CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team

October 30, 2020

Disclaimer

- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of CDC

Background

- U.S. government has a responsibility for public safety with respect to vaccines
  - Monitoring is independent from manufacturers and covers all vaccines
  - USG maintains the largest, most robust, and most sophisticated safety monitoring systems available in the United States
  - USG agencies collaborate on monitoring

Background (cont.)

- CDC's Advisory Committee on Immunization Practices (ACIP) has established a COVID-19 Vaccine Safety Technical Sub-Group
  - Advise CDC and other federal partners on planning and preparation for post-authorization/post-licensure safety monitoring of COVID-19 vaccines
  - Independently review and evaluate safety data
- Post-authorization/post-licensure safety data on COVID-19 vaccines will be regularly presented at public ACIP meetings

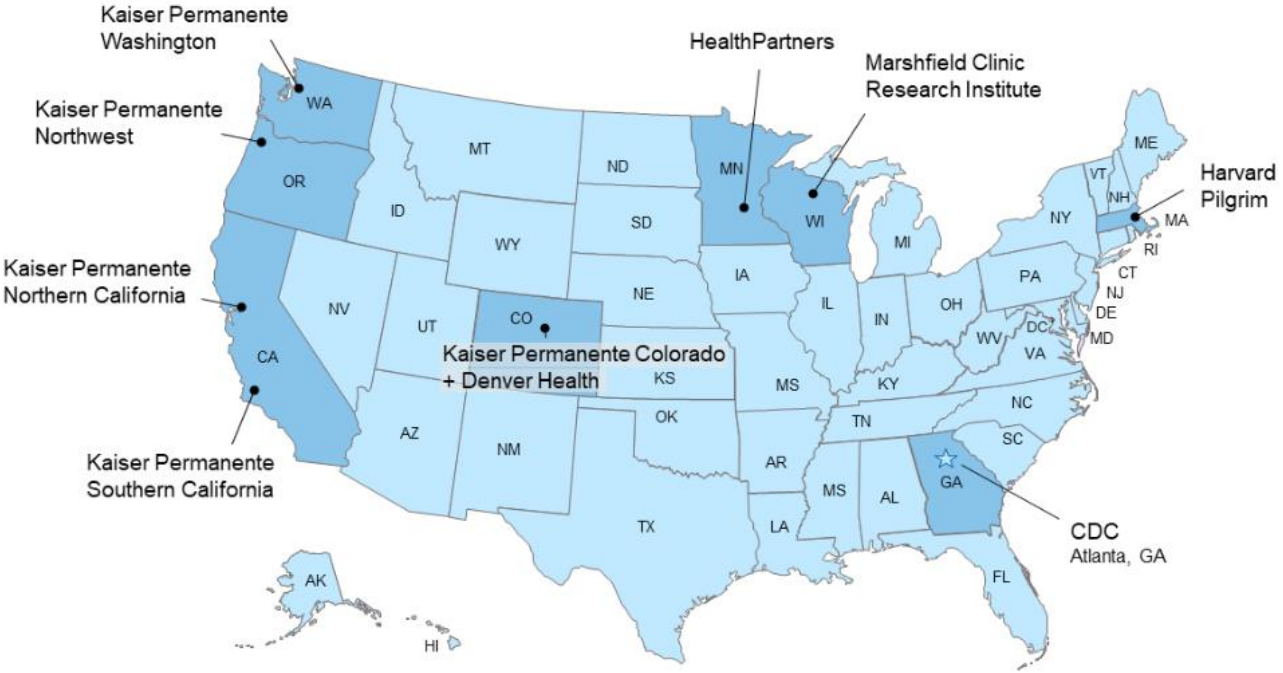
Topics

- Updates on Vaccine Safety Datalink (VSD) monitoring and the Clinical Immunization Safety Assessment (CISA) Project clinical consult service
- Vaccine Adverse Event Reporting System (VAERS)
  - Healthcare professionals' role in reporting adverse events
- **V-safe** smartphone-based active surveillance
  - Healthcare professionals' role in facilitating patient enrollment into **v-safe**

