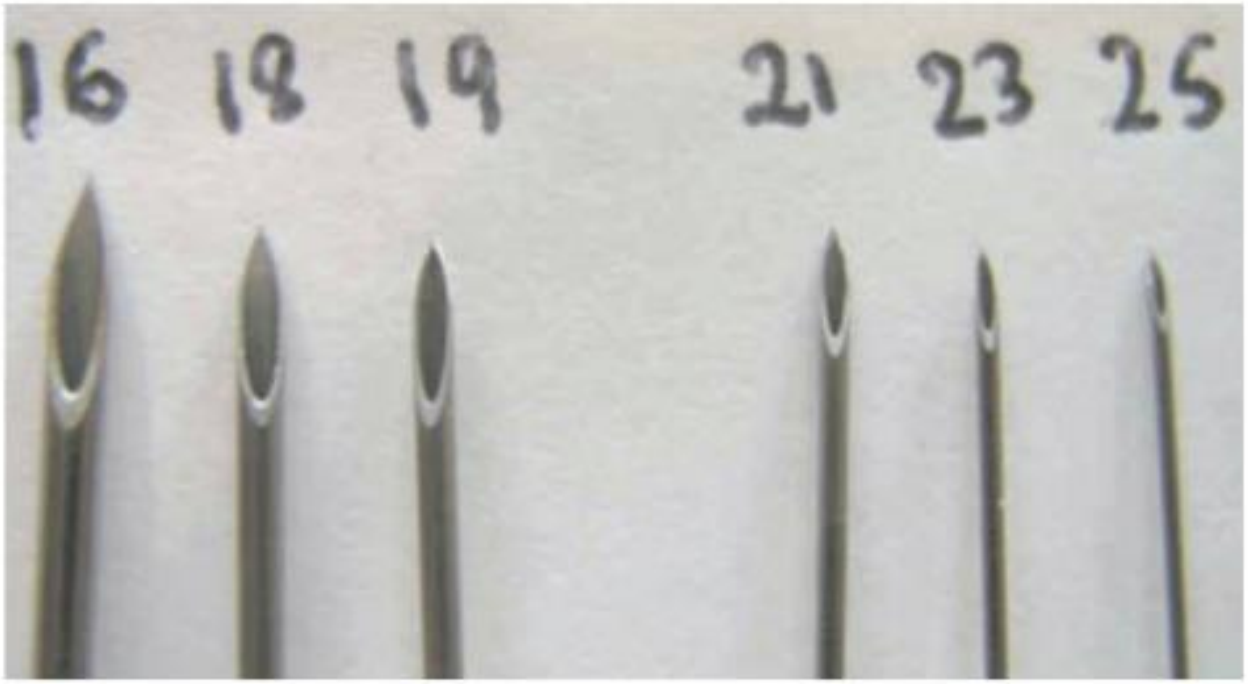
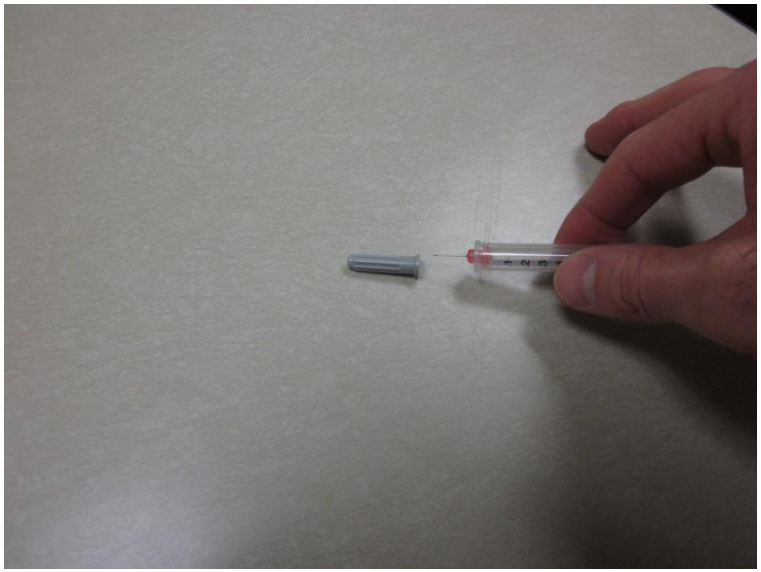


Figure 1. 16-gauge to 25-gauge micropuncture needles.

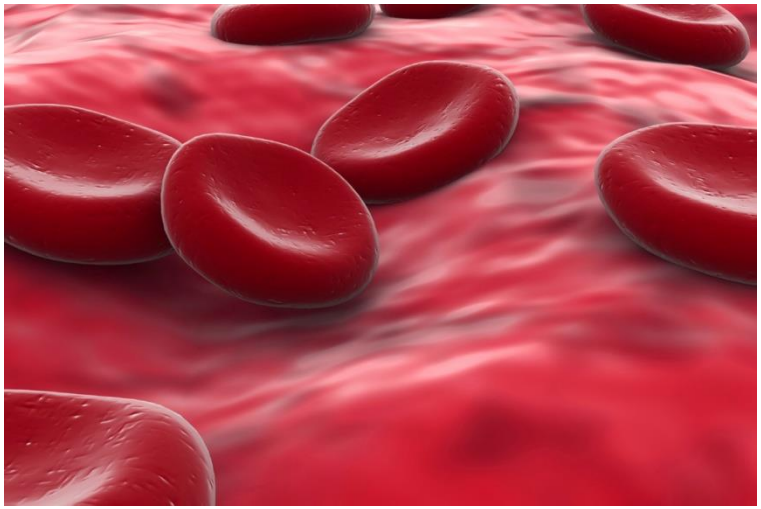
IM injection technique

- Needle used only for the drawing up of a fluid can be re-capped using the “one hand scoop technique”



IM injection technique

- Needles that have been used on people are never re-capped before discarding them
- High risk of “stick” with contamination



