The Vaccines are Coming!



PAUL REVERE'S RIDE-APRIL 19, 1773 .- DRAWN BY CHARLES G. BUSH -- (SEE THE PORM,

DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

December 08, 2020

Discussion Topics

- Welcome and Opening Remarks
- COVID-19 Vaccine Updates
- Expert Vaccine Allocation Panel
- COVID-19 Texas Vaccine Allocation & Shipment
- COVID-19 Vaccine Storage, Handling & Administration
- COVID-19 Vaccine Safety Monitoring & Reporting

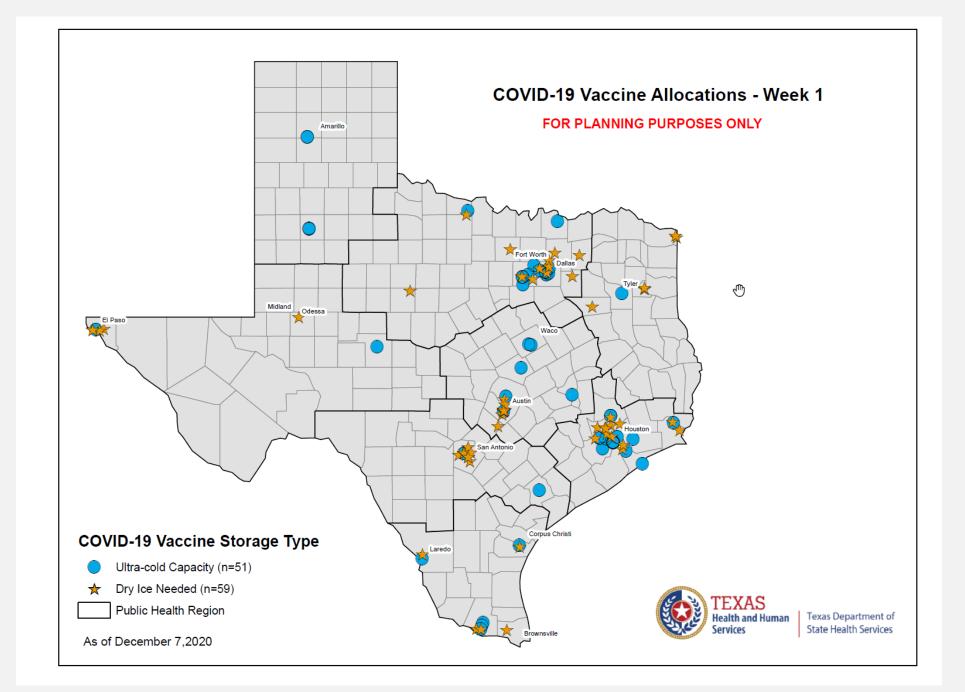
Texas Department of State Health Services • Q&A

