Washington State Department of Health

COVID-19 VACCINE STORAGE &HANDLING AND VACCINE ADMINISTRATION WEBINAR

January 27, 2022

Before We Start…

- All participants will be muted for the presentation.
- You may ask questions using the Q&A box, and questions will be answered at the end of the presentation.
- Continuing education is available for nurses, medical assistants, pharmacists, and pharmacy technicians attending the webinar or watching the recording.
- If you're watching in a group setting and wish to claim CE credit, please make sure you register for the webinar and complete the evaluation as an individual.
- You can find more information on our webinar page.

Continuing Education

- The planners and speakers of this activity have no relevant financial relationships with any commercial interests pertaining to this activity.
- Information about obtaining CEs will be available at the end of this webinar.

COVID-19 Vaccine Storage and Handling

ANGELA BOYER, MPH

The information is current as of 1/25/2022

COVID-19 Vaccines

Pfizer:

Ages 5-11 (Orange Cap)

- 2-dose series separated by at least 21 days
- Minimum order: 100 doses (10-dose multidose vial)

Ages 12 years and older (Purple Cap)

- No longer available to order

Ages 12 years and older (Gray cap)

- 2-dose separated by at least 21 days
- Minimum order: 300 doses (6-dose multidose vial)

Pfizer-BioNTech COVID-19 Vaccine

- Vaccine will arrive at a temperature between -80°C and -60°C (-112°F to -76°F) in a thermal shipping container with dry ice.
  - Immediately unpack the thermal shipping container following the manufacturer's directions.
- Ancillary Kits are delivered separately from vaccine and include:
  - Mixing supplies: Diluent, needles, syringes, and sterile alcohol prep pads.
  - Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE.

Pfizer Vaccine

Description	Formulations		
	Dilute Prior to Use	*Do Not Dilute*	*Dilute Prior to Use*
Age Group	12 years and older	12 years and older	5 to <12 years*
Vial Cap Color	PURPLE 	GRAY (Coming soon) 	ORANGE 
Dose	30 mcg	30 mcg	10 mcg
Injection Volume	0.3 mL	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	2.25 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)
Storage Conditions			
ULT Freezer (-90°C to -60°C)	9 months	9 months	9 months
Freezer (-25°C to -15°C)	2 weeks	N/A	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks	10 weeks

Pfizer Expiration

- Some of the Pfizer vaccine was sent out with the incorrect expiration date printed on the box
- The correct expiration for Pfizer Grey and Orange cap is 9 months from the manufacture date, as seen below
- The CDC has created a the COVID-19 Vaccine Lot Number and Expiration Date Report

Printed Manufacturing Date	9-Month Expiry Date*
06/2021	Feb. 28, 2022
07/2021	Mar. 31, 2022
08/2021	Apr. 30, 2022
09/2021	May 31, 2022
10/2021	Jun. 30, 2022
11/2021	July. 31, 2022
12/2021	Aug. 31, 2022
01/2022	Sept. 30, 2022
02/2022	Oct. 31, 2022

Pfizer-BioNTech COVID-19 Vaccine (Gray cap and Orange cap)

Storage Details:

- Store in the original carton to protect from light.
- Ultra-Cold Freezer
  - Between -80°C and -60°C (-112°F and -76°F)
  - 9 months
- Freezer
  - **Do NOT store or transport at standard freezer temperatures**
- Refrigerator
  - Between 2°C and 8°C (36°F and 46°F)
  - Store for up to 10 weeks

Pfizer-BioNTech COVID-19 Vaccine (Gray and Orange Cap)

Thawed Doses:

- Avoid exposure to direct sunlight and ultraviolet light.
- Do not refreeze once thawed.
- Thawed under refrigeration at 2°C to 8°C (35°F to 46°F)
  - A carton of 10 vials will take up to 4 hours to thaw.
  - Undiluted vials may be stored in refrigeration for up to 31 days.
- Thawed at room temperature at up to 25°C (77°F)
  - Will take approximately 30 minutes to thaw.
  - Undiluted vials may be stored at room temperature for no more than 12 hours.
- Discard any unused vaccine 12 hours after dilution (orange cap)
- Discard any vaccine 12 hours after puncture (gray cap)

COVID-19 Vaccines

Moderna:

- 2-dose series separated by at least 28 days
- 18 years of age and older
- Minimum order: 100 doses (10-dose multidose vial)

Janssen (Johnson & Johnson):

- Single dose
- 18 years and older
- Minimum order: 100 doses (10-dose multidose vial)

Moderna COVID-19 Vaccine

Vaccine will arrive frozen between -50°C and -15°C (-58°F and 5°F)

Immediately unpack the vaccine shipment following the manufacturer's directions.

Ancillary Kits are delivered separately from vaccine and includes:

- Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE.

Moderna COVID-19 Vaccine

Thawed Doses:

- Thawed vials can be handled in room light conditions.
- Do not refreeze once thawed.
- Thawed under refrigeration between 2°C and 8°C (36°F and 46°F)
  - Will take approximately 2 hours and 30 minutes to thaw.
  - May be stored for up to 30 days.
  - Let each vial stand at room temperature for 15 minutes before administering.

Moderna COVID-19 Vaccine

Thawed Doses (continued):

- Thawed at room temperature between 15°C and 25°C (59°F and 77°F)
  - Will take approximately 1 hour to thaw.
  - May be stored at room temperature for a total of 24 hours.
- After the first dose has been withdrawn, the vial should be held between 2°C and 25°C (36°F and 77°F).
- Vials should be discarded 12 hours after the first puncture.

Moderna COVID-19 Vaccine

Storage Details:

- Store in the original carton to protect from light.
- Freezer
  - Between -50°C and -15°C (-58° and 5°F)
  - Vaccine may be stored until the expiration date.
- Refrigerator
  - Between 2°C and 8°C (36°F and 46°F)
  - Store for up to 30 days
- Room Temperature
  - Between 8°C and 25°C (46° and 77°F)
  - Store for up to 24 hours.

Janssen (Johnson & Johnson) COVID-19 Vaccine

Storage Details:

- Store in the original carton to protect from light.
- Do not store frozen.
- Refrigerator
  - Between 2°C and 8°C (36°F and 46°F).
  - Unpunctured vials may be stored until the expiration date.
  - After puncturing the multidose vial seal, store for up to 6 hours.
- Room temperature
  - Between 9°C and 25°C (47°F and 77°F).
  - Unpunctured vials may be stored for up to 12 hours.
  - After puncturing the multidose vial seal, store for up to 2 hours.

Janssen (Johnson & Johnson) COVID-19 Vaccine

Vaccine will arrive at a refrigerated temperature of 2°C to 8°C (36°F and 46°F).

Immediately unpack the vaccine shipment following the manufacturer's directions.

Ancillary Kits are delivered separately from vaccine and includes:

- Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE.

Co-Administration of Vaccine

- The Department is excited providers are taking the opportunity to administer publicly supplied vaccines along with the COVID-19 vaccine
- All facilities must ensure appropriate paperwork is completed for each vaccine program prior to the clinic occurring
- Must have the appropriate pack outs and equipment for transporting and monitoring vaccine

COVID-19 Vaccine Storage Equipment

Equipment requirements for the COVID-19 Vaccine Program:

- Purpose-built, pharmaceutical grade, or stand-alone refrigerator(s), freezer(s) or ultra-cold freezer(s)

Thermometer Requirements

Approved DDLs	Examples
Fridge/Freezer	Accucold https://www.accucold.com/temperature-monitoring AeroScout: https://www.stanleyhealthcare.com/en-me/products/vfc-300-wi-fi-data-logger American BioTech Supply: https://americanbiotechsupply.com/accessories/temperature-monitoring-devices InTemp Bluetooth Temperature with Glycol Bottle (Logistics) Data Logger (CX402-Txxx) FisherbrandTraceable Excursion-Trac Datalogging Thermometers:Dataloggers | Fisher Scientific (purchase units with bottle probes, not stainless-steal probes)
Ultra-Cold	InTemp CX405 RTD Dry Ice Data Logger (CX405) Fisherbrand™ Traceable™ Excursion-Trac™ Ultra-Low Temperature

COVID-19 Vaccine Transport Equipment

- Ensure it is meant to transport vaccine
- Can be a portable refrigerator/freezer or qualified pack out
- Use a temperature monitoring device
- Contact us with questions

COVID Vaccine Transport Requirements

If transfer of vaccine is needed, the following process must be completed prior to the first vaccines being transported.

