US Outbreak Investigations Highlight the Need for Safe Injection Practices and Basic Infection Control

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Preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), represents a basic expectation anywhere health care is provided. This is true both in terms of patient and provider protections. Health care should provide no avenue for the transmission of these potentially life-threatening infections; yet, unsafe medical practices continue to contribute to much of the worldwide disease burden that is associated with HBV and HCV. Even in wealthy countries, such as the United States, the challenge of consistently providing safe care is not always met, as evidenced by increasing reports of outbreaks that have been associated with unsafe injection practices and related breakdowns in basic infection control. Current understanding of viral hepatitis transmission in United States health care settings indicates progress over the past several decades with respect to the risks from transfusions or blood products. Likewise, risks to health care providers from

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sharps injuries and other blood and body fluid exposures have been reduced as a consequence of widespread hepatitis B vaccination and the adoption of safer work practices.\(^9\) Increasing recognition of outbreaks involving patient-to-patient spread of HBV and HCV infections, however, has uncovered a disturbing trend. This article highlights the importance of basic infection control and the need for increased awareness of safe injection practices.

**OUTBREAKS: RECENT UNITED STATES EXPERIENCE**

The detection of outbreaks of health care–associated viral hepatitis is haphazard; many barriers exist that hinder effective public health surveillance and investigation.\(^3,4\) Most new infections are asymptomatic and there is a low index of suspicion for health care–associated bloodborne virus transmission among patients and providers. Outbreaks and sporadic transmission events are likely underrecognized.\(^4,7,8\) Nonetheless, a recent review of United States viral hepatitis outbreak experience revealed 33 outbreaks that occurred in nonhospital settings, such as outpatient clinics (N = 12); dialysis centers (N = 6); and long-term care facilities (N = 15).\(^4\) These outbreaks resulted in 448 recognized cases of HBV or HCV infection during 1998 to 2008.

Increasingly, these events have resulted in large public health notifications and facility closures.\(^4\) Between 2007 and 2009, outpatient clinics were identified as the sites of at least four outbreaks of HBV or HCV infections that resulted from unsafe practices, such as improper use of syringes, needles, and medication vials.\(^5,9-11\) In these incidents, many tens of thousands of patients were needlessly placed at risk for infection because of unsafe medical practices and were sent letters advising them to undergo testing for HBV, HCV, and HIV. For example, over 40,000 patients were impacted by an outbreak of HCV infections that occurred in an endoscopy clinic in Nevada.\(^9\) Most recently, a chemotherapy clinic has become the epicenter of a hepatitis B outbreak investigation; approximately 60,000 cancer patients who received treatment at this clinic have been contacted and recommended to undergo testing.\(^11\) In turn, the media, legislators, and other officials have noted a public health crisis in affected communities where confidence in the health care system, including routine preventive services, has been undermined.

The outbreaks with the most widespread impact have occurred in outpatient settings, where attention to infection control is lacking relative to inpatient settings.\(^3,12,13\) In these settings, transmission of HBV and HCV has been attributed to syringe reuse or other infection control lapses that resulted in contamination of injectable medications or flush solutions.\(^3,4,7,14\) The delivery of anesthetics was a common factor in approximately half of these outbreaks.\(^4\) Physicians and other health care providers should be aware of the potential consequences of unsafe injection practices. Besides compromising patient safety, unsafe care may also put providers themselves at risk of licensing board actions or malpractice suits (Box 1).

**SYRINGE REUSE**

The risks associated with syringe reuse and, more generally, the risks associated with improperly handled injectable medications, seem to be underappreciated (Box 2).\(^14,15\) Essentially, any form of syringe reuse is a dangerous practice. A misperception that may underlie some of the risky behaviors is the mistaken belief that contamination is limited to the needle device when a syringe and needle are used as unit. Instead, as was demonstrated by decades of experimental studies, contamination does extend to the syringe when injections are administered by the intramuscular, intradermal, intravenous (IV), or other routes.\(^16-24\) Additional potential for

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syringe contamination results from the negative pressure that occurs if a contaminated needle is removed from the syringe. In the case of IV administration, the risk for syringe contamination is not eliminated by intervening lengths of IV tubing or the presence of heparin locks or valves. Use of a contaminated needle or syringe to withdraw medication from a vial can result in transfer of contaminants to the vial, as shown in Fig. 1.

