



# Maternal RSV vaccine safety monitoring in the Vaccine Adverse Event Reporting System (VAERS) and V-safe

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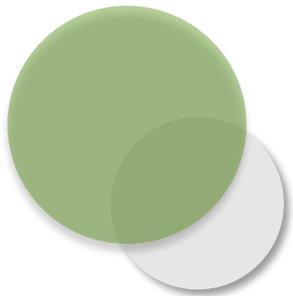
**Advisory Committee for Immunization Practices**

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# Vaccine Adverse Event Reporting System (VAERS)



VAERS



## Vaccine Adverse Event Reporting System

Co-managed by  
CDC and FDA

<http://vaers.hhs.gov>

The screenshot shows the VAERS website homepage. At the top, the VAERS logo is followed by the text "Vaccine Adverse Event Reporting System" and the URL "www.vaers.hhs.gov". A navigation bar contains links for "About VAERS", "Report an Adverse Event", "VAERS Data", "Resources", and "Submit Follow-Up Information". The main content area features a question "Have you had a reaction following a vaccination?" with two numbered steps: "1. Contact your healthcare provider." and "2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*". Below this is an "Important" notice in a green box: "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." To the right is a photo of a family looking at a laptop. Below the photo is a "What is VAERS?" link. Further down, there are four tiles: "REPORT AN ADVERSE EVENT" (with a photo of a doctor and patient), "SEARCH VAERS DATA" (with a photo of hands on a tablet), "REVIEW RESOURCES" (with a photo of a woman reading), and "SUBMIT FOLLOW-UP INFORMATION" (with a photo of a woman at a computer). Each tile includes a brief description of the function.

# VAERS

## Strengths

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

- VAERS accepts all reports from all reporters without making judgments on causality or judging 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

## Limitations

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

# Approaches to analyzing VAERS data

- For more than a decade VAERS has been used as part of vaccine safety surveillance for vaccines used in pregnancy (e.g., influenza, Tdap, COVID-19)
  - Descriptive analysis
    - Clinical review of individual reports
    - Aggregate descriptions of automated data (e.g., counts of reported adverse events)
    - Calculation of reporting rates for pregnancy outcomes (if doses of RSV vaccine administered in pregnancy or vaccination coverage data available are available)
  - Statistical analysis
    - Historical approaches have included data mining; under discussion

# Search for RSV pregnancy reports and clinical review

- Search of reports:
  - Specific Medical Dictionary for Regulatory Activities (MedDRA) codes: exposure during pregnancy, drug exposure during pregnancy, maternal exposure during pregnancy
  - Affirmative answer on Question 8 in VAERS form (pregnancy status)

8. Pregnant at time of vaccination?:  Yes     No     Unknown  
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)
  - String search of text fields (symptoms, pre-existing illness, medical history) for 'preg'
- Medical records requested for ALL pregnancy reports
- Clinicians review reports to confirm they are pregnancy reports and categorize the main adverse event/s of interest

# VAERS surveillance of adverse events of special interest (AESI) after RSV vaccination

- Primary AESIs
  - Selected for historical, theoretical, or observed safety concerns (i.e., in clinical trials)
  - VAERS will obtain medical records for all reports (serious<sup>1</sup> and non-serious)
  - CDC will review records and abstract clinically important information
  - AESIs may be added to or removed from the list as appropriate
- Secondary AESIs
  - Monitored via periodic (e.g., weekly) automated data tables
  - Can be added to primary AESI list if safety concerns identified

<sup>1</sup> Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect

# Adverse events of special interest (AESI) after RSV vaccines

Will be monitored in VAERS for all RSV vaccines, including for reports among pregnant persons

## Primary AESIs

- **Outcomes of general interest**
  - Death
- **Neurologic/neuroinflammatory conditions**
  - Guillain-Barre Syndrome (GBS), including Miller Fisher variant
  - Acute disseminated encephalomyelitis (ADEM)
  - Transverse myelitis (TM)
  - Chronic inflammatory demyelinating polyneuropathy (CIDP)
- **Allergic reactions**
  - Anaphylaxis
- **Cardiac conditions**
  - Atrial fibrillation
  - Other supraventricular tachycardias (SVT)

## Secondary AESIs

- **Neurologic/neuroinflammatory conditions**
  - Optic neuritis
  - Multiple sclerosis
  - Bell's palsy
  - Encephalitis/Encephalomyelitis
  - Meningitis/Meningoencephalitis
  - Myelitis
- **Other conditions**
  - Vaccination errors
  - AEs following simultaneous administration with COVID-19, inactivated influenza, or other adult vaccines

# Pregnancy-specific outcomes to be monitored in VAERS and abstracted after maternal RSV vaccine

- Pregnancy reports after maternal RSV vaccine
  - Premature/preterm birth
  - Stillbirth
  - Spontaneous abortion
  - Gestational diabetes
  - Preeclampsia/eclampsia/gestational hypertension
  - Birth defects
  - Maternal and infant deaths
  - Other selected adverse infant outcomes/AEs



- New version of V-safe developed starting Summer 2023
  - Leverages existing CDC IT infrastructure
  - Includes email and text messaging options
  - First use for RSV vaccines received by persons aged 60 and older
  - Use for maternal RSV vaccines planned for later this fall
  
- **V-safe objectives:**
  1. Characterize local and systemic reactogenicity during days 0-7 after vaccination
  2. Characterize health impacts during a 6-week post-vaccination follow-up period
  3. Identify participants who report medically attended events after vaccination and encourage completion of a VAERS report

# Thank you

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