- Complete the CDC Redistribution Agreement.
- Complete a COVID-19 Vaccine Transfer Request in IIS at least 24 hours before each intended movement of vaccine
- Ensure receiving provider is enrolled and approved as a COVID-19 vaccine provider with Department of Health
- Ensure that the receiving facility is within 1 hour drive of the distributing facility

Storage & Handling for Transport

- Examples of approved packouts:
  - C Safe Global https://csafeglobal.com/
  - MaxQ https://www.packmaxq.com/post/maxq-launches-new-maxplus-vaccine-cooler
  - TempArmour Vaccine Carrier https://www.temparmour.com/vaccine_carrier
  - TempTrust Extreme https://blog.mesalabs.com/blog/revolutionary-temptrust-extreme-168-hour-qualified-packaging
  - Vericor https://www.vericormed.com/
  - Cordova Cooler https://shop.cordovaoutdoors.com/20-qt-sidekick/

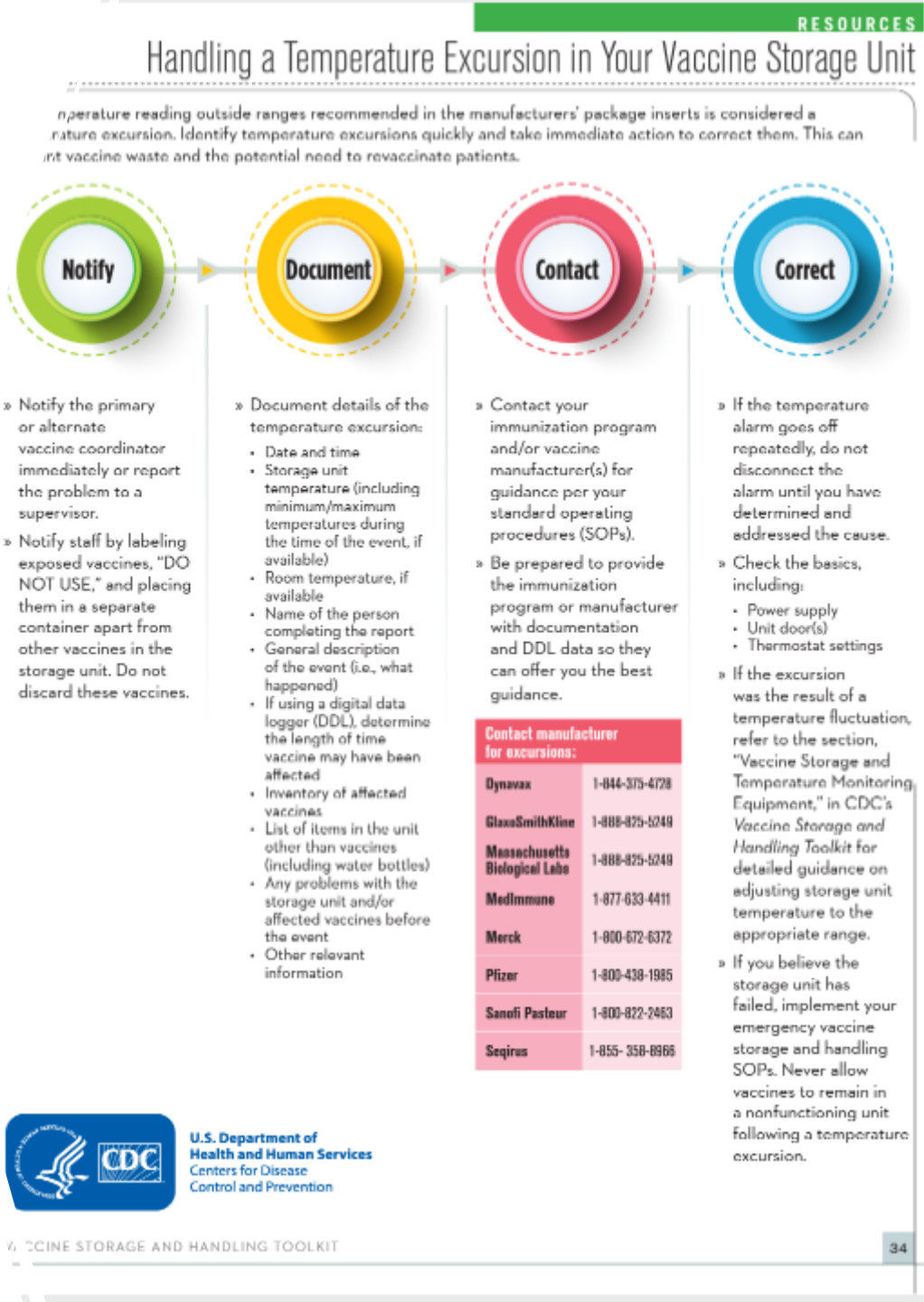
General Transport System Recommendations	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System*	Yes	No
Manufacturer's Original Shipping Container	Yes (as a last resort)	No
Hard-sided Cooler*	Yes	No

Storage & Handling for Transport Cont'd

	Transport Temp Before Puncture	Transport temp after puncture
Pfizer Peds (Orange cap and Gray cap)	• Tray containing vaccine vials between -90°C and -60°C • Individual vials between 2°C and 8°C	Not recommended
Moderna	• 50°C and -15°C or 2°C and 8°C (36°F and 46°F) for up to 12 cumulative hours, once or multiple times	2°C and 25°C for up to 12 hours.
Janssen	2°C and 8°C	2°C and 8°C for up to 6 hours

COVID Vaccine Temperature Excursion

- COVID-19 Vaccine providers follow the same steps for handling temperature excursions.
  - Exception: COVID-19 vaccine cannot be returned. Providers should dispose of vaccine waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste.
  - For more information: [COVID-19 Vaccine Temperature Excursion Guide]



RESOURCES

Handling a Temperature Excursion in Your Vaccine Storage Unit

…perature reading outside ranges recommended in the manufacturers' package inserts is considered a …rature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can …nt vaccine waste and the potential need to revaccinate patients.

Notify

» Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.

» Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document

» Document details of the temperature excursion:

- Date and time
- Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
- Room temperature, if available
- Name of the person completing the report
- General description of the event (i.e., what happened)
- If using a digital data logger (DDL), determine the length of time vaccine may have been affected
- Inventory of affected vaccines
- List of items in the unit other than vaccines (including water bottles)
- Any problems with the storage unit and/or affected vaccines before the event
- Other relevant information

Contact

» Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).

» Be prepared to provide the immunization program or manufacturer with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:	
Dynavax	1-844-375-4728
GlaxoSmithKline	1-888-825-5249
Massachusetts Biological Labs	1-888-825-5249
MedImmune	1-877-633-4411
Merck	1-800-672-6372
Pfizer	1-800-438-1985
Sanofi Pasteur	1-800-822-2463
Seqirus	1-855- 358-8966

Correct

» If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.

» Check the basics, including:

- Power supply
- Unit door(s)
- Thermostat settings

» If the excursion was the result of a temperature fluctuation, refer to the section, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's *Vaccine Storage and Handling Toolkit* for detailed guidance on adjusting storage unit temperature to the appropriate range.

» If you believe the storage unit has failed, implement your emergency vaccine storage and handling SOPs. Never allow vaccines to remain in a nonfunctioning unit following a temperature excursion.

