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Patient Notification for Bloodborne Pathogen Testing due to Unsafe Injection Practices in the US Health Care Settings, 2001–2011

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Abstract

Background: Syringe reuse and other unsafe injection practices can expose patients to bloodborne pathogens (eg, hepatitis B and C viruses and human immunodeficiency virus). Evidence of such infection control lapses has resulted in patient notifications, but the scope and magnitude of these events have not been well characterized.

Objectives: To summarize patient notification events resulting from unsafe injection practices in the US health care settings.

Methods: We examined records of events that involved communications to groups of patients, conducted during 2001–2011, advising bloodborne pathogen testing stemming from potential exposures to unsafe injection practices.

Results: We identified 35 patient notification events related to unsafe injection practices in at least 17 states, resulting in an estimated total of 130,198 patients notified. Among the identified notification events, 83% involved outpatient settings and 74% occurred since 2007, including the 4 largest events (> 5000 patients per event). The primary breach identified (≥ 16 events; 44%) was syringe reuse to access shared medications (eg, single-dose or multidose vials). Twenty-two (63%) notifications stemmed from the identification of viral hepatitis transmission, whereas 13 (37%) were prompted by the discovery of unsafe injection practices, absent evidence of bloodborne pathogen transmission.

Conclusions: Unsafe injection practices represent a form of medical error that have manifested as large-scale adverse events, affecting thousands of patients in a wide variety of health care settings. Our findings suggest that increased oversight and attention to basic infection control are needed to maintain patient safety, along with research to identify best practices for triggering and managing patient notifications.

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Keywords

exposure notifications; medical errors; injections; infection control

Medical errors can result in various forms of patient harm, including transmission of health care-associated infections.[1–3] Errors related to delivery of injections (eg, syringe reuse), long recognized in international settings, have recently been identified in the US health care settings and have resulted in outbreaks of hepatitis C virus (HCV), hepatitis B virus (HBV), and bacterial pathogens.[1–3] In addition, patients who were potentially exposed to unsafe injection practices have often required notification by a health department or health care facility to advise testing for blood-borne pathogen infections (eg, HCV, HBV, and human immunodeficiency virus).[1,2,4–6] These infections are often asymptomatic and not readily diagnosed without deliberate efforts by patients and practitioners.

Because of longstanding interest and expertise in injection safety,[7] the Centers for Disease Control and Prevention (CDC) serves as the primary consultant to health departments and health care institutions on associated investigations and risk assessments and routinely provides guidance on related patient notification issues. Collectively, the scope and nature of these notification events have not been well described. In light of growing national interest and recognition of the serious threat of unsafe injection practices to patient safety,[8,9] we summarized the recent US experience related to notification events stemming from these lapses.

METHODS

We summarized information from the US patient notification events that occurred since 2001. We defined an injection-safety–related notification event as written communication (ie, letter) directed to a group of patients—advising individuals to seek bloodborne pathogen testing due to a potential exposure to inappropriate use and handling of supplies (eg, syringes, needles, intravenous tubing, medication vials, and parenteral solutions) for administering injections and infusions. In certain situations, notification occurred in multiple phases involving different patient groups or health care facilities; we treated these as a single event. We excluded incidents that involved isolated errors impacting a single patient.[10] Patient notification events prompted by other infection control breaches that are not related to the delivery of parenteral medications, including reuse of blood sampling equipment (eg, fingerstick devices) and errors with uncertain risk for bloodborne pathogen transmission (eg, endoscope reprocessing errors), were also excluded.

Although there is no formal system in the nation for tracking patient notification events, CDC has maintained records of all injection–safety-related investigations and notification events that involved CDC participation, consultation and/or laboratory assistance. These include published articles, official reports, investigation notes, and email correspondences. Through established channels (including CDC field staff), health departments managing injection-safety investigations have kept CDC informed of the occurrence of these events in their state. In addition, since at least 2004, CDC staff has actively searched for injection–safety-related events using online sources such as ProMed newsletter and Google news alerts

(examples of terms used include, “unsafe injection” and “hepatitis”) and used this information on occasion to engage health departments and health care institutions. We reviewed CDC records to identify injection-safety patient notifications conducted from January 2001 through December 2011 that met the aforementioned criteria. For notification events where CDC records were incomplete, we contacted health department personnel who had firsthand knowledge of the investigation and/or direct access to relevant data. In several instances, information from media reports was used to provide details that were lacking from both CDC and health department records. To supplement and help validate our review, we searched PubMed for any publications on injection-safety notification events.