Welcome & Opening Remarks

Imelda Garcia, MPH

Associate Commissioner, Laboratory & Infectious Disease Services Division





COVID-19 Vaccine Updates

Saroj Rai, PhD, MPH



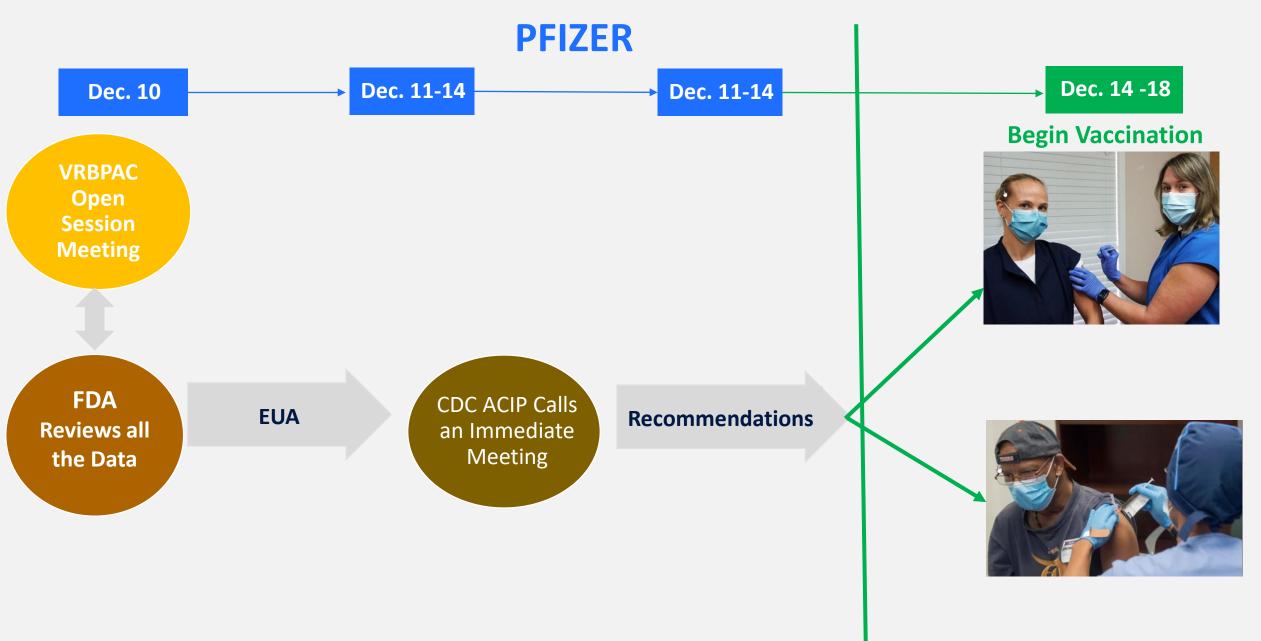
COVID-19 Vaccine Updates

Phase III Vaccine Candidates	Technology Platform	Storage & Handling	Dose (Intramuscular Injection)	
Pfizer	m-RNA	Ultra-low frozen: 6mos Refrigerated: 5 days	2 (0, 21 days)	
moderna	m-RNA	Frozen: 6mos Refrigerated: 30 days	2 (0, 28 days)	
	Viral Vector (Non-Replicating)	Refrigerated: 6mos	2 (0, 28 days)	
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Phase III Version		Efficacy & Safety			
Vaccine Candidates	Platform	Study Design	Interim Analysis	Completion of Primary Endpoint	Status
Pfizer	m-RNA	 N=44,000 ≥ 12 yrs Randomization (1:1) Placebo vs. Vaccine (Saline vs. 30 µg) 2 doses (0, 21 days) 	• 90% effectiveness (94 cases)	 95% vaccine efficacy (162 placebo vs. 8 vaccine) 30 severe case (30 placebo vs. 0 vaccine) Consistent efficacy across age, gender, race/ethnicity No serious adverse reported to date 	EUA Filed
moderna	m-RNA	 N=30,000 ≥ 18 yrs Randomization (1:1) Placebo vs. Vaccine (Saline vs. 100 µg) 2 doses (0, 28 days) 	 94.5% vaccine efficacy (90 placebo vs. 5 vaccine) 11 severe case (11 placebo vs. 0 vaccine) 16% adults ages >65 yrs 21% diverse population No serious adverse reported to date Grade 3 (>2%): Fatigue, myalgia, arthralgia, headache, pain, & redness at injection site 	 94.1% vaccine efficacy (185 cases in placebo vs. 11 vaccine) 11 severe case (11 placebo vs. 0 vaccine) 17% adults ages >65 yrs 21% diverse population 1 death in the placebo group 	EUA Filed
AstraZeneca	Viral Vector (Non- Replicating)	 UK Study N=12,390 ≥ 18 yrs 1 Dose vs. 2 Doses vs. MenACWY Brazil Study N=10,300 ≥ 18 yrs 2 does vaccine vs. MenACWY/Saline 	 90% vaccine efficacy (half dose/full dose (5x10¹⁰ vp) with n=2,741 62% vaccine efficacy (full dose/full dose (n=8,895) Combined efficacy of 70% (131 COVID-19 cases) No serious adverse events have been reported thus far 		
Janssen Jansten Jansten Jahren Jahren	Viral Vector (Non- Replicating)	 N=60,000 ≥ 18 yrs Randomization (1:1) Placebo vs. Vaccine (Saline vs. 5×10¹⁰ vp) 1 doses 			