IM injection technique

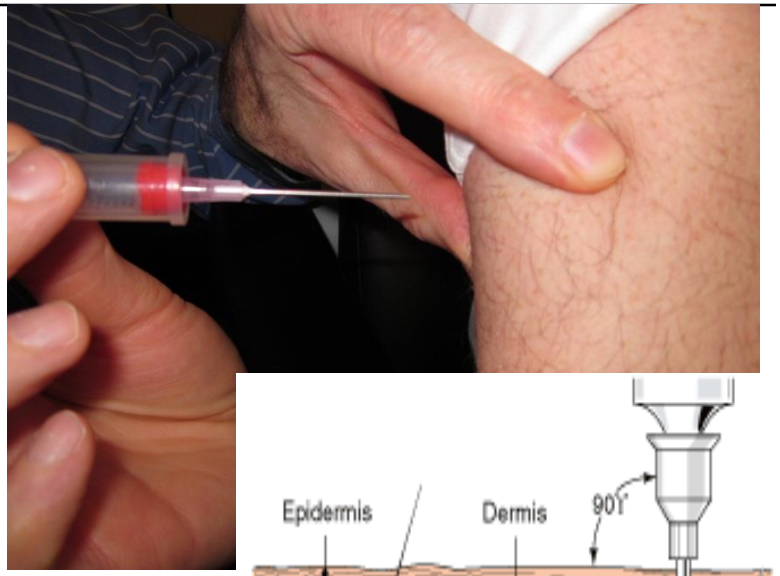
- All needles disposed of in a sharps container: they are now usually clear to allow for viewing contents

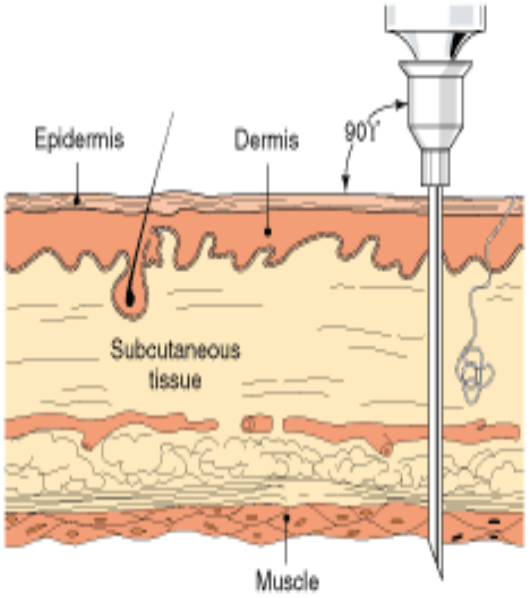
Intramuscular injection technique

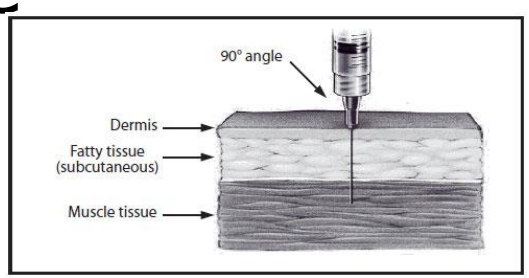
- Deposits medication into muscular tissue free of major vessels and nerves
- Typically given in the deltoid (most vaccines) or gluteus muscles (outer buttocks). Sometimes the thigh (epipen)
- Much more rapid onset of action than subcutaneous route due to the greater blood supply of the tissue

Intramuscular technique

- Clean site with alcohol pad
- Pull skin taught
- Insert needle at 90-degree angle
- Inject medication / vaccine