We compiled the following information for each notification event identified: the affected state(s), time period, health care setting(s), type of unsafe injection practice(s) and implicated medications, confirmation of bloodborne pathogen transmission, the party that conducted the notification (eg, health care facility or the health department), and the total number of patients notified.

Review by the CDC Institutional Review Board was not required because none of the CDC records and correspondences with health departments contained patient identifiers, and no patients were contacted as part of this review.

RESULTS

We identified 35 patient notification events related to unsafe injection practices in 17 states and the District of Columbia from 2001 through 2011 (Table 1).[7,11–35] Thirty-one (89%) of the identified events were associated with investigations that involved CDC participation, consultation and/or laboratory assistance, whereas 4 events (11%) were managed by health departments working closely with facilities. No additional events were identified through searches of peer-reviewed medical literature.

The estimated total number of persons notified as a result of a potential exposure to unsafe injection practices was 130,198; the median number of persons notified per event was 669 (range, 25–63,000 persons). Seventy-four percent of the identified notification events occurred since 2007 (n = 26), including all 4 of the events that affected more than 5000 patients.

Twenty-two (63%) notification events were conducted in the context of identified HBV or HCV transmission, including 19 events that were associated with a recognized outbreak (detection of 2 or more cases). Of these 22 notification events, 19 (86%) involved patient-to-patient transmission, in which an infected patient was the source of infection for other patients. The other 3 events involved transmission from HCV-infected providers who abused injectable narcotics and exposed patients in the process of diverting these medications. The remaining 13 (37%) notification events were prompted by the discovery of unsafe injection practices, absent evidence of bloodborne pathogen transmission. For 2 events, unsafe practices were identified during public health investigations of outbreaks of bacterial infections. Most of the remaining events were prompted by reports from health care personnel regarding observed or suspected breaches by another provider. In several,

notification and testing identified patients with viral hepatitis infection, but whether these persons acquired the infection as a result of the breach was not determined conclusively.[27,29,30]

The primary breach implicated was accessing shared injectable medications with reused syringes (at least 16 notification events). However, overt reuse of syringes or insulin pens from one patient to another was also identified (at least 12 notification events), including the reuse of prefilled syringes to administer influenza vaccine or botulinum toxin. Other unsafe injection practices included the reuse of intravenous administration sets, single-use medication vials, and bags of saline solutions for multiple patients. Medications that were commonly implicated included anesthesia medications, such as propofol (7 notification events) and fentanyl (mainly in the context of narcotics diversion), saline flush solutions, and various infusion therapies containing vitamins or chelating agents. Eighty-three percent (n = 29) of notification events were associated with outpatient settings, including physician offices, specialty clinics, and alternative medicine clinics. In 21 (60%) notification events, letters to patients were sent by the health department in place of the provider or facility; all of these events involved an outpatient setting.

DISCUSSION

In the context of unsafe injection practices, the primary purpose of notification is to inform patients of their potential exposure to substandard care and advise bloodborne pathogen testing. Full disclosure of serious clinical adverse events to affected patients is increasingly becoming the standard of practice.[4,5,36] For errors that convey a high risk of physical harm to patients, the rationale for patient disclosure is compelling, irrespective of the number of patients involved and whether disease transmission has been established.[6]

Public health has a critical role in the investigation of injection safety breaches and ensuing notification activities,[6] particularly when the identified breach extends across multiple health care facilities or involves providers who are not fully cooperative or capable of objectively and effectively managing the process themselves. Oftentimes, resulting infections might remain undetected unless patients are advised to undergo testing. This was evident in a recent public health investigation that involved a broad patient notification, resulting in the discovery of a second cluster of viral transmission in a separate facility where the implicated provider had also worked.[16] Thus, if not for the notification, the true extent of disease transmission and patient harm would have been underestimated.

