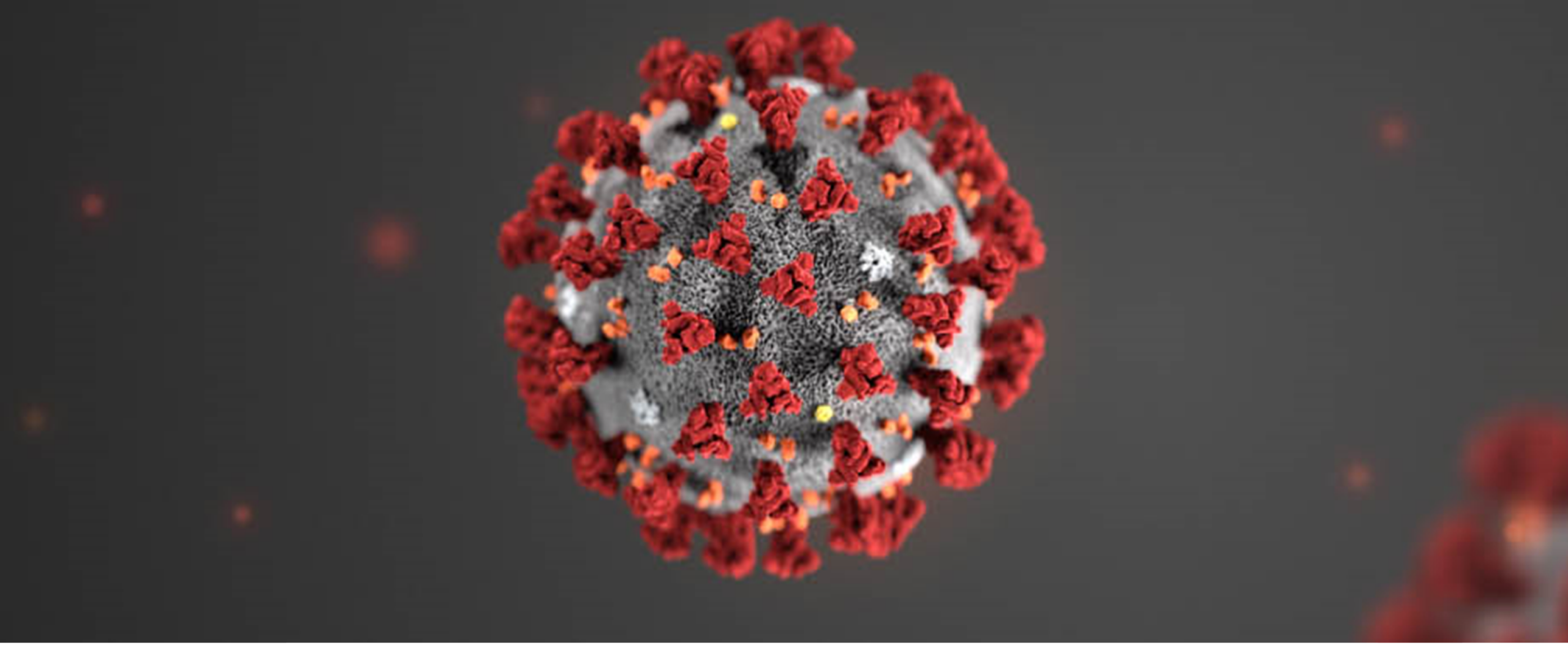

Washington State Department of Health

UW TASP Meeting
December 15, 2020

Pfizer-BioNTech COVID-19 Vaccine

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OFFICE OF IMMUNIZATION AND CHILD PROFILE

