SUPPLEMENT B

Infection Control Breach Investigations

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The Council for Outbreak Response: Healthcare-Associated
Infections and Antimicrobial-Resistant Pathogens

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B.0   Introduction

Outbreak investigation has been included within the scope of public health agencies' missions since their inception, and deficits in infection control are frequently identified during healthcare outbreaks. In contrast, the investigation of isolated reports of potentially serious infection control breaches, in the absence of known patient infections, represents relatively new territory. Increasingly, state and local public health program staff find themselves investigating infection control breaches to determine the risk of communicable disease transmission and to identify individuals who may have been exposed but have not yet developed or been diagnosed with infection or colonization.

A public health agency may receive an infection control breach report from healthcare providers or facilities, patients, or accrediting organizations. In recent years, the Centers for Medicare & Medicaid Service (CMS) has mandated reporting of infection control breaches discovered during accreditation or certification survey visits to public health agencies, increasing the ability of disease control epidemiologists to recognize and respond to infection control breaches. Examples of the types of breaches that are reported include the reuse of single-use devices and the failure to follow requirements for reprocessing reusable medical equipment. Public health

authorities should be prepared to appropriately investigate such reports and to provide guidance and support to implicated health care providers or facilities so that follow-up actions can be implemented.

Investigation of serious infection control breaches often involves components and steps similar to those of outbreak investigation, and thus the principles discussed in *Chapter 5, Investigation and Control*, are applicable to the investigation of isolated infection control breach reports as well. A key aspect in the response to an infection control breach is consideration of patient notification (i.e., informing affected individuals about an outbreak or breach). Triggers for notifying patients include situations in which patients 1) have experienced harm, 2) may be able to provide information useful in the identification and or mitigation of a potential harm, or 3) may require an alteration in their healthcare. Patient notification in the context of infection control breaches typically involves Trigger 2, as described by Schaefer et al. (see section 1, reference 1, below). Additional information on patient notifications can also be found in *Chapter 8, Notification and Communication*.

The following three sections provide an overview of resources that public health agencies and healthcare partners can reference to assist in the investigation of infection control breaches.

Supplement B Infection Control Breach Investigations

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B.1   Investigation of Infection Control Breaches

Below are some key resources that provide useful background, materials, and advice to assist in the investigation of and response to infection control breaches, including patient notification, as well as examples of publications in which infection control breach investigators described their specific findings and experiences.

1. Schaefer MK, Perkins KM, Link-Gelles R, Kallen AJ, Patel PR, Perz JF. Outbreaks and infection control breaches in health care settings: Considerations for patient notification. *Am J Infect Control.* 2020;48(6):718–724. doi: 10.1016/j.ajic.2020.02.013

   Schaefer and colleagues provide a useful framework for patient notification considerations, including a description of triggers for performing a notification when investigating an infection control breach and examples of commonly encountered scenarios.

2. Patel PR, Srinivasan A, Perz JF. Developing a broader approach to management of infection control breaches in healthcare settings. *Am J Infect Control.* 2008;36:685–690. doi: 10.1016/j.ajic.2008.04.255

   In this paper, Patel et al. introduce a number of useful concepts and suggested approaches for investigating infection control breaches, many of which were later revisited and expanded upon by Schaefer et al. in 2020 (reference 1 from this section).

3. Centers for Medicare and Medicaid Services (CMS). Infection control breaches which warrant referral to public health authorities. Published May 30, 2014. Revised October 28, 2016. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-36.pdf

   Beginning in 2014, CMS required the reporting of infection control breaches discovered during accreditation or certification survey visits to public health agencies.

4. Braun BI, Chitavi SO, Perkins KM, et al. Referrals of infection control breaches to public health authorities: Ambulatory care settings experience, 2017. *Jt Comm J Qual Patient Saf.* 2020;46(9): 531–541. doi: 10.1016/j.jcjq.2020.05.005

   The authors characterize and summarize infection prevention and control (IPC) breaches that were identified by Joint Commission surveyors during the ambulatory health care and office-based surgery accreditation process and reported to state health departments in 2017.

5. Centers for Disease Control and Prevention (CDC). Injection Safety: Patient Notification Toolkit. https://www.cdc.gov/injectionsafety/pntoolkit/index.html

   This CDC toolkit provides step-wise guidance to assist public health agencies and healthcare facilities in the notification of patients following identification of an infection control breach. The toolkit is intended to be used after a decision has been made to notify patients and offers resources and template materials (such as sample notification letters) as well as some essential tips and strategies.

6. Schoonover H, Haydon K. Incident command structure using a daily management system and the Centers for Disease Control and Prevention's Patient Notification Toolkit drives effective response to an infection control breach. *J Healthc Risk Manag.* 2018;38(2):19–26. doi: 10.1002/jhrm.21323

   The authors describe how an incident command structure, information management system, and the CDC Patient Notification Toolkit were used to drive an effective response to an infection control breach—resulting in 92% of affected patients completing the recommended testing.

