



V-safe: CDC's newest vaccine safety monitoring system

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Disclaimer

- The findings and conclusions in this presentation are those of the presenter and do not necessarily represent the official position of the CDC
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC
- Information about COVID-19 vaccination approvals, authorizations, and clinical guidance is current as of the dates listed in this presentation, but may change in the future

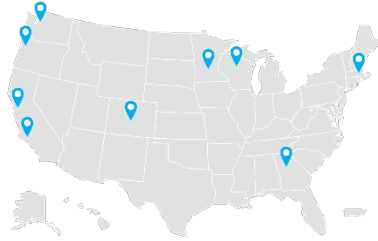
CDC vaccine safety monitoring

CDC monitors the safety of vaccines using strong, complementary systems—both new and established

VAERS



VSD



CISA Project



V-safe



Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA)

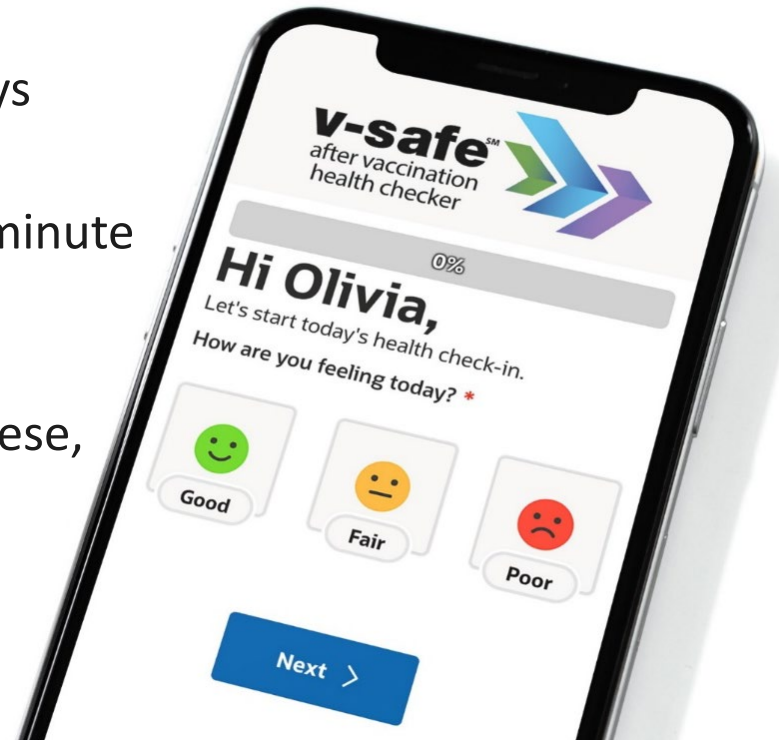
Establishing the first generation of V-safe

V-safe was established to help monitor the safety of COVID-19 vaccines

- Safety monitoring for authorized or approved COVID-19 vaccines in the United States
- Established December 2020 through donated services from Oracle Corporation
- Goals:
 - Rapidly provide data from recently vaccinated persons to CDC
 - Provide reactogenicity data during the first week after vaccination

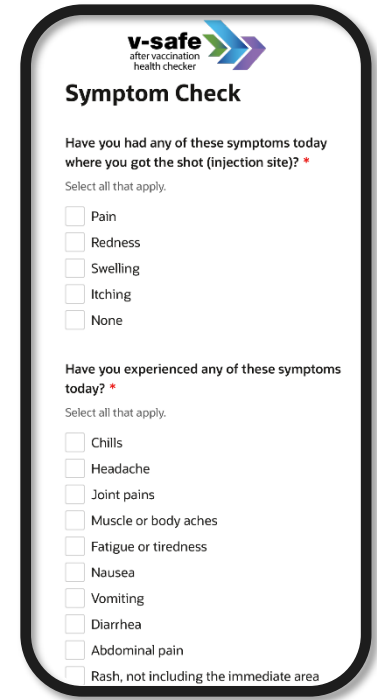
V-safe: smartphone-based vaccine safety monitoring

