

***COVID-19***  
***Vaccines***

*Pandemic Provider*  
**Educational Packet**

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## **Summary of Recent Changes**

*Revisions were made on May 20, 2021*

### **Pfizer COVID-19 Vaccine Storage and Handling**

- [Pfizer COVID-19 Vaccine Storage and Handling Label](#)

### **Vaccine Administration**

- [Pfizer COVID-19 Vaccine Preparation and Administration Summary](#)
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### **Pfizer COVID-19 Vaccine Administration**

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## **COVID-19 Vaccine Healthcare Educational Materials**

- [CDC V-Safe Guide](#)



# **STOP! COVID-19 Vaccine**

Before you proceed, please read the following:

- COVID-19 vaccines are **only** to be placed in a refrigerator, freezer or ultra-cold storage that has been **pre-approved** by the Tennessee Department of Health's Immunization Program (VPDIP)
- COVID-19 vaccines are not to be taken off-site unless a mobile clinic plan has been submitted and **pre-approved** by VPDIP
- COVID-19 vaccines must **ALWAYS** be placed in a refrigerator, freezer, ultra-cold storage, or transport cooler that is continuously monitored with a **pre-approved** digital data logger or integrated temperature monitor
- Never administer vaccines that have experienced temperatures outside of the accepted range. Mark them "DO NOT USE" and contact [temperature.health@tn.gov](mailto:temperature.health@tn.gov)
- COVID-19 vaccines are **NEVER** to be placed in a dorm-style refrigerator or freezer or in the freezer space of a combination refrigerator/freezer unit
- COVID-19 vaccines are not to be transferred to another site without the consent of VPDIP
- Ensure there is an emergency plan for the storage of vaccines in the event there is failure of the primary storage unit

**Failure to comply with the directions listed above may result in spoilage of vaccines and re-vaccination of vaccine recipients**

Questions may be directed to [VPDIP.pandemic@tn.gov](mailto:VPDIP.pandemic@tn.gov)

# COVID-19 Vaccines: Important Contact Numbers

## COVID-19 Vaccine General Public Information:

COVID-19 TN Department of Health Public Information Lines: **877-857-2945** or **833-556-2476**

- Monday-Friday, 10am-8pm CT
- Saturday and Sunday, 10am-4pm

## COVID-19 Vaccine Provider Questions:

COVID-19 Vaccine Provider Question Call-Line: **800-404-3006**

- Monday-Friday, 8:00am-4:30pm CT

Information about becoming a COVID-19 Vaccine Provider, email: [VPDIP.Pandemic@tn.gov](mailto:VPDIP.Pandemic@tn.gov)

## COVID-19 Vaccine Temperature Excursions:

Report immediately: **800-404-3006** or e-mail [Temperature.Health@tn.gov](mailto:Temperature.Health@tn.gov) with your facility's Vaccines for Children (VFC) or COVID-19 Provider PIN number and contact information.

- Monday-Friday, 8:00am-4:30pm CT

If the temperature excursion occurs after business hours, email [Temperature.Health@tn.gov](mailto:Temperature.Health@tn.gov) and call **800-404-3006** during business hours the following day to report.

## TennIIS Questions:

TennIIS Help Desk (general assistance): **844-206-9927** or [TennIIS.Help@TN.gov](mailto:TennIIS.Help@TN.gov)

- Monday-Friday, 7am-6pm CT

TennIIS Facility Registration and User Management (register a facility, add or deactivate users, apply for user permissions): **615-741-7207** or email: [TennIIS.Registration@TN.gov](mailto:TennIIS.Registration@TN.gov)

- Monday-Friday, 8am-4:30pm CT

TennIIS Training (contact for information for training opportunities for TennIIS patient management, clinical and immunizations questions): **844-206-9927**

- Monday-Friday, 8am-4:30pm CT

**Pfizer COVID-19 Vaccine**

*Vaccine Storage  
and  
Handling*

# Pfizer-BioNTech COVID-19 Vaccine

## Storage and Handling Summary



### Basics

- Store vaccine in an ultra-cold freezer, thermal shipping container, freezer, or refrigerator. See guidance below for each storage unit.
- Follow the manufacturer's instructions for returning the thermal shipping container.
- Check and record storage unit temperatures each workday. See guidance below for each type of storage unit. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

- Vaccine can be ordered in 2 amounts:
  - 1170 doses per tray
  - 450 doses divided between 3 boxes. Each box contains 25 vials.

### Deliveries

#### Vaccine

Use CDC's Delivery Checklist for Pfizer-BioNTech Vaccine when accepting a delivery and unpacking vaccine.  
When vaccine is delivered:

1. Open the thermal shipping container. Press the stop shipment button on the temperature monitoring device for 5 seconds.
2. The LED indicator light will change to a solid color and a temperature status report will be e-mailed to the person who ordered the vaccine.
3. Proceed based on the color of the LED indicator light:  
**No color or red:** Wait for the status report.  
**Green:** Unpack the vaccine.

4. Follow the manufacturer's guidance for unpacking the vaccine. Inspect the trays.
  - Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
  - If storing the vaccine at ultra-cold temperatures, return vaccine to frozen storage within 5 minutes.
5. If not using the thermal shipping container to store vaccine, return the thermal shipping container per the manufacturer's instructions.
  - Ensure ALL the vaccine has been removed before returning the container.

#### Dry Ice Safety

1. Dry ice is needed to maintain proper temperatures in the thermal shipping container.
2. Ensure staff has proper PPE and is trained to handle dry ice safely.

3. Do not use or store dry ice in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. A leak in such an area could cause a depletion of oxygen in the atmosphere, which may lead to asphyxiation.

#### Ancillary Supply Kit

An ancillary supply kit will be delivered separately from the vaccine and includes:

- **Mixing supplies:** Diluent, needles, syringes, and sterile alcohol prep pads
  - Mixing supplies are packaged separately with a green identification label.
  - Do NOT use mixing supplies to administer vaccine.
- **Administration supplies:** Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE.
  - Ancillary supply kits have been reconfigured to support the number of doses ordered.

# Pfizer-BioNTech COVID-19 Vaccine

## Storage and Handling Summary



### Thermal Shipping Container

CDC recommends providers consider using the thermal shipping container for **temporary storage** only. The container requires significant support to store vaccine at proper temperatures, including trained staff, a regular supply of dry ice, and standard operating procedures for regular maintenance.

Use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature.

- Review contact information.

- If the contact for your order (inVTrckS) is not valid, you will NOT be notified in the event of a temperature excursion. Contact your jurisdiction's immunization program for assistance.
- If your contact is valid and you are not receiving e-mails or cannot load email hyperlinks, refer to Controlant for troubleshooting (<https://in.controlant.com/onitemonitoring>).
- Identify up to 4 contacts to receive e-mails and text alerts on the container's temperature status.
- Review **DAILY** e-mails on the status of the container.
- Click the link in daily e-mails to access and download all temperature data. Save the Excel file summarizing all temperature data for at least 3 years.

- Save the return shipping label provided in your shipping container at delivery. Use the shipping label to return the thermal shipping container with Controlant TMD after 30 days.
- Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days thereafter. Follow manufacturer's guidance for adding dry ice.
- Dry ice will be sent for the first re-icing unless you opt out when placing the vaccine order.
- Additional dry ice shipments will NOT be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

Removing vaccine vials/doses for use:

- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.
- Store vaccine vials upright in the tray and protect from light.

### Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between -80°C and -60°C (-112°F and -76°F).

- Store vaccine vials upright in the tray or box.
- Protect from light.
- Vaccine may be stored until the expiration date.
- As the expiration date approaches, contact the manufacturer to determine if it has been extended. Do not discard vaccine without ensuring the expiration date has passed.

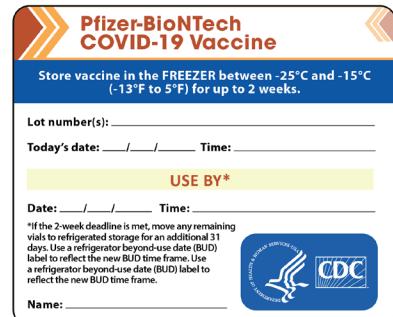
### Freezer

Before mixing, the vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. This beyond-use date replaces the manufacturer's expiration date. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks.

- These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter.
- If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
- Use CDC's freezer storage temperature log for COVID-19 vaccine to document storage unit temperatures.
- Monitor how long the vaccine has been in the freezer using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.

- Store the vaccine in the tray or box.
- Protect from light.
- Do not use dry ice for freezer storage.
- Vials stored in the freezer may be returned one time to ultra-cold temperature storage (-80°C to -60°C [-112°F to -76°F]).
  - Once returned to ultra-cold storage, the 2-week time frame is suspended.
- Vaccine stored in the freezer can be transferred to refrigerator storage where it can be stored for up to 1 month (31 days).

\*Dry ice will not be provided for Pfizer 450 COVID-19 vaccine orders.



# Pfizer-BioNTech COVID-19 Vaccine

## Storage and Handling Summary



### Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days). After 31 days, contact the manufacturer for guidance. If directed to discard any remaining vials, follow the manufacturer's and your jurisdiction's guidance for proper disposal.

- Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.
- Vaccine can be ordered in 2 amounts:
- Store the vaccine in the tray or box.
- Protect from light.
- Do NOT refreeze thawed vaccine.

### Temperature Monitoring

**Ultra-cold freezer, freezer, refrigerator:** Storage unit temperatures must be monitored regularly, checked, and recorded at the beginning of the workday to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

- Ultra-cold temperatures: Use a probe designed specifically to measure ultra-cold temperatures.
- Frozen and refrigerated storage: Use a probe buffered with glycol, glass beads, sand, or Teflon®.

Check and record the temperature daily using CDC's temperature log. Use one of the options below:

#### ■ Option 1 (preferred): Minimum/Maximum (Min/Max) Temperature

Most DDLs display min/max temperatures. Check and record the min/max temperatures at the start of each workday.

#### ■ Option 2: Current Temperature

If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

**Thermal Shipping Container:** Use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature. See thermal shipping container information above.

### Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

### Mixed Vaccine

- Once mixed, vaccine can be left at room temperature (2°C to 25°C [35°F to 77°F]) for up to 6 hours.
- Discard any remaining vaccine after 6 hours.
- Mixed vaccine should NOT be returned to freezer storage.
- Minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

### Disposal

Once vaccine has reached its expiration or beyond-use date, contact the manufacturer for guidance on whether it can still be used. If instructed to dispose of vaccine, dispose of the vial (with any remaining vaccine) and packaging as medical waste according to your local and state regulations. Contact your jurisdiction's immunization program (<https://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html>) for guidance.

- Do NOT return vaccine in the thermal shipping container.

**CDC's Pfizer-BioNTech COVID-19 Vaccine materials** <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

**CDC's Vaccine Storage and Handling Toolkit** <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

**CDC's Pfizer Beyond-Use Date (BUD) labels** <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf>

**CDC's Delivery Checklist** <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/delivery-checklist.pdf>

**CDC's Freezer and Refrigerator Temperature Logs** <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

For additional information, refer to the manufacturer's website at [www.cvdvaccine.com](http://www.cvdvaccine.com)

# Pfizer-BioNTech COVID-19 Vaccine

**Ages:** 12 years of age and older

**Use for:** Any dose in the 2-dose series.  
COVID-19 vaccines are NOT interchangeable.  
Both doses should be COVID-19 vaccine (Pfizer).

**Route:** Intramuscular (IM) injection

**Prior to administration, mix with 0.9% sodium chloride  
(normal saline, preservative-free) diluent ONLY.**

**Beyond Use Date/Time:**

**Freezer:** Between -25°C and -15°C  
(-13°F to 5°F) for up to 2 weeks

**Refrigerator:** Between 2°C and 8°C  
(36°F and 46°F) for up to 31 days.

**Mixed vaccine:** Use within 6 hours  
of mixing.



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(-13°F to 5°F) for up to 2 weeks

**Refrigerator:** Between 2°C and 8°C  
(36°F and 46°F) for up to 31 days.

**Mixed vaccine:** Use within 6 hours  
of mixing.



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**Ages:** 12 years of age and older

**Use for:** Any dose in the 2-dose series.  
COVID-19 vaccines are NOT interchangeable.  
Both doses should be COVID-19 vaccine (Pfizer).

**Route:** Intramuscular (IM) injection

**Prior to administration, mix with 0.9% sodium chloride  
(normal saline, preservative-free) diluent ONLY.**

**Beyond Use Date/Time:**

**Freezer:** Between -25°C and -15°C  
(-13°F to 5°F) for up to 2 weeks

**Refrigerator:** Between 2°C and 8°C  
(36°F and 46°F) for up to 31 days.

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of mixing.



# Pfizer-BioNTech COVID-19 Vaccine

**Ages:** 12 years of age and older

**Use for:** Any dose in the 2-dose series.  
COVID-19 vaccines are NOT interchangeable.  
Both doses should be COVID-19 vaccine (Pfizer).

**Route:** Intramuscular (IM) injection

**Prior to administration, mix with 0.9% sodium chloride  
(normal saline, preservative-free) diluent ONLY.**

**Beyond Use Date/Time:**

**Freezer:** Between -25°C and -15°C  
(-13°F to 5°F) for up to 2 weeks

**Refrigerator:** Between 2°C and 8°C  
(36°F and 46°F) for up to 31 days.

**Mixed vaccine:** Use within 6 hours  
of mixing.



# Pfizer-BioNTech COVID-19 Vaccine

Temperature Log for Ultra-Cold Vaccine Storage (Fahrenheit) Days 1-15



Store COVID-19 vaccine (Pfizer) between -112°F and -76°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

## Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

## Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.



If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use.**"
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_

PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Time															
	Staff initials															
	Min/Max temperatures															

Temperatures above -76°F and below -112°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM																				
	Staff initials																						
	-76°F																						
	-77°F																						
	-78°F																						
	-79°F																						
	-80°F																						
	-81°F																						
	-82°F																						
	-83°F																						
	-84°F																						
	-85°F to -112°F																						

For additional information, see the vaccine manufacturer's product information at [www.cvdvaccine.com](http://www.cvdvaccine.com)

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log.

# Pfizer-BioNTech COVID-19 Vaccine

Temperature Log for Ultra-Cold Vaccine Storage (Fahrenheit) Days 16-31



Store COVID-19 vaccine (Pfizer) between -112°F and -76°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

## Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

## Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

! If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use.**"
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_ PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Time																
	Staff initials																
	Min/Max temperatures	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

Temperatures above -76°F and below -112°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM														
	Staff initials																
	-76°F																
	-77°F																
	-78°F																
	-79°F																
	-80°F																
	-81°F																
	-82°F																
	-83°F																
	-84°F																
	-85°F to -112°F																

For additional information, see the vaccine manufacturer's product information at [www.cvdvaccine.com](http://www.cvdvaccine.com)

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log.

# Pfizer-BioNTech COVID-19 Vaccine

Temperature Log for Ultra-Cold Vaccine Storage (Celsius) Days 1-15



Store COVID-19 vaccine (Pfizer) between -80°C and -60°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

## Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

## Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

! If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use**".
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_

PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Time															
	Staff initials															
	Min/Max temperatures	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Temperatures above -60°C and below -80°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM														
	Staff initials																
	-60°C																
	-61°C																
	-62°C																
	-63°C																
	-64°C																
	-65°C																
	-66°C																
	-67°C																
	-68°C																
	-69°C to -80°C																

For additional information, see the vaccine manufacturer's product information at [www.cvdvaccine.com](http://www.cvdvaccine.com)

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log.

# Pfizer-BioNTech COVID-19 Vaccine

Temperature Log for Ultra-Cold Vaccine Storage (Celsius) Days 16–31



Store COVID-19 vaccine (Pfizer) between -80°C and -60°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

## Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

## Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

! If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use**".
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_

PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Time																
	Staff initials																
	Min/Max temperatures	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Temperatures above -60°C and below -80°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM														
	Staff initials																
	-60°C																
	-61°C																
	-62°C																
	-63°C																
	-64°C																
	-65°C																
	-66°C																
	-67°C																
	-68°C																
	-69°C to -80°C																

# COVID-19 Vaccine

## Temperature Log for Refrigerator Vaccine Storage (Fahrenheit) Days 1-15



Store COVID-19 vaccines between 36°F and 46°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

### Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

### Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.



If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use**".
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_

PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Time															
	Staff initials															
	Min/max temperatures															

Temperatures lower than 36°F and higher than 46°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM																				
	Staff initials																						
	36°F																						
	37°F																						
	38°F																						
	39°F																						
	40°F																						
	41°F																						
	42°F																						
	43°F																						
	44°F																						
	45°F																						
	46°F																						

For additional information, see the vaccine manufacturer's product information.

12/22/2020

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Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

# COVID-19 Vaccine

## Temperature Log for Refrigerator Vaccine Storage (Fahrenheit) Days 16–31



Store COVID-19 vaccines between 36°F and 46°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

### Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

### Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.



If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use**".
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_

PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Time																
	Staff initials																
	Min/max temperatures	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

Temperatures lower than 36°F and higher than 46°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM														
	Staff initials																
	36°F																
	37°F																
	38°F																
	39°F																
	40°F																
	41°F																
	42°F																
	43°F																
	44°F																
	45°F																
	46°F																

# COVID-19 Vaccine

## Temperature Log for Refrigerator Vaccine Storage (Celsius) Days 1–15



Store COVID-19 vaccines between 2°C and 8°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

### Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

### Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.



If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use**".
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_

PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Time															
	Staff initials															
	Min/max temperatures															

Temperatures lower than 2°C and higher than 8°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM																		
	Staff initials																				
	2°C																				
	3°C																				
	4°C																				
	5°C																				
	6°C																				
	7°C																				
	8°C																				

# COVID-19 Vaccine

Temperature Log for Refrigerator Vaccine Storage (Celsius) Days 16–31



Store COVID-19 vaccines between 2°C and 8°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See [CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum](#), for additional information.

## Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)

1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

## Option 2: Current Temperature

1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.



If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use**".
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month \_\_\_\_\_

PIN Number \_\_\_\_\_

Facility Name \_\_\_\_\_

OPTION 1	Day of the month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Time																
	Staff initials																
	Min/max temperatures																

Temperatures lower than 2°C and higher than 8°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OPTION 2	Time	AM	PM														
	Staff initials																
	2°C																
	3°C																
	4°C																
	5°C																
	6°C																
	7°C																
	8°C																

For additional information, see the vaccine manufacturer's product information.

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

# COVID-19 Vaccine Expiration Date Tracking Tool



Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction.

**Product name:** \_\_\_\_\_ **Manufacturer:** \_\_\_\_\_ **Original Expiration Date:** \_\_\_\_\_

**Expiration date info is available at** (include all available information from manufacturer; website, app, phone number.)

Date	Lot Number	Updated Expiration Date	Info Source	Name
Example: 09/01/2020	ABC123DEF456	06/30/2021	<input checked="" type="checkbox"/> Website <input type="checkbox"/> Barcode	Susie Smith RN

# Pfizer-BioNTech COVID-19 Vaccine

Beyond-Use Date (BUD) Tracking Labels for  
Vaccine During Freezer or Refrigerator Storage



Vaccine that has not been mixed has specific beyond-use dates for frozen and refrigerated storage.  
Use these labels to ensure beyond-use dates are followed.

## Storing Vaccine in the Freezer

Pfizer-BioNTech COVID-19 Vaccine may be stored in the freezer between -25°C and -15°C (-13°F and 5°F) for up to 2 weeks.

- Remove the vaccine from ultra-cold temperature storage.
- Complete the information on the freezer storage label and attach it to the container or resealable plastic bag holding the vaccine vials.
- Once labeled, store the vaccine vials in the freezer between -25°C and -15°C (-13°F and 5°F) for up to 2 weeks.
- If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 1 month (31 days).
- Update the beyond-use date labels to reflect the new BUD time frame.
- Keep vials removed from ultra-cold storage at the same time together.



**Pfizer-BioNTech COVID-19 Vaccine**

Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.

Lot number(s): 123456A

Today's date: 05/18/2021 Time: 2:30 PM

**USE BY\***

Date: 06/01/2021 Time: 2:30 PM

\*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 31 days. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.

Name: Amy Nurse RN

The CDC logo, featuring a stylized eagle and the text "DEPARTMENT OF HEALTH & HUMAN SERVICES USA" and "CDC".

## Storing Vaccine in the Refrigerator

Pfizer-BioNTech COVID-19 Vaccine can be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days.).

- Remove vaccine vials from ultra-cold or frozen temperature storage.
- Complete the information on the refrigerator storage label and attach it to the container or resealable plastic bag holding the vaccine vials.
- Once labeled, store the vaccine vials in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days).
- As the 1 month (31 days) deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.
- Do NOT refreeze the vaccine.



**Pfizer-BioNTech COVID-19 Vaccine**

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days.

Lot number(s): 123456A

Today's date: 06/01/2021 **USE BY\*** Date: 07/01/2021

\*As the 31 day deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Vaccine may be transported for 12 cumulative hours.

Transport date	<u>06/07</u>		
Time in transport:	<u>2 hrs</u>		
Time remaining:	<u>10 hrs</u>		

Name: Amy Nurse RN

The CDC logo, featuring a stylized eagle and the text "DEPARTMENT OF HEALTH & HUMAN SERVICES USA" and "CDC".

# Pfizer-BioNTech COVID-19 Vaccine

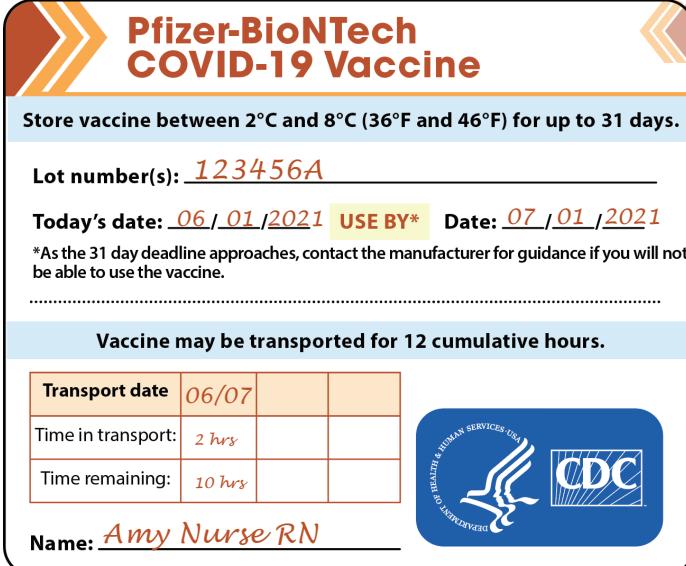
Beyond-Use Date (BUD) Tracking Labels for  
Vaccine During Freezer or Refrigerator Storage



## Transporting Vaccine Between 2°C and 8°C (36°F and 46°F)

Pfizer-BioNTech COVID-19 Vaccine may be transported for 12 cumulative hours (e.g., vaccine transported for 2 hours today has 10 hours of transport time remaining). Follow transportation guidance for Pfizer-BioNTech COVID-19 Vaccine in CDC's *Vaccine Storage and Handling Toolkit, COVID-19 Addendum*.

- When you have completed vaccine transport for the day, remove any remaining vials from the transport container.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport, if needed.
- Once you have completed this information, store vaccine upright in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to the indicated BUD.
- Any time used for transport between 2°C and 8°C (36°F and 46°F) counts against the 1 month (31 days) limit for storage between 2°C and 8°C (36°F and 46°F).



A tracking label for Pfizer-BioNTech COVID-19 Vaccine. The label is white with blue and orange text. At the top, it says "Pfizer-BioNTech COVID-19 Vaccine". Below that, a blue bar contains the text "Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days." The label includes fields for "Lot number(s)" (123456A), "Today's date" (06/01/2021), "USE BY\*" (07/01/2021), and "Date" (07/01/2021). A note below states: "\*As the 31 day deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine." A blue bar at the bottom says "Vaccine may be transported for 12 cumulative hours." Below this are three tables for recording transport information:

Transport date	06/07		
Time in transport:	2 hrs		
Time remaining:	10 hrs		

Name: Amy Nurse RN



CDC's Pfizer-BioNTech Storage and Handling Summary [www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf](http://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf)

CDC's Refrigerator and Freezer Temperature Logs [www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html](http://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html)

CDC's Vaccine Storage and Handling Toolkit [www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

# Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days.

Lot number(s): \_\_\_\_\_

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_ USE BY\* Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

\*As the 31 day deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Vaccine may be transported for 12 cumulative hours.

Transport date			
Time in transport:			
Time remaining:			



Name: \_\_\_\_\_

# Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days.

Lot number(s): \_\_\_\_\_

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_ USE BY\* Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

\*As the 31 day deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Vaccine may be transported for 12 cumulative hours.

Transport date			
Time in transport:			
Time remaining:			



Name: \_\_\_\_\_

# Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 31 days.

Lot number(s): \_\_\_\_\_

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_ USE BY\* Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

\*As the 31 day deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Vaccine may be transported for 12 cumulative hours.

Transport date			
Time in transport:			
Time remaining:			



Name: \_\_\_\_\_

# Pfizer-BioNTech COVID-19 Vaccine

Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.

Lot number(s): \_\_\_\_\_

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_\_

USE BY\*

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_\_

\*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 31 days. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.



Name: \_\_\_\_\_

# Pfizer-BioNTech COVID-19 Vaccine

Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.

Lot number(s): \_\_\_\_\_

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_\_

USE BY\*

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_\_

\*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 31 days. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.



Name: \_\_\_\_\_

# Pfizer-BioNTech COVID-19 Vaccine

Store vaccine in the FREEZER between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.

Lot number(s): \_\_\_\_\_

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_\_

USE BY\*

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_\_

\*If the 2-week deadline is met, move any remaining vials to refrigerated storage for an additional 31 days. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame. Use a refrigerator beyond-use date (BUD) label to reflect the new BUD time frame.



Name: \_\_\_\_\_



# Temperature Log

## when Transporting Vaccine at Refrigerated Temperatures



### When transporting refrigerated vaccines, use:

- A portable refrigerator or vaccine storage container qualified to maintain temperatures between 2°C and 8°C (36°F and 46°F).
- A digital data logger (DDL) with a thermal buffer and external temperature display (preferred). Place the probe as close as possible to the vaccine.
- This temperature log to document temperatures and how long the vaccine is in the portable storage container.

### Temperature monitoring and transport time frames

- Most DDLs display minimum/maximum (min/max) temperatures.\*
- Record the time and min/max temperatures:
  - At the start of transport
  - Every time the portable storage container is opened
  - When transport is completed
- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.\*
- Beyond-use date/time (BUD), if applicable, are included in transport time. For example, if the vaccine may be stored at refrigerated temperature for 120 hours, transport is included in this time frame.



If the temperature is out of range,  
**TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine "**Do Not Use**."
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Today's date: \_\_\_\_\_

Transport start time: \_\_\_\_\_

Transport end time: \_\_\_\_\_

Provider name: \_\_\_\_\_

Facility name: \_\_\_\_\_

PIN number: \_\_\_\_\_

Temperatures measured in (circle one): **Celsius**    **Fahrenheit**

Time																			
Staff initials																			
Min/max temperatures																			

Temperatures lower than 2°C (36°F) and higher than 8°C (46°F) are out of range.\* Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

- After packing the vaccine, open the portable storage container only when necessary.
- If using a company or personal vehicle, transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Avoid leaving the portable storage container in direct sunlight or unattended.
- If needed, transport diluents with their corresponding vaccines to ensure there are equal amounts of vaccines and diluents. Follow the manufacturer's guidance for specific temperature requirements for diluents.

- Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's *Vaccine Storage and Handling Toolkit* for additional guidance.
- Refer to CDC's *Vaccine Storage and Handling Toolkit* for additional guidance when transporting vaccines.

\* If the DDL does not measure min/max temperatures, check and record temperatures hourly.

<sup>a</sup> Follow the manufacturer's guidance if it differs from this time frame.

