SUPPLEMENT A

Medical Product Investigations

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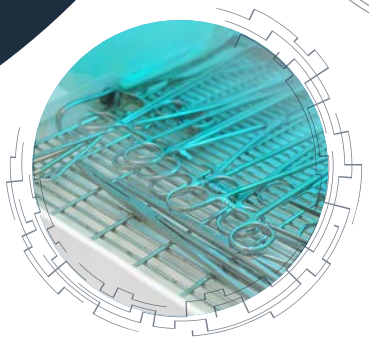
Medical Product Investigations



A.0 Introduction

Healthcare-associated infections (HAIs) and outbreaks can be caused by the use of contaminated medical products. These medical products include devices (also known as instruments or equipment) and drugs (also known as medications), as well as biological products, nutrition products, and patient care items.

The general principles outlined in the *CORHA Principles and Practices* can be employed when responding to events related to medical product contamination. These investigations often involve infection control assessments and require the active coordination of investigation partners across multiple jurisdictions. Readers are encouraged to familiarize themselves with the full *Principles and Practices* text, as details addressed in other chapters or supplements are not repeated here.

Supplement A addresses some unique challenges associated with medical product contamination events. One challenge is difficulty with identifying connections between one or more patient infections and specific medical products. Often, patient records lack documentation of medical product use. In addition, there are limitations to investigators' ability to identify or obtain potentially contaminated products, such as when suspected items have been used and replaced by new item lots or product types. Moreover, the source of contamination—whether user error or a manufacturing deficit—can be difficult to distinguish, even when there is a clear association with medical product use; this is particularly evident at early stages of an outbreak response. As a result, this type of investigation is often marked by tensions and a sense of urgency, as investigators seek to determine whether the outbreak is localized and contained, or represents a product safety issue with broad potential for harm.

A.1 Background: Intrinsic and Extrinsic Contamination

Contamination of medical products can result from errors that occur during their production, manufacturing, or packaging, as well as during their transportation or storage. Contamination can also occur during the preparation and use of medical products at the point of patient care, and may even result from intentional misuse or tampering.

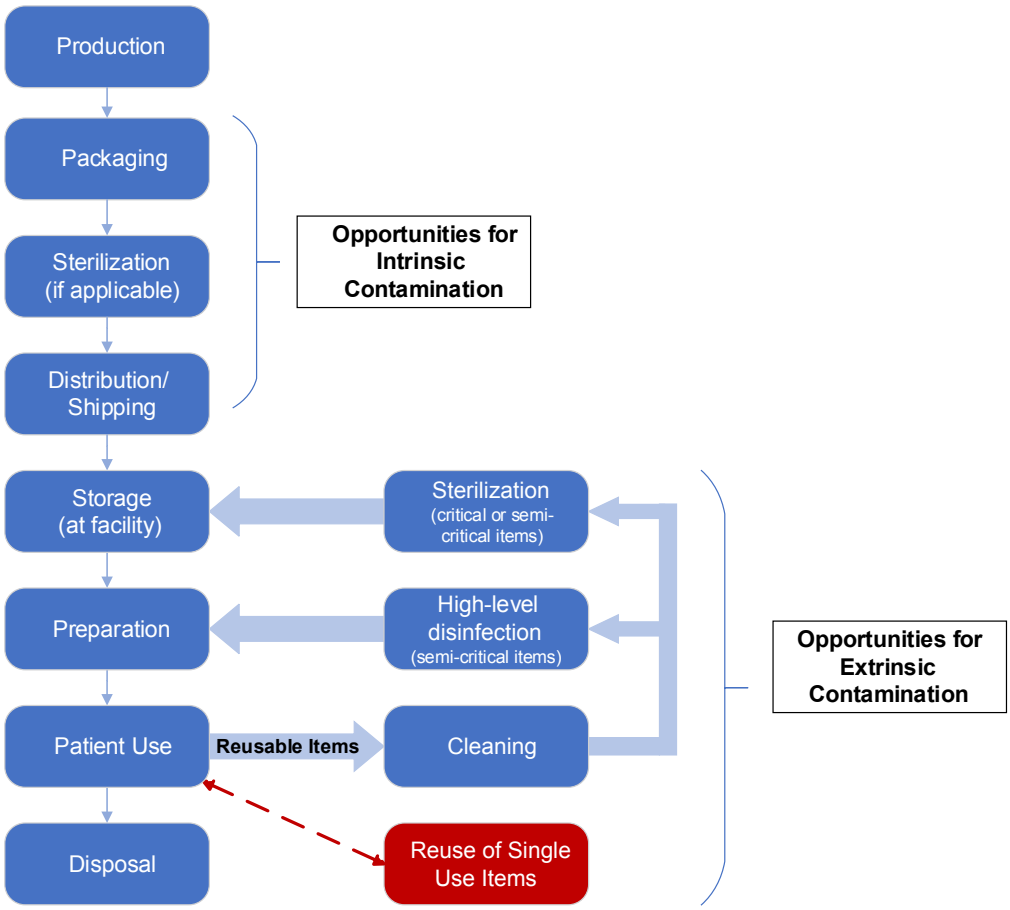
Investigators find it helpful to distinguish two broad categories of medical product contamination. **Intrinsic contamination** occurs before the product arrives at its point of use in a healthcare facility. In addition to traditional manufactured products, compounded