- Self-registration on smartphone at vsafe.cdc.gov
- Used text messages that link to web surveys
- Surveys were brief – requiring less than a minute to complete
- Available languages: English, Spanish, Chinese, Korean, and Vietnamese



Health surveys included questions about local and systemic reactions and health events

- Surveys sent daily during the week following each dose of vaccine then weekly through 6 weeks and at 3, 6, and 12 months
- Questions solicited adverse events and health impacts after COVID-19 vaccination
- Daily surveys asked questions about
 - Local reactions (e.g., injection site pain)
 - Systemic reactions (e.g., fatigue)
 - Health impacts (e.g., medical care)
- Surveys included questions to identify participants potentially interested in and eligible for a pregnancy registry



v-safe
after vaccination
health checker

Symptom Check

Have you had any of these symptoms today where you got the shot (injection site)? *

Select all that apply.

- Pain
- Redness
- Swelling
- Itching
- None

Have you experienced any of these symptoms today? *

Select all that apply.

- Chills
- Headache
- Joint pains
- Muscle or body aches
- Fatigue or tiredness
- Nausea
- Vomiting
- Diarrhea
- Abdominal pain
- Rash, not including the immediate area

V-safe facilitated reporting of medically attended events to VAERS

1. V-safe registrant completed survey

v-safe
after vaccination
health checker

75%

Health Impact

Did any of the symptoms or health conditions you reported today cause you to: *

Select all that apply.

- Be unable to work or attend school
- Be unable to do your normal daily activities
- Get care from a doctor or other healthcare professional
- None of the above

[Previous](#) [Submit](#)

Received medical care

2. V-safe call center followed up on a medically attended health event



3. V-safe call center completed a VAERS report if indicated

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS Report an Adverse Event VAERS Data Resources Submit Follow-Up Information

Completion Status Report an Adverse Event - Patient Information Instructions | en Español

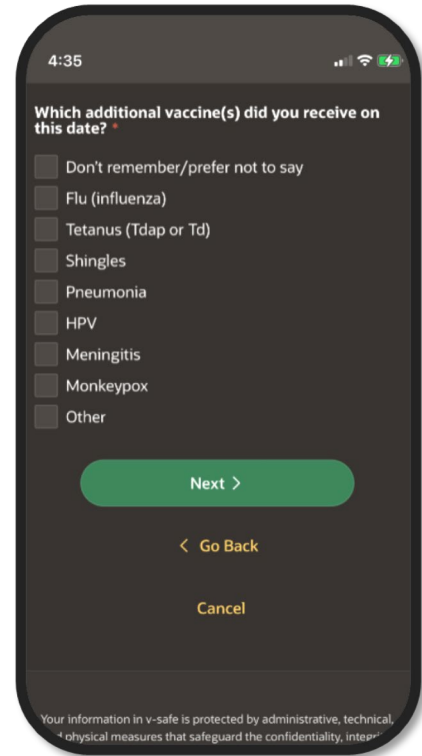
Patient Information
 Reporter Information
 Facility Information
 Vaccine Information
 Additional Information

Note: Fields marked with an * are essential and should be completed.

Item 1 Patient first name: Patient last name:
Street address:
City: State: County:
Zip code: Phone: Email:
Date of birth: * Sex: Male Female Unknown
Date of vaccination: * Time: AM PM
Date adverse event started: Time:

V-safe was updated over time to reflect policy changes

- Additional manufacturers
- Dependent feature
- Simultaneous vaccination
- Booster doses
- Surveys for young children
- (V-safe for Mpox)



How data are used

- **Presentations:**
 - V-safe data are regularly presented to the Advisory Committee on Immunization Practices and other stakeholders
- **Publications:**
 - Our goal is to rapidly provide data to the public via publications like MMWR
 - Over 25 publications to date (<https://pubmed.ncbi.nlm.nih.gov/collections/64312280/?sort=pubdate>)
- **Public data sharing:**
 - V-safe datasets are available at <https://data.cdc.gov>