Topics to be Covered

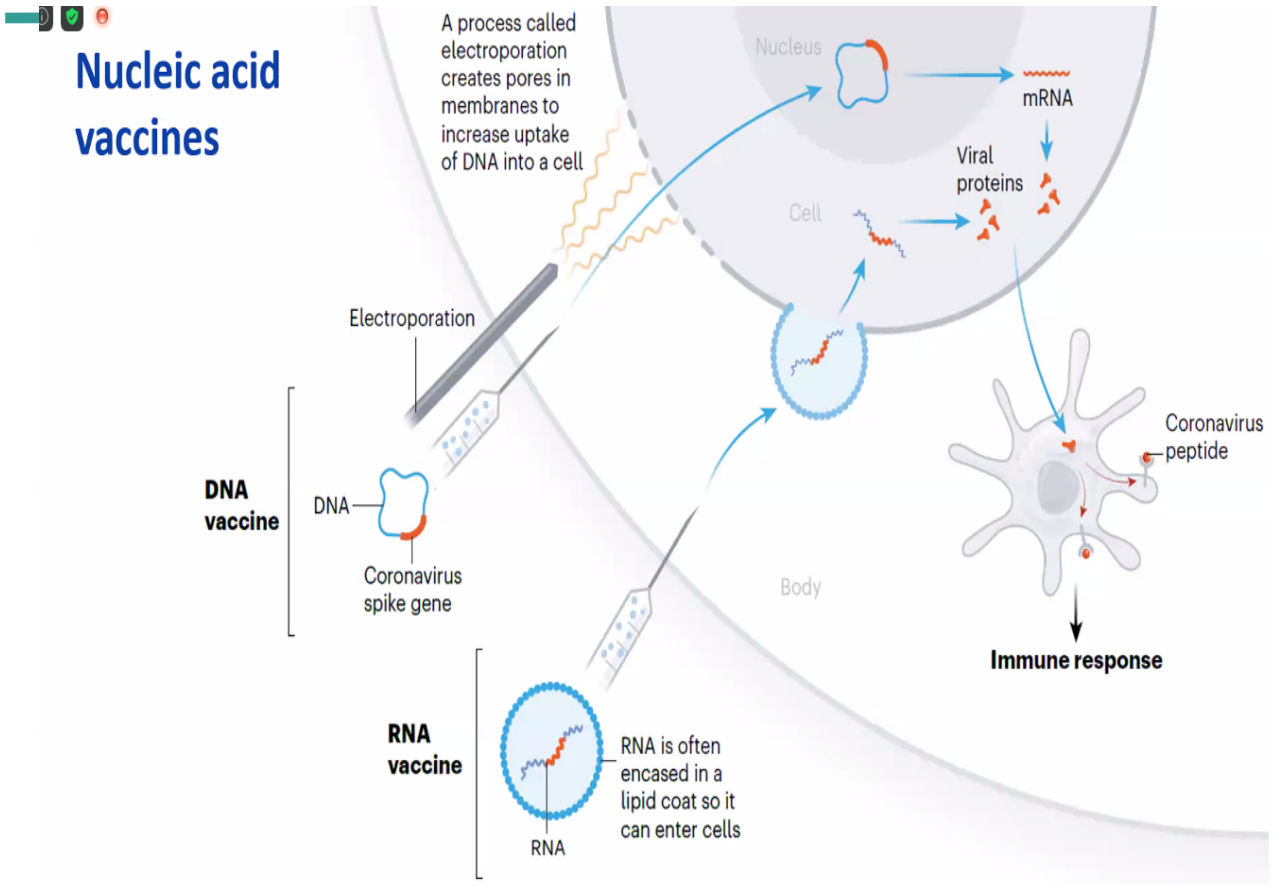
- mRNA technology
- ACIP review of evidence
- Vaccine recommendations
- Product packaging and storage and handling
- Vaccine safety
- Vaccine distribution timeline
- Resources

mRNA Vaccine Technology

- Researchers have been studying them for decades.
- Early stage clinical trials using mRNA vaccines for influenza, Zika, rabies, and cytomegalovirus (CMV).
- To trigger an immune response, many vaccines put a weakened or inactivated virus into our bodies—not mRNA vaccines.
- mRNA vaccines teach our cells how to make a protein called the “spike protein”. The spike protein is found on the surface of the virus that causes COVID-19.
- Once the instructions (mRNA) are inside the muscle cells, the cells use them to make the protein piece. The cell displays the protein piece on its surface. Our immune system recognizes that the protein doesn’t belong there and stimulates an immune response and makes antibodies.
- Benefits: use of non-infectious element, shorter manufacturing times, developed in a laboratory using a DNA template, process can be standardized and scaled up quickly

Explaining mRNA COVID-19 vaccines

- mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response
  - Like all vaccines, COVID-19 mRNA vaccines have been **rigorously tested** for safety before being authorized for use in the United States
  - mRNA technology is **new, but not unknown**. They have been studied for more than a decade
  - mRNA vaccines **do not contain a live virus** and do not carry a risk of causing disease in the vaccinated person
  - mRNA from the vaccine never enters the nucleus of the cell and **does not affect or interact with a person's DNA**



Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

ACIP Review of Evidence for Pfizer-BioNTech COVID-19 Vaccine

Phase 2/3 Clinical Trials

- **44,000 healthy subjects enrollment target**
  - Stable chronic disease allowed
  - Stable HIV, HBV, HCV
- **At least 40% ages 56 years or older**
- **Balanced racial and ethnicity profile**
  - Black/African American
  - Asian
  - Hispanic/Latinx
- **Immunocompromised excluded**