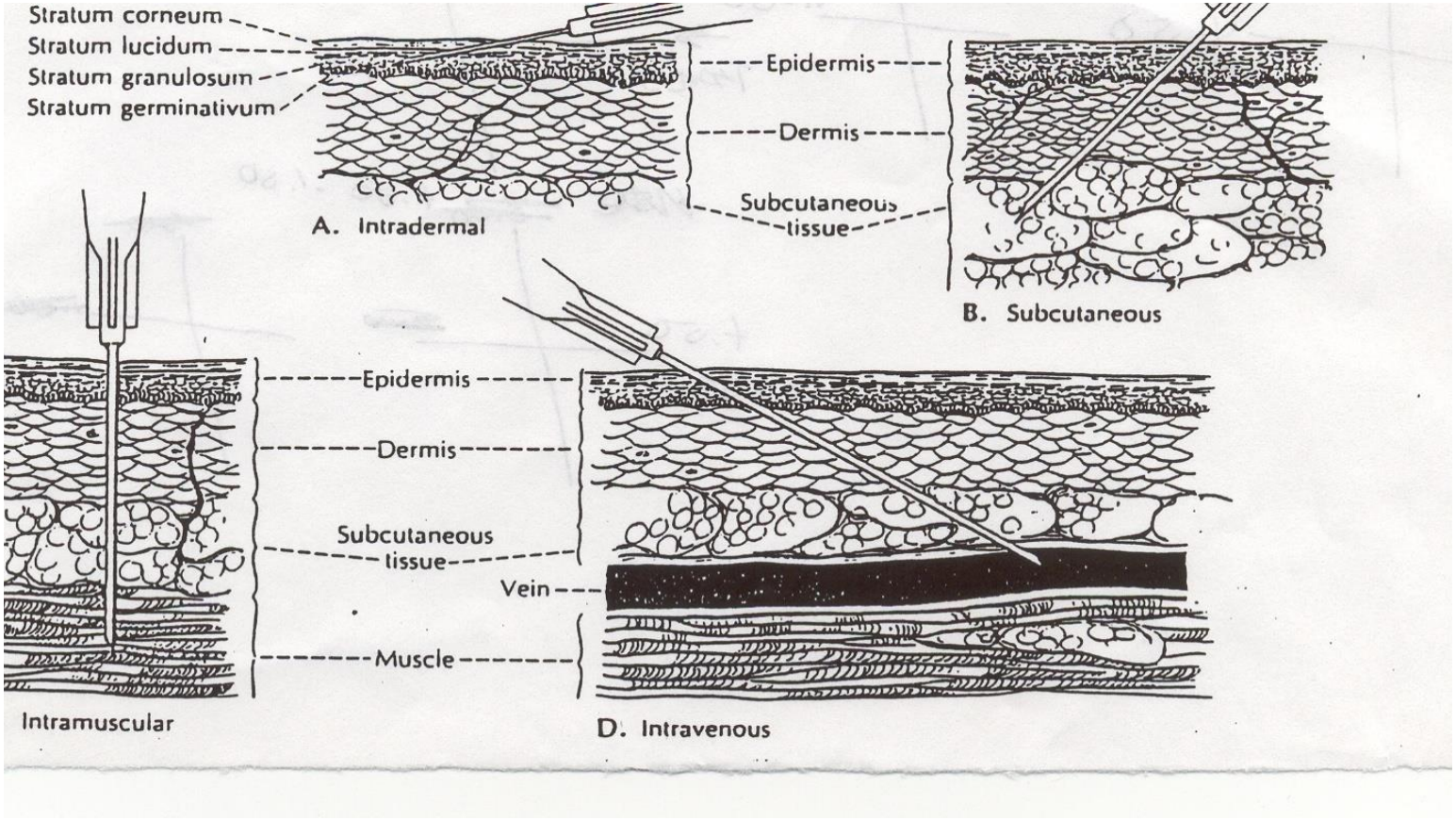






Smith et al., 2000, p. 387

Injection sites



Vaccination Providers

- Currently Phase 1A is only utilizing hospitals that were prepared to administer the vaccine to all healthcare personal
- An email was sent in October by the IDOH asking them to enroll as vaccine providers
- Phase 1B and 2 will expand to local health departments and commercial pharmacies
- Enrollment will be a phased process based on vaccine availability

Vaccination Providers

- Physicians and facilities who routinely give vaccines are enrolled in the Vaccines For Children (VFC) Program and record administration of these vaccines in Children and Hoosier Immunization Registry Program (CHIRP), Indiana's immunization information system
- The IDOH has created an online enrollment portal for providers that will upload to the CDC's COVID-19 Vaccination Program Provider Agreement and Profile Form
- Registered COVID-19 vaccination providers will order COVID-19 vaccine through CHIRP

What about optometrists?

- If granted permission to administer vaccines, be on the lookout for emails from the IDOH, likely similar to the vaccination updates from them that have been emailed through the Indiana Professional Licensing Agency
- Pay attention to information relayed by the Indiana Optometric Association
- Much of the information needed to enroll is similar to what is included in enrolling for the VFC/CHIRP so the process will likely involve more paperwork for optometrists
- Link to CDC's COVID-19 Vaccination Program Provider Agreement and Profile Form: https://scdhec.gov/sites/default/files/media/document/COVID19-Vaccination_Program_Provider_Agreement_and_Profile_Form.pdf

Pfizer-BioNTech Vaccine

- Suspension for IM injection
- Administered in two doses, 3 weeks apart
- 0.3 mL each
- Approved for ages 16+

Important Links for Providers

- Fact Sheet for Healthcare Providers Administering Vaccine found here: https://www.fda.gov/media/144413/download
- Videos for product storage & handling, preparation & administration, and returning the thermal shipping container found here: https://www.cvdvaccine-us.com/product-storage-and-dry-ice

Storage and Handling

- Shipped in thermal shipping containers with dry ice
- Each vial tray contains either 25 or 95 multi-dose vials

Storage

- Option 1
  - Remove vial trays and store in ultra-low freezer
  - -112°F to -76°F
  - Closed-lid vial trays can be at room temp for up to 5 min to transfer and open-lid up to 3 min, and then must remain in freezer for 2 hours before use
- Option 2
  - Use thermal shipping container as temporary storage
  - Must be consistently refilled with dry ice
  - With proper planning and limiting opening of container, dry ice will need to be replaced about every 5 days

Storage

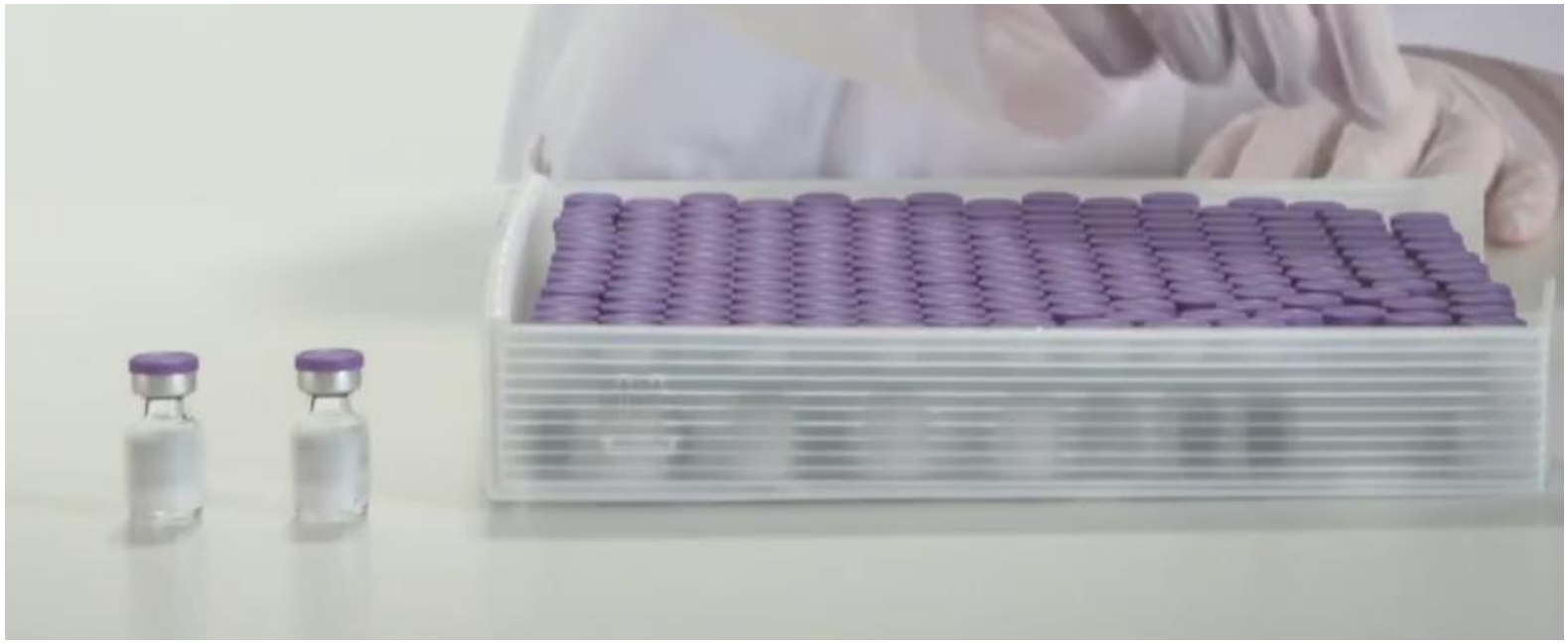
- Do not refreeze thawed vials
- Do not open vial trays or remove vials until ready for thawing
- Minimize exposure to room light
- Avoid direct sunlight and ultraviolet light

