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Unsafe Injections: Duty to Warn?

Background

Public health authorities play a critical role in the investigation of disease outbreaks and notifications of persons potentially exposed to communicable diseases. The duty to warn extends to situations involving unsafe healthcare practices, including unsafe injection practices like syringe reuse that can expose patients to bloodborne pathogens (hepatitis B, hepatitis C, and HIV). However, the investigation of these harmful practices can be fraught with challenges, particularly when transmission of infections has not been clearly identified or the risk of patient exposure is uncertain. Health departments and healthcare facilities must often face the ethical dilemma of how to balance transparency with the potential harms of patient notification.

Medical errors related to the delivery of injections (e.g., syringe reuse between patients) represent a serious lapse in infection control. Such lapses have resulted in numerous outbreaks of healthcare-associated transmission of hepatitis B (HBV) and hepatitis C (HCV) virus (1, 2). While long recognized as a problem in developing countries, unsafe injection practices have recently gained attention in the United States. Reports of outbreaks associated with unsafe injection practices are increasing, primarily in the outpatient arena. A review of U.S. viral hepatitis outbreaks from 2001-2011 revealed 18 outbreaks due to unsafe injection practices that resulted in over 350 recognized cases of HBV or HCV infections and that occurred across various outpatient settings, including specialty clinics and physician offices (3).

Many of these outbreaks have led to notifications of large numbers of patients, advising them to seek testing for bloodborne pathogens (HBV, HCV, HIV). In the United States, 35 patient notification events related to unsafe injection practices occurred in at least 17 states from 2001 through 2011, resulting in over 130,000 patients notified (4). Although an outbreak precipitated the majority of these notification events (n=22; 63%), 13 (37%) were prompted by the discovery of unsafe injection practices, absent clear evidence of bloodborne pathogen transmission at the time of investigation. Early in their clinical course, bloodborne pathogen infections are difficult to recognize, often being asymptomatic. As a result, patients exposed to unsafe injection practices are usually, upon being notified, given the opportunity to seek testing, even in the absence of a known outbreak.

Beside reuse of a syringe to access shared injectable medications, another commonly identified lapse in injection safety is reuse of single-dose (or single-use) medications for multiple patients. Overt reuse of syringes and insulin pens between patients has also been reported (4). Many of these injection safety lapses have involved patient-to-patient transmission, in which an infected patient was the source of infection for other patients. However, more recently, provider-to-patient transmission in the context of narcotics diversion (i.e., provider stealing a controlled substance, such as fentanyl, from the workplace for illicit purposes) has emerged as an important cause of injection-safety related outbreaks (4, 5). In this situation, an infected provider (e.g., active HCV infection) steals a syringe containing a narcotic intended for patients, self-administers the narcotic, and reuses the same syringe to inject patients or to access medication vials or bags, thereby contaminating medications used for subsequent patients (4). In the past

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decade, at least 4 HCV outbreaks have been linked to narcotics diversion by a provider, including a recent multistate outbreak involving a single HCV-infected provider suspected of diverting fentanyl who worked in a number of different facilities located across several states (6-9). These outbreaks have resulted in at least 70 cases of HCV infection and the notification of over 20,000 persons in a dozen states.

The Drug-Free Workplace Act of 1988 requires federal grantees and contractors, which may include certain healthcare institutions, to provide a drug-free workplace (10). However, there is no federal requirement or national standard for drug testing of all healthcare providers. In addition, there is no national mandate for routine screening of healthcare providers for bloodborne pathogens (11, 12). State laws and policies for testing of providers also vary substantially. Nonetheless, it is generally recommended that healthcare institutions provide voluntary confidential testing of their employees for bloodborne pathogens and establish policies in accordance with state statutes to manage testing of providers who may have exposed patients to blood or hazardous body fluids (12).

Given their scope, injection safety lapses and related notification activities pose challenges to public health that intertwine the practical and the ethical (13). One practical challenge lies in determining the appropriate course of action for situations in which the extent of patient exposure cannot be determined precisely. Another involves healthcare facilities that are uncooperative or incapable of effectively and objectively managing the investigative and notification process themselves. These practical challenges affect how to weigh ethically the benefits of patient notifications against anxiety and other potential harms for patient groups when exposures are uncertain; and how to ensure adequacy of patient notifications when the contact information of a substantial proportion of affected patients may be missing or incorrect. Similarly, there is a need to identify best disclosure strategy and patient preferences regarding overall communication methods and materials, because the typical notification strategy, written communication, may cause undue alarm or emotional harm.

