COVID-19 Vaccination Plan

South Dakota Department of Health

March 23, 2021

We will begin in just a few moments. Thanks!

Information is current as of 03.23.2021

Not intended for press or for reporting purposes.
This is an **emerging, rapidly evolving situation**. Information in this presentation is current as of March 23, 2021. Please check the South Dakota Department of Health website for the most current information and guidance.

[COVID.sd.gov](https://COVID.sd.gov)
Agenda

Update on Vaccination – Tim Heath

SDIIS Updates – Brett Oakland

Training Update – Carol Chalcraft
Update on Vaccination
Doses Administered

Total Doses Administered: 350,149
State Allocation

- Manufacturer: Janssen - 4,876
- Manufacturer: Moderna - 168,459
- Manufacturer: Pfizer - 176,814

Total Persons Administered a Vaccine: 218,702
State Allocation

- Doses: Janssen - Series Complete - 4,876
- Doses: Moderna - 1 dose - 43,307
- Doses: Moderna - Series Complete - 62,576
- Doses: Pfizer - 1 dose - 39,088

Percent of State Population with at least 1 Dose: 37%
State & Federal Allocation

- Doses: 1 dose - 37.33%
- Doses: Series Complete - 23.36%

Not intended for press or for reporting purposes.
SD DOSES Ordered All Partners

Not intended for press or for reporting purposes.
SD DOSES Ordered All Partners

Not intended for press or for reporting purposes.
<table>
<thead>
<tr>
<th></th>
<th>Doses Ordered</th>
<th>Doses Shipped</th>
<th>Doses Delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>561,345</td>
<td>537,575</td>
<td>521,335</td>
</tr>
<tr>
<td>Jurisdiction</td>
<td>381,690</td>
<td>362,360</td>
<td>350,260</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>72,420</td>
<td>69,280</td>
<td>69,280</td>
</tr>
<tr>
<td>Federal Entity</td>
<td>107,235</td>
<td>105,935</td>
<td>101,795</td>
</tr>
</tbody>
</table>
# Federal Partners in SD (107,235 ordered)

<table>
<thead>
<tr>
<th></th>
<th>First Dose</th>
<th>Second Dose</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOP</td>
<td>100</td>
<td>97</td>
<td>197</td>
</tr>
<tr>
<td>VA</td>
<td>14,508</td>
<td>11,282</td>
<td>25,790</td>
</tr>
<tr>
<td>IHS</td>
<td>22,057</td>
<td>13,983</td>
<td>36,040</td>
</tr>
<tr>
<td>DOD</td>
<td>3,452</td>
<td>1,816</td>
<td>5,268</td>
</tr>
<tr>
<td>Totals</td>
<td>40,117</td>
<td>27,178</td>
<td>67,295</td>
</tr>
</tbody>
</table>

*Not intended for press or for reporting purposes.*
SD DOSES Administered All Partners

**Diagram:**

- **First Doses:**
  - Pfizer: 185,441
  - Moderna: 167,314
- **Second Doses:**
  - Pfizer: 115,865
  - Moderna: 105,391
- **Unknown Doses:**
  - Pfizer: 69,505
  - Moderna: 61,754
  - Janssen: 4,675
  - Vaccine Unknown: 13