CDC U.S. Department of Health and Human Services Centers for Disease Control and Prevention

…CCINE STORAGE AND HANDLING TOOLKIT 34

Reducing Vaccine Waste

Tips to Reduce Waste

- Follow your emergency vaccine use plan if you need to quickly administer doses of vaccine that would otherwise be wasted.
- Contact the Department of Health at covid.vaccine@doh.wa.gov if you have a large number of vials that you can't use before the expiration date.
- For more information, see these tips on how to reduce COVID-19 vaccine waste (PDF).
- Ensure that your facility is reconciling inventory in the IIS

Vaccine Advertisement Page

- As a reminder, the department continues to encourage providers to use the Vaccine Advertisement Page within the Immunization Information System (IIS)
- This resource allows providers to post any excess doses providers may have on had and allows for providers to request for a transfer of vaccine in a quantity smaller than the minimum package size
- COVID-19 Vaccine Depots are also an option for providers to acquire vaccine in a smaller quantity; dosed available for transfer will also be posted on the Vaccine Advertisement Page

Resources Expiration Extensions

- CDC has created a the COVID-19 Vaccine Lot Number and Expiration Date Report
- This report will provide LOT number, and correct expiration dates to include any extensions that have been granted to the specific LOT number
- This report includes information for Moderna, Janssen and Pfizer
- Access to this database requires individuals to register, and is only accessible to public health, healthcare, and pharmacy organizations

Contact Information

	Pfizer-BioNTech	Moderna	Janssen
Authorizations and Approvals	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
CDC Vaccine Information	www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
Manufacturer Contact Information	**Website:** www.cvdvaccine.com **Medical information:** 800-438-1985 **Customer service:** 800-879-3477	**Website:** www.modernatx.com **Medical Information:** 866-663-3762	**Website:** www.vaxcheck.jnj **Medical information:** 800-565-4008

https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf

Resources

- Thermometer Requirements and Temperature Monitoring Guide
- COVID-19 Vaccine Management page
  - https://www.doh.wa.gov/Emergencies/COVID19/HealthcareProviders/VaccineInformationforHealthcareProviders/Management

COVID-19 Resources

Emergency Use Authorization (EUA):

- Janssen COVID-19 Vaccine (Johnson & Johnson)
- Moderna COVID-19 Vaccine
- Pfizer-BioNTech COVID-19 Vaccine

CDC Storage and Handling Toolkit

For any COVID-related storage and handling questions, please email covid.vaccine@doh.wa.gov.

COVID-19 Vaccine Program Communication

- COVID-19 Vaccine Partner Newsletter – sent out weekly.
- COVID-19 Vaccine Partner Meeting – 1st and 3rd Tuesday.
  - To register for either of these, email covid.vaccine@doh.wa.gov

COVID-19 Vaccine Information for Health Care Providers webpage:

- Includes instructions for providers on enrolling in the COVID-19 Vaccine Program and reporting requirements.
- COVID-19 vaccine toolkit and resources for enrolled providers.
- Information on vaccines, including vaccine administration, vaccine management and vaccine safety.

COVID-19 Vaccine webpage:

- General vaccine information including a vaccine locator, the safety and efficacy of the vaccine, frequently asked questions and more.

Questions?

Angela Boyer, MPH
COVID-19 Vaccine Storage &Handling Specialist
angela.boyer@doh.wa.gov

COVID-19 Vaccination Program Main Contact Information
covid.vaccine@doh.wa.gov

COVID-19 Vaccine Administration and Boosters

KRISTINA BARNES, MSN, MN, RN

Terms

- **Primary Series**
  - 2-dose series of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) or a single dose of Janssen vaccine
- **Additional Primary Dose**
  - A subsequent dose of vaccine administered to people who likely did not mount a protective immune response after initial vaccination. An additional primary mRNA COVID-19 vaccine dose is recommended for moderately or severely immunocompromised people who received a 2-dose mRNA vaccine primary series.
- **Booster Dose**
  - A subsequent dose of vaccine administered to enhance or restore protection by the primary vaccination which might have waned over time.
- **Homologous Booster Dose**
  - The same vaccine product used for the booster dose as was administered for the primary series
- **Heterologous Booster Dose**
  - The vaccine product used for the booster dose differs from the product administered for the primary series

Primary and Additional Doses

Vaccine Manufacturer	Age Indication	Vial Cap Color denoting formulation	Dose	Injection Volume	Number of Doses in primary series (interval between doses	Additional Primary Dose in Immunocompromised People (interval since second dose)
Pfizer BioNTech	5-11 years	Orange	10 mcg	0.2 ml	2 (21 days)	1 (≥ 28 days)
Pfizer BioNTech	≥ 12 years	Purple or Gray	30 mcg	0.3 ml	2 (21 days)	1 (≥ 28 days)
Moderna	≥ 18 years	Not applicable	100 mcg	0.5 ml	2 (28 days)	1 (≥ 28 days)
Janssen (Johnson & Johnson)	≥ 18 years	Not applicable	$5x10^{10}$ viral particles	0.5 ml	1 (Not applicable)	Not Applicable

Booster Doses

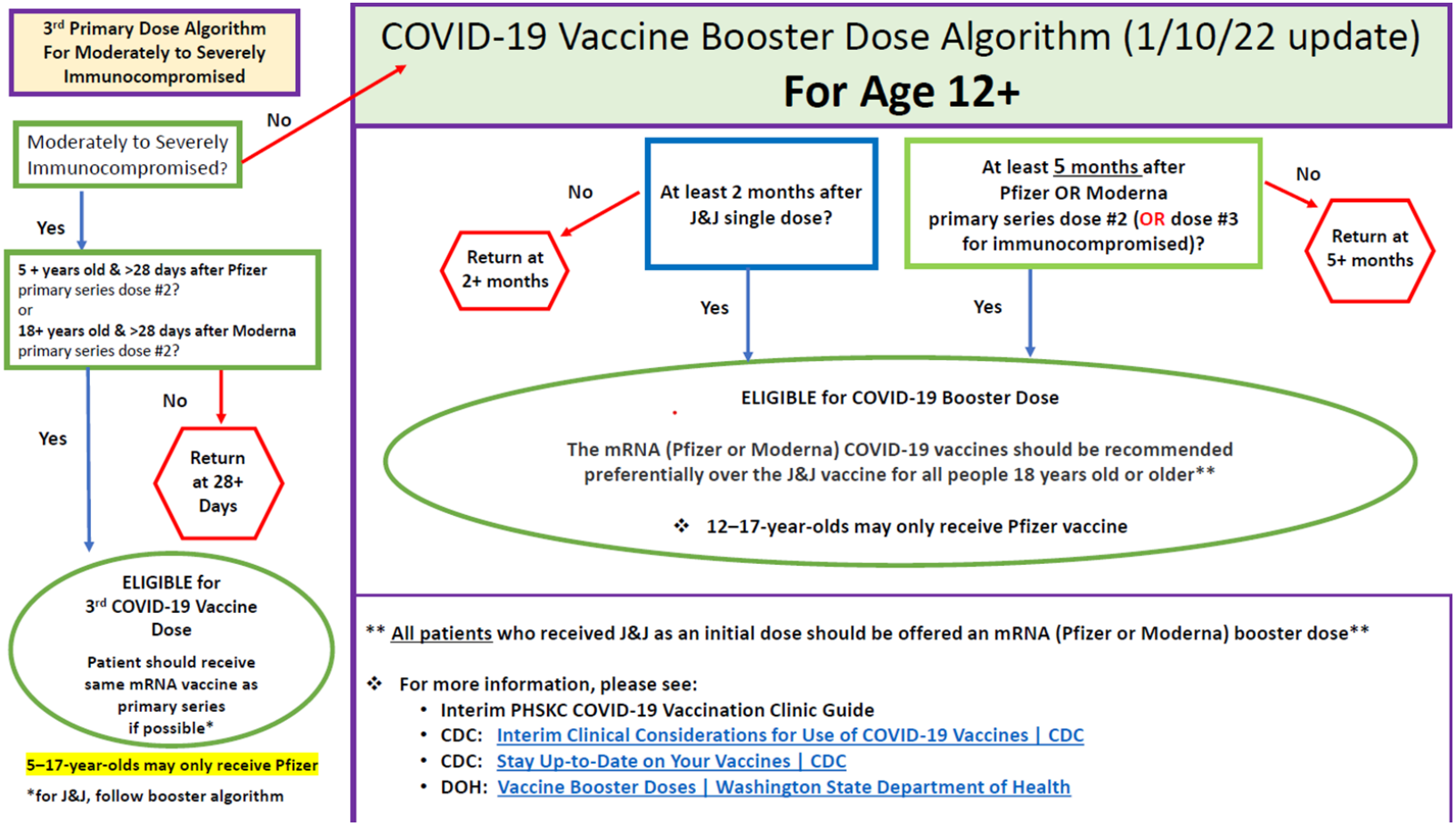
Type of Vaccine Received	Who Should Get a Booster	When to Get a Booster	Which Booster You Can Get
Pfizer-BioNTech	Everyone aged 12 years and older	At least 5 months after completing your primary COVID-19 vaccination series	• Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations • Teens aged 12-17 years may only get a Pfizer-BioNTech COVID-19 vaccine booster
Moderna	Adults aged 18 years and older	At least 5 months after completing your primary COVID-19 vaccination series	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations
Johnson & Johnson's Janssen	Adults aged 18 years and older	At least 2 months after receiving your J&J/Janssen COVID-19 vaccination	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most* situations