Thawing

- Option 1
  - In refrigerator
  - 35°F to 46°F
  - Can be stored for up to 5 days
  - Cartons take 2-3 hours to thaw, fewer vials take less time
- Option 2
  - At room temperature
  - Up to 77°F
  - Can be stored for no more than 2 hours
  - Vials take 30 minutes to thaw

Thawing

- Plan ahead for the day or week to know how many multiple-dose vials to use



Diluting Vials

- ONLY Pfizer-BioNTech vaccine needs to be diluted
- Dilutant not provided
- Diluted with 1.8 mL of 0.9% Sodium Chloride Injection, USP
- ONLY THIS
- Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other

- Step 1
  - Gently invert vaccine vial 10 times; do not shake
  - Inspect liquid; Should be white to off-white suspension and may contain opaque amorphous particles

- Step 2
  - Cleanse 0.9% Sodium Chloride Injection, USP vial stopper with antiseptic swab
  - Using aseptic technique, withdraw 1.8 mL of dilutant
  - 3 mL syringe with 21 G needle or narrower recommended

- Step 3
  - Cleanse vaccine vial stopper with antiseptic swab
  - Inject prepared dilutant into vaccine vial
  - Don’t forget to equalize vial pressure by withdrawing 1.8 mL of air into syringe before removing from vial

- Step 4
  - Gently invert vial 10 times; do not shake
  - Inspect the vaccine
  - Record date and time of dilution on vial label

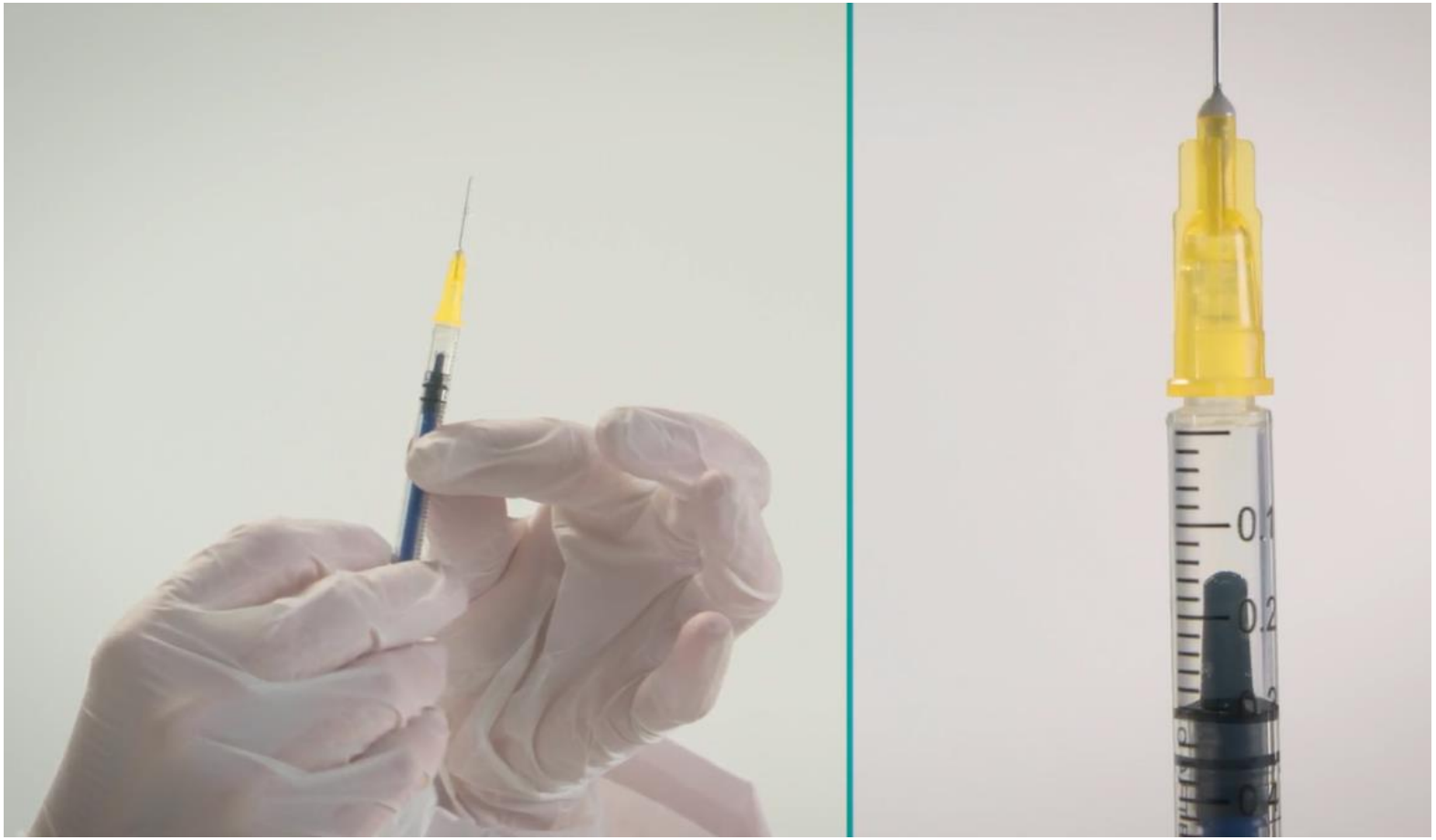
Dilution

- Once diluted, store between 35°F to 77°F
- Diluted vaccine must be used within 6 hours
- Any remaining vaccine must be discarded