Vaccine Safety Datalink (VSD)

VSD

Vaccine Safety Datalink



9 participating integrated healthcare organizations

Data on over 12 million persons per year

VSD planned monitoring and evaluation for COVID-19 vaccine safety

- Near real-time sequential monitoring (Rapid Cycle Analysis [RCA])
- Monitoring for vaccine-mediated enhanced disease (VMED)
- Studies to evaluate COVID-19 vaccine safety during pregnancy, including fetal death and infant outcomes
- Tree-temporal scan data mining
- Projects to assess:
  - Changes in healthcare utilization during COVID-19 and impact on AE monitoring
  - Utility of smartphone technology to enhance vaccine safety monitoring
  - Multisystem inflammatory syndrome (MIS-C and MIS-A) as vaccine AEs
  - Safety in an expanded underserved VSD population
  - Knowledge, attitudes, beliefs around acceptance/refusal of COVID-19 vaccination

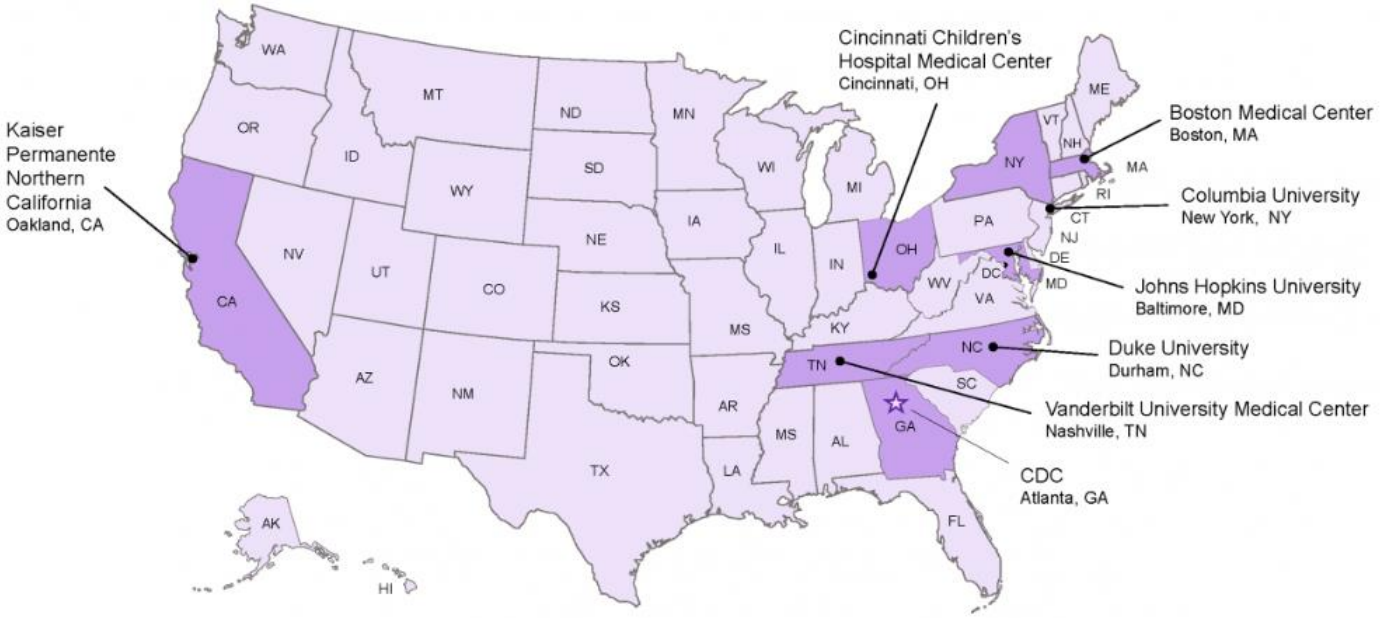
Preliminary list of VSD pre-specified outcomes for RCA