# **PFIZER/BIONTECH COVID-19 VACCINE**

## **Unpackaging and Re-icing**

## **Thermal Shippers**

Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP)

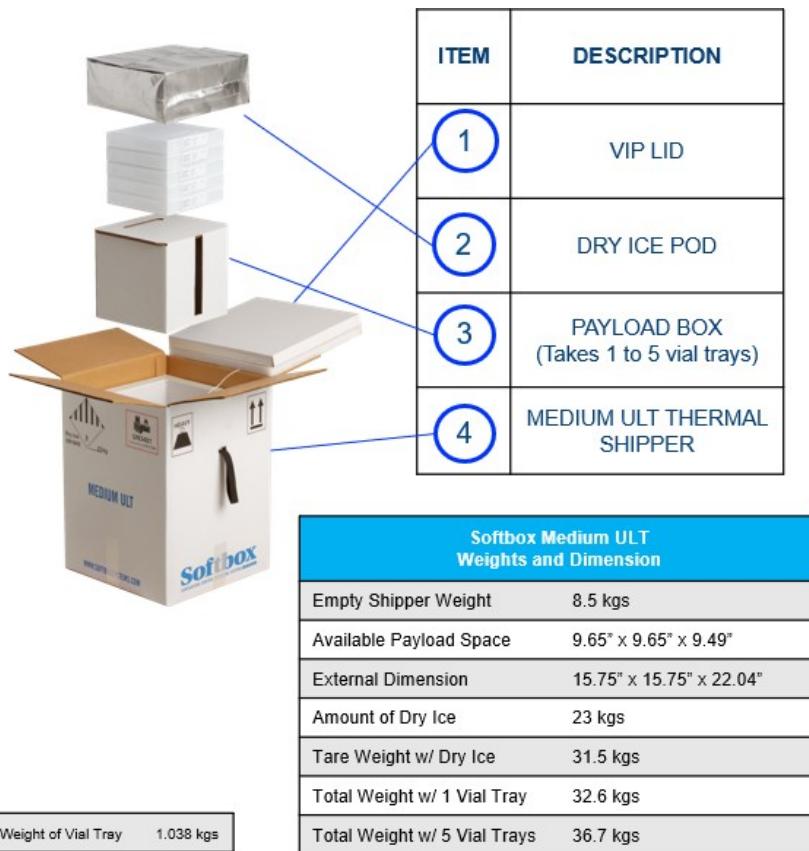
TENNESSEE DEPARTMENT OF HEALTH

# ***Unpacking and Re-icing the Thermal Shipping Container – Softbox Medium ULT Parcel Shipper***

## ***Unpacking***

***Video – Storage and Handling - How to store and handle the thermal shipping container, dry ice, and vaccine vial trays.***

***Video – Returning the Thermal Shipping Container – How to return the thermal shipping container after use.***

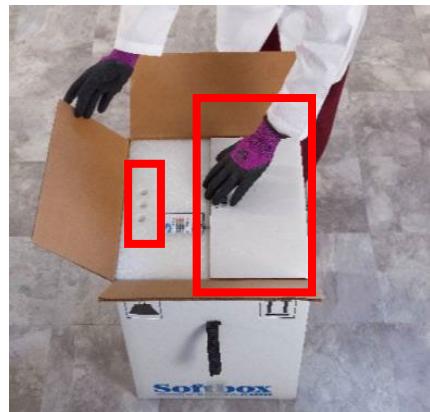


**Step 1:** Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas can result in depletion of oxygen, resulting in asphyxiation.

**Step 2:** In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.



**Step 3:** Open the lid. **Note:** One side of the thermal shipping container is permanently affixed so it is recommended to use the three-finger hole cut on the foam. If opening the thermal shipper for the first time, press the "stop" button on the GPS-enabled data logger unit.



Once the lid is opened, the dry ice pod in silver wrapping (Item 2 in labeled image) will be seen as illustrated below.



**Step 4:** While wearing insulated (thermal) gloves, take out the Dry Ice Pod. Do not touch the Dry Ice Pod without thermal gloves, as it can cause cold burns to skin.



**Step 5:** Remove the Payload Box (Item 3) from the thermal shipper by carefully unfolding the handles and then pulling directly upwards with both handles at the same time.



**Step 6:** Once received, the vials should be inspected. Remove the vial trays immediately from the thermal shipping container, inspect, and return to frozen storage within 3 minutes. Store in an ultra-low temperature freezer or prepare for use. If shipper will be used as temporary storage for remaining vial trays, immediately re-insert the trays within these 3 minutes and follow the re-icing instructions described below, starting at Step 5.

**Note:** For other activities where just the vial tray must be removed from frozen storage, vial trays should not be at room temperature for longer than 10 minutes before being returned to frozen storage.



**Step 7:** If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return to manufacturer.

Dry ice must be discarded in a well-ventilated area before returning the thermal shipping container.

## ***Re-icing***

**Step 1:** Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation.

**Step 2:** In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.



**Step 3:** Open the lid. **Note:** One side of the thermal shipping container is permanently affixed so it is recommended to use the three-finger hole cut on the foam.



Once the lid is opened, the dry ice pod will be seen, as illustrated below.



**Step 4:** While wearing insulated (thermal) gloves, take out the Dry Ice Pod. Do not touch the Dry Ice Pod without thermal gloves, as it can cause cold burns to skin.



**Step 5:** Fill the sides of the payload sleeve with dry ice until it's equal with the corrugated structure.



**Step 6:** Reinsert the Dry Ice Pod and fill with dry ice, leaving room to close the Dry Ice Pod.



**Step 7:** Close the Dry Ice Pod.



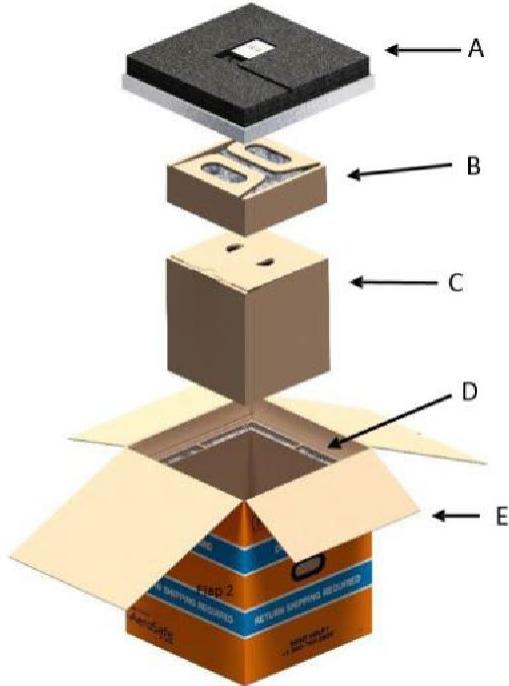
**Step 8:** Close the Lid, the Outer Corrugated Shipper and reseal with tape.



## Unpacking and Re-icing the Thermal Shipping Container – Aerosafe 47L4 Parcel Shipper with Dry Ice

### ***Unpacking:***

	Description
A	VIP Lid
B	Dry Ice Tray
C	Payload Box
D	Corner Dry Ice Scaffold
E	47L7 Shipper



- 
- Step 1:** Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation.
- Step 2:** In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.





- Step 3:** Remove the VIP Lid carefully as the temperature monitor probe is connected to the Payload Box. Care should be taken to not disconnect the probe from the Payload Box.



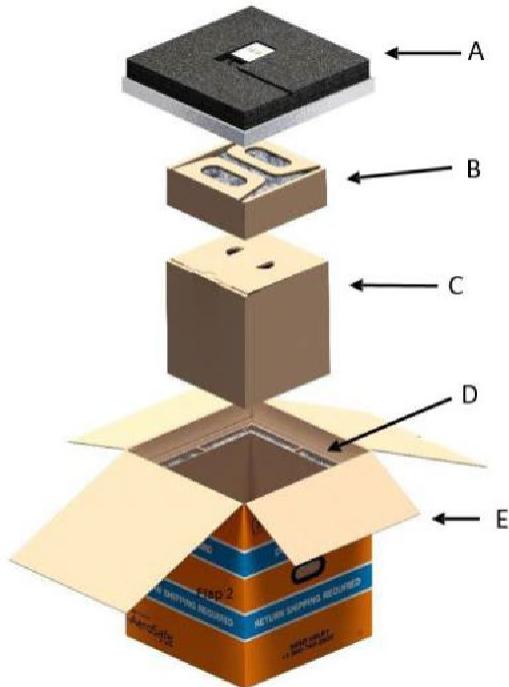
- Step 4:** While wearing insulated (thermal) gloves, take out the Dry Ice Tray.

- Step 5:** Remove the Payload Box from the thermal shipper by carefully pulling directly upwards. Care should be taken to not disconnect the probe from the Payload Box.



- Step 6:** Open the Payload Box and remove the vial tray.
- Step 7:** Take out the product for inspection and immediately (within 3 minutes of opening) store in an ultra-low temperature freezer or prepare for use. If shipper will be used as temporary storage for remaining vial trays, immediately re-insert the trays within this 3 minutes and follow the re-icing instructions below, starting with Step 5.
- If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return to manufacturer. Dry ice must be discarded in a well-ventilated area before returning the thermal shipping container.

	Description
A	VIP Lid
B	Dry Ice Tray
C	Payload Box
D	Corner Dry Ice Scaffold
E	47L7 Shipper




---

### **Re-icing:**

- Step 1:** Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation.
- Step 2:** In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.



**Step 3:** Remove the VIP lid (Item A).



**Step 4:** While wearing insulated (thermal) gloves, take out the Dry Ice Tray (Item B) as required to get better access to the Scaffolding to begin re-icing.

**Step 5:** Fill the Scaffolding (Item D of the shipper) with dry ice to the top of the scaffolding.

**Step 6:** Reinsert the Dry Ice Tray (Item B) on top of the Payload Box (Item C). Fill the Dry Ice Tray (Item B) with dry ice to the top.



**Step 7:** Add the VIP Shipper Lid (Item A) back on top.



**Step 8:** Fold the outer corrugated flaps and reseal shipper with tape.



# Packing Vaccines for Transport During Emergencies

Dry ice should **never** be used for an emergency pack out. Pfizer vaccine that has been thawed or refrigerated should **never** be placed back into ultra-cold storage conditions. Vaccine that has been placed in an ultra-cold freezer should **not** be placed back into a thermal shipping container with dry ice for transport.

## Packing Vaccines for Transport during Emergencies

### Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

### 1 Gather the Supplies



#### Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



#### Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



#### Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



#### Temperature monitoring device

Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

#### Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**



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Health and Human Services  
Centers for Disease  
Control and Prevention

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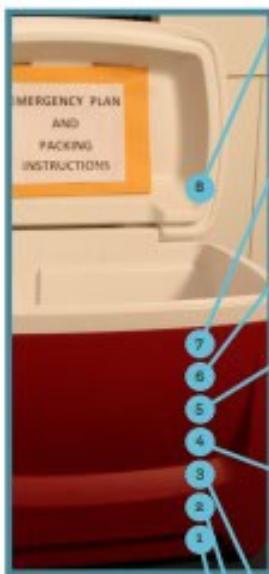
Visit [www.cdc.gov/vaccines/](http://www.cdc.gov/vaccines/) and H  
for more information, or your state  
health department.

## Packing Vaccines for Transport during Emergencies

### 2 Pack for Transport

#### Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



#### NOTE:

This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

**Close lid** – Close the lid and attach DDL display and temperature log to the top of the lid.

**Conditioned frozen water bottles** – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

**Insulating material** – Another sheet of cardboard may be needed to support top layer of water bottles.

**Insulating material** – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™.

**Vaccines** – Add remaining vaccines and diluents to cooler, covering DDL probe.

**Temperature monitoring device** – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

**Vaccines** – Stack boxes of vaccines and diluents on top of insulating material.

**Insulating material** – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

**Insulating material** – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

**Conditioned frozen water bottles** – Line bottom of the cooler with a single layer of conditioned water bottles.

### 3 Arrive at Destination

**Before opening cooler** – Record date, time, temperature, and your initials on vaccine temperature log.

**Storage** – Transfer boxes of vaccines quickly to storage refrigerator.

**Troubleshooting** – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

# Vaccine Administration – Intramuscular (IM) Injection

**YOU CALL THE SHOTS**

## Vaccine Administration: Intramuscular (IM) Injection Children 7 through 18 years of age

**Administer these vaccines by IM injection:**

- *Haemophilus influenzae type b (Hib)*
- *Hepatitis A (HepA)*
- *Hepatitis B (HepB)*
- *Hepatitis A and hepatitis B (HepA-HepB [18 years of age and older])*
- *Human papillomavirus (HPV vaccine)*
- *Influenza vaccine, inactivated (IIV)*
- *Influenza vaccine, recombinant (RIV4 [18 years of age and older])*
- *Inactivated polio vaccine (IPV)\**
- *Meningococcal conjugate (MenACWY)*
- *Meningococcal serogroup B (MenB)*
- *Pneumococcal conjugate (PCV13)*
- *Pneumococcal polysaccharide (PPSV23)\**
- *Tetanus and diphtheria toxoid (Td)*
- *Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap)*

\*May also be administered by subcutaneous injection

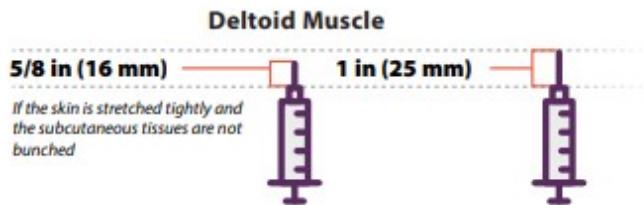
To ensure vaccines are safe and effective, it's important to prepare and administer them correctly:

- Follow aseptic technique.
- Use a new needle and syringe for each injection.
- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.<sup>†</sup>

<sup>†</sup>Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

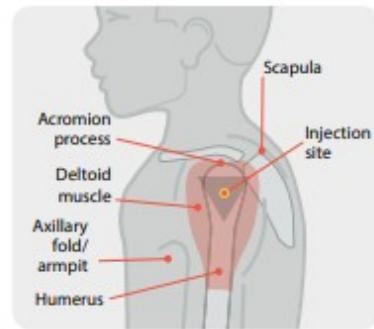
### 1. Use the correct syringe and needle.

- Administer vaccine using either a 1-mL or 3-mL syringe.
  - Use a 22- to 25-gauge needle.
  - Use the correct needle length (5/8- to 1.5-inch needle).<sup>\*</sup>
- <sup>\*</sup>The anterolateral thigh may be used. For children:  
• 7 through 10 years of age, use a 1- to 1.25-inch (25–32 mm) needle  
• 11 through 18 years of age, use a 1- to 1.5-inch (25–38 mm) needle



### 2. Identify the injection site.

- Preferred site: Deltoid muscle in the upper arm
- Use anatomical landmarks to determine the injection site. The deltoid muscle is a large, rounded, triangular shape. Find the acromion process, which is the bony point at the end of the shoulder. The injection site will be below the bone and above the axillary fold/armpit.



### 3. Administer the vaccine correctly.

- Inject the vaccine into the middle and thickest part of the muscle. Insert the needle at a 90-degree angle and inject all of the vaccine in the muscle tissue.
- If administering more than one vaccine in the same arm, separate the injection sites by 1 inch if possible.

For additional information, go to CDC's vaccine administration resource library at [www.cdc.gov/vaccines/hcp/admin/resource-library.html](http://www.cdc.gov/vaccines/hcp/admin/resource-library.html).



11/16/20

# YOU CALL THE SHOTS

## Vaccine Administration: Intramuscular (IM) Injection Adults 19 years of age and older

### Administer these vaccines by IM injection:

- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Hepatitis A and hepatitis B (HepA-HepB)
- Human papillomavirus (HPV vaccine)
- Influenza vaccine, inactivated (IIV)
- Influenza vaccine, recombinant (RIV4)
- Meningococcal conjugate (MenACWY)
- Meningococcal serogroup B (MenB)
- Pneumococcal conjugate (PCV13)
- Pneumococcal polysaccharide (PPSV23)\*
- Tetanus and diphtheria toxoid (Td)
- Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap)
- Zoster, recombinant (RZV)

\*May also be administered by subcutaneous injection

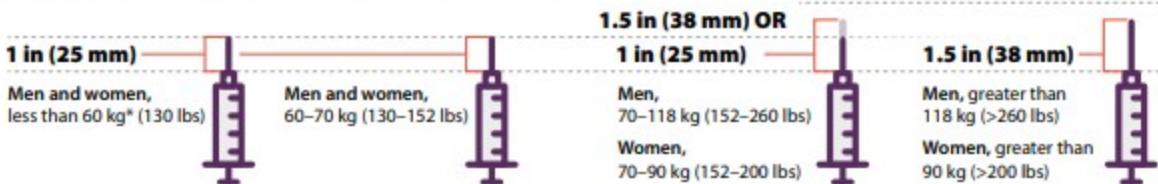
To ensure vaccines are safe and effective, it's important to prepare and administer them correctly:

- Follow aseptic technique.
- Use a new needle and syringe for each injection.
- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.<sup>†</sup>

*<sup>†</sup>Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.*

### 1. Use the correct syringe and needle.

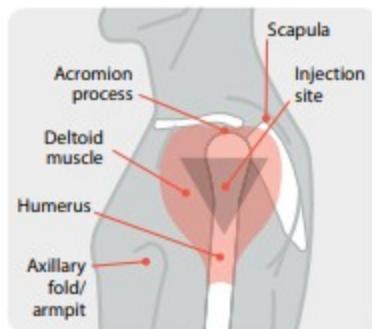
- Administer vaccine using either a 1-mL or 3-mL syringe.
- Use a 22- to 25-gauge needle.
- Use the correct needle length based on the patient's gender and weight. For adults, use a 1- to 1.5-inch needle.



*<sup>\*</sup>Some experts recommend a 5/8-inch needle for men and women who weigh less than 60 kg (130 lbs). If used, the skin must be stretched fully and the subcutaneous tissues must not be bunched.*

### 2. Identify the injection site.

- Recommended site: Deltoid muscle in the upper arm
- Use anatomical landmarks to determine the injection site. The deltoid muscle is a large, rounded, triangular shape. Find the acromion process, which is the bony point at the end of the shoulder. The injection site will be approximately 2 inches below the bone and above the axillary fold/armpit.



### 3. Administer the vaccine correctly.

- Inject the vaccine into the middle and thickest part of the muscle. Insert the needle at a 90-degree angle and inject all of the vaccine in the muscle tissue.
- If administering more than one vaccine in the same arm, separate the injection sites by 1 inch if possible.

For additional information, go to CDC's vaccine administration resource library at [www.cdc.gov/vaccines/hcp/admin/resource-library.html](http://www.cdc.gov/vaccines/hcp/admin/resource-library.html).



# COVID-19 Vaccines:

## Pfizer Vaccine Storage Timeline

1

Receive the COVID-19 Vaccine in the thermal shipper. Disable the GPS-enabled device by pressing the "stop" button after receiving the thermal shipper. If the thermal container is opened, it should be opened no more than two times a day at 3 minutes for vaccine removal or 5 minutes for replenishing dry ice.

2

Take 5 minutes to check shipment for broken vials and quantity. If there are any problems with the shipment, please notify VDPIP within 2 hours of receipt by calling 800-404-3006.

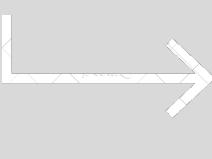
3

Accept the inventory order in TennIIS through the Vaccine Ordering Management System (VOMS).

4

Recharge dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days thereafter. On day 30, the remaining vaccine must be moved to an ultra-cold freezer, freezer or refrigerator.

 If the vaccine is to be used at an event, be sure to move the vaccine to a refrigerator at least 3 hours prior to the event.

 Vaccines may be stored in the refrigerator for up to one month (31 days). Once refrigerated, vaccine cannot be refrozen.

5

Check and record the temperature of each vaccine storage unit. Temperature checks should be done once in the AM and once in the PM. Any excursions should be reported **immediately**.

 Print temperature logs weekly and maintain your records for 3 years.

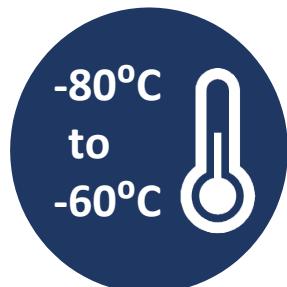
# COVID-19 Vaccines: Pfizer Vaccine Viability



## Thermal Shipping Container

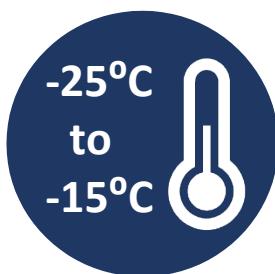
**Duration:** 30 days

**Requirements:** Recharge dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days thereafter; limit box opening to twice a day, 3 minutes per opening; constant temperature monitoring



## Ultra-Cold Freezer

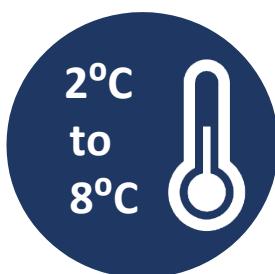
**Duration:** Vaccine may be stored until the expiration date **Requirements:** Store vaccine tray only (without dry ice or packaging); constant temperature monitoring



## Freezer

**Duration:** up to 2 weeks

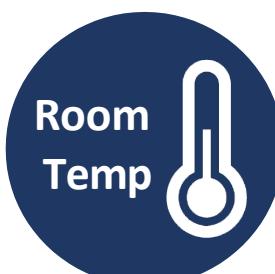
**Requirements:** Constant temperature monitoring



## Refrigeration

**Duration:** for up to 1 month (31 days)

**Requirements:** Constant temperature monitoring



## Room Temperature UNDILUTED

**Duration:** 2 hours

**Requirements:** None

## Room Temperature DILUTED

**Duration:** 6 hours

**Requirements:** Dilute only with provided normal saline solution

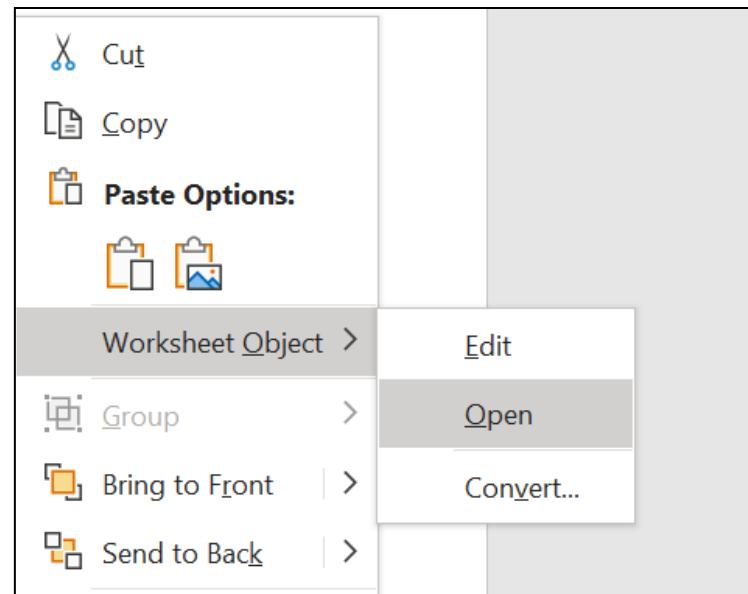
# COVID-19 Vaccines: Pfizer Shipper Monitoring Form

The below form can be used to monitor the access to the Pfizer vaccine shipper.

COVID-19 VACCINE CARRIER LOG								
THIS BOX CAN ONLY BE OPENED TWICE DAILY -- RECORD ALL INSTANCES WHEN BOX IS OPENED AND CLOSED								
DATE BOX WAS PACKAGED	11/29/2020							
DATE BOX IS RECEIVED	12/1/2020							
DATE	DAY	TIME OPENED	TIME CLOSED	DATA LOGGER NUMBER OF VIALS REMOVED TEMP		DRY ICE RECHARGE (DAYS 0, 5 & 10)	INITIALS	
12/1/2020	1	1ST TIME	7:15AM	7:18AM		5	12/1/2020	KH
DRY ICE RECHARGE DAY								
	2	1ST TIME						
		2ND TIME						
	3	1ST TIME						
		2ND TIME						
	4	1ST TIME						
		2ND TIME						
	5	1ST TIME						
DRY ICE RECHARGE DAY								
	6	1ST TIME						
		2ND TIME						
	7	1ST TIME						
		2ND TIME						
	8	1ST TIME						
		2ND TIME						
	9	1ST TIME						
		2ND TIME						
	10	1ST TIME						
DRY ICE RECHARGE DAY								
	11	1ST TIME						
		2ND TIME						
	12	1ST TIME						
		2ND TIME						
	13	1ST TIME						
		2ND TIME						
	14	1ST TIME						
		2ND TIME						
STOP -- VIALS IN THIS BOX EXPIRE AFTER 30 DAYS THE LAST VIALS CAN BE MOVED TO AN ULTRA COLD FREEZER UNTIL EXPIRES, FREEZER FOR 2 WEEKS, OR REFRIGERATION FOR ONE MONTH (31 DAYS)								

To access:

- Right click on the image
- Select “Worksheet Option”
- Select Open



# COVID-19 Vaccine Storage and Handling Guidance

Tennessee Vaccine-Preventable Diseases and Immunization Program

# COVID-19 Vaccine Storage and Handling Guidance

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Tennessee Vaccine-Preventable Diseases and Immunization Program

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## Section One: Introduction

Vaccines must be stored and handled properly in order to prevent and eradicate vaccine-preventable diseases. Failure to properly store and handle vaccines results in financial loss, revaccination, and reduced public confidence in vaccines. Vaccines that have been exposed to improper conditions have reduced potency, resulting in inadequate immune response and poor protection against disease.

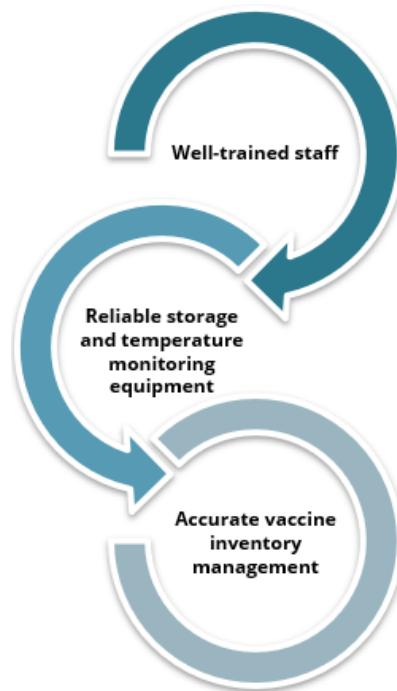
The temperature-controlled environment used to maintain and transport vaccines in optimal condition is called the **vaccine cold chain**. The cold chain begins with the storage unit at the manufacturing plant, extends to the transport and delivery of vaccine and storage at a clinic, and ends with administration of the vaccine to a patient.

Every time a vaccine is exposed to improper conditions (e.g., overexposure to heat, cold, or light), its potency is reduced. If a refrigerated vaccine is exposed to freezing temperature just once, its potency can be destroyed.

This document is designed to assist providers in properly storing and handling federal COVID-19 vaccine as part of the Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP) COVID-19 Vaccination Program. It is a modified version of the Centers for Disease Control and Prevention (CDC) [Storage and Handling Toolkit](#), which you are highly recommended to review in order to fully understand the breadth of information, recommendations, and resources available to assist you in properly storing and handling your vaccine supply. CDC's [You Call the Shots Module Ten](#) is also a recommended training for understanding vaccine storage and handling.

Always refer to the manufacturer information and package inserts or contact the manufacturer directly for detailed storage and handling protocols for individual vaccines.

