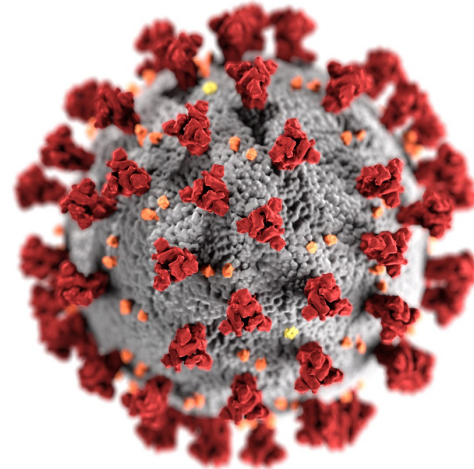


Update on CDC COVID-19 vaccine safety monitoring systems: V-safe and VAERS

October 19, 2021

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Vaccine Safety Team
CDC COVID-19 Vaccine Task Force



cdc.gov/coronavirus

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Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the U.S. Food and Drug Administration (FDA)
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or FDA



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U.S. CDC Vaccine Safety Contributions to COVID-19 Vaccine Program

General safety profile

Reactogenicity after 1st and 2nd dose

mRNA vaccine safety in pregnancy

Safety of Pfizer vaccine among adolescents

In-depth reviews: adverse events of special interest



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CDC vaccine safety monitoring

- Authorized COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

v-safe



VAERS



VSD



CISA Project



Full list of U.S. COVID-19 vaccine safety monitoring systems

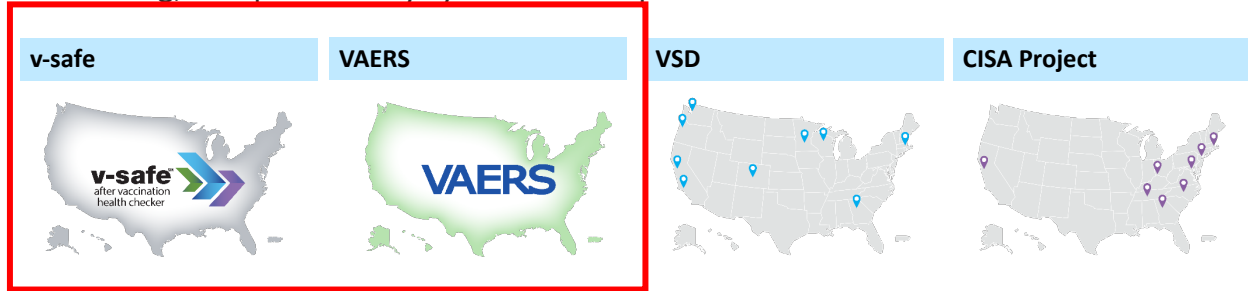
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

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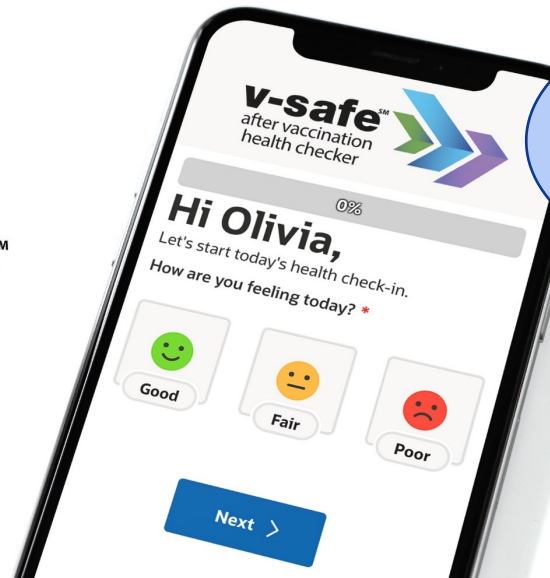
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Smartphone-based active safety monitoring



<http://cdc.gov/vsafe>



Now available!

