

The Vaccines
are Coming!



PAUL REVERE'S RIDE—April, 19, 1775.—Drawn by Charles G. Bush.—(See the Poem,

DISCLAIMER

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

December 04, 2020

Discussion Topics

- Welcome and Opening Remarks
- COVID-19 Vaccine Updates
- Expert Vaccine Allocation Panel
- COVID-19 Texas Vaccine Allocation & Shipment
- COVID-19 Vaccine Safety Monitoring & Reporting
- Q&A



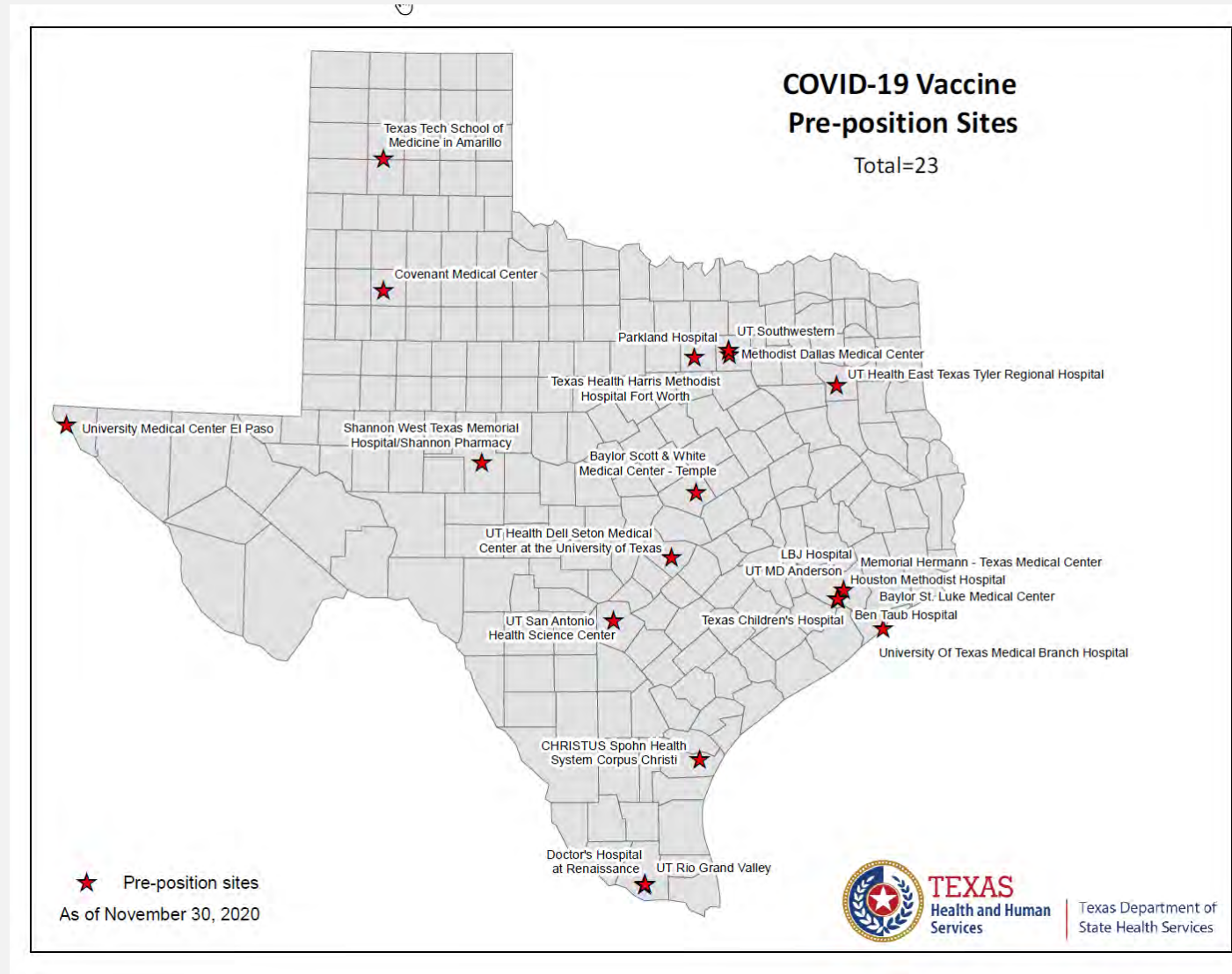
Welcome & Opening Remarks



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PHR	County	Pre-Positioned Facility
1	Lubbock	Covenant Medical Center
1	Potter	Texas Tech School of Medicine Amarillo
2/3	Tarrant	Texas Health Harris Methodist Hospital Fort Worth
2/3	Dallas	Methodist Dallas Medical Center
2/3	Dallas	Parkland Hospital
2/3	Dallas	UT Southwestern Medical Center
4/5N	Smith	UT Health East Texas Tyler Regional Hospital
6/5S	Harris	Memorial Hermann - Texas Medical Center
6/5S	Harris	UT MD Anderson
6/5S	Harris	CHI St. Luke's Health Baylor College of Medicine
6/5S	Harris	Texas Children's Hospital
6/5S	Harris	LBJ Hospital
6/5S	Harris	Ben Taub Hospital
6/5S	Harris	Houston Methodist Hospital
6/5S	Galveston	University of Texas Medical Branch Hospital
7	Bell	Baylor Scott & White Medical Center - Temple
7	Travis	UT Health Dell Seton Medical Center at the University
8	Bexar	UT San Antonio Health Science Center
9/10	Tom Green	Shannon West Texas Memorial Hospital
9/10	El Paso	University Medical Center El Paso
11	Hidalgo	Doctor's Hospital at Renaissance
11	Hidalgo	UT RGV
11	Nueces	Christus Spohn Hospital Corpus Christi



COVID-19 Vaccine Updates





Saroj Rai, PhD, MPH







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COVID-19 Vaccine Updates

Phase III Vaccine Candidates	Technology Platform	Storage & Handling	Dose (Intramuscular Injection)
	m-RNA	Ultra-low frozen: 6mos Refrigerated: 5 days	2 (0, 21 days)
