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

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cdc.gov/coronavirus

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
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

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

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

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**Smartphone-based active safety monitoring**

- Now available!
  - Enrolling adolescents
  - 3rd dose reporting

http://cdc.gov/vsafe
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

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)
New v-safe participants

- Can register themselves or dependents at any time: after 1\textsuperscript{st}, 2\textsuperscript{nd} or 3\textsuperscript{rd} 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

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
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

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

http://vaers.hhs.gov
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

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
How to report an adverse event to VAERS

- go to [vaers.hhs.gov](http://vaers.hhs.gov)
- submit a report online

for help:

call 1-800-822-7967

e-mail info@VAERS.org

video instructions [https://youtu.be/sbCWhcQADF](https://youtu.be/sbCWhcQADF)
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 ✔

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
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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Extra slides
1. text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

vaccine recipient completes web survey*

2. clinically important health impact reported
   ✓ received medical care

   Call center

3. V-safe call center conducts active telephone follow-up on a clinically important event and takes a VAERS report if appropriate

   Call center

4. pregnancy registry team conducts outreach to assess eligibility for registry and obtain consent for enrollment and follow-up

   * Selected web surveys capture information on pregnancy status

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**CISA**

Clinical Immunization Safety Assessment (CISA) Project

- clinical consult services*
- clinical research

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