Immunocompromised individuals

An additional (third) dose for immunocompromised patients, given at least 28 days after their second dose to improve their immune response. These patients may also get a booster dose at least 5 months after completing their third mRNA vaccine dose

https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/VaccineBoosterDoses,
https://www.doh.wa.gov/Emergencies/COVID19/HealthcareProviders/VaccineInformationforHealthcareProviders/AbouttheVaccines

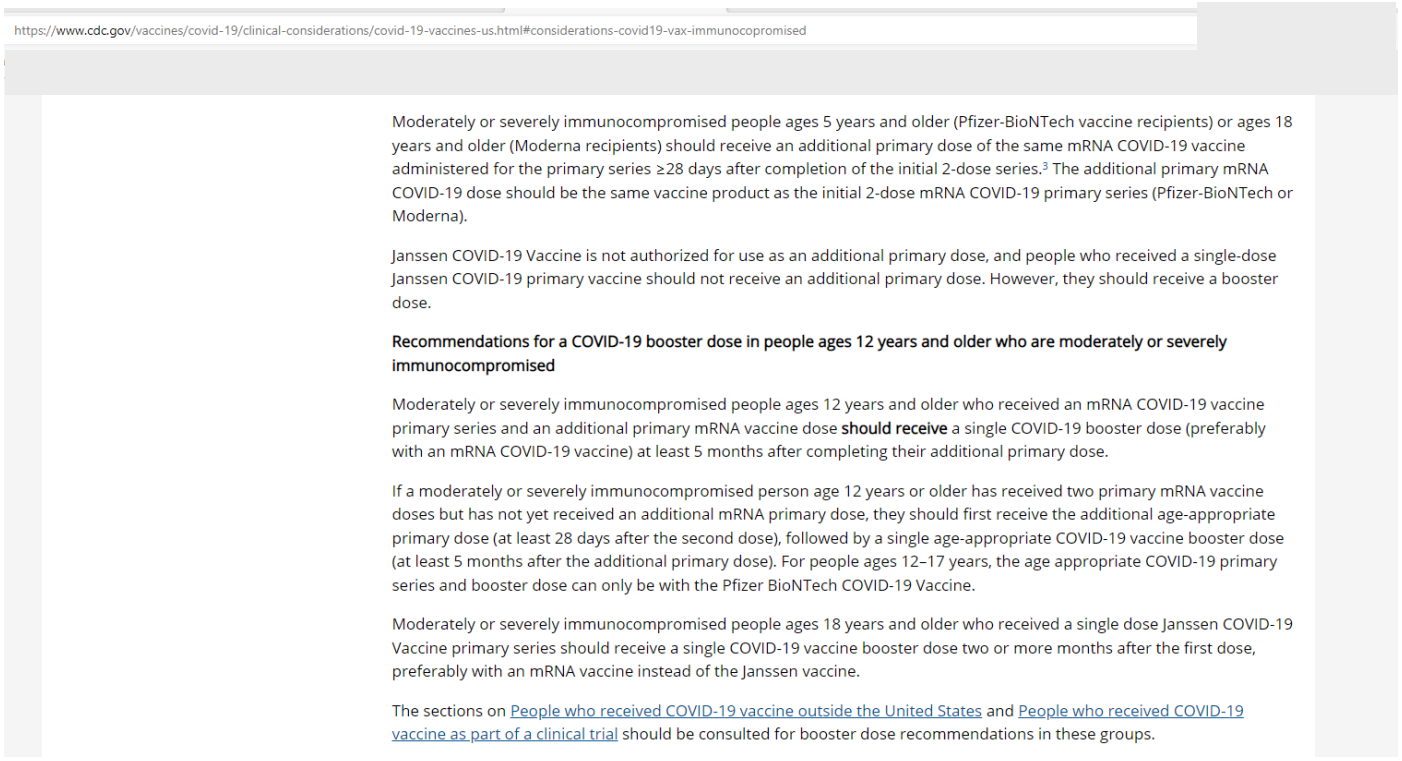
Booster Dose Algorithm



Case Study Booster Doses

- The client is a 48-year-old who reports having and immunocompromising health condition. She received Pfizer doses on 1 June 2021, 28 June 2021, and 30 July 2021. Is she eligible for a booster dose?

Solution



https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-immunocopromised

Moderately or severely immunocompromised people ages 5 years and older (Pfizer-BioNTech vaccine recipients) or ages 18 years and older (Moderna recipients) should receive an additional primary dose of the same mRNA COVID-19 vaccine administered for the primary series ≥28 days after completion of the initial 2-dose series.[3] The additional primary mRNA COVID-19 dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary series (Pfizer-BioNTech or Moderna).

Janssen COVID-19 Vaccine is not authorized for use as an additional primary dose, and people who received a single-dose Janssen COVID-19 primary vaccine should not receive an additional primary dose. However, they should receive a booster dose.

Recommendations for a COVID-19 booster dose in people ages 12 years and older who are moderately or severely immunocompromised

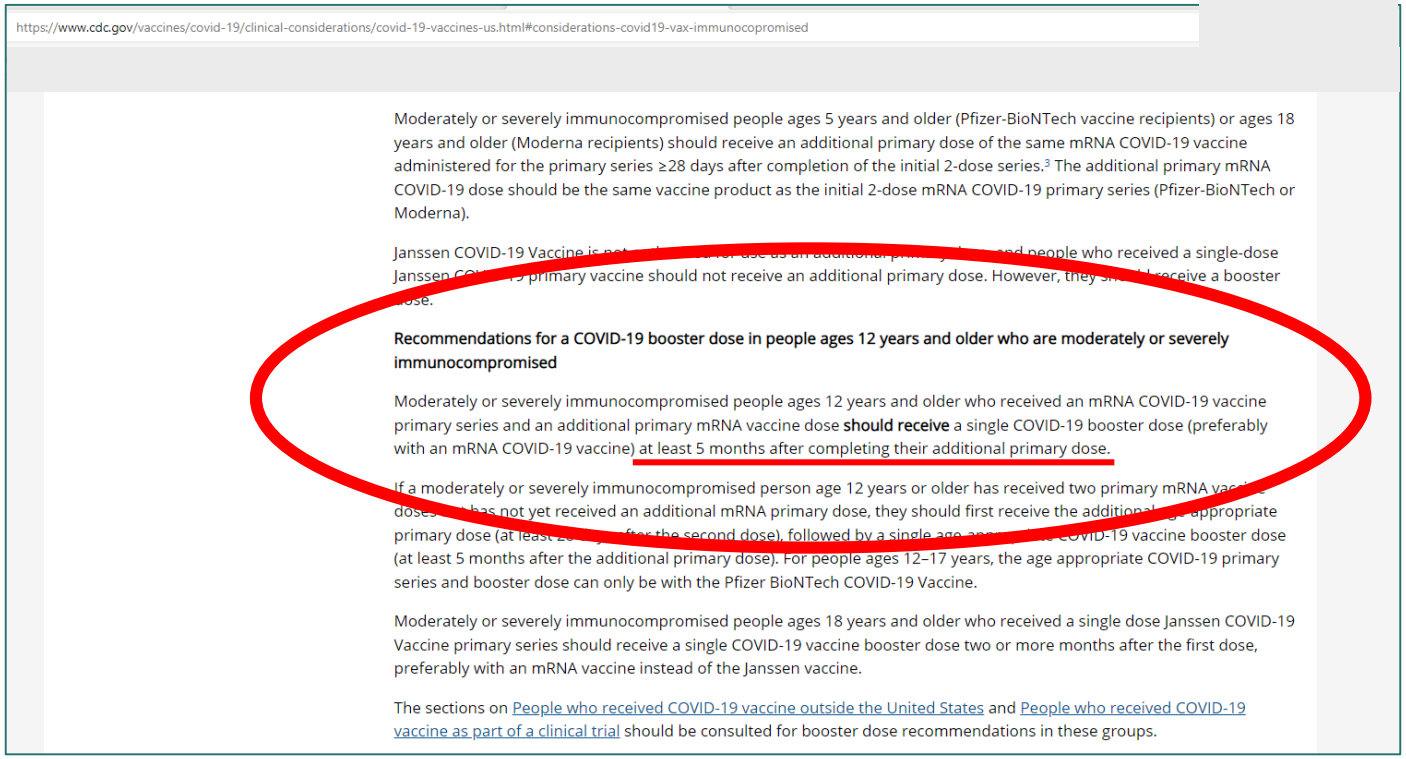
Moderately or severely immunocompromised people ages 12 years and older who received an mRNA COVID-19 vaccine primary series and an additional primary mRNA vaccine dose **should receive** a single COVID-19 booster dose (preferably with an mRNA COVID-19 vaccine) at least 5 months after completing their additional primary dose.