*Not intended for press or for reporting purposes.*
Weekly 1st Doses Projected

Pfizer 11,700

Moderna 8,300

Janssen 1,000

Not intended for press or for reporting purposes.
Pfizer vaccine yields 6 doses

Moderna has 10 doses per vial

Janssen has 5 doses per vial

DO NOT POOL VACCINE FROM MULTIPLE VIALS

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<table>
<thead>
<tr>
<th>Priority Group</th>
<th>Eligible</th>
<th>Vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>19,265</td>
<td>23,431</td>
</tr>
<tr>
<td>1B</td>
<td>10,867</td>
<td>3,196</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vaccinated-not including CVS/Walgreens (5807)</td>
</tr>
<tr>
<td>1C</td>
<td>49,642</td>
<td>24,832</td>
</tr>
<tr>
<td>1D</td>
<td>265,561</td>
<td>123,389</td>
</tr>
<tr>
<td>1E</td>
<td>227,448</td>
<td>1,232</td>
</tr>
<tr>
<td>Phase</td>
<td>Population Group</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Everyone 16 years and older</td>
<td></td>
</tr>
<tr>
<td>1E</td>
<td>Includes public-facing workers in essential and critical infrastructure</td>
<td></td>
</tr>
<tr>
<td>1D</td>
<td>Fire service personnel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Funeral service workers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Teachers and other school/college staff</td>
<td></td>
</tr>
<tr>
<td>1C</td>
<td>Persons with underlying medical conditions under the age of 65</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Persons with high risk medical conditions in congregate settings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High risk patients - dialysis, post-transplant, and active cancer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High risk patients - elderly, high risk patients - diabetic, post-transplant, and active cancer</td>
<td></td>
</tr>
<tr>
<td>1B</td>
<td>Frontline healthcare workers and other healthcare workers (e.g., lab, dental, VS, emergency)</td>
<td></td>
</tr>
<tr>
<td>1A</td>
<td>Long-term care residents</td>
<td></td>
</tr>
</tbody>
</table>

**Estimated Vaccine Availability**

Note: The vaccine allocation and administration is handled by the VA - Veteran Affairs. The South Dakota Department of Health is following the recommendations of the Advisory Committee of Immunization Practices (ACIP) to guide vaccination efforts.
Underlying Medical Conditions

• Asthma (moderate-to-severe)

• Cancer

• Cerebrovascular Disease (affects blood vessels and blood supply to the brain)

• Chronic Kidney Disease

• COPD (Chronic Obstructive Pulmonary Disease)

• Cystic Fibrosis

• Diabetes Mellitus (type 1 and type 2)

• Down Syndrome

• Heart Conditions, such as Heart Failure, Coronary Artery Disease, or Cardiomyopathies
Underlying Medical Conditions

- Hypertension or High Blood Pressure
- Immunocompromised State (weakened immune system)
- Liver Disease
- Neurologic Conditions, such as Dementia
- Pregnancy
- Pulmonary Fibrosis (having damaged or scarred lung tissues)
- Severe Obesity (BMI ≥ 40 kg/m2)
- Sickle Cell Disease
- Thalassemia (a type of blood disorder)
Not intended for press or for reporting purposes.
Reduction in MMR containing doses administered for the Months of Jan and Feb 2019, 2020, 2021. SDIIS data

Not intended for press or for reporting purposes.
SDIIS Updates
South Dakota Immunization Information System (SDIIS)

• **SDIIS Training:** [https://doh.sd.gov/COVID/Vaccine/Providers.aspx](https://doh.sd.gov/COVID/Vaccine/Providers.aspx)

  - NEW look to the website!
  - SDIIS trainings:
    - DATA ENTRY TRAINING
    - VACCINE COORDINATOR TRAINING

*Not intended for press or for reporting purposes.*
South Dakota Immunization Information System (SDIIS)

• **SDIIS Training:** [https://doh.sd.gov/COVID/Vaccine/Providers.aspx](https://doh.sd.gov/COVID/Vaccine/Providers.aspx)
  - COVID-19 VACCINE DATA ENTRY TRAINING
  - **SDIIS User Application** – link available
  - SDIIS 1 - **Login and Settings** (updated 03/08/21)
  - SDIIS 2 - **Search for Patients and Edit Information** (updated 03/08/21)
  - SDIIS 3 - **Give Vaccine** (updated 03/08/21)

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South Dakota Immunization Information System (SDIIS)

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  - SDIIS 5 - [Inventory Management](https://doh.sd.gov/COVID/Vaccine/Providers.aspx) (updated 03/08/21)
  - SDIIS 5a - [Wastage Reconciliation](https://doh.sd.gov/COVID/Vaccine/Providers.aspx) (updated 03/08/21)
  - SDIIS 6 - [Vaccine Transfer](https://doh.sd.gov/COVID/Vaccine/Providers.aspx) (updated 03/08/21)
  - SDIIS 7 - [Patient Detail Report](https://doh.sd.gov/COVID/Vaccine/Providers.aspx) (01/05/21)