Preparation

- Using aseptic technique, cleanse vial stopper with a single-use antiseptic swab
- Withdraw 0.3 mL of Pfizer-BioNTech vaccine

- Verify final dosing volume of 0.3 mL
- Check for discoloration or particles



Preparation

- Diluted vials contain up to 6 doses of 0.3 mL
- Regardless of type of syringe or needle
  - Each dose MUST contain 0.3 mL of vaccine
  - Discard remaining vaccine that will not provide a full dose
  - Do not pool excess vaccine from multiple vials

Administration

- Must communicate to recipient or caregiver information consistent with "Fact Sheet for Recipients and Caregivers" prior to administration
- This information can be found here: http://labeling.pfizer.com/ShowLabeling.aspx?id=14472

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

- Administer shot intramuscularly
- Watch for signs and symptoms of an acute allergic reaction

Moderna Vaccine

- Suspension for IM injection
- Administered in two doses, 4 weeks apart
- 0.5 mL each
- Approved for ages 18+

Important Links for Providers

- Fact Sheet for Healthcare Providers Administering Vaccine found here: https://www.fda.gov/media/144637/download
- Video for storage & handling found here: https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling

Storage and Handling

- Shipped frozen using existing shipping practices
- Each carton contains 10 multi-dose vials

Storage

- Option 1
  - Store frozen in original cartons to protect from light
  - -13°F to 5°F
  - Can be stored until expiration date
- Option 2
  - Store refrigerated in original cartons to protect from light
  - 36°F to 46°F
  - Can be stored for 30 days

Thawing

- Option 1
  - In refrigerator
  - 36°F to 46°F
  - Thaw for 2 hours and 30 minutes, then let stand at room temperature for 15 minutes before use
  - Unpunctured vials can be stored up to 30 days
- Option 2
  - At room temperature
  - 59°F to 77°F
  - Thaw for 1 hour
  - Unpunctured vials may be stored for up to 12 hours
- Do not refreeze thawed vials

Preparation

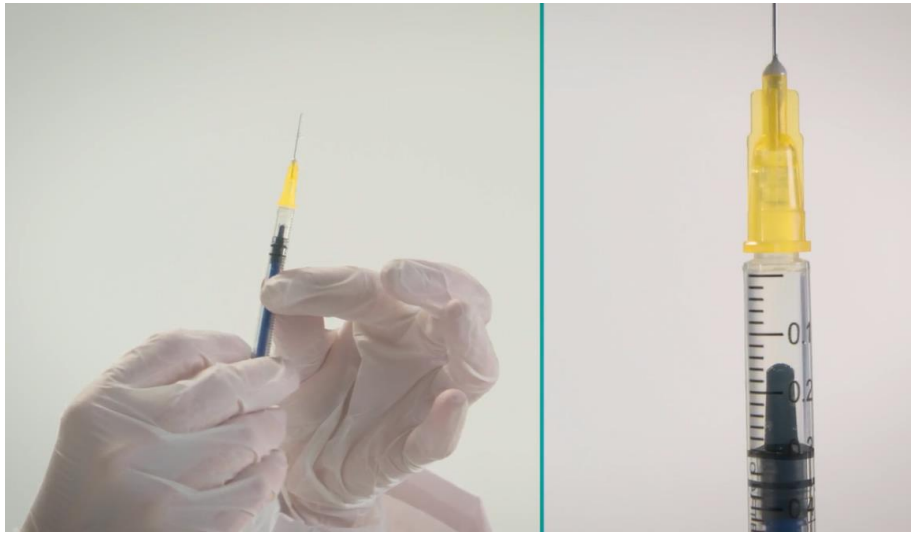
- Swirl vial gently after thawing and between each withdrawal; do NOT shake
- Do NOT dilute vaccine

Preparation

- Using aseptic technique, cleanse vial stopper with a single-use antiseptic swab
- Withdraw 0.5 mL of Moderna vaccine

Preparation

- Verify final dosing volume of 0.5 mL
- Check for discoloration or particles
  - Vaccine is white to off-white suspension that may contain white or translucent particulates



Preparation

- Once punctured, record date and time of first use on vial label
- Store between 36°F to 77°F
- Punctured vaccine vials must be used within 6 hours

Administration

- Must communicate to recipient or caregiver information consistent with "Fact Sheet for Recipients and Caregivers" prior to administration
- This information can be found here: https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

- Administer shot intramuscularly
- Watch for signs and symptoms of an acute allergic reaction

Comparing the Two

	Pfizer-BioNTech	Moderna
Type	mRNA	mRNA
Age Approved	16+	18+
Shot Sequence	2 shots, 3 weeks apart	2 shots, 4 weeks apart
Injection Type	Intramuscular	Intramuscular
Storage	Ultra-low freezer or dry ice (-112°F to -76°F)	Freezer (-13°F to 5°F) or Fridge (36°F to -46°F)
Diluted?	YES	NO
Doses per vial	~6	10
Effectivity	95%	95%

Vaccination Record Card

- Regardless of Pfizer-BioNTech or Moderna vaccine, a completed COVID-19 vaccination record card must be provided to recipient
- Included with each shipment

EJ Hersom/Defense.gov

Vaccine side effects

- Almost all issues with vaccine side effects occur within two months of receiving the vaccine
- No adjuvant or preservative (thimerosal for example) in Pfizer-Biontech or Moderna vaccine

What defines adverse effect?