If a moderately or severely immunocompromised person age 12 years or older has received two primary mRNA vaccine doses but has not yet received an additional mRNA primary dose, they should first receive the additional age-appropriate primary dose (at least 28 days after the second dose), followed by a single age-appropriate COVID-19 vaccine booster dose (at least 5 months after the additional primary dose). For people ages 12–17 years, the age appropriate COVID-19 primary series and booster dose can only be with the Pfizer BioNTech COVID-19 Vaccine.

Moderately or severely immunocompromised people ages 18 years and older who received a single dose Janssen COVID-19 Vaccine primary series should receive a single COVID-19 vaccine booster dose two or more months after the first dose, preferably with an mRNA vaccine instead of the Janssen vaccine.

The sections on People who received COVID-19 vaccine outside the United States and People who received COVID-19 vaccine as part of a clinical trial should be consulted for booster dose recommendations in these groups.

Solution



https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-immunocopromised

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Janssen COVID-19 Vaccine is not [illegible] for use as an additional primary [illegible] and people who received a single-dose Janssen COVID-19 primary vaccine should not receive an additional primary dose. However, they should receive a booster dose.

Recommendations for a COVID-19 booster dose in people ages 12 years and older who are moderately or severely immunocompromised

Moderately or severely immunocompromised people ages 12 years and older who received an mRNA COVID-19 vaccine primary series and an additional primary mRNA vaccine dose **should receive** a single COVID-19 booster dose (preferably with an mRNA COVID-19 vaccine) at least 5 months after completing their additional primary dose.

If a moderately or severely immunocompromised person age 12 years or older has received two primary mRNA vaccine doses but has not yet received an additional mRNA primary dose, they should first receive the additional age appropriate primary dose (at least 28 days after the second dose), followed by a single age appropriate COVID-19 vaccine booster dose (at least 5 months after the additional primary dose). For people ages 12–17 years, the age appropriate COVID-19 primary series and booster dose can only be with the Pfizer BioNTech COVID-19 Vaccine.

Moderately or severely immunocompromised people ages 18 years and older who received a single dose Janssen COVID-19 Vaccine primary series should receive a single COVID-19 vaccine booster dose two or more months after the first dose, preferably with an mRNA vaccine instead of the Janssen vaccine.

The sections on People who received COVID-19 vaccine outside the United States and People who received COVID-19 vaccine as part of a clinical trial should be consulted for booster dose recommendations in these groups.

Moderna Booster Considerations

- Be aware, each Moderna vial may only be punctured a maximum of 20 times.
  - Consider batching syringes in quantities of 20 to ensure adherence to this safety requirement.
- Syringe size
  - Recently, some syringe packs have been distributed with 1 ml syringes that have hash marks every 0.02 ml instead of 0.01 ml. These should not be used for Moderna boosters because the syringe does not have a corresponding hash mark at the 0.25 ml dose.

Boosters after Vaccination Outside the United States

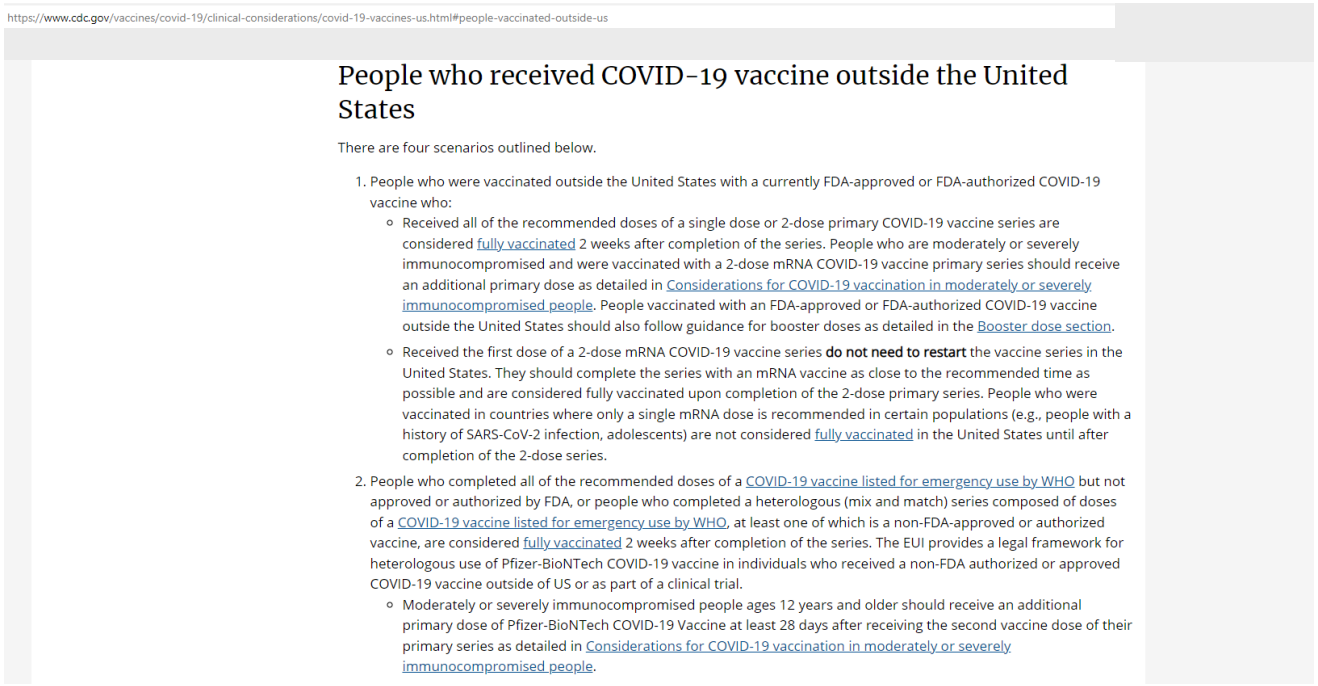
- CDC issued EUI for use of Pfizer BioNTech COVID-19 Vaccine
- EUI Recommends Pfizer booster for those completing series outside U.S. that was non-FDA authorized/approved
- EUI recommends booster for those completing series through clinical trials of non-FDA approved/authorized vaccine
- If the individual has not completed the series of WHO EUL COVID-19 vaccinations, they should be offered an mRNA vaccine to complete the series

Name	FDA Approved	WHO EUL
Pfizer/Comirnaty	Yes	Yes
Moderna	Yes	Yes
Janssen (J&J)	Yes	Yes
AstraZeneca	No	Yes
Covishield	No	Yes
SinoPharm	No	Yes
Sinovac	No	Yes
Covaxin	No	Yes

Case Study International Vaccination

- While staying in Belgium, your client had received two doses of Astra Zeneca at the EU recommended intervals and is requesting a booster dose. Do you provide a booster, and which one?