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Clinical Trials – Demographic Characteristics

Characteristic	BNT162b2 (N=20033) N (%)	Placebo (N=20244) N (%)	Total (N=40277) N (%)
Sex			
Female	9794 (48.9)	10107 (49.9)	19901 (49.4)
Male	10239 (51.1)	10137 (50.1)	20376 (50.6)
Age at vaccination			
Mean years (SD)	50.3 (15.73)	50.1 (15.78)	50.2 (15.76)
Median (years)	51.0	51.0	51.0
Min, max (years)	(12, 89)	(12, 91)	(12, 91)
Age group			
16 to <18 years	77 (0.4)	76 (0.4)	153 (0.4)
16 to 54 years	11589 (57.8)	11743 (58.0)	23332 (57.9)
>55 years	8396 (41.9)	8454 (41.8)	16850 (41.8)
≥65 years	4294 (21.4)	4319 (21.3)	8613 (21.38)
≥75 years	860 (4.3)	852 (4.2)	1712 (4.3)
Race			
American IndianAlaska Native	131 (0.7)	122 (0.6)	253 (0.6)
Asian	880 (4.4)	883 (4.4)	1763 (4.4)
Black/African American	1957 (9.8)	1972 (9.7)	3929 (9.8)
Native Hawaiian/Pacific Islander	54 (0.3)	29 (0.1)	83 (0.2)
White	16387 (81.8)	16619 (82.1)	33006 (81.9)
Multiracial	523 (2.6)	493 (2.4)	1016 (2.5)
Not reported	101 (0.5)	126 (0.6)	227 (0.6)
Ethnicity			
Hispanic or Latino	5272 (26.3)	5281 (26.1)	10553 (26.2)
Not Hispanic or Latino	14652 (73.1)	14847 (73.3)	29499 (73.2)
Not reported	109 (0.5)	116 (0.6)	225 (0.6)
Comorbidities			
Yes	9278 (46.3)	9314 (46.0)	18592 (46.2)
No	10755 (53.7)	10930 (54.0)	21685 (53.8)
Obesity	6934 (34.6)	7093 (35.0)	14027 (34.8)

Source: www.fda.gov/media/144337/download

ACIP Review of Evidence

Benefits and Harms:

Summary of the Available Evidence: Benefits

- The clinical trial for the Pfizer-BioNTech COVID-19 vaccine demonstrated very high efficacy of the 2-dose regimen against symptomatic, laboratory-confirmed COVID-19. The overall efficacy was 95% (95% CI: 90.3%, 97.6%).

High certainty of evidence

- For hospitalization due to COVID-19, 5 events occurred, all in the placebo group. Vaccine effectiveness against hospitalization was 100% (95% CI: -9.9%, 100%).

Low certainty of evidence

- Deaths were uncommon, 2 in the vaccine group and 4 in the placebo group.

Very low certainty of evidence

Source: Oliver, S, 12/12/2020; Advisory Committee on Immunization Practice meetings available: https://www.cdc.gov/vaccines/acip/meetings/index.html. Accessed 12/12/2020.

ACIP Review of Evidence

Benefits and Harms:

Summary of the Available Evidence: Harms

- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (0.6% vs 0.5%).

Moderate certainty of evidence

- Severe reactions were more common in vaccinated; any grade ≥3 reaction was reported by 8.8% of vaccinated vs. 2.1% of placebo group.

High certainty of evidence

Source: Oliver, S, 12/12/2020; Advisory Committee on Immunization Practice meetings available: https://www.cdc.gov/vaccines/acip/meetings/index.html. Accessed 12/12/2020.

Local and Systemic Reactions

- Most common reactions similar to routine vaccines: sore arm, fatigue, headache, and muscle pain. Frequency of these effects in people younger than 55 include:
  - About 80 percent reported pain at injection site
  - About 50 percent reported fatigue and headache
  - Less than one-third (30 percent) reported muscle pain
- Most reactions occur within two days of getting the vaccine and last about a day
- More common among people 55 years or older than among those younger than 55
- More common after the second dose than the first dose

Vaccine Recommendations

ACIP Recommendations

- On December 12, 2020, ACIP recommended use of the Pfizer-BioNTech COVID-19 vaccine in persons 16 years of age and older under the FDA's Emergency Use Authorization

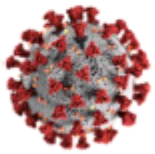
- ACIP recommends that when a COVID-19 vaccine is authorized by FDA and recommended by ACIP, that 1) health care personnel and 2) residents of long-term care facilities be offered vaccination in the initial phase of the COVID-19 vaccination program

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

BNT162b2 Vaccine

Proposed Indication:

Prevention of Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2



Individuals 16 years of age and older

DOSE LEVEL and REGIMEN	• 30 µg • 2 doses given greater than or equal to 21 days apart
PRESENTATION	• 5 dose multidose vial
*** **STORAGE**	• -80°C to -60°C • 5 days at 2°-8°C

Source: Gruber, W., 12/11/2020; Advisory Committee on Immunization Practice meetings available: https://www.cdc.gov/vaccines/acip/meetings/index.html. Accessed 12/13/2020.