**Overt Reuse of Syringes**

Reuse of syringes is a primary example of an unsafe injection practice that has resulted in HBV and HCV transmission. Overt syringe reuse involves reuse of a single syringe to administer parenteral medication or flush solutions to more than one patient. The danger of this practice was made clear in an Oklahoma outbreak that was investigated in 2002. Here, an anesthetist in a pain remediation clinic routinely prepared a single needle and syringe at the beginning of each clinic session for each of three medications: midazolam, fentanyl, and propofol. These three needles and
inherent risks. One such incident involved influenza vaccine that was drawn from a multidose vial into a 3-mL syringe that was then used to administer 0.5-mL unit doses to multiple patients, with the needle changed between patients.⁶ Another incident involved a Michigan dermatologist who was suspected of reusing syringes; this resulted in approximately 13,500 patient notifications.⁷ Several recent incidents involved the reuse of insulin pens, which are single patient-use items, for multiple patients.⁸ Providers reported that they believed that changing the needles on the device was sufficient to prevent the transmission of infection. Several thousand patients were notified in these incidents. The Food and Drug Administration issued an alert reminding providers that insulin pens and cartridges must not be shared because of the risk of transmitting bloodborne pathogens and that the same risk may exist with shared use of any injection device.⁹,¹⁰

Contamination of Shared Medications by Reused Syringes

The reuse of syringes to withdraw medication or solutions has also repeatedly been shown to result in HBV and HCV transmission. This type of error does not typically involve overt reuse of the syringe for multiple patients as described previously. Instead, the syringe is reused to draw up additional medication for a single patient, administered, and then discarded. Because this action can contaminate the vial or bag containing the medication or solution, subsequent patients can be exposed to infectious virus or other microbes if that vial or bag is reused (see Box 1). Numerous outbreaks have been associated with this practice. For example, in a Nevada endoscopy center outbreak investigated in 2008, it was discovered that two nurse anesthetists routinely reused syringes, after changing needles, to obtain additional doses of propofol for individual patients who required additional sedation.⁹ Although the syringe was discarded at the end of the procedure, any remaining medication in the single-dose propofol vial was used for subsequent patients. Patient-to-patient transmission of HCV on two separate days was documented using epidemiologic data and supported with viral sequencing results. Over 40,000 patients who had undergone procedures at this facility were potentially exposed to this long-standing practice and placed at risk of bloodborne pathogen transmission.⁹ In another example, 99 patients treated at a hematology-oncology clinic in Nebraska were infected with HCV after a nurse reused syringes, after drawing blood from central venous catheters, to withdraw saline solution from 500-mL bags for flush procedures.⁷,⁹,¹¹,¹² Each bag of saline solution was routinely used as a common source of flush for 25 to 50 patients.¹³

Transmission potential is magnified when facilities use vials or bags of medication and infusates that contain quantities in excess of those needed for routine single-patient use. Although these medications are often labeled as single-use (ie, single-dose), the large volume in the container may lead to the perception that they are suitable for multipatient use.¹⁴ Large-volume single-dose or multidose medications are particularly risky because syringe reuse or other breaches in aseptic technique may result in a large reservoir of contaminated material that serves to perpetuate transmission to multiple patients. To reduce costs, some providers have pooled leftover contents from multiple vials to obtain a sufficient dose, risking serial contamination of additional vials and putting further patients at risk.¹⁵,¹⁶ It is important that single-dose containers only be used once for a single procedure on a single patient (Box 3).¹⁷ Additionally, the Centers for Disease Control and Prevention (CDC) recommends limiting use of multidose vials of medication to single patients to offer an extra barrier of protection against unrecognized syringe reuse or other means of contamination.
Box 3
Injection safety recommendations