We found that the majority of notification events associated with patient-to-patient transmission were linked to reuse of syringes to withdraw medication from a container that was used for subsequent patients introducing risks of contamination and spread of infection.[2] Overt syringe reuse between patients was less frequently identified but accounted for the majority of patient notification events that were conducted in the absence of known disease transmission. According to a survey of health care providers who prepared and/or administered parenteral medications, nearly 1% have reused a syringe directly from one patient to another[37]; such dangerous practice may stem from the misconception that changing only the needle is sufficient to prevent disease transmission.[2,37] It is unsettling to

consider that the events we identified may only represent a small fraction of a larger problem.

Limiting the use of medication vials to individual patient use could have prevented many of the associated outbreaks that we identified. In most instances, the shared medication (eg, propofol, saline) was labeled as single dose (or single use), meaning that it was approved only for use on a single patient. Providers have reported confusion over the appropriate use of medications packaged in large-volume vials in excess of the quantity required for routine singlepatient procedures,[2,37,38] emphasizing the need for targeted education in this area.

We identified 3 notification events associated with provider-to-patient transmission that involved fentanyl theft by a provider, resulting in at least 40 cases of HCV infection and the notification of over 13,000 patients.[23–26] In these incidents, HCV infection was transmitted to patients as a consequence of overt syringe reuse (after the HCV-infected provider had self-injected) or from contamination of medication that was accessed with a used syringe. Because provider education may not be sufficient to prevent patient harm associated with narcotics diversion, prevention efforts should focus on developing engineered-safety medical devices, such as syringes that change color to indicate prior use or incorporate tamper-evident packaging in their design.

Eighty-three percent of identified notification events involved outpatient settings, including all 4 of the largest notification events. This finding might partly reflect an increasing trend toward outpatient health care delivery as well as a growing recognition of the risks associated with unsafe injection practices.[39] Although our finding may also be attributed to differential reporting due to the greater dependence of outpatient facilities on public health authorities, growing evidence indicates that infection control in these settings varies greatly.[40,41] One study found that approximately two thirds of ambulatory surgical centers had lapses in infection control, including unsafe injection practices.[42] Furthermore, unlike acute care hospitals, most outpatient facilities do not fall within the purview of state or federal licensing/certification agencies and are not routinely inspected for adherence to recommended practices.

Our US study has several limitations that likely resulted in an underestimation of the number of patients notified. First, without a centralized system for tracking patient notifications, we likely identified a fraction of all notification events resulting from unsafe injection practices. Second, differential reporting and publication bias might have overrepresented notifications in outpatient settings and in certain states. Third, the sources of data occasionally contained incomplete information on the total number of patients notified, as well as the number of patients who subsequently received testing and had results available for review. Fourth, our summary focused on written notifications sent to patients and did not take into account notifications conducted only by verbal communication (eg, phone calls). Finally, it should be noted that the scope of our review was limited to the US patient notifications. A number of large-scale, international injection-safety-related events have taken place in recent years but were not captured in our analysis.[43–45]

In summary, since 2001, unsafe injection practices have resulted in the notification of over 130,000 patients, likely reflecting a sample of actual US notification events. Efforts are needed to improve the identification of notification events, identify best practices for conducting and managing patient notifications, ensure adequate and thorough investigations, and most importantly, prevent the occurrence of unsafe injection practices. This will require raising awareness among facilities to engage public health authorities when serious lapses are identified, allowing consistent tracking of these events and guidance on the notification process. In addition, conducting research to manage ethical challenges and to identify patient preferences regarding communication materials will inform development of best disclosure strategies.[4,5] Finally, prevention of notification events and promotion of basic patient safety will require a comprehensive approach consisting of greater attention to basic infection control, increased oversight, and advancement and uptake of technologic innovation.

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TABLE 1.

Pateint Notification Events for Bloodborne Pathogen Testing due to Unsafe Injection Practices—United States, January 2001–December 2011

