COVID-19 vaccine post-authorization safety monitoring update

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Vaccine Safety Team

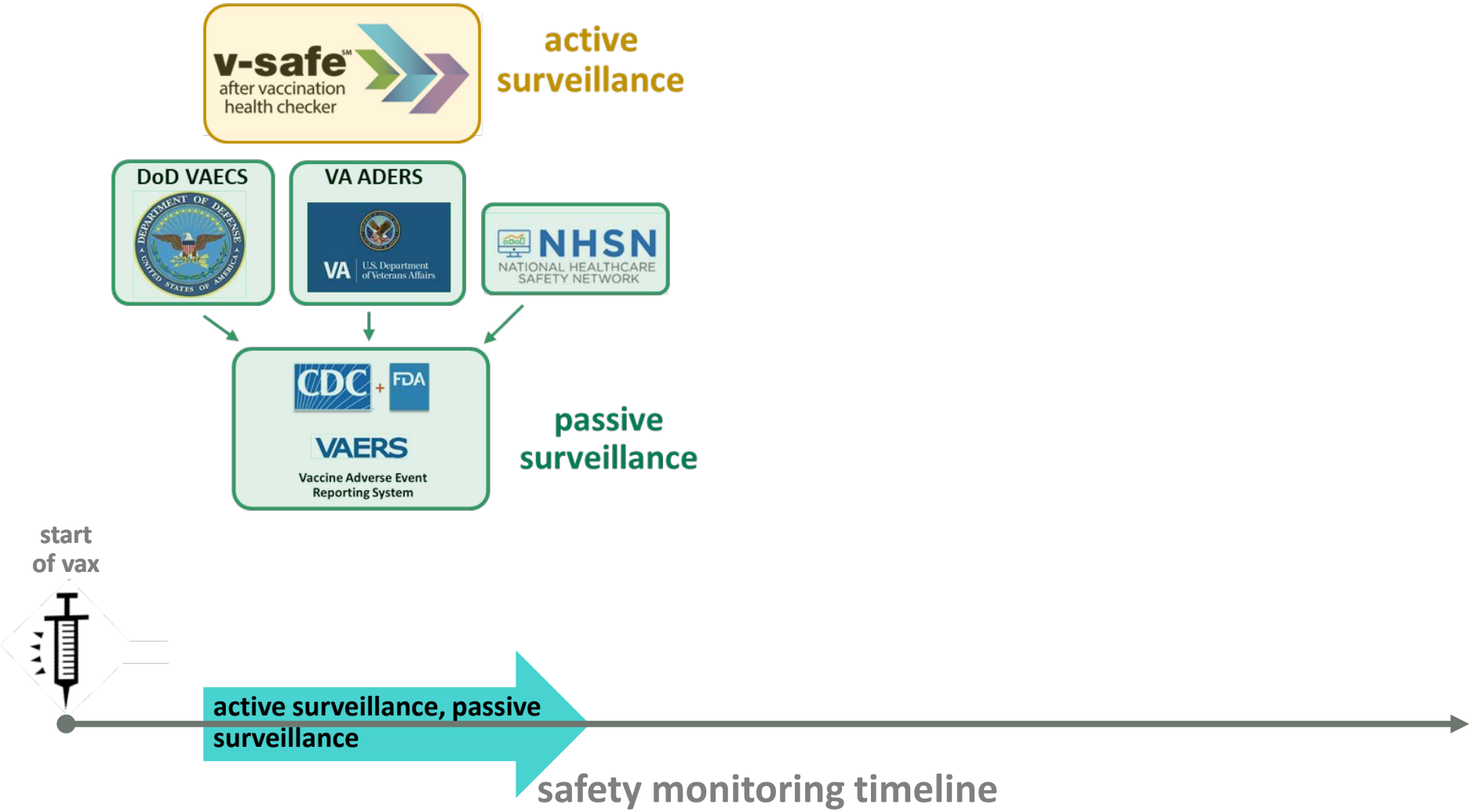
Safety monitoring timeline and covered populations in early vaccination