Administration

- 2-dose series administered intramuscularly 3 weeks apart
- Administration of 2nd dose within 4-day grace period (e.g., day 17-21) considered valid
- If >21 days since 1st dose, 2nd dose should be administered at earliest opportunity (but no doses need to be repeated)
- Both doses are necessary for protection; efficacy of a single dose has not been systematically evaluated

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Interchangeability with other COVID-19 vaccine products

- Pfizer-BioNTech COVID-19 vaccine not interchangeable with other COVID-19 vaccine products
  - Safety and efficacy of a mixed series has not been evaluated
- Persons initiating series with Pfizer-BioNTech COVID-19 vaccine should complete series with same product
- If two doses of different mRNA COVID-19 vaccine products inadvertently administered, no additional doses of either vaccine recommended at this time
  - Recommendations may be updated as further information becomes available or additional vaccine types authorized

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Coadministration with other vaccines

- Pfizer-BioNTech COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines
  - Due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines

- If Pfizer-BioNTech COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Persons with a history of SARS-CoV-2 infection

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Data from phase 2/3 clinical trials suggest vaccination safe and likely efficacious in these persons

- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation
- No minimal interval between infection and vaccination
- However, current evidence suggests reinfection uncommon in the 90 days after initial infection, and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19

- Data not currently available to establish safety and efficacy of vaccine in these groups

- These individuals may still receive COVID-19 vaccine unless otherwise contraindicated

- Individuals should be counseled about:
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow all current guidance to protect themselves against COVID-19

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Reference: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Pregnant women

- There are no data on the safety of COVID-19 vaccines in pregnant women
  - Animal developmental and reproductive toxicity (DART) studies are ongoing
  - Studies in humans are ongoing and more planned

- mRNA vaccines and pregnancy
  - Not live vaccines
  - They are degraded quickly by normal cellular processes and don't enter the nucleus of the cell

- COVID-19 and pregnancy
  - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
  - Might be an increased risk of adverse pregnancy outcomes, such as preterm birth

- If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision.

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Reference: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

Pregnant women

- Considerations for vaccination:
  - level of COVID-19 community transmission (risk of acquisition)
  - her personal risk of contracting COVID-19 (by occupation or other activities)
  - the risks of COVID-19 to her and potential risks to the fetus
  - the efficacy of the vaccine
  - the known side effects of the vaccine
  - the lack of data about the vaccine during pregnancy

- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes

- Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended.

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Reference: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

Breastfeeding/Lactating women

- There are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion
- mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant
- If a lactating woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Reference: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

Reactogenicity

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
- Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19
- Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms
  - Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time, due to lack of information on impact of use on vaccine-induced antibody responses

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Contraindications and Precautions

- Severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine is a **contraindication**.
- CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination.
- In persons who report a history of anaphylaxis to another vaccine or injectable therapy, a risk assessment should be conducted to determine type of reaction. These persons may still receive vaccine, but counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.
- A history of mild allergic reaction to a vaccine or injectable therapy is **not** a contraindication or precaution.
- Allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications [including the oral equivalents of injectable medications]) are not a contraindication or precaution.
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs. Vaccine providers should observe patients with a history of anaphylaxis for 30 minutes after vaccination. All other persons should be observed for 15 minutes after vaccination.

www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html

Algorithm for the triage of persons presenting for Pfizer-COVID-19 vaccine

	PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** •Immunocompromising conditions •Pregnancy •Lactation **ACTIONS** •Additional counseling* •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 food, pet, insect, venom, environmental, latex, etc., allergies •History of allergy to oral medications (including the oral equivalent of an injectable medication) •Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) •Family history of anaphylaxis **ACTIONS** •15-minute observation period	**ALLERGIES** •History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine) •History of severe allergic reaction (e.g., anaphylaxis) to an injectable medication **ACTIONS:** •Risk assessment •Potential deferral of vaccination •30-minute observation period if vaccinated	**ALLERGIES** •History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine **ACTIONS** •Do not vaccinate

