COVID-19 Vaccine Ancillary Kit Syringe and Needle Deficiency Reporting

Prepared by CDC Vaccine Task Force – Distribution and Data

Purpose

The purpose of this document is to provide information on how to report deficiencies in syringes and needles contained in ancillary kits provided in support of federal COVID-19 vaccination efforts. This reporting process does not cover supplies procured outside the federal system.

Scope

The document is intended to assist jurisdictions and planners in developing policies and procedures for reporting ancillary kit deficiencies.

Assumptions

- Jurisdictions have completed comprehensive plans and standard operating procedures for receipt of ancillary kits for COVID-19 vaccine.
- Procedures have been implemented by jurisdictions and partners to ensure the ancillary kits are inspected upon receipt.

Reporting Processes

Vaccination providers are encouraged to report any issues with syringes and needles contained in the ancillary kits that are shipped with their federal vaccine orders. The reporting process has four steps to ensure enough information is gathered so trends in packaging and shipping problems can be identified. Please photograph any identified deficiencies to support the reported deficiencies and possible investigation (see sample photos provided).

1. Report deficiencies to McKesson directly; the customer service desk is charged with responding to problems and identifying trends.

   McKesson Customer Service
   Phone #: 833-272-6634
   Email: SNSSupport@McKesson.com
2. Report deficiencies to the state health department or clinic/hospital leadership, who may then contact the Operation Regional Liaison Officer. This helps to identify trends in problem equipment.
3. If a deficiency leads to an error or injury during vaccine administration, include the event in your report to the Vaccine Adverse Event Reporting System (VAERS). You can submit a VAERS report at https://vaers.hhs.gov/reportevent.html.
4. Because syringes and needles are classified as medical devices, providers and facilities are encouraged to report any deficiencies by completing US Food and Drug Administration (FDA) form 3500:

- Per the FDA guidelines: If the case report involves more than one (1) faulty medical device, please prepare a complete copy of Form FDA 3500 that identifies one device and attach an additional copy of Form FDA 3500, with only Section E filled in, for each additional device.
  - Link to FDA form 3500: https://www.accessdata.fda.gov/scripts/medwatch/
  - Information on how to file the report: https://www.fda.gov/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda

Be prepared to provide photos, lot number, order number, date ordered, and date received when filing a report.

Reportable Syringe and Needle Deficiencies

Sample Photos – Please photograph any deficiencies in syringes or other ancillary supplies.

Contaminants in Needle Hub	
Contaminants in syringe barrel	
Plunger seal wrong way	

Bent needle