Key contributions of V-safe to COVID-19 vaccine safety

From December 2020 through June 2023, over 10 million persons participated in V-safe

April 2021

mRNA vaccine
safety in
pregnancy*

Preliminary Findings of mRNA Covid-19
Vaccine Safety in Pregnant Persons

June 2021

Reactogenicity
after primary
series and
booster doses

JAMA Insights
Reactogenicity Following Receipt
of mRNA-Based COVID-19 Vaccines

August 2021

Rapid
preliminary
safety data
post-
authorization

MMWR
COVID-19 Vaccine Safety in Adolescents Aged 12–17 Years —
United States, December 14, 2020–July 16, 2021

July 2022

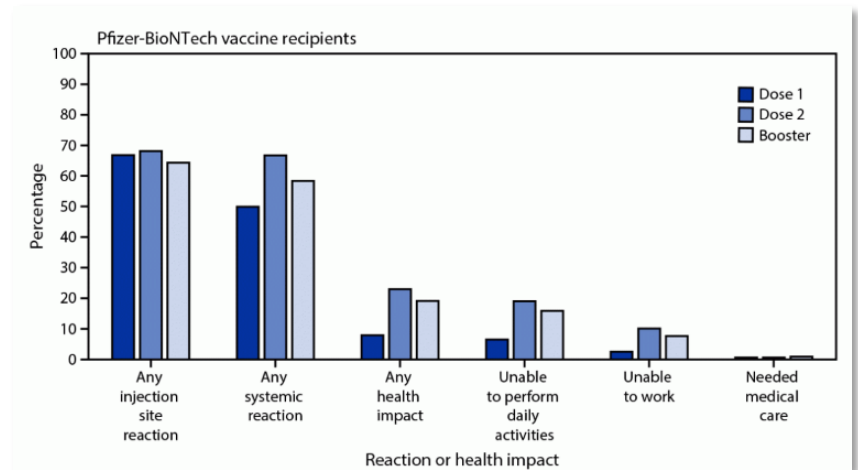
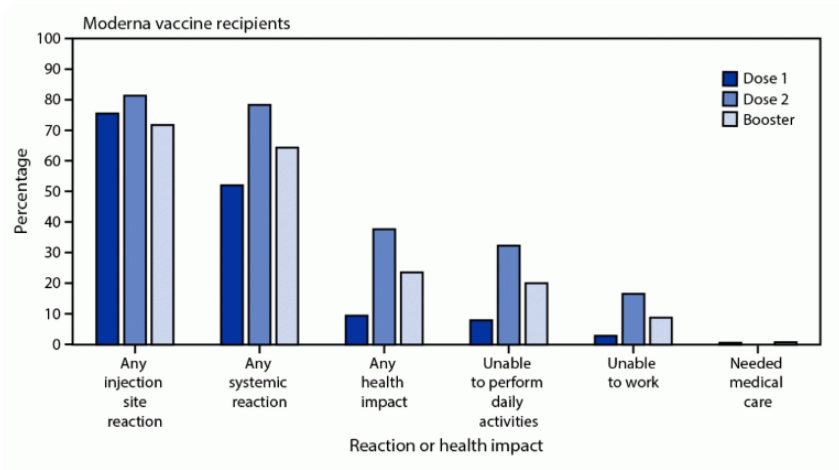
Reactogenicity
after
simultaneous
administration
with influenza
vaccine

JAMA Network | Open
Reactogenicity of Simultaneous COVID-19 mRNA Booster
and Influenza Vaccination in the US

*V-safe identified pregnant people for enrollment in [Vaccine Pregnancy Registry | CDC](#)

Use of V-safe data

Adverse reactions and health impacts reported by adults aged ≥ 18 years who received a homologous Moderna (N = 307,998), or Pfizer-BioNTech (N = 332,588) COVID-19 vaccine booster, by dose



Haue AM, et al. Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults — United States, September 22, 2021–February 6, 2022. MMWR Morb Mortal Wkly Rep 2022.