- Enrolling adolescents
- 3rd dose reporting

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Active safety monitoring for COVID-19 vaccines

- **V-safe** is a CDC smart-phone based monitoring program for COVID-19 vaccine safety
 - uses text messaging and web surveys to check-in with vaccine recipients after vaccination
 - participants can report how they feel after COVID-19 vaccination
 - reports are accepted after dose 1, 2, and 3
 - includes active telephone follow-up by CDC for reports of a medically-attended health impact event

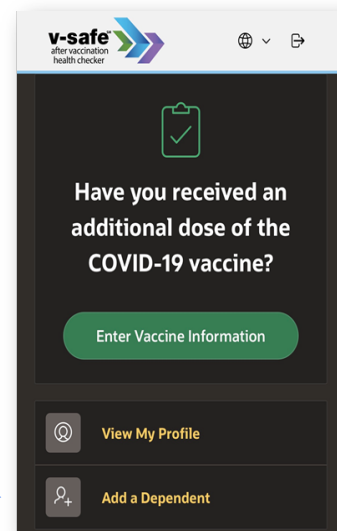


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New v-safe features for existing participants

Additional doses can now be entered

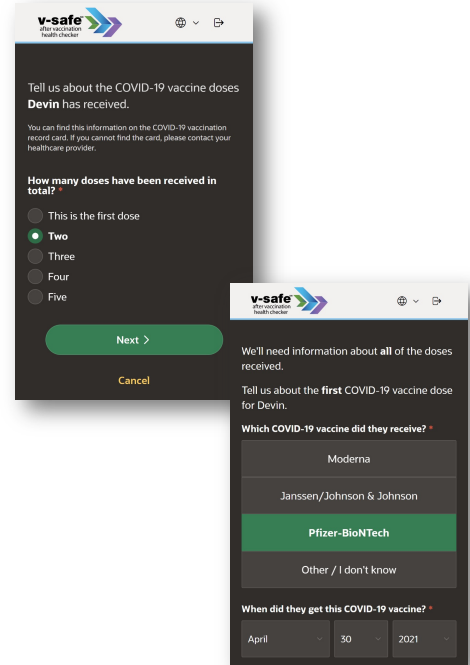
Dependents can be added to a profile (up to 6 per phone number)




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New v-safe participants

- Can register themselves or dependents at any time: after 1st, 2nd or 3rd dose.
- Dependents can be added, even if the primary smartphone account is not a **v-safe** participant
- **V-safe** check in schedule:
 - Days 0-7
 - Weeks 2-6
 - Month 3, 6, and 12
 - Schedule restarts after each dose received



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**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.*


*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. CS324195-A 04/27/2021

Promoting v-safe in practice


- **When:**
 - Talk about the importance of **v-safe** at vaccination
 - Encourage enrollment during observation period
- **How:**
 - Provide **v-safe** information sheet to patients
 - Display posters of **v-safe**
 - Direct patients to the QR code or vsafe.cdc.gov



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at vsafe.cdc.gov OR Aim your smartphone's camera at this code



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Your participation in v-safe helps protect all Americans from COVID-19 Here's how:

- You register and share your vaccination experience with **v-safe**
- Your vaccine experience information is combined with information from millions of Americans also enrolled in **v-safe**
- CDC studies and analyzes the information. Vaccine safety profiles are compiled and shared with the public
- Unvaccinated Americans learn about the safety of COVID-19 vaccine and can feel confident to get vaccinated
- More people in our communities are vaccinated. We are all better protected from COVID-19

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



VAERS

Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov>



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EUA requirements for healthcare providers to report adverse events to VAERS following COVID-19 vaccine

- Vaccine administration errors (whether or not associated with an adverse event)
- Serious adverse events regardless of causality
 - Death
 - Life threatening adverse event
 - Inpatient hospitalization or prolongation of existing hospitalization
 - A persistent or significant incapacity or disruption of the ability to conduct normal life functions
 - A congenital anomaly/birth defect
 - An important medical event based on appropriate medical judgement that may jeopardize the individual and may require medical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death