*An effective vaccine cold chain relies on...*



The Tennessee Department of Health are not authorized to assess, validate, verify, or endorse products or services of private companies. When purchasing storage and handling equipment, keep in mind that products labeled as "CDC-compliant" have not been reviewed by the CDC or the Tennessee Department of Health.

Always contact the Tennessee Vaccine-Preventable Diseases and Immunization Program if you are unsure if a specific product meets requirements.

## Section Two: Staff and Training

Clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs should be maintained near vaccine storage units where staff can find them. Additionally, well-trained staff are necessary for implementing SOPs at the facility. Staff should be trained on storage and handling procedures as part of new employee orientation, annually, whenever new vaccines are added to the inventory, and whenever storage and handling recommendations change. A template Routine and Emergency Vaccine Management Plan (REVMP) may be found in [Appendix A](#).

At a minimum, SOPs should contain plans and information for three major areas:

- 1) **General:** contact information for vaccine manufacturers, equipment service providers, and important facility staff; job descriptions; regularly used forms; and staff training requirements
- 2) **Vaccine inventory management:** ordering vaccines, monitoring storage, etc.
- 3) **Emergency:** steps to take in the event of equipment malfunctions, power failures, or other emergencies that can compromise storage conditions

A **primary vaccine coordinator** should be designated for ensuring all vaccines are stored and handled correctly. A **back-up vaccine coordinator** should also be appointed to act in the absence of the primary coordinator. Both coordinators should be responsible for:

- Ordering vaccine (once available) and overseeing receipt/storage of deliveries
- Maintaining all documentation, such as vaccine inventory and temperature logs
- Monitoring operation of vaccine storage equipment and systems
- Organizing vaccines in storage units, including rotating stock at least weekly so vaccines with earlier expiration dates are used first and removing expired vaccines
- Monitoring temperature data on storage units, including:
  - Setting up temperature monitoring devices (TMDs)
  - Checking minimum/maximum temperatures for the last 24 hours in the morning and checking current temperatures in the morning and afternoon
  - Reviewing temperature data weekly for shifts in temperature trends
  - Responding to and reporting temperature excursions
- Organizing vaccine-related training and ensuring staff complete training
- Overseeing vaccine transport when necessary

- Overseeing emergency procedures, such as tracking inclement weather conditions and ensuring appropriate handling of vaccines during a disaster or power outage

VPDIP requires completion of CDC's COVID-19 Vaccine Training Modules for all primary and back-up coordinators at all sites enrolled in the COVID-19 Vaccination Program.

Pharmacists signing the Storage and Handling portion of the COVID-19 Provider Agreement are also required to complete the training modules. Continuing Education Units (CEUs) are available upon completion of each module and must be provided to VPDIP for review.

Current training modules are listed below and may be found on [CDC's COVID-19 Vaccine Training Modules Homepage](#).

- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
- Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know
- Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know
- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know

## Section Three: Equipment

### Vaccine Storage Unit Recommendations

**Purpose-built or pharmaceutical grade units** are designed specifically for storing biologics such as vaccines. These units:

- Can be compact, under-the-counter style or large
- Often have microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistant temperature detector [RTD], or thermistor)
- Often have fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature

**Household grade units** can be an acceptable alternative under the right conditions. When using these units, **the freezer compartment of a combination unit should never be used to store vaccines**, and certain areas of the refrigerated compartment should be avoided as well. **Separate standalone freezers are necessary for storing frozen vaccine.**

If a **manual defrost freezer** is used, an appropriate back-up freezer must be available to store vaccine in when the main freezer is being defrosted. A defrost plan should be

included in the storage and handling SOPs, and the unit should be defrosted when the unit has accumulated to a thickness of approximately 1 cm.

**Dormitory-style and bar-style units** may **never** be used to store vaccine. These units have a single external door and evaporator plate (cooling coil) that is usually located in the "freezer" within the refrigerator. These units place vaccine at high risk of freezing.

### Storage Unit Placement

Vaccine temperature stability requires air circulation around the outside of the storage unit. Recommendations for where to place refrigerators and freezers include:

- Unit should be in well-ventilated room with standard room temperatures (between 20°C and 25°C [68°F and 77°F]) and space between the unit, ceiling, and walls
- Nothing should block the cover of the motor compartment
- Unit should be firm and level, with bottom of unit above floor
- Door should be able to open and close smoothly and fit squarely against unit body

### Stabilizing Temperatures in New and Repaired Units

Prior to storing vaccines in a new or repaired unit, check and record the minimum and maximum temperatures each workday for two to seven days. Once you have **two consecutive days** of temperatures within the recommended range, the unit is stable and can be used for vaccine storage.

### Recommended Temperature Ranges

Different COVID-19 vaccines have different recommended temperature ranges.

**Refrigerated vaccines** should be stored in refrigerators maintained at temperatures between 2°C and 8°C. **Frozen vaccines** should be stored in freezers maintained at temperatures between -25°C and -15°C. **Ultra-cold vaccines** should be stored in freezers or dry ice shipping container in which product is received between -95°C and -60°C.

### Temperature Monitoring Devices (TMD)

All storage units must be equipped with a specific type of TMD known as a digital data logger (DDL). DDLs provide details on all temperatures the unit has reached at preset intervals. DDLs should have the following features:

- Detachable, buffered probe (or digitally buffered device that mimics buffered probe)
- Alarms (audible or visual) for out-of-range temperatures, with parameters set as:
  - Refrigerator low alarm (too cold) set to trigger after 15 consecutive minutes or longer below 2.0°C

- Refrigerator high alarm (too warm) set to trigger after 60 consecutive minutes or longer above 8.0°C
- Freezer high alarm (too warm) set to trigger after 60 consecutive minutes or longer above -15°C
- Low-battery indicator
- Active display outside of unit that allows current, minimum, and maximum temperatures to be monitored without opening unit door
- Recommended uncertainty of +/- 0.5°C
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures **at least every 30 minutes**
- Ability to easily download data for review
- Ability to report temperatures in Celsius
- A current and valid Certificate of Calibration

A **back-up DDL with a valid and current Certificate of Calibration** must also be available on-site and readily available in case a primary DDL malfunctions or requires re-calibration. The back-up DDL should be stored outside of the storage unit until needed, and it should have a different calibration re-testing date than the primary DDLs so that one may be used while the other is being replaced or sent out for re-calibration.

### Certificate of Calibration Testing

Calibration testing ensures the accuracy of DDLs against nationally accepted standards. Calibration testing should be done every one or two years or according to the manufacturer's suggested timeline. Certificates of Calibration testing should indicate one or more of the following about the testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Manual Recognition Arrangement (MRA) signatory body
- Traceable to standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Certificates of Calibration Testing should also include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less

#### The following TMDs should not be used

- Alcohol or mercury thermometers
- Bimetal stem TMDs
- TMDs used for food
- Chart recorded
- Infrared TMDs
- TMDs that do not have a current and valid Certificate of Calibration testing

### Temperature Probe Placement

The DDL probe should be placed in the middle area of the storage unit with the vaccines. Anchoring the probe will prevent it from being moved. It should **not** be placed in the doors, near or against the walls, close to vents, or on the floor of the unit as temperatures in these locations may differ significantly from the temperature in the zone where vaccine is stored.

### Monitoring Vaccine Temperature and Equipment

#### Daily Checks

Current temperatures should be reviewed for each storage unit **twice a day** (once in the morning and once in the afternoon). During the morning temperature check, the minimum and maximum temperature for the past 24 hours should also be reviewed.

If your DDL can record twice daily readings, use this function and document readings on the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#). If your DDL can document the initials of the person that completes the reading, the sign-off sheet does not need to be completed. If your DDL cannot document readings on the DDL report at all, use the [Refrigerator](#) and [Freezer](#) Temperature Logs to document checks.

#### Weekly Checks

Additionally, DDL reports must be printed, reviewed, and signed by the Vaccine Coordinator each week and maintained with temperature logs for three years.

## Power Supply

The following precautions must be taken to protect the unit's power supply:

- Plug in only one unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged
- Post "DO NOT UNPLUG" signs at outlets and on units
- Post "DO NOT TURN OFF" signs on fuses and circuit breakers
- Use caution when using power outlets that can be tripped or switched off and avoid using built-in circuit switches which may have reset buttons, outlets that can be activated by a wall switch, and multi-outlet power strips
  - If built-in current switches or power strip surge protection must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer.

## Organizing and Storing Vaccine

### **Store vaccines in their original packaging with lids closed until ready for administration.**

Loose vials or syringes may be exposed to unnecessary light and may be more difficult to track for expiration dates. Not storing vaccines in the original packaging affects inventory management and increases the risk of administration errors. Best practices for correct storage of vaccines within a refrigerator or freezer include:

- Store each type of vaccine/diluent in original packaging and in a separate container
- Position vaccines/diluents 2-3 inches from unit walls, ceilings, floor, and door.
  - If using a household-grade unit, do not store vaccines/diluents directly under cooling vents; in deli, fruit, or vegetable drawers; or on refrigerator door shelves. These areas may expose vaccines to unstable temperatures and insufficient air flow.
- Label shelves/containers to identify where each type of vaccine/diluent is stored.
- Store vaccines/diluents with similar packaging/names or with pediatric/adult formulations on different shelves.
- Store diluents with the corresponding refrigerated vaccine. Never store diluent in a freezer. Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
  - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccine.

- Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
- The freezer of a combination household-grade unit may be used for non-vaccine, medical storage, as long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.
- Arrange vaccines/diluents in rows and allow space between them to promote air circulation.
- Place vaccines/diluents with the earliest expiration dates in front of those with later expiration dates.
- Place water bottles on the top shelf, floor, and in the door racks. Putting water bottles help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.
  - Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

## Regular Maintenance of Equipment

Vaccine storage units and DDLs require regular maintenance to ensure proper operation. On a regular basis, check seals and door hinges, clean coils and other compartments per manufacturer direction, defrost manual-defrost freezers when the frost exceeds either 1cm or the manufacturer's suggested limit (when defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures), clean the interior of each unit to discourage bacterial and fungal growth, and test any back-up generator quarterly and have it served annually.

## Section Four: Pfizer/BioNTech COVID-19 Vaccine Storage

### Using the Thermal Shipping Container for Vaccine Storage

Vaccine that is stored in a thermal shipping container should maintain temperatures between -80°C and -60°C (-112°F to -76°F). The thermal shipping container should be stored at 15°C-25°C (59°F –77°F). **Thermal shipping containers may not be used for vaccine storage beyond 30 days.** Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

A Digital Data Logger (DDL) capable of monitoring ultra-cold temperatures must be placed in the location of the vial tray if the thermal shipping container is being used for storage. CDC will provide a temporary DDL with each thermal shipper that may be activated while utilizing the container for vaccine storage. All DDLs purchased separately must have a current, valid Certificate of Calibration.

The thermal shipping container should be re-iced every five days. Re-icing every 5 days helps maintain the level of dry ice and the temperature of the vaccine product. The thermal shipping container should not be opened more than 2 times per day and should not be opened for more than three (3) minutes at a time. Strict adherence to this guideline will ensure the thermal shipping container can maintain ultra-cold storage conditions.

To properly replenish the container, add dry ice to the maximum lines within the payload insert areas and dry ice pod. The thermal shipper and Controlant temperature data logger should be returned to Pfizer within 30 business days of delivery.

Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered "thawed" and is to be moved to the refrigerator for use within 31 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine that is stored in the thermal shipping container with the temporary DDL provided will be continuously monitored. Providers using this method of vaccine storage will not be required to document minimum and maximum daily temps, as the DDLs provided will not have a temperature display. Instead, providers utilizing this method of vaccine storage should review and print the DDL reports provided by Pfizer and/or Controlant to each Primary and Back-up Vaccine Coordinator listed on the COVID-19 Provider Agreement.

### **Using an Ultra-cold Freezer for Vaccine Storage**

Vaccine that is stored in an ultra-cold freezer should be stored between -80°C and -60°C (-112°F to -76°F). Pfizer/BioNTech COVID-19 vaccine may be stored in ultra-cold freezers for up to six (6) months. Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered "thawed" and is to be moved to the refrigerator for use within 31 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine stored in ultra-cold freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

### Using a Freezer for Vaccine Storage

Pfizer/BioNTech COVID-19 vaccine that is stored in a freezer should be stored between -25°C and -15°C (-13°F to 5°F). Pfizer/BioNTech COVID-19 vaccine may be stored in a freezer for up to two (2) weeks. **NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit.** Vaccine stored at frozen temperatures **must** be stored in a separate, approved standalone freezer. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Frozen vials stored or transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). This includes vials that are held up to two weeks at -25°C to -15°C (-13°F to 5°F), and at risk of not being used in time. Any time that the vials are stored or transported at -25°C to -15°C count against the two-week limit. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed two weeks. CDC is updating Pfizer Beyond-Use Date Labels to track this two-week timeframe.

Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine

storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

### Using a Refrigerator for Vaccine Storage

Pfizer/BioNTech COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Pfizer/BioNTech COVID-19 vaccine may be stored in a refrigerator for up to 1 month (31 days). Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

## Section Five: Moderna COVID-19 Vaccine Storage

### Using a Freezer for Vaccine Storage

Moderna COVID-19 vaccine that is stored in a freezer should be stored between -50°C and -15°C (-58°F to 5°F). Moderna COVID-19 vaccine may be stored in a freezer for up to six (6) months. **NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit.** Vaccine stored at frozen temperatures **must** be stored in a separate, approved standalone freezer. Unpunctured vials may be stored

between 8° to 25°C (46° to 77°F) for a total of 24 hours. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

### Using a Refrigerator for Vaccine Storage

Moderna COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Moderna COVID-19 vaccine may be stored in a refrigerator for up to thirty (30) days. Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

## Section Six: Janssen COVID-19 Vaccine

### Using a Refrigerator for Vaccine Storage

Janssen COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Do **not** store Janssen COVID-19 vaccine in a freezer or ultra-cold freezer.

Janssen COVID-19 vaccine may be stored in a refrigerator for up to three (3) months. Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

## Section Seven: Temperature Excursions (TEs)

Temperature excursions (TEs) occur when there is a temperature reading outside of the recommended temperature range for a vaccine. When a TE occurs, VPDIP must be notified as quickly as possible at 800-404-3006 during business hours or the next business morning (Monday – Friday, 8:00 AM – 4:30 PM CT) and before any vaccine is administered.

**Notify VPDIP if one of the following occurs**

- Refrigerated vaccines reach temperatures colder than 2°C or warmer than 8°C
- Frozen vaccines reach temperatures colder than -25° or warmer than -15°C
- Ultra-cold vaccines reach temperatures colder than -95°C or warmer than -60°C
- TE is part of a pattern of frequent excursions, regardless of duration
- TE concerns regardless of one of the above criteria

If a TE occurs, follow these steps:

1. Troubleshoot to see if you can identify why unit went out-of-range (e.g., unit is unplugged, unit door is open or not sealed adequately, thermostat is set incorrectly, probe has been moved from center of unit, or coils and vents have excess dust) and attempt to return vaccine to proper storage conditions if still out-of-range by.
  - a. If outside of business hours and temperature is still out-of-range and cannot be restored to proper temperatures, execute emergency plan.
2. Label vaccines “Do not use until notified by VPDIP,” and do not use until approved.
3. Call VPDIP for further instruction.
4. Download DDL report, noting how long the temperature has been out of range and the minimum/maximum temperatures.
5. Send the DDL report/temperature log by fax to (615) 401-6829 or by email to [Temperature.Health@tn.gov](mailto:Temperature.Health@tn.gov). Include facility PIN and name on report.
6. Wait for notification from VPDIP whether the vaccine can be used.

## Section Eight: Vaccine Inventory Management

The vaccine cold chain becomes the provider's responsibility once delivery is made to the facility. The following section provides information on ensuring that vaccines are unpacked, stored, prepared, administered, and transported correctly.

### Scheduling and Receiving Deliveries

Staff members who may accept deliveries should be trained to immediately notify the vaccine coordinator or other designated personnel when deliveries arrive.

### Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after arrival. Check the shipment to ensure:

- No damage occurred to the package during transport
- The correct types and quantities of vaccines (and diluents, if applicable)
- No expired or soon-to-expire products were shipped
- No TEs occurred during transit (using the cold chain monitor [CCM])

**Unopened/unpacked boxes should not be placed in a storage unit because the cool packs shipped with the vaccine can make the vaccine too cold if placed inside the storage unit.**

Ultra-cold vaccine may be shipped in coolers packed in dry ice. These coolers should be repacked with dry ice within 24 hours of receipt and repacked again within 5 days or per manufacturer recommendations.

### Stock Rotation and Removal

On a regular basis, vaccine stock should be rotated and checked for expired doses. Expired vaccines and diluents should be removed immediately to avoid inadvertent administration. Vaccines with earlier expiration dates should be placed in front of those with later expiration dates.

### Preparing Vaccines for Administration

Preparing vaccines is the final step in the cold chain before administering to the patient. Best practices for handling vaccines include:

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Only prepare vaccines when you are ready to administer them.
- Check expiration dates and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared.

## Section Nine: Vaccine Transport

### Vaccine Transport to Offsite PODs or Mobile Clinics

**Vaccines should never be transported to an offsite clinic, POD, or mobile clinic without written approval from the VPDIP Program.** It is imperative that your facility has the appropriate equipment and processes in place to ensure the vaccine cold chain is maintained before, during, and after transport. Please contact [Vaccine.Storage@tn.gov](mailto:Vaccine.Storage@tn.gov) if your facility intends to conduct mobile or offsite clinics. A vaccine storage and handling expert will evaluate your proposed equipment and protocols to ensure vaccine can be

safely transported offsite. Required equipment includes a portable plug-in vaccine refrigerator and/or freezer and approved DDLs with valid Certificates of Calibration. Written protocols for vaccine transport will also be required.

## Emergency Vaccine Transport

**Vaccines should not be routinely transported.** However, **emergencies** such as storage unit failure or power outage may require vaccine transport; in these instances, ensure precautions are taken to protect your supply by using the appropriate packing materials and procedures. CDC's [Packing Vaccines for Transport during Emergencies](#) is a useful tool that details proper procedures for doing so. Highlights include:

- Diluents should be included with their corresponding vaccines during transport to ensure there is always an adequate amount for reconstitution.
  - If diluents typically stored at room temperature (20°C to 25°C [68°F to 77°F]) will be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines. Diluents should **never** be frozen, even during transport. When packing vaccines and diluents for transport, place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.
- Maintain a sufficient supply of materials needed for emergency vaccine transport of your maximum inventory. Materials include:
  - Portable vaccine refrigerators/freezer units (preferred)
  - Qualified containers and packouts
  - Hard-sided insulated containers or Styrofoam™
  - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4°C to 5°C
    - Follow manufacturer's instructions for use to reduce the risk of freezing vaccines during transport
  - Insulation materials such as bubble wrap and corrugated cardboard – enough to form two layers per container
  - DDLs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures. In an emergency situation, a system with conditioned water bottles can be used.

**Never** use commercially available soft-sided food or beverage coolers, and only use the original shipping materials that vaccines were initially shipping on or conditioned water bottle transport systems as a last resort in emergencies. In **no situation** should the frozen gel packs or coolant packs from the original shipments be re-used.

## Planning and Preparing for Transport

Emergency vaccine packing and transport protocols should be included within your facility's SOPs to ensure you are prepared for a situation in which your vaccine supply must be transported.

- Staff should be trained to pack vaccines correctly.
- Prior to transport, take an inventory of vaccines and record actions to protect vaccines during transport.
- Use the COVID-19 vaccine Transport log in Appendix B to record the time vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.
- When in transport, only open unit doors when necessary and only after all preparation for packing and moving vaccines has been completed.
- Avoid leaving containers where they may be exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.

## Monitoring Temperatures During and After Transport

While in transport, vaccines should still be continuously monitored using a DDL. DDLs used in vaccine transport have the same requirements as the ones used during routine storage and handling. Upon arrival at the destination, vaccines should be immediately stored in a storage unit with a DDL. A DDL report from the DDL used in transport should be printed, reviewed for TEs, and maintained with COVID-19 vaccine records for three (3) years.

## Section Ten: Emergency Vaccine Storage and Handling

Equipment failures, power outages, severe weather conditions, and natural disasters can happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, additional plans should be in place for emergencies.

You may choose to have a backup storage unit within your facility where vaccine can be stored if the primary storage unit fails. Additionally, you may have a generator that is

activated if power is compromised to the facility. However, even if a generator is available, additional backup plans should be in place for transport out of the facility.

### **Alternative Storage Facility**

A working agreement should be established with at least one alternative storage facility as part of emergency vaccine storage and handling planning. This agreement should include 24-hour access to this facility.

### **After Hours Facility Access**

A relationship with your facility's building manager and/or security staff should be maintained to ensure that you are able to access your vaccine supply outside of normal business hours. Relevant staff should maintain copies of information regarding building access and security procedures at home.

# Routine and Emergency Vaccine Management Plan (REVMP)

## KEEP YOUR MANAGEMENT PLAN NEAR VACCINE STORAGE UNITS

The Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP) requires COVID-19 Vaccination Program providers to maintain a vaccine management plan for routine and emergency situations. This document is a template for information, such as guidelines, protocols, contact information, and staff training, about your practice. None of the information included in this template may be excluded in the plan.

Review and update your plan at least once a year, when COVID-19 Vaccination Program requirements change, and when staff with designated vaccine management responsibilities change. Key practice staff must sign and acknowledge the signature log annually and whenever your plan is revised.

CDC Site Visit Reviewers may ask to review your plans during routine and drop-in site visits.

## STAFF ROLES AND CONTACT INFORMATION

**Facility Name:** \_\_\_\_\_

**Facility Address:** \_\_\_\_\_

**Facility Phone Number:** \_\_\_\_\_ **COVID PIN:** \_\_\_\_\_

Role/Responsibility	Name	Phone Number	Email Address
Chief Medical Officer			
Chief Executive Officer or Chief Fiduciary Officer			
Primary Vaccine Coordinator			
Back-up Vaccine Coordinator			
Pharmacist			
Receives Vaccines			
Stores Shipping			
Handles Vaccines			

Please refer to [Page 3](#) of this document for descriptions of the key duties assigned to designated vaccine management staff.

Staff must sign and date the [Acknowledgement and Signature Log](#) at the end of this document to confirm that they understand and agree to the duties assigned to them.

## COVID-19 REQUIRED TRAINING LOG

Please list designated vaccine management personnel and have them sign and acknowledge that they have completed required training.

Primary and Back-up Vaccine Coordinators must complete CDC's COVID-19 Vaccine Training Modules. Additionally, if a pharmacist is listed as the signatory under the Storage and Handling section of the COVID-19 Provider Agreement, this individual must complete the training modules. These modules include a [General Overview of Immunization Best Practices](#), [Moderna COVID-19 Vaccine](#), [Janssen COVID-19 Vaccine](#), and [Pfizer COVID-19 Vaccine](#). Staff at your facility that routinely handle or administer COVID-19 vaccine are recommended to also participate in these trainings, in case of staff turnover.

Name and Title	Signature	Date Training Completed			
		General Overview	Moderna	Pfizer	Janssen
Primary Vaccine Coordinator					
Back-up Vaccine Coordinator					
Pharmacist					

## KEY DUTIES FOR DESIGNATED VACCINE MANAGEMENT STAFF

All staff who work with COVID-19 vaccines should be familiar with all requirements outlined in the COVID-19 Vaccination Program Provider Agreement. Below are highlights of key duties for designated vaccine management staff.

### **CMO/CEO:**

- Complies with all federal vaccine management requirements, including key areas outlined in this plan
- Oversees designated vaccine management staff to ensure COVID-19 program requirements are being met
- Designates one employee as Primary Vaccine Coordinator
- Designates one employee as Back-up Vaccine Coordinator
- Authorizes and reports changes to Primary and Back-up Vaccine Coordinators, CEO, or CMO to the COVID-19 Onboarding Team at [Vaccine.Onboarding@tn.gov](mailto:Vaccine.Onboarding@tn.gov) as soon as possible following any changes
- Meets and documents required training for designated vaccine management staff
- Ensures designated vaccine management staff are skilled and knowledgeable regarding VPDIP Program requirements for temperature monitoring and storage equipment
- Ensures practice's vaccine inventory management is consistent with VPDIP Program requirements
- Ensures practice's vaccine storage units and temperature monitoring devices meet VPDIP program requirements
- Updates and revises vaccine management plans at least annually and whenever necessary
- Reviews VPDIP program requirements and management plans with staff at least annually and whenever necessary

### **Primary Vaccine Coordinator:**

- Completes all required training modules
- Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

### **Back-up Vaccine Coordinator:**

- Completes all required training modules
- Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

### **Pharmacist (only required if a pharmacist signed Storage and Handling section of Provider Agreement):**

- Completes all required training modules
- Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

**The Primary Vaccine Coordinator should review and acknowledge the following requirements by checking the box next to each item:**

## VACCINE STORAGE EQUIPMENT

### ***Equipment:***

- This facility uses VPDIP-compliant and approved vaccine storage refrigerator(s) and/or freezer(s)
- Vaccine storage units maintain recommended unit temperature ranges:
  - Refrigerator: between 2 and 8 °C
  - Freezer: between -15 °C and -25 °C
  - Ultra-cold Freezer: between -96 °C and -60 °C
- Vaccine storage units have adequate capacity to store vaccine supply at all times
- Vaccine storage units are routinely cleaned inside, kept dust-free outside, and have proper seals on the doors
- This facility keeps maintenance and repair records for vaccine storage units on file and makes them available to review upon request by VPDIP or CDC Site Visit Reviewers

### ***Power Supply:***

- Each vaccine storage unit is directly plugged into a wall outlet
- No vaccine storage unit is controlled by a light switch, power strips, or surge protectors with on/off switch
- Extension cords are never used to connect storage units to an outlet
- Plug guards are used to prevent power interruption
- "DO NOT UNPLUG" signs are posted at each outlet and at the circuit breakers

### ***Set-up:***

- Vaccine storage units are set up according to requirements outlined in the [CDC Storage and Handling Toolkit](#)
- Vaccine storage units are located away from direct sunlight and away from walls to allow air circulation
- Vaccines are never stored in the doors, drawers, or bins of storage units
- Drawers/deli crispers are removed from vaccine storage units
- Vaccines are stored 2-3 inches away from the walls, air vents, and floors of vaccine storage units to allow space for air circulation
- To stabilize temperatures, frozen cold packs are kept in **standalone** freezers and water bottles are kept on the top shelf, in the door, and on bottom of refrigerators where vaccines cannot be stored.
- The freezer compartment of a combination refrigerator/freezer storage unit is **NEVER** used for vaccine storage
- Dorm-style units are **NEVER** used for vaccine storage
- Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine
- Buffered DDL probes are placed in the center of the vaccine storage units, near the vaccines
- DDL displays are securely attached on the outside of vaccine storage units
- Vaccines are stored in their original packaging until administered
- Food, beverages, and laboratory specimens are never stored in vaccine storage units
- When medication or biologic media (not inoculated) are stored in the same unit as vaccines, they are placed on the shelves below vaccines

## TEMPERATURE MONITORING EQUIPMENT

### ***Digital Data Loggers (DDLs):***

- Each vaccine storage unit has a continuous temperature monitoring device with the following capabilities:
  - Data that can be routinely downloaded

- Active display that is placed on the outside of the unit door to allow for reading temperatures without opening the unit door
- Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature
- Alarm for out-of-range temperatures
- Low battery indicator
- Accuracy of +/- 0.5°C
- Memory storage of at least 4,000 readings
- User-programmable logging interval (or reading rate)
- Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature
- Each DDL has a current and valid Certificate of Calibration (also known as a Report of Calibration Testing)
- Each DDL has a digital display of current, minimum, and maximum temperatures
- Each DDL displays temperatures in degrees Celsius (°C)
- Each DDL is set to alarm when:
  - Temperature in refrigerator goes **above** 8°C or **below** 2°C
  - Temperature in freezer goes **above** -15°C or **below** -25 °C
- Probes are placed in the center of vaccine storage units and never in the unit doors, near or against the walls, underneath air vents, or on unit floors
- DDL batteries are replaced every six months or as needed
- There is at least one back-up DDL that is readily available on-site to ensure that temperature assessment and recordings can be performed twice a day

#### ***DDL Calibration:***

- All primary and back-up DDLs are calibrated as recommended by the manufacturer
- DDL calibration is done by either a laboratory accredited by an ILAC MRA signatory body or an entity that provides documentation demonstrating that calibration testing meets ISO/IEC 17025 International standards for calibration testing and traceability
- Certificates of Calibration are maintained in a readily accessible area, until expiration, and presented to VPDIP staff for review upon request
- DDLs are replaced on or before expiration date listed on device
- DDLs are replaced when no longer accurate within +/- 0.5°C

#### ***Safeguarding Vaccines, Handling, and Reporting Temperature Excursions:***

- When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage
- Temperature excursions are reported immediately to 800-404-3006 or [Temperature.Health@tn.gov](mailto:Temperature.Health@tn.gov)
- Vaccines involved in temperature excursions are labelled "Do Not Use Until Further Notice"
- This facility has an Emergency Vaccine Management Plan to follow in case of power outage, appliance malfunction, severe weather conditions, or human error that may affect vaccine viability
- When necessary to transport vaccine to another storage unit or to a predetermined site, facility always follows CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid

#### ***Temperature Monitoring and Documentation:***

- Vaccine storage unit temperatures are read twice a day, when the clinic opens and before it closes
  - Minimum and maximum temperatures are read and recorded once each day
  - AM temperatures are read and recorded before opening vaccine storage units

- PM temperatures are read and recorded at the end of each day, allowing time for corrective actions in the event of out-of-range unit temperatures
- [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are posted on storage unit doors or nearby
- [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are completed daily and DDL reports are printed weekly
- [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are initialed by person who documents temperatures
- Completed temperature logs are maintained for three years and made available to VPDIP upon request for review

Please refer to the [VPDIP website](#) for guidance on [Temperature Monitoring and Excursions](#)

## INVENTORY MANAGEMENT

### ***Inventory Maintenance:***

- Physical vaccine inventory is reconciled in TennIIS daily
- Facility has adopted an inventory control system
- Accurate records, including packing slips and inventory management records, are maintained and made available upon request to VPDIP
- Vaccines that are drawn up and not used are disposed of correctly and recorded in TennIIS
- Facility stores diluent for vaccine appropriately
- Facility clearly labels diluents that are not packed with its vaccine so they can be easily identified
- Diluents are not placed in the freezer

### ***Stock Rotation, Returns, and Transfers***

- Vaccine stock is rotated monthly to assure that vaccines with the shortest expiration dates are used first
- If vaccine expires or spoils, it is:
  - Removed from storage unit
  - Reconciled appropriately in TennIIS
  - Returned to the vaccine manufacturer or wasted per VPDIP guidance
- If vaccine is due to expire within two weeks and will not be used, this facility will:
  - Notify VPDIP at [VPDIP.Pandemic@tn.gov](mailto:VPDIP.Pandemic@tn.gov) about vaccine
  - Request a transfer approval from VPDIP
- If facility needs to transfer or transport vaccine, CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid is followed
- This facility does not return the following items:
  - Used syringes with or without needles
  - Syringes with vaccine drawn up and not used
  - Broken or damaged vaccine vials
  - Multi-dose vials that have already been withdrawn
- Spoiled, expired, or wasted vaccine are reported to VPDIP before placing a new vaccine order

### **Vaccine Ordering:**

NOTE: While supplies are limited, TDH will continue to allocate doses directly to providers. Any orders submitted through VOMS will be rejected. VPDIP will communicate to all vaccinating providers when ordering is permitted.

- Orders are submitted in TennIIS and placed according to clinic-based eligibility data, assigned order frequency, vaccine usage, and current inventory in stock.
- A physical vaccine inventory is conducted before placing a vaccine order
- This facility places orders with sufficient inventory on hand to allow time for order processing delivery
- This facility confirms operation hours in TennIIS before submitting each order
- This facility reports any changes to the practice's hours to VPDIP to avoid receiving vaccine shipments when the clinic is closed or staff is not available

### **Receiving and Inspecting Vaccine Shipments:**

- Staff is familiar with procedures for accepting vaccine shipments in TennIIS
- Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, and that the vaccines being delivered match those listed on the packing slip and order confirmation
- This facility assumes responsibility for all COVID-19 vaccine that is shipped to its site
- This facility never rejects a vaccine shipment
- Shipment discrepancies and vaccines exposed to out-of-range temperatures are reported to VPDIP at 800-404-3006 or [Temperature.Health@tn.gov](mailto:Temperature.Health@tn.gov) immediately
- Vaccines are stored immediately and appropriately upon delivery
- Vaccines are accepted in the TennIIS inventory upon receipt

## VACCINE STORAGE UNIT INFORMATION

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Refrigerator (3)				
Refrigerator (4)				
Freezer (1)				
Freezer (2)				
Freezer (3)				
Freezer (4)				

Where are your digital data logger reports and temperature logs located?

If you have a manual defrost freezer, please provide a description of your plan for regular defrosting \*:

\* A defrost plan is required for providers with a manual defrost freezer. The plan should include 1) where you will transfer vaccines, 2) what equipment will be used to transfer vaccines, and 3) when/how often you will defrost your freezer.

**VPDIP must be notified before transporting vaccines, and all temperature excursions that occur during transport must be reported to VPDIP.**

## DIGITAL DATA LOGGER AND CALIBRATION INFORMATION

**Primary Data Loggers (must have one for each unit listed in previous section):**

DDL Brand, Model # /Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting

**Primary Data Loggers (must have at least one readily available on-site):**

Data Logger Model/Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting

**Calibration Company:** \_\_\_\_\_ **Phone Number:** \_\_\_\_\_

**Location of Certificates of Calibration:** \_\_\_\_\_

## USEFUL EMERGENCY NUMBERS

Service	Name	Main Phone Number	Alternate Number	Email Address
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair Company				
Point of Contact for Vaccine Transport				

VPDIP Team	Main Phone Number	Alternate Number	Email Address	Fax Number
Temperature Excursions (available Monday – Friday, 8AM – 4:30PM) *	<b>(800) 404-3006</b>	<b>615-741-7247</b>	<a href="mailto:Temperature.Health@tn.gov">Temperature.Health@tn.gov</a>	<b>(615) 401-6829</b>
Vaccine Storage and Handling	<b>(800) 404-3006</b>	<b>615-741-7247</b>	<a href="mailto:Vaccine.Storage@tn.gov">Vaccine.Storage@tn.gov</a>	
VOMS (available Monday – Friday, 8AM – 4:30PM) *	<b>(800) 404-3006</b>	<b>615-741-7247</b>	<a href="mailto:TennIIS.VOMS@tn.gov">TennIIS.VOMS@tn.gov</a>	
TennIIS Help Desk (available Monday – Friday, 7AM – 6PM) *	<b>(844) 206-9927</b>		<a href="mailto:TennIIS.Help@tn.gov">TennIIS.Help@tn.gov</a>	

\* All times are in Central Time Zone. Unavailable on all [Tennessee State Holidays](#)

# Emergency Vaccine Management Plan

The following sections include space for information and necessary actions to take in the event of an emergency, such as unit malfunction, mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Role/Responsibility	Name	Phone Number	Email Address

Does the clinic have a generator? If so, where is it located?

If your clinic does not have a generator, and/or your vaccine storage unit fails, it may be necessary to transport vaccine to alternate storage locations.\* Please identify two back-up locations:

Alternate Vaccine Storage Location	Address and City	Point of Contact Name	POC Contact Information

\* Alternate storage locations must have vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements outlined by VPDIP and the CDC Storage and Handling Toolkit

I have confirmed that the point of contact for the alternate storage locations will accept my vaccines during an emergency situation.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Where is the location of your emergency packing supplies?

**If you have a generator and no back-up locations, the generator should be tested quarterly and serviced once a year. In the section below, please record the last date that the generator was tested and serviced and sign and date each time this occurs during the year.**

**The REVMP does not need to be re-submitted each time the generator is tested or serviced, but it will be reviewed during routine and drop-in site visits:**

**Quarterly Tests**

Quarter	Signature	Date
Q1		
Q2		
Q3		
Q4		

**Annual Service**

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## OTHER USEFUL EMERGENCY INFORMATION

Complete the following information for emergency storage units that will be used by your facility for emergencies that do not require an alternate storage location.\*

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Freezer (1)				
Freezer (2)				

\* **Alternate storage locations must have vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements outlined by VPDIP and the CDC Storage and Handling Toolkit**

**Use the following guidance for safeguarding vaccines in the event of planned or unplanned power interruptions (e.g. power outages, severe weather, building maintenance/repairs, etc.):**

***Before an Emergency:***

- Maintain emergency contact information for designated vaccine management personnel
- Place water bottles on the top shelf, in the door, and on the bottom of vaccine refrigerators, where vaccines cannot be stored to stabilize temperatures. Place frozen cold packs in standalone freezers for similar purposes.
- Identify alternate vaccine storage locations (e.g. a local hospital, a local health department, or another COVID-19 provider). Ensure the location has adequate space to accommodate vaccines and that their temperature monitoring equipment meets requirements.
- Update necessary contact information for alternate vaccine storage locations, including facility name, address, contact person, and telephone number.
- Stock emergency supplies as indicated in CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
- Label and keep accessible any necessary vaccine packing and transport supplies, copies of vaccine transport job aids, facility floor plans when available, and other related information
- Be familiar with back-up power sources for commercial, laboratory, and pharmacy-grade storage units

***During an Emergency:***

- Assess the situation. Do not open the vaccine storage unit.
- Determine the cause of the power failure and estimate the time it will take to restore power.
- Notify key vaccine management staff listed on the Emergency Plan as appropriate
- If the power outage is expected to be short-term, usually restored within 2 hours:
  - Record the time that the outage started, unit temperatures (current, minimum, and maximum) for each day, and the room temperature
  - Place a "DO NOT OPEN" sign on the storage unit(s) to conserve cold air mass
  - Monitor the temperature until power is restored
- If the outage is expected to be long-term, usually longer than 4 hours, consider moving vaccines to an alternative unit or facility. See details below, under Relocating Vaccine.

***NOTE: Temperatures in vaccine storage units tend to increase faster during power outages. As a result, clinics may need to monitor temperature more frequently and/or transport vaccines to an alternate location sooner.***

### ***Relocating Vaccine:***

If a power outage is expected to be long-term (e.g. not restored by the end of the day) or storage units are not working properly, prepare to relocate vaccines to alternate storage locations. If moving vaccines, **a DDL must remain with the vaccine at all times.**

#### **Before transporting vaccines:**

- Review CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
- Contact the alternate storage facility to verify that they can accept the vaccines
- If transport or relocation is not feasible (e.g. alternate location is not available or travel conditions are unsafe):
  - Keep units closed and document the current, minimum, and maximum temperatures for each day
- Notify the VPDIP Team at 800-404-3006 or [Temperature.Health@tn.gov](mailto:Temperature.Health@tn.gov)

#### **Packaging and transporting vaccines:**

- Complete the [Refrigerated Vaccine Transport Log](#) and/or the [Freezer Vaccine Transport Log](#)
- Attach DDL to cooler
- Prepare cooler(s) for transport following CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
  - Use frozen cold packs for frozen vaccines. Never use dry ice.
  - Use conditioned (slightly defrosted) frozen packs for refrigerated vaccines. Placing refrigerated vaccine directly on frozen packs and packaging it without sufficient insulation may freeze and therefore, damage vaccine. If clinic does not have time to condition frozen packs, refrigerated cold packs or cold water bottles may be used.
- Package and prepare diluent
  - Diluents stored in the refrigerator should be transported with refrigerated vaccines
  - Diluents stored at room temperature should be transported at room temperature
  - Diluents packaged with their vaccine should be transported with their vaccine
- Upon arrival at the alternate vaccine storage location, document total vaccine transport time, the current, minimum, and maximum temperatures in the transport cooler(s), and the current, minimum, and maximum temperatures in the alternate storage unit(s).

#### ***After Power is Restored:***

- Verify storage units are functioning properly and temperatures are within range before attempting to move any vaccine
- Follow the same transportation procedures and transfer vaccine back to its original storage unit
- Vaccine kept at the proper temperature during the power outage, whether transported or not, may be used
- For any vaccine not stored at proper temperature:
  - Segregate it in the storage unit
  - Mark it "Do Not Use Until Further Notice"
  - Contact the VPDIP Team at 800-404-3006 to report the excursion
- Never return vaccine to the vaccine distributor without authorization from VPDIP

# Acknowledgement and Signature Log

Please sign and date this acknowledgement and signature log when you update practice-specific information.

By signing this log, facility staff are acknowledging that they have reviewed, understand, and agree to the key duties assigned to them as vaccine management personnel for this facility.

Updates and comments to changes made in Routine and Emergency Vaccine Management Plans:

**CMO:**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**PRIMARY Vaccine COORDINATOR:**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**BACK-UP Vaccine COORDINATOR:**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**CEO/CFO:**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Pharmacist (if applicable):**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# COVID-19 Vaccine

## Refrigerated Vaccine Transport Log



**Instructions:** Complete this log when transporting vaccines to an alternate or back-up refrigerator.

Date: \_\_\_\_\_

Provider Name: \_\_\_\_\_ COVID/VFC PIN: \_\_\_\_\_

Transferred To: \_\_\_\_\_ COVID/VFC PIN: \_\_\_\_\_

Vaccines Transferred Due To:  Power Outage  Excess Supply  Short Dated  Unit Malfunction  Building Maintenance  Other: \_\_\_\_\_

### Vaccine Inventory Information – may also attach most recent reconciliation report from TennIIS.

Vaccine	Lot Number	Number of Doses	Expiration Date	Vaccine Previously Transported? ( Yes/No)	Comments

### Temperature Monitoring Information

Temperature of vaccine in refrigerator prior to transfer: \_\_\_\_\_ Celsius/Fahrenheit: \_\_\_\_\_ Time: \_\_\_\_\_

Temperature of vaccine in cooler before departure: \_\_\_\_\_ Celsius/Fahrenheit: \_\_\_\_\_ Time: \_\_\_\_\_

Temperature of vaccine in cooler upon arrival: \_\_\_\_\_ Celsius/Fahrenheit: \_\_\_\_\_ Time: \_\_\_\_\_

Temperature of back-up refrigerator: \_\_\_\_\_ Celsius/Fahrenheit: \_\_\_\_\_ Time: \_\_\_\_\_

Contact the VFC Program (800-404-3006) if temperatures during transport exceed recommended ranges.

Total Transport Time: \_\_\_\_\_ Min/Hr



## Pfizer COVID-19 Vaccine

# *Vaccine Administration*

# Pfizer-BioNTech COVID-19 Vaccine

## Vaccine Preparation and Administration Summary



### General Information

Vaccine: Pfizer-BioNTech COVID-19 Vaccine

Diluent: 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 6 doses per vial

Dosage: 0.3 mL

**Vaccine MUST be mixed with diluent before administration.**

### Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
  - **Refrigerator:** Between 2°C and 8°C (36°F and 46°F)  
Unpunctured vials may be stored in the refrigerator for up to 1 month (31 days).
  - **Room temperature (for immediate use):** Up to 25°C (77°F)  
Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).

### Prepare the Vaccine

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.\*



Remove vaccine from the freezer or refrigerator. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing.



Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent. The expiration dates for the diluent and the vaccine are located on the respective vials.



With the vaccine at room temperature, gently invert vial 10 times. **Do not shake the vial.** If the vial is shaken, contact the manufacturer. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.



Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, **withdraw 1.8 mL** of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent every time. **Do NOT** use bacteriostatic normal saline or other diluents to mix the vaccine.



Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.



Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.



Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. **Do not shake.** If the vial is shaken, contact the manufacturer.



Note the date and time the vaccine was mixed on the vial.



Keep mixed vaccine between 2°C and 25°C (36°F to 77°F), minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Administer within 6 hours. **Discard any unused vaccine after 6 hours.** Do not return to freezer storage.



\*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

# Pfizer-BioNTech COVID-19 Vaccine

## Vaccine Preparation and Administration Summary



### Administer the Vaccine

#### Assess recipient status:

- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.



#### Choose the correct equipment, including the correct needle size.

- Use a new, sterile needle and syringe for each injection. Use low dead-volume syringes/needles to extract 6 doses from a single vial. If sufficient low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes per vial (e.g., 4 low dead-volume syringes and 2 non-low dead-volume syringes).



#### Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe.

- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.3 mL.
- If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and contents.
- **Do NOT** combine vaccine from multiple vials to obtain a dose.



Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle\* to withdraw and administer the vaccine. Ensure the prepared syringe is not cold to the touch.



Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.



Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated).



Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.



Observe recipients after vaccination for an immediate adverse reaction:

- **30 minutes:** Persons with a:
  - » History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
  - » Contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech vaccine
  - » History of anaphylaxis due to any cause
- **15 minutes:** All other persons



\*It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or contaminated.

### Scheduling Doses

Vaccination History <sup>†‡</sup>	And	Then	Next Dose Due
0 doses		Give dose 1 today	Give dose 2 at least 21 days after dose 1 <sup>§</sup>
1 dose (Pfizer COVID-19 Vaccine)	It has been at least 21 days since dose 1	Give dose 2 today	Series complete; no additional doses needed
	It has not been at least 21 days from dose 1	No dose today	Give dose 2 at least 21 days after dose 1 <sup>§</sup>
2 doses (Pfizer COVID-19 Vaccine) at least 21 days apart <sup>§</sup>			Series complete; no additional doses needed
2 doses (1 product unknown) at least 28 days apart <sup>‡</sup>			Series complete; no additional doses needed

<sup>†</sup>COVID-19 vaccines and other vaccines may be administered at the same visit, as well as within 14 days of each other. When deciding whether to administer COVID-19 vaccines and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

<sup>‡</sup>Every effort should be made to determine which vaccine product was received as the first dose. In exceptional situations in which the vaccine product given for the first dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at least 28 days after the first dose.

**Administer the second dose as close to the recommended interval (21 days) as possible.** If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Doses inadvertently administered less than 21 days apart do not need to be repeated.

# Pfizer-BioNTech COVID-19 Vaccine

## Vaccine Preparation and Administration Summary



## Contraindications and Precautions

### Contraindications:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
- Immediate allergic reaction\* of any severity to a previous dose or known (see Table 1 for a list of ingredients in COVID-19 vaccine products)

**Note:** Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).<sup>†</sup>

### Precautions:

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of an immediate allergic reaction\* to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote).<sup>†</sup>
- Moderate to severe acute illness

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at [www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).

## Management of Anaphylaxis

Be prepared to manage medical emergencies.

- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

For more information, please see Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at [www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html).

## Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (i.e., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.

Document each recipient's vaccine administration information in the:

### ■ Medical record:

- Vaccine and the date it was administered
- Manufacturer and lot number
- Vaccination site and route
- Name and title of the person administering the vaccine

### ■ Personal vaccination record card (shot card):

Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.

### ■ Immunization information system (IIS) or “registry”:

Report the vaccination to the appropriate state/local IIS.

## Reporting Adverse Events

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety reporting requirements per the Food and Drug Administration’s conditions for use of an authorized vaccine throughout the duration of the EUA

Adverse events should be reported even if the cause is uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration. Submit reports to [www.vaers.hhs.gov](https://www.vaers.hhs.gov).

For additional information, see the vaccine manufacturer’s product information at [www.cvdvaccine.com](https://www.cvdvaccine.com).

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A>

\*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

<sup>†</sup>Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project [https://www.cdc.gov/vaccinesafety/ensuringSafety/monitoring\\_cisa/index.html](https://www.cdc.gov/vaccinesafety/ensuringSafety/monitoring_cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

# Pfizer-BioNTech COVID-19 Vaccine

## Vaccine Preparation and Administration Summary



**Table 1: Ingredients included in COVID-19 vaccines**

The following is a list of ingredients for the [Pfizer-BioNTech](#), [Moderna](#), and [Janssen](#) COVID-19 vaccines reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
<b>Active ingredient</b>	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
<b>Inactive ingredients</b>	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

\*None of the vaccines contain eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients in vaccines and medications can be found in the package insert. [CDC's vaccine excipient summary](#) and the National Institutes of Health [DailyMed database](#) can also be used as resources.

# Pfizer-BioNTech COVID-19 Vaccine

## Vaccine Preparation



**Prepare the injection with the correct needle length based on the recipient's age.**

**Gender and weight should be considered for adults 19 years of age and older.**

- Use aseptic technique to mix the vaccine and prepare the injection.
- Prepare the vaccine using a **NEW** vial of diluent and a **NEW** vial of vaccine **EVERY TIME**.
- Prepare the injection using a new, sterile needle and syringe **EVERY TIME**.



### » Mixing Vaccine

#### Do



Use the needles and syringes labeled for mixing vaccine and diluent in the ancillary supply kit.



Use 0.9% sodium chloride (normal saline, preservative-free) ONLY.



Mix 1.8 mL of the diluent with the thawed vaccine.\* Slowly inject diluent to prevent excess foaming or bubbling.



Gently invert the vial 10 times before and after adding the diluent.



Discard the diluent vial after mixing the vaccine.

#### Don't



Do **NOT** use needles and syringes designated for administration to mix vaccine and diluent.



Do **NOT** use bacteriostatic normal saline or other diluents.



Do **NOT** use all the diluent in the vial.



Do **NOT** shake the vial.



Do **NOT** use or save any remaining diluent to mix with additional vials of vaccine or for other uses.

\*Using a 21-gauge or narrower needle

### » Withdrawing 6 doses of vaccine from the vial

After mixing, a vial of Pfizer-BioNTech COVID-19 vaccine contains six 0.3 mL doses of vaccine. Use low dead-volume syringes and/or needles to withdraw 6 doses.

- If sufficient quantities of low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non low-dead volume syringes per vial.

#### Do



When mixing and withdrawing vaccine, insert the needle into different places on the vial septum.



Leave needle in vial to remove air bubbles, when applicable.



If, after withdrawing 5 doses, the amount of vaccine left in the vial is not a full dose, discard the vial and remaining vaccine.

#### Don't



Do **NOT** use the same insertion point every time. This may cause vaccine to leak from the vial.



Do **NOT** remove air bubbles with the needle outside of the vial as vaccine can be easily lost in the process.



Do **NOT** combine remaining vaccine from multiple vials to obtain a full dose.

# Pfizer-BioNTech COVID-19 Vaccine

## Standing Orders for Administering Vaccine to Persons 16 Years of Age and Older



**Note:** For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

### » Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

### » Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

### » Procedure

- Assess persons 12 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:
  - Has not completed a COVID-19 vaccination series, regardless of brand. If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen vaccine has been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of PfizerBioNTech COVID-19 Vaccine, administer the second dose at an interval of least 21 days (but preferably before 42 days).\*
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines>
- Pfizer-BioNTech COVID-19 vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.<sup>¶</sup>
- Defer vaccination with Pfizer-BioNTech COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.

### ◦ Contraindications:

- » Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
- » Immediate allergic reaction<sup>‡</sup> of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of vaccine components)

**Note:** Persons who have a contraindication to the mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).<sup>#</sup> Prior to administration of Janssen COVID-19 Vaccine, inform women 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group.<sup>†</sup> Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.

### ◦ Precautions:

- » Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- » History of an immediate allergic reaction<sup>‡</sup> of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polyethylene glycol (PEG) or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- » People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote)<sup>#</sup>
- » Moderate to severe acute illness

\*Administer the second dose as close as possible to the recommended interval (21 days). If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Second doses inadvertently administered less than 21 days apart do not need to be repeated.

<sup>¶</sup>When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

<sup>‡</sup>An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

<sup>#</sup>Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the [Clinical Immunization Safety Assessment COVIDvax Project](#). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

• People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 vaccine.

• People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

<sup>†</sup>Educational materials are available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html>

# Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine  
to Persons 16 Years of Age and Older



Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site <sup>†</sup>
Female or male fewer than 130 lbs	22–25	5/8 §–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–11/2"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs	22–25	11/2"	Deltoid muscle of arm

<sup>†</sup>Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

<sup>§</sup>Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- Provide all recipients and/or parents/legal guardians with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 12 through 18 years of age:
    - » Needle gauge/length: 22-25 gauge, 1-inch
    - » Site: Deltoid muscle of arm.
  - 19 years of age and older: See chart above.
  - Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine.
- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - » Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - » Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - » Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

- Additional preparation and administration information is available on the manufacturer's website at [www.cvdvaccine.com](http://www.cvdvaccine.com).
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - » **30 minutes:** Persons with a:
      - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
      - Contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech Vaccine
      - History of anaphylaxis due to any cause
    - » **15 minutes:** All other persons
  - Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.
  - For more information, please see:
    - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination** at <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>
    - » **CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions,"** at <https://www.cdc.gov/vaccines/hcp/acip-recommendations/general-recommendations/adverse-reactions.html>

# Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine  
to Persons 16 Years of Age and Older



- » Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at <https://www.immunize.org/catg.d/p3082.pdf>

- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under [Emergency Use Authorization \(EUA\)](#), healthcare professionals are required to report to VAERS:
    - » Vaccine administration errors (whether associated with an adverse event [AE] or not)

- » Serious AEs (irrespective of attribution to vaccination)
- » Multisystem inflammatory syndrome (MIS) in [adults](#) or [children](#)
- » Cases of COVID-19 that result in hospitalization or death
- » Any additional AEs and revised safety requirements per the [Food and Drug Administration's](#) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to [VAERS](#):
  - » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

## » Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ effective \_\_\_\_\_ until rescinded or until \_\_\_\_\_.  
Medical director (or other authorized practitioner)  
\_\_\_\_\_/\_\_\_\_\_ /\_\_\_\_\_

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders

» **Table 1: Ingredients included in COVID-19 vaccines**

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
<b>Active ingredient</b>	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
<b>Inactive ingredients</b>	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3phosphocholine	1,2-distearoyl-sn-glycero-3phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

\*None of the vaccines contain eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients in vaccines and medications can be found in the package insert. [CDC's vaccine excipient summary](#) and the National Institutes of Health [DailyMed database](#) can also be used as resources.

## **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 12 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.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

## **WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE**

### **WHAT IS COVID-19?**

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

### **WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?**

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 12 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “[\*\*What is an Emergency Use Authorization \(EUA\)?\*\*](#)” section at the end of this Fact Sheet.

## **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
- have ever fainted in association with an injection

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

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

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

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

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

## **WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?**

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

## **HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?**

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

## **HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?**

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

## **WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?**

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

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

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

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

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

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- diarrhea
- vomiting
- arm pain

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

## **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Pfizer-BioNTech COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

## **WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

## **ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?**

Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

## **CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

## **WHAT IF I AM PREGNANT OR BREASTFEEDING?**

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

## **WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?**

No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

## **KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

## **ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

<b>Global website</b>	<b>Telephone number</b>
<a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> 	1-877-829-2619 (1-877-VAX-CO19)

## **HOW CAN I LEARN MORE?**

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

## **WHERE WILL MY VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## **CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

## **WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

## **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp) or call 1-855-266-2427.

## **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



Manufactured by  
Pfizer Inc., New York, NY 10017

**BIONTECH**

Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

LAB-1451-4.2a

Revised: 10 May 2021



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 05/2021

## **FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)**

### **EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 12 years of age and older.

#### **SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS**

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### **DESCRIPTION OF COVID-19**

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

## DOSAGE AND ADMINISTRATION

### Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

#### Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F) until the expiry date printed on the label. Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

#### Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F).

#### Thawed Vials Before Dilution

##### *Thawed Under Refrigeration*

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

### *Thawed at Room Temperature*

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

### Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

### Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

### **Dosing and Schedule**

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

### Dose Preparation

#### *Prior to Dilution*

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] (see *Storage and Handling*).
- Refer to thawing instructions in the panels below.

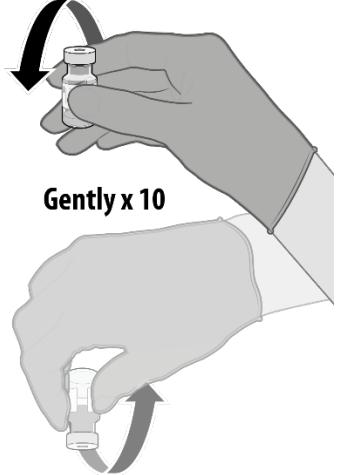
#### *Dilution*

Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine

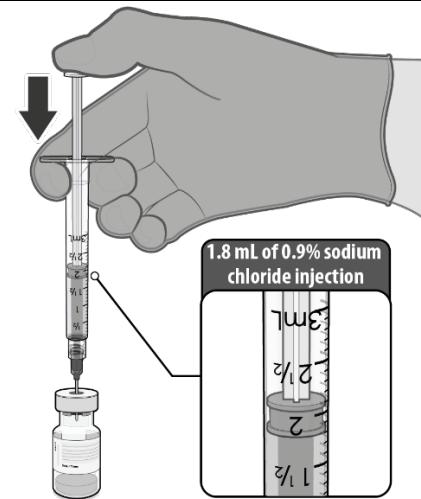
and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.

After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

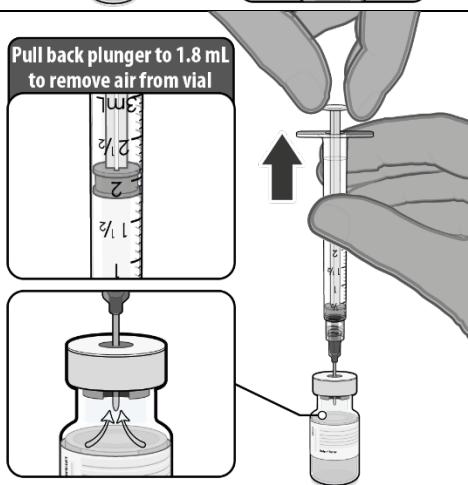
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	<ul style="list-style-type: none"><li>• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:<ul style="list-style-type: none"><li>○ Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month.</li><li>○ Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.</li></ul></li><li>• Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.</li></ul>
	<ul style="list-style-type: none"><li>• Before dilution invert vaccine vial gently 10 times.</li><li>• <u>Do not shake</u>.</li><li>• Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.</li><li>• Do not use if liquid is discolored or if other particles are observed.</li></ul>

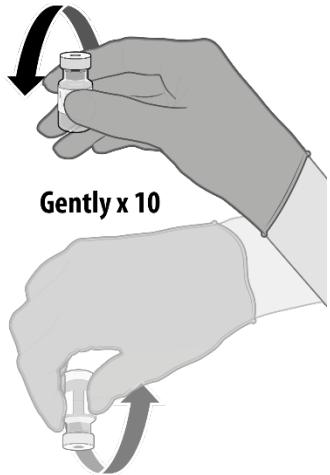
## DILUTION



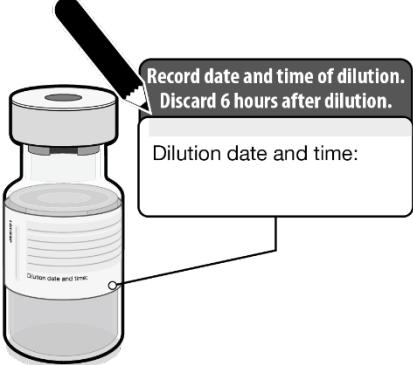
- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.



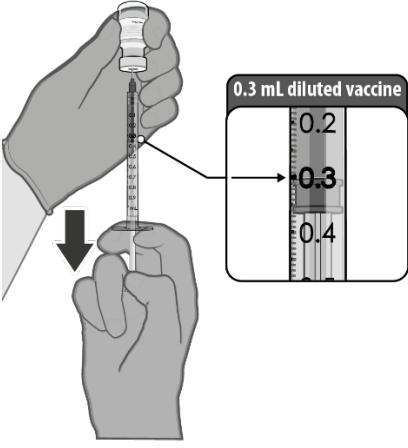
- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.



- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

	<ul style="list-style-type: none"> <li>• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.</li> <li>• Store between 2°C to 25°C (35°F to 77°F).</li> <li>• Discard any unused vaccine 6 hours after dilution.</li> </ul>
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## PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE

	<ul style="list-style-type: none"> <li>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.3 mL</u> of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.</li> <li>• Each dose must contain 0.3 mL of vaccine.</li> <li>• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.</li> <li>• Administer immediately.</li> </ul>
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## Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

## **Contraindications**

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (see *Full EUA Prescribing Information*).

## **Warnings**

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

## **Adverse Reactions**

### *Adverse Reactions in Clinical Trials*

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy (see *Full EUA Prescribing Information*).

### *Adverse Reactions in Post Authorization Experience*

Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, and pain in extremity (arm) have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

## **Use with Other Vaccines**

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

## **INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS**

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website [www.cvdvaccine.com](http://www.cvdvaccine.com) to obtain the Fact Sheet) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

## **MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION**

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 12 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
  - vaccine administration errors whether or not associated with an adverse event,
  - serious adverse events\* (irrespective of attribution to vaccination),
  - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
  - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

\* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

## **OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.**

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

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.

<b>Website</b>	<b>Fax number</b>	<b>Telephone number</b>
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

## **ADDITIONAL INFORMATION**

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

<b>Global website</b>	<b>Telephone number</b>
<a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> 	1-877-829-2619 (1-877-VAX-CO19)

## **AVAILABLE ALTERNATIVES**

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

## **FEDERAL COVID-19 VACCINATION PROGRAM**

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see <https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html>.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

## AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 12 years of age and older.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at:  
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

## The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp), email [cicp@hrsa.gov](mailto:cicp@hrsa.gov), or call: 1-855-266-2427.



Manufactured by  
Pfizer Inc., New York, NY 10017

**BIONTECH**

Manufactured for

BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

LAB-1450-8.2b

Revised: 19 May 2021

END SHORT VERSION FACT SHEET

Long Version (Full EUA Prescribing Information) Begins On Next Page

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# **FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION**

## **PFIZER-BIONTECH COVID-19 VACCINE**

### **FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS\***

- 1 AUTHORIZED USE**
- 2 DOSAGE AND ADMINISTRATION**
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  - 2.2 Administration Information
  - 2.3 Vaccination Schedule for Individuals 12 Years of Age and Older
- 3 DOSAGE FORMS AND STRENGTHS**
- 4 CONTRAINDICATIONS**
- 5 WARNINGS AND PRECAUTIONS**
  - 5.1 Management of Acute Allergic Reactions
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- 8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING  
ADVERSE EVENTS AND VACCINE ADMINISTRATION  
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- 10 DRUG INTERACTIONS**
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  - 18.1 Efficacy in Participants 16 Years of Age and Older
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  - 18.3 Immunogenicity in Adolescents 12 Through 15 Years of Age
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- 20 PATIENT COUNSELING INFORMATION**
- 21 CONTACT INFORMATION**

\* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

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# **FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION**

## **1 AUTHORIZED USE**

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

## **2 DOSAGE AND ADMINISTRATION**

For intramuscular injection only.

### **2.1 Preparation for Administration**

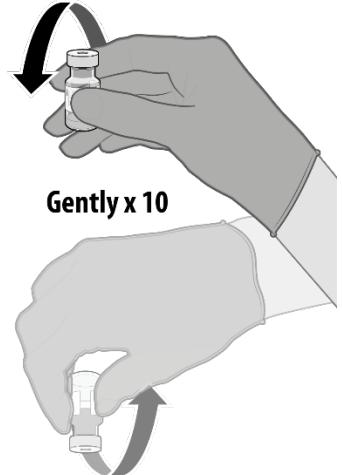
#### Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] [*see How Supplied/Storage and Handling (19)*].
- Refer to thawing instructions in the panels below.

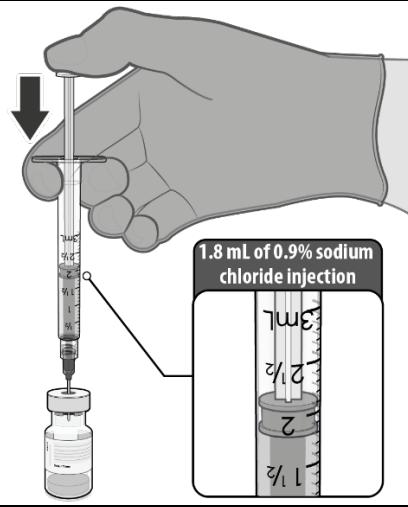
#### Dilution

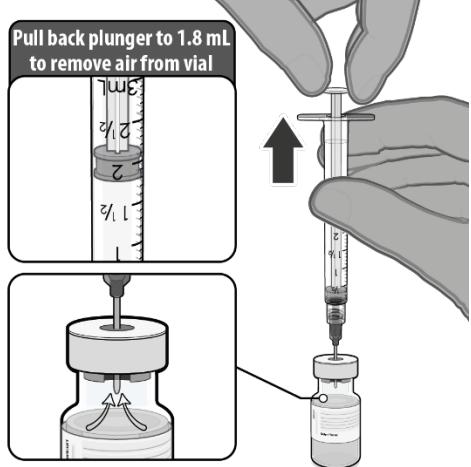
- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. Do not add more than 1.8 mL of diluent.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.

## THAWING PRIOR TO DILUTION

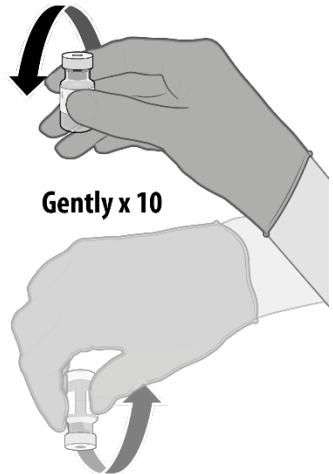
	<ul style="list-style-type: none"> <li>Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:             <ul style="list-style-type: none"> <li>Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month.</li> <li>Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.</li> </ul> </li> <li>Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.</li> </ul>
 <p>Gently x 10</p>	<ul style="list-style-type: none"> <li>Before dilution invert vaccine vial gently 10 times.</li> <li><u>Do not shake.</u></li> <li>Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain <u>white to off-white opaque amorphous particles</u>.</li> <li>Do not use if liquid is discolored or if other particles are observed.</li> </ul>

## DILUTION

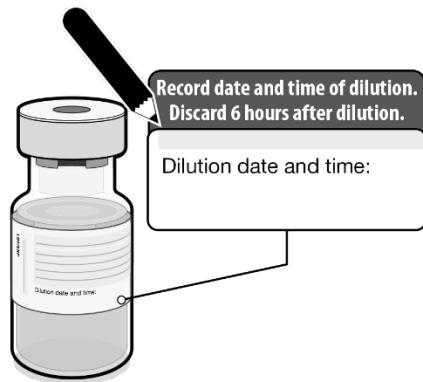
	<ul style="list-style-type: none"> <li>Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.</li> <li>Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).</li> <li>Cleanse the vaccine vial stopper with a single-use antiseptic swab.</li> <li>Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.</li> </ul>
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- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.

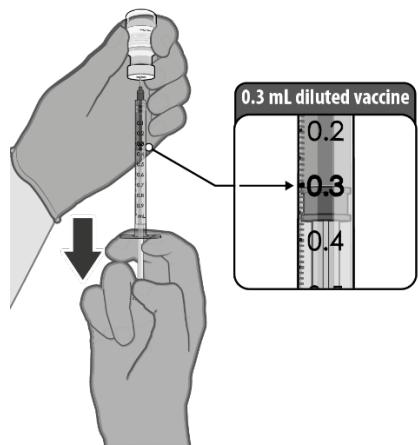


- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.



- Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 6 hours after dilution.

## **PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE**



- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately.

### **2.2 Administration Information**

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

### **2.3 Vaccination Schedule for Individuals 12 Years of Age and Older**

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

## **3 DOSAGE FORMS AND STRENGTHS**

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

## **4 CONTRAINDICATIONS**

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine [see Description (13)].

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Management of Acute Allergic Reactions**

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

### **5.2 Syncope**

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

### **5.3 Altered Immunocompetence**

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

### **5.4 Limitation of Effectiveness**

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

## **6 OVERALL SAFETY SUMMARY**

**It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.**

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

## 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 12 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 46,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively) and 2,260 adolescents are 12 through 15 years of age (1,131 and 1,129 in the vaccine and placebo groups, respectively).

In Study 2, all participants 12 to <16 years of age, and participants 16 years of age and older in the reactogenicity subset, were monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination]. Tables 1 through 6 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID 19 Vaccine and placebo.

### Participants 16 Years of Age and Older

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older had been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants 16 years and older enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

### Solicited Local and Systemic Adverse Reactions

Across both age groups, 18 through 55 years of age and 56 years and older, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

**Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age<sup>‡</sup> – Reactogenicity Subset of the Safety Population\***

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N <sup>a</sup> =2291 n <sup>b</sup> (%)	Placebo Dose 1 N <sup>a</sup> =2298 n <sup>b</sup> (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N <sup>a</sup> =2098 n <sup>b</sup> (%)	Placebo Dose 2 N <sup>a</sup> =2103 n <sup>b</sup> (%)
<b>Redness<sup>c</sup></b>				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
<b>Swelling<sup>c</sup></b>				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
<b>Pain at the injection site<sup>d</sup></b>				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

<sup>‡</sup> Eight participants were between 16 and 17 years of age.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

**Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age<sup>‡</sup> – Reactogenicity Subset of the Safety Population\***

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N <sup>a</sup> =2291 n <sup>b</sup> (%)	Placebo Dose 1 N <sup>a</sup> =2298 n <sup>b</sup> (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N <sup>a</sup> =2098 n <sup>b</sup> (%)	Placebo Dose 2 N <sup>a</sup> =2103 n <sup>b</sup> (%)
<b>Fever</b>				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
<b>Fatigue<sup>c</sup></b>				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)

	<b>Pfizer-BioNTech COVID-19 Vaccine</b> <b>Dose 1</b> <b>N<sup>a</sup>=2291</b> <b>n<sup>b</sup> (%)</b>	<b>Placebo</b> <b>Dose 1</b> <b>N<sup>a</sup>=2298</b> <b>n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine</b> <b>Dose 2</b> <b>N<sup>a</sup>=2098</b> <b>n<sup>b</sup> (%)</b>	<b>Placebo</b> <b>Dose 2</b> <b>N<sup>a</sup>=2103</b> <b>n<sup>b</sup> (%)</b>
<b>Headache<sup>c</sup></b>				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
<b>Chills<sup>c</sup></b>				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)
<b>Vomiting<sup>d</sup></b>				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
<b>Diarrhea<sup>e</sup></b>				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
<b>New or worsened muscle pain<sup>c</sup></b>				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
<b>New or worsened joint pain<sup>c</sup></b>				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
<b>Use of antipyretic or pain medication<sup>f</sup></b>	<b>638 (27.8)</b>	<b>332 (14.4)</b>	<b>945 (45.0)</b>	<b>266 (12.6)</b>

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

‡ Eight participants were between 16 and 17 years of age.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

**Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population\***

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N <sup>a</sup> =1802 n <sup>b</sup> (%)	Placebo Dose 1 N <sup>a</sup> =1792 n <sup>b</sup> (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N <sup>a</sup> =1660 n <sup>b</sup> (%)	Placebo Dose 2 N <sup>a</sup> =1646 n <sup>b</sup> (%)
<b>Redness<sup>c</sup></b>				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
<b>Swelling<sup>c</sup></b>				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
<b>Pain at the injection site<sup>d</sup></b>				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

**Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population\***

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N <sup>a</sup> =1802 n <sup>b</sup> (%)	Placebo Dose 1 N <sup>a</sup> =1792 n <sup>b</sup> (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N <sup>a</sup> =1660 n <sup>b</sup> (%)	Placebo Dose 2 N <sup>a</sup> =1646 n <sup>b</sup> (%)
<b>Fever</b>				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Fatigue<sup>c</sup></b>				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	<b>Pfizer-BioNTech COVID-19 Vaccine</b> <b>Dose 1</b> <b>N<sup>a</sup>=1802</b> <b>n<sup>b</sup> (%)</b>	<b>Placebo</b> <b>Dose 1</b> <b>N<sup>a</sup>=1792</b> <b>n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine</b> <b>Dose 2</b> <b>N<sup>a</sup>=1660</b> <b>n<sup>b</sup> (%)</b>	<b>Placebo</b> <b>Dose 2</b> <b>N<sup>a</sup>=1646</b> <b>n<sup>b</sup> (%)</b>
<b>Headache<sup>c</sup></b>				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
<b>Chills<sup>c</sup></b>				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
<b>Vomiting<sup>d</sup></b>				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
<b>Diarrhea<sup>e</sup></b>				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
<b>New or worsened muscle pain<sup>c</sup></b>				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
<b>New or worsened joint pain<sup>c</sup></b>				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
<b>Use of antipyretic or pain medication</b>	<b>358 (19.9)</b>	<b>213 (11.9)</b>	<b>625 (37.7)</b>	<b>161 (9.8)</b>

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

## Unsolicited Adverse Events

### *Serious Adverse Events*

In Study 2, among participants 16 through 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7,960, placebo = 7,934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

### *Non-Serious Adverse Events*

In Study 2 in which 10,841 participants 16 through 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

The higher frequency of reported unsolicited non-serious adverse events among Pfizer-BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

## Adolescents 12 Through 15 Years of Age

In an analysis of Study 2, based on data up to the cutoff date of March 13, 2021, 2,260 adolescents (1,131 Pfizer-BioNTech COVID-19 Vaccine; 1,129 placebo) were 12 through 15 years of age. Of these, 1,308 (660 Pfizer-BioNTech COVID-19 Vaccine and 648 placebo) adolescents have been followed for at least

2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine. The safety evaluation in Study 2 is ongoing.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among adolescents who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the adolescents who received the Pfizer-BioNTech COVID-19 Vaccine, 50.1% were male and 49.9% were female, 85.9% were White, 4.6% were Black or African American, 11.7% were Hispanic/Latino, 6.4% were Asian, and 0.4% were American Indian/Alaska Native.

#### Solicited Local and Systemic Adverse Reactions

The mean duration of pain at the injection site after Dose 1 was 2.4 days (range 1 to 10 days), for redness 2.4 days (range 1 to 16 days), and for swelling 1.9 days (range 1 to 5 days) for adolescents in the Pfizer-BioNTech COVID-19 Vaccine group.

**Table 5: Study 2 – Frequency and Percentages of Adolescents With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population\***

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N <sup>a</sup> =1127 n <sup>b</sup> (%)	Placebo Dose 1 N <sup>a</sup> =1127 n <sup>b</sup> (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N <sup>a</sup> =1097 n <sup>b</sup> (%)	Placebo Dose 2 N <sup>a</sup> =1078 n <sup>b</sup> (%)
<b>Redness<sup>c</sup></b>				
Any (>2 cm)	65 (5.8)	12 (1.1)	55 (5.0)	10 (0.9)
Mild	44 (3.9)	11 (1.0)	29 (2.6)	8 (0.7)
Moderate	20 (1.8)	1 (0.1)	26 (2.4)	2 (0.2)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Swelling<sup>c</sup></b>				
Any (>2 cm)	78 (6.9)	11 (1.0)	54 (4.9)	6 (0.6)
Mild	55 (4.9)	9 (0.8)	36 (3.3)	4 (0.4)
Moderate	23 (2.0)	2 (0.2)	18 (1.6)	2 (0.2)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Pain at the injection site<sup>d</sup></b>				
Any	971 (86.2)	263 (23.3)	866 (78.9)	193 (17.9)
Mild	467 (41.4)	227 (20.1)	466 (42.5)	164 (15.2)
Moderate	493 (43.7)	36 (3.2)	393 (35.8)	29 (2.7)
Severe	11 (1.0)	0 (0.0)	7 (0.6)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

**Table 6: Study 2 – Frequency and Percentages of Adolescents with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population\***

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N <sup>a</sup> =1127 n <sup>b</sup> (%)	Placebo Dose 1 N <sup>a</sup> =1127 n <sup>b</sup> (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N <sup>a</sup> =1097 n <sup>b</sup> (%)	Placebo Dose 2 N <sup>a</sup> =1078 n <sup>b</sup> (%)
<b>Fever</b>				
≥38.0°C	114 (10.1)	12 (1.1)	215 (19.6)	7 (0.6)
≥38.0°C to 38.4°C	74 (6.6)	8 (0.7)	107 (9.8)	5 (0.5)
>38.4°C to 38.9°C	29 (2.6)	2 (0.2)	83 (7.6)	1 (0.1)
>38.9°C to 40.0°C	10 (0.9)	2 (0.2)	25 (2.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Fatigue<sup>c</sup></b>				
Any	677 (60.1)	457 (40.6)	726 (66.2)	264 (24.5)
Mild	278 (24.7)	250 (22.2)	232 (21.1)	133 (12.3)
Moderate	384 (34.1)	199 (17.7)	468 (42.7)	127 (11.8)
Severe	15 (1.3)	8 (0.7)	26 (2.4)	4 (0.4)
<b>Headache<sup>c</sup></b>				
Any	623 (55.3)	396 (35.1)	708 (64.5)	263 (24.4)
Mild	361 (32.0)	256 (22.7)	302 (27.5)	169 (15.7)
Moderate	251 (22.3)	131 (11.6)	384 (35.0)	93 (8.6)
Severe	11 (1.0)	9 (0.8)	22 (2.0)	1 (0.1)
<b>Chills<sup>c</sup></b>				
Any	311 (27.6)	109 (9.7)	455 (41.5)	73 (6.8)
Mild	195 (17.3)	82 (7.3)	221 (20.1)	52 (4.8)
Moderate	111 (9.8)	25 (2.2)	214 (19.5)	21 (1.9)
Severe	5 (0.4)	2 (0.2)	20 (1.8)	0 (0.0)
<b>Vomiting<sup>d</sup></b>				
Any	31 (2.8)	10 (0.9)	29 (2.6)	12 (1.1)
Mild	30 (2.7)	8 (0.7)	25 (2.3)	11 (1.0)
Moderate	0 (0.0)	2 (0.2)	4 (0.4)	1 (0.1)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Diarrhea<sup>e</sup></b>				
Any	90 (8.0)	82 (7.3)	65 (5.9)	43 (4.0)
Mild	77 (6.8)	72 (6.4)	59 (5.4)	38 (3.5)
Moderate	13 (1.2)	10 (0.9)	6 (0.5)	5 (0.5)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<b>New or worsened muscle pain<sup>c</sup></b>				
Any	272 (24.1)	148 (13.1)	355 (32.4)	90 (8.3)
Mild	125 (11.1)	88 (7.8)	152 (13.9)	51 (4.7)
Moderate	145 (12.9)	60 (5.3)	197 (18.0)	37 (3.4)
Severe	2 (0.2)	0 (0.0)	6 (0.5)	2 (0.2)

	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 1</b> <b>N<sup>a</sup>=1127</b> <b>n<sup>b</sup> (%)</b>	<b>Placebo Dose 1</b> <b>N<sup>a</sup>=1127</b> <b>n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 2</b> <b>N<sup>a</sup>=1097</b> <b>n<sup>b</sup> (%)</b>	<b>Placebo Dose 2</b> <b>N<sup>a</sup>=1078</b> <b>n<sup>b</sup> (%)</b>
New or worsened joint pain <sup>c</sup>				
Any	109 (9.7)	77 (6.8)	173 (15.8)	51 (4.7)
Mild	66 (5.9)	50 (4.4)	91 (8.3)	30 (2.8)
Moderate	42 (3.7)	27 (2.4)	78 (7.1)	21 (1.9)
Severe	1 (0.1)	0 (0.0)	4 (0.4)	0 (0.0)
Use of antipyretic or pain medication <sup>f</sup>	413 (36.6)	111 (9.8)	557 (50.8)	95 (8.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

### Unsolicited Adverse Events

In the following analyses of Study 2 in adolescents 12 through 15 years of age (1,131 of whom received Pfizer-BioNTech COVID-19 Vaccine and 1,129 of whom received placebo), 98.3% of study participants had at least 30 days of follow-up after Dose 2.

### *Serious Adverse Events*

Serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.1% of placebo recipients. There were no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

### *Non-Serious Adverse Events*

Non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 5.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 5.8% of placebo recipients. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy plausibly related to the study intervention were imbalanced, with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (7) vs. the placebo group (1). There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

## 6.2 Post Authorization Experience

The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)

Gastrointestinal Disorders: diarrhea, vomiting

Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

## **8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS**

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events\* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

\*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

### Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

**IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:**

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
  - a. Write “Pfizer-BioNTech COVID-19 Vaccine EUA” as the first line.
  - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
  - a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
  - b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
  - c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

#### Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

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

Website	Fax number	Telephone number
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

## **10 DRUG INTERACTIONS**

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

## **11 USE IN SPECIFIC POPULATIONS**

### **11.1 Pregnancy**

#### Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the

intramuscular route on four occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

## 11.2 Lactation

### Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

## 11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12 through 18 years of age is based on safety and effectiveness data in this age group and in adults.

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 12 years of age.

## 11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy [*see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)*]. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

## 13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

## 14 CLINICAL PHARMACOLOGY

### 14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

## **18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA**

### **18.1 Efficacy in Participants 16 Years of Age and Older**

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the  $\geq 56$ -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion of Study 2, based on data accrued through November 14, 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 7 presents the specific demographic characteristics in the studied population.

**Table 7: Demographics (population for the primary efficacy endpoint)<sup>a</sup>**

	<b>Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)</b>	<b>Placebo (N=18,379) n (%)</b>
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
$\geq 12$ through 15 years <sup>b</sup>	46 (0.3)	42 (0.2)
$\geq 16$ through 17 years	66 (0.4)	68 (0.4)
$\geq 16$ through 64 years	14,216 (77.9)	14,299 (77.8)
$\geq 65$ through 74 years	3176 (17.4)	3226 (17.6)
$\geq 75$ years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other <sup>c</sup>	534 (2.9)	516 (2.8)

	<b>Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)</b>	<b>Placebo (N=18,379) n (%)</b>
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities <sup>d</sup>		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

- a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.
- b. 100 participants 12 through 15 years of age with limited follow-up in the randomized population received at least one dose (49 in the vaccine group and 51 in the placebo group). Some of these participants were included in the efficacy evaluation depending on the population analyzed. They contributed to exposure information but with no confirmed COVID-19 cases, and did not affect efficacy conclusions.
- c. Includes multiracial and not reported.
- d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
  - Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
  - Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
  - Obesity (body mass index  $\geq 30 \text{ kg/m}^2$ )
  - Diabetes (Type 1, Type 2 or gestational)
  - Liver disease
  - Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 through 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 through 17 years of age began enrollment from September 16, 2020, and 12 through 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 8.

**Table 8: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*</b>			
<b>Subgroup</b>	<b>Pfizer-BioNTech COVID-19 Vaccine N<sup>a</sup>=18,198</b> <b>Cases n1<sup>b</sup></b> <b>Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=18,325</b> <b>Cases n1<sup>b</sup></b> <b>Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
All subjects <sup>e</sup>	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6) <sup>f</sup>
16 through 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1) <sup>g</sup>
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9) <sup>g</sup>
<b>First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection</b>			
<b>Subgroup</b>	<b>Pfizer-BioNTech COVID-19 Vaccine N<sup>a</sup>=19,965</b> <b>Cases n1<sup>b</sup></b> <b>Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=20,172</b> <b>Cases n1<sup>b</sup></b> <b>Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
All subjects <sup>e</sup>	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3) <sup>f</sup>
16 through 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7) <sup>g</sup>
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9) <sup>g</sup>

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

\* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- a. N = Number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of participants at risk for the endpoint.
- e. No confirmed cases were identified in adolescents 12 through 15 years of age.
- f. Credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for  $\theta=r(1-VE)/(1+r(1-VE))$ , where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
- g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

## 18.2 Efficacy in Adolescents 12 Through 15 Years of Age

A descriptive efficacy analysis of Study 2 has been performed in approximately 2,200 adolescents 12 through 15 years of age evaluating confirmed COVID-19 cases accrued up to a data cutoff date of March 13, 2021.

The efficacy information in adolescents 12 through 15 years of age is presented in Table 9.

**Table 9: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age without evidence of prior SARS-CoV-2 infection*</b>			
	<b>Pfizer-BioNTech COVID-19 Vaccine N<sup>a</sup>=1005 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=978 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI<sup>e</sup>)</b>
Adolescents 12 through 15 years of age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)
<b>First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age with or without evidence of prior SARS-CoV-2 infection</b>			
	<b>Pfizer-BioNTech COVID-19 Vaccine N<sup>a</sup>=1119 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=1110 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI<sup>e</sup>)</b>
Adolescents 12 through 15 years of age	0 0.170 (1109)	18 0.163 (1094)	100.0 (78.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

\* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

### 18.3 Immunogenicity in Adolescents 12 Through 15 Years of Age

In Study 2, an analysis of SARS-CoV-2 50% neutralizing titers 1 month after Dose 2 in a randomly selected subset of participants demonstrated non-inferior immune responses (within 1.5-fold) comparing adolescents 12 through 15 years of age to participants 16 through 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2 (Table 10).

**Table 10: Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Adolescents 12 Through 15 Years of Age to Participants 16 Through 25 Years of Age (Immunogenicity Subset) –Participants Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population**

		Pfizer-BioNTech COVID-19 Vaccine			
		12 Through 15 Years n <sup>a</sup> =190	16 Through 25 Years n <sup>a</sup> =170	12 Through 15 Years/ 16 Through 25 Years	
Assay	Time Point <sup>b</sup>	GMT <sup>c</sup> (95% CI <sup>c</sup> )	GMT <sup>c</sup> (95% CI <sup>c</sup> )	GMR <sup>d</sup> (95% CI <sup>d</sup> )	Met Noninferiority Objective <sup>e</sup> (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer) <sup>f</sup>	1 month after Dose 2	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic-acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (up to 1 month after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 were included in the analysis.

- a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
- b. Protocol-specified timing for blood sample collection.
- c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
- d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [12 through 15 years of age] – Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).
- e. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.
- f. SARS-CoV-2 50% neutralization titers (NT50) were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA\_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

## 19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2). After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

### Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F) until the expiry date printed on the label. Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept

frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

### Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F).

### Thawed Vials Before Dilution

#### *Thawed Under Refrigeration*

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

#### *Thawed at Room Temperature*

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

### Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

### Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

## **20 PATIENT COUNSELING INFORMATION**

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## 21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
<a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a>  	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).



Manufactured by  
Pfizer Inc., New York, NY 10017

**BIONTECH**

Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

LAB-1457-8.2b

Revised: 19 May 2021



Department of  
Health

# COVID-19 Vaccines: Provider Packet

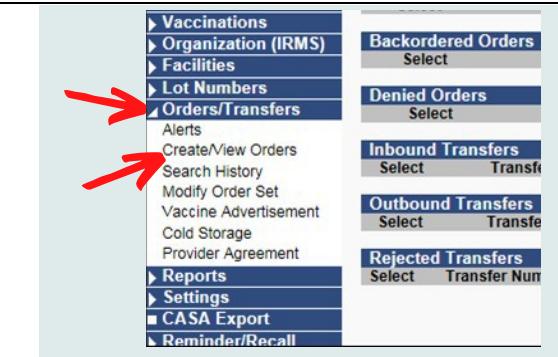
## Pfizer COVID-19 Vaccine

# *Vaccine Management*

# Vaccine Ordering Management System (VOMS) Receiving

## 1) Select Create/View Orders

To receive an order, go back to the Main page. After clicking on the main page, you will see an "Orders/Transfers" tab. Click the tab. Once the tab expands, click Create/View Orders.



## 2) View Current Order/Transfer List

After selecting the Create/View Orders tab, a Current Order/Transfer List page will appear.

Current Order/Transfer List		
Inbound Orders	Select	Order Number
Backordered Orders	Select	Order Number
Denied Orders	Select	Order Number
Inbound Transfers	Select	Transfer Number PIN
Outbound Transfers	Select	Transfer Number PIN
Rejected Transfers	Select	Transfer Number PIN Submit Date

## 3) Arrow in select column

In the "Select" column under Inbound Orders, press the arrow next to the order number for the order that you want to view.

Current Order/Transfer List						
Inbound Orders		Order Number	PIN	Submit Date	Approval Date	Status
...	...	15281	162015	02/06/2017		In Manual Review
...	...	14886	162015	11/29/2016	11/29/2016	Shipped
...	...	14888	162015	11/29/2016	11/30/2016	Shipped

## 4) Verify/Receive Shipment

To receive the shipment, for each vaccine, you need to:

- Insert the quantity in the "Receipt Quantity"
- If needed, insert quantities in the "Rejected Quantity"
- If you need to reject a quantity, choose a "Reason for Rejecting" from the dropdown
- Upon reviewing the order details for accuracy, press "Receive" to confirm your order.

Order Details									
Shipped Quantity	Receipt Quantity	Rejected Quantity	Vaccine	Funding Source	Manufacturer	Lot Number	Expiration Date	Reason for rejecting	
20	20		Hep A, ped/adol, 2 dose	VFC	GLAXOSMITHKLN	9TS3T	11/09/2018	Select-	
Comments									
30	10	20	DTaP-Hep B-IPV	VFC	GLAXOSMITHKLN	M9L74	11/18/2018	Shipment is incomplete	
Comments									
									Cancel Receive

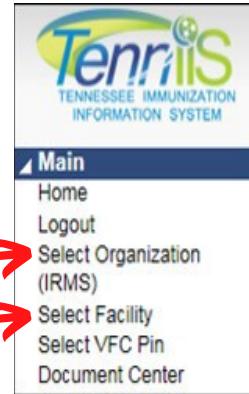
\*After inserting receipt quantity, rejecting quantity (if applicable), and picking a reason for rejecting, be sure to check the Vaccine, Manufacturer, Lot number and Expiration Date before receiving the order.



# Vaccine Ordering Management System (VOMS) Reconciliation

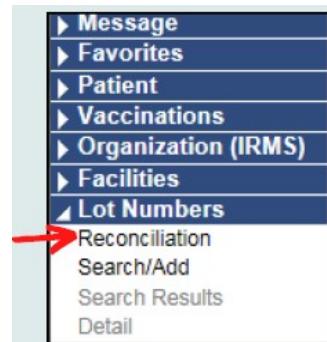
## 1) Select Organization and Facility

Upon logging into VOMS, you will press "Select Organization" from the "Main" drop down, pressing submit. Afterwards, go to "Select facility" and press continue.



## 2) Locate "Reconciliation" Tab

Under "Lot Numbers," you will see "Reconciliation." Press this to continue.



## 3) Reconciliation Page

After clicking "Reconciliation," this page should appear. Within this page, you are able to view the vaccines available within your facility. This includes their lot numbers, expiration, and quantity. After printing the reconciliation page, count and record your physical inventory of vaccine. Record the number underneath the "Physical Inventory" column. Once on the reconciliation page, some vaccines will appear highlighted in red or yellow. Yellow highlighted vaccines are expiring soon. Red highlighted vaccines have expired and need to be discarded of and reordered.

HBs (Engerix-B)	HPV (Gardasil)	Menactra (5 SDV)	01/13/2017	2	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Meningococcal	MCV4® (Menactra)	U5410AA	09/21/2017	4	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>
MMR (MMR-V)		L037356	09/28/2017	6	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Pneumococcal conjugate PCV-13 (Prevenar 13)		M77275	08/31/2017	5	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rotavirus	monovalent (Immunobiological)	A41CB323A	02/13/2017	5	0.0	No Category Required	No Reason Required	PUB	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Tdap (Adacel® / Boostrix®)		L2972	11/17/2017	9	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>
DTaP (Daptacel® / Infanrix®)		4RK3D	04/27/2018	8	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Haemophilus influenzae type b (Hib)		9TS3T	11/09/2018	10	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Human papillomavirus 2 dose (Gardasil® / Gardasil 9®)		U540710	01/14/2019	10	0.0	No Category Required	No Reason Required	PUB	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Human papillomavirus 2 dose (Vaxigard®)		ZTSK4	10/26/2018	0	0.0	No Category Required	No Reason Required	VFC	<input type="checkbox"/>	<input checked="" type="checkbox"/>

# Vaccine Ordering Management System (VOMS) Reconciliation

## 4) Count and Record Inventory

After printing the reconciliation page, count and record your physical inventory of vaccine. Record the number underneath the "Physical Inventory" column.

Organization (IRM#): ALLIED PEDIATRICS Facility: ALLIED PEDIATRICS						
Vaccine	Lot Number	Exp Date	Quantity on Hand	Physical Inventory	Adjustment	
DTaP	354K7	05/29/2017	30			
DTaP/HPV/BIV	L49EE	05/04/2017	22			
DTaP/IPV	33J53	05/29/2017	30			
Hep A 2 dose - Ped/Adol	P3JA2	05/04/2016	40			
Hep B Ped/Adol - Preserv Free	A8X07	05/06/2017	19			
HBs-IGG-T	U076AAA	05/03/2017	43			
HPV-9	KD26246	01/28/2017	3			
IPV	L1130-1	04/11/2017	10			
Meningococcal B, recombinant	151301C	12/31/2016	19			
MMR	LD26551	07/16/2017	30			
Pneumococcal, PCV-13	J23965	11/30/2016	0			
Pneumococcal, PCV-13	MF77340	05/31/2017	70			
Tdap	Z728X	09/15/2017	10			
Varicella	KD02649	02/10/2016	0			
Varicella	LD41204	10/20/2017	30			

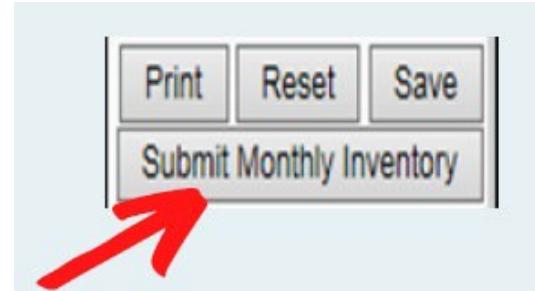
## 5) Input Data

Once you have physically recorded your vaccine count, go back to the reconciliation page and enter the quantity under "Physical Inventory." Don't forget to select a category and reason for the vaccines if the quantity on hand is different from the physical inventory.

Reconcile Inventory							
Vaccine	Lot Number	Exp Date	Quantity on Hand	Physical Inventory	Adjustment (+/-)	Category	Reason
DTaP (Infanrix®)	42SKY	11/16/2017	10	0	-2.0	Spoiled	Refrigerator/Freezer Too Cold
DTaP (Infanrix®)	42NL4	12/09/2017	6	0	-6.0	-select--	-select--
DTaP diphtheria antigens	C5014AA	07/29/2016	7	2	-5.0	Administered	Administered but not linked to a vaccine

## 6) Submit Inventory

Once you have completed the reconciliation page, it is now time to submit. Before submitting, check to make sure changes were successfully saved. If not, check for error messages.



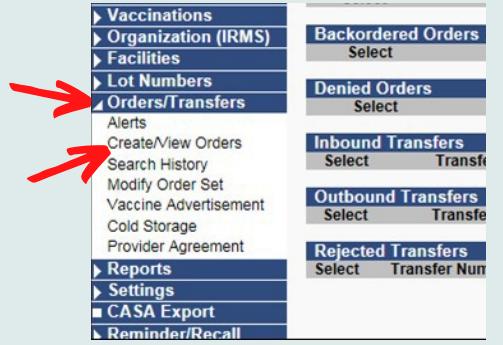
\*Make sure to click on "Submit Monthly Inventory," to submit.

\*Don't forget to reconcile once a month, even if you do not order vaccine.



# Transferring Vaccines To Another Location

- 1) Using the Navigation Menu, click on the "Orders/Transfers" tab.
- 2) Click "Create/View Orders" to show the current Order/Transfer List.



- 3) Click on the "Create Transfer" button.

Transfer Number	PIN	Submit Date	Sending Organization (IRMS)/Facility
22	100015	09/03/2014	TENNESSEE PEDIATRICS / DR. JOEY SMITH
24	2013	09/05/2014	TN TEST ORG / TN TEST FACILITY 1

Number	PIN	Submit Date	Receiving Organization (IRMS)/Facility	Reject Date	Rejected By	Status

[Create Order](#) [Create Transfer](#)

- 4) Select the organization/facility you wish to send the vaccine to from the dropdown list.

**Create Transfer**

Sending Organization (IRMS)	KNOX COUNTY HEALTH DEPARTMENT-MAIN
Sending Facility	
Submitter	CATHY LEE (CLEE)
<b>Receiving Organization (IRMS)</b>	TENNESSEE PEDIATRICS (1001)
<b>Receiving Facility</b>	DR. JOEY SMITH

- 5) Find the vaccine and lot number on the list.

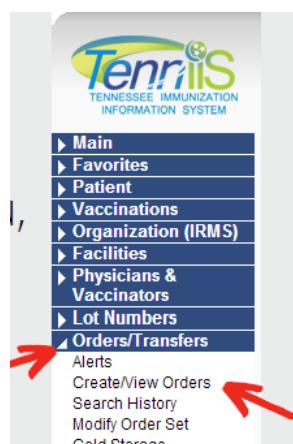
- 6) Enter the number of doses you wish to transfer. There is no need to enter in zeroes for blank categories. You must put in a transfer reason or it will not allow you to submit.

Transfer Details						
Transfer Quantity	Vaccine	Lot Number	Quantity Available	Public	Expiration Date	Transfer Reason
0	DTaP (Infanrix®)	112233	10	Y	01/01/2016	
0	DTaP (Infanrix®)	123456	9	N	01/01/2016	
0	Hep A 2 dose - Pedi/Adol - (Havrix® / Vaqta® / Engerix-B®)	01/01/2016	21	Y	01/01/2016	
10	Hep B Pedi/Adol - Preserv Free (Recombivax® / Engerix-B®)	MM112233	25	N	02/28/2016	employees
0	Td Adult, Preserv Free (Decavac® / Tenivac®)	123	15	Y	01/01/2016	
0	Td Adult, Preserv Free (Decavac® / Tenivac®)	J0055P33	20	Y	02/28/2015	
0	Tdap (Boostrix® / Adacel®)	TDAP13876GSK	10	N	10/21/2014	
0	Varicella (Varivax®)	123456	50	Y	01/01/2017	
0	Varicella (Varivax®)	LL001122	52	Y	02/28/2016	

- 7) Click "Create Transfer."

# Receiving Transferred Vaccines

- 1) Using the Navigation Menu, click on the "Orders/Transfers" tab.
- 2) Click "Create/View Orders" to show the current Order/Transfer List.



- 3) Select the arrow next to the order you are receiving.

Select	Transfer Number	PIN	Submit Date	Sending Organization (IRMS)/Facility
<input type="button" value="→"/>	22	TNA471001	09/03/2014	KNOX COUNTY HEALTH DEPARTMENT-MAIN

- 4) Enter the Receipt Quantity, Rejected Quantity (if applicable), and the Reason for Rejecting.

Transfer Details									
Shipped Quantity	Receipt Quantity	Rejected Quantity	Vaccine Manufacturer	Lot Number	Expiration Date	Reason	Inventory Action	Reason for rejecting	
6	3		DTaP	CSL	123456	01/01/2016	Creating a New Lot	Shipment is incomplete	

- 5) Click "Receive" and the inventory will be added.

Transfer Details									
Shipped Quantity	Receipt Quantity	Rejected Quantity	Vaccine Manufacturer	Lot Number	Expiration Date	Reason	Inventory Action	Reason for rejecting	
9	6	3	DTaP	CSL	123456	01/01/2016	Creating a New Lot	Shipment is incomplete	

# Reporting Adverse Events and Administration Errors

An “adverse event following immunization” is an adverse health problem or condition that happens after vaccination. It may be truly caused by the vaccine or an unrelated coincidence.

Per the COVID-19 Vaccination Program Provider Agreement, healthcare providers are required to report clinically important adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS). Healthcare providers are strongly encouraged to report vaccine administration errors.

VAERS is a national early warning system to detect possible safety problems in U.S. licensed vaccines.

## Two Ways to Submit an Online Report to VAERS

### Report Online to VAERS (Preferred)

1

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and re-turned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.

**URL for online form:** [https://vaers.hhs.gov/  
esub/index.jsp](https://vaers.hhs.gov/esub/index.jsp)

2

### Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

**URL for PDF form:** [https://vaers.hhs.gov/  
uploadFile/index.jsp](https://vaers.hhs.gov/uploadFile/index.jsp)

### Information needed for reporting

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of adverse event(s)
- Medical tests and laboratory results (if applicable)

For additional information about VAERS, visit <https://vaers.hhs.gov/index.html>.

Email [info@VAERS.org](mailto:info@VAERS.org) or call 1-800-822-7967 for further assistance with reporting to VAERS.

## Pfizer COVID-19 Vaccine

*Vaccine TennIIS  
Information*

# Tennessee Immunization Information System (TennIIS) Quick Reference Guide

## Reminder/Recall

### What is included in this guide?

1. [How do you select the patient list you want to include in reminder/recall?](#)
2. [How do you review the patient reminder/recall list?](#)
3. [How do you generate the notifications to send to the patients?](#)

### What is reminder/recall?

Reminder/recall is a system that allows providers to notify patients about upcoming or past due vaccinations.

Notifications can be generated in the following formats:

- Generate a patient list
- Print letters
- Generate auto-dialer content
- Generate mail-merge
- Create custom postcards
- Send email
- Print address labels

### When should reminder/recall be used?

- That decision is made by your clinic based on the size of your patient population. However often you choose to do it (weekly, monthly, etc.), it is helpful to include reminder/recall into your regular workflow.
- Reminder/recall can also be helpful to use when you have vaccine that is about to expire. This helps decrease wastage and ensures patients are up-to-date with vaccines.

### Who is this Quick Reference Guide for?

- This guide is meant for providers who want to improve vaccination rates by reminding patients of upcoming or past due vaccines.

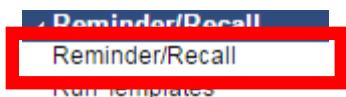
### Why do you care about reminder/recall?

- It can help prevent disease by improving the timeliness and completion of recommended immunizations.
- It can help your practice improve your coverage rates.
- Viewing a patient list pulled from reminder/recall in TennIIS can help you determine if your patient list is up-to-date.

## How do you select the patient list you want to include in reminder/recall?

1. Click **Reminder/Recall** in the TennIIS navigation menu on the left side of the screen.

2. Click the **Reminder/Recall** link and the reminder/recall module will load on the screen.



3. Under the "How do you want to run this Reminder/Recall" section, select from the options on the page.

### How do you want to run this Reminder/Recall?

- For all patients you own
- For all patients you have seen at your facility
- Include Inactive Patients (Excluding deceased)

Due Date Timeframe:

Field	Description
<b>For all patients you own</b>	A patient is considered to be under your organization/facility's ownership if that is the last place where they received an administered vaccine in TennIIS. Schools, pharmacies, and local health departments cannot own patients in TennIIS.
<b>For all patients you have seen at your facility</b>	This pulls all of the patients that have received a record of an administered vaccine, a historical vaccine, or a demographic change from your organization/facility. This will generate a larger patient list than running by ownership.
<b>Include Inactive Patients (excluding deceased)</b>	If selected, patients flagged as inactive are included in the patient list, except for patients marked as deceased. If not selected, inactive patients are not included.
<b>Due Date Timeframe</b>	This determines which patients to include based on the Recommended Date column on the forecast.

## Reminder/Recall

### How do you select the patient list you want to include in reminder/recall?

4. Under the “Who do you want to contact?” section, select from the options on the page.

#### Who do you want to Contact?

Patient Location:

Patient Age Range

Patient Birth Date

Patient Gender

Exclude patients who were sent a notification in the last:  
  Days  Weeks  Months  Years

Advanced

Field	Description
<b>Patient Location</b>	Filter patients by organization or facility.
<b>Patient Age Range</b>	Only one of these two options can be selected. Patient age range is the default.
<b>Patient Birth Date</b>	For <b>Patient Age Range</b> , enter the number of days, months, or years (and select which one from the drop-down lists) for the starting and ending age range. Note that you cannot enter a number that is zero or less.  For <b>Patient Birth Date</b> , enter the starting birthdate in the From field and the ending birthdate in the Through field.
<b>Patient Gender</b>	Select one or more gender options using the drop-down list.
<b>Exclude patients who were sent a notice in the last...</b>	To exclude patients who were sent a reminder/recall notification in a specific timeframe, enter a number and then select days, weeks, months, or years from the drop-down list.

#### Advanced

Advanced view options include physician, health plan, facility type, association, program, high risk category, state, county, region, zip code, appointment date, deferred vaccinations only, compromised vaccinations, and do not include confidential vaccinations. These allow you to apply more filters when selecting the patient list.

## Reminder/Recall

### How do you select the patient list you want to include in reminder/recall?

5. Under the “**Which vaccines would you like to include?**” section, select from the options on the page, then click Generate Patient List.

**Which vaccines would you like to include?**

Select a series ?

- CUSTOM
- ADOLESCENT SERIES
- HPV 3 DOSES
- 4:3:1:3:3:1:4 CHILDHOOD SERIES

I only want to see my patients who are:

Due for all selected vaccines

One dose away

One visit to complete the series

Clear
Schedule
→ Generate Patient List

Field	Description
<b>Select a series</b>	Select a vaccine series from the drop-down menu. A list of vaccines that makes up the series appears in the box below the drop-down menu.
<b>I only want to see my patients who are...</b>	<p>Select a vaccination status for patients that applies to the selected vaccines:</p> <ul style="list-style-type: none"> <li><b>Due for all selected vaccines</b> (default) - Reminder/recall returns a list of patients who are due for one or more of the selected vaccines.</li> <li><b>One Dose Away</b> - Reminder/recall returns a list of patients who are one dose away from completing the required number of doses for the selected series.</li> <li><b>One Visit to Complete the Series</b> - Reminder/recall returns a list of patients who are one visit away from completing the entire vaccine series, which could include multiple vaccines that could be completed in one visit.</li> </ul>

**Congratulations, you have just generated a reminder/recall patient list!**

# Reminder/Recall

## How do you review the patient reminder/recall list?

1. Clicking **Generate Patient List** takes you to the second step, reviewing the list of patients.

**What patients do you want to add to your recall group?**

Remove Patients who don't have an available

Name  Phone  Address  Email

Remove Patients who have received more than **Select** notifications.

Last	First	Age	Vaccines Due	Available Contact Methods	R/R Attempts	Reason for Inactivation
DUMBLEDORE	ALBUS	2	11		0	Select
GRANGER	HERMIONE	2	4		0	Select
HAMILTON	ALEXANDER	2	9		0	Select
JEFFERSON	THOMAS	2	7		0	Select
LOVEGOOD	LUNA	2	11		0	Select
MADISON	JAMES	2	10		0	Select
MALFOY	DRACO	2	7		0	Select
PRINCESS	CINDERELLA	2	6		0	Select
SMITH	BECKY	2	5		0	Select
WEASLEY	RON	2	4		0	Select

Showing 1 to 10 of 10 entries

PreviousNext

2. You can remove categories of patients from the list by selecting one of the **Remove** options at the top.
3. The **list of patients** retrieved appears below the Remove options. To see more information about a patient, hover the mouse over the patient's name.
4. To **remove a patient** from the list, click the checkbox on the left side of the patient's name to remove the checkmark, or select a **Reason for Inactivation** (which will also deselect the patient from the list). Removed patients will appear greyed out.  
(If a reason for inactivation is selected, the patient is removed from the list and their Patient Status on the demographics page is changed to Inactive once you click **Submit**).
5. To **re-add a patient** to the list, click the checkbox (after which a checkmark appears).

# Reminder/Recall

## How do you review the patient reminder/recall list?

What patients do you want to add to your recall group?

Remove Patients who don't have an available

Name  Phone  Address  Email

Remove Patients who have received more than  notifications.

Last	First	Age	Vaccines Due	Available Contact Methods	R/R Attempts	Reason for Inactivation
<input checked="" type="checkbox"/> DUMBLEDORE	ALBUS	2	11		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> GRANGER	HERMIONE	2	4		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> HAMILTON	ALEXANDER	2	9		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> JEFFERSON	THOMAS	2	7		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> LOVEGOOD	LUNA	2	11		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> MADISON	JAMES	2	10		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> MALFOY	DRACO	2	7		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> PRINCESS	CINDERELLA	2	6		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> SMITH	BECKY	2	5		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>
<input checked="" type="checkbox"/> WEASLEY	RON	2	4		0	<input style="border: 1px solid #ccc; padding: 2px 5px;" type="button" value="Select"/>

Showing 1 to 10 of 10 entries

Previous Next



6. To export the list of patients, click **Export Patient List** and follow the prompts.
7. When finished with the patient list, click **Submit** to save the changes. The next page is where you can select an action to use with the list.

**Congratulations, you have reviewed your reminder-recall patient list!**

## Reminder/Recall

### How do you generate the notifications to send to patients?

1. After you click Submit on the patient list page, the **action page** opens. At the top of the page are icons with numbers next to them, showing how many total patients are included, along with how many mailing addresses, telephone numbers, cell phone numbers, and email addresses are available for the list of patients.
2. On the action page are **icons** that represent the different types of notifications to send to patients. Each icon is a link you can click to generate that type of file.

The screenshot shows the 'Action Page' after a patient list has been submitted. At the top, there are five green icons with counts: a person icon (10), a house icon (10), a telephone icon (0), a smartphone icon (0), and an envelope icon (0). Below this, a blue header bar asks, 'What do you want to do with your selected recall group?'. The main content area contains nine blue icons arranged in a grid, each with a corresponding label:

Generate A Patient List	Print Letters	Generate Auto-Dialer Content
Generate Mail-Merge	Create Custom Post Cards	Create Avery 8387 Postcards
Print Labels	Save As a Patient Group (Cohort)	Send Email

## Reminder/Recall

### How do you generate the notifications to send to patients?



[Generate A Patient List](#)

This action generates an HTML file that displays a detailed **list of your patients**, including their vaccination forecast.



[Create Avery 8387 Postcards](#)

This action generates a reminder/recall postcard for each patient on the patient list, which can be printed on **Avery 8387** postcards. You can define the dimensions of the postcard and the message content.



[Print Letters](#)

This action generates a **reminder-recall letter** for each patient on the patient list.



[Print Labels](#)

This action generates a PDF file that can be printed on **Avery 5160 labels** or similar.



[Generate Auto-Dialer Content](#)

This action generates an HTML file that can be used with any external **auto-dialer** application.



[Save As a Patient Group \(Cohort\)](#)

This action saves your final patient reminder/recall list as a **patient group (cohort)** that you can use again for reminder/recall notifications. If the patient list represents a specific service population that you intend to send notifications to on a regular basis, saving the list as a cohort can save time and effort.



[Generate Mail-Merge](#)

This action generates a text file that can be used with any external **mail-merge** application.



[Send Email](#)

This action generates a reminder/recall **email** for each patient on the patient list.

**Congratulations, you have generated notifications for your reminder/recall patient list!**

# Tennessee Immunization Information System (TennIIS)

## Mass Immunizations Module Quick Reference Guide

### Description of this guide:

This guide describes TennIIS functionality in the **MASS IMMUNIZATIONS MODULE** for all TennIIS users with the Mass Immunizations permission.

### Included in this guide:

- **Before the Mass Immunization Event:**
  - [Setting Lot Number Defaults](#)
  - [Adding/Updating Vaccinators](#)
- **During the Mass Immunization Event:**
  - [Searching for a Patient](#)
  - [Adding a New Patient](#)
  - [Adding Administered Vaccines](#)
  - [Viewing and Printing Patient Records](#)

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS)

## Mass Immunizations Module Quick Reference Guide

### Before the Mass Immunization Event: Setting Lot Number Defaults

It is important to record the vaccine lot number whenever a vaccine is administered, as this information is critical in the event of a vaccine recall or report of an adverse event after vaccination.

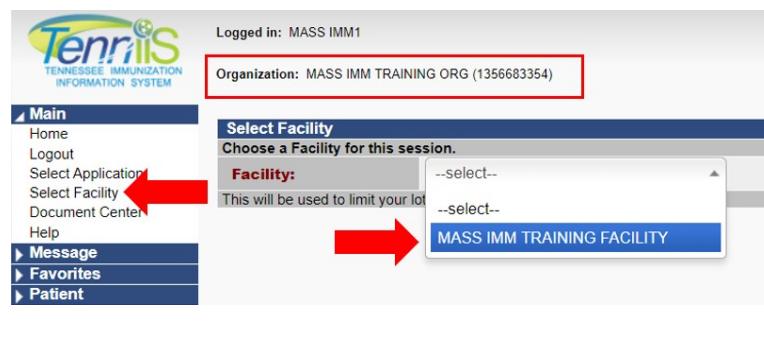
Each facility will designate one or more individuals who will have "Default Vaccine Management" permission. These users will set the lot number for the vaccines that are being used during the mass immunization event by entering the lot number default(s) in their facility settings or personal settings.

Setting the default lot number(s) results in the lot number being automatically populated in the patient's TennIIS record when anyone administering vaccines during the mass immunization event records an administered vaccine in TennIIS. When the administered vaccine and lot number are added to the patient record, the vaccine dose is subtracted from the TennIIS inventory which maintains vaccine dose accountability and accurate inventory management.

#### 1) Select a Facility

Login to TennIIS and verify that the correct Organization and Facility are displayed.

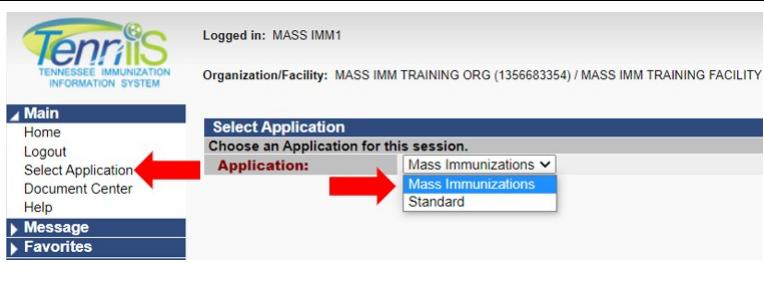
If the correct facility is not displayed, click "Select Facility" under the Main tab in the navigation menu and select the correct facility from the drop-down, then click the "Continue" button.



#### 2) Navigate to the Mass Immunizations Module

In the navigation menu, click "Select Application."

Select Mass Immunizations from the Application drop-down and click the "Submit" button.



Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS)

## Mass Immunizations Module Quick Reference Guide

### 3a) Set Facility Default Lot Numbers

Users with the “Default Vaccine Management” permission can set Default Lot Numbers for all users within a facility.

To set facility Default Lot Numbers, click “Facility” under the Settings tab in the navigation menu. Next click **Default Lot Numbers**. On the next screen, select the vaccine and lot number that will be used in the mass immunization event, click the arrow button to the right to add the vaccine, then click the Save button.

**Note:** Check that "Override Facility Settings" is NOT checked in the user's personal settings.

Mass Immunizations  
Logged in: MASS IMM  
Organization/Facility: MASS IMM TRAINING ORG (1356683354) / MASS IMM TRAINING FACILITY

**Facility Settings**

Patient Defaults [click to update](#)  
City: Zip Code:  
State: Phone Area Code:  
Campaign:

Vaccination Defaults [click to update](#)  
Vaccinator: Facility: Default Date:

**Lot Defaults** [Default Lot Numbers](#)  
Vaccine Name Manufacturer / Lot Number / Facility / Funding Source / Exp Date

VIS Publication Date Defaults [click to add](#)  
Vaccine Name Pub Date1 Pub Date2 Pub Date3

Vaccine Default Volume [click to add](#)  
Vaccine Name Default Volume

Mass Immunizations  
Logged in: MASS IMM  
Organization/Facility: MASS IMM TRAINING ORG (1356683354) / MASS IMM TRAINING FACILITY  
Date: September 10, 2020

**Lot Defaults Add/Update**

Facility: MASS IMM TRAINING FACILITY

Active Lots:

Unselected: MASS IMM TRAINING FACILITY / DTaP / 3247G347 / PUB  
MASS IMM TRAINING FACILITY / Hep A, pediarid, 2 dose / 1958459 / PUB  
MASS IMM TRAINING FACILITY / Influenza, injectable, preservative free / SDF544 / PUB  
**MASS IMM TRAINING FACILITY / influenza, injectable, MDCK, preservative free, quadrivalent / 466TR475 / PUB**  
MASS IMM TRAINING FACILITY / influenza, injectable, MDCK, preservative free, quadrivalent / PABIGH / 317  
MASS IMM TRAINING FACILITY / influenza, injectable, MDCK, preservative free, quadrivalent / SDGH56 / 317  
MASS IMM TRAINING FACILITY / influenza, injectable, MDCK, preservative free / 456H230 / PUB  
MASS IMM TRAINING FACILITY / influenza, injectable, quadrivalent, preservative free / 789FG321B / PUB

Selected: **MASS IMM TRAINING FACILITY / influenza, injectable, quadrivalent, preservative free / 789FG321B / PUB**

Cancel Save

### 3b) Set Personal Lot Defaults

Personal Lot Defaults should only be used if the facility has **not** set lot defaults in the facility settings.

To set **Lot Defaults** for individual users, click “Personal” under the Settings tab in the navigation menu. On the Personal Settings screen, click **Lot Defaults** to expand the section.

Select the vaccine description for the vaccine that will be used in the mass immunization event from the drop-down list. Next click the link below the manufacturer field and select the lot number for the vaccine that will be used in the mass immunization event from the pop-up menu. Click the “Add” button.

Organization/Facility: MASS IMM TRAINING ORG (1356683354) / MASS IMM TRAINING FACILITY

**Personal Settings**

Override Facility Settings  
Update Contact Information  
Street: 1000 JAMES ROBERTSON PKWY  
City: NASHVILLE  
State: TENNESSEE  
Zip Code: 37243  
County: DAVIDSON

Work Phone: Email: [Update](#)

**Lot Defaults**

Vaccine Description: influenza, injectable, quadrivalent, preservative free  
Manufacturer: SEQUIRUS [Click to select](#)

Lot Number: 789FG321B  
Lot Facility: MASS IMM TRAINING FACILITY

Add

Vaccine/Med Name Manufacturer / Lot Num [https://test.tennesseeiis.gov/iisits/selectLotNumber.do?luis\\_vaccine\\_code=75](#)

Select Lot Number
Select Manufacturer Lot Facility Funding Source Dose Available Dose Volume
SEQURUS 789FG321B MASS IMM TRAINING FACILITY PUB 16302021 57.0

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS)

## Mass Immunizations Module Quick Reference Guide

- 4) **Note:** If the lot number for the vaccine to be used in the mass vaccination event is not listed in the pop-up menu:
1. Make sure that the correct Vaccine Description was selected. The selected vaccine description must match the vaccine description in the TennIIS inventory.
  2. Make sure the lot number is in the TennIIS inventory. Users with the Lot Number Manager Access permission can view the TennIIS inventory.
  3. If the lot number for the vaccine to be used in the mass vaccination event is not listed, it will need to be added before the event. Contact [TennIIS.VOMS@tn.gov](mailto:TennIIS.VOMS@tn.gov) or 615-741-7247 for assistance. Health Departments can contact their Regional Immunization Representative for assistance.

Logged in: MASS IMM1

Organization/Facility: MASS IMM TRAINING ORG (1356853354) / MASS IMM TRAINING FACILITY Date: September 19, 2020

Main	Message	Vaccine	Lot Number	Exp Date	Quantity on Hand	Physical Inventory	Adjustment (+/-)	Category	Reason	Funding Source	Batch	Add Row
	Lot Numbers	DTap (Infanrix®)	3247GJ4	12/31/2022	100		0.0	-No Category Required	-No Reason Required-	PUB		<input data-bbox="1514 270 1535 297" type="button" value="+"/>
		Hep A, ecd, adq, 2 dose (Merck® / Havrix®)	123649B	12/31/2022	100		0.0	-No Category Required	-No Reason Required-	PUB		<input data-bbox="1514 312 1535 340" type="button" value="+"/>
		Influenza, injectable, MMRV, preservative free, quadrivalent (Free (Recombivax-H®) / Engerix-B®)	SDF564	12/31/2022	100		0.0	-No Category Required	-No Reason Required-	PUB		<input data-bbox="1514 354 1535 382" type="button" value="+"/>
		Influenza, injectable, MMRV, preservative free, quadrivalent (Fluavelve®) / ProQuad®)	468TR47S	06/30/2021	95		0.0	-No Category Required	-No Reason Required-	PUB		<input data-bbox="1514 397 1535 424" type="button" value="+"/>
		Influenza, injectable, MMRV, preservative free, quadrivalent (Fluavelve®) / ProQuad®)	PA860H	06/30/2021	200		0.0	-No Category Required	-No Reason Required-	31F		<input data-bbox="1514 439 1535 466" type="button" value="+"/>
		Influenza, injectable, MMRV, preservative free, quadrivalent (Fluavelve®) / ProQuad®)	SDGH88	06/30/2021	198		0.0	-No Category Required	-No Reason Required-	317		<input data-bbox="1514 481 1535 508" type="button" value="+"/>
		Influenza, injectable, MMRV, preservative free, quadrivalent (Fluavelve®) / ProQuad®)	456-23G	06/30/2021	100		0.0	-No Category Required	-No Reason Required-	PUB		<input data-bbox="1514 523 1535 551" type="button" value="+"/>
		Influenza, injectable, quadrivalent, preservative free (Fluimunozone®/Fluzone®)	768FG321B	06/30/2021	07		0.0	-No Category Required	-No Reason Required-	PUB		<input data-bbox="1514 566 1535 593" type="button" value="+"/>
		Tdip (Adacel® / Boostrix®)	447FSD75	12/31/2022	100		0.0	-No Category Required	-No Reason Required-	PUB		<input data-bbox="1514 608 1535 635" type="button" value="+"/>

Inventory Last Submitted: 09/11/2020

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# Tennessee Immunization Information System (TennIIS)

## Mass Immunizations Module Quick Reference Guide

### Before the Mass Immunization Event: Adding/Updating Vaccinators

The facility point of contact (POC) is responsible for managing the list of Physicians and Vaccinators for their facility. "Vaccinators" are individuals who administer vaccines to patients. Individuals added as a vaccinator will be listed in the drop-down menu on the Vaccination Detail screen in TennIIS and in the Vaccinator drop-down within the Mass Immunizations Module.

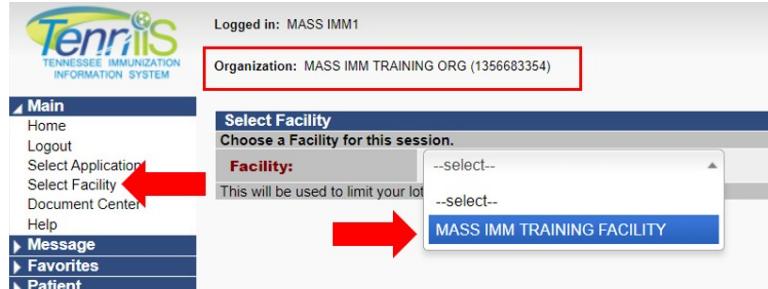
If a vaccinator is selected when an administered vaccine is added to a patient record, the vaccinator's name will be displayed on the Vaccination Detail Screen in TennIIS. The Patient Detail Report lists the vaccinator's name, and the report can be run for all vaccinators within a facility or limited to specific vaccinators.

Note: Adding or inactivating vaccinators is not the same as adding or inactivating TennIIS users.

**1) Select a facility**

Login to TennIIS and verify that the correct Organization/Facility is displayed.

If the correct facility is not displayed, click "Select Facility" under the Main tab in the navigation menu and select the correct facility from the drop-down, then click the "Continue" button.



Logged in: MASS IMM1  
 Organization: MASS IMM TRAINING ORG (135668354)

Select Facility  
 Choose a Facility for this session.  
**Facility:**  
 This will be used to limit your location  
 --select--  
 --select--  
**MASS IMM TRAINING FACILITY**

**2) Navigate to Physicians & Vaccinators**

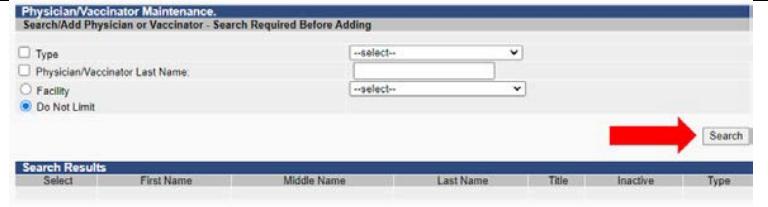
In the navigation menu, click "Physicians & Vaccinators."

Click Search/Add.



- ▶ Main
- ▶ Message
- ▶ Favorites
- ▶ Patient
- ▶ Vaccinations
- ▶ Physicians & Vaccinators**
- ▶ Search/Add
- ▶ Search Results
- ▶ Detail
- ▶ Scan Sheet
- ▶ Reports
- ▶ Settings
- ▶ Reminder/Recall
- ▶ Exports
- ▶ Scheduled Reports

**3) On the Physician/Vaccinator Maintenance screen, click the Search button to review the list of vaccinators.**



Physician/Vaccinator Maintenance.  
 Search/Add Physician or Vaccinator - Search Required Before Adding

<input type="checkbox"/> Type	--select--
<input type="checkbox"/> Physician/Vaccinator Last Name:	(empty text field)
<input type="radio"/> Facility	--select--
<input checked="" type="radio"/> Do Not Limit	

**Search Results**

Select	First Name	Middle Name	Last Name	Title	Inactive	Type

**Search**

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS)

## Mass Immunizations Module Quick Reference Guide

### 4) Edit Existing Vaccinators

To edit an existing vaccinator, click the Select button for that vaccinator.



Search Results					
Show [ 100 ] entries	Search:	First Name	Middle Name	Last Name	Title
<input type="button" value="Select"/>		MASS		IMM1	RN
<input type="button" value="&gt;&gt;"/>		MASS		IMM2	RN
<input type="button" value="&gt;&gt;"/>		MASS		IMM4	RN
<input type="button" value="&gt;&gt;"/>		MASS		IMMRN3	
<input type="button" value="&gt;&gt;"/>		MASS		IMMRN5	

Showing 1 to 5 of 5 entries

### 5) On the Physician/Vaccinator Maintenance [Detail] screen, click the Edit button at the bottom right, make the necessary changes and click the Save button.



Physician/Vaccinator Maintenance [Update]

Physician Id: SIIISCLIENT4992  
 First Name: MASS  
 Middle Name:  
 Last Name: IMM1  
 Title: RN  
 Specialty: Other  
 SSN:  
 BOMEX:  
 DO:  
 Medicaid PIN:  
 Medicaid Group:  
 NPI:  
 Medical License Number:  
 Terminal Distributor's License:  
 Other Provider Id:  
 Organization: 1356683354 - MASS IMM TRAINING ORG  
 Facility: MASS IMM TRAINING FACILITY  
 Phone Number:  
 Phone Number Extension:  
 Fax Number:  
 Email:  
 District/Region:  
 Inactive:  
 Automatic Ownership Blocked:  
 Comments:  
 Provider Tax ID:  
 Type: VACCINATOR

Cancel | Reset | Save

### 6) Adding Vaccinators

To add a vaccinator, click the Add button on the Physician/Vaccinator Maintenance screen.



Physician/Vaccinator Maintenance

Search/Add Physician or Vaccinator - Search Required Before Adding

Type: Physician/Vaccinator Last Name  
 Organization: 1356683354 - MASS IMM TRAINING ORG  
 Facility:  
 Facility Group:  
 VFC PIN:

Search Results

Select	First Name	Middle Name	Last Name	Title	Inactive	Type
<input type="button" value="&gt;&gt;"/>	MASS		IMM1	RN	V	
<input type="button" value="&gt;&gt;"/>	MASS		IMM2	RN	V	
<input type="button" value="&gt;&gt;"/>	MASS		IMM4	RN	V	
<input type="button" value="&gt;&gt;"/>	MASS		IMMRN3		V	
<input type="button" value="&gt;&gt;"/>	MASS		IMMRN5		V	

Showing 1 to 5 of 5 entries

Back | Add

### 7) Enter the vaccinator's information (required fields in red) and click the Save button



Physician/Vaccinator Maintenance [Add]

First Name: Massimm  
 Middle Name:  
 Last Name: Trainer  
 Title: RN

Specialty:  
 SSN:  
 BOMEX:  
 DO:  
 Medicaid PIN:  
 Medicaid Group:  
 NPI:  
 Medical License Number:  
 Terminal Distributor's License:  
 Other Provider Id:  
 Organization: 1356683354 - MASS IMM TRAINING ORG  
 Facility: MASS IMM TRAINING FACILITY  
 Phone Number:  
 Phone Number Extension:  
 Fax Number:  
 Email:  
 District/Region:  
 Inactive:  
 Automatic Ownership Blocked:  
 Comments:  
 Provider Tax ID:  
 Type: VACCINATOR

Save

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS)

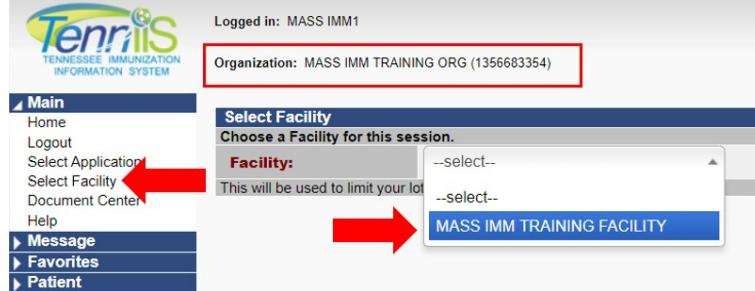
## Mass Immunizations Module Quick Reference Guide

### During the Mass Immunization Event: Searching for a Patient

#### 1) Select a facility

Login to TennIIS and verify that the correct Organization/Facility is displayed.

If the correct facility is not displayed, click "Select Facility" under the Main tab in the navigation menu and select the correct facility from the drop-down, then click the "Continue" button.



Logged in: MASS IMM1  
Organization: MASS IMM TRAINING ORG (1356683354)

Select Facility  
Choose a Facility for this session.  
Facility:   
This will be used to limit your lot  
--select--  
--select--  
**MASS IMM TRAINING FACILITY**

#### 2) Navigate to the Mass Immunizations Module

In the navigation menu, click "Select Application."

Select Mass Immunizations from the Application drop-down and click the "Submit" button.



Logged in: MASS IMM1  
Organization/Facility: MASS IMM TRAINING ORG (1356683354) / MASS IMM TRAINING FACILITY

Select Application  
Choose an Application for this session.  
Application:   
**Mass Immunizations**  
**Standard**

#### 3) Searching for a patient

In the navigation menu, click "Search/Add" under the Patient tab.

Enter the patient's first and last name or initials and date of birth in the search fields and click the Search button.



Mass Immunizations  
Logged in: MASS IMM1  
Organization/Facility: MASS IMM TRAINING ORG (1356683354) / MASS IMM TRAINING FACILITY  
Date: September 10, 2020

Patient Search  
Patient Information  
First Name or Initial:  m  
Last Name or Initial:  m  
Birth Date: 01/01/1958

Search

#### 4) Search results are displayed at the bottom of the next screen.

If the patient has an existing immunization record in TennIIS, the patient's name will appear in the search results. Click the arrow button next to the patient's name to select the patient.

If the patient's name is not listed, the patient will need to be added as a new patient (see "[Adding a New Patient](#)" below).



Mass Immunizations  
Logged in: MASS IMM1  
Organization/Facility: MASS IMM TRAINING ORG (1356683354)  
Date: September 10, 2020

Search Criteria  
Patients found with:  
First Initial = "m" and Birthday = "01/01/1958"  
OR  
Last Initial = "m" and Birthday = "01/01/1958"

Search Results  
Records Found = 2

Select	First Name	Middle Name	Last Name	Birth Date	Grid First Name	Mother's Maiden
<input type="button" value="→"/>	MICKEY		MOUSE	01/01/1958		
<input type="button" value="→"/>	MINNIE		MOUSE	01/01/1958		

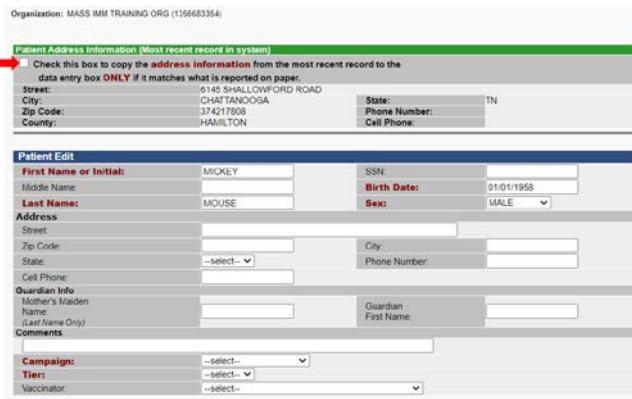
Before adding a new patient, check to make sure the patient you want to add is not listed above.

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS) Mass Immunizations Module Quick Reference Guide

- 5) Verify the patient's demographic information. If the address listed at the top of the page is correct, check the box in the upper left corner to add that information to the fields below. If changes need to be made, enter the changes in the "Patient Edit" section. Fields in RED are required.

**Adding the patient's current phone number is crucial and necessary for recalling patients when they need additional doses or other vaccines.**



## During the Mass Immunization Event: Adding a New Patient

- 1) If the patient is not listed in the search results, click the "Add New Patient" button.



- 2) Add the patient's demographic information. Required fields are red.

**Adding the patient's current phone number is crucial and necessary for recalling patients when they need additional doses or other vaccines.**



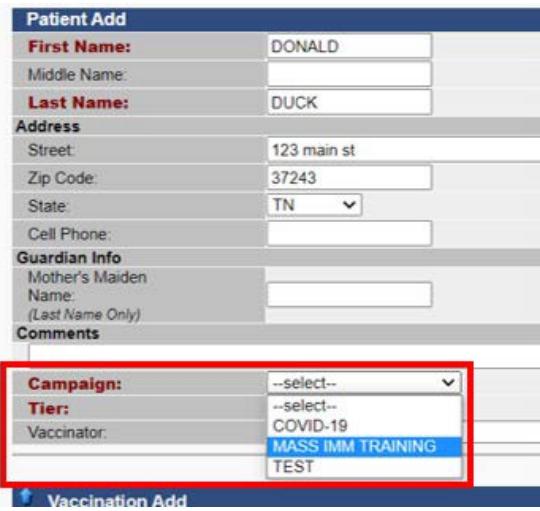
Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS) Mass Immunizations Module Quick Reference Guide

## During the Mass Immunization Event: Adding Administered Vaccines

- 1) From the Patient Edit (existing patients) or the Patient Add (new patients) screen, select a **Campaign** from the drop-down list (required).

Campaigns are set by TennIIS Program Administrators. If the campaign for your mass vaccination event is not listed, contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 615-741-7247.



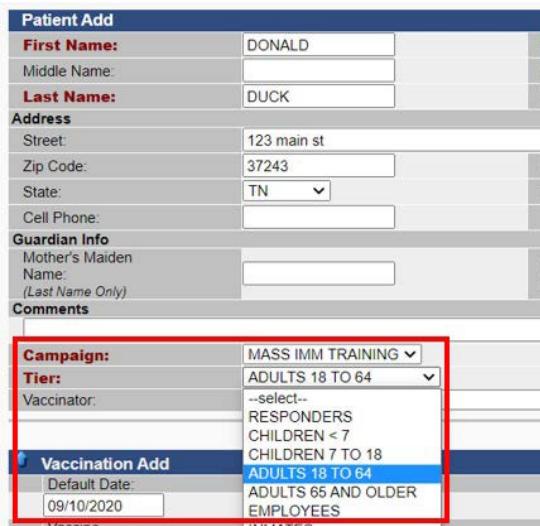
**Patient Add**

**Campaign:** --select--  
**Tier:** --select--  
**Vaccinator:** COVID-19  
**MASS IMM TRAINING**  
**TEST**

**Vaccination Add**

- 2) After selecting a Campaign, select a Tier group from the drop-down list (required).

Tier groups are set by TennIIS Program Administrators and may differ from those shown in this example. If the tier group for your mass vaccination event is not listed, contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 615-741-7247.



**Patient Add**

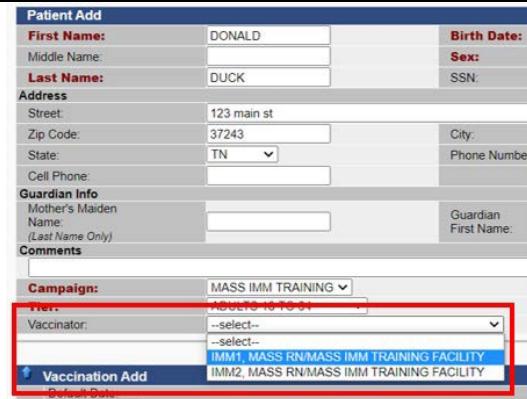
**Campaign:** MASS IMM TRAINING  
**Tier:** ADULTS 18 TO 64  
**Vaccinator:** --select--  
**RESPONDERS**  
**CHILDREN < 7**  
**CHILDREN 7 TO 18**  
**ADULTS 18 TO 64**  
**ADULTS 65 AND OLDER**  
**EMPLOYEES**

**Vaccination Add**

- 3) After selecting a Campaign and Tier group, select the vaccinator (the individual who administered the vaccine) from the drop-down list (optional).

If a vaccinator is not selected when the vaccination is recorded in TennIIS, one can be added later using the Edit Record button on the Vaccination Detail screen.

The facility point of contact can add/update vaccinators for the facility.



**Patient Add**

**Campaign:** MASS IMM TRAINING  
**Tier:** ADULTS 18 TO 64  
**Vaccinator:** --select--  
**IMM1, MASS RN/MASS IMM TRAINING FACILITY**  
**IMM2, MASS RN/MASS IMM TRAINING FACILITY**

**Vaccination Add**

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS)

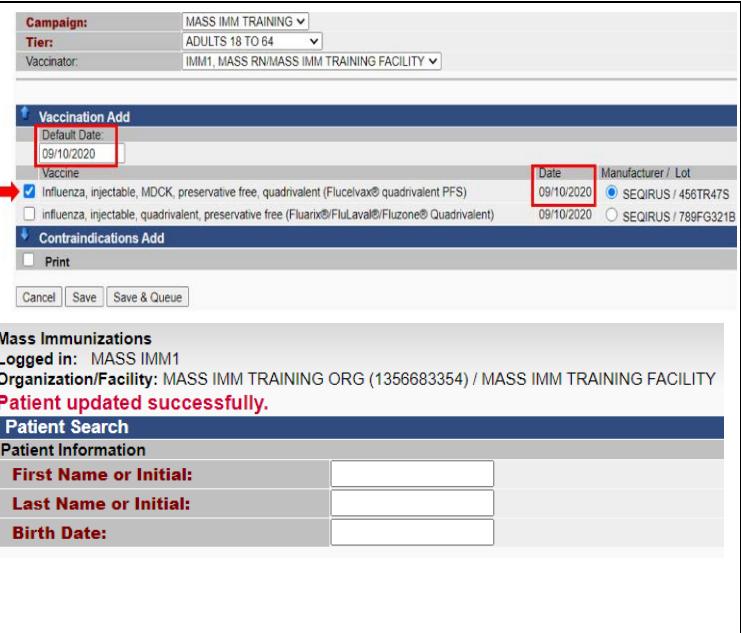
## Mass Immunizations Module Quick Reference Guide

- 4) Check the appropriate box for the vaccine and lot number being administered. Only the vaccines that were set up for the campaign and the lot number defaults in the facility/personal settings will appear in this list. In some cases there will be only one option shown.