Challenges

- V-safe for COVID-19 relied on donated services from Oracle Corporation
- Limitation: without access to the survey-building software, responding quickly to new vaccination campaigns (e.g. Mpox) was difficult
- Free text responses were challenging to analyze
 - Received >7.6 million free text responses
 - Natural language processing results were nonspecific
 - Required a new contract to MedDRA code responses for analysis
- V-safe (first generation) operations concluded June 2023

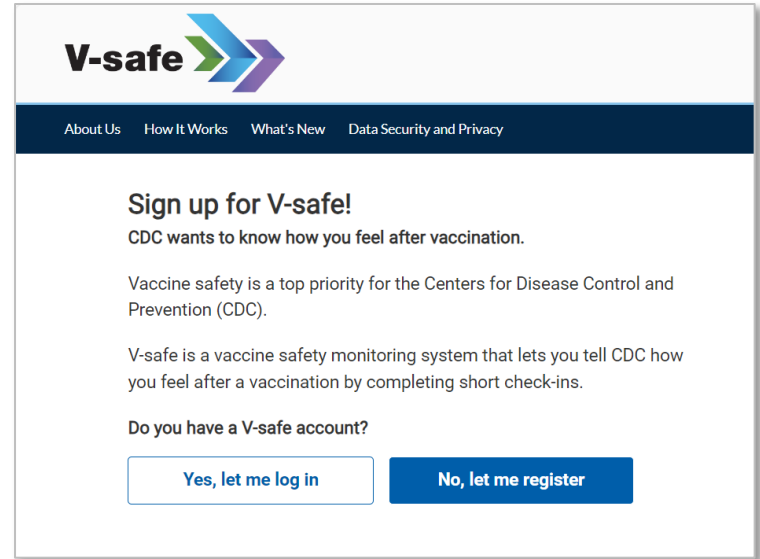
Conclusions

- V-safe complements the existing vaccine safety surveillance systems
 - Rapidly provides data on reactogenicity during the week after vaccination
- V-safe greatly contributed to COVID-19 vaccine safety monitoring
 - Describing reactogenicity in the days following vaccination
 - Facilitating reports of medically attended adverse events to VAERS
 - Identifying pregnant women for enrollment in the pregnancy registry
- Given its success, a smartphone-based survey system can be utilized for other vaccine campaigns

Establishing the second generation of V-safe

Second generation of V-safe established Fall 2023

- Most changes were to the system
 - Adaptable: easy to add new vaccination protocols
 - Responsive: able to respond quickly to health concerns
 - Configurable: supports complex survey logic
- User experience is similar
 - First generation V-safe users must create a new account
 - Demographic and contact information collected at registration
 - Includes both email and text messaging functionality
- Vaccines currently monitored:
 - RSV vaccines for older adults (est. October 2023)
 - RSV vaccines for pregnant persons (est. December 2023)
 - COVID-19 vaccines for persons aged 6 months and older (est. January 2024)