pharmaceuticals are also included in this category when produced outside (upstream) of the receiving healthcare facility. **Extrinsic contamination**, on the other hand, results from errors made during the product's storage, preparation, and use in a healthcare facility. This can include inappropriate reuse of single-use items and deficiencies in reprocessing of reusable items. As summarized in Figure A.1, there are many points at which a medical product could become contaminated; assessments related to root cause analysis should consider the possibilities of both intrinsic and extrinsic contamination events.

Intrinsic contamination events can result in widespread outbreaks. They may affect patients in multiple states or regions of the US or may even be global in scope. Notable incidents of intrinsic medical product contamination have included the presence of *Exserohilum rostratum* in methylprednisolone acetate from a compounding pharmacy,[1] *Burkholderia cepacia* complex in oral docusate,[2] *Serratia marcescens* in prefilled heparin flushes,[3] and *Mycobacterium chimaera* in heater-cooler devices.[4] Depending on gaps in the manufacturing process, contaminated products may include parts of lots or entire lots. All known lots of the specific product may be contaminated or only lots produced in a certain facility during a certain time period or lots including certain raw materials.

Many examples of extrinsic contamination events are presented in *Chapter 2, table 2.2*. Notable incidents have stemmed from unsafe injection practices and inadequate reprocessing of endoscopes. Unsafe injection practices,

Figure A.1 | Opportunities for Intrinsic Contamination or Extrinsic Contamination, from Production through Patient Use and Reprocessing



including reuse of syringes or single-dose vials and preparation of parenteral medications in contaminated environments (e.g., near sinks) have caused numerous outbreaks of hepatitis B and hepatitis C viruses as well as outbreaks of bacterial and fungal pathogens. While extrinsic contamination often results from errors committed by healthcare personnel, it can also reflect problems with a product's design or instructions for use, which predispose the product to become contaminated at the point of use. For example, Carbapenem-resistant Enterobacterales (CRE) transmission has been associated with duodenoscopes that were reprocessed in accordance with approved instructions; in this instance, a protocols investigation revealed that the intricate design of the particular endoscope product made it very difficult to clean and disinfect.[5]

A.2 Detection and Reporting

Many different pathogens or medical products can be involved in medical product contamination events. Table A.1 illustrates examples of organ systems, products, and pathogens that can be encountered together in association with transmission events or outbreaks stemming from medical product contamination. The examples shown may span both intrinsic and extrinsic contamination events. In addition, pathogens introduced through a contaminated medical product to one organ system may be detected in another organ system due to subsequent spread. Nonetheless, this table may be a helpful aid in recognizing and evaluating possible causes of product-related transmission relative to clinical illness and other factors. Practitioners should maintain a high index of suspicion for medical product involvement and bear in mind that individuals who are immunocompromised or receive frequent medical procedures may be at greater risk for infection.

Healthcare facilities and providers should report infections and potential outbreaks suspected to be linked to medical products. Product concerns should be conveyed early. For example, a single patient infection may warrant notification to public health authorities if there is a severe outcome (e.g., hospitalization or death) and the infection type suggests a route of infection possibly related to a medical product (see Table A.1). Identifying and reporting associations between HAIs and medical products requires active efforts to identify relevant patient exposures. Reports can be directed to public health jurisdictions and regulatory agencies (including via the US Food and Drug Administration's [FDA's] MedWatch) as well as to manufacturers.

Public health authorities should consider the possible role of medical products when investigating healthcare-associated infections (HAIs), even if this concern has not been raised by the facility. Due to the potential for widespread harm, public health agencies should engage state, local, and federal partners early in investigations of outbreaks that could be related to intrinsically contaminated medical products.