	m-RNA	Frozen: 6mos Refrigerated: 30 days	2 (0, 28 days)
	Viral Vector (Non-Replicating)	Refrigerated: 6mos	2 (0, 28 days)
	Viral Vector (Non-Replicating)	Refrigerated: 6mos	1

Phase III Vaccine Candidates	Technology Platform	Efficacy & Safety			Regulatory Status
		Study Design	Interim Analysis	Completion of Primary Endpoint	
	m-RNA	<ul style="list-style-type: none"> • N=44,000 • ≥ 12 yrs • Randomization (1:1) • Placebo vs. Vaccine (Saline vs. 30 μg) • 2 doses (0, 21 days) 	<ul style="list-style-type: none"> • 90% effectiveness (94 cases) 	<ul style="list-style-type: none"> • 95% vaccine efficacy (162 placebo vs. 8 vaccine) <ul style="list-style-type: none"> - 30 severe case (30 placebo vs. 0 vaccine) • Consistent efficacy across age, gender, race/ethnicity • No serious adverse reported to date 	EUA Filed
	m-RNA	<ul style="list-style-type: none"> • N=30,000 • ≥ 18 yrs • Randomization (1:1) • Placebo vs. Vaccine (Saline vs. 100 μg) • 2 doses (0, 28 days) 	<ul style="list-style-type: none"> • 94.5% vaccine efficacy (90 placebo vs. 5 vaccine) <ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> • 94.1% vaccine efficacy (185 cases in placebo vs. 11 vaccine) <ul style="list-style-type: none"> - 11 severe case (11 placebo vs. 0 vaccine) - 17% adults ages >65 yrs - 21% diverse population • 1 death in the placebo group 	EUA Filed
	Viral Vector (Non-Replicating)	<p>UK Study</p> <ul style="list-style-type: none"> • N=12,390 • ≥ 18 yrs • 1 Dose vs. 2 Doses vs. MenACWY <p>Brazil Study</p> <ul style="list-style-type: none"> • N=10,300 • ≥ 18 yrs • 2 does vaccine vs. MenACWY/Saline 	<ul style="list-style-type: none"> • 90% vaccine efficacy (half dose/full dose (5×10^{10} 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 		
	Viral Vector (Non-Replicating)	<ul style="list-style-type: none"> • N=60,000 • ≥ 18 yrs • Randomization (1:1) • Placebo vs. Vaccine (Saline vs. 5×10^{10} vp) • 1 doses 			