  - Vaccine Finder Training

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Not intended for press or for reporting purposes.
South Dakota Immunization Information System (SDIIS)

- **SDIIS User Access Application**
  - Used to request access for new users to SDIIS
  - Used for those who need view/enter data into the SDIIS
  - **NEW:** Section regarding vaccinator status

- Find on the Provider Education website
- [https://doh.sd.gov/COVID/Vaccine/Providers.aspx](https://doh.sd.gov/COVID/Vaccine/Providers.aspx)

- Vaccine Coordinators: you are welcome to submit a list of users who are no longer using their access account. We will remove the account from SDIIS.

Not intended for press or for reporting purposes.
South Dakota Immunization Information System (SDIIS)

• **Website:** sdiis.sd.gov
• **Locked Out**

- You have exceeded the maximum number of login attempts. Please contact your system administrator for assistance.
- Three (3) failed attempts to log in will result in LOCKOUT.
- Login information is case sensitive
- LOCKOUT will last for 15 minutes.
  - If you know your login information, try again in 15 minutes
  - If you forgot your login information, notify Immunization Registry Coordinator to reset password.
  - LOCKOUT will still continue for 15 minutes even after reset.

*Not intended for press or for reporting purposes.*
South Dakota Immunization Information System (SDIIS)

• **COVID-19 Vaccine Data Entry Reminders**
  - Use simple search parameters when searching for patients in SDIIS.
    - Use first initial and birthdate, or
    - Use first three letters of first and last name
    - Remember to consider given name vs. nickname – e.g. James vs. Jim
    - Spaces and punctuation = extra characters = different spelling
      - e.g. VAN, Mc, O’ – One word vs. multiple words
    - Please ensure that the **name and birthdate match** the person who is vaccinated. Check address and phone, anything to help confirm patient identity
    - Avoid creating duplicate records.
    - If multiple patient searches come up empty, then you may **ADD NEW PATIENT**
  
  - When selecting priority group, DO NOT select Priority Group “2nd Dose” if patient record does not already have one dose. If you know the patient received a first dose, but you don’t see it, then you don’t have the right record.
  - Ensure that the 2nd dose of COVID-19 vaccine is the same brand as the first dose

  - **ALL COVID-19 vaccine records in SDIIS must have an ADDRESS** (City, State, Zip, County)
  - **ALL COVID-19 vaccine records in SDIIS must include GENDER, RACE, ETHNICITY** (Hispanic Origin in SDIIS)

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Training Update

Not intended for press or for reporting purposes.
Check Out Newly Designed COVID-19 Vaccine Education and Resource Website

All information for healthcare providers is under one heading.

– it is now listed under “Healthcare Providers” and not “Vaccine”.

It will change some URL’s– the links are not broken—the URLs are just different.

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COVID-19 VACCINE INFORMATION FOR HEALTHCARE PROVIDERS

NOTE: Please check this web page twice weekly for updated material.

Provider ENROLLMENT  Vaccination REPORTING

Vaccinator TRAINING  Storage & Handling TRAINING  Data Entry TRAINING  Vaccine Coordinator TRAINING

Janssen | Moderna | Pfizer-BioNTech | Vaccine Finder | VAERS | V-Safe | Vaccine Guidance | SD Vaccination Plan

JANSSEN COVID-19 VACCINE

Janssen Website

Janssen Resources:
- Janssen Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older (CDC)
- Janssen Vaccine Preparation and Administration Summary (CDC)
- Janssen Storage and Handling Summary (CDC)
- EUA Janssen Vaccine Provider Fact Sheet

Contact Information:
- Email: injvaccineAE@its.inj.com
- Phone: 1-800-565-4006 (toll free) or 908-455-9922
- Fax: 215-293-9855

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COVID-19 VACCINE TRAINING FOR VACCINATORS

Attention: Please note changes to the COVID-19 vaccine education plan for newly enrolled providers or providers who haven't yet submitted a training attestation.