Table A.1 | Groupings of Organ Systems and Infection Types with Contaminated Medical Products and Pathogens

ORGAN SYSTEM	CONTAMINATED MEDICAL PRODUCT	EXAMPLE PATHOGENS, BY SOURCE
Bloodstream Infections	• Medications or products administered intravenously • Intravenous lines, ports, or tubing • Wound care products or dressings	**Environmental** • Nontuberculous mycobacteria • *Serratia marcescens* • *Stenotrophomonas maltophilia* • *Burkholderia cenocepacia* **Skin flora** • *Staphylococcus species*

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Table A.1 | Groupings of Organ Systems and Infection Types with Contaminated Medical Products and Pathogens

ORGAN SYSTEM	CONTAMINATED MEDICAL PRODUCT	EXAMPLE PATHOGENS, BY SOURCE
Skin and Wound Infections	• Skin care cleaning products or dressings (e.g., alcohol prep pads and bandages) • Wound care products or dressings	**Skin flora** • *Staphylococcus species* **Environmental** • *Bacillus cereus* • *Aspergillus*
Gastrointestinal Infection/ Colonization	• Duodenoscopes, endoscopes, etc. • Ingested products (e.g., medications, infant formula, and other nutritional products) • Products administered through feeding tubes (e.g., nasogastric tubes or percutaneous endoscopic gastrostomy (PEG) tubes)	**Environmental (e.g., soil, water, and gastrointestinal flora)** • *Escherichia coli (E. coli)* • *Carbapenem- or vancomycin-resistant Enterobacterales (CRE or VRE)* • *Cronobacter* • *Listeria monocytogenes* • *Burkholderia cepacia*
Neurologic Infections	• Medications or products used during lumbar punctures • Medications or products administered through patches, ports, implants, or catheters with delivery into the central or peripheral nervous system • Medications or products administered ocularly (e.g., drops, implants, ophthalmic procedures, and drains)	**Environmental** • Fungal species • Nontuberculous mycobacteria
Respiratory Infections	• Ventilators, intubation sequence products • Aerosolization and nebulizer products	**Environmental (e.g., soil and water)** • *Pseudomonas aeruginosa* • *Stenotrophomonas maltophilia*
Genitourinary Infections	• Urinary catheters • Ureteroscopes or devices used for treatment or diagnosis of genitourinary conditions	**Environmental (e.g., soil, water, gastrointestinal flora)** • *Pseudomonas aeruginosa* • *E. coli* • CRE or VRE

A.3 Investigation

Investigations of healthcare-associated outbreaks due to medical product contamination can be approached using many of the principles described elsewhere in the *CORHA Principles and Practices.* The remainder of Supplement A focuses primarily on investigation procedures for outbreaks that potentially involve drugs and devices, with an emphasis on intrinsic product contamination. For resources specific to blood, organ, and tissue contamination, see Box A.1.

Multiple avenues of investigation may need to be pursued simultaneously. Early in an investigation, working hypotheses related to both extrinsic and intrinsic contamination may be in play; initial investigation activities may have to cover both possibilities. These activities could include a targeted assessment of relevant healthcare delivery practices and rapid correction of any identified gaps in infection control procedures. At the same time, it might also be helpful to sequester implicated products (both opened/unopened) and collect information such as photos, product or medical lot numbers or identifiers, manufacturer instructions for use (IFUs), facility protocols, purchase orders, and other records related to the implicated product(s). See Box A.2 for a list of assessment questions and considerations for information collection when organizing a medical product-related investigation.

As outlined in Table A.1, previously observed patterns and associations involving specific medical products, organ systems, pathogens, and infection types are useful to consider when initiating an investigation. To help distinguish intrinsic from extrinsic contamination, consider two hallmarks of intrinsic contamination. First, intrinsic contamination events are not readily explained by infection control practice deficiencies. Second, intrinsic contamination events are marked by the appearance of additional outbreak signals. Reporting product contamination concerns to the United States Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) can help "connect the dots." In some cases, reporting can be supplemented by organizing an active outreach process (e.g., via CDC/Epi-X or clinician listservs) to determine whether similar concerns have been identified elsewhere.

Entities with detailed knowledge of the possible modes of contamination of medical products at the production, distribution, storage, and use stages should be engaged early and can include the following:

- Manufacturers
- Distributers
- Licensure boards of pharmacy, medicine, nursing, etc.
- State and federal public health agencies (e.g., CDC and FDA)
- Laboratory partners
- Infection prevention personnel
- Healthcare organizations

Collaboration and communication, particularly among public health agencies, healthcare facilities, and regulatory agencies, serve to increase awareness, evaluate patterns and processes at a broader scale, and confirm widespread intrinsic contamination events as early as possible. Additional communication activities, including engaging impacted patients, can be performed using guidance outlined in *Chapter 8, Notification and Communication.*

Unique product testing considerations attend medical product investigations. For example, suspected products or devices should be sequestered (i.e., cease their use but do not discard them). As outlined in *Chapter 6, Laboratory Best Practices,* laboratories have differing capabilities; public health and regulatory partners can often facilitate product or environmental testing support in a manner that is consistent with requirements pertaining to documentation and chain of custody for sample transport.

