

Infection Control Breach Referral Protocol

Background

In May 2014, the Center for Clinical Standards and Quality/Survey & Certification Group, of the Center for Medicare and Medicaid Services (CMS), issued a memorandum (S&C:14-36-ALL) to State Survey Agencies mandating that any identified breach of generally accepted infection control standards must be referred to appropriate state authorities for public health assessment and management. CMS Memo 14-36-ALL provides an additional channel through which public health can become aware of ongoing infection control issues in a variety of healthcare settings.

Public Health Significance

Some types of infection control breaches, including, but not limited to, medication injection practices and disinfection and sterilization of medical devices and equipment, pose a risk of bloodborne pathogen transmission that warrants engagement of public health authorities to conduct risk assessment and, if necessary, to implement the process of patient notification. These functions are outside the jurisdiction of CMS, but fall within the authority of the State's public health agencies.

Infection control breaches are divided into two categories based on the qualitative risk assessment:

1. Category A

Breaches that have an established precedent for the transmission of bloodborne pathogens, and involves a gross error or demonstrated high risk procedure.

Examples of Category A breaches include:

- a. Reuse of needles or syringes between patients; and
- b. Reuse of contaminated syringes to access multi-dose medication vials or intravenous fluid bags.

2. Category B

Breaches that involve infection control where the likelihood of blood exposure resulting from the breach is uncertain, but thought to be less than would occur with Category A breach. Examples of Category B breaches include:

- a. Scope reprocessing performed with incorrect disinfectant solutions or those performed with a shorter duration than is recommended by the manufacturer; and
- b. Probes and needles that were sterilized but the retained tissue was not physically removed from biopsy probe channel.

Division of Infectious Disease Epidemiology (DIDE)

350 Capitol Street Room 125, Charleston, WV 25301-3715

Phone: (304) 558-5358 Fax: (304) 558-6335 www.dide.wv.gov

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State Survey Agency (SA) or Accrediting Organizational (AO) Responsibilities

The CMS issued memorandum S&C:14-36-ALL (see Appendix A) mandates that if the SAs or AOs identify any breaches of generally accepted infection control standards they must refer them, as directed, to the state health department for public health assessment and management. If a breach has been identified, the SAs or AOs will notify the Healthcare Associated Infections (HAI) Program Director and/or Centers for Disease Control and Prevention (CDC) via email or letter. Some types of infection control breaches that must be reported:

1. Unsafe injection practices
2. Unsafe use of sharps
3. Inadequate or inappropriate disinfection and sterilization of medical devices

State Health Responsibilities

Decisions on how to manage the breach will be made in consultation with the West Virginia Department of Health and Human Resources (DHHR), Bureau for Public Health, Division of Infectious Disease Epidemiology (DIDE) Director or Medical Epidemiologist, HAI Program Director or designee, other program staff as needed and may or may not require the CDC. State health responsibilities include the following:

1. Notification Response:
 - a. Calls regarding any infection control breach should be routed to the HAI Program Director or designee.
 - b. Emails/information sent to the HAI Program Director will be shared with the DIDE Outbreak Team, Office Director, Division Director, and Surveillance Director.
 - c. The nature of the breach should be noted in the IDOutbreak folder, "Infection Control Breach" subfolder.
 - d. Within the subfolder, a new folder should be created titled "Infection Control Breach {Facility Name} {Date}."
2. Initial Investigation
 - a. Timeframe
 - i. Category A breach- An on-site visit will be made within 2-3 business days from the date of initial notification.
 - ii. Category B breach- The need and timeframe for an on-site facility visit should be determined based on, but not limited to, staff interviews, review of instrument reprocessing, review of procedure, record review, and exposure timeframe.
 - iii. Additional data gathering will ensue in accordance with the type of breach, to include, but not limited to, research of instruments, disinfectants and process, staff interviews.

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3. On-going updates will be provided to DHHR's Office of Epidemiology and Prevention Services (OEPS) Director about the breach, investigation, and findings. These updates will be provided on a weekly basis and more frequently if warranted.
4. On-site Visits
 - a. Communication and scheduling of visit will be correlated with the facility administrator, infection preventionist or designee.
 - b. Direct observation of practices or disinfection and sterilization will be conducted.
 - c. Verify risk level and notify and involve key stakeholders at local health department, DHHR leadership, DHHR's Office of Health Facility Licensure and Certification (OHFLAC), CDC, etc.
 - d. If necessary, cross-referencing with public health records will be conducted.
5. After the on-site visit is complete, decisions on how to manage the breach will be made in consultation with the DIDE Director and/or medical epidemiologist, HAI Program Director or designee, outbreak team, or other staff leads as required.
6. The OEPS Director will be notified of the investigation findings and recommended actions. Should a patient notification be recommended at any point during the investigation, the Bureau for Public Health Commissioner/State Health Officer will be notified of the breach, investigation, and recommendations. The Commissioner/State Health Officer will make the final decision or recommendations regarding further actions or notification.

Laboratory Responsibilities

If warranted, DHHR's Office of Laboratory Services (OLS) will work with the Bureau for Public Health to arrange for specimen collection, testing and prompt reporting in accordance with CDC recommendations.

Local Health Responsibilities

The local health department may be called upon to participate in the on-site visit and/or assistance with specimen collection. If patient notification is deemed necessary, the local health department will be included in all communications.

Disease Control & Prevention Objectives

The objective for disease control and prevention is to limit the number of patients potentially exposed to blood borne pathogens via contaminated medical equipment by conducting a thorough investigation of the reported breach.

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Disease Surveillance Objectives

1. To identify and monitor characteristics of infection control breaches in West Virginia.
2. To identify areas at risk for infection control breaches in West Virginia.
3. To provide appropriate public health interventions and referral for infection control breaches.

References

1. CMS Memorandum: *Infection Control Breaches Warranting Referral to Public Health Authorities*. October 26, 2016. Retrieved from:
<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-36.pdf>
2. Steps for evaluating an infection control breach. CDC. Date accessed: January 30, 2019.
https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html

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