Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage

Prepared by CDC Vaccine Task Force, Distribution and Pharmacy

Purpose

The purpose of this document is to provide information on identifying, handling, disposing of, and reporting waste in COVID-19 vaccination programs. This information does not cover waste management for other Centers for Disease Control and Prevention (CDC) vaccination programs.

Scope

This document is intended to assist jurisdictions and planners in developing policies and procedures for handling COVID-19 vaccine waste. Jurisdictions should review and update existing vaccination plans to implement these practices.

Additionally, because of regulatory requirements, jurisdictions may need to develop standard operating procedures (SOPs) for medical waste disposal in accordance with state law and local practice.

Assumptions

- Jurisdictions and providers have completed comprehensive plans and SOPs for administration of COVID-19 vaccine.
- Jurisdictions, providers, and partners understand state laws and regulations for the disposal of medical waste.
- Jurisdictions, providers, and partners have implemented measures to reduce waste in COVID-19 vaccine storage, transport, handling, and administration in accordance with the CDC COVID-19 Vaccination Program Playbook and manufacturer's guidance.
- Waste is expected in any vaccination program. As the availability and administration of vaccine doses increase, the reported levels of waste will also increase. The reporting of wastage does not reflect negatively on a program.

Identifying Waste

Though every effort is made to reduce the volume of wastage in a vaccination program, sometimes it's necessary to identify doses as "waste" in order to ensure patient safety and vaccine effectiveness. There are many circumstances in which a vaccine dose might be identified as wasted, including when it is insufficient for use, spoiled, or expired. Below are examples of instances when vaccine may be identified as waste:

- COVID-19 vaccine temperatures must be monitored using a digital data logger (DDL) with vaccine storage units on site and with shipping containers during transport. Any time a temperature monitoring device indicates that the vials are out of temperature range, this is a temperature excursion and the vaccine may need to be identified as waste. This applies to temperature monitoring devices included in initial vaccine shipping containers (e.g., Pfizer-BioNTech requires the Controlant temperature monitoring device in its shipping containers). If a temperature excursion occurs, contact the manufacturer to determine if the vaccine can still be used. If the vaccine is determined to be non-viable, it must be declared as waste and

destroyed according to local regulations. Avoid temperature excursions by ensuring that appropriate temperature monitoring devices and storage units are available at on-site and off-site locations and during transport.

- Each COVID-19 vaccine product has differing times the vial remains valid once it is removed from the freezer or refrigerator and once a vial is punctured. If these times are exceeded, vials must be identified as "waste" and destroyed in accordance with local regulations. Careful planning helps to ensure only the necessary number of doses are prepared.
- Each Pfizer-BioNTech COVID-19 vaccine vial is labeled as containing 6 doses; however, this is dependent on the type of syringe used to extract the doses. If low dead-volume syringes are not available, the vial will contain 5 doses and the final sixth dose will fall short of the required 0.3 mL volume. In this case, the remaining unused sixth dose will be identified as waste. **Remaining vaccine from multiple vials cannot be combined to make a single dose.**
- COVID-19 vaccines have a limited shelf life. Any vial of vaccine that exceeds the shelf life indicated by the manufacturer should be disposed of as regulated medical waste in consultation with the manufacturer. Because COVID-19 vaccine expiration dates may change, always check with the manufacturer to determine expiration dates before disposing of the product.

Compromised Vaccine

Vials of COVID-19 vaccines (Pfizer-BioNTech, Moderna, and Janssen [Johnson & Johnson]) are monitored during shipping to ensure the temperature remains within a prescribed range.