Path to Vaccination



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PFIZER

Dec. 10

Dec. 14

Dec. 14

Dec. 16 -17

VRBPAC
Open
Session
Meeting

FDA
Reviews all
the Data

EUA

CDC ACIP Calls
an Immediate
Meeting

Recommendations

Dec. 14 -15

Pre-Positioning
Facility # 1

Pre-Positioning
Facility # 2

Begin Vaccination



BLA (Biologics License Application)
EUA (Emergency Use Authorization)
EA (Expanded Access)

MODERNA

Dec. 17

Dec. 21

Dec. 21

Dec. 22-23

VRBPAC
Open
Session
Meeting



FDA
Reviews all
the Data

EUA

CDC ACIP Calls
an Immediate
Meeting

Recommendations

Vaccination



BLA (Biologics License Application)
EUA (Emergency Use Authorization)
EA (Expanded Access)

Expert Vaccine Allocation Panel (EVAP)



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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 health 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.

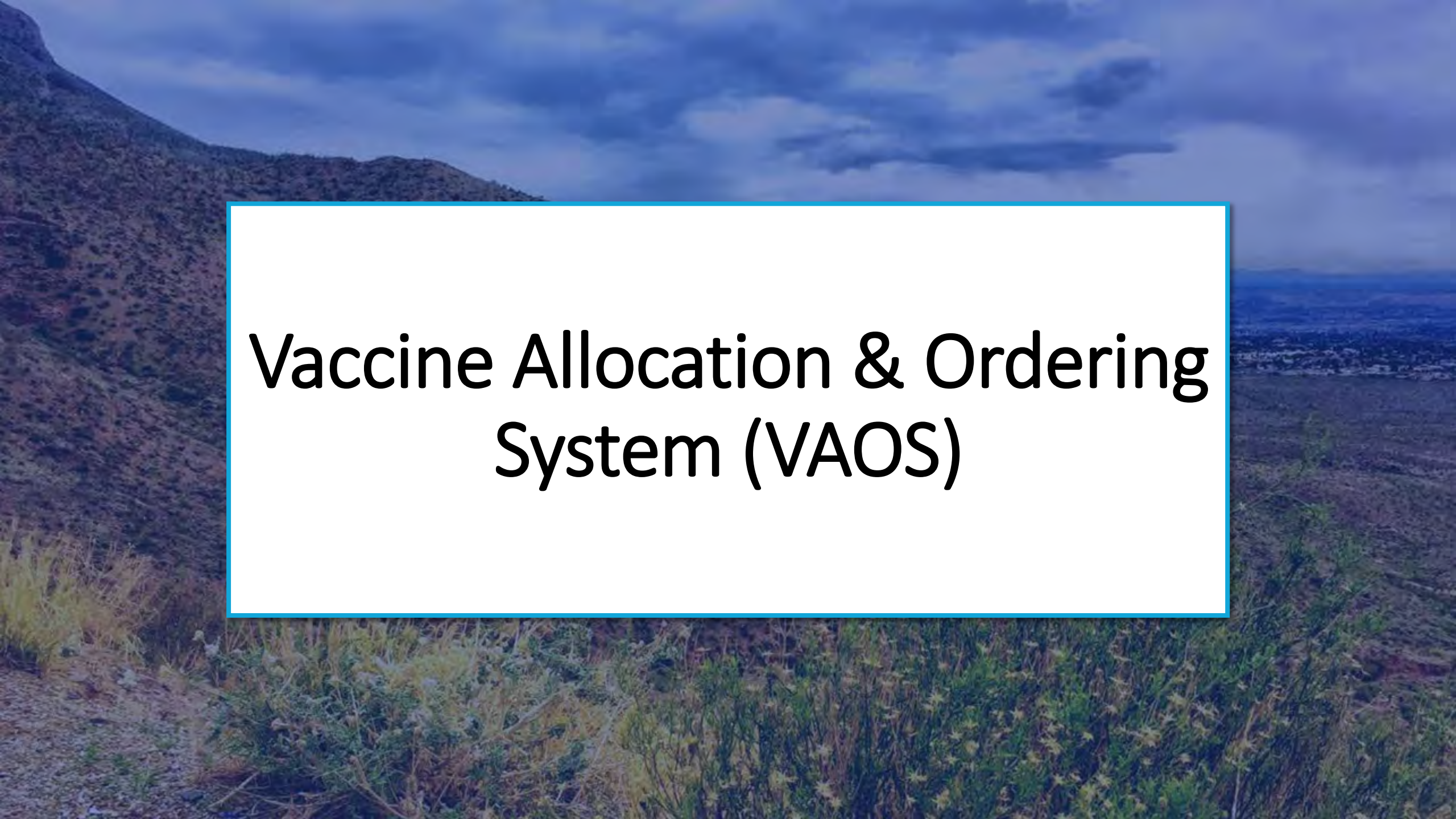
<https://gov.texas.gov/news/post/governor-abbott-dshs-announce-covid-19-vaccine-distribution-plan>