7. Arnold S, Melville SK, Morehead B, Vaughan G, Moorman A, Crist MB. Notes from the Field. Hepatitis C transmission from inappropriate reuse of saline flush syringes for multiple patients in an acute care general hospital — Texas, 2015. *MMWR Morb Mortal Wkly Rep.* 2017;66:258–260. doi: 10.15585/mmwr.mm6609a4

> *This report provides an example of an infection control breach investigation that uncovered hepatitis C virus transmission.*

8. Rasmussen SA, Goodman RA (editors). The *CDC Field Epidemiology Manual*. Oxford University Press; 2018. https://www.cdc.gov/eis/field-epi-manual/index.html

> *This manual does not address infection control breaches specifically, but provides a comprehensive resource for responding to outbreaks, with many principles that can also be applied to infection control breach investigations. Particularly relevant chapters to healthcare infection control breach investigations include Chapter 3, Conducting a Field Investigation; Chapter 12, Communicating During an Outbreak or Public Health Investigation; and Chapter 18, Healthcare Settings.*

B.2   Selected Infection Control Resources and References

Below are general resources for understanding the basic principles of infection control as well as some detailed resources relevant to a few more commonly reported infection control breaches.

1. Centers for Disease Control and Prevention (CDC). Infection Control. https://www.cdc.gov/infectioncontrol/index.html

> *The base directory for CDC infection control resources, this web page includes links to resources for standard and transmission-based precautions, infection control guidelines (see reference 2 in this section), training and education resources, and tools for specific healthcare settings.*

2. Centers for Disease Control and Prevention (CDC). Infection Control: Guidelines and Guidance Library. https://www.cdc.gov/infection-control/hcp/guidance/index.html

> *This web page contains links to a variety of CDC infection control guidelines and documents including those developed under the auspices of the Healthcare Infection Control Practices Advisory Committee (HICPAC).*

3. Association for Professionals in Infection Control and Epidemiology (APIC). The APIC Text. https://apic.org/resources/apic-text/

> *This comprehensive infection control resource, compiled by APIC, is organized by chapter. A subscription is required.*

4. Centers for Disease Control and Prevention (CDC). Essential Elements of a Reprocessing Program for Flexible Endoscopes — Recommendations of the HICPAC. https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html.

> *Because many breaches involve medical device reprocessing techniques, this CDC resource can assist public health agencies in related investigations and can be a useful document with which to share and help educate facilities.*

5. Centers for Disease Control and Prevention (CDC). Injection Safety: Safe Injection Practices and Your Health. https://www.cdc.gov/injectionsafety/index.html

> *This CDC webpage provides information about safe injection practices. Safe injection practices are part of standard precautions and are aimed at maintaining basic levels of patient safety and healthcare provider protections.*

6. Centers for Disease Control and Prevention (CDC). Injection Safety: Considerations for Blood Glucose Monitoring and Insulin Administration. https://www.cdc.gov/injection-safety/hcp/infection-control/index.html

> *This CDC resource provides essential background for the investigation of infection control breaches associated with blood glucose monitoring (or other forms of point-of-care testing involving capillary blood samples) or insulin pens and other medication cartridges.*

7. Dolan SA, Arias KM, Felizardo G, Barnes S, Kraska S, 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

> *This position paper from the Association for Professionals in Infection Control and Epidemiology describes risks and outbreaks associated with unsafe injection practices and associated recommendations.*

B.3   Investigation of a Drug Diversion Event

Broadly speaking, when prescription medicines are obtained or used illegally, the process is called "drug diversion." Healthcare providers who steal prescription medicines, such as opioids, for their own use place patients at risk for harm. This risk can include exposure to infectious diseases. For example, when a provider commits diversion by tampering with or otherwise misusing injection supplies, medications, or other equipment, these items may become contaminated with hepatitis B or C virus, human immunodeficiency virus (HIV), or bacteria. Drug diversion investigations involve assessments and actions that are akin to infection control breach investigations but include many special considerations. The resources listed below provide guidance and useful background for the investigation of healthcare drug diversion events.

1. Schaefer MK, Perz JF. Outbreaks of infections associated with drug diversion by US health care personnel. *Mayo Clin Proc*. 2014; 89(7):878–887. doi: 10.1016/j.mayocp.2014.04.007

> *This review article summarizes a variety of drug diversion–related outbreak investigations and includes a table describing key investigation steps.*

2. Centers for Disease Control and Prevention (CDC). Injection Safety: Clinician Brief: Drug Diversion. https://www.cdc.gov/injection-safety/hcp/clinical-overview/index.html

> *This CDC website provides information on drug diversion including outbreaks associated with drug diversion, resources for clinicians, and additional resources.*

3. Council of State and Territorial Epidemiologists (CSTE). Healthcare-Associated Infections (HAI) Drug Diversion Planning and Response Toolkit for State and Local Health Departments. Published June 2019. https://www.cste.org/page/Drug-Diversion-Toolkit

> *This Council of State and Territorial Epidemiologists (CSTE) toolkit provides information on best practices when responding to a drug diversion event and provides resources informed by past drug diversion investigations.*

4. Clark J, Fera T, Fortier C, et al. ASHP Guidelines on Preventing Diversion of Controlled Substances. Am J Health Syst Pharm. 2022;79(24):2279-2306. doi: 10.1093/ajhp/zxac246

> *A framework from the American Society of Health-System Pharmacists, this guidance document describes controlled substance diversion prevention programs and provides a useful context for public health partners and others charged with investigating a drug diversion report.*

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Disclaimers: The findings and conclusions in this document are those of the authors and do not necessarily represent the official views of the CDC nor those of other CORHA member organizations.

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