- Never administer medications from the same syringe to more than one patient, even if the needle is changed.
- Consider a syringe or needle contaminated after it has been used to enter or connect to a patient's intravenous catheter, infusion bag or administration set.
- Do not enter a vial with a used syringe or needle.
- Never use medications packaged as single-use vials for more than one patient.
- Assign medications packaged as multi-use vials to a single patient whenever possible.
- Do not use bags or bottles of intravenous solution as a common source of supply for more than one patient.
- Follow proper infection-control practices during the preparation and administration of injected medications.


CONTAMINATION OF EQUIPMENT, SUPPLIES, AND THE ENVIRONMENT

Equipment, supplies, and the environment can become contaminated and facilitate HBV and HCV transmission.\textsuperscript{3,4} For example, in an outbreak that occurred in a private medical practice, 38 patients acquired HBV infection from injections that typically combined vitamins and steroids prepared using multidose vials that were stored in a workspace where used needles and syringes were dismantled and discarded.\textsuperscript{37} Injections should be prepared in a clean environment that is not adjacent to areas where potentially contaminated items are placed (see Box 2).\textsuperscript{36} If multidose vials are used to prepare IV medications for multiple patients, these should be restricted to a centralized medication area.\textsuperscript{36} Unless these multidose vials are dedicated to a single patient, they should not enter the patient treatment or procedure area. In hemodialysis settings where blood contamination can occur frequently in patient care areas, neither multidose nor single-dose medications should be handled at the patient treatment station.\textsuperscript{35,38} Standard Precautions also indicate that vials should be stored in accordance with manufacturer's recommendations (eg, held at room temperature or under refrigeration) and that vials should be discarded whenever sterility has been compromised or is in doubt.\textsuperscript{36} Providers should be aware that the bacteriostatic agents used in multidose vials are not effective against viruses, such as HCV and HBV.

Bloodborne pathogen transmission also results from improper use and handling of patient equipment in the context of blood glucose monitoring.\textsuperscript{4,28,39-44} Transmission has occurred when (1) equipment designed for use by a single person (eg, spring-loaded fingerstick devices; blood glucose meters) was inappropriately used for multiple patients; (2) equipment used for multiple patients (eg, blood glucose meters) was not cleaned and disinfected between each use; and (3) staff failed to wear gloves, change gloves, or perform hand hygiene for fingerstick procedures. Although transmission of this type has most clearly been recognized in long-term care facilities, conditions that could facilitate sporadic transmission by blood glucose monitoring...
and related diabetes care may be present in a wide array of settings, including hospitals. In addition, although bloodborne pathogen transmission has not been reported in association with prothrombin time and International Normalized Ratio (INR) point-of-care testing devices, the increased use of these devices deserves attention. Their similarity to blood glucose monitoring equipment suggests a need for appropriate procedures to prevent transmission in physicians’ offices, anticoagulation clinics, long-term care, and other settings where these devices are used.

This points to another misperception that likely contributes to health care-associated bloodborne virus transmission: cleaning of equipment and shared devices is only necessary when blood or other contamination is visible. This is not true. For example, one study, which used an assay to detect occult blood, found that 30% of blood glucose meters in routine use in hospitals were contaminated with blood. Further, HBV and HCV have been shown to remain infectious in the environment in dry blood for up to a week and 16 hours, respectively; either virus may be present in the absence of visible blood in sufficient quantities to cause infection. The CDC recommends that blood glucose meters should only be used for multiple patients if they are cleaned and disinfected after every use, because these devices frequently become contaminated with blood. According to Standard Precautions, facilities should establish policies and procedures for containing, transporting, and handling all patient-care equipment, instruments, and devices that may be contaminated with blood or body fluids. Additional recommendations that specifically address safe blood glucose monitoring and diabetes care are available and emphasize the importance of single-use autodisabling lancets, avoidance of shared blood glucose meters, appropriate hand hygiene, and safe injection practices for insulin delivery.