COVID-19 Texas Vaccine Allocation Process

Joshua Hutchison, Vaccine Data and Finance Manager





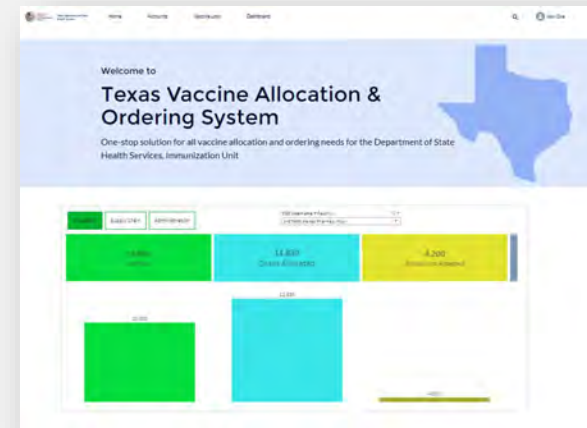
Vaccine Allocation & Ordering System (VAOS)

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:**

1

ACCESSING DASHBOARDS

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

2

ACKNOWLEDGING ALLOCATIONS

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

3

CONFIRMING SHIPMENTS

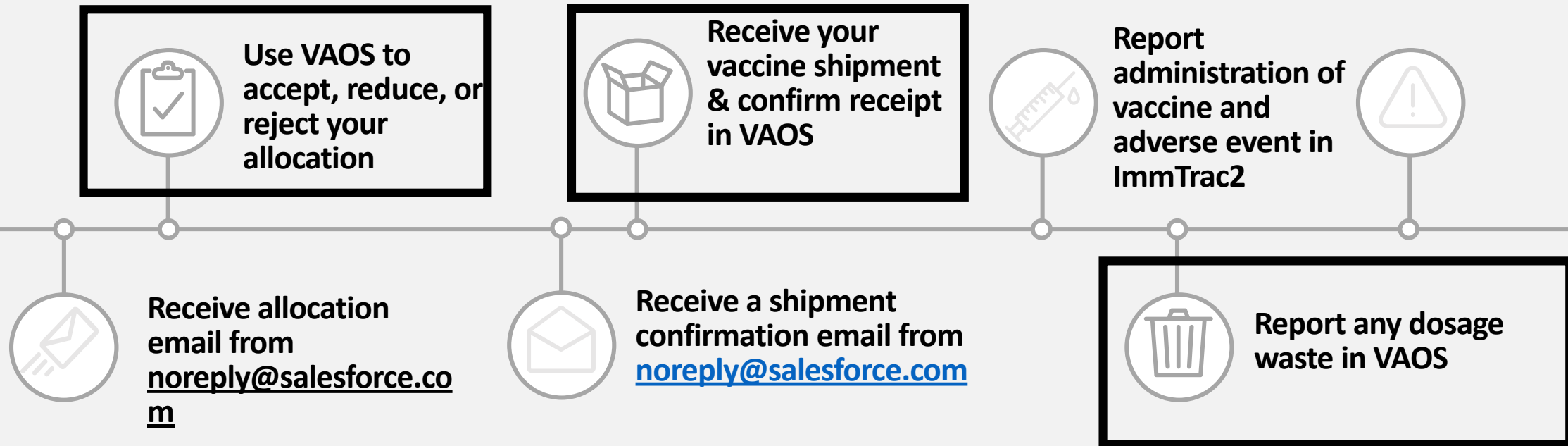
Required once you receive your vaccine doses