Path to Vaccination



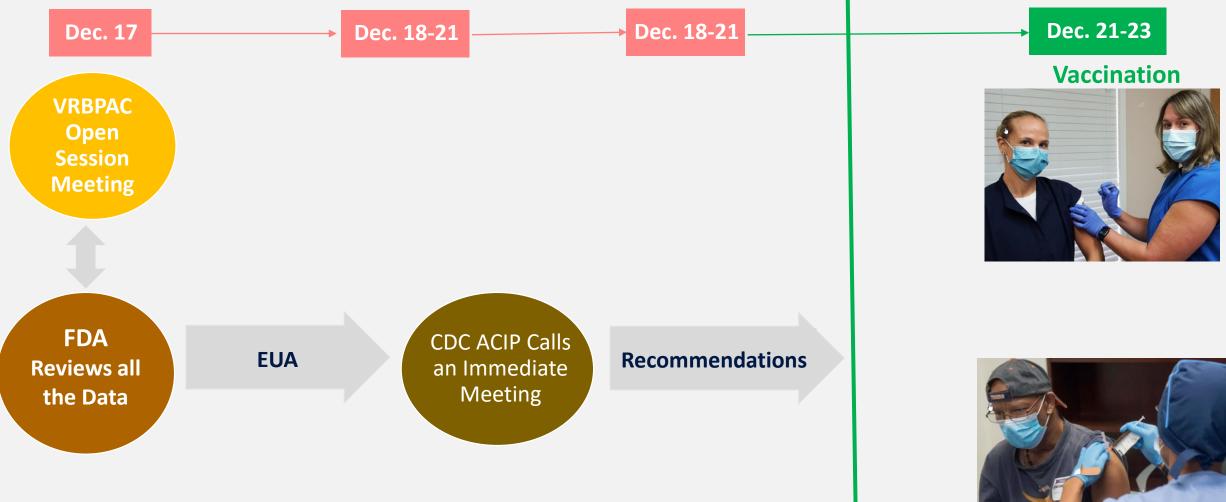


BLA (Biologics Licensure Application)

EUA (Emergency Use Authorization)

EA (Expanded Access)





BLA (Biologics Licensure Application)

EUA (Emergency Use Authorization)

EA (Expanded Access)

Expert Vaccine Allocation Panel (EVAP)

Imelda Garcia, MPH

Associate Commissioner, Laboratory & Infectious Disease Services Division



COVID-19 Expert Vaccination Allocation Panel (EVAP)

- Texas has convened a team of appointed external and internal subject-matter experts (SME) into the COVID-19 Expert Vaccine Allocation Panel (EVAP) to develop vaccine allocation strategies as recommendations to the Texas Commissioner of Health.
- The panel will develop and apply guiding principles in their recommendations.
- The recommendations from the EVAP will be sent to the Texas Commissioner of Health for final approval.
- EVAP voting members

https://www.dshs.texas.gov/coronavirus/immunize/evap.aspx



Texas Guiding Principles

- **Protecting health care workers** who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the health care infrastructure for all who need it.
- **Protecting front-line workers** who are at greater risk of contracting COVID-19 due to the nature of their work providing critical services and preserving the economy.
- **Protecting vulnerable populations** who are at greater risk of severe disease and death if they contract COVID-19.
- **Mitigating heath inequities** due to factors such as demographics, poverty, insurance status and geography.
- **Data-driven allocations** using the best available scientific evidence and epidemiology at the time, allowing for flexibility for local conditions.
- **Geographic diversity** through a balanced approach that considers access in urban and rural communities and in affected ZIP codes.
- **Transparency** through sharing allocations with the public and seeking public feedback.

https://gov.texas.gov/news/post/governor-abbott-dshs-announce-covid-19-vaccine-distribution-plan



COVID-19 Critical Population Update Phase 1A Healthcare Workers Definition – First Tier

- 1. Hospital staff working directly with patients who are positive or at high risk for COVID-19. Includes:
 - a. Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.)
 - b. Additional clinical staff providing supporting laboratory, pharmacy, diagnostic and/or rehabilitation services
- 2. Long-term care staff working directly with vulnerable residents. Includes:
 - a. Direct care providers at nursing homes, assisted living facilities, and state supported living centers
 - b. Physicians, nurses, personal care assistants, custodial, food service staff
- 3. EMS providers who engage in 9-1-1 emergency services like pre-hospital care and transport
- 4. Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients
- 5. Residents of long-term care facilities



COVID-19 Critical Population Update Phase 1A Healthcare Workers Definition – Second Tier

- 1. Staff in outpatient care offices who interact with symptomatic patients. Includes:
 - a. Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.).
 - b. Clinical staff providing diagnostic, laboratory, and/or rehabilitation services
 - c. Non 9-1-1 transportation for routine care
- 2. Direct care staff in freestanding emergency medical care facilities and urgent care clinics.
- 3. Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individuals who may have COVID.
- 4. Public health and emergency response staff directly involved in administration of COVID testing and vaccinations.
- 5. Last responders who provide mortuary or death services to decedents with COVID-19. Includes:
 - Embalmers and funeral home workers who have direct contact with decedents
 - Medical examiners and other medical certifiers who have direct contact with decedents.
- 6. School nurses who provide health care to students and teachers.



COVID-19 Texas Vaccine Allocation Process

Joshua Hutchison, Vaccine Data and Finance Manager



Vaccine Allocation & Ordering System (VAOS)

Overview

As a COVID-19 Vaccine Provider, you will use the Vaccine Allocation & Ordering System (VAOS) and Vaccine Management Dashboard to perform tasks related to COVID-19 vaccine management.



