CORHA Potential Medical Product-Related Infection/Outbreak: Assessment Questions

June 2019

Scope:

This document is intended to help establish a more systematic and consistent approach to assessing a medical product-related healthcare outbreak and response activities. This document presents information and questions for use by health departments, healthcare facilities, and other affected parties after detection/identification of possible medical product involvement in a cluster of infections or outbreak.

Background:

Medical products such as devices, drugs, and biologics, play crucial roles in medical diagnosis and treatment. They also present risks. For example, patient infections can occur when a medical product is contaminated during manufacturing, compounding, storage, preparation, use, or misuse.

Early detection of safety signals combined with robust investigation methods are needed to:

- Identify the presence of medical product infection risks
- Determine whether problems identified with a medical product extend beyond what is detected at a single facility or with a single patient
- Inform decision-making (e.g., whether to initiate a regulatory action)
- Support swift actions to identify cause, contain threat, and prevent harm
- Communicate findings, actions, and recommendations to stakeholders
- Apply findings and lessons learned to prevent recurrence, increase vigilance, and drive improvements

Information Gathering and Coordination:

The following includes areas of focus for asking specific questions about the situation, identifying epidemiology and medical products to aid in information gathering, and informing and supporting a coordinated and effective response. The parties and stakeholders involved should determine which questions need to be answered early on to make effective decisions, and what information should be collected prior to taking initial actions or making preliminary recommendations.

A. High-level questions about the situation

- What types of adverse events have been identified? How was the situation detected and brought to light? To whom were the concerns reported and when?
- What patient harm has occurred, such as infections, serious complications/injuries, deaths?
- What are the specific product concerns? What is the potential for further patient harm at this facility or elsewhere?
- Which parties are currently involved in this investigation? How can we best organize ourselves to assess the situation and make sure that any necessary controls or actions get implemented?
- Who are the stakeholders in the investigation, including medical product, epidemiologic/public health perspective, laboratory, and healthcare facility/providers perspectives? What are their roles and responsibilities and immediate next steps and timelines? Are there any stakeholders missing, and if so what are the plans to engage them?
- Have the key stakeholders agreed upon the primary objectives and roles/responsibilities for collecting and sharing information? What are the immediate next steps and deliverables?
- What information is needed to support timely decision-making (e.g., whether to institute a product recall)? What are the most effective ways of gathering and sharing this information?
- What are the investigation objectives/goals? Are the goals clear?
- Have short-term and long-term goals been identified and placed in a timetable?

- What steps are needed to assure a timely and coordinated response moving forward? Is there a need for an Incident Command System (ICS) structure at the local, state, or federal level?

B. Key Questions – Descriptive Epidemiology
- What is/are the primary clinical outcome(s) or presentation(s) of concern?
- Have specific pathogens been identified; if so, from what specimen source(s)?
- What is the magnitude of impact as currently understood in terms of the numbers of patients currently affected and the number/location of facilities that are reporting adverse events?
- Describe the setting, the primary affected patient population; does this include children, pregnant women, the elderly or immunocompromised?
- Is there a working hypothesis for root cause(s)?
- What other possible source(s) of contamination and possible route(s) of transmission require evaluation?
- Has a case definition been established? Are there criteria available to classify cases as suspect, possible, or confirmed?
- Is there a need for additional case finding (consider person-place-time) and others with potential exposure? How should this be organized and who will implement and lead this?
- What information needs to be collected as part of case finding activities (e.g., patient characteristics, healthcare exposures, laboratory findings)? Has there been a call for cases at the local, state (e.g., Health Alert Network, known as HAN), or national (e.g., Epidemic Information Exchange, called Epi-X) level? If so, what was the message and how was it delivered?
- Based on currently available information, is there a need to implement enhanced infection control practices within affected facilities?
- Have public health partners taken steps to ensure that patient isolates will be saved? Has any testing been performed on patient or product samples? If so, what were the dates of the testing and what are the preliminary findings? What types of testing are still needed to inform decision-making?
- Are unopened product samples available to be collected?

C. Product-related questions
- Does patient-level documentation (e.g., medical record) indicate the exact product name, the product manufacturer, product code, lot number, and expiration date? If not, are there receipts or invoices from the time of the treatment or procedure to assist in identifying these data?
- What is the exact product name? Is there a product code?
- Who is the manufacturer?
- What is the lot number and expiration date?
- Can you provide pictures of the product, including how it is packaged and stored?
- Can you provide pictures or Internet links for product brochures, instructions for use (IFU), other documentation?
- Can you describe how this product is used?
- Can you describe how this product is reprocessed?
- Can you describe how reprocessing information (such as biological indicators, chemical indicators, and physical parameters) is collected and monitored?
- If the product is reusable, has it been quarantined?
- Has a third-party service or repair organization been involved in the maintenance of the device?
- Has a MedWatch report been filed by the healthcare facility?

For **devices**,

  - What is the intended function of the device? (What is it FDA-cleared for?) What was it being used for?
  - Is the device still working properly? Has any malfunction or damage been identified?

- Can a Unique Device Identifier be located?
- Is the device part of a kit? Does the device have accessories? If so, what are the accessories? Are any of these components sterile, reprocessed or part of a kit?
- Is this a water-containing device or is water or ice used with the device? If so, is the water (or ice) sterile, filtered, or tap?
- Is the device intended to be sterile or non-sterile?
- Is this a single-use device?
- Does the device require reprocessing? If so, explain how, where, and by whom.
    - Is there a facility document that describes how reprocessing should occur?
- Does the device require maintenance? If so, what is the schedule? When was maintenance last performed? By whom? Was any damage identified?
- When was the device acquired and first put into use? What is the vendor's role?
- What is the current status (e.g., still in use, removed from service) of the device?
- What steps have been taken to evaluate use of the device with regards to:
    - Routine handling (including adherence with IFUs and any applicable infection control practices)?
    - Reprocessing and/or maintenance?

For **drugs**,

- What is/are the clinical indications/applications? How is/are the drugs in question being administered and for what purpose?
    - What is the drug FDA-approved for? What was it being used for?
    - Are the drugs labeled as sterile or non-sterile?
    - Were they supplied as part of a kit?
    - In what form were the drugs supplied (e.g., vial, bag, syringe)?
        - For manufactured drugs, provide the National Drug Code (NDC) and lot number, or, if applicable, the Investigational New Drug (IND) Application identifier.
        - For drugs supplied by a compounder, provide pharmacy information.
    - How were the drugs acquired (e.g., from a distributor, OTC, online)?
    - How are the drugs stored prior to being administered? Under what conditions?
    - How were the drugs manipulated between receipt at your facility and administration? Under what conditions? By whom?
    - Did multiple patients receive drug from a single-use medication container or from a multi-dose medication container? Explain.
    - If any of the drugs are controlled substances, how is security maintained?
    - Is the drug delivered in a multi-dose vial or container? If so, are the opened date and expiration date clearly labeled?
- What is the current status (e.g., still in use, removed from service) of the drug(s)?
- Is there any remaining drug available to be saved or tested?
    - Is this an unopened product (e.g., unaccessed vial) or has it been opened?
    - Does the saved drug product have the same lot number and expiration date as what the patient received?
- What steps have been taken to evaluate use of the drug with regards to:
    - Storage, handling, preparation and administration (including adherence with IFUs and applicable infection control practices or pharmacy standards)?
    - Evaluation of potential for abuse, mishandling or tampering?