COVID-19 vaccine post-authorization safety monitoring update

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CDC COVID-19 Vaccine Task Force
Vaccine Safety Team
Safety monitoring timeline and covered populations in early vaccination
start of vax

active surveillance

active surveillance

safety monitoring timeline
start of vax

DoD VAECs

VA ADERS

NHSN

active surveillance

CDC + FDA

VAERS

passive surveillance

start of vax

safety monitoring timeline

active surveillance, passive surveillance
start of vax

active surveillance

passive surveillance

individual case consults

active surveillance, passive surveillance, case consults

safety monitoring timeline
start of vax

active surveillance, passive surveillance, case consults

passive surveillance

individual case consults

safety monitoring timeline

large-linked database monitoring

DoD VAECs

VA ADERS

VA EHR & data warehouse

NHSN

CDC

VSD

Vaccine Safety DataLink

FDA

Vaccine Adverse Event Reporting System

CISA

Clinical Immunization Safety Assessment (CISA) Project

FDA Vaccine Surveillance Program

Federal Partners

BEST Initiative

PRISM

Harvard Pilgrim Healthcare Institute

VA Department of Veterans Affairs US Department of Defense National Institute on Aging

DoD DMSS Defense Medical Surveillance System
<table>
<thead>
<tr>
<th>Monitoring systems</th>
<th>Population</th>
<th>Healthcare workers</th>
<th>LTCF residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAERS (CDC &amp; FDA)</td>
<td>General U.S. population, VA and DoD patient populations, NHSN acute care and long-term care facilities</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>VA ADERS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DoD VAECS</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CDC NHSN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V-safe (CDC)</td>
<td>All COVID-19 vaccine recipients eligible</td>
<td>Yes</td>
<td>Limited</td>
</tr>
<tr>
<td>VSD (CDC)</td>
<td>Insured patients in VSD sites</td>
<td>Yes</td>
<td>Limited</td>
</tr>
<tr>
<td>FDA-CMS</td>
<td>Medicare recipients (90+% of 65 y/o in the U.S., including 650K LTCF residents)</td>
<td>Limited</td>
<td>Yes</td>
</tr>
<tr>
<td>BEST &amp; PRISM (FDA)</td>
<td>Insured patients in BEST &amp; PRISM sites</td>
<td>Yes</td>
<td>Limited</td>
</tr>
<tr>
<td>VA EHR &amp; data warehouse</td>
<td>Enrolled VA patients</td>
<td>Limited</td>
<td>Yes</td>
</tr>
<tr>
<td>DoD DMSS</td>
<td>Active duty military (limited info on beneficiaries [i.e., family members, retirees])</td>
<td>Yes</td>
<td>Limited</td>
</tr>
<tr>
<td>Genesis HealthCare (Brown U. &amp; NIH-NIA)</td>
<td>Long-term care facility residents (~35,000 long stay residents)</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Routine systems

**signal detection**

- VAERS (DoD & CDC & FDA)
- VA ADERS (VA)
- VA EHR & data warehouse
- VSD (CDC)
- FDA-CMS (FDA & CMS)
- DMSS (DoD)

**signal assessment**

- VSD (CDC)
- FDA-CMS (FDA & CMS)
- VA EHR & data warehouse
- VSD (CDC)
- CISA (CDC)
- DMSS (DoD)

New systems

**signal detection**

- v-safe (CDC)
- BEST* (FDA)
- Sentinel surveillance (DoD MTFs)
- NHSN (CDC)
- Genesis LTCF (Brown U. & NIH)

**signal assessment**

- BEST* (FDA)
- Other EHR and payer partners (FDA)

*DoD and IHS have VAERS data sharing agreements with CDC; #BEST includes most of the major partners from Sentinel PRISM
Safety monitoring in long-term care facility residents
VAERS is the nation’s early warning system for vaccine safety

Co-managed by CDC and FDA

http://vaers.hhs.gov
VAERS covers the entire U.S. population

- 320 million U.S. residents as a covered population for safety monitoring
- All ages, races, occupations (including healthcare workers) states/jurisdictions, healthy people, those with chronic health problems, long-term care facility residents, older adults living in the community, etc.
VA Adverse Drug Event Reporting System (ADERS)

- Includes VA healthcare workers
- Includes 8,000 residents per day in VA LTCFs
National Healthcare Safety Network (NHSN)

- 17,000 LTC facilities
- Aggregate voluntary reporting of vaccine doses administered and counts of non-specific AEs
- Guidance on reporting AEs to VAERS

Adverse Events following COVID-19 Vaccine(s)

Clinically significant adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) at [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html). To help identify reports from NHSN sites, please enter your NHSN orgID in Box 26 of the VAERS form.

Clinically significant adverse events include vaccine administration errors and serious adverse events (such as death, life-threatening conditions, or inpatient hospitalization) that occur after vaccination, even if it is not certain that vaccination caused the event.

Other clinically significant adverse events may be described in the provider emergency use authorization (EUA) fact sheets or prescribing information for the COVID-19 vaccine(s). Healthcare providers should comply with VAERS reporting requirements described in EUAs or prescribing information.