A.4 Concluding a Medical Product Investigation

Chapter 5, Investigation and Control, describes important steps for concluding an investigation, which also apply to those involving medical product contamination. These include the following:

- Implementing control measures (e.g., infection control practices, product recall, and/or product removal)
- Ongoing surveillance and detection protocols depending on product/device distribution
- Monitoring until no additional cases are detected

In addition to the aforementioned steps, medical product contamination investigations may also involve some unique opportunities for implementing lessons learned. These can include process improvement and quality assurance efforts at the manufacturing, distribution, or facility level to detect and prevent future events. These collaborative processes can be important not just for stakeholders involved in a specific event but also for professional organizations and regulatory authorities at the national level, ultimately leading to improved patient safety and outcomes.

A.5 Summary

Medical products play crucial roles in medical diagnosis and treatment in health care settings. They also can present infection risks to patients. Early detection of medical product safety signals, combined with robust investigations, are needed to do the following:

- Evaluate and confirm the presence of a medical product infection risk
- Inform decision-making, e.g., whether to initiate product removal or regulatory action

Additional "Keys to Success" related to medical product investigations have been summarized in Box A.3. Working together, public health agencies, healthcare facilities, regulatory authorities, and other medical product investigation partners can support swift actions to identify causes of infection, contain threats, and prevent harm.

References

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3. West K, Janelle S, Schutz K, et al. Outbreak of Serratia marcescens bacteremia in pediatric patients epidemiologically linked to pre-filled heparin flushes. *Infect Control Hosp Epidemiol*. 2019;40(10):1201–1202. doi: 10.1017/ice.2019.196
4. Perkins KM, Lawsin A, Hasan NA, et al. Notes from the Field. Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States. MMWR *Morb Mortal Wkly* Rep 2016;65:1117–1118. doi: http://dx.doi.org/10.15585/mmwr.mm6540a6
5. Humphries RM, Yang S, Kim S, Muthusamy VR, Russell D, Trout AM, Zaroda T, Cheng QJ, Aldrovandi G, Uslan DZ, Hemarajata P. Duodenoscope-related outbreak of a carbapenem-resistant Klebsiella pneumoniae identified using advanced molecular diagnostics. *Clin Infect Dis*. 2017 Oct 1;65(7):1159-66.

CORHA Keys to Success

Medical Product Investigations

1. Maintain a high index of suspicion for medical product contamination and report concerns to appropriate public health and regulatory agencies (including FDA MedWatch), as well as to manufacturers.
2. Consider both intrinsic and extrinsic contamination opportunities when formulating initial investigation steps and control actions.
3. Include individuals with specific product or device manufacturing expertise and engage state and federal support resources early in an investigation.
4. Communicate investigation findings to investigation partners, affected patients, and healthcare providers to support improved outcomes.
5. Leverage what lessons are learned to help detect and prevent future events (e.g., inform process improvement and quality assurance efforts at the manufacturing, distribution, or facility level).

Box A.1 | Resources for Investigations of Blood, Biologic, Tissue, and Organ Contamination

Centers for Disease Control and Prevention (CDC) — Blood Safety
https://www.cdc.gov/blood-safety/about/index.html

Centers for Disease Control and Prevention (CDC) — National Healthcare Safety Network — Biovigilance Component
https://www.cdc.gov/nhsn/biovigilance/index.html

Food and Drug Administration (FDA) — Biologics
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics

Food and Drug Administration (FDA) — Tissue
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/tissue-safety-availability

Centers for Disease Control and Prevention (CDC) — Clinical Guidance for Transplant Safety
https://www.cdc.gov/transplant-safety/hcp/clinical-guidance/index.html

Health Resources and Services Administration (HRSA) — Organ Procurement & Transplantation Network (OPTN)
https://optn.transplant.hrsa.gov/professionals/by-topic/patient-safety/

Box A.2 | CORHA Potential Medical Product–Related Outbreak: Assessment Questions

This tool is also available on the CORHA website (link)

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?

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?

Box A.2 | CORHA Potential Medical Product–Related Outbreak: Assessment Questions

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), and 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?

Box A.2 | CORHA Potential Medical Product–Related Outbreak: Assessment Questions

- 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?

For the most up-to-date version please visit: https://www.corha.org/resources/corha-interim-potential-medical-product-related-infection-outbreak-assessment-questions/

Appendix A: Key Resources & Additional Reading

Medical Product Investigations – Key Resources

1. Dolan SA, Arias KM, Felizardo G, et al. APIC position paper: Safe injection, infusion, and medication vial practices in health care. *Am J Infect Control*. 2016;44(7):750–757. doi: 10.1016/j.ajic.2016.02.033.
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Contaminated Medical Products – Selected Examples

Endoscopes

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Heater-Cooler Devices

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Appendix A: Key Resources & Additional Reading

Medication/Product

1. Dolan SA, Littlehorn C, Glodé MP, Det al. Association of Bacillus cereus infection with contaminated alcohol prep pads. *Infect Control Hosp Epidemiol*. 2012;33(7):666–671. doi:10.1086/666334
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