Jurisdictions should ensure that providers know that they must open vaccine packages immediately, check the temperature monitor device, inspect the vaccine, compare the vaccine received with the vaccine product on the packing list, and store vaccine at the appropriate temperature. If the provider believes the vaccine shipment is compromised, temperature monitors are out of range, or monitors have not been activated, providers should place the vaccine in the proper vaccine storage unit at the recommended temperature and mark as "do not use" until they receive additional guidance. If there are concerns about temperature excursions during shipment, providers and/or awardee staff should also immediately contact the manufacturer (for the Pfizer-BioNTech vaccine) or McKesson (for centrally distributed Moderna and Johnson & Johnson Janssen vaccines) to report the excursion.

Providers are also required to monitor temperatures of vaccines stored on site. If there is a temperature excursion while vaccine is stored on site, the vaccine should be placed in/remain in the vaccine storage unit at the proper vaccine storage temperature and marked as "do not use." The provider or awardee staff should then contact the manufacturer for guidance about vaccine viability following the guidance in CDC's Vaccine Storage and Handling Toolkit.

If guidance from CDC or the manufacturer indicates the vaccine cannot be used, providers should remove the vials from storage and dispose of them in accordance with state law and local practice to avoid unintentional administration. Report the discarded vaccine as waste as directed in the "Reporting" section of this document.

Vaccine Disposal

The COVID-19 Vaccination Provider Agreement states that providers should dispose of COVID-19 vaccine waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste.

Reporting

Reporting of Wasted COVID-19 Vaccines

The COVID-19 Vaccination Program Agreement requires providers to report wastage information in VTrckS. To document wasted COVID-19 vaccines:

- Use the VTrckS ExIS Interface for Wastage* to report vaccine that cannot be administered because it is spoiled/wasted or expired.
- **For Pfizer vials, if a sixth dose cannot be extracted from a vial, it must be recorded as waste. Use the same VTrckS ExIS Interface for Wastage* and select "other" as the option for wastage code.**
- Jurisdictions should follow their routine processes for submitting wastage information to VTrckS by either uploading a wastage file using the ExIS interface in VTrckS or by direct entry into VTrckS.
- Federal agencies and pharmacies can use VPoP to generate wastage files to upload into VTrckS.
- Required fields for submitting wastage information into VTrckS include:
    a. Provider PIN,
    b. National Drug Code (NDC),
    c. number of doses wasted,
    d. wastage reason (this is required; use one of the wastage codes provided in VTrckS).

**Details about reporting vaccine wastage are available in the VTrckS Training Library (jurisdictions) and at the VTrckS Materials for Commercial and Federal Partners link in SAMS (federal agencies/pharmacy chains).*

Tips to Reduce Vaccine Waste

Share the following tips with providers to assist them in ensuring COVID-19 vaccine doses are not wasted:

- If a provider location has a few leftover reconstituted doses at the end of the day, consider using them to vaccinate easily accessible qualified individuals in the community interested in receiving vaccine. Remember, the federal government has advised COVID-19 vaccination providers that viable doses should never be wasted, even if it means vaccinating an individual outside the current groups prioritized for vaccination.
- If there are a substantial number of expiring vials, reach out to the jurisdiction's health department to discuss the situation and come up with a plan that is acceptable to both parties.
- Work with the jurisdiction in advance to determine thresholds for the number of vials in danger of being wasted that would trigger a call to the health department for guidance.
- Every effort should be made to coordinate the number of vials needed with the anticipated number of patients when preparing for daily clinics to help reduce over-thawing and transport (when necessary) of vaccine.

Important Contact Information

Pfizer Customer Service: (800) 666-7248 or cvgovernment@pfizer.com
Moderna Customer Service: 1-866-MOD-ERNA or 1-866-663-3762

Janssen Customer Service: 1-800-565-4008 or JSCCOVIDTEMPEXCURSION@its.jnj.com
McKesson Customer Service: 1-833-272-6634 or SNSSupport@McKesson.com

Resources

CDC COVID-19 Vaccination Program Playbook
COVID-19 Vaccine Storage and Handling Toolkit
2020 Vaccines For Children Program Operations Guide
CDC Centralized Vaccine Distribution Guide