In **VAOS**, you will be able to acknowledge vaccine allocations, confirm received shipments, view distribution information, and report waste.



The Vaccine Management Dashboard is accessed through VAOS and allows you to monitor your vaccine allocations, distribution supply, and administration metrics.

Understanding your Provider Actions in VAOS

As a Provider, you have **four primary functions in VAOS**:

ACCESSING DASHBOARDS

Useful for seeing your allocations, distribution supply, and administration metrics

ACKNOWLEDGING ALLOCATIONS

Required for your allocated vaccine doses to be submitted into the CDC ordering system

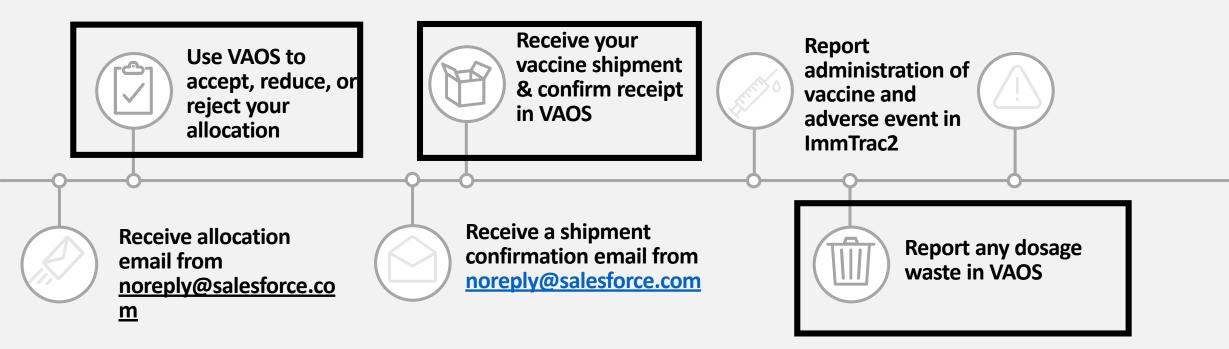
CONFIRMING SHIPMENTS

Required once you receive your vaccine doses

REPORTING WASTE

Required to track how many doses are unused/wasted

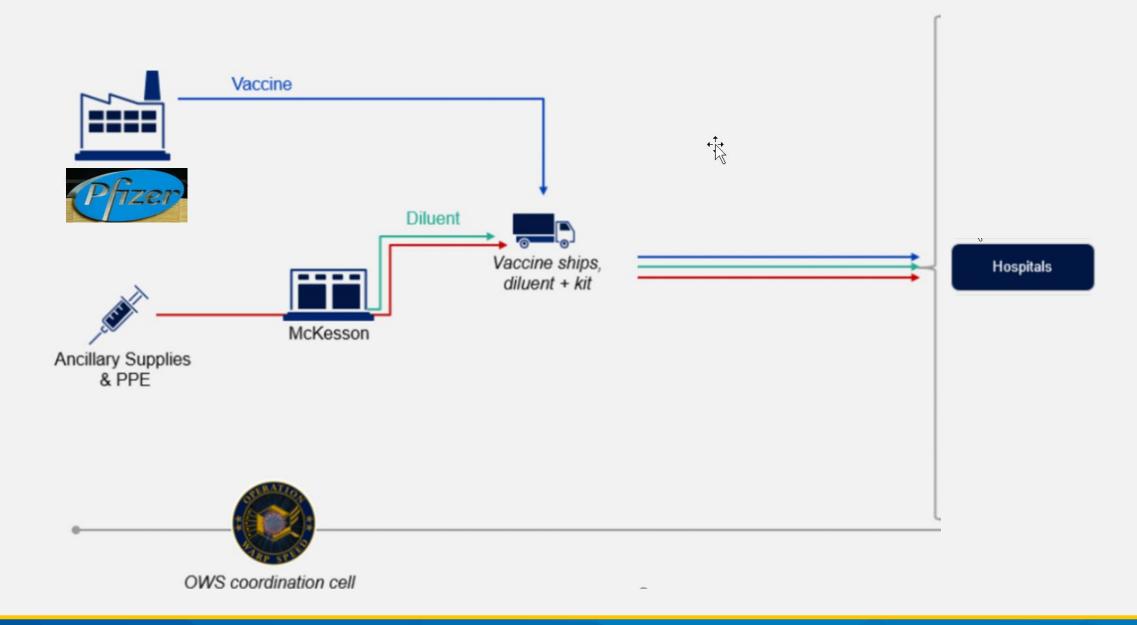
Key Vaccine Management Actions for Providers