5. Number of residents with clinically significant COVID-19 vaccine adverse events identified this week

5.1. Pfizer-BioNTech COVID-19 vaccine
5.2. Moderna COVID-19 vaccine
5.3. AstraZeneca COVID-19 vaccine
5.4. Janssen COVID-19 vaccine

Assurance of Confidentiality: The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

CDC 57 xxx
Pharmacy partnership program for LTCF vaccination

- Pharmacy partners may vaccinate in 70-80% of LTCFs
  - Can provide early denominator information (COVID-19 vaccine doses administered) in LTCF residents
    - Will improve the accuracy of reporting rate estimates
  - Outreach to pharmacy partners on VAERS reporting planned
Rapid Cycle Analysis (RCA) in 65+ y/o adults

- FDA RCA in CMS data
  - 55-60 million 65+ y/o (92% of the U.S. elderly), including ~650K LTCF residents
  - Data are refreshed weekly with weekly sequential analyses
  - CMS Medicare (FFS) average data lag is around 4 weeks; average data lag can be up to 5-6 weeks for hospitalizations (mostly due to hospital stay)

- VA RCA in VA electronic health record and data warehouse
  - Historically, 60% of VA patients who get flu vaccination are 65+ y/o (~1.56 million 65+ y/o vaccinated for flu annually in recent years)
  - ~8,000 LTCF (VA Community Living Centers) residents per day
  - Data refreshed weekly with weekly sequential analyses
  - Approximate 1-week average data lag; up to around 4 weeks for hospitalization (mostly due to hospital stay)
Rapid Cycle Analysis (RCA) in 65+ y/o adults

- CDC RCA in the Vaccine safety Datalink (VSD)
  - 1.8 million 65+ y/o (9 integrated health systems)
  - Data refreshed weekly with weekly sequential analyses
  - Approximate 1- to 2-week average data lag; up to around 6 weeks for hospitalization (mostly due to hospital stay)
Case evaluations of adverse events

Planned activities

- Rapid processing and review of reports to VAERS classified as serious* and for adverse events of special interest
- Investigation of clusters of clinically serious adverse events by multidisciplinary CDC teams if necessary
- Clinical case reviews by CDC’s Clinical Immunization Safety Assessment (CISA) Project

*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
Coordination, communication, and implementation
ACIP COVID-19 Vaccine Safety Technical Sub-Group (VaST)

- Built off lessons learned from H1N1 vaccine safety monitoring
- Terms of reference and composition are finalized and VaST is ready to begin reviewing data once implementation commences
  - Co-Chaired by ACIP member and a National Vaccine Advisory Committee (NVAC) member
  - ACIP and NVAC representation
  - 7 independent expert consultants
  - ACIP federal agency ex officio members (NIH, FDA, OIDP, CMS, HRSA, IHS)
  - Veterans Affairs (VA) and Department of Defense (DoD) liaisons
VaST post-implementation objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccine safety data
- Serve as the central hub for technical SMEs from federal agencies conducting post-authorization/approval safety monitoring to share vaccine safety surveillance data
- Advise on analyses, interpretation, and data presentation
- Liaise with the ACIP COVID-19 Vaccines WG on issues of safety data presentation to the ACIP and application of safety data to policy decisions
Communication: product dissemination and outreach

- Distribute communications materials to state health officials, healthcare providers, and healthcare systems
- Provide up-to-date information and Q&A on CDC COVID-19 website
- Conduct ongoing partner outreach and engagement to raise awareness of v-safe and VAERS reporting requirements
  - Healthcare provider professional organizations
  - Public health partners
  - Healthcare organization and other private sector partners
  - Long-term care partners
  - Pharmacy partners
Summary

- Early data on COVID-19 vaccine safety in healthcare workers will be mainly available through v-safe and VAERS and systems that report into VAERS.
- Early data on safety in LTCF residents will be mainly available through VAERS and systems that report into VAERS.
- VAERS is a long-standing established safety monitoring system that is critical to monitoring new vaccines during the early uptake period.
- Large-linked database monitoring systems (e.g., CDC’s Vaccine Safety Datalink) will provide safety data when vaccines become more widely available in priority groups and in the general population.
- Efforts are ongoing to increase awareness and provide information needed to partners for safety monitoring.
COVID-19 vaccine safety gets stronger with your participation

Your role

Public health partners
- promote participation in v-safe ✓
- promote reporting to VAERS ✓
- communicate with your partners on vaccine safety ✓

Healthcare providers
- encourage patient participation in v-safe ✓
- report adverse events to VAERS ✓
- communicate with patients on vaccine safety ✓
How to report an adverse event to VAERS

- Go to vaers.hhs.gov and submit a report online
- For help: call 1-800-822-7967, email info@VAERS.org
- Video instructions https://www.youtube.com/watch?v=sbCWhcQADFE

How to contact CDC at CDC-INFO

- Go to https://www.cdc.gov/cdc-info/index.html
- Call 1-800-CDC-INFO (800-232-4636)

Safety information resources

Questions