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

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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.
©2009 TSE Publishing, Inc.
IM injection technique

- Needle used only for the drawing up of a fluid can be recapped 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
- Diluant 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.
Administer shot intramuscularly

Watch for signs and symptoms of an acute allergic reaction
Modern 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

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

**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.

<table>
<thead>
<tr>
<th>Website</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
</table>

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.

<table>
<thead>
<tr>
<th>Email</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:ModeraPV@modernatx.com">ModeraPV@modernatx.com</a></td>
<td>1-866-599-1342</td>
<td>1-866-MODERNA (1-866-663-3762)</td>
</tr>
</tbody>
</table>
Post-Vaccination

Patient Education:
- Provide a vaccination card to the recipient or their caregiver
- Included in shipment
- Make sure to list manufacturer and lot #
**Reminder! Return for a second dose!**

¡Recuerda! ¡Regreso para la segunda dosis!

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date / Fecha</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 vaccine</td>
<td>mm/dd/yy</td>
</tr>
<tr>
<td>Vacuna contra el COVID-19</td>
<td></td>
</tr>
</tbody>
</table>

| Other/Otra                     | mm/dd/yy     |

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


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

Stress importance of returning for 2\textsuperscript{nd} 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

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

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product CPT code</th>
<th>Administration code – dose 1</th>
<th>Administration code – dose 2</th>
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</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>91300</td>
<td>0001A</td>
<td>0002A</td>
</tr>
<tr>
<td>Moderna</td>
<td>91301</td>
<td>0011A</td>
<td>0012A</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>91302</td>
<td>0021A</td>
<td>0022A</td>
</tr>
</tbody>
</table>

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