* See Special Populations section for information on patient counseling in these group

Source: www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf

Public health recommendations for vaccinated persons

- Protection from vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated

- No vaccine is 100% effective

- Given the currently limited information on how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts, vaccinated persons should continue to follow all current guidance to protect themselves and others, including:
  - Wearing a mask
  - Staying at least 6 feet away from others
  - Avoiding crowds
  - Washing hands often
  - Following CDC travel guidance
  - Following quarantine guidance after an exposure to someone with COVID-19
  - Following any applicable workplace or school guidance

https://www.cdc.gov/coronavirus/2019-ncov/index.html

Making a Strong Recommendation for COVID-19 Vaccination

1. Start from a place of empathy and understanding
2. Assume patients will want to be vaccinated but may not know when to expect it
3. Give a strong recommendation
   - Patients consistently rank healthcare providers as their most trusted source for vaccine information
   - Share the importance of COVID-19 vaccines to protect patients' health as well as the health of those around them
4. Listen to and respond to questions
5. Wrap up the conversation and let patients know you are open to continuing the conversation

Benefits of Getting Vaccinated

www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html

- COVID-19 vaccination will help keep you from getting infected
- Vaccination is a safer way to build immunity
  - COVID-19 can be serious and you can develop life-threatening complications
  - There is no way to know how the virus will affect you
- Vaccination is an important tool to help stop the pandemic in addition to current public health practices including wearing masks and social distancing

Storage and Handling

Resources:
Fact sheet for providers: www.fda.gov/media/144413/download
CDC Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Product Packaging Overview

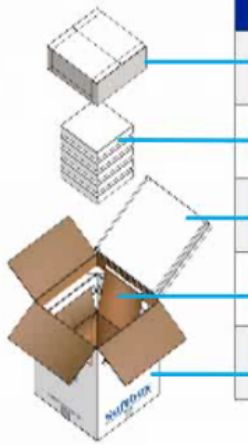
1 Primary Packaging

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

2 Secondary Packaging "Single Tray"

- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

3 Tertiary Container: Thermal Shipper



Item	Description
1	Dry Ice Pod
2	Payload (Vial Trays)
3	Inner Lid
4	Payload Sleeve
5	Outer Carton

- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT (-75±15°C) up to 10 days if stored at 15°C to 25°C temperatures without opening.
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice

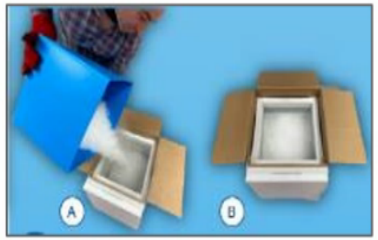
Pfizer BioNTech Vaccine Storage and Handling

1 Ultra-Low Temperature Freezer

- Store as frozen liquid at -75°C±15°C for long term storage.
  - Emergency Use vials are labeled as -70°C±10°C, however they can be safely stored in a freezer set to -75°C±15°C
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

2 Thermal Shipper Designed for Temporary Storage



- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Multiple dry ice replenishments possible; up to 3 re-icings.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper to be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice monitor

3 2 to 8°C Refrigerator

- Can be stored at 2 to 8°C up to 5 days
- Room temperature hold time is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

Vaccine Preparation and Administration

Point Of Use (POU)

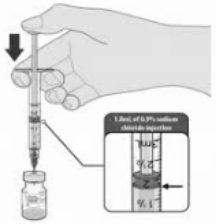
Removing the Vials to Thaw

From storage, **remove 1 vial for every 5 recipients** according to planned vaccinations schedule.

Vials may be stored in the refrigerator for 5 days (120 hours).

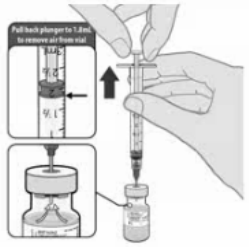
Dilute the Vaccine

Obtain 0.9% Sodium Chloride Injection, USP for use as a diluent
Do not use any alternate diluents.



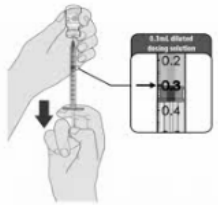
Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.

Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.

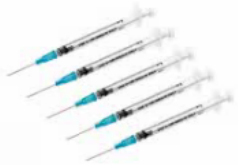


Preparing the Dose

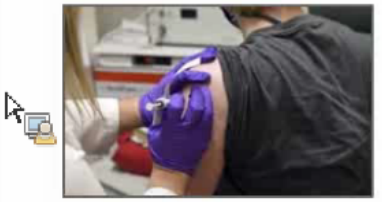
Draw up <u>0.3 mL</u> of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection.

