

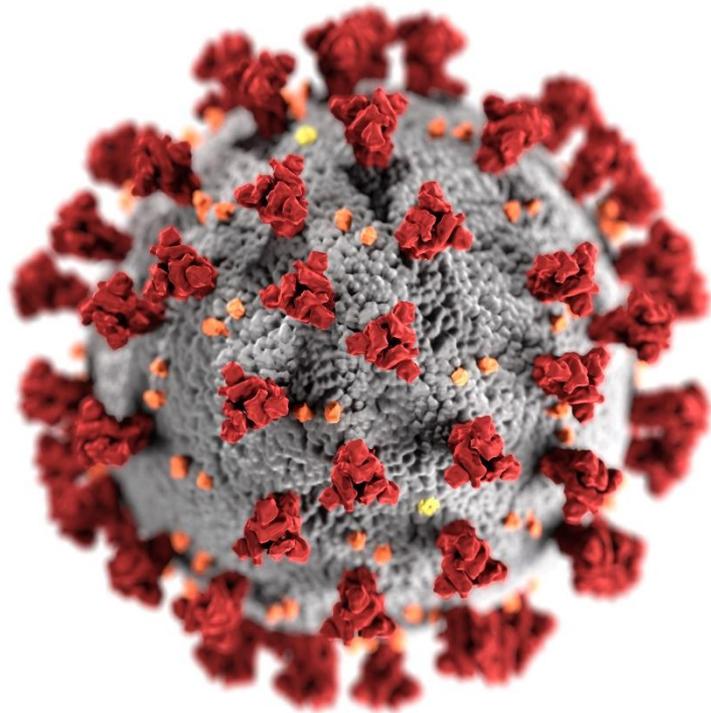
Lessons learned during deployment of a new smartphone-based safety monitoring system

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HPV Prevention and Control Board

15 April 2021



cdc.gov/coronavirus

Outline

- Description of **v-safe**SM after vaccination health checker tool
- Infrastructure and teams supporting **v-safe** project
- Enrollment and feedback from participants
- Key research findings to date
- Lessons learned

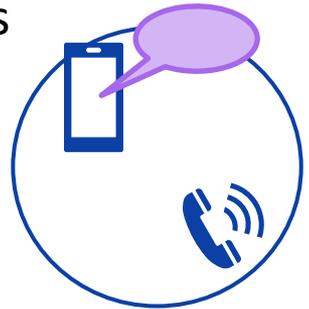


Description of v-safe



Active safety monitoring for COVID-19 vaccines

- **v-safe** is CDC's new "after vaccination health checker" program:
 - Allows participants to opt in for text links to web surveys after vaccination
 - Helps participants report side effects and health impact events after vaccination
 - Includes active telephone follow-up by CDC for reports of medically attended health impacts
 - Captures information on pregnancy status and enables follow-up for enrollment in a pregnancy registry





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

Navigation: 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, learning tools, and other resources.
- SUBMIT FOLLOW-UP INFORMATION**
Upload additional information related to VAERS reports.

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



Thu, Feb 18, 2:00 PM

Hi Tariya, It's time for your daily v-safe check-in.

https://v-safe-uat.covid19-screening.org/1/2/Mv2Ji-aZA_cG8w

Reply STOP to opt out



1. periodic text reminders for health check-ins

✓ received medical care

Call center



2. v-safe call center conducts active follow-up and collection of VAERS reports





Thu, Feb 18, 2:00 PM

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https://v-safe-uat.covid19-screening.org/1/2/Mv2Ji-aZA_cG8w

Reply STOP to opt out



1. periodic text reminders for health check-ins

✓ received medical care

Call center



2. v-safe call center conducts active follow-up and collection of VAERS reports

Call center



3. active follow-up with pregnant vaccinees for enrollment in long-term follow-up study

Daily surveys



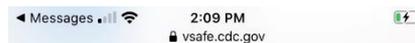
Hi Tanya,

Let's start today's health check-in.

