CORHA Spring Meeting

CDRH/FDA

05/23/2018

Background

- Medical products, such as devices and drugs, play a crucial role in the treatment and diagnosis of illness and disease. They also present risks.
- These risks can manifest as patient infections when a medical product is contaminated or misused.
- Early detection of concerns, combined with robust investigation methods, are needed to:
  - confirm the presence of medical product infection risks,
  - determine whether there may be a wider problem that is not limited to single institution, and
  - inform decision making (e.g., whether to consider a product recall)

Ambitions

FDA seeks to assist partners with potential contaminations and outbreaks. When foundational pieces of information are provided, we can begin assisting. Recognizing that these investigations are shared responsibility, we propose a draft questions to aid in the approach to the investigative process. This information is intended to establish a more systematic and consistent approach to medical product-related healthcare outbreak response.

Purpose

To receive feedback from public health response partners as to whether this information would be of benefit and what information should be included.

Information (Essential and important)-Device specific

- What is the exact device name?
- Who is the manufacturer?
- What is the lot number and expiration date?
- What is the intended function of the device?
- Is this a water-containing device or is water or ice used with the device? Is the water sterile, filtered, or tap?
- Does the device have accessories? If so, what are the accessories?
- Is the device and the accessory:
  - sterile or non-sterile?
  - reprocessed?
  - part of a kit?

Information-Epidemiology

- **How was this situation first detected?**
  - Did this involve routine disease surveillance, a cluster of cases, savvy clinicians, etc.?
- **Is there a working hypothesis? What is the product concern?**
  - What possible contamination source(s) and transmission route(s) are suspected?
- **How many cases are known? Has a case definition been established?**
  - Case count, timeframe, patient demographics/susceptibility, types of facilities/care
  - Pathogen, infection type, specimen source (e.g., blood, respiratory, urine, stool)
- **What is the patient impact? Any adverse events (injury, death, etc.)?**
  - What is the magnitude of impact (number of patients, localized vs. national)?
- **What patient isolates and product samples are available?**
  - What has been tested by the facility, public health laboratory, or federal partners?
- **Have states contacted other facilities or issued local or national alerts?**

Feedback

- Would this information help with the investigative process when a medical product is involved?
- In addition to epi and key medical product information, what other information should be included?

Thank you! And, more to come…