If your facility’s COVID-19 Vaccine Coordinator has submitted a training attestation previously, there is no need to complete the attestation process again but please make sure to stay up to date as information is changing rapidly.

Individual vaccinators and support personnel must complete all required training according to the tasks they will perform. Your facility’s COVID-19 Vaccine Coordinator will submit a training attestation form indicating all vaccinators and ancillary personnel have completed required training. This is necessary for your facility to receive COVID-19 vaccine.

There may be additional education requirements in the future as new vaccines and information become available. New required education will be noted with a red date in parenthesis - for example (03/18/21) - behind the new training link.

Additional resources you may find useful are listed on the vaccine provider page on our website. If you have questions, please feel free to contact Carol Chalcraft at 605-773-2664 or at carol.chalcraft@state.sd.us.

TRAINING FOR PERFORMING VACCINATIONS

Training for Vaccinators:
- **UPDATED!** COVID-19 Vaccine Training Modules (CDC)
- EUA Janssen Vaccine Provider Fact Sheet
- EUA Moderna Vaccine Provider Fact Sheet
- EUA Pfizer-BiONTech Vaccine Provider Fact Sheet
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (updated 03-03-21)

Summary Documents for Your Convenience:
- Janssen Prep and Administration Summary (CDC)
- Moderna Prep and Administration Summary (CDC)
- Pfizer-BioNTech Prep and Administration Summary (CDC)

Not intended for press or for reporting purposes.
COVID-19 VACCINE STORAGE & HANDLING TRAINING

Attention: Please note changes to the COVID-19 vaccine education plan for newly enrolled providers or providers who haven’t yet submitted a training attestation.

If your facility’s COVID-19 Vaccine Coordinator has submitted a training attestation previously, there is no need to complete the attestation process again but please make sure to stay up to date as information is changing rapidly.

Individual storage and handling personnel must complete all required training according to the tasks they will perform. Your facility’s COVID-19 Vaccine Coordinator will submit a training attestation form indicating all vaccinators and ancillary personnel have completed required training. This is necessary for your facility to receive COVID-19 vaccine.

There may be additional education requirements in the future as new vaccines and information become available. New required education will be noted with a red date in parenthesis - for example (03/18/21) - behind the new training link.

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STORAGE AND HANDLING VACCINE TRAINING

Storage and Handling Training:
- Vaccine Storage and Handling Toolkit (CDC)

Summary Documents for Your Convenience:
- Janssen Storage and Handling Summary (CDC)
- Moderna Storage and Handling Summary (CDC)
- Pfizer-BioNTech Storage and Handling Summary (CDC)
COVID-19 VACCINE DATA ENTRY TRAINING

Attention: Please note changes to the COVID-19 vaccine education plan for newly enrolled providers or providers who haven’t yet submitted a training atestation.

If your facility’s COVID-19 Vaccine Coordinator has submitted a training atestation previously, there is no need to complete the atestation process again but please make sure to stay up to date as information is changing rapidly.

Individual data entry personnel must complete all required training according to the tasks they will perform. Your facility’s COVID-19 Vaccine Coordinator will submit a training atestation form indicating all vaccinators and ancillary personnel have completed required training. This is necessary for your facility to receive COVID-19 vaccine.

There may be additional education requirements in the future as new vaccines and information become available. New required education will be noted with a red date in parenthesis - for example (03/16/21) - behind the new training link.

Additional resources you may find useful are listed on the vaccine provider page on our website. If you have questions, please feel free to contact Carol Chalcraft at 605-773-2664 or at carol.chalcraft@state.sd.us.

Please click the following link for an individual SDIIS user access account application.

- SDIIS User Application

REGISTRY DATA ENTRY TRAINING

Please view the following trainings if you are responsible for entering COVID-19 vaccination data into the South Dakota Immunization Information System (SDIIS).