Indirect contact transmission, such as that observed in the hemodialysis environment, can occur when proper attention is not given to the cleaning and disinfection of equipment, supplies, and the hands of health care personnel. Patients receiving long-term hemodialysis, whose care involves repeated and prolonged vascular access in an environment that is shared with other patients, have historically been at high risk for acquiring bloodborne infection. Infection control recommendations for the hemodialysis setting have been established and were incorporated into recently revised Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage for end-stage renal disease facilities. The new requirements underscore the importance of proper medication handling and environmental decontamination and establish a framework for enforcing appropriate practices in this setting.

Care of the environment and adherence to Standard Precautions is important wherever health care is delivered. Certain health care settings may be associated with higher risks for transmission, however, not only by virtue of the procedures performed, but also the underlying prevalence among the patient population. For example, a prospective study of patients treated in 308 representative dialysis facilities in the United States and several other developed nations found that higher facility HCV prevalence was independently predictive of incident HCV infections. This finding highlights that opportunities for potential transmission increase as the prevalence of HCV-infected patients in a facility grows. Hepatitis treatment centers may also have a high prevalence of HCV-infected patients and multiple opportunities for cross-contamination. As such, these facilities should take special care to ensure complete adherence to safe injection practices, environmental cleaning, appropriate care of invasive equipment, and other recommended precautions.

Endoscope reprocessing is another area that warrants specific attention. Failures to adhere to endoscope reprocessing guidelines have been associated with numerous outbreaks of bacterial infections. Patient notifications and concerns over
bloodborne pathogen transmission have also resulted from these types of lapses.\textsuperscript{60}\ There has been little convincing evidence that endoscopes alone have served as the source of HBV or HCV transmission; unsafe injection practices including syringe reuse may have been overlooked in several incidents.\textsuperscript{14,58,60,61}\ The risk of bloodborne pathogen transmission from endoscopes that have been appropriately cleaned but not undergone high-level disinfection is likely very small.\textsuperscript{56,60–62}\ Nonetheless, reprocessing failures can pose a number of other infectious disease risks and resulting notifications can have widespread adverse impacts on patients and their family members. Recent examples have involved US Department of Veterans Affairs medical facilities in which over 10,000 patients were notified and offered bloodborne pathogen testing because they were exposed to improperly reprocessed endoscopy equipment.\textsuperscript{63}\ Health care providers and institutions must ensure that their staff are appropriately trained in and adhere to recommended endoscope reprocessing procedures as part of their basic infection control and patient safety program.\textsuperscript{57–65,84}\n
THE CLINICIAN’S ROLE IN IDENTIFYING HEALTH CARE–ASSOCIATED INFECTIONS

Clinicians can play a key role in helping to recognize and contain health care–associated viral hepatitis infections by reporting potential clusters or incident cases. The outbreaks that are investigated by health departments and the CDC likely underrepresent the true burden of health care–associated HCV and HBV infections in the United States.\textsuperscript{4}\ Although traditional risk factors, such as high-risk sexual behaviors and injection-drug use, still contribute to the current epidemiology of acute HBV and HCV infections, approximately 50% of persons interviewed do not report behavioral risks as part of routine case-investigations for acute hepatitis B or C.\textsuperscript{65}\ Unacknowledged behavioral risk factors likely explain a portion of the cases without identified risks or exposures, but unrecognized medical transmission might also account for many of these cases.\textsuperscript{4}\ This should serve as a reminder to physicians diagnosing patients with acute viral hepatitis to report these cases and carefully consider the role of health care exposures, especially among older adult populations or others who do not report traditional risk factors for infection.\textsuperscript{9}\ In particular, potential clusters involving two or more cases with a common health care procedure during the likely exposure period should immediately be reported to public health authorities. Likewise, a single case of acute hepatitis B or C (or documented seroconversion) occurring in a cancer, hemodialysis, or transplant patient, long-term care resident, or routine blood donor represents a “red flag” for medical transmission that deserves thorough investigation.