Pfizer Vaccine Candidate Shipment



Pfizer Vaccine Candidate Distribution & Shipment



Direct Shipment to Points of Vaccination





Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

Temperature & Location Tracking During Transportation



- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the government. Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites: Although there is no guarantee that the vaccin vill be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has 4

Vaccine Shipment – Provider Emails

Once the EUA has been issued and the vaccine is ready for distribution, you will receive shipment information and tracking numbers from the vendors. Please ensure that you are able to receive e-mails from the following addresses:

cvgovernment@pfizer.com	Pfizer Customer Service	
Pfizer.logistics@controlant.com	For communication from Controlant, including:	
	 Notice at time of vaccine shipment with tracking 	
	information	
	 Exceptions for either shipment delay or cancellation 	
	Delivery Quality Report	
SNSSupport@McKesson.com	For communication from McKesson about ancillary kits	

Please note, for the first shipment, you will receive ancillary supplies between Dec 9-11, prior to the arrival of the vaccine.



COVID-19 Texas Vaccine Allocation Summary

- Weekly allocation
- No need to hold back vaccine for the 2nd dose
- Please report doses administered into ImmTrac2 within 24 hours
- Please ensure all contact information is correct in the provider portal
- Ensure able to receive emails from the specific email addresses



Pfizer Vaccine Candidate Storage, Handling and Administration

Saroj Rai, PhD, MPH



Overview of Shipping, Storage & Handling

Thermal Shipper Arrival



The thermal shipper that the vaccine arrives in can be used as temporary storage, so long as dry ice is replenished upon receipt and every 5 days (up to 30 days).

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The thermal shipper maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Storage & Handling

Storage options for vials/trays include:



 Ultra Low Temperature Freezer at -80° and -60°C (-112 to -76°F) for up to 6 months

2 ----->

- Thermal Shipper at -90°C to -60°C (-130°F to -76°F) for up to 30 days from delivery, if replenished with dry ice upon receipt and every 5 days
- Refrigerator at 2 to 8 °C (35.6° to 46.4°F) for up to 120 hours (5 days)



Vial are glass and should be handled with care. Visual inspection prior to use should be carried out.



Vials should be protected from light and kept in the original packaging.



Vials should always remain upright in trays during storage.

Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has a

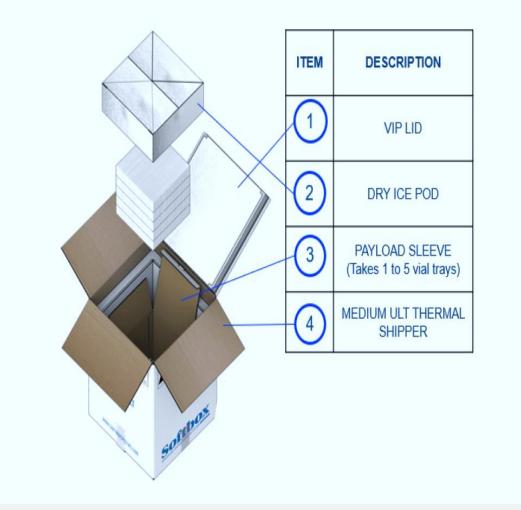
Returning Thermal Shipper

3



The thermal shipping container may be used as temporary storage for up to 30 days from delivery, including temperature data logger.

Ultra Low Temperature Thermal Shipper – Overview of Pack Out



Softbox Medium ULT Weights and Dimension			
Empty Shipper Weight	8.5 kgs		
Available Payload Space	9.65" × 9.65" × 9.49"		
External Dimension	15.75" x 15.75" x 22.04"		
Amount of Dry Ice	23 kgs		
Tare Weight w/ Dry Ice	31.5 kgs		
Total Weight w/ 1 Vial Tray	32.6 kgs		
Total Weight w/ 5 Vial Trays	36.7 kgs		

Weight of Vial Tray	1.038 kgs
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Ultra-Low Temperature Freezer (ULTF)

Temperature

- Store as frozen liquid at -80°C to -60 °C (-112°F to -76°F) for long term storage up to 6 months.
- Different size of ULT freezers are may be available for purchase by points of vaccination
- A small size (under or over the countertop ULT Freezers can store as much as 30K doses).

Product Transfer from Thermal Shipper to ULTF







Remove Dry Ice Pod from shipper Remove the Payload Box from the thermal shipper by carefully pulling directly upwards with the handles.