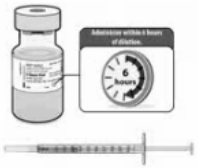


For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.



Vaccine Administration





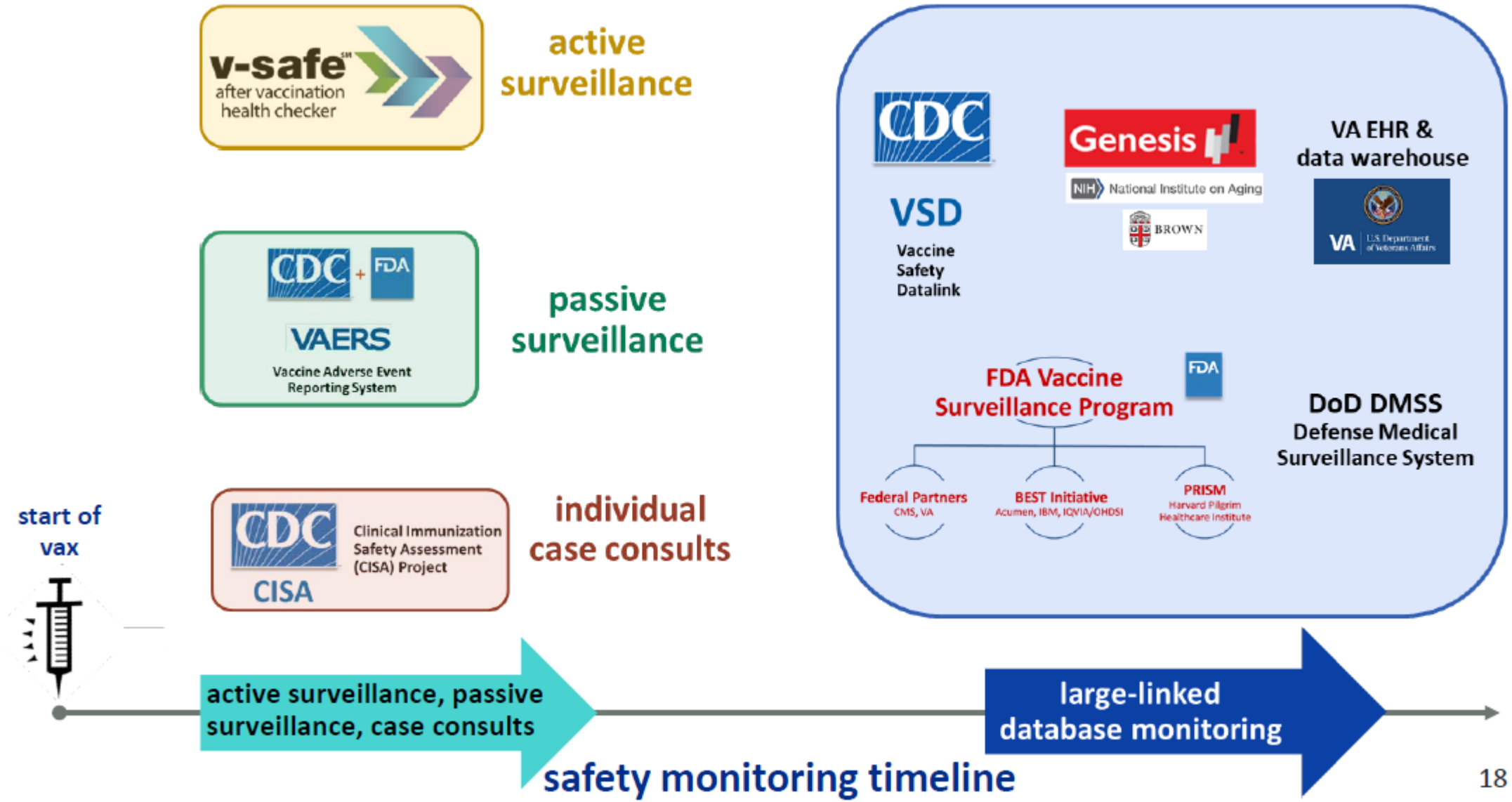
Pfizer BioNTech COVID-19 Vaccine 30 mcg/0.3 mL

Diluted vials must be used within 6 hours from the time of dilution and stored between 2°C to 25°C (35°F to 77°F).

A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.