4

REPORTING WASTE

Required to track how many doses are unused/wasted

Key Vaccine Management Actions for Providers



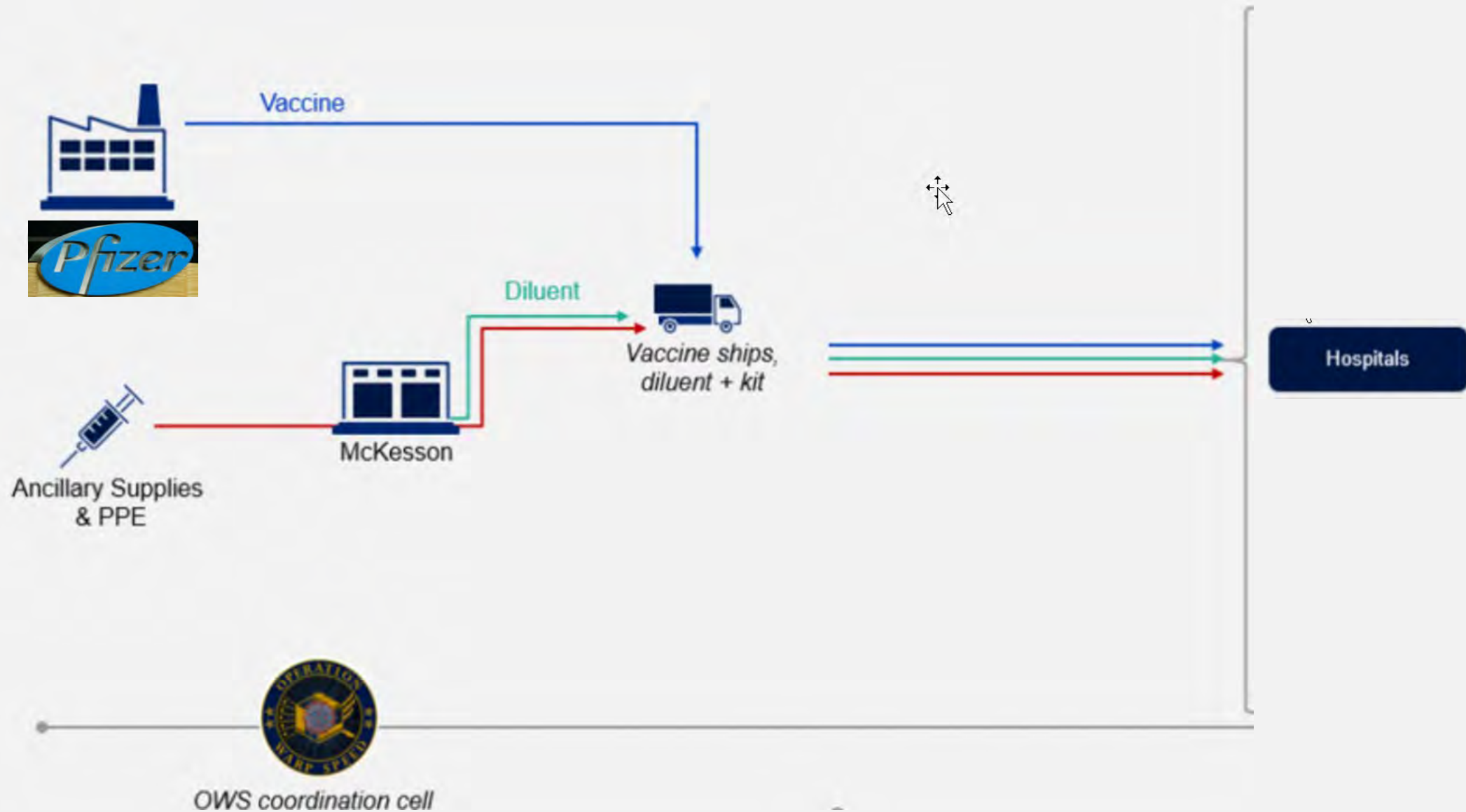
Pfizer Vaccine Candidate Shipment



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Pfizer Vaccine Candidate Distribution & Shipment



Direct Shipment to Points of Vaccination

Direct Shipments* to Vaccination Center by Transport Courier



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.

