An Approach to Managing Infection-Control Breaches (3/09)


Instrument-reprocessing errors and other infection-control breaches in health-care settings can present unique challenges for health-care professionals and public health officials, particularly in the absence of known disease transmission. In many instances, the major challenge is determining whether patient notification and testing for bloodborne pathogens (e.g., hepatitis C virus [HCV], hepatitis B virus [HBV] and human immunodeficiency virus [HIV]) is required. Widespread patient notifications can be resource and labor intensive and are not without potential harms to patients notified.

According to the authors, the evaluation of an infection-control breach should be influenced by two critical distinctions: 1) whether bloodborne pathogen (e.g., HCV, HBV, and/or HIV) transmission was possible (vs. only bacteria or other nonbloodborne microbes) and 2) whether the breach involved a demonstrated or suspected high-risk practice (Category A) or was one that posed a lower risk of bloodborne pathogen transmission (Category B). These distinctions should be made early to help guide subsequent decisions. A severe breach that involved a gross error in aseptic practice usually warrants patient notification and testing. A less severe breach might warrant disclosure to patients without a recommendation for testing. The nature of the infection-control breach and circumstances that surround it—along with input from key stakeholders, including public health—should be used when making decisions about patient notification and testing.

The authors describe an approach to management of these incidents that focuses on risk of bloodborne pathogen transmission and the role of public health and other stakeholders. If bloodborne pathogen transmission from the breach is identified or suspected, a thorough epidemiologic and laboratory investigation is indicated.

- **Identification of infection-control breach**: identify nature of the breach, type of procedure, and biologic substances involved; review recommended reprocessing methods or aseptic technique; institute corrective action as early as possible.
- **Additional data gathering**: determine the timeframe for the breach and number of patients involved; identify exposed patients with evidence of HBV, HCV, or HIV infections through medical records and/or public health surveillance data; conduct a literature review and consult with experts.
- **Notify and involve key stakeholders**: infection-control professionals, risk management, local/state health departments, affected health-care providers, and licensing or other regulatory agencies as needed.
- **Qualitative assessment of breach**: if possible, classify the breach as Category A or B (Category A involves a gross error or demonstrated high-risk practice; Category B involves a breach with lower likelihood of blood exposure).
- **Decision regarding patient notification and testing**: if Category A—patient notification and testing is warranted; if Category B, consider the following in the decision: potential risk of transmission, public concern, and duty to warn vs. harm of notification.
- **Communications and logistical issues**: develop communication materials; consider post-exposure prophylaxis if appropriate; determine who will conduct testing, obtain consent, and/or perform counseling if appropriate; determine if follow-up testing is needed; facilitate public inquiry and communication; address media/legal issues.

DECS Comment: The protocol described in this article can help guide individuals when managing potential infection-control breaches. As the authors stated, a multidisciplinary approach is necessary and should involve knowledgeable infection-control staff and other personnel who can make technical and ethical judgments in an impartial manner that supports patients’ best interests. In addition to the items discussed above, individuals should also consider local medical
Another excellent resource is an article by Drs. Rutala and Weber describing how to assess the risk of disease transmission after potential disinfection and sterilization failures. As they point out, with anything concerning infection control, prevention is preferable to correcting deficiencies in procedures that can result in potential exposure. It is key to assess the potential risk of disease transmission and then determine whether the magnitude of the risk warrants further action such as patient notification. For example, many sterilization processes (e.g., steam sterilization) have an enormous safety margin, and small deviations from standard practice may not represent a patient hazard. Both articles include protocols that may be helpful if a clinic experiences an infection-control breach, as well as sample letters, press releases, and risk assessment scenarios.

References