Participants enroll in specific vaccine protocols

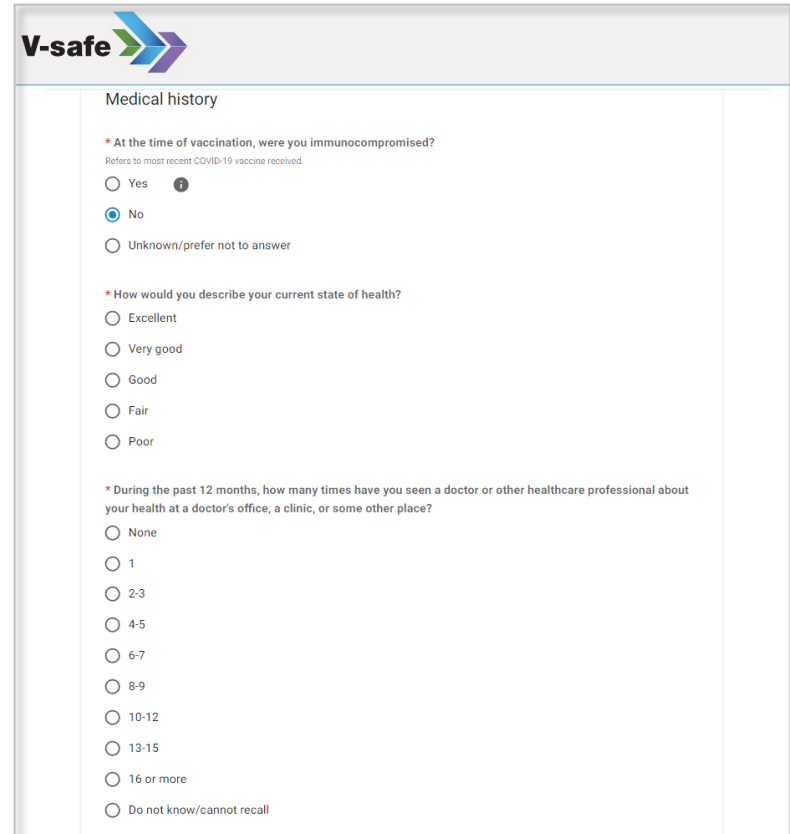
The screenshot displays the V-safe web application interface. At the top left is the V-safe logo. The top right shows the user's name 'Vsafe Testname', a help icon, and a language dropdown set to 'English'. Below the navigation bar are links for 'Home', 'Health Check-ins', 'Vaccination History', and 'My Account'. A row of buttons includes 'Vsafe Testname' (with a notification icon), 'Dependent1 Testname', 'Dependent2 Testname', 'View More', and 'Add Dependent'. A greeting 'Hello, Vsafe Testname' is displayed. A central grey box asks 'Has Vsafe Testname received a new vaccine?' and provides instructions: 'To enter a new vaccine, click "Enroll". To add another dose, select from the table below.' An 'ENROLL' button is present. Below this is a section titled 'Enrolled Activities for Vsafe Testname' with a 'DOWNLOAD CSV' button. A table lists activities with columns for 'Enrolled Activities', 'To Do', 'Date Enrolled', 'Vaccine Date', and 'Notification Preferences'.

Enrolled Activities	To Do	Date Enrolled	Vaccine Date	Notification Preferences
RSV for 60 years and older		10/20/2023	10/20/2023	📧
COVID-19	CHECK-IN	02/15/2024	02/15/2024	📧

- Can enroll in multiple protocols simultaneously
- Can enroll dependents
- Can view pending actions and navigate to dependent profiles

New questions included to determine baseline health

- Each vaccine protocol includes questions about a participant's health at the time of vaccination
 - Immunocompromise
 - Current state of health
 - Healthcare utilization in past year



V-safe

Medical history

* At the time of vaccination, were you immunocompromised?
Refers to most recent COVID-19 vaccine received.

Yes No Unknown/prefer not to answer

* How would you describe your current state of health?

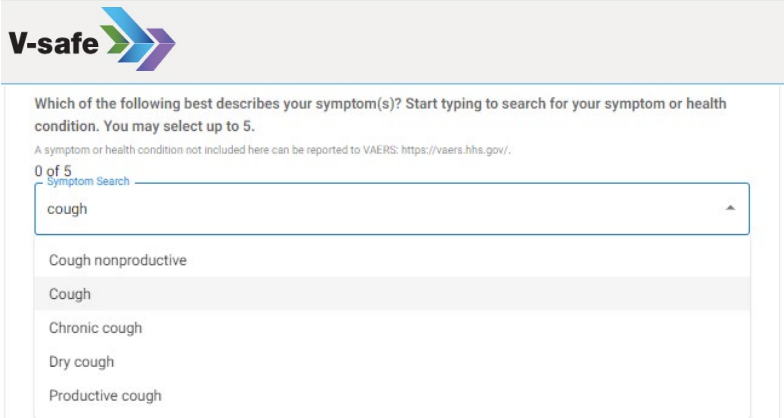
Excellent
 Very good
 Good
 Fair
 Poor


* During the past 12 months, how many times have you seen a doctor or other healthcare professional about your health at a doctor's office, a clinic, or some other place?