How are you feeling today? *



Next >



Fever Check

Have you had a fever or felt feverish today? *

- Yes
 No

Do you know your highest temperature reading from today? *

- Yes - in degrees Fahrenheit
 Yes - in degrees Celsius
 No - I don't remember the reading
 No - I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit). *

 °F

< Previous

Next >



Daily surveys

4:04

it.covid19-screening.org

v-safe
after vaccination
health checker

75%

Symptom Check

Have you had any of these symptoms at or near the injection site today? *

Select all that apply.

- Pain
- Redness
- Swelling
- Itching
- None

Have you experienced any of these symptoms today? *

< >   

4:04

vsafe-uat.covid19-screening.org

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 around the injection site
- None

Any other symptoms or health conditions you want to report

< Previous Next >

< >   

4:04

it.covid19-screening.org

v-safe
after vaccination
health checker

100%

Health Impact

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

Select all that apply.

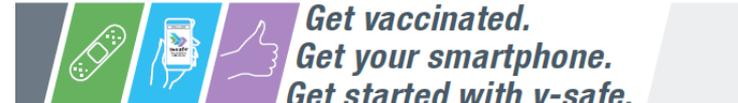
- Be unable to work
- Be unable to do your normal daily activities
- Get care from a doctor or other healthcare professional
- None of the above

< >   



Awareness and enrollment

- *Ideal:*
 - All sites provide information sheet immediately after vaccination.
- *Reality:*
 - Many sites are not providing sheets (not mandatory).
 - Some sites are including **v-safe** information but as a small statement within a broader vaccination visit handout.
 - Some participants enter via cdc.gov/vsafe.



**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 2pm 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. 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.

11/25/20



v-safe™
after vaccination
health checker

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



Infrastructure for v-safe



Key v-safe infrastructure activities

- Platform improvements
- Data management
- Inquiries
- Technical support and troubleshooting
- Other questions
- Pregnancy registry
- Communications



Key v-safe infrastructure activities

Presentations to partner organizations and jurisdictions



Development and improvement of platform



Contracts and staffing



Answering inquiries from v-safe users (both technical and non-technical)



v-safeSM
after vaccination
health checker

Data management and analytics



Communications



Pregnancy Registry



Presentation and publication of v-safe data



Enrollment and feedback from participants



Enrollment in v-safe – as of April 12, 2021

- 7.7 million active v-safe participants
- 85 million health check-in surveys completed
- More than 86,000 potential pregnancies identified
- More than 4,200 enrolled in pregnancy registry



Social media reactions to v-safe

- **“I did the v-safe. In addition to the whole data geek thingy I liked them checking on me.”**
- **“v-safe has been better at checking in on me than I am on my friends and family”**
- **“I really like these v-safe cdc check-ins. Like I’m not worried about side effects, it just feels nice to get texted”**
- **“I’ve been ghosted by v-safe. After a week of asking me daily how I’m doing, now it never texts me anymore. Was it something I said?”**



Key findings from v-safe health surveys



First month of COVID-19 vaccine safety monitoring

Morbidity and Mortality Weekly Report (MMWR)
CDC

First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021

Weekly / February 26, 2021 / 70(8);283-288

On February 19, 2021, this report was posted online as an MMWR Early Release.

Julianne Gee¹; Paige Marquez¹; John Su¹; Geoffrey M. Calvert¹; Ruiling Liu¹; Tanya Myers¹; Narayan Nair²; Stacey Martin¹; Thomas Clark¹; Lauri Markowitz¹; Nicole Lindsey¹; Bicheng Zhang¹; Charles Licata¹; Amelia Jazwa¹; Mark Sotir¹; Tom Shimabukuro¹ ([View author affiliations](#))

[View suggested citation](#)

Summary

What is already known about this topic?

Two COVID-19 vaccines have received Emergency Use Authorization for administration in the United States. In preauthorization clinical trials, local and systemic reactions were reported; no serious safety problems were detected.

What is added by this report?

Monitoring, conducted as part of the U.S. vaccination program, indicates reassuring safety profiles for COVID-19 vaccines. Local and systemic reactions were common; rare reports of anaphylaxis were received. No unusual or unexpected reporting patterns were detected.

What are the implications for public health practice?

