COVID VACCINE STORAGE AND HANDLING INCIDENT GUIDE

Use this process and guiding questions to aid in approaching any temperature excursions or storage and handling incidents identified through site visits, temperature log reviews, or reported by staff.

Please sign up for email alerts at the **COVID-19 Vaccination Provider Requirements and Support | CDC** website to be notified when updates are made or check the website often (below).

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

PROCESS GUIDELINE STEPS:

Vaccine Administration Errors: A **vaccine administration error** is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm.

Some examples include:

- **Coadministration**
- **Mixed Series**
- **Incorrect Site or route** - other than preferred site or alternate site
- **Age** - unauthorized age group
- **Dosage** - higher or lower than authorized dose volume
- **Storage and Handling** - dose administered after improper storage
- **Diluent (Pfizer only)** - incorrect diluent type or volume

For all vaccine administration errors:
Review CDC revaccination guide checklist:

- **COVID-19 Vaccine Administration Errors and Deviations (cdc.gov)**
- **Vaccine Adverse Event Reporting System (VAERS) (hhs.gov)**

A. Identify vaccine types on site

Which COVID vaccine presentations are in the impacted unit and in what quantities

1. If you have Childhood Vaccine Program (CVP) or adult vaccines from public supply, ensure those programs are notified.
   a. WAChildhoodVaccines@doh.wa.gov
   b. WAAdultVaccines@doh.wa.gov

B. Check WAIIS COVID vaccine ordering and/or transfer

- Remove any potentially impacted vaccine listed on the vaccine advertisement page in the IIS. **How to Search and Advertise Available COVID-19 Vaccine (wa.gov)**
- If it is determined vaccines are not viable, report wastage where appropriate for your facility (i.e. in Vaccine Finder, PrepMod, IIS, etc.) as required and dispose of properly. **How to Report Wastage of the COVID-19 Vaccine in IIS**

C. Temperature Excursion
* Identify timeframe

When was the incident discovered?

Follow the steps in the **COVID-19 vaccine temperature excursion guide (wa.gov)**

1. If any data is missing, what is the last day they have temperature data for?
2. Make sure to add previous excursion time to the current time **Vaccine Storage and Handling Toolkit (cdc.gov)**
3. If excursion occurred for over a week then record and REVIEW temperature data each week per the COVID-19 Vaccine Provider agreement **cdc-covid19-vaccination-program-provider-agreement-6d.pdf**

D. Identify the Cause:

Common causes of Storage and Handling Incidents include:

a. Staff error

b. Equipment error- If so, possibly need to repair or acquire new equipment. Some resource options:

https://scitechls.com/lab-maintenance/best-practices-for-maintaining-an-ultra-low-freezer/

http://www.dialrefrigeration.com/ultra-low-freezer-service.html

c. Probe is located too close to the front of the unit-move it to the center Intentional or Sabotage: If so, please see to the appropriate contacts for reporting. **Health Professions Complaint Process: Washington State Department of Health**

d. What are the causes, what are the lessons learned? What is the facility going to do differently moving forward to prevent this from happening again? Would your staff benefit from additional training and resources?

e. For more information on vaccine storage and handling:
   i. **https://www.cdc.gov/vaccines/recs/storage/default.htm**
   ii. **Centers for Disease Control and Prevention's (CDC) Storage and Handling Toolkit**
   iii. **Vaccine Management Plan (wa.gov)**
   iv. **Thermometer Requirements Guide (wa.gov)**
   v. **Off-Site Vaccination Clinic Guidelines (wa.gov)**

f. Contact DOH if any issues arise or further assistance is needed. Report all temperature excursions to the email **COVID.vaccine@doh.wa.gov** and call the manufacturers of each vaccine involved in the excursion to verify vaccine viability.

E. Revaccination Plan Efforts

Contact COVID.Vaccine@doh.wa.gov for guidance:

Some efforts should include these steps:

1. Contact patients by phone, letters, EMR to send notifications to revaccinate ASAP.
2. Re-enter records in IIS if previously invalidated. Invalidating **COVID-19 Doses in WAIIS- December 2021.pdf**
3. Patient notification should include communicating a date at which doses will be marked invalid in the IIS and what that could mean for patients.
4. Follow all three steps above to ensure full protection.
5. Contact DOH for Care-A-Van team revaccination or other support. **Care-a-Van | DOH (wa.gov)**
6. Prepare for potential media release and best practice is to have a communications contact person identified for inquires.

F. Fraud and Tampering

1. **Vaccine Fraud Report Inspector General: Enforcement Actions | HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG**
2. Office of Inspector General, U.S. Department of Health & Human Services:
   a. Submit a hotline complaint tips line for potential fraud, water, abuse, mismanagement in the U.S. Dept of Health and Human Services' programs **https://tips.oig.hhs.gov/**
   b. or 1-800-HHS-TIPS (1-800-447-8477) U.S. Department of Justice investigation and prosecution of wrongdoing related to the crisis.
   c. **Fake COVID-19 (Vaccination Record Card)**
   d. **Health Professions Complaint Process: Washington State Department of Health**

Washington State Department of Health

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For persons with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).