None
 1
 2-3
 4-5
 6-7
 8-9
 10-12
 13-15
 16 or more
 Do not know/cannot recall

Health surveys vary slightly by vaccine protocol

- Surveys are sent daily during the first week, then weekly through 6 weeks after vaccination
 - Daily surveys ask questions about
 - Local reactions (e.g., injection site pain)
 - Systemic reactions (e.g., fatigue)
 - Health impacts (e.g., medical care)
 - Worsening of symptoms for persons who reported immunocompromise at vaccination
- Weekly surveys solicit new symptoms or conditions after vaccination



V-safe 

Which of the following best describes your symptom(s)? Start typing to search for your symptom or health condition. You may select up to 5.

A symptom or health condition not included here can be reported to VAERS: <https://vaers.hhs.gov/>.

0 of 5
Symptom Search

Cough nonproductive

Cough

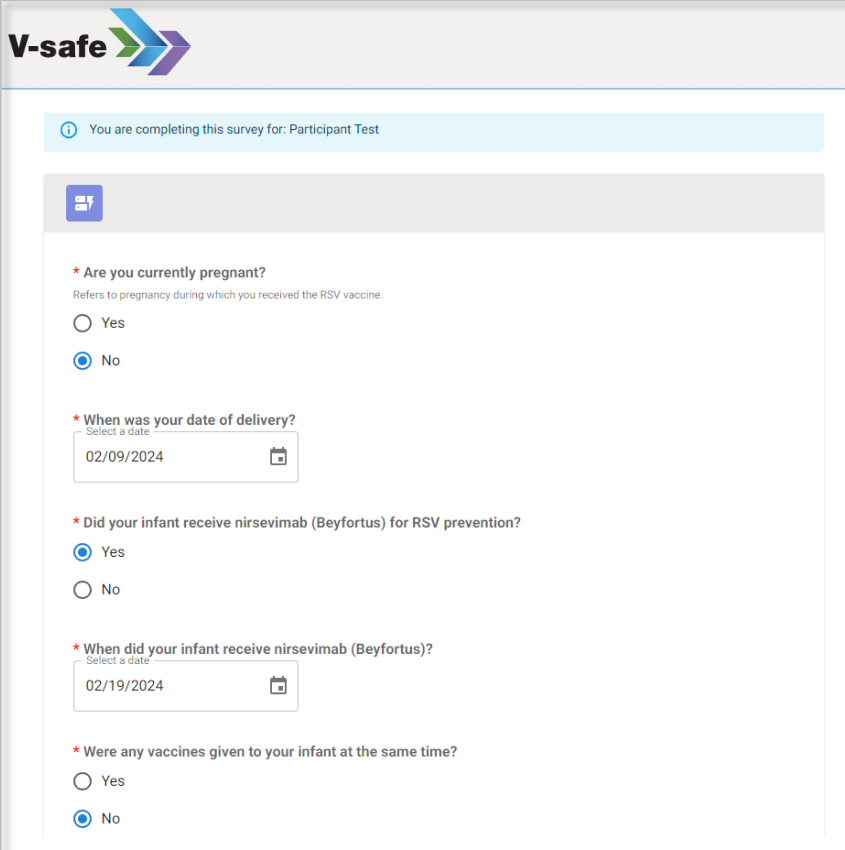
Chronic cough

Dry cough

Productive cough

Maternal RSV vaccine protocol includes additional surveys and questions

- History of preterm delivery
- Current pregnancy
 - High-risk status
 - Multiplicity
 - Estimated of delivery
 - Date of delivery
 - If infant received nirsevimab for RSV