Immediately store vial trays in an ultra-low temperature (ULT) freezer. Do not open the vial trays until you are ready to remove vials for thawing or use. Monitor freezer temperatures





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

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

Product Packaging Overview

Vials



2 mL Type 1 glass preservative-free

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

Trays



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

Thermal Shipper



- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- · Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT -90°C to -60°C (-130°F to -76°F) up to 10 days if stored at 15°C to 25°C (5° to 77°F) temperatures without opening
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice.

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Key Timing Considerations

TRAYS



Open-lid vial trays, or vials trays containing less than 195 vials removed from frozen storage (< -60°C) may be at room temperature (< 25°C) for up to **3 minutes** for transfer between ultra low temperature environments or to remove vials for thawing or use.

5 MINS Closed-lid vial trays containing 195 vials removed from frozen storage (< -60°C) may be at room temperature (< 25°C) for up to **5 minutes** for transfer between ultra low temperature environments.

2 HRS After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least **2 hours** before they can be removed again.



VIALS

Once an individual vial is removed from a vial tray at room temperature, it should <u>not be</u> <u>returned to frozen storage</u> and should be thawed for use.

Cold Storage Comparison

ULTF (up to 6 months)	Thermal (up to 30 Days)	Fridge (up to 5 Days) Minimum 4 Immunizers	
No Restriction	Minimum 2 Immunizers		
Minimum 960 patients in 6 months	Minimum 960 patients in 30 days	Minimum 960 patients in 5 days No	
Yes	No		
No	Yes	No	
	(up to 6 months) No Restriction Minimum 960 patients in 6 months Yes	(up to 6 months)(up to 30 Days)No RestrictionMinimum 2 ImmunizersMinimum 960 patients in 6 monthsMinimum 960 patients in 30 daysYesNo	

Refrigerator Usage

Product Refrigeration

Product can be stored at 2 to 8 °C (35.6° to 46.4°F) refrigerator up to 120 hours (5 days).

Product Thawing

Based on current stability studies, a tray of 25 vials or 195 vials may take up to 2 or 3 hours to thaw in the refrigerator, respectively, whereas a fewer number of vials will thaw in less time.

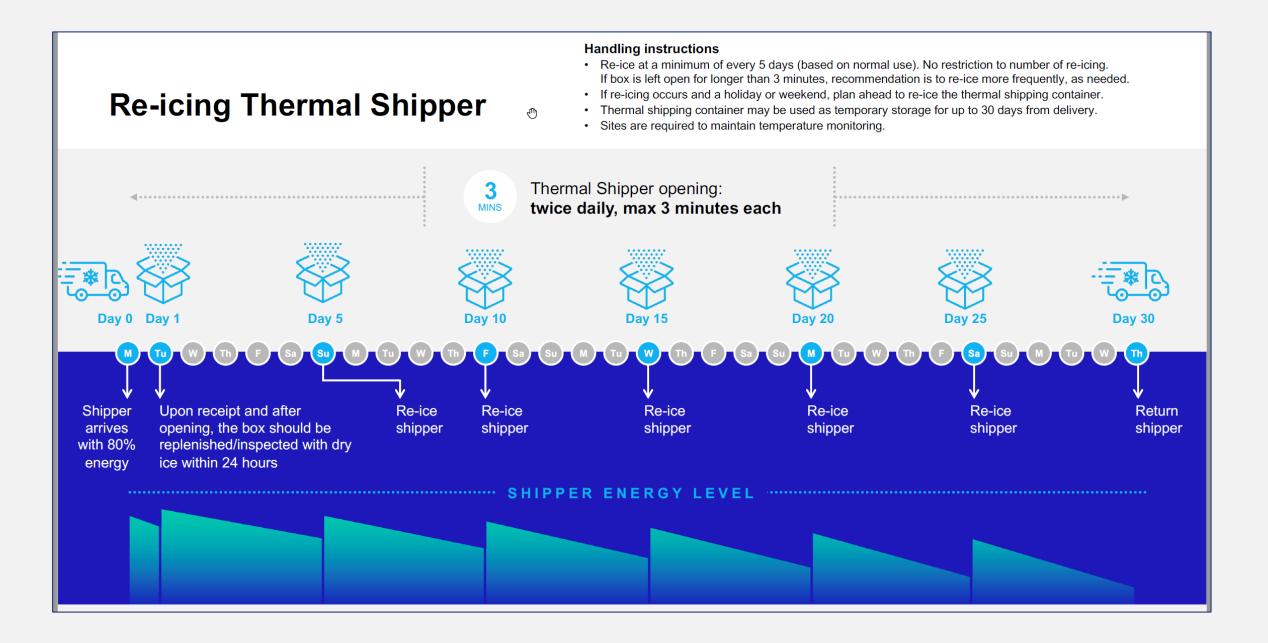
Either: Transfer the frozen vials immediately to a refrigerator at 2 to 8 °C (35.6° to 46.4°F).