Adverse events = unintended, unexpected pharmacologic effects that occur when a medication is administered correctly

VS.

Side effect = secondary unwanted effect as a result of drug therapy

Side effects in clinical trials

- Pfizer-Biontech
- Pain at injection site 84%
- Fatigue 63%
- Headache 55%
- Muscle pain 38%
- Chills 32%
- Joint pain 24%
- Fever 14%
- Swelling at injection site 10%, redness 10%

- Moderna
- Pain at injection site 92%
- Fatigue 70%
- Headache 65%
- Myalgia 62%
- Arthralgia 46%
- Chills 45%
- Nausea 23%
- Fever 16%
- Swelling 15%, redness 10%

Side effects

- Most all of these side effects are secondary to a robust immune response, which is what we want
- So not really side effects so much as expected effects

Shot sequence

- Pfizer-Biontech: One shot followed by a second shot 3 weeks later
- Moderna: One shot followed by second shot one month later
- Adverse expected effects tend to be worse after second dose: the immune system is “primed”

Adverse effects

- Required by ISDH to keep patients for 15 minutes at facility to monitor for AEs
  - If history of anaphylaxis or allergic reaction, monitor for 30 minutes.

AE - Anaphylaxis

- Though rare, anaphylactic reactions have occurred from COVID-19 vaccine
- Providers should have a plan in place in case of need for emergency medical attention
- Be able to identify immediate allergic reactions and have meds (such as epi pen, anti-histamines) on site

What AEs are you required to report?

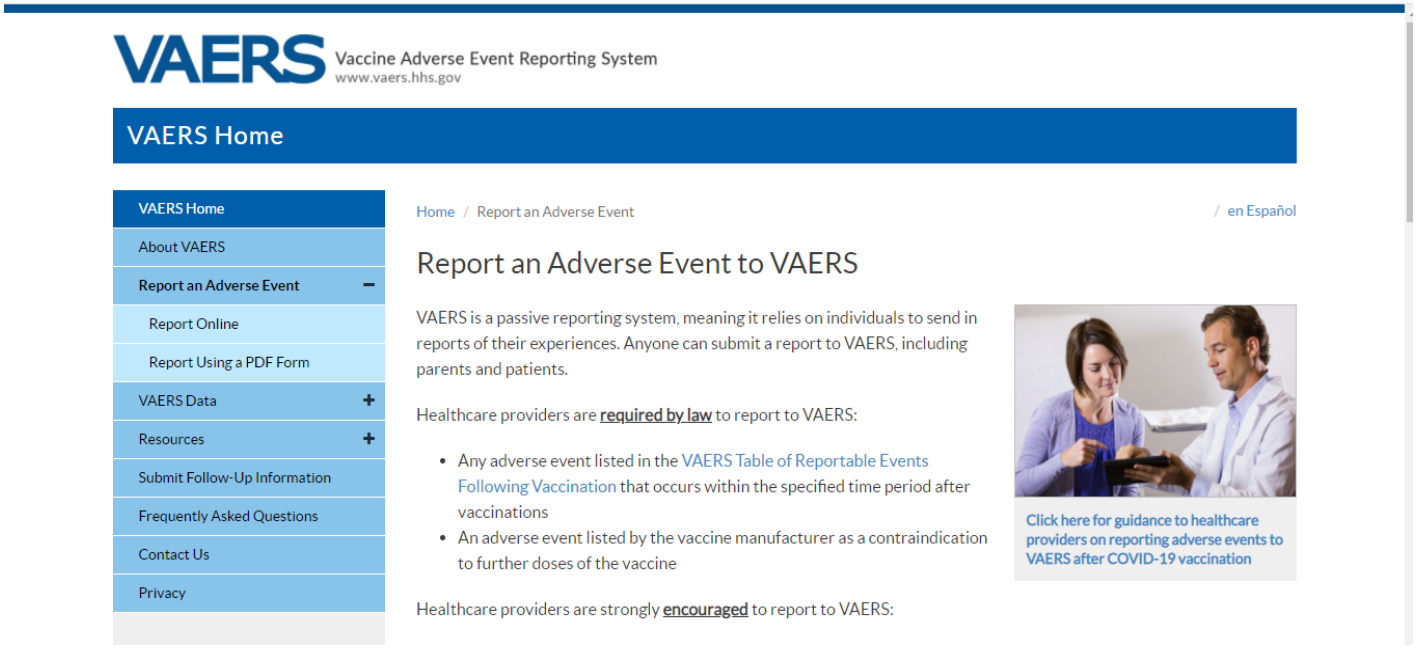
- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality.
  - Serious =
    - Death
    - Life threatening
    - AE requiring hospitalization
    - Persistent incapacity
    - Congenital anomaly/birth defect
    - Medical event that may require medical or surgical intervention to prevent one of the above outcomes
- Post vaccination cases of Multisystem inflammatory Syndrome
- Post vaccination cases of COVID-19 resulting in hospitalization or death

AE Reporting

Encouraged to report to VAERS any clinically significant AEs following vaccination, even if you are not sure if vaccination caused the event

Reporting AEs

Vaccine Adverse Event Reporting System



https://vaers.hhs.gov/reportevent.html

Phone: 1-800-822-7967

VAERS

- Online reporting system - required by law
  - Can also fax a PDF of form

Submit:

- Patient information
  - Demographics
  - Medical history
- Vaccine information
  - Date administered, manufacturer, lot #
  - Route, body site
- Reporter/Facility
- Describe AE and outcome

*Provide as much detail as possible

Reporting to manufacturer
(not required)