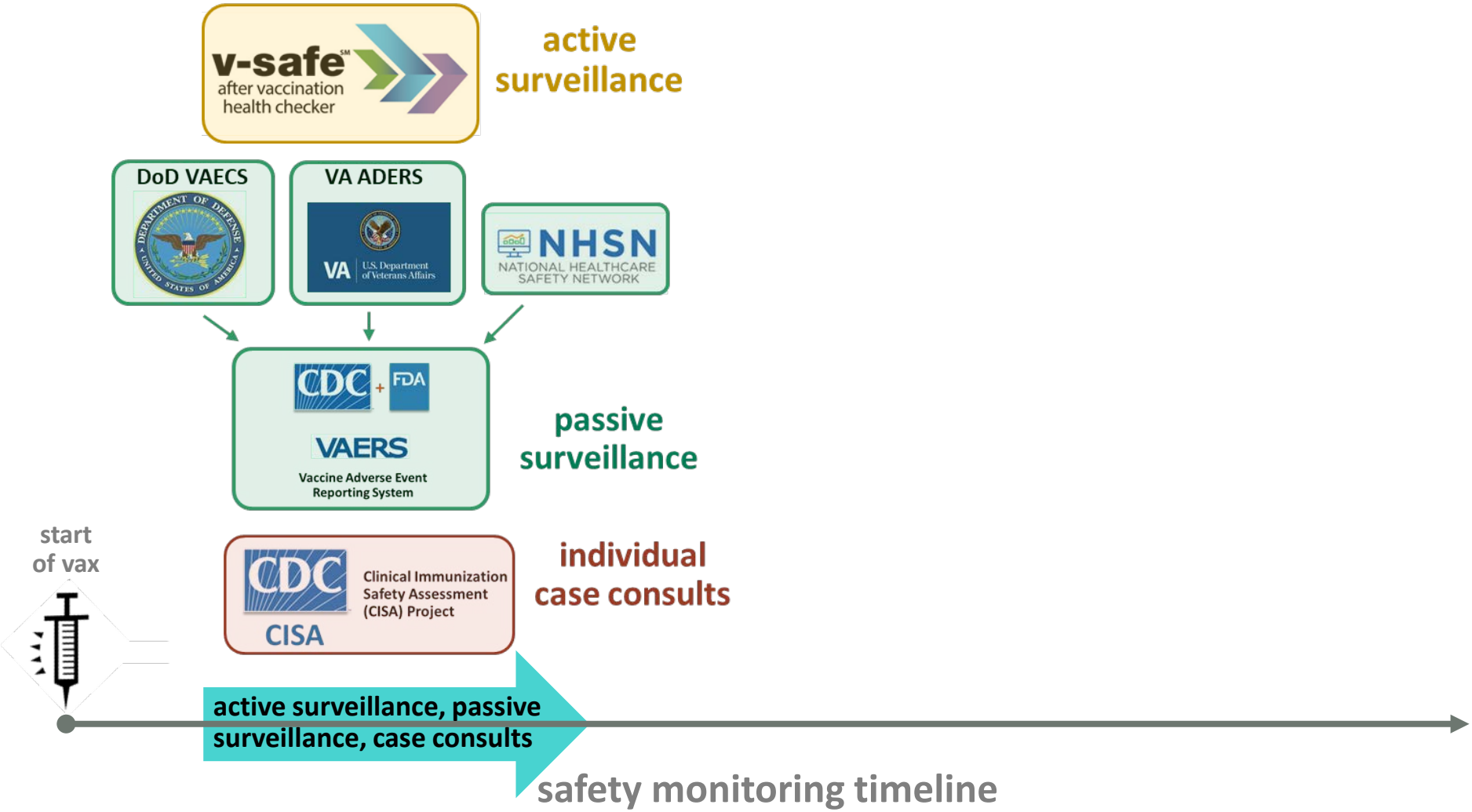
start
of vax

safety monitoring timeline

v-safe℠
after vaccination
health checker

active surveillance


v-safe
after vaccination health checker
active surveillance
DoD VAECS
VA ADERS
VA U.S. Department of Veterans Affairs
NHSN
NATIONAL HEALTHCARE SAFETY NETWORK
CDC + FDA
VAERS
Vaccine Adverse Event Reporting System
passive surveillance
start of vax
active surveillance, passive surveillance
safety monitoring timeline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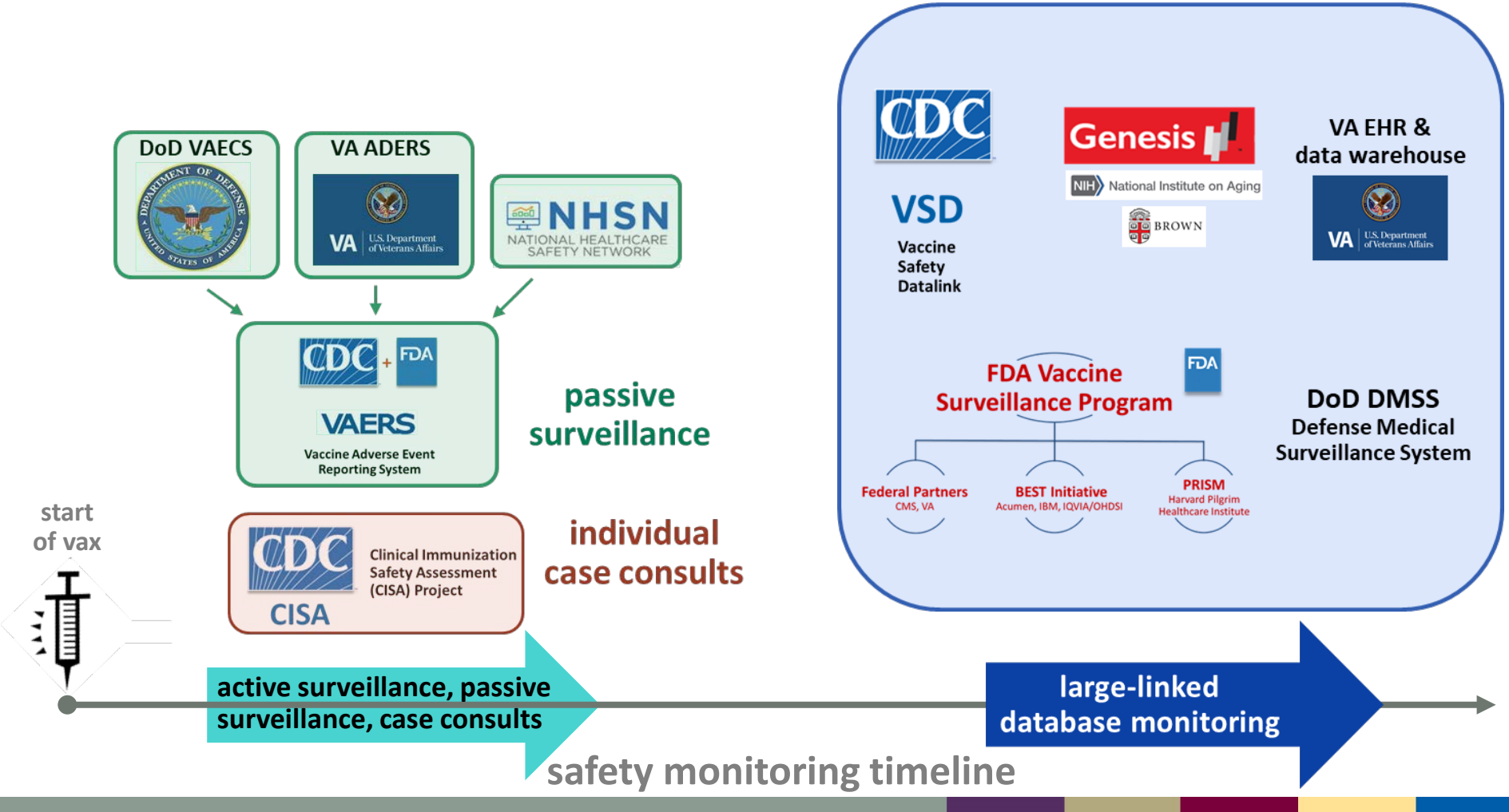
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CISA
individual case consults
CDC
VSD
Vaccine Safety Datalink
Genesis
NIH National Institute on Aging
BROWN
VA EHR & data warehouse
VA U.S. Department of Veterans Affairs
FDA Vaccine Surveillance Program
FDA
DoD DMSS
Defense Medical Surveillance System
Federal Partners
CMS, VA
BEST Initiative
Acumen, IBM, IQVIA/OHDSI
PRISM
Harvard Pilgrim Healthcare Institute
active surveillance, passive surveillance, case consults
large-linked database monitoring
safety monitoring timeline

Monitoring systems and populations

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

Routine systems

signal detection

VAERS* (CDC & FDA)

VAECS (DoD)

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

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

Vaccine Adverse Event Reporting System

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.