Health care providers and vaccine recipients can be reassured about the safety of Pfizer BioNTech and Moderna COVID-19 vaccines. Counseling vaccine recipients to expect transient local and systemic

Article Metrics

Altmetric:

Platform	Count
News	177
Blogs	5
Policy documents	1
Twitter	1385
Facebook	4
Reddit	5
Video	1
Mendeley	16

Citations: 0

Views: 120,120
Views equals page views plus PDF downloads

<https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm>

- Describes reports to VAERS and **v-safe** of health events after receipt of mRNA vaccines
- Most common solicited reactions after vaccination reported to **v-safe**: injection site pain, fatigue, headache, myalgia, chills
- Findings for reactogenicity consistent with reporting in phase 3 clinical trials
- Recommendation for patient counseling to set expectations, ease concerns, and encourage series completion



Reactogenicity following receipt of mRNA-based COVID-19 vaccines

The screenshot shows the top portion of a JAMA Insights article. At the top left, there are social media icons and a 'New Online' badge. The article title is 'Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines'. Below the title, the authors are listed: Johanna Chapin-Bardales, PhD, MPH¹; Julianne Gee, MPH¹; Tanya Myers, PhD, MSc¹. The article is dated April 5, 2021. On the right side, there are buttons for 'Download PDF', 'Cite This', 'Permissions', and 'Comment'. Below these buttons is a 'Coronavirus Resource Center' link and a 'SCHEDULED MAINTENANCE' notice. At the bottom of the screenshot, there is a 'Trending' section with a 'Research' article titled 'Immunogenicity of the Ad26.COV2.S COVID-19 Vaccine' and a 'News' article titled 'Building Health Care Better Means Reining In Costs'.

<https://jamanetwork.com/journals/jama/fullarticle/2778441>

- Describes local and systemic reactogenicity reported to **v-safe** in first week after mRNA COVID-19 vaccination
 - Pain, fatigue, headache, and myalgia were the top solicited reactions after either dose of vaccine
 - Reactogenicity most common on day after vaccination
 - Reactogenicity was substantially higher after the second dose
 - Less reactogenicity reported in **v-safe** participants ≥ 65 years of age



Preliminary findings of mRNA COVID-19 vaccine safety in pregnant persons

Manuscript in press

- Characterization of initial safety of mRNA COVID-19 vaccines in pregnant persons based on reports to VAERS, **v-safe**, and the **v-safe** pregnancy registry
 - Substantial numbers of self-reported pregnant persons have registered in **v-safe**
 - Local and systemic reactogenicity similar to non-pregnant persons
 - No safety signals in this preliminary look at safety findings
 - Longitudinal follow-up continues in **v-safe** pregnancy registry



Lessons learned – early days of v-safe



Lessons learned

- User requirements change.
- Technology-based solutions need technology support.
- SMS technology is complex.
- **V-safe** is open to all, but complete promotion has been difficult to achieve.
- Public response to **v-safe** has been positive.
- Maternal vaccine recipients are highly motivated to contribute to research.
- Early assessments have been reassuring.



Acknowledgements

Centers for Disease Control and Prevention

COVID-19 Vaccine Task Force

COVID-19 Vaccine Task Force, Vaccine Safety Team

Immunization Safety Office

Division of Healthcare Quality Promotion

v-safe Team

v-safe participants

Oracle Health Sciences

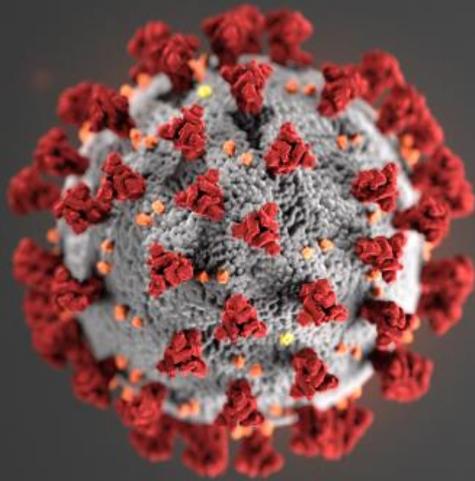
v-safe Development and Support Teams



More information available at:

cdc.gov/vsafe





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

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.

