HHS Public Access

Author manuscript

Am J Infect Control. Author manuscript; available in PMC 2021 June 01.

Published in final edited form as:

Am J Infect Control. 2020 June ; 48(6): 718–724. doi:10.1016/j.ajic.2020.02.013.

Outbreaks and infection control breaches in health care settings: Considerations for patient notification

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Keywords

Patient communication; Infection control infringement; Health care

BACKGROUND

The Division of Healthcare Quality Promotion (DHQP), within the Centers for Disease Control and Prevention (CDC), provides assistance to health departments and health care facilities investigating potential outbreaks and infection control breaches.[1–3] These consultations typically involve assessments regarding potential risk of pathogen transmission and need for patient notification (ie, informing affected individuals about the outbreak or breach).[4–6] These assessments can be challenging. The available information might not be sufficient to clearly characterize patient harms and infection risks. Accepted standards regarding patient notification in these situations are lacking. Stakeholder consensus on the best path forward can be difficult to obtain as the expectations of patients, health care providers, health care facilities, and public health do not always align.

CDC/DHQP previously published a framework describing a qualitative approach to the assessment of infection control breaches that occur in the absence of documented pathogen transmission.[4] The framework highlighted exposures such as syringe reuse that clearly pose high risk of bloodborne pathogen transmission and warrant notification and testing of patients. Emphasis was placed on bloodborne pathogen risks as these infections can have serious long-term consequences but are often silent. Patients might not know they are infected or receive appropriate care absent notification and testing. The framework clarified the importance of notifying patients for breaches that have been shown in the past to result in bloodborne pathogen transmission (ie, Category A breach). Less clear in the framework were the triggers for patient notification in response to breaches that pose lower or uncertain risk of bloodborne pathogen transmission (ie, Category B breaches) or other breaches or health care exposures (eg, contaminated medical product) that might not pose risk of

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Conflicts of interest: None to report.

bloodborne pathogen transmission but could still potentially transmit bacteria or other pathogens. Notification of patients as part of outbreak investigations was also not addressed in the previous framework.

CDC/DHQP favors a transparent and proactive approach to patient notification for health care-associated infection control breaches and outbreak investigations.[7] In this paper, we offer an expanded framework based on ethical principles,[8] including Transparency (truth telling), Beneficence (moral duty to act in patients' best interests), and Autonomy (respect patients' ability and right to make decisions and manage their own health). This framework can be employed during the investigation of serious infection control breaches and outbreaks (both potential and confirmed) and builds on previous work regarding notifying patients about medical errors.[9–12] It also adds specificity to existing codes of ethics for physicians[13] and nurses,[14] such as the Code of Medical Ethics from the American Medical Association which states that "Even when new information regarding the medical error will not alter the patient's medical treatment or therapeutic options, individual physicians who have been involved in a (possible) medical error should: Disclose the occurrence of the error, explain the nature of the (potential) harm, and provide the information needed to enable the patient to make informed decisions about future medical care…"[13] In this expanded framework, we describe 3 primary triggers for performing patient notification and then use scenarios to illustrate their application. Triggers for public disclosures (ie, alerting people not immediately affected by the outbreak or breach) and the process for performing a patient notification are beyond the scope of this framework.

TRIGGERS FOR PERFORMING PATIENT NOTIFICATION IN THE CONTEXT OF A HEALTH CARE-ASSOCIATED OUTBREAK OR INFECTION CONTROL BREACH

We describe 3 main triggers to perform patient notification when investigating a possible health care-associated outbreak or infection control breach. The triggers identified here are advisory in nature