PREVENTING HEALTH CARE–ASSOCIATED BLOODBORNE VIRUS INFECTIONS

Outbreaks have occurred in a variety of health care settings and affected differing patient populations. A common thread, however, is that they were all devastating to the patients who were impacted, damaged public trust in health care institutions, and ultimately resulted from the failure of providers to understand and follow the most basic concepts of injection safety and infection control.\textsuperscript{66}\ The CDC and other groups have published best practice guidance to prevent health care–associated infections and to assist facilities in risk assessment and investigation of identified breaches in infection control.\textsuperscript{36,60}\ Awareness, understanding, and implementation of these recommendations all remain suboptimal. These trends and findings point to the need for a multifaceted approach focusing on surveillance, oversight, enforcement, safety engineered technologies, and continued education efforts aimed at ensuring safe injection practices in all health care settings.
Efforts toward enforcement of basic standards of infection control are being pursued at both the state and federal levels, as illustrated by the following examples. New York State has long required all of its licensed health care professionals to undergo training in infection control and barrier precautions at the time their license is obtained and every 4 years thereafter. New Jersey requires that outpatient endoscopy and other surgical centers retain the services of a licensed infection control professional. New York and Nevada have recently increased licensing, accreditation, and inspection requirements for physician offices and clinics that perform procedures that involve certain levels of anesthesia or sedation. At the federal level, CMS has recently begun to incorporate expanded infection control requirements into its Conditions for Coverage for outpatient settings including hemodialysis and ambulatory surgical centers. With assistance from the CDC, CMS has also provided infection control guidance, including information on injection and medication safety, to surveyors for use during facility inspections.

In addition to enforcement strategies, there are still many opportunities and needs for targeted educational initiatives. The continued occurrence of outbreaks, such as those described in this article, highlight a lack of awareness and understanding by health care providers of issues related to injection safety and infection control and indicate an urgent need for improved education at all levels of health care delivery. This includes attention to professional curricula at nursing and medical schools to ensure appropriate investments in basic knowledge of infection transmission and prevention, and to vocational training for other health professionals who likewise need to have a clear understanding of basic infection prevention requirements. Ongoing reinforcement of training is equally important and could benefit from periodic certification requirements, such as those implemented at many state health departments to ensure that restaurant food-handlers are appropriately trained. Examples of available resources to assist providers are listed in Box 4.

The CDC is working with states and other partners to develop sufficient plans to respond to outbreaks of disease caused in part by the reuse of syringes in outpatient settings and to ensure that infection control measures are adhered to broadly, including provider education and patient awareness activities. As part of this effort, the Safe Injection Practices Coalition, a broad-based group of national health care leaders, was established in 2008. This coalition is working to raise awareness and knowledge of safe injection practices among the public and health care providers through its “One and Only” campaign.

**Box 4**

Injection safety and related infection control resources

The Centers for Disease Control and Prevention

Injection Safety Website: http://www.cdc.gov/ncidod/dhqp/injectionsafety.html

Division of Healthcare Quality Promotion: http://www.cdc.gov/ncidod/dhqp/index.html

Division of Viral Hepatitis: http://www.cdc.gov/ncidod/diseases/hepatitis/

Safe Injection Practices Coalition One and Only Campaign
http://www.oneandonlycampaign.org

The World Health Organization Safe Injection Global Network
http://www.who.int/injection_safety/en/
SUMMARY

Recent increases in the reported number of HBV and HCV outbreaks and related incidents involving breakdowns in basic infection control have exposed tens of thousands of patients to needless risks and undermined trust in the health care system. This trend must be reversed. It is critical that medical professionals and others recognize the responsibility of all health care providers to implement safe care practices, the need for strengthened public health surveillance, and the importance of enhanced infection control education. With the spotlight now being directed at this issue, health care providers everywhere need to pause, with their staff and colleagues, to review injection procedures and other aspects of care to ensure that safe practices are understood and followed by all.

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