- SDIIS 1 - Login and Settings (updated 03/08/21)
- SDIIS 2 - Search for Patients and Edit Information (updated 03/08/21)
- SDIIS 3 - Give Vaccine (updated 03/08/21)

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Additional resources you may find useful are listed on the vaccine provider page on our website. If you have questions, please feel free to contact Carol Chalcraft at 605-773-2664 or at carol.chalcraft@state.sd.us.

Please click the following link for an individual SDIIS user access account application.

- SDIIS User Application

**VACCINE COORDINATORS TRAINING**

Please view the following trainings if you are responsible for managing clinic COVID-19 vaccine inventories in the South Dakota Immunization Information System (SDIIS).

- **SDIIS 1 - Login and Settings** *(updated 03/08/21)*
- **SDIIS 2 - Search for Patients and Edit Information** *(updated 03/08/21)*
- **SDIIS 3 - Give Vaccine** *(updated 03/08/21)*
- **SDIIS 4 - Ordering and Receiving** *(updated 03/08/21)*
- **SDIIS 5 - Inventory Management** *(updated 03/08/21)*
  - **SDIIS 5a - Wastage Reconciliation** *(updated 03/08/21)*
- **SDIIS 6 - Vaccine Transfer** *(updated 03/08/21)*
- **SDIIS 7 - Patient Detail Report** *(01/05/21)*

- Vaccine Finder Training

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VAERS - VACCINE ADVERSE EVENT REPORTING SYSTEM

**VAERS Website** - 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 vaccination
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- **NEW!** 10 Things Healthcare Providers Need to Know About VAERS (CDC)

Contact VAERS at:
- **Phone:** 800-822-7967 | **Fax:** 877-721-0366 | **E-mail:** info@vaers.org
- For non-urgent concerns, email covid19vasesafety@cdc.gov. For emergencies relating to COVID-19 vaccine safety, call CDC Emergency Operations Center at **(770) 488-7100.**

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**VSAFE**

**V-safe website** - CDC is requesting that healthcare providers give patients a v-safe information sheet at the time of vaccination and encourage them to enroll and fill out the surveys when prompted to do so.

- **NEW!** V-safe COVID-19 Pregnancy Registry (CDC)
- **NEW!** FAQ's about V-safe (CDC)

Contact Information: Call 800-232-4636 | TTY 888-232-6348 | Open 24 hours, 7 days a week

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**GENERAL VACCINE GUIDANCE**

- **UPDATED OFTEN!** List of Updated CDC Guidance (CDC)
- Immunization Action Coalition COVID-19 website (IAC)
- Clinical Care Considerations for COVID-19 Vaccination (CDC)
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the U.S. ([updated 03-03-21](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/considerations.html))
- Clinical Questions about COVID-19: Questions and Answers (CDC)
- Vaccine Education Center at the Children’s Hospital of Philadelphia (CHOP)

**Long-Term Care Facility Guidance**

- **Long-Term Care Facilities Toolkit** - This toolkit from the CDC provides long-term care facility (LTCF) administrators and clinical leadership with information and resources to help build vaccine confidence among healthcare personnel (HCP) and residents.
- **NEW!** How Long-Term Care Facilities Can Help Monitor COVID-19 Vaccine Safety (CDC)
- **NEW!** Vaccine Safety Monitoring for Long-term Care Facility Staff. VAERS (YouTube)
- **NEW!** Vaccine Safety Monitoring for Long-term Care Facility Staff and Caregivers: v-safe (YouTube)
- FAQ’s about COVID-19 in LTCF (CDC)
- Post-Vaccination Considerations for Long-Term Care Residents (CDC)
- Guidance for Vaccinating Older Adults and People with Disabilities at Vaccination Clinics (CDC)

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COVID-19 vaccines are safe and effective.

More than 50 million people in the United States have received COVID-19 vaccines, and these vaccines have undergone the most intensive safety monitoring in U.S. history. This monitoring includes using both established and new safety monitoring systems to make sure that COVID-19 vaccines are safe.
Vaccine Confidence

What Does it Mean?

the trust that patients, their families, and providers have in:

• Recommended vaccines and
• Providers who administer vaccines
Factors that can influence decision making

• Cultural, Social, and Political factors, Individual, group and vaccine-specific factors.
• Some may want more information about COVID-19 vaccines,
• People may have previous experiences that affect their trust and confidence in the health system.