State*	Year Notified†	Health Care Setting	No. Persons Notified‡, n	Unsafe Injection Practices§	Medication(s) Involved	Notified by Whom	References
Evidence of bloodborne pathogen transmission at the time notification was initiated‖							
Patient-to-patient transmission							
New York	2001	Endoscopy clinic	2009	Suspected syringe reuse contaminating medication vials	Unspecified anesthesia medications	Health department	Centers for Disease Control and Prevention,[7] New York City Department of Health and Mental Hygiene, unpublished data
New York	2002	Physician office	1042	Mishandling of medication vials and injection equipment, medication preparation in contaminated environment	Atropine, dexamethasone, and vitamin B_{12}	Health department	Centers for Disease Control and Prevention,[7] Samandari et al[11]
Oklahoma	2002	Pain management clinic affiliated with a hospital	908	Overt syringe reuse from one patient to another	Midazolam, fentanyl, and propofol	Affiliated hospital	Centers for Disease Control and Prevention,[7] Comstock et al[12]
Nebraska	2002	Hematology/oncology clinic	613	Syringe reuse contaminating saline bags	Saline flush	Health department	Centers for Disease Control and Prevention,[7] Macedo de Oliveria et al[13]
New York	2003	Endoscopy clinic	1199	Suspected needle or syringe reuse contaminating medication vials	Unspecified anesthesia medications	Health department	Marx et al,[14] New York City Department of Health and Mental Hygiene, unpublished data
California	2003	Pain management clinic	52	Suspected syringe reuse contaminating medication vials	Lidocaine	Health department	San Diego County Department of Health and Human Services, unpublished data

State*	Year Notified†	Health Care Setting	No. Persons Notified‡, n	Unsafe Injection Practices§	Medication(s) Involved	Notified by Whom	References
Florida	2005	Alternative medicine clinic	253	Mishandling of medication vials, failure to prepare and store intravenous infusions under aseptic conditions	Unspecified chelating agent	Health department	Sanderson et al[15]
New York	2007¶	Pain management clinic, physician office (orthopedic)	9000	Syringe reuse contaminating medication vials	Bupivacaine, ketorolac, triamcinolone, iohexol (contrast)	Health department	New York State Department of Health, unpublished data
New York	2007	Multiple endoscopy and ambulatory surgical centers	4490	Suspected syringe reuse contaminating medication vials	Propofol	Health department	Gutelius et al[16]
New York	2008	Endoscopy clinic	259	Suspected mishandling of single-dose vials for multiple patients	Propofol	Health department	New York City Department of Health and Mental Hygiene, unpublished data
Nevada	2008	Ambulatory surgical centers (single-purpose endoscopy clinics)	63,000	Syringe reuse contaminating medication vials	Propofol	Health department	Fischer et al,[17] Centers for Disease Control and Prevention,[18] Southern Nevada Health District[19]
North Carolina	2008	Cardiology clinic	1205	Syringe reuse contaminating medication vials	Saline flush	Health department	Moore et al[20]
New Jersey	2009	Hematology/oncology clinic	4600	Mishandling of medication vials, medication preparation in contaminated environment, common-use saline bag for multiple patients	Saline flush, possibly unspecified chemotherapy agents	Health department	Greeley et al[21]
Florida	2009	Alternative medicine clinic	163	Syringe reuse contaminating medication vials, mishandling of	Various infusion therapies, including EDTA and vitamin C	Clinic, health department	Florida Department of Health, unpublished data

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State*	Year Notified†	Health Care Setting	No. Persons Notified‡, n	Unsafe Injection Practices§	Medication(s) Involved	Notified by Whom	References
				medication preparation			
New York	2009	Endoscopy clinic	3287	Suspected syringe reuse contaminating medication vials	Propofol	Health department	New York City Department of Health and Mental Hygiene, unpublished data
New Jersey	2010	Hospital	80	Suspected mishandling of single-dose vials for multiple patients	Propofol	Hospital	New Jersey Department of Health and Senior Services, unpublished data
New Jersey	2010	Long-term care facility	182	Suspected mishandling of insulin pens for multiple patients, mishandling of medication preparation	Insulin, other unspecified medications	Long-term care facility, health department	New Jersey Department of Health and Senior Services, unpublished data
California	2011	Pain management clinic	2293	Syringe reuse contaminating medication vials, mishandling of medication preparation	Lidocaine, iohexol (contrast), sodium bicarbonate	Health department	Los Angeles County Department of Public Health[22]
New York	2011	Pain management clinic	466	Suspected syringe reuse contaminating medication vials	Propofol, midazolam, lidocaine	Health department	New York City Department of Health and Mental Hygiene, unpublished data
Provider-to-patient transmission							
Texas, Virginia, District of Columbia	2004	Hospitals	543	Contamination of vials/syringes, narcotics diversion by provider	Fentanyl	Hospitals	Nahill,[23] CDC, unpublished data
Colorado, New York	2009	Hospitals, ambulatory surgical center	8690	Syringe reuse, narcotics diversion by provider	Fentanyl	Hospitals and ambulatory surgical center	Denver Channel,[24] Colorado Department of Public Health and Environment[25]
Florida	2010	Multispecialty clinic affiliated with a hospital	3929	Syringe reuse, narcotics	Fentanyl	Hospital	Hellinger et al[26]