Thermal Shippers may have slight differences depending on manufacturer.

*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the governments.

Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution



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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 <u>Controlant</u> , including: <ul style="list-style-type: none">• 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

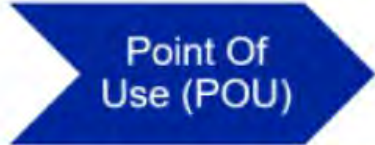


Pfizer Vaccine Candidate

Storage, Handling and Administration



Vaccine Preparation and Administration



Removing the Vials to Thaw



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

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

Dilute the Vaccine

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



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

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



Preparing the Dose



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



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



Vaccine Administration



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

Pfizer BioNTech COVID-19 Vaccine
30 mcg/0.3 mL

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



21 DAYS

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



Point Of
Use (POU)



COVID-19 Vaccine Safety Monitoring



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Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness

Monitoring Plan	Type	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
www.vaers.hhs.gov

About VAERS

Report an Adverse Event

VAERS Data

Resources

Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *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 you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*



What is VAERS?



REPORT AN ADVERSE EVENT

Report significant adverse events after vaccination.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find materials, publications, training tools, and other resources.



SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

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



<https://www.youtube.com/watch?v=sbCWhcQADFE>

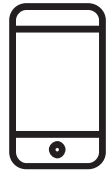


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New Vaccine Adverse Event Reporting System (VAERS) Website and Ways to Report

v-safe | *after vaccination health checker*



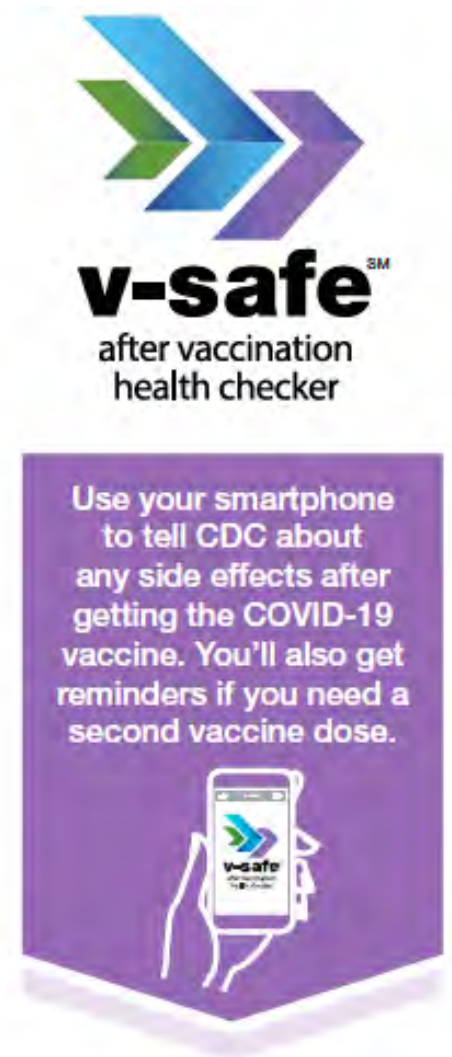
V-safe is a smartphone-based tool that uses text messaging and web surveys to provide **personalized health check-ins** after someone receives a COVID-19 vaccination.



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.