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VAERS

VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

key strengths

- Rapidly detects potential safety problems
- Can detect rare adverse events

key limitations

- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect ←



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How to report an adverse event to VAERS

- go to vaers.hhs.gov
- submit a report online

for help:

call
1-800-822-7967

email
info@VAERS.org

video instructions
<https://youtu.be/sbCWhcQADFE>

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How to report an adverse event to VAERS

Vaccine Information

17. Enter all vaccines given on the date listed in item 4: (Route is HOW the vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Body site	Dose number in series
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

18. Describe the adverse event(s), treatment, and outcome(s), if any:

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s):
 Yes No Unknown

21. Result or outcome of adverse event(s):

Doctor or other healthcare professional office/clinic visit

Emergency room/department or urgent care

Hospitalization

Number of days (if known)

Hospital Name

City

State

Prolongation of existing hospitalization

Life threatening illness

Disability or permanent damage

Patient died

Date

Congenital anomaly or birth defect

None of the above

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Your role

COVID-19 vaccine safety gets stronger with your participation and promotion

general public

- participate in **v-safe** ✓
- report adverse event to **VAERS** ✓

healthcare providers

- encourage patients to participate in **v-safe** ✓
- continue to report clinically important adverse events to **VAERS** ✓
- respond to requests from **VAERS** to provide medical records ✓

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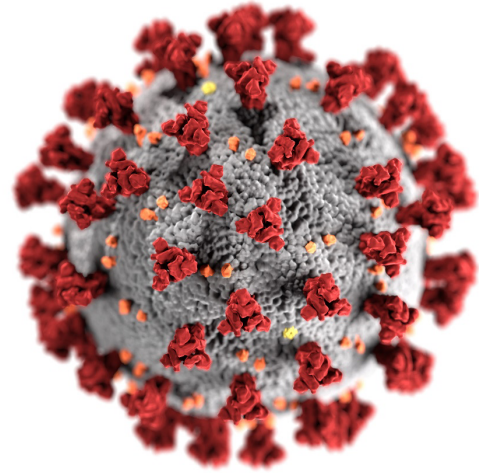
CDC needs your help!

What you can do:

- We need health care providers to promote **v-safe** to vaccine recipients and encourage enrollment
 - Include promotion of adolescent and booster/additional doses
- We need health care providers to report to VAERS
 - And rapidly respond to requests for medical records
- Robust enrollment and participation in **v-safe** provides real-time experiences following COVID-19 vaccination
 - Allows CDC to inform the public on what to expect following vaccination
 - Provides necessary information to establish and maintain COVID-19 vaccine confidence

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Thank you!