Case Description

A local hospital has notified you, the local health department director, about a cluster of acute hepatitis C virus (HCV) infections that is likely due to narcotics diversion by a healthcare worker. Investigation by the hospital indicated that the only common exposure among the HCV-infected patients was receipt of intravenous fentanyl (an opioid commonly used for pain control) in the post-anesthesia care unit (PACU) following their surgical procedure. In addition, molecular typing of the patients' virus demonstrated a matching HCV strain, suggesting a common source.

The hospital also reported that a nurse working in the PACU was recently caught stealing a syringe of fentanyl, a powerful opioid analgesic. The nurse admitted to self-administering fentanyl from syringes that were intended for patients, replacing the syringes with saline, and returning the filled syringes to patient care. Although the nurse claimed she started diverting fentanyl about two months ago, hospital records indicated that she was working in the PACU on days when each HCV-infected patient had received fentanyl, which dated back to at least 6

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months prior. Furthermore, the nurse denied stealing fentanyl outside of the PACU; however, on more than one occasion, she was seen in other parts of the hospital on days when she was not scheduled to work. The nurse has been employed by the hospital for the past 5 years, and there is no documentation of her HCV status and other bloodborne pathogens, including hepatitis B and HIV.

The hospital is concerned that additional patients may have been exposed to HCV or other bloodborne pathogens resulting from narcotics diversion by the nurse. At present, in the state where the hospital is located, there is no legislation requiring healthcare providers to undergo bloodborne pathogen testing. The hospital administration is requesting assistance from the local health department in determining if the hospital should notify patients advising bloodborne pathogen testing.

Discussion Questions

1. Who are the stakeholders who should be considered in deciding if a patient notification should be conducted?
2. What values should be prioritized when attempting to balance the duty to warn and desire for transparency with the need to minimize patient anxiety from unnecessary notifications?
3. Assume a patient notification is to be conducted. In justifying your answers to the following questions, bear in mind that you must balance the duty to warn and desire for transparency with the need to minimize patient anxiety from unnecessary notifications.
 - a. Who should be notified?
 - b. What information is sufficient to determine which patients were potentially exposed?
 - c. How far back in time should notification extend?
 - d. What is the duty to warn when the risk of exposure is less certain (e.g., although the nurse denied diverting narcotics outside of the PACU, she occasionally accessed other patient-care areas of the hospital)?
4. Should a patient notification be conducted in this case? Justify your answer on the basis of the evidence, the ethics, and the economics of the situation.
5. In this scenario, should recommendations for bloodborne pathogen testing be limited to HCV or should patients also be tested for other bloodborne pathogens (i.e., hepatitis B virus, HIV)?
6. Is there a justification for public health authorities to compel drug testing or bloodborne pathogen testing of implicated employees as part of this outbreak investigation?
7. How can and how should public health fulfill its professional and ethical obligations in carrying out a public health investigation in parallel to a criminal investigation involving

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narcotics diversion?

8. What practical and ethical implications would it have if the hospital could compel the provider suspected of narcotics diversion to undergo bloodborne pathogen testing?
9. Suppose evidence pointed to narcotics diversion as the cause of the outbreak, but the actual person diverting the drugs is unknown.
 - a. How would this impact your assessment of patient exposure?
 - b. How would this impact your decision regarding which patients to notify?
 - c. Would any investigative steps you take to ascertain information guide the notification process?
 - d. Would this provide justification for requiring health personnel to be drug tested?
10. Suppose the affected healthcare facility was an independent outpatient clinic that lacked the personnel and monetary resources to conduct a patient notification. Does public health have a role and responsibility to ensure potentially exposed patients are notified?
11. Do you notify next-of-kin of deceased patients, even if there is minimal risk to next-of-kin? Should next-of-kin of deceased patients be notified when the risk of patient exposure is less certain?
12. Where should exposed patients go for bloodborne pathogen testing? Is it the responsibility of the implicated facility or the health department to offer testing? Who should pay for testing?
13. Should the health department track results of bloodborne pathogen testing? Should patient specimens be collected by the health department for advanced molecular testing? When would it be useful for the health department to conduct an epidemiologic study and/or determine if specific patient infections are linked to the outbreak?

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