21 DAYS

Vaccine Safety


v-safe
after vaccination health checker
active surveillance
CDC + FDA
VAERS
Vaccine Adverse Event Reporting System
passive surveillance
CDC
CISA
Clinical Immunization Safety Assessment (CISA) Project
individual case consults
CDC
VSD
Vaccine Safety Datalink
Genesis
NIH National Institute on Aging
BROWN
VA EHR & data warehouse
VA U.S. Department of Veterans Affairs
FDA Vaccine Surveillance Program
FDA
Federal Partners
CMS, VA
BEST Initiative
Acumen, IBM, IQVIA/OHDSI
PRISM
Harvard Pilgrim Healthcare Institute
DoD DMSS
Defense Medical Surveillance System
start of vax
active surveillance, passive surveillance, case consults
large-linked database monitoring
safety monitoring timeline
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Monitoring systems and populations

	Monitoring systems	Population	Healthcare workers	LTCF residents
early	**VAERS** (CDC & FDA) VA ADERS DoD VAECS CDC NHSN	General U.S. population, VA and DoD patient populations, NHSN acute care and long-term care facilities	Yes	Yes
early	**V-safe** (CDC)	All COVID-19 vaccine recipients eligible	Yes	Limited
later	**VSD** (CDC)	Insured patients in VSD sites	Yes	Limited
later	**FDA-CMS**	Medicare recipients (90+% of 65 y/o in the U.S., including 650K LTCF residents)	Limited	Yes
later	**BEST & PRISM** (FDA)	Insured patients in BEST & PRISM sites	Yes	Limited
later	**VA EHR & data warehouse**	Enrolled VA patients	Limited	Yes
later	**DoD DMSS**	Active duty military (limited info on beneficiaries [i.e., family members, retirees])	Yes	Limited
later	**Genesis HealthCare** (Brown U. & NIH-NIA)	Long-term care facility residents (~35,000 long stay residents)	No	Yes

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov

Get vaccinated.
Get your smartphone.
Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2pm local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act; and the Freedom of Information Act.

12/01/20

v-safe℠
after vaccination
health checker

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.

Sign up with your smartphone's browser at
vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

Role for Healthcare Leaders

COVID-19 vaccine safety gets stronger with your participation

Public health partners

- promote participation in **v-safe** ✓
- promote reporting to **VAERS** ✓
- communicate with your partners on vaccine safety ✓

Healthcare providers

- encourage patient participation in **v-safe** ✓
- report adverse events to **VAERS** ✓
- communicate with patients on vaccine safety ✓

Vaccine Distribution Timeline

Projected Timeline

Pfizer Vaccine

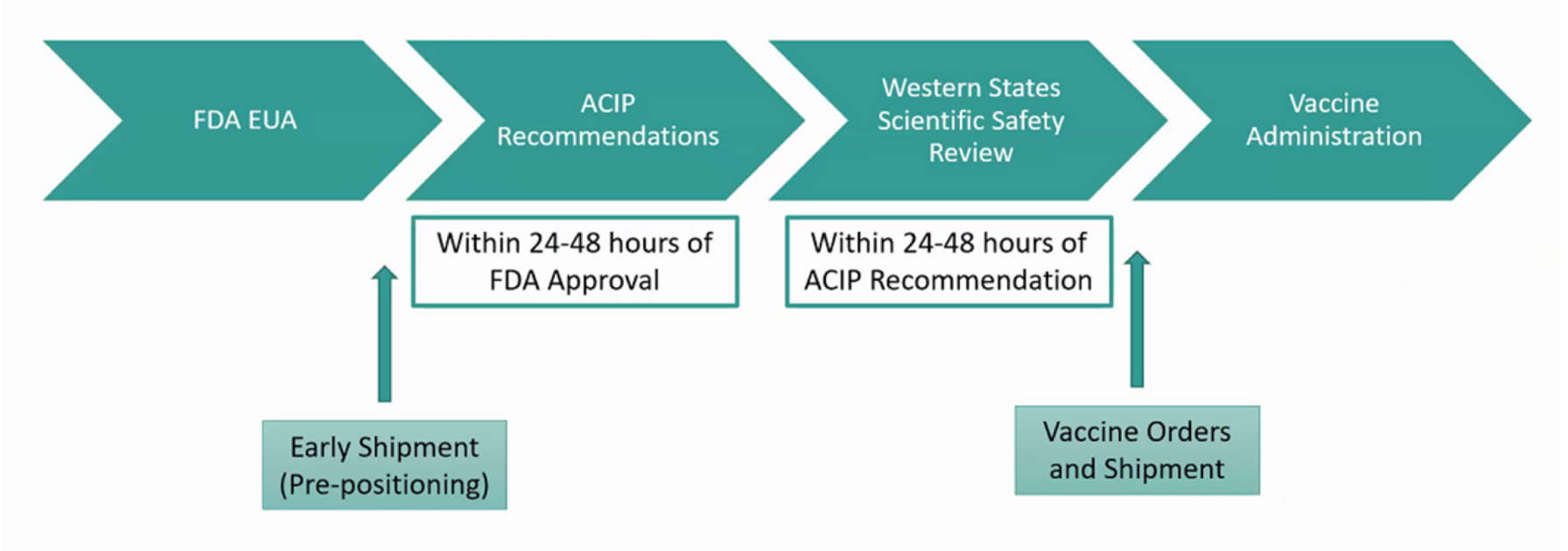
- November 20 - Pfizer submits Emergency Use Authorization (EUA) request
- December 10 - FDA's Vaccines and Related Biological Products Advisory Committee
- December 11 – ACIP meeting with Pfizer data/GRADE presented
- December 11 – FDA EUA decision
- December 12 – Western States Pact Scientific Safety Review
- December 12 – ACIP meeting with Pfizer vote
- December 14 – MMWR publication for Pfizer vaccine. GRADE/EtR tables and clinical considerations published.
- December 14 – Vaccine distribution to early ship sites & and ordering opens for others