V-safe

You are completing this survey for: Participant Test

*** Are you currently pregnant?**
Refers to pregnancy during which you received the RSV vaccine.

Yes
 No

*** When was your date of delivery?**
Select a date

02/09/2024

*** Did your infant receive nirsevimab (Beyfortus) for RSV prevention?**

Yes
 No

*** When did your infant receive nirsevimab (Beyfortus)?**
Select a date

02/19/2024

*** Were any vaccines given to your infant at the same time?**

Yes
 No

COVID-19 surveys include specific questions for children aged <2 years

V-safe 

*** In the past 24 hours, did Testdependent have any of these symptoms at or near the COVID-19 vaccine injection site? Select all that apply.**

Please rate symptoms as: Mild = symptoms noticeable, but they aren't a problem. Moderate = symptoms limit normal daily activities. Severe = symptoms make normal daily activities difficult or impossible.

- Pain
- Mild
- Moderate
- Severe
- Redness
- Swelling
- Groin or underarm swelling/tenderness (same side as injection)
- Rash at or near injection site
- Itching
- None

V-safe 

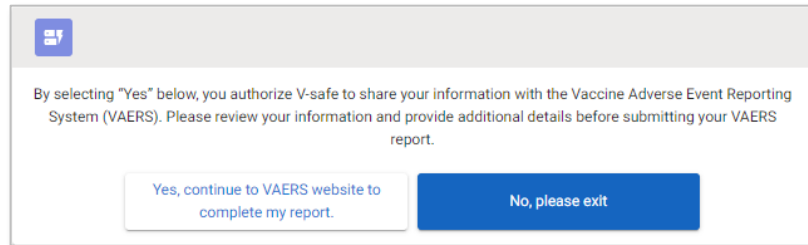
*** In the past 24 hours, did Testdependent have any of these symptoms? Report new symptoms noted after vaccination. Select all that apply.**

Please rate symptoms as: Mild = symptoms noticeable, but they aren't a problem. Moderate = symptoms limit normal daily activities. Severe = symptoms make normal daily activities difficult or impossible.

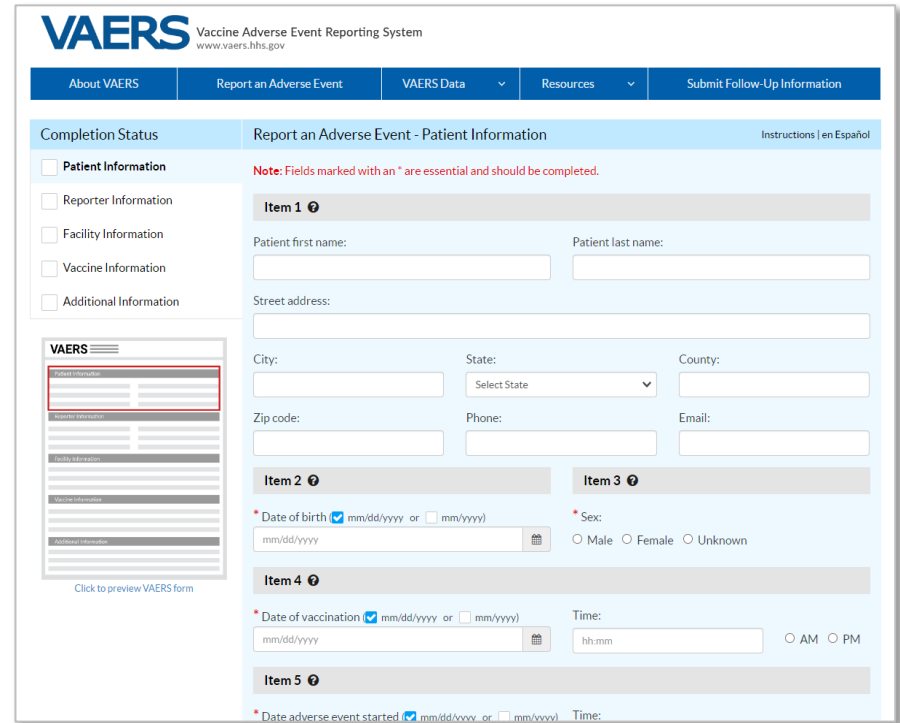
- Sleepiness
- Irritability/crying
- Loss of appetite
- Vomiting
- Diarrhea
- Rash, not including the immediate area around the injection site
- Other
- None