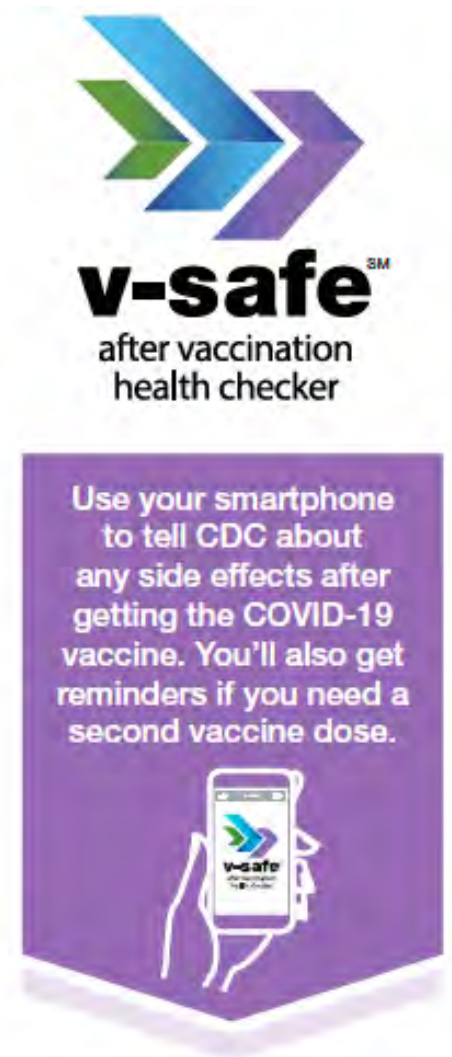
V-safe will also remind them to get their second COVID-19 vaccine dose, if needed.



v-safe | *after vaccination health checker*

How long do v-safe check-ins last?

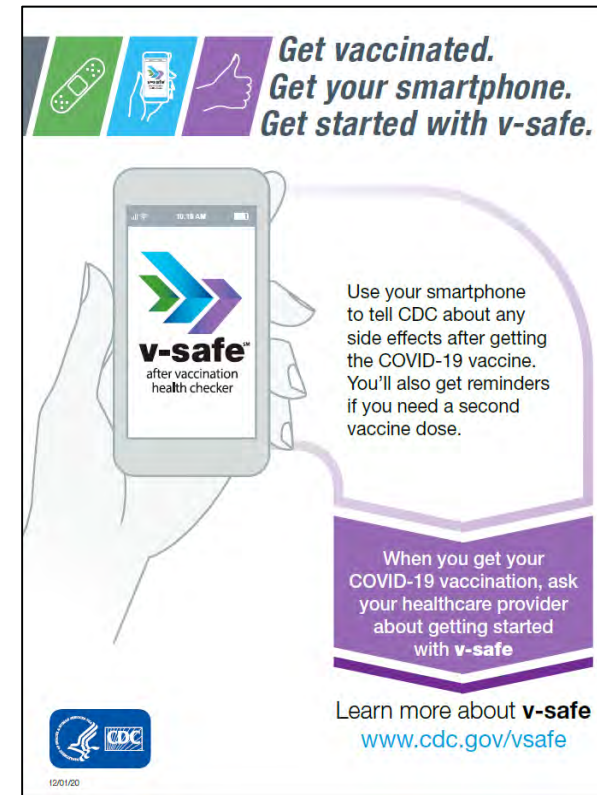
- During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing.
- Then you will get check-in messages once a week for up to 5 weeks.
- The questions **v-safe** asks should take less than 5 minutes to answer.
- If you need a second dose of 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.



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

<https://vsafe.cdc.gov/>



**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.

When you get your COVID-19 vaccination, ask your healthcare provider about getting started with v-safe

Learn more about **v-safe**
www.cdc.gov/vsafe

12/01/20

v-safe info poster



**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.

How can I participate?
Once you get a COVID-19 vaccine, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

How long do v-safe check-ins last?
During the first week after you get your COVID-19 vaccine, you will get check-in messages on questions v-safe asks should you need a second dose of the vaccine. Check-in messages will continue for 12 months after your final dose.

Is my health information confidential and private?
Yes. Your personal information is confidential and private.

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:

Use your smartphone's browser to go to vsafe.cdc.gov OR Aim your smartphone's camera at this code

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 your COVID-19 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. **Congratulations!** You're all set! If you complete your registration before 2pm local time, v-safe will start your initial health check-in around 2pm that day. If you register after 2pm, 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 2pm 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

v-safe info sheets

Resources

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



DISCLAIMER

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December 04, 2020