Solution



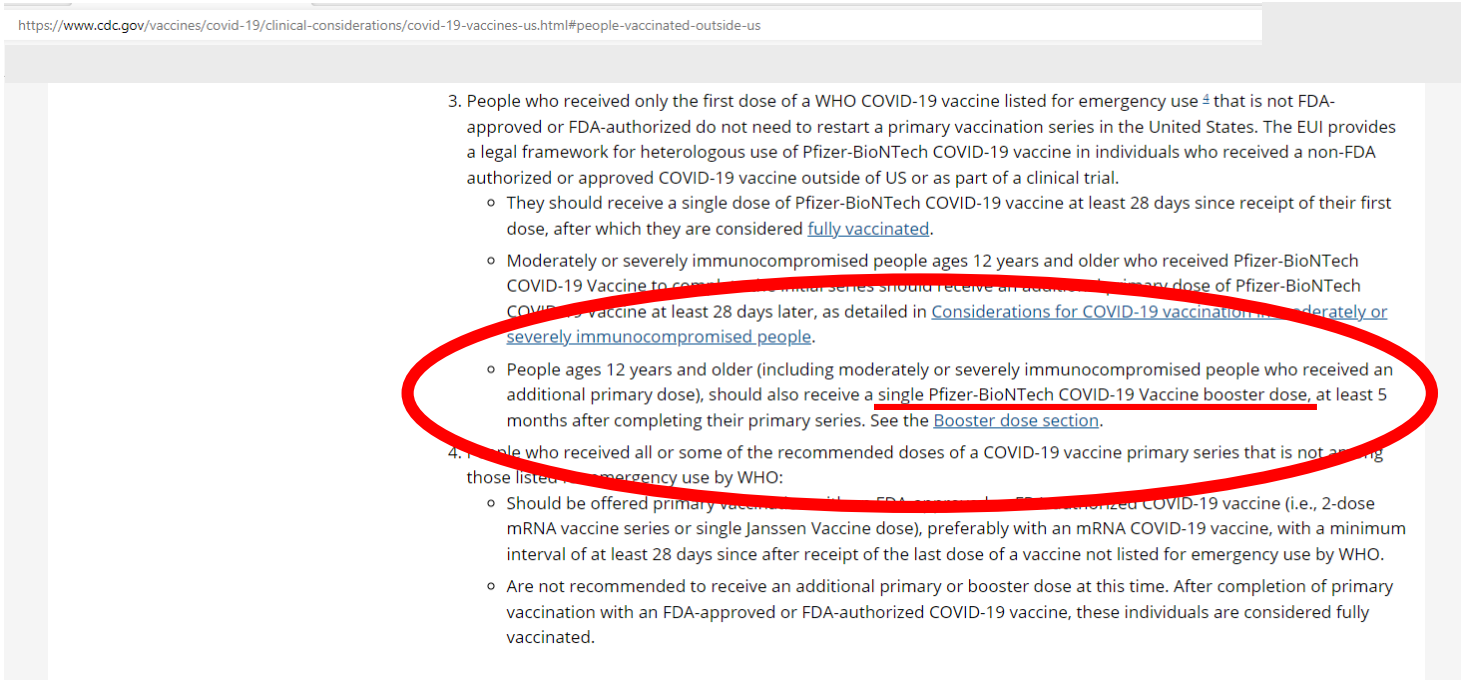
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us

People who received COVID-19 vaccine outside the United States

There are four scenarios outlined below.

1. People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine who:
   - Received all of the recommended doses of a single dose or 2-dose primary COVID-19 vaccine series are considered fully vaccinated 2 weeks after completion of the series. People who are moderately or severely immunocompromised and were vaccinated with a 2-dose mRNA COVID-19 vaccine primary series should receive an additional primary dose as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people. People vaccinated with an FDA-approved or FDA-authorized COVID-19 vaccine outside the United States should also follow guidance for booster doses as detailed in the Booster dose section.
   - Received the first dose of a 2-dose mRNA COVID-19 vaccine series **do not need to restart** the vaccine series in the United States. They should complete the series with an mRNA vaccine as close to the recommended time as possible and are considered fully vaccinated upon completion of the 2-dose primary series. People who were vaccinated in countries where only a single mRNA dose is recommended in certain populations (e.g., people with a history of SARS-CoV-2 infection, adolescents) are not considered fully vaccinated in the United States until after completion of the 2-dose series.
2. People who completed all of the recommended doses of a COVID-19 vaccine listed for emergency use by WHO but not approved or authorized by FDA, or people who completed a heterologous (mix and match) series composed of doses of a COVID-19 vaccine listed for emergency use by WHO, at least one of which is a non-FDA-approved or authorized vaccine, are considered fully vaccinated 2 weeks after completion of the series. The EUI provides a legal framework for heterologous use of Pfizer-BioNTech COVID-19 vaccine in individuals who received a non-FDA authorized or approved COVID-19 vaccine outside of US or as part of a clinical trial.
   - Moderately or severely immunocompromised people ages 12 years and older should receive an additional primary dose of Pfizer-BioNTech COVID-19 Vaccine at least 28 days after receiving the second vaccine dose of their primary series as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people.

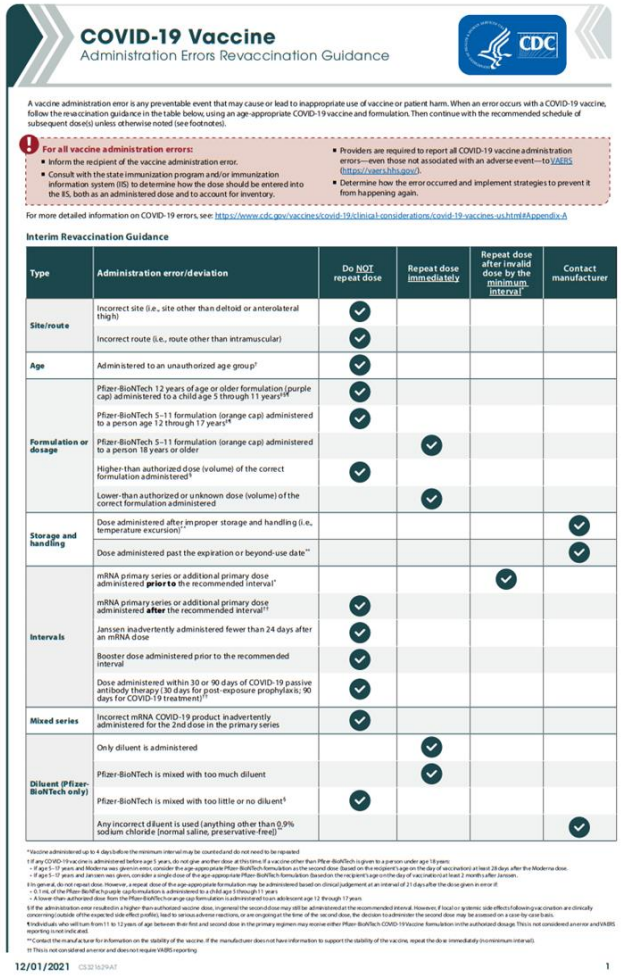
Solution


https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us

3. People who received only the first dose of a WHO COVID-19 vaccine listed for emergency use [4] that is not FDA-approved or FDA-authorized do not need to restart a primary vaccination series in the United States. The EUI provides a legal framework for heterologous use of Pfizer-BioNTech COVID-19 vaccine in individuals who received a non-FDA authorized or approved COVID-19 vaccine outside of US or as part of a clinical trial.
    - They should receive a single dose of Pfizer-BioNTech COVID-19 vaccine at least 28 days since receipt of their first dose, after which they are considered fully vaccinated.
    - Moderately or severely immunocompromised people ages 12 years and older who received Pfizer-BioNTech COVID-19 Vaccine to complete initial series should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine at least 28 days later, as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people.
    - People ages 12 years and older (including moderately or severely immunocompromised people who received an additional primary dose), should also receive a single Pfizer-BioNTech COVID-19 Vaccine booster dose, at least 5 months after completing their primary series. See the Booster dose section.
4. People who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not among those listed for emergency use by WHO:
    - Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., 2-dose mRNA vaccine series or single Janssen Vaccine dose), preferably with an mRNA COVID-19 vaccine, with a minimum interval of at least 28 days since receipt of the last dose of a vaccine not listed for emergency use by WHO.
    - Are not recommended to receive an additional primary or booster dose at this time. After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated.