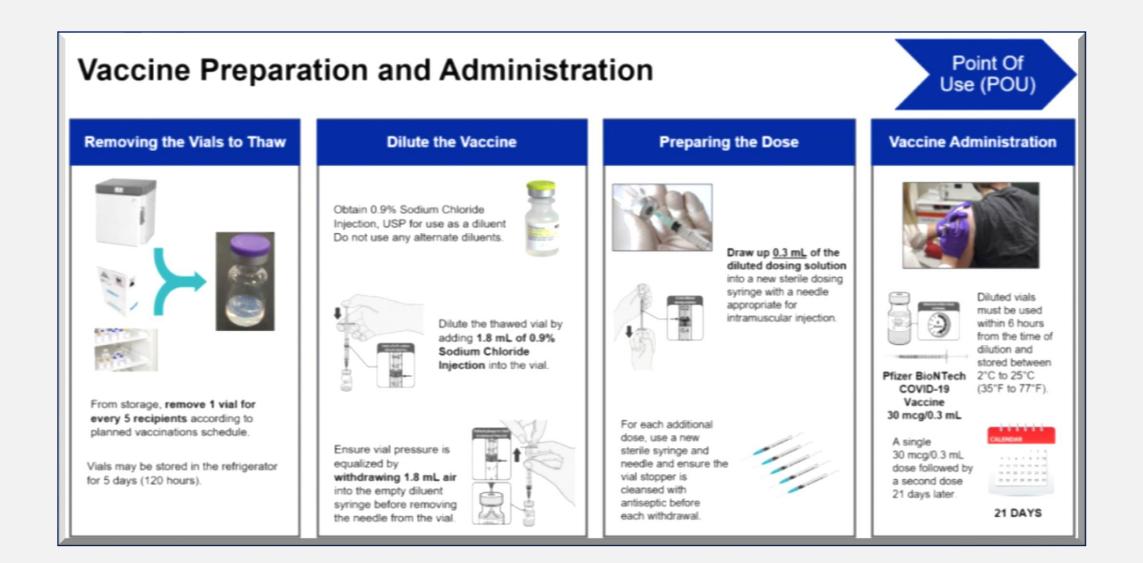
Or: Vials needed for immediate use can be thawed at room temperature (30 minutes); room temperature hold time is no more than 2 hours.

Vials thawed at room temperature form condensation on the outside of the vial, so thawing in a secondary container is recommended.

Vials may be stored in the refrigerator prior to dilution for up to 5 days (120 hours).

Vials may be held at room temperature for no more than 2 hours prior to dilution.

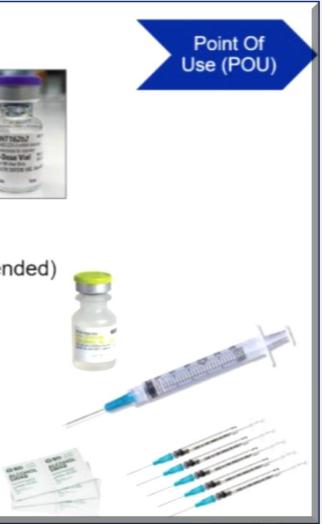




Vaccine Preparation Instruction

Supplies Required to Prepare:

- 1 Vial Pfizer BioNTech COVID-19 Vaccine
- 1 Vial 0.9% Sodium Chloride Injection (at least 2 mL)
- 1 diluent syringe/needle (3 mL or 5mL syringe/21 G needle recommended)
- 5 dosing syringes/needles (1 mL syringe/ IM injection needle)
- · Other ancillary materials such as alcohol swabs, gloves, PPE



COVID-19 Vaccine Safety Monitoring



COVID-19 Vaccine Safety Monitoring

Monitoring Plan	Туре	Lead Federal Agency	Collaborating Agencies and Partners
Vaccine Adverse Event Reporting System (VAERS)	Passive	CDC	FDA
Biologics Effectiveness and Safety (BEST) System	Active	FDA	Several Health Plans, Academia, IBM Watson
FDA-Center for Medicare & Medicaid Services (CMS) Partnership	Active	FDA	CMS
FDA and other Government Entities Partnership	Active / Passive	FDA	CDC, CMS, VA, NIH, DOD & IHS
Vaccine Effectiveness Surveillance Plans	Passive	FDA	CDC
Vaccine Safety Datalink (VSD)	Passive	CDC	9 Health Plans
Clinical Immunization Safety Assessment (CISA) Project	Active	CDC	7 Medical Research Centers
V-safe	Active	CDC	FDA



VAERS

Vaccine Adverse Event **Reporting System**

Co-managed by CDC and FDA

http://vaers.hhs.gov

VAERS Vaccine Adverse Event Reporting System

Report an Adverse Event VALUE Data Resources

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.