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

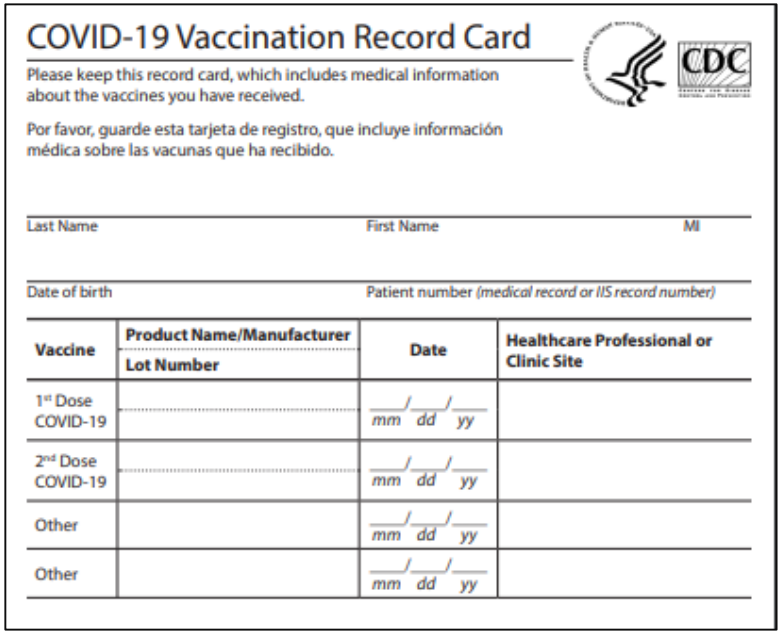
To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

Post-Vaccination

Patient Education:

- Provide a vaccination card to the recipient or their caregiver
- Included in shipment
- Make sure to list manufacturer and lot #



COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

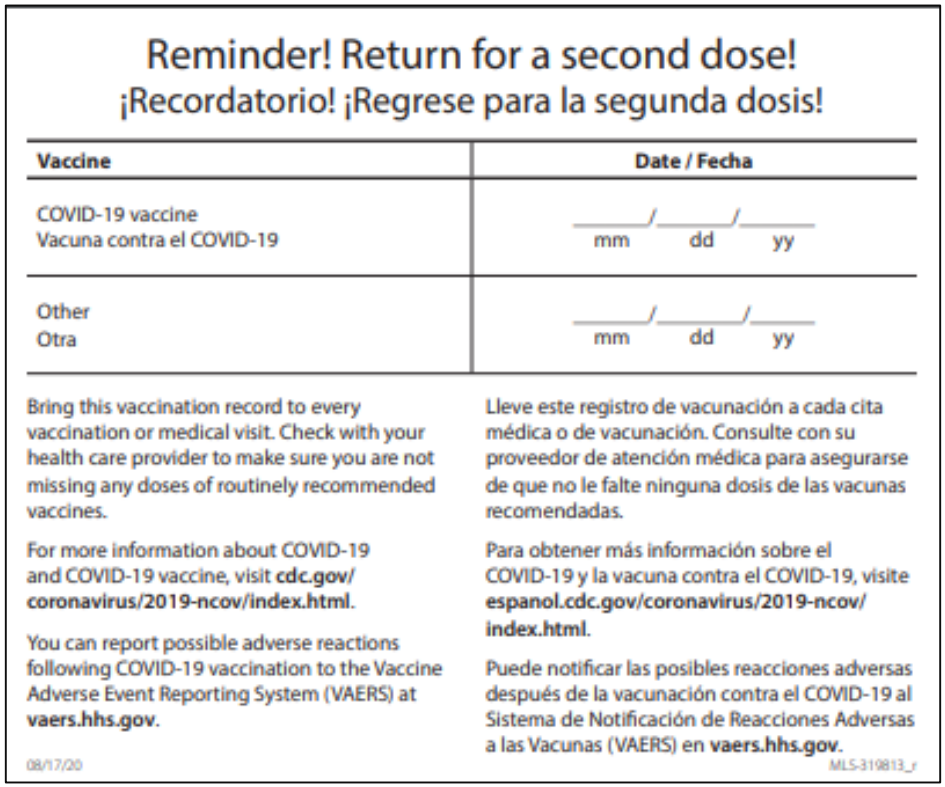
Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name | First Name | MI

Date of birth | Patient number *(medical record or IIS record number)*

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1st Dose COVID-19		___/___/___ mm dd yy	
2nd Dose COVID-19		___/___/___ mm dd yy	
Other		___/___/___ mm dd yy	
Other		___/___/___ mm dd yy	

Back side



Reminder! Return for a second dose!
¡Recordatorio! ¡Regrese para la segunda dosis!

Vaccine	Date / Fecha
COVID-19 vaccine Vacuna contra el COVID-19	_____/_____/_____ mm dd yy
Other Otra	_____/_____/_____ mm dd yy

Bring this vaccination record to every vaccination or medical visit. Check with your health care provider to make sure you are not missing any doses of routinely recommended vaccines.

For more information about COVID-19 and COVID-19 vaccine, visit **cdc.gov/coronavirus/2019-ncov/index.html**.

You can report possible adverse reactions following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) at **vaers.hhs.gov**.

Lleve este registro de vacunación a cada cita médica o de vacunación. Consulte con su proveedor de atención médica para asegurarse de que no le falte ninguna dosis de las vacunas recomendadas.

Para obtener más información sobre el COVID-19 y la vacuna contra el COVID-19, visite **espanol.cdc.gov/coronavirus/2019-ncov/index.html**.

Puede notificar las posibles reacciones adversas después de la vacunación contra el COVID-19 al Sistema de Notificación de Reacciones Adversas a las Vacunas (VAERS) en **vaers.hhs.gov**.