Errors and Deviations

- **Site/Route**
  - DO NOT REPEAT DOSE
- **Age**
  - DO NOT REPEAT DOSE
- **Formulation or Dosage**
  - ONLY REPEAT DOSE IF:
    - FORMULATION FOR AGES 5-11 YEARS GIVEN TO PERSON OVER AGE 18 YEARS
    - LOWER THAN AUTHORIZED OR UNKNOWN DOSE OF CORRECT FORMULATION ADMINISTERED
- **Storage and Handling**
  - CONTACT MANUFACTURER; IF NO INFORMATION, REPEAT DOSE



COVID-19 Vaccine
Administration Errors Revaccination Guidance

CDC

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. When an error occurs with a COVID-19 vaccine, follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine and formulation. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes).

For all vaccine administration errors:
- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS (https://vaers.hhs.gov).
- Determine how the error occurred and implement strategies to prevent it from happening again.

For more detailed information on COVID-19 errors, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-A

Interim Revaccination Guidance

Type	Administration error/deviation	Do NOT repeat dose	Repeat dose immediately	Repeat dose after invalid dose by the minimum interval*	Contact manufacturer
Site/route	Incorrect site (i.e., site other than deltoid or anterolateral thigh)	✓			
	Incorrect route (i.e., route other than intramuscular)	✓			
Age	Administered to an unauthorized age group†	✓			
Formulation or dosage	Pfizer-BioNTech 12 years of age or older formulation (purple cap) administered to a child age 5 through 11 years§¶	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person age 12 through 17 years¶	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person 18 years or older		✓		
	Higher-than authorized dose (volume) of the correct formulation administered§	✓			
	Lower-than authorized or unknown dose (volume) of the correct formulation administered		✓		
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)**				✓
	Dose administered past the expiration or beyond-use date**				✓
Intervals	mRNA primary series or additional primary dose administered **prior to** the recommended interval*			✓	
	mRNA primary series or additional primary dose administered **after** the recommended interval††	✓			
	Janssen inadvertently administered fewer than 24 days after an mRNA dose	✓			
	Booster dose administered prior to the recommended interval	✓			
	Dose administered within 30 or 90 days of COVID-19 passive antibody therapy (30 days for post-exposure prophylaxis; 90 days for COVID-19 treatment)††	✓			
Mixed series	Incorrect mRNA COVID-19 product inadvertently administered for the 2nd dose in the primary series	✓			
Diluent (Pfizer-BioNTech only)	Only diluent is administered		✓		
	Pfizer-BioNTech is mixed with too much diluent		✓		
	Pfizer-BioNTech is mixed with too little or no diluent§	✓			
	Any incorrect diluent is used (anything other than 0.9% sodium chloride [normal saline, preservative-free])				✓

*Vaccine administered up to 4 days before the minimum interval may be counted and do not need to be repeated.
† If any COVID-19 vaccine is administered before age 5 years, do not give another dose at this time. If a vaccine other than Pfizer-BioNTech is given to a person under age 18 years:
- If age 5–17 years and Moderna was given in error, consider the age-appropriate Pfizer-BioNTech formulation as the second dose (based on the recipient's age on the day of vaccination) at least 28 days after the Moderna dose.
- If age 5–17 years and Janssen was given, consider a single dose of the age-appropriate Pfizer-BioNTech formulation (based on the recipient's age on the day of vaccination) at least 2 months after Janssen.

§ In general, do not repeat dose. However, a repeat dose of the age-appropriate formulation may be administered based on clinical judgement at an interval of 21 days after the dose given in error if:
- 0.1 mL of the Pfizer-BioNTech purple cap formulation is administered to a child age 5 through 11 years
- A lower than authorized dose from the Pfizer-BioNTech orange cap formulation is administered to an adolescent age 12 through 17 years

¶ If the administration error resulted in a higher than authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.
‡ Individuals who will turn from 11 to 12 years of age between their first and second dose in the primary regimen may receive either Pfizer-BioNTech COVID-19 Vaccine formulation in the authorized dosage. This is not considered an error and VAERS reporting is not indicated.
** Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).
†† This is not considered an error and does not require VAERS reporting.

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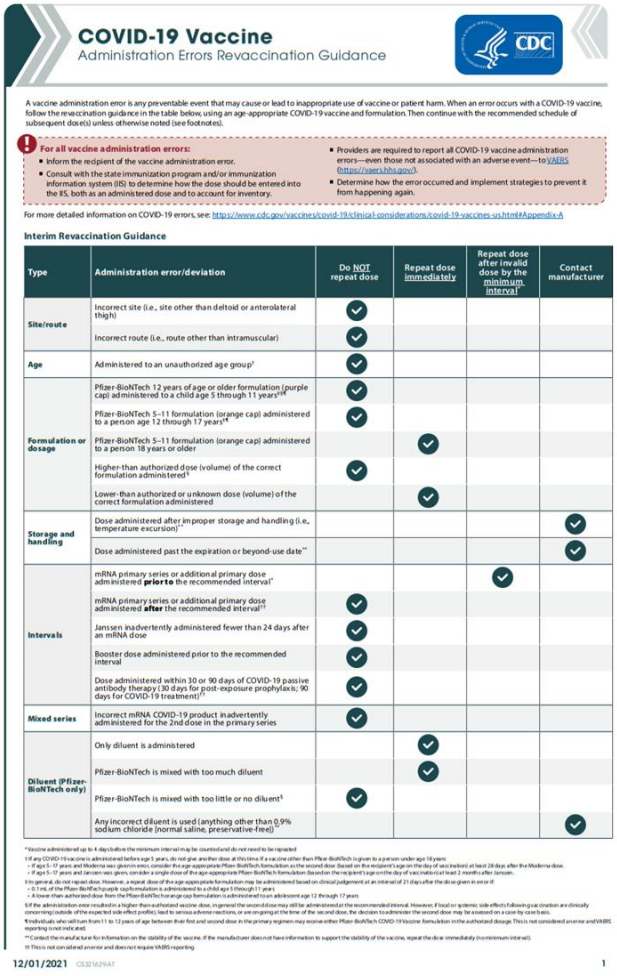
Errors and Deviations

- **Intervals**
  - DO NOT REPEAT DOSE
- **Mixed Series**
  - DO NOT REPEAT DOSE
- **Diluent (Pfizer BioNTech only)**
  - REPEAT DOSE IF ONLY DILUENT OR EXCESS DILUENT IS GIVEN
  - DO NOT REPEAT DOSE IF TOO LITTLE/NO DILUENT GIVEN
  - CONTACT MANUFACTURER IF INCORRECT DILUENT IS USED. IF NO INFORMATION, REPEAT DOSE.



COVID-19 Vaccine
Administration Errors Revaccination Guidance

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. When an error occurs with a COVID-19 vaccine, follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine and formulation. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes).

For all vaccine administration errors:
- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS (https://vaers.hhs.gov/).
- Determine how the error occurred and implement strategies to prevent it from happening again.

For more detailed information on COVID-19 errors, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-A

Interim Revaccination Guidance

Type	Administration error/deviation	Do NOT repeat dose	Repeat dose immediately	Repeat dose after invalid dose by the minimum interval[1]	Contact manufacturer
Site/route	Incorrect site (i.e., site other than deltoid or anterolateral thigh)	✓			
	Incorrect route (i.e., route other than intramuscular)	✓			
Age	Administered to an unauthorized age group[2]	✓			
Formulation or dosage	Pfizer-BioNTech 12 years of age or older formulation (purple cap) administered to a child age 5 through 11 years[3,4]	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person age 12 through 17 years[4]	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person 18 years or older		✓		
	Higher-than authorized dose (volume) of the correct formulation administered[5]	✓			
	Lower-than authorized or unknown dose (volume) of the correct formulation administered		✓		
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)[6,7]				✓
	Dose administered past the expiration or beyond-use date[6,8]				✓
Intervals	mRNA primary series or additional primary dose administered **prior to** the recommended interval[1]			✓	
	mRNA primary series or additional primary dose administered **after** the recommended interval[1]	✓			
	Janssen inadvertently administered fewer than 24 days after an mRNA dose	✓			
	Booster dose administered prior to the recommended interval	✓			
	Dose administered within 30 or 90 days of COVID-19 passive antibody therapy (30 days for post-exposure prophylaxis; 90 days for COVID-19 treatment)[9]	✓			
Mixed series	Incorrect mRNA COVID-19 product inadvertently administered for the 2nd dose in the primary series	✓			
Diluent (Pfizer-BioNTech only)	Only diluent is administered		✓		
	Pfizer-BioNTech is mixed with too much diluent		✓		
	Pfizer-BioNTech is mixed with too little or no diluent[4]	✓			
	Any incorrect diluent is used (anything other than 0.9% sodium chloride [normal saline, preservative-free])[10]				✓

*Vaccine administered up to 4 days before the minimum interval may be counted and do not need to be repeated
† If any COVID-19 vaccine is administered before age 5 years, do not give another dose at this time. If a vaccine other than Pfizer-BioNTech is given to a person under age 18 years:
- If age 5–17 years and Moderna was given in error, consider the age-appropriate Pfizer-BioNTech formulation as the second dose (based on the recipient's age on the day of vaccination) at least 28 days after the Moderna dose.
- If age 5–17 years and Janssen was given, consider a single dose of the age-appropriate Pfizer-BioNTech formulation (based on the recipient's age on the day of vaccination) at least 2 months after Janssen.

