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

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Vaccine Adverse Event Reporting System (VAERS)

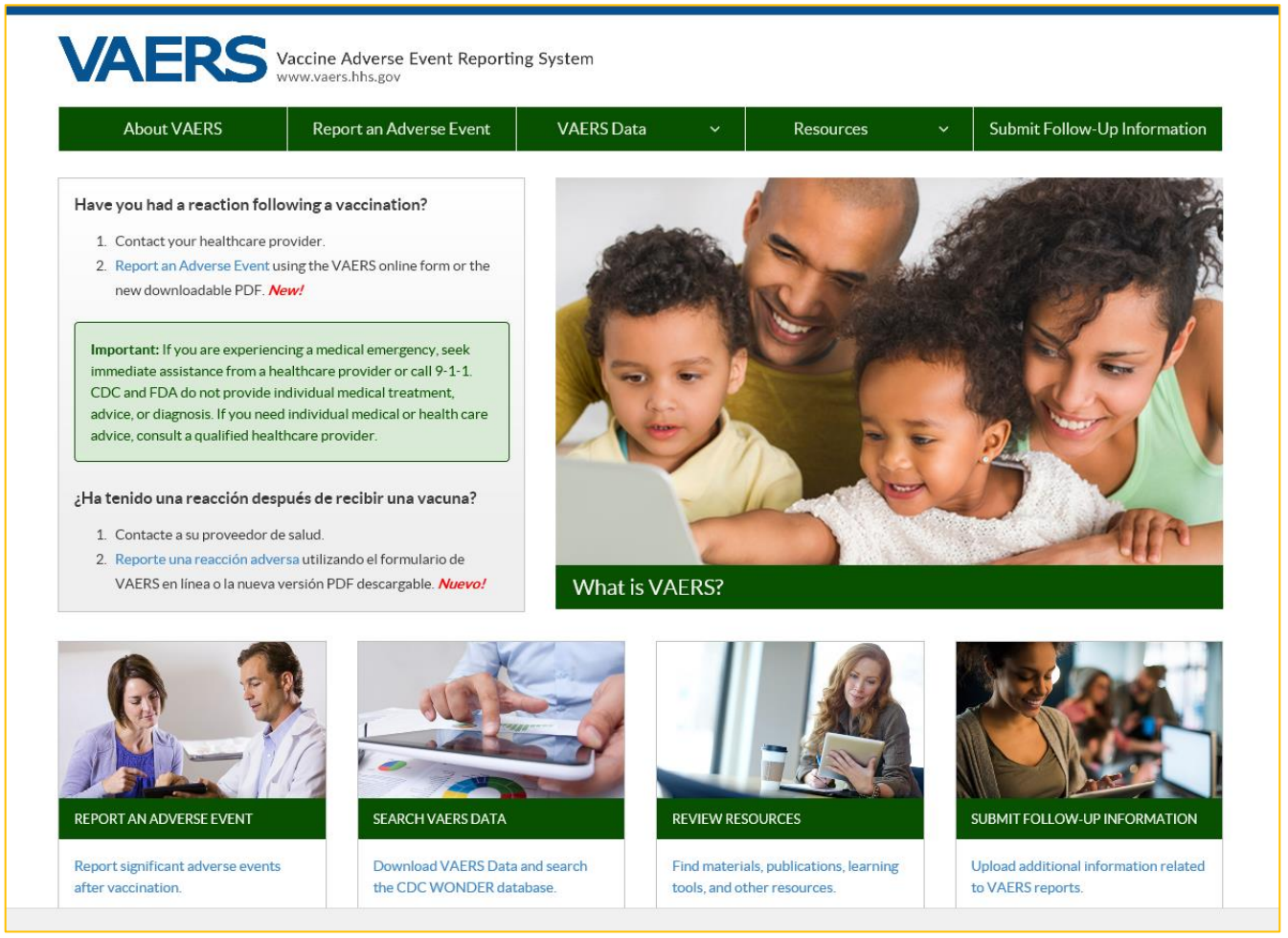
CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov



VAERS

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 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

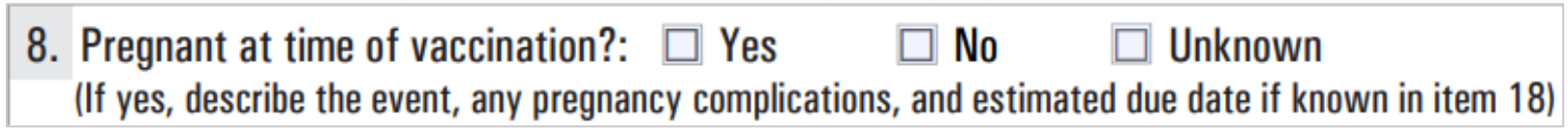
Approaches to analyzing VAERS data

- 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

*Reported adverse events are coded using Medical Dictionary for Regulatory Activities terms (https://www.meddra.org/)

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)



  - 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[1] 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

[1] 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

V-safe

- 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