State*	Year Notified†	Health Care Setting	No. Persons Notified‡, n	Unsafe Injection Practices§	Medication(s) Involved	Notified by Whom	References
				diversion by provider			
Absence of known bloodborne pathogen transmission at the time notification was initiated							
Rhode Island	2005	Physician office	669	Overt syringe reuse from one patient to another	Vitamin B_{12}	Health department	Rhode Island Department of Health, unpublished data
Michigan	2007	Physician office (dermatology)	13,500	Suspected overt syringe reuse and reuse of surgical instruments from one patient to another	Unspecified	Health department	Kent County Health Department[27]
New York	2008	Physician office (obstetrics/gynecology)	36	Overt syringe reuse from one patient to another	Influenza vaccine	Physician office	New York State Department of Health[28]
New York	2008	Hospital	185	Suspected overt reuse of insulin pen from one patient to another	Insulin	Hospital	NewsInferno[29]
Texas	2009	Hospital	2114	Overt reuse of insulin pen from one patient to another	Insulin	Hospital	William Beaumont Army Medical Center[30]
West Virginia#	2009	Pain management clinic	110	Syringe reuse contaminating medication vials	Various medication including triamcinolone and lidocaine, iopamidol (contrast)	Health department	Radcliffe et al[31]
Florida	2009	Hospital	1851	Overt reuse of saline bag and intravenous tubing from one patient to another	Saline	Hospital	Broward General Medical Center[32]
New York	2010	Physician office	25	Suspected overt syringe reuse from one patient to another	Influenza vaccine	Physician office	New York State Department of Health, unpublished data
Pennsylvania	2010	Outpatient clinic affiliated with a hospital	250	Overt syringe reuse from one patient to another	Botulinum toxin	Affiliated hospital	Fabregas[33]
Colorado	2011	Outpatient clinic	171	Overt syringe reuse from one patient to another	Influenza vaccine	Clinic	Dickinson,[34] Colorado Department of Public Health

State*	Year Notified†	Health Care Setting	No. Persons Notified‡, n	Unsafe Injection Practices§	Medication(s) Involved	Notified by Whom	References
							and Environment, unpublished data
Mississippi#	2011	Oncology clinic	623	Overt syringe reuse from one patient to another, and syringe reuse over multiple days contaminating saline bags and heparin bags	Heparin and saline flushes	Health department	Mississippi State Department of Health, unpublished data
Wisconsin	2011	Primary care clinic	2345	Overt reuse of insulin demonstration pen from one patient to another	Saline or possibly nonsterile water	Clinic	Seely,[35] Wisconsin Division of Public Health, unpublished data
Wisconsin	2011	Hospital	56	Overt reuse of insulin demonstration pen from one patient to another	Saline or possibly nonsterile water	Hospital	Wisconsin Division of Public Health, unpublished data

*This indicates only the states where facilities associated with patient notifications were located and does not take into account additional states where affected patients might have been residing at the time of potential exposure or notification.

†For notification events that had multiple rounds of notifications, this indicates the year of first round of notifications.

‡Represents the estimated minimum number of patients notified.

§Indicates documented lapses (based on direct observations or interviews with the implicated provider) unless otherwise specified.

‖These notification events took place in the context of public health investigations in which health care was recognized as the source of hepatitis B or C virus transmission.

¶Preliminary investigation involved initial notification of 98 patients in 2005, but formal notification activities were not conducted until 2007.

#Patient notifications prompted by breaches identified in the context of a bacterial outbreak: Staphylococcus aureus infections following epidural injections in West Virginia, *Pseudomonas aeruginosa*, and *Klebsiella pneumoniae* infections in Mississippi.

CDC indicates Centers for Disease Control and Prevention; EDTA, ethylenediamine tetraacetic acid.