Take time to listen to their concerns and answer their questions

Not intended for press or for reporting purposes.
A message from CDC

Please ask healthcare professionals to encourage patients to get a COVID-19 vaccine as soon as one is available to them, and to enroll in v-safe.

“I strongly recommend you get vaccinated. The vaccine will help keep you from getting COVID-19, and if you do get COVID-19 after you get vaccinated, it may help keep you from getting seriously ill. Getting vaccinated yourself you may also help protect people around you.”

“I am encouraging everyone who receives a COVID-19 vaccine to enroll in v-safe. This is a smartphone tool you can use to tell CDC if you have any side effects after vaccination. If you report serious side effects, someone from CDC will call to follow up.”

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How does participation in v-safe makes a difference?

• Tells CDC if they have any side effects after a COVID-19 vaccine.

• Helps CDC monitor the safety of COVID-19 vaccines in near real time.

• Any serious health problems can be quickly investigated by CDC’s medical experts and scientists.

• [Vaccine Adverse Event Reporting System](https://www.vaers.hhs.gov) (VAERS) and the [Vaccine Safety Datalink (VSD)](https://www.cdc.gov/vaccines/safety-datalink/index.html), will also be used to evaluate vaccine safety.

*These systems are part the nation’s comprehensive approach to vaccine safety.*

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How long do v-safe check-ins last?

• First week after receiving vaccine, v-safe will send a text message daily to ask how you are doing.

• Once weekly check in messages for up to 5 weeks

• If second dose needed v-safe will provide new 6-week check-in process.

• Finally, you’ll receive check-ins 3, 6, and 12 months after your final dose of vaccine.

• The questions v-safe asks take less than 5 minutes to answer.

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How Long-Term Care Facilities Can Help Monitor COVID-19 Vaccine Safety

What LTCF administrators should know

Staff and residents of nursing homes and assisted living facilities are among the first groups to receive COVID-19 vaccines in the United States. As an administrator, your and your staff’s participation in vaccine safety monitoring is essential to ensuring the safety of COVID-19 vaccines. No safety concerns have been detected to date, but ongoing monitoring will continue.

CDC has expanded safety surveillance through new systems and additional information sources, as well as by scaling up existing safety monitoring systems. Here’s how you can help:

- Participate in v-safe after receiving a COVID-19 vaccine, and encourage staff and residents to also participate.
- Report resident adverse events to the Vaccine Adverse Event Reporting System (VAERS).

What is v-safe?

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Long Term Care Facilities
V-safe YouTube Videos

- Vaccine Safety Monitoring for Long-term Care Facility Staff and Caregivers: v-safe – YouTube

- Use v-safe to tell CDC how you’re feeling after COVID-19 vaccination – YouTube

- Share your COVID-19 vaccination experience with v-safe - YouTube

Not intended for press or for reporting purposes.
What is the v-safe COVID-19 Pregnancy Registry?

- The **v-safe** voluntary COVID-19 Vaccine Pregnancy Registry collects health information from people who receive COVID-19 vaccines shortly before or during pregnancy.

- COVID-19 vaccination **considerations for people who are pregnant or breastfeeding**.
New CDC Webpages on COVID-19 Vaccine Safety related to Pregnancy:

- COVID-19 Vaccine Monitoring Systems for Pregnant People | CDC
- V-safe COVID-19 Pregnancy Registry
Reporting Adverse Events Following COVID-19 Vaccination

The federal government takes all reports of adverse events following vaccination seriously. Both the U.S. Food and Drug Administration (FDA) and CDC are monitoring the safety of COVID-19 vaccines. CDC uses numerous vaccine safety monitoring systems, including VAERS, to monitor adverse events occurring after vaccination.
VAERS & COVID-19 vaccines: HCP’s must report:

- Vaccine administration errors, whether associated with an adverse event or not
- Serious adverse events (as defined by federal law), regardless of causality, including death
- a life-threatening event
- inpatient hospitalization or prolongation of existing hospitalization persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- congenital anomaly/birth defect
- an important medical event that, based on appropriate medical judgement, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS-C or MIS-A)
- Cases of COVID-19 that result in hospitalization or death

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Strengths and limitations to VAERS

VAERS is a robust, nationwide reporting system. It is subject to several important limitations.