§ In general, do not repeat dose. However, a repeat dose of the age-appropriate formulation may be administered based on clinical judgement at an interval of 21 days after the dose given in error if:
- 0.1 mL of the Pfizer-BioNTech purple-cap formulation is administered to a child age 5 through 11 years
- A lower-than-authorized dose from the Pfizer-BioNTech orange-cap formulation is administered to an adolescent age 12 through 17 years

¶ If the administration error resulted in a higher-than-authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.
# Individuals who will turn from 11 to 12 years of age between their first and second dose in the primary regimen may receive either Pfizer-BioNTech COVID-19 Vaccine formulation in the authorized dosage. This is not considered an error and VAERS reporting is not indicated.
** Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).
†† This is not considered an error and does not require VAERS reporting.

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Footnotes to Errors and Deviations Document

* Vaccine administered up to 4 days before the minimum interval may be counted and do not need to be repeated
† If any COVID-19 vaccine is administered before age 5 years, do not give another dose at this time. If a vaccine other than Pfizer-BioNTech is given to a person under age 18 years:
• If age 5–17 years and Moderna was given in error, consider the age-appropriate Pfizer-BioNTech formulation as the second dose (based on the recipient's age on the day of vaccination) at least 28 days after the Moderna dose.
• If age 5–17 years and Janssen was given, consider a single dose of the age-appropriate Pfizer-BioNTech formulation (based on the recipient's age on the day of vaccination) at least 2 months after Janssen.
‡ In general, do not repeat dose. However, a repeat dose of the age-appropriate formulation may be administered based on clinical judgement at an interval of 21 days after the dose given in error if:
• 0.1 mL of the Pfizer-BioNTech purple cap formulation is administered to a child age 5 through 11 years
• A lower-than-authorized dose from the Pfizer-BioNTech orange cap formulation is administered to an adolescent age 12 through 17 years
§ If the administration error resulted in a higher-than-authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.
¶ Individuals who will turn from 11 to 12 years of age between their first and second dose in the primary regimen may receive either Pfizer-BioNTech COVID-19 Vaccine formulation in the authorized dosage. This is not considered an error and VAERS reporting is not indicated.
** Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).
†† This is not considered an error and does not require VAERS reporting

Case Study Errors and Deviations

- A 12-year-old client inadvertently receives the Pfizer pediatric dose as his first dose and now has returned to get the second dose of the series. What vaccine should the child receive? Will they need to repeat the first dose?

Solution

https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-errors-deviations.pdf

Type	Administration error/deviation	Do NOT repeat dose	Repeat dose immediately	after invalid dose by the minimum interval*	Contact manufacturer
Site/route	Incorrect site (i.e., site other than deltoid or anterolateral thigh)	✓			
	Incorrect route (i.e., route other than intramuscular)	✓			
Age	Administered to an unauthorized age group†	✓			
Formulation or dosage	Pfizer-BioNTech 12 years of age or older formulation (purple cap) administered to a child age 5 through 11 years‡§¶	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person age 12 through 17 years‡¶	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person 18 years or older		✓		
	Higher-than authorized dose (volume) of the correct formulation administered§	✓			
	Lower-than authorized or unknown dose (volume) of the correct formulation administered		✓		
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)**				✓

Solution

https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-errors-deviations.pdf

Type	Administration error/deviation	Do NOT repeat dose	Repeat dose immediately	after invalid dose by the minimum interval*	Contact manufacturer
Site/route	Incorrect site (i.e., site other than deltoid or anterolateral thigh)	✓			
	Incorrect route (i.e., route other than intramuscular)	✓			
Age	Administered to an unauthorized age group†	✓			
Formulation or dosage	Pfizer-BioNTech 12 years of age or older formulation (purple cap) administered to a child [illegible] through 11 years‡§	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person age 12 through 17 years‡¶	✓			
	Pfizer-BioNTech 5–11 formulation (orange cap) administered to a person 18 years or older		✓		
	Higher-than authorized dose (volume) of the correct formulation administered§	✓			
	Lower-than authorized or unknown dose (volume) of the correct formulation administered		✓		
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)**				✓

v-safe Program

Active Safety Monitoring for COVID-19 Vaccines

v-safe is a new CDC smartphone-based monitoring program for COVID-19 vaccine safety:

- Uses text messaging and web surveys to check in with vaccine recipients after vaccination
- Participants can report any side effects or health problems after COVID-19 vaccination.
- Parents/guardians can enroll adolescents (ages ≥12 years) in v-safe and complete health check-ins on their behalf.
- Includes active telephone follow-up by CDC for reports of significant health impact

v-safe COVID-19 Vaccine Pregnancy Registry collects additional health information from v-safe participants who report being pregnant at the time of vaccination or a positive pregnancy test after vaccination.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

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VAERS

Reporting of vaccine adverse events

- Adverse events in COVID-19 vaccine recipients are required to be reported to VAERS.*
- FDA's COVID-19 vaccine EUAs and EUA/BLA require vaccination providers to report
  - Vaccine administration errors
  - Serious adverse events
  - Cases of multisystem inflammatory syndrome
  - Cases of COVID-19 that result in hospitalization or death

  Reporting is encouraged for all other clinically significant adverse events, even those not clearly attributable to vaccination.

*Instructions for submitting a report to VAERS is available at https://vaers.hhs.govexternal or by calling 1-800-822-7967.

Obtaining Continuing Education Contact Hours

- Continuing education (CE) contact hours are available for nurses, medical assistants, pharmacists and pharmacy technicians
- Expiration date is 4/27/22
- Successful completion of this continuing education activity includes the following:
  - Attending the entire live webinar or watching the webinar recording
  - Completing the evaluation available after the webinar or webinar recording
  - **On the evaluation, please choose which type of continuing education certificate you wish to obtain**
- **Please note:** CE certificates are NOT generated after evaluation completion—CE certificates will be sent by DOH via email within a few weeks after evaluation completion
- If you have any questions about CE credit, contact Trang Kuss at trang.kuss@doh.wa.gov

Power of Providers Initiative

Power of Providers Initiative

- Despite COVID-19 vaccination rates reaching over 70%, the state of Washington continues to experience outbreaks of COVID-19 disease.
- Given the rise of different COVID-19 variants, we want to vaccinate as many people against COVID-19 disease as possible.
- The Power of Providers Initiative asks **ALL** health care providers to help with this effort by signing up and committing to SAVE:
  - Seek
  - Ask/Educate
  - Vaccinate (or refer)
  - Empower
- Health care providers who don't vaccinate still want to help protect the community against COVID-19 disease, and they can sign up for the POP Initiative too!

Power of Providers Initiative - SAVE

- **Seek** – seek out your patient or client's vaccination status.
- **Ask/Educate** – ask them about the vaccine and offer education.
- **Vaccinate** – If the patient agrees to vaccination, vaccinate them or provide a referral for vaccination.
- **Empower** – Empower your patients to share their vaccination status with the community.

Power of Providers Initiative – Sign Up

The initiative is supported by over 20 different state health associations, Governor Inslee, and the Secretary of Health, Umair A. Shah.

We encourage all health care providers, vaccinating or not, to sign up for the initiative and help the state reduce COVID-19 disease.

To read more about the Power of Providers and to sign up, visit our web page at **www.doh.wa.gov/pop**

Providers that sign up will receive a certificate and other materials to help them with the POP Initiative.

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.