V-safe facilitates reporting to VAERS

- Participants reporting a medically attended health impact are prompted to complete a VAERS report
- May opt to prepopulate select fields in the VAERS report with information provided to V-safe



By selecting "Yes" below, you authorize V-safe to share your information with the Vaccine Adverse Event Reporting System (VAERS). Please review your information and provide additional details before submitting your VAERS report.



VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

Completion Status: Report an Adverse Event - Patient Information Instructions | en Español

Patient Information
 Reporter Information
 Facility Information
 Vaccine Information
 Additional Information

Note: Fields marked with an * are essential and should be completed.

Item 1

Patient first name: Patient last name:

Street address:

City: State: County:

Zip code: Phone: Email:

Item 2

* Date of birth mm/dd/yyyy or mm/yyyy * Sex: Male Female Unknown

mm/dd/yyyy

Item 3

Item 4

* Date of vaccination mm/dd/yyyy or mm/yyyy Time: AM PM

mm/dd/yyyy

Item 5

* Date adverse event started mm/dd/yyyy or mm/yyyy Time:

mm/dd/yyyy

[Click to preview VAERS form](#)

<https://vaers.hhs.gov/esub/index.jsp>

Challenges and next steps

- **Challenges:**
 - Improving participation
 - More diverse population of respondents
- **Next steps:**
 - Continued surveillance of new vaccines
 - Engaging vaccination providers
 - New methods of promotion

Increasing V-safe participation – We need your help

- Ensure vaccination partners are aware of V-safe
 - Information sheets
 - Social media posts
 - Communications to vaccine recipients
- **Vaccines currently monitored:**
 - RSV vaccines for older adults and pregnant persons
 - COVID-19 vaccines for persons aged 6 months and older
- Materials and more information available at:

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/index.html>

What is V-safe?

V-safe is an innovative vaccine safety monitoring system that allows you or your dependent to quickly and easily share how you feel after getting a vaccine. It takes just a few minutes to enroll, and then you will receive V-safe notifications through text messages or emails to complete **short, confidential health check-ins**. Your participation in V-safe makes a difference—it helps others know what to expect in the days following vaccination, and it helps CDC monitor the safety of vaccines for everyone.

V-safe features:

- Receive health check-ins via text or email after vaccination.
- Enroll your dependents and complete check-ins on their behalf.
- Share how you feel after getting a vaccine dose.

How can I enroll, and how does it work?

V-safe is available for several vaccines. Go to vsafe.cdc.gov to find out if you are eligible to enroll. If you are eligible, follow the prompts to register for V-safe health check-ins. During the first week after vaccination, V-safe will send you a text message or email notification each day to ask how you are feeling. Then you will get check-in messages once a week for up to 5 weeks. Depending on your answers, V-safe may send you a link to submit a report in the Vaccine Adverse Event Reporting System (VAERS).

You can opt out at any time by texting "STOP" when V-safe sends you a text message or by clicking "unsubscribe" when V-safe sends you an email. You can also opt back in by changing your preferred method of contact, found in your user profile. **Your personal information in V-safe is protected so that it stays confidential and private.***

How can I enroll my dependent?

To enroll a dependent in V-safe, **add them to your existing account**, or create a new account if you don't have one yet. Enrolling a dependent does not require you to enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: www.cdc.gov/vsafe

*V-safe gathers data employing strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws including the Privacy Act of 1974, standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Federal Information Security Management Act, and the Freedom of Information Act.



Sign up with your smartphone, tablet, or computer at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code



Need help with V-safe?

Call
1-833-748-1979

Email
CARS.HelpDesk@cdc.gov

Visit
www.cdc.gov/vsafe



CS324195-V 10/05/2023

Acknowledgements

- VAERS and V-safe teams

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.