Moderna Vaccine

- November 30 - Moderna submits Emergency Use Authorization (EUA) request
- December 17 - FDA's Vaccines and Related Biological Products Advisory Committee Review
- December 18 – ACIP meeting with Moderna data/GRADE presented
- December 19 – Possible FDA EUA decision
- December 20 – If EUA issued, then ACIP meeting with Moderna vote, allocation of phase 1b/c vote
- December 21 – Moderna MMWR published; Allocation of Phase 1b/c MMWR published.
- December 21-22 - Western States Pact Scientific Safety Review
- December 22 – Vaccine allocation availability for ordering and distribution

Western Pact: Independent review of vaccine safety

- WA, OR, NV, and CO joined California's Scientific Safety Review Workgroup
- Will independently review any COVID-19 vaccine approved by FDA
- Includes nationally-recognized scientists with expertise in immunizations and public health; Washington has 2 representatives on workgroup



Phase 1A COVID-19 Vaccine Allocation Guidance

- High-risk workers in health care settings
- High-risk first responders
- Residents and staff of nursing homes, assisted living facilities, and other community-based, congregate living settings where most individuals over 65 years of age are receiving care, supervision, or assistance

Link: WA State COVID-19 Vaccine Allocation Guidance for Phase 1A

CDC Provider Education Resources

- Different COVID-19 Vaccines | CDC
- Understanding COVID-19 mRNA Vaccines
- Ensuring COVID-19 Vaccines Work | CDC
- Facts about COVID-19 Vaccines
- How CDC Is Making COVID-19 Vaccine Recommendations | CDC
- Vaccine Education and Training for Healthcare Professionals | CDC
- COVID-19 Vaccination Resources
- Answering Patients' Questions
- Making a Strong Recommendation for COVID-19 Vaccination
- CDC toolkit for healthcare organizations

Additional Resources

- FDA COVID-19 Information
- Pfizer BioNTech Fact Sheet for Recipients and Caregivers
- Pfizer BioNTech Fact Sheet for healthcare providers
- ACIP recommendations
- DOH healthcare provider resources and recommendations
- Manufacturer vaccine training series:

Date & Time	Password
Attendee December 14, 2020 10:00 AM ET	jQxkNAZ5h97
Attendee December 14, 2020 5:00 PM ET	yyJM8HMbV23
Attendee December 15, 2020 10:00 AM ET	yyXXMHkY623
Attendee December 15, 2020 5:00 PM ET	cXQqYzTM352
Attendee December 16, 2020 10:00 AM ET	yDxuqt6Pg52
Attendee December 16, 2020 5:00 PM ET	auKMUdmJ687
Attendee December 17, 2020 10:00 AM ET	TMr7GvMc2P2
Attendee December 17, 2020 5:00 PM ET	PPxyyuGP249
Attendee December 18, 2020 10:00 AM ET	GawpMXB2X95
Attendee December 18, 2020 5:00 PM ET	w3kBrP9ReU3

Communication & Updates

- COVID Vaccine Email: COVID.Vaccine@doh.wa.gov
- Register for DOH COVID-19 Vaccine Partner Calls (first and third Tuesdays of each month from 9-10am): https://attendee.gotowebinar.com/register/1788685926669226507

Questions?

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.