- Acute disseminated encephalomyelitis (ADEM)
- Acute myocardial infarction (AMI)
- Anaphylaxis
- Acute respiratory distress syndrome (ARDS)
- Arthritis and arthralgia / joint pain
- Convulsions / seizures
- Disseminated intravascular coagulation (DIC)
- Encephalitis / myelitis / encephalomyelitis / meningoencephalitis / meningitis / encephalopathy (not ADEM or TM)
- Guillain-Barré syndrome (GBS)
- Immune thrombocytopenia (ITP)
- Kawasaki disease (KD)
- Multisystem Inflammatory Syndrome (MIS-C and MIS-A)
- Myocarditis / pericarditis
- Narcolepsy / cataplexy
- Stroke – hemorrhagic and ischemic
- Transverse myelitis (TM)
- Venous thromboembolism (VTE)

Clinical Immunization Safety Assessment (CISA) Project

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

CISA Project consult service for COVID-19 vaccine safety

- Supports U.S. healthcare providers and health departments on complex clinical vaccine safety questions
- Assists with evaluations of patients with adverse events after COVID-19 vaccine or in making clinical decisions about administering COVID-19 vaccine to a person who may be at increased risk for an adverse event
  - Advice from CDC and the CISA Project is meant to assist in decision-making, rather than provide direct patient management
- Available to U.S. healthcare providers and health departments by contacting CDC-INFO*

*https://www.cdc.gov/cdc-info/index.html

Vaccine Adverse Event Reporting System (VAERS)

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov

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

Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

  - VAERS accepts all reports from all reporters without making judgments on causality or clinical seriousness of the event
  - As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

Approaches to analyzing VAERS data

- Traditional methods
  - Clinical review of individual reports
  - Aggregate report review (automated data), e.g., case counts, frequencies of adverse event coding terms, reporting rates, reporting trends over time
- Statistical data mining methods
  - Detects disproportional reporting of specific vaccine-adverse event combinations in VAERS database

Preliminary list of VAERS AEs of special interest*

- **COVID-19 disease**
- **Death**
- **Vaccination during pregnancy and adverse pregnancy outcomes**
- **Guillain-Barré syndrome (GBS)**
- Other clinically serious neurologic AEs (group AE)
  - Acute disseminated encephalomyelitis (ADEM)
  - Transverse myelitis (TM)
  - Multiple sclerosis (MS)
  - Optic neuritis (ON)
  - Chronic inflammatory demyelinating polyneuropathy (CIDP)
  - Encephalitis
  - Myelitis
  - Encephalomyelitis
  - Meningoencephalitis
  - Meningitis
  - Encephalopathy
  - Ataxia
- **Seizures / convulsions**
- **Stroke**
- **Narcolepsy / cataplexy**
- Autoimmune disease
- **Anaphylaxis**
- Non-anaphylactic allergic reactions
- **Acute myocardial infarction**
- **Myocarditis / pericarditis**
- **Thrombocytopenia**
- **Disseminated intravascular coagulation (DIC)**
- **Venous thromboembolism (VTE)**
- Arthritis and arthralgia (not osteoarthritis or traumatic arthritis)
- **Kawasaki disease**
- **Multisystem Inflammatory Syndrome (MIS-C, MIS-A)**
- Acute respiratory distress syndrome (ARDS)

*VAERS reports of AEs of special interest in blue will be clinically reviewed by CDC scientists

Healthcare professionals' (HCP) role in VAERS reporting

- HCPs have been CDC's longstanding partners for reporting vaccine adverse events (AEs) to VAERS
  - VAERS depends on HCPs to identify and report suspected AEs, even if they aren't sure if a vaccine caused an AE
- HIPAA permits reporting of vaccine AEs and medical documentation (e.g., medical records) to VAERS for public health purposes
- HCP participation in VAERS reporting will enable public health officials to have accurate and timely information on the safety of COVID-19 vaccines
- Specific guidance on VAERS reporting for vaccines authorized for use under Emergency Use Authorization (EUA) will be forthcoming

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

Review reporting requirements and submit reports.