08/17/20

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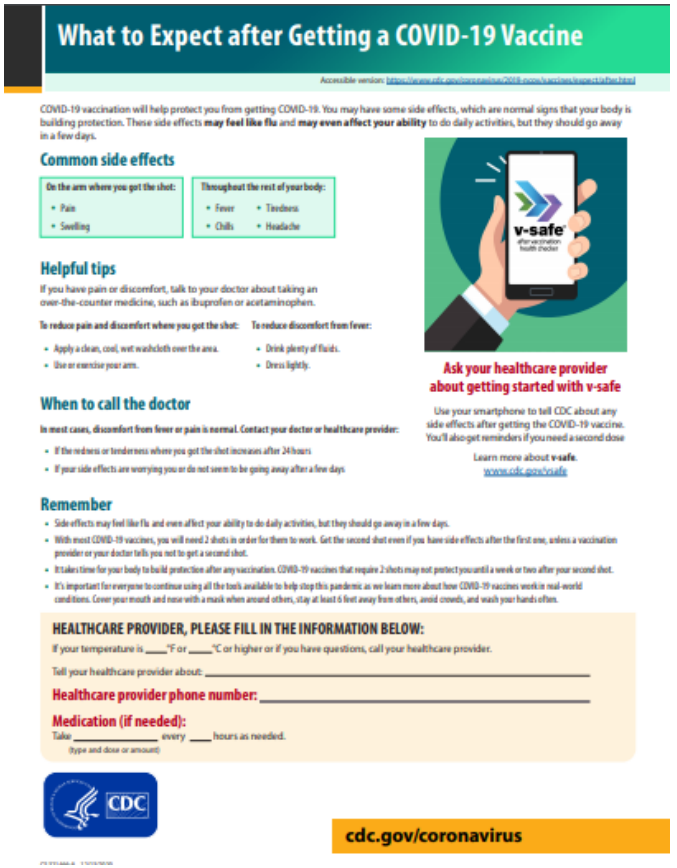
Stress importance of returning for 2nd dose!

Post-Vaccination

Patient Education:

- Required to provide patient with EUA vaccine fact sheet for recipients and caregivers
  - Specific to either Pfizer or Moderna
- Can also handout CDC fact sheet "what to expect"
  - Includes V-Safe instructions



What to Expect after Getting a COVID-19 Vaccine

Accessible version: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

Common side effects

On the arm where you got the shot:	Throughout the rest of your body:	
• Pain	• Fever	• Tiredness
• Swelling	• Chills	• Headache

Helpful tips

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot:
- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

To reduce discomfort from fever:
- Drink plenty of fluids.
- Dress lightly.

When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:
- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

Ask your healthcare provider about getting started with v-safe

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 dose.

Learn more about **v-safe**.
www.cdc.gov/vsafe

Remember

- Side effects may feel like flu and even affect your ability to do daily activities, but they should go away in a few days.
- With most COVID-19 vaccines, you will need 2 shots in order for them to work. Get the second shot even if you have side effects after the first one, unless a vaccination provider or your doctor tells you not to get a second shot.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until a week or two after your second shot.
- It's important for everyone to continue using all the tools available to help stop this pandemic as we learn more about how COVID-19 vaccines work in real-world conditions. Cover your mouth and nose with a mask when around others, stay at least 6 feet away from others, avoid crowds, and wash your hands often.

HEALTHCARE PROVIDER, PLEASE FILL IN THE INFORMATION BELOW:

If your temperature is ____°F or ____°C or higher or if you have questions, call your healthcare provider.

Tell your healthcare provider about: _____

Healthcare provider phone number: _____

Medication (if needed):

Take _____ every ____ hours as needed.
(type and dose or amount)

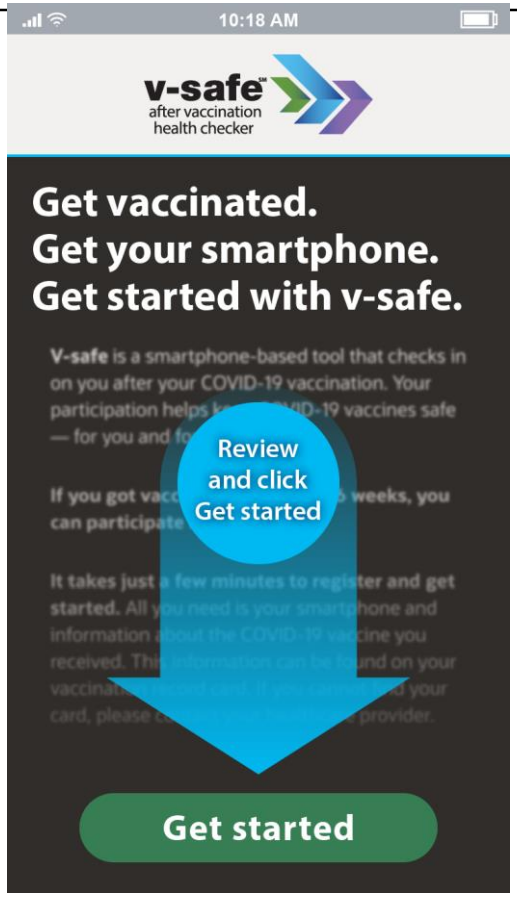
CDC

cdc.gov/coronavirus

Available to download/print at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

V-Safe

- Smartphone app for health check-ins post-vaccination.
- Uses text messaging and web surveys
- CDC tool to monitor for side effects
- Helps to remind patients to go in for second dose
- Any clinically important events reported by a participant would be sent to VAERS for follow-up



Documentation

- **Medical record:**
  - Vaccine, date it was administered, manufacturer, lot number, vaccination site and route
  - Patient's consent
  - Record name and title of the person administering
- **Immunization information system:**
  - Report the vaccination to the appropriate state/local agency
- Required to keep documentation regarding immunization x 7 years

Billing

Manufacturer	Product CPT code	Administration code – dose 1	Administration code – dose 2
Pfizer	91300	0001A	0002A
Moderna	91301	0011A	0012A
AstraZenaca	91302	0021A	0022A

At each visit use appropriate product CPT code and either administration code 1 or 2.

Billing for administration only. Assuming at this time that product is obtained at no cost to provider.

Cost

- No cost to patients
  - No co-pay, no deductible
- Can bill insurance for reimbursement to administer shot
  - Per CMS website:
  - 2 dose-series initial dose $16.94 and second dose $28.39
  - $28.39 for a single-dose COVID-19 vaccine (none currently fit this)
    - Geographically adjusted

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