**VAERS is not designed to assess cause and effect** so VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness.

Most reports to VAERS are voluntary, subject to biases.

Data from VAERS reports should always be interpreted with these limitations in mind.
What happens after a VAERS report is submitted?

• Submitter receive electronic confirmation the report was received.

• CDC and FDA experts monitor VAERS reports to identify adverse events that need to be studied further.

• Vaccine safety experts review all serious reports.
CDC follow-up on VAERS reports

To better understand the circumstances around a particular adverse event:

- VAERS staff from CDC and FDA request follow-up medical records on reports that are classified as “serious.”

- Serious reports include all adverse events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or congenital anomaly/birth defect.

- VAERS staff may also request follow-up medical records on adverse events of specific interest, like anaphylaxis.

Not intended for press or for reporting purposes.
What happens when a death is reported to VAERS

- CDC requests medical records about the person’s death, including an autopsy report (if available) from medical authorities, as well as a death certificate and other relevant medical records.

- Physicians in the CDC’s Immunization Safety Office review all reports of death following COVID-19 vaccination.

- CDC routinely analyzes death reports in a systematic way to detect unusual or unexpected patterns.

- VAERS scientists do not routinely reach out to the individuals or family members who submitted the report.

- There is no expectation of state or local health departments to conduct investigations into reported deaths after vaccination.

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How CDC reports potential vaccine safety issues

• CDC regularly presents COVID-19 vaccine safety updates to the Advisory Committee on Immunization Practices (ACIP).

• Publishes the latest vaccine safety findings in medical literature, including the *Morbidity and Mortality Weekly Report (MMWR)*.

• You can learn more about COVID-19 vaccine safety monitoring. Also see CDC’s clinical resources for COVID-19 vaccines.

• Additionally, VAERS data with patient identifiers removed are available to the public at HHS VAERS Data.

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If a patient inadvertently received a different brand of mRNA vaccine as a second dose, does it need to be repeated with the correct brand?

There are no data on the safety or efficacy of a mixed-brand mRNA vaccine schedule. For this reason, both doses in the series should be the same brand. However, if a recipient is inadvertently given a different brand of mRNA vaccine for the second dose, the CDC does not currently recommend that the patient receive a repeat dose of either product.

If a patient received a dose of mRNA COVID-19 vaccine, but cannot obtain a second dose of the original brand of mRNA vaccine, what should we do?

Once a series is initiated, the first choice is to complete the mRNA COVID-19 vaccine series with the same brand. In exceptional circumstances where the same brand cannot be obtained, the series may be completed with a different mRNA brand.

Only in situations where no second dose of mRNA COVID-19 vaccine may be given (due to availability or contraindication), a single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. Patients who receive the Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series.
Storage and Handling

Train staff on routine vaccine storage and handling and emergency Standing Operating Procedures (SOPs.)

Keep SOPs near vaccine storage units and make sure staff knows where to find them.

Storage and handling training should be completed:

• As part of new employee orientation

• Annually as a refresher for all staff involved in immunization and vaccine storage and handling activities

• Whenever new vaccines are added to inventory

• Whenever recommendations for storage and handling of vaccines are updated
Clinician Outreach and Communication Activity (COCA) Call/Webinar:

Last week, CDC held a Clinician Outreach and Communication Activity (COCA) Call/Webinar to provide an update on vaccine safety and vaccine effectiveness, as well as to provide guidance to healthcare providers about how to address patients’ questions and concerns. Please share this link to the recorded Call/Webinar and encourage clinicians to watch the recorded webinar:

“What Every Clinician Should Know about Vaccine Safety and Effectiveness and How to Address Patient Questions and Concerns.”
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