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

VAERS Home

- VAERS Home
- About VAERS
- Report an Adverse Event −
  - Report Online
  - Report Using a PDF Form
- VAERS Data +
- Resources +
- Submit Follow-Up Information
- Frequently Asked Questions
- Contact Us
- Privacy

Home / Report an Adverse Event / en Español

Report an Adverse Event to VAERS

VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

Online reporting is strongly encouraged. Please report clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

The Vaccine Adverse Event Reporting System (VAERS) accepts all reports, including reports of vaccination errors. Guidance on reporting vaccination errors is available if you have additional questions.

Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

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

- Patient Information
- Reporter Information
- Facility Information
- Vaccine Information
- Additional Information

Click to preview VAERS form

Report an Adverse Event - Patient Information

Instructions | en Español

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

Item 1

Patient first name:

Patient last name:

Street address:

City:

State: Select State

County:

Zip code:

Phone:

Email:

Item 2

* Date of birth (mm/dd/yyyy or mm/yyyy)

mm/dd/yyyy

Item 3

* Sex: Male Female Unknown

Item 4

* Date of vaccination (mm/dd/yyyy or mm/yyyy)

mm/dd/yyyy

Time:

hh:mm

AM PM

Item 27

U.S. Military/Department of Defense status at the time of vaccination:

- [ ] Active Duty
- [ ] Reserve
- [ ] National Guard
- [ ] Beneficiary
- [ ] Other Military Status:

Item 28

Vaccinated at Military/DoD site:

- ○ Yes
- ○ No

Warning: Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Prev | Submit

How to report to VAERS

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


v-safe
after vaccination
health checker

v-safe
after vaccination
health checker

- **V-safe** is a new smart-phone based active surveillance program for COVID-19 vaccine safety
  - Uses text messaging to initiate web-based survey monitoring
  - Conducts electronic health checks on vaccine recipients
    - Daily for first week post-vaccination; weekly thereafter until 6 weeks post-vaccination
    - Additional health checks at 3, 6, and 12 months post-vaccination
  - Includes active telephone follow-up through the VAERS program with vaccine recipients reporting a clinically important event during any **v-safe** health check
    - A VAERS report will be taken during telephone follow-up, if appropriate
  - Captures information on pregnancy status and enables follow-up on pregnant women

1. Text message check-in or email from CDC (daily 1st week post-vaccination and weekly thereafter until 6 weeks post-vaccination)

   Vaccine recipient completes web survey

Vaccine recipient

v-safe after vaccination health checker

2. Clinically important event(s) reported
   - ✓ Missed work
   - ✓ Unable to do normal daily activities
   - ✓ Received medical care

VAERS call center

3. A VAERS customer service representative conducts active telephone follow-up on a clinically important event and completes a VAERS report if appropriate

v-safe
after vaccination
health checker

- **V-safe** will allow estimation of:
  - Rates of local and systemic reactogenicity
  - Rates of clinically important adverse events following COVID-19 vaccination and symptoms and conditions associated with these adverse events

- Healthcare professionals (HCPs) will play an important role in **v-safe** enrollment
- CDC asks that:
  - HCPs provide a one-page **information sheet*** to patients at vaccination
  - HCPs counsel patients on the importance of enrolling in **v-safe**
- CDC will provide information on how to briefly counsel patients on **v-safe**

*CDC will create an electronic version of the **v-safe** information sheet for printing

Summary

Summary

- The Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA) Project, and other planed projects are key components of COVID-19 vaccine safety monitoring and adverse event assessment
- VAERS is the U.S. frontline vaccine safety monitoring system
  - VAERS traditionally has provided the initial data on the safety profile of new vaccines when they are introduced for use in the population
  - Healthcare providers (HCPs) can play an important role in identifying and reporting potential AEs to VAERS: **HCPs are partners in safety monitoring**
- **V-safe** is a new smart-phone based active surveillance program
  - HCPs can play an important role in helping CDC enroll patients in **v-safe** at the time of vaccination: **HCPs are partners in safety monitoring**

Questions?