VAERS

VA Adverse Drug Event Reporting System (ADERS)

- Includes VA healthcare workers
- Includes 8,000 residents per day in VA LTCFs

reports to VAERS

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1070
Transmittal Sheet
May 15, 2020

ADVERSE DRUG EVENT REPORTING AND MONITORING

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes national policy for the reporting, monitoring, and surveillance of adverse drug events (ADEs) entered into VHA's voluntary ADE reporting system for observed adverse drug reactions (ADRs) and new ADEs at Department of Veterans Affairs (VA) medical facilities. ***NOTE***: *This directive also maintains national policy, which is co-managed by the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) on the reporting requirements of ADEs due to vaccines.*

4. POLICY

It is VHA policy that ADEs voluntarily reported to VA ADERS that meet the criteria of serious adverse drug events must be reported to FDA MedWatch. ADEs due to vaccines must be reported to VAERS. The ADEs and observed ADRs in subjects participating in VA clinical trials or research protocols must be reported into VA ADERS, when appropriate, to enhance Veteran safety. ***NOTE:*** *ADRs are the majority of the ADEs reported to the VA ADERS program, but for clarity, both ADE and ADR are noted here.*

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

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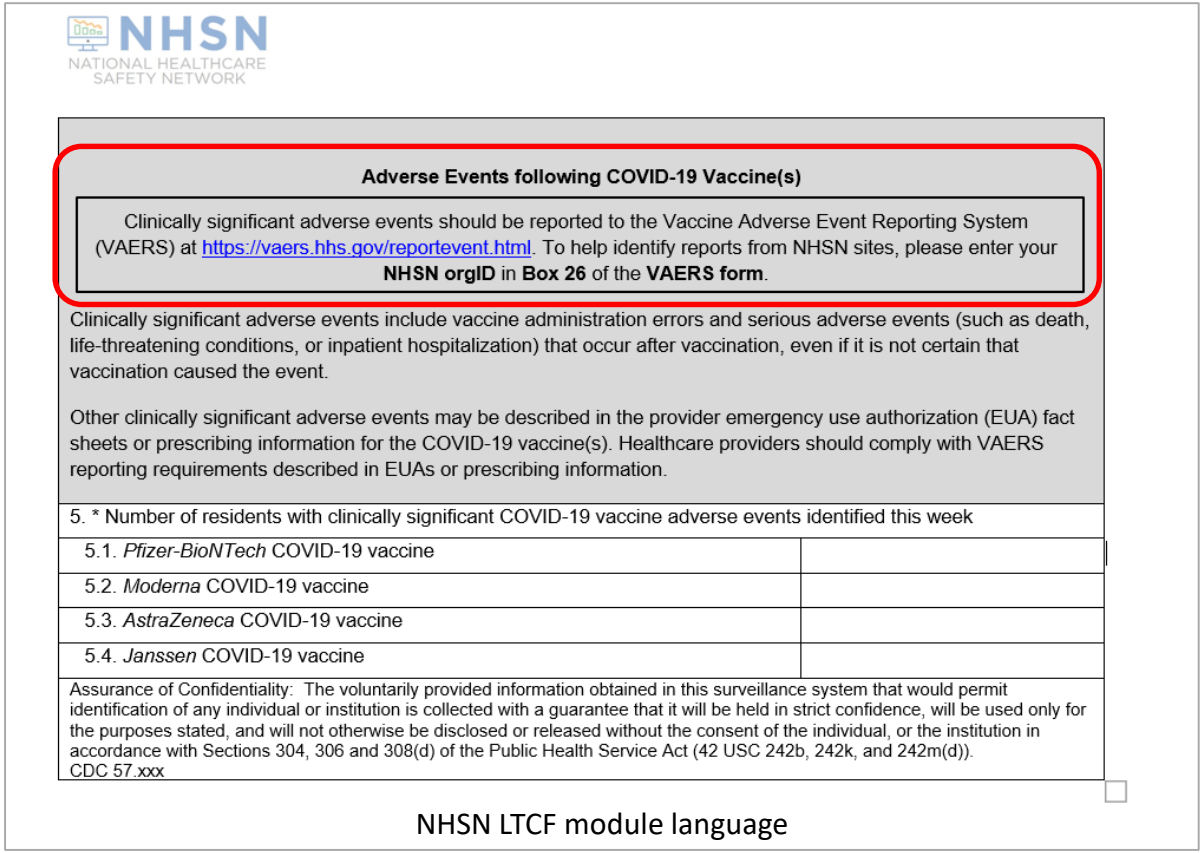
https://www.va.gov/vhapublications/publications.cfm?pub=1

National Healthcare Safety Network (NHSN)



NHSN
NATIONAL HEALTHCARE SAFETY NETWORK

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. 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

NHSN LTCF module language

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

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

Your role

COVID-19 vaccine safety gets stronger with your participation

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)

CDC-INFO
You have questions? We have answers.
CDC's national contact center and publications fulfillment system

Safety information resources

- https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Questions