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

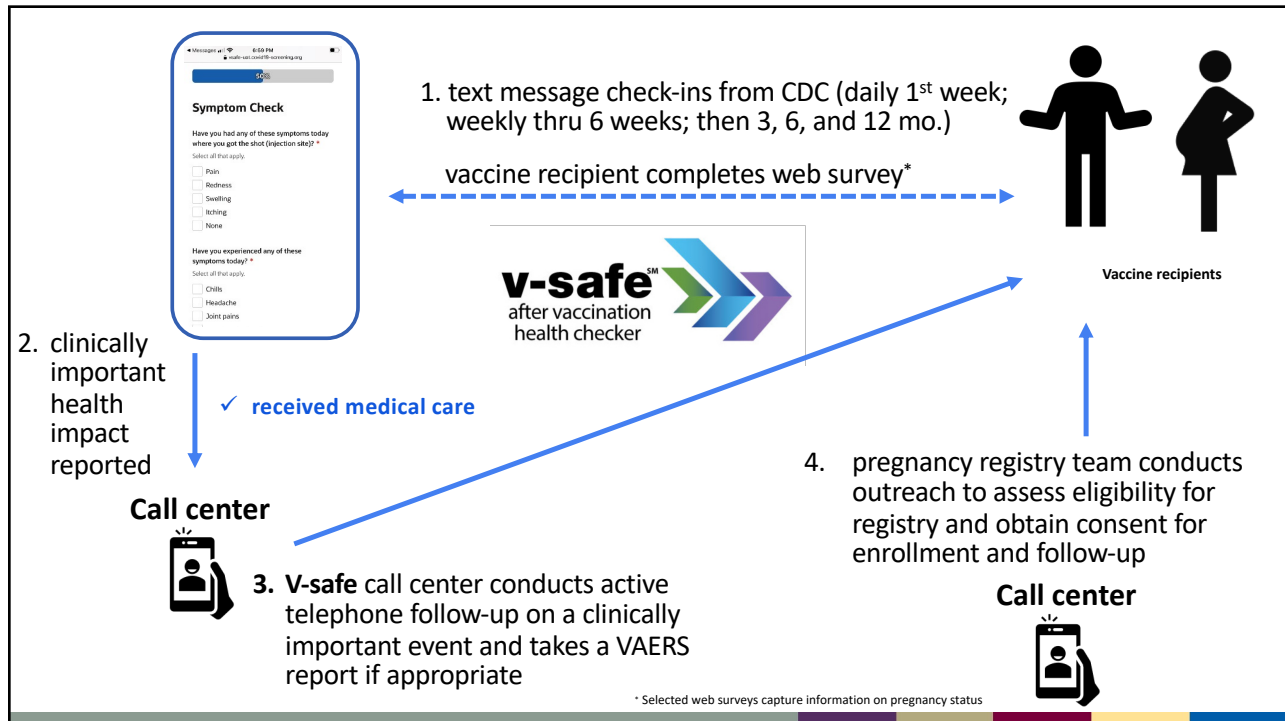
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Extra slides

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CDC

CISA

Clinical Immunization Safety Assessment (CISA) Project

7 participating medical research centers with vaccine safety experts

- clinical consult services*
- clinical research

*More information about clinical consults available at: <http://www.cdc.gov/vaccinesafety/Activities/CISA.html>

Kaiser Permanente Northern California Oakland, CA

Cincinnati Children's Hospital Medical Center Cincinnati, OH

Boston Medical Center Boston, MA

Columbia University New York, NY


Johns Hopkins University Baltimore, MD

Duke University Durham, NC

Vanderbilt University Medical Center Nashville, TN

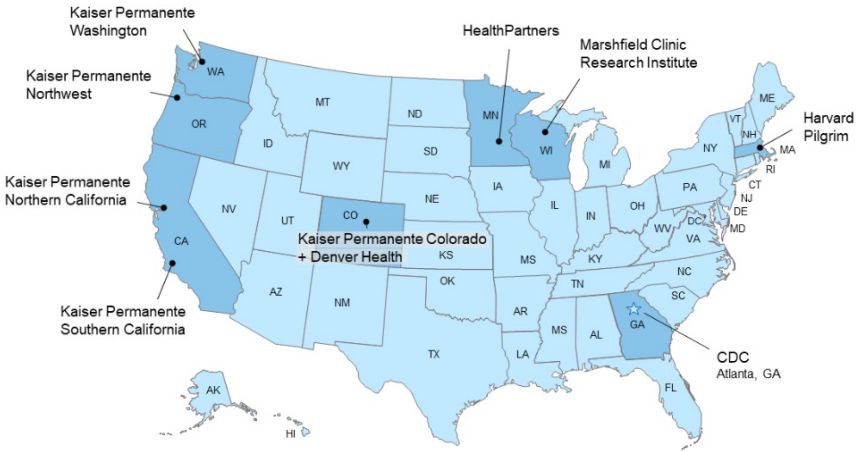
CDC Atlanta, GA

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VSD

Vaccine Safety Datalink



- 9 participating integrated healthcare organizations
- Data on over **12 million** persons per year



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