Ensure that the correct vaccination date is the date shown in the Date column. If the date is not correct, enter the correct date in the Default Date box.

Click the Save button to record the vaccination or the Cancel button to start over.

If the lot number being administered is not listed, contact your facility's mass immunization event coordinator or [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov).



The screenshot shows the 'Vaccination Add' screen. At the top, there are dropdown menus for 'Campaign' (MASS IMM TRAINING), 'Tier' (ADULTS 18 TO 64), and 'Vaccinator' (IMM1, MASS RN/MASS IMM TRAINING FACILITY). Below these are sections for 'Vaccination Add' and 'Contraindications Add'. Under 'Vaccination Add', the 'Default Date' field contains '09/10/2020'. A red arrow points to this field. To its right, the 'Date' field for the selected vaccine ('Influenza, injectable, MDCK, preservative free, quadrivalent (Flucelvax® quadrivalent PFS)') also contains '09/10/2020'. There are two radio buttons for manufacturer/lot: 'SEQIRUS / 456TR47S' (selected) and 'SEQIRUS / 789FG321B'. The 'Patient updated successfully.' message is displayed at the bottom of the page.

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# Tennessee Immunization Information System (TennIIS)

## Mass Immunizations Module Quick Reference Guide

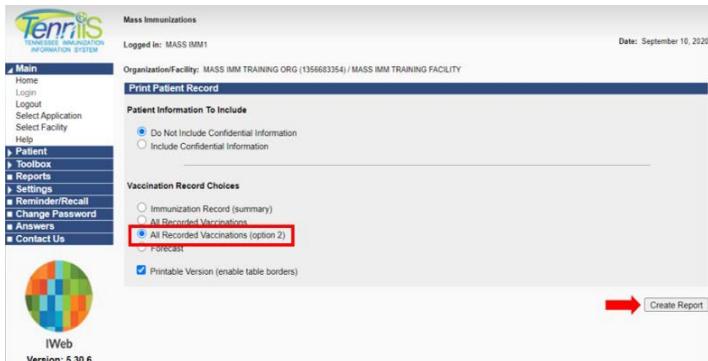
### During the Mass Immunization Event: Viewing and Printing Patient Records

- 1) Immediately after adding a vaccine to a patient's record and before searching for the next patient, you can print a copy of the patient's complete TennIIS record.

To print a patient record for the previous patient, click the Reports tab in the navigation menu then click Patient Record.



- 2) Select "All Recorded Vaccinations (option 2)" and click the "Create Report" button.



- 3) The Patient Vaccination Record will open in a new window.

The patient's complete TennIIS record will be displayed. Upcoming due dates and overdue dates for additional vaccinations are listed below the recorded vaccination dates.

Print the record using your internet browser's print function or press "Ctrl + P."

Sign or stamp the printed record with your facility information in case the patient or another provider have questions about the record.

Patient Vaccination Record (option 2)				
All Recorded Vaccinations (option 2)				
Patient Name:	DONALD DUCK			
Patient Address:				
Date of Birth:	01/01/1970			
Age:	50y			
Vaccine	Dose	Date	Age	
<b>FLU</b> Influenza, injectable, MDCK, preservative free, quadrivalent	1	09/10/2020	50y	
<b>ZOSTER</b> zoster recombinant	1	02/15/2020	50y	
<b>Tdap</b> Tdap	1	01/01/2019	49y	
<b>Vaccines</b>	<b>Due</b>			
MMR	01/01/1971			
DTaP/DT/Td	01/29/2019			
ZOSTER	04/11/2020			
FLU	07/01/2021			
Signature of physician or authorized representative of health agency:				

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.

# COVID-19 Vaccines: Guidance if TennIIS is Offline

In the event that TennIIS were to be offline due to technical difficulties, the below spreadsheet can be used to collect the required data elements for entry when back online.

Patient MRN	Patient First Name	Patient Last Name	Patient DOB (YYYYMMDD)	Patient Gender (M=Male; F=Female; O=Other; U=Unknown)	Patient Address Street	Patient Address City	Patient Address State	Patient Address Zip	Patient Address County	Patient Race	Patient Ethnicity	Organization	Administering Facility RXA-11 Value (if known). Otherwise, Admin Facility Name	Vaccination Date (YYYYMMDD)	Vaccination CVX Code
00000001															
00000002															
00000003															
00000004															
00000005															
00000006															
00000007															
00000008															
00000009															
00000010															
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00000049															

To access:

- Right click on the image
- Select “Worksheet Option”
- Select Open

- Refrigerated vaccines reach temperatures colder than 2°C or warmer than 8°C
- Frozen vaccines reach temperatures colder than -25° or warmer than -15°C
- Ultra-cold vaccines reach temperatures colder than -95°C or warmer than -60°C
- TE is part of a pattern of frequent excursions, regardless of duration
- TE concerns regardless of one of the above criteria

**Pfizer COVID-19 Vaccine**

# Healthcare Educational Information

## Vaccine Information: mRNA Vaccines

## What are COVID-19 Vaccines?

- There are many COVID-19 vaccines in development.
- Currently, there are two mRNA vaccines that have been approved for use in the United States. Both of these vaccines have shown that they can reduce the chance of getting COVID-19 by 95%.
- The two vaccines in use in the United States are the Moderna Vaccine and the Pfizer-BioNTech Vaccine.
- Both mRNA vaccines require two doses to provide protection against the virus.
- Early data show the vaccines are effective across all ages, races, and health conditions.

## How do mRNA vaccines work?

- mRNA vaccines provide the body with a genetic “recipe” so the body can produce the “spike protein” that is found on the surface of the virus. The body sees the protein as foreign and makes antibodies to destroy it. If the body is later infected with the virus, the antibodies recognize the spike protein and destroy the virus before it can cause illness.
- COVID-19 mRNA vaccines are given in the upper arm muscle.

## When will I be able to get a vaccine?

- While vaccine supply is limited, first priority will be to vaccinate hospital staff who have direct contact with patients or materials that are potential infectious as well as first responders with direct contact to the public (e.g., EMS and law enforcement). Eventually, anyone who wants a vaccine will be able to get a vaccine unless there is a medical contraindication.
- For more information regarding the phases of vaccine distribution in Tennessee, please visit <https://covid19.tn.gov/covid-19-vaccines/vaccine-phases/>.

## Are COVID-19 vaccines safe?

- **Yes!** Vaccine safety is the first priority!
- These vaccines have already been given to tens of thousands of volunteers and have been shown to be safe and very effective at preventing them from getting sick with COVID-19.
  - The vaccine will continue to be monitored to make sure any rare problems are found as soon as possible and studied to see if they were caused by the vaccine.
  - While the possibility of a rare but serious adverse event cannot be ruled out, rare events could occur in <0.01% of people who receive a COVID-19 vaccine. The case fatality rate of COVID-19 in Tennessee is currently >1%, or approximately 100 times greater than the chance of the vaccine causing a serious event.



Remember, vaccines don't work unless people get vaccinated. Please help control the pandemic by receiving a vaccine when it is offered to you!

For more information, please visit  
COVID-19 Vaccine Facts



<https://www.tn.gov/health/cedep/ncov/>

**mRNA Vaccine Second Dose Information****What happens if I don't get the second dose of COVID-19 vaccine?**

You likely won't be protected against COVID-19. The first dose "primes" the immune system. The second dose creates the lasting protection.

**What happens if I don't get the second dose of vaccine on time?**

You need to go get it as soon as possible, even if you are late.

**I didn't feel well after the first dose. Will I feel bad after the second?**

Just as with the first dose, it is not uncommon to experience low-grade fever, fatigue, or headache after you receive the vaccine. These symptoms usually go away after a day or two. The symptoms of COVID-19 are often much worse and can be life-threatening. It's important to get the second dose to protect yourself, your family and your community.

**Where can I get the second dose?**

The facility that gave you the first dose should give you your second dose. Contact them or your local health department.

**Do I have to get the same vaccine as last time?**

YES! There are currently TWO different vaccines available (Moderna and Pfizer-BioNTech). You MUST get the same brand you received the first time. If you do not know which one you received, the facility where you received your first dose can help you or you can contact your local health department.



**Reminder:** Check the vaccine card that was given to you when you received your first dose or check your phone to see if you took a picture of it.



**Pfizer Vaccine** is due 21 days after the first dose.



**Moderna Vaccine** is due 28 days after the first dose.



# 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 2 p.m. 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?

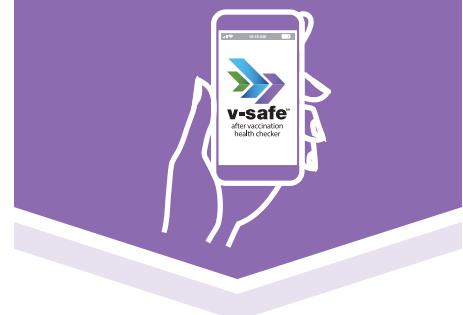
During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **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.\*



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](https://vsafe.cdc.gov)

OR

Aim your smartphone's camera at this code



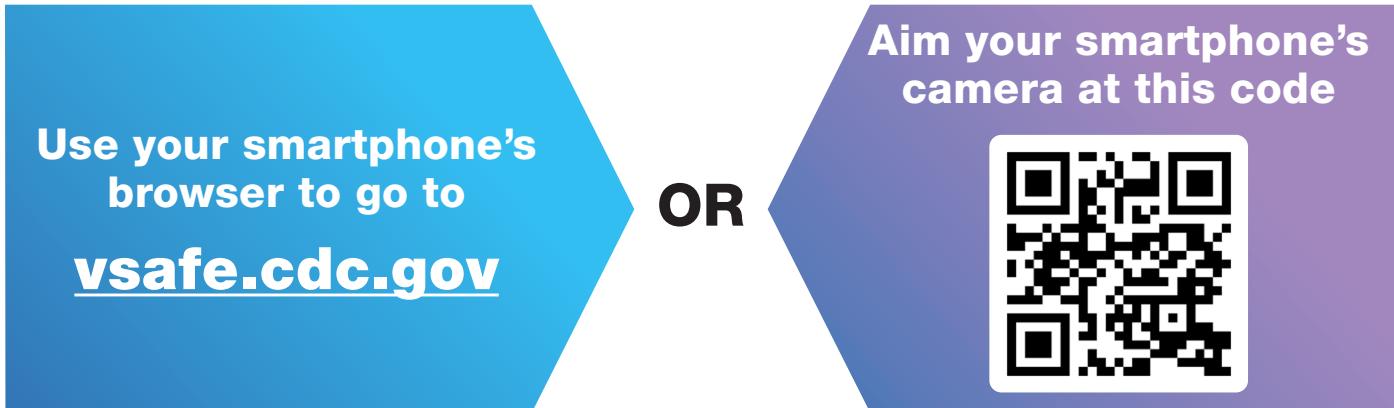
\*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

# How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

## Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2 p.m. local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2 p.m., **v-safe** will start your initial health check-in immediately after you register—just follow the instructions.

You will receive a reminder text message from **v-safe** when it's time for the next check-in—around 2 p.m. local time. Just click the link in the text message to start the check-in.

## Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

## Troubleshooting

### How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

### How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

### Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)  
TTY 888-232-6348  
Open 24 hours, 7 days a week  
Visit [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)





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



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Sign up with your smartphone's browser at  
[vsafe.cdc.gov](https://vsafe.cdc.gov)

**OR**  
Aim your smartphone's camera at this code



Learn more about **v-safe** [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)



# COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals



Healthcare professionals who are knowledgeable about evidence-based immunization strategies and best practices are critical to implementing a successful vaccination program. They are key to ensuring that vaccination is as safe and effective as possible. Some healthcare professionals administering COVID-19 vaccine may have extensive experience with immunization practices, since they routinely administer recommended vaccines in their clinical practice. For others, administering COVID-19 vaccine may be their first clinical experience with vaccination. Below is a list of immunization training and educational materials, including basic and COVID-19-vaccine-specific information.

## »Vaccine Storage and Handling

Vaccine storage and handling practices are only as effective as the staff who implement them. Staff who are well-trained in general storage and handling principles and follow standard operating procedures for vaccine management are critical to ensuring vaccine supply potency and patient safety.

Training Program / Reference Material	Description
<a href="#"><u>You Call the Shots: Vaccine Storage and Handling</u></a>	An interactive, web-based immunization training course on storage and handling best practices and principles.
<a href="#"><u>"Keys to Storing and Handling Your Vaccine Supply" video</u></a>	This video is designed to decrease vaccine storage and handling errors by demonstrating recommended best practices and addressing frequently asked questions.
<a href="#"><u>Vaccine Storage and Handling Toolkit</u></a>	Comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.
<a href="#"><u>Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum</u></a>	The <i>Vaccine Storage and Handling Toolkit</i> , COVID-19 Vaccine Addendum, provides information, recommendations, and resources on storage and handling best practices to help safeguard the COVID-19 vaccine supply and ensure patients receive safe and effective vaccines.
<a href="#"><u>Epidemiology and Prevention of Vaccine-Preventable Diseases</u></a>	Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 5 is dedicated to vaccine storage and handling (updated 2020).

## »Vaccine Administration

Healthcare professionals who will administer vaccines should receive comprehensive, competency-based training in vaccine administration policies and procedures before administering vaccines. Staff's vaccine administration knowledge and skills should be validated using a skills checklist and maintained using quality improvement processes.

<a href="#"><u>You Call the Shots: Vaccine Administration</u></a>	An interactive, web-based vaccine administration course that provides training using videos, job aids, and other resources.
<a href="#"><u>Vaccine administration videos</u></a>	Short, skill-based demonstration videos of vaccine administration activities, including injection techniques based on age and medication preparation.
<a href="#"><u>Skills Checklist for Vaccine Administration</u></a>	This checklist from the Immunization Action Coalition is a self-assessment tool for healthcare professionals who administer vaccines.
<a href="#"><u>Epidemiology and Prevention of Vaccine-Preventable Diseases</u></a>	Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 6 is dedicated to vaccine administration (updated 2020).

# COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals



## » Communicating with Patients about Vaccines

Healthcare professionals play a key role in improving vaccine acceptance as they are in contact with patients throughout the office visit. By fostering a culture of immunization in the practice, both providers and patients can vaccinate with confidence.

<a href="#"><u>How Nurses and Medical Assistants Can Foster a Culture of Immunization in the Practice video</u></a>	Research shows that healthcare professionals are patients' most trusted source of information when it comes to vaccines. By highlighting key points before, during, and after a patient's visit, this presentation will support vaccine conversations and reinforce best practices for improving vaccination coverage.
<a href="#"><u>"#HowIRecommend" vaccination video series</u></a>	These videos explain the importance of vaccination, how to effectively address questions from patients about vaccine safety and effectiveness, and how clinicians routinely recommend same-day vaccination for their patients.
<a href="#"><u>Provider Resources for COVID-19 Vaccine Conversations with Patients</u></a>	Information for healthcare providers on how to talk to patients about COVID-19 vaccines, including giving strong recommendations, setting expectations about vaccine availability, and preparing to answer likely patient questions.
<a href="#"><u>Epidemiology and Prevention of Vaccine-Preventable Diseases</u></a>	Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 3, discusses essential strategies healthcare professionals can use when talking to patients about vaccines (updated 2020).

## » COVID-19 Vaccine Training and Clinical Materials

This suite of COVID-19 vaccine training programs and clinical materials for healthcare professionals include general and product-specific information. A variety of topics and formats are available. All are based on manufacturer's guidance and vaccine recommendations made by the Advisory Committee on Immunization Practices (ACIP). **These trainings and materials will be made available as each vaccine product is authorized by FDA**

<a href="#"><u>COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers</u></a>	A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage/handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is authorized by FDA.
<a href="#"><u>COVID-19 Vaccine Webinar Series</u></a>	These interactive, web-based training modules offer a real-world perspective on different issues around COVID-19 vaccines. Each webinar is approximately 15 minutes and offers CE.
<a href="#"><u>Clinical materials</u></a>	COVID-19 vaccine screening form for contraindications and precautions Expiration date tracker Reporting a temperature excursion IIS off-line vaccine administration documentation tool Guide to ancillary supplies kit (for staff helping providers order vaccine) COVID-19 vaccine frequently asked clinical questions web page Prevaccination screening form

# COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals



<u>Clinical Considerations</u>	Interim Clinical Considerations Guidance Severe Allergic Reactions Vaccinating Special Populations
<u>Pfizer vaccine materials</u>	Online training module Vaccine preparation and administration summary Storage and handling summary Temperature log for ultra-cold freezer units, including online fillable PDF version Beyond use date tracker labels for refrigerator storage Standing orders template Storage labels for refrigerator Temperature logs for the refrigerator Infographic poster for vaccine preparation Checklist for vaccine delivery
<u>Moderna vaccine materials</u>	Online training module Vaccine preparation and administration summary Guidance for transporting vaccines Storage and handling summary Temperature log for freezer units Beyond use date tracker labels for refrigerator storage Standing orders template Storage labels for refrigerator Temperature logs for the refrigerator
<u>Janssen vaccine materials</u>	Online training module Vaccine preparation and administration summary Storage and handling summary Standing orders template Temperature logs for the refrigerator Guidance for transporting vaccines Storage labels for the refrigerator

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Department of  
Health

# COVID-19 Vaccines: Provider Packet

Pfizer COVID-19 Vaccine

## Appendix

# COVID-19 Vaccination Record Card

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

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



Last Name

First Name

MI

Date of birth

Patient number (*medical record or IIS record number*)

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

Reminder! Return for a second dose!

## ¡Recordatorio! ¡Regrese para la segunda dosis!

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

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

For more information about COVID-19 and COVID-19 vaccine, visit [cdc.gov/coronavirus/2019-ncov/index.html](https://www.cdc.gov/coronavirus/2019-ncov/index.html).

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

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

Para obtener más información sobre el COVID-19 y la vacuna contra el COVID-19, visite [espanol.cdc.gov/coronavirus/2019-ncov/index.html](https://espanol.cdc.gov/coronavirus/2019-ncov/index.html).

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

# COVID-19 Pfizer BioNTech or Moderna Vaccination

PLEASE PRINT

Patient FIRST Name:	LAST Name:	MI:
Maiden Name (Optional):		
DOB: / /	Current Age:	Sex: <input type="checkbox"/> F <input type="checkbox"/> M <input type="checkbox"/> Other
Race: <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Other <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Unknown		
Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Non-Hispanic or Latino <input type="checkbox"/> Unknown		
Address:	City:	State: Zip:
Cell Phone: ( )	Alternate Phone: ( )	

The following questions will help determine if there is any reason you should not receive a COVID immunization injection. **Questions should be answered for the person who will be vaccinated.**

If a question is not clear, please ask a healthcare provider to explain.

- |  |                              |                             |
|--|------------------------------|-----------------------------|
| 1. Younger than 18 years old?.....   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. History of any immediate allergic reaction, of any severity, after a previous dose of mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG]) or polysorbate?..... | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Cause/Allergy: _____   |                              |                             |
| 3. History of immediate allergic reaction of any severity to any substance?.....   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Cause/Allergy: _____   |                              |                             |
| 4. Ever received a COVID-19 vaccine?.....  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Date: _____ Manufacturer: _____  |                              |                             |
| 5. Sick today, including symptomatic/asymptomatic infection with COVID-19?.....  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 6. Received passive antibody therapy for COVID-19 in the last 90 days?.....  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 7. Pregnant or breastfeeding?.....   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

**Request for Administration of COVID-19 Vaccine for the above-named recipient:** I acknowledge that I have received the Vaccine Information Statement or Emergency Use Authorization Information Sheet and the Tennessee Department of Health's Notice of Privacy Practices. I have had an opportunity to ask questions regarding the vaccine and understand the risks and benefits. I am aware that, to provide protection against the virus that causes COVID-19, two doses of this same vaccine may be required. I acknowledge that I may receive a reminder for a second dose by text (if cell phone number provided, standard messaging rates may apply), phone call, or mail.

PATIENT/PARENT OR GUARDIAN/POWER OF ATTORNEY SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

*This consent is valid for 12 months from date signed.*

# COVID-19 Pfizer BioNTech or Moderna Vaccination

Vaccination Site [name, address] \_\_\_\_\_

## AREA FOR OFFICIAL USE ONLY

Nursing Immunization [INJECTION #1] Documentation

Manufacturer: Pfizer

Dose: 0.3 mL

Pfizer EUA Date: 12/2020

Manufacturer: Moderna

Dose: 0.5 mL

Moderna EUA Date: 12/2020

Route: IM

Site Administered:  Right Deltoid     Left Deltoid     [Other]

Lot Number: \_\_\_\_\_ Expiration Date: / /

Date Given: / / Provider number: \_\_\_\_\_ (Optional)

Signature: \_\_\_\_\_

*Signature indicates immunization given according to PHN Protocol*

Vaccine NOT given secondary to contraindication:

Verbal Order obtained from \_\_\_\_\_ to proceed with immunization per protocol;  
readback completed. Special Instructions:

PHN Signature: \_\_\_\_\_

## AREA FOR OFFICIAL USE ONLY

Nursing Immunization [INJECTION #2] Documentation

Manufacturer: Pfizer

Dose: 0.3 mL

Pfizer EUA Date: 12/2020

Manufacturer: Moderna

Dose: 0.5 mL

Moderna EUA Date: 12/2020

Route: IM

Site Administered:  Right Deltoid     Left Deltoid     [Other]

Lot Number: \_\_\_\_\_ Expiration Date: / /

Date Given: / / Provider number: \_\_\_\_\_ (Optional)

Signature: \_\_\_\_\_

*Signature indicates immunization given according to PHN Protocol*

Vaccine NOT given secondary to contraindication:

Verbal Order obtained from \_\_\_\_\_ to proceed with immunization per protocol;  
readback completed. Special Instructions:

PHN Signature: \_\_\_\_\_





## Vacuna de Pfizer BioNTech o Moderna contra el COVID-19

FAVOR USAR LETRA DE MOLDE

**PRIMER** nombre del paciente

**APELLIDO:**

**INICIAL DEL  
SEGUNDO  
NOMBRE**

**Apellido de soltera (opcional):**

**FECHA DE NACIMIENTO:**

**Edad actual:**

**Sexo:**  F  M  Otro

**Raza:**  Blanca  Negra o afroamericana  Asiática  Indígena americana o natural de Alaska  Otra

Natural de Hawái o de Islas del Pacífico  Desconocida

**Etnia:**  Hispana o latina  No hispana ni latina  Desconocida

**Dirección:**

**Ciudad:**

**Estado:**

**Código postal:**

**Celular:** ( )

**Teléfono alternativo:** ( )

**Las siguientes preguntas ayudarán a determinar si hay alguna razón por la que no debería recibir la vacuna inyectable contra el COVID. Responda a estas preguntas respecto a la persona que recibirá la vacuna.**

*Si una pregunta no está clara, solicite explicación a un proveedor de salud.*

1. ¿Tiene menos de 18 años de edad? .....  Sí  No

2. ¿Tiene antecedentes de reacciones alérgicas inmediatas de cualquier intensidad después de una dosis previa de la vacuna de ARNm contra el COVID-19 o cualquiera de sus componentes (incluso el PEG -polietilenglicol- o el polisorbato)? .....  Sí  No

**Causa/Alergia:**

3. ¿Tiene antecedentes de reacciones alérgicas inmediatas de cualquier intensidad a alguna sustancia? .....  Sí  No

**Causa/Alergia:**

4. ¿Le han puesto una vacuna contra el COVID-19 antes? .....  Sí  No

**Fecha:** \_\_\_\_\_ **Fabricante:** \_\_\_\_\_

5. ¿Está enfermo hoy, por ejemplo, con infección sintomática/asintomática de COVID-19? .....  Sí  No

6. ¿Ha recibido terapia pasiva con anticuerpos contra el COVID-19 en los últimos 90 días? .....  Sí  No

7. ¿Está embarazada o amamantando? .....  Sí  No

**Solicitud de administración de vacuna contra el COVID-19 para el receptor arriba mencionado:** Reconozco que he recibido la declaración de datos de la vacuna o la hoja informativa de autorización para uso de emergencia y el aviso de prácticas de privacidad del Departamento de Salud de Tennessee. Tuve la oportunidad de hacer preguntas sobre la vacuna y entiendo los riesgos y beneficios. Estoy al tanto de que, para brindar protección contra el virus que causa el COVID-19, puede que se requieran dos dosis de esta misma vacuna. Reconozco que puede ser que reciba un recordatorio de la segunda dosis, vía texto (si doy mi número de celular, puede que apliquen cobros estándar de mensajería), por teléfono o correo.



## Vacuna de Pfizer BioNTech o Moderna contra el COVID-19

FIRMA DEL PACIENTE/PADRE O TUTOR/PORTADOR DE PODER LEGAL: \_\_\_\_\_ FECHA: \_\_\_\_\_  
*Este consentimiento vale por 12 meses desde la fecha en que se firmó.*

Departamento de Salud del Condado de [ingrese el condado]

Lugar del centro de vacunación [dirección]

### ÁREA SOLO PARA USO OFICIAL

Documentación de vacuna por el enfermero [INYECCIÓN #1]

Fabricante: Pfizer

Dosis: 0.3 mL

Fecha de autorización para uso de emergencia  
para Pfizer 12/2020

Vía: IM

Punto de administración:  Deltoides derecho

Deltoides izquierdo

Fabricante: Moderna

Dosis: 0.5 mL

Fecha de autorización para uso de emergencia  
para Moderna 12/2020

[Otro]

Número de lote: \_\_\_\_\_

Fecha de vencimiento: / /

Fecha de administración: / /

Número del proveedor: \_\_\_\_\_ (Opcional)

Firma: \_\_\_\_\_

*La firma indica que la vacuna se administró según el protocolo de enfermería de salud pública*

Vacuna NO administrada debido a contraindicación:

Orden verbal obtenida de \_\_\_\_\_ para proceder con la inmunización según protocolo;  
se hizo lectura de confirmación. Instrucciones especiales:

**Firma del enfermero en salud pública:**

### ÁREA SOLO PARA USO OFICIAL

Documentación de vacuna por el enfermero [INYECCIÓN #2]

Fabricante: Pfizer

Dosis: 0.3 mL

Fecha de autorización para uso de emergencia  
para Pfizer 12/2020

Vía: IM

Punto de administración:  Deltoides derecho

Deltoides izquierdo

Fabricante: Moderna

Dosis: 0.5 mL

Fecha de autorización para uso de emergencia  
para Moderna 12/2020

[Otro]

Número de lote: \_\_\_\_\_

Fecha de vencimiento: / /

Fecha de administración: / /

Número del proveedor: \_\_\_\_\_ (Opcional)

Firma: \_\_\_\_\_

*La firma indica que la vacuna se administró según el protocolo de enfermería de salud pública*

Vacuna NO administrada debido a contraindicación:

Orden verbal obtenida de \_\_\_\_\_ para proceder con la inmunización según protocolo;  
se hizo lectura de confirmación. Instrucciones especiales:

**Firma del enfermero en salud pública**