About VAERS

2. Anyort an Adverse Every using the WAERS online form or the new downloadable PCF New!

Important. If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment. advice, or diagnosis, if youriend individual medical or health care advice, consult a qualified healthcare provider.

"Ha tenida una reacción después de recibir una vacuna?

- 1. Contacte a sa proveedor ce salut.
- Reporte una reacción advenue utilizando el formulario de VAERS en Inea & Is nueve version PDF descargable. Norvel





REPORT AN ADVERSE EVENT

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after excention



Download V#ERS Data and laanos the CDC WDNOT R database.



REVEW RESOURCES

Finantionals, publications, Mailling, SDER, and other ENDLY ON



Submit Follow-Up Information

SUBAAT FOLLOW UP INFORMATION

Upoid Mational Vitorial Converted 45 VIERS reports.

VAERS is the nation's frontline system for monitoring vaccine safety

What is VAERS?

Search







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New Vaccine Adverse Event Reporting System (VAERS) Website and Ways to Report

Q

V-Safe | after vaccination health checker

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V-safe is a smartphone-based tool that uses text messaging and web surveys to provide **personalized health check-ins** after someone receives a COVID-19 vaccination.



Vaccine recipients can quickly tell the CDC if they have any side effects. The CDC may follow up with them by phone to get more information.



V-safe will also remind them to get their second COVID-19 vaccine dose, if needed.



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.



V-Safe | after vaccination health checker

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.



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.



v-safe | your role as a provider

- Give patients a v-safe information sheet at the time of vaccination
- Encourage them to enroll and fill out the surveys when prompted

Get vaccinated. Get vaccinated. Get your smartphone. Get your smartphone. Get started with v-safe. 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 v-safe 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. after vaccinatio Your participation in CDC's vkeep COVID-19 vaccines sat How to register and use v-safe You will need your smartphone and information about the COVID-19 vaccine you received. This How can I participat information can be found on your vaccination record card; if you cannot find your card, please conta Use your smartphone Once you get a COVID-19 va your smartphone. Participati to tell CDC about any Register 1. Go to the v-safe website using one of the two options below any time. You will receive te local time. To opt out, simply text message. You can also s side effects after getting v-safe the COVID-19 vaccine. How long do v-safe after vaccination Jse your smartphone's browser to go to You'll also get reminders During the first week after you you a text message each day will get check-in messages or health checker OR if you need a second vsafe.cdc.gov questions v-safe asks should you need a second dose vaccine dose. 6-week check-in process s vaccine experience as well Read the instructions. Click Get Started 12 months after your final of 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 Is my health informa v-safe and click Verify. 5. At the top of the screen, click Enter your COVID-19 vaccine information Yes. Your personal informat 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. Review your vaccine information. If correct, click Submit, if not, click Go Back. When you get your Congrats! You're all set! If you complete your registration before 2pm local time, v-safe will start COVID-19 vaccination. as your initial health check-in around 2pm that day. If you register after 2pm, v-safe will start your initia health check-in immediately after you register - just follow the instructions. your healthcare provider You will receive a reminder text message from v-safe when it's time for the next check-in - around 2pm local time. Just click the link in the text message to start the check-in about getting started Complete a v-safe health check-in with v-safe 1. When you receive a v-safe check-in text message on your smartp ine, click the link when re-2. Follow the instructions to complete the check-in. Troubleshooting leed help with y-safe Call 800-CDC-INFO (800-232-4636) TTY 888-232-6348 How can I come back and finish a check-in later if I'm interrupted? Learn more about **v-safe** Open 24 hours, 7 days a week CAR EDG · Click the link in the text message reminder to restart Visit www.cdc. and complete your check-in. www.cdc.gov/vsafe 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 instruction:

v-safe info sheets

https://vsafe.cdc.gov/

v-safe info poster

Resources

- COVID-19 Vaccine Provider Registration Information: <u>www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx</u>
- FAQ for Providers <u>https://www.dshs.texas.gov/immunize/covid19/COVIDproviderfaq.pdf</u>
- DSHS COVID-19 Vaccine Provider hotline:
- (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or Email: <u>COVID19VacEnroll@dshs.texas.gov</u>
- Website to enroll as a COVID-19 Vaccine Provider: <u>EnrollTexasIZ.dshs.texas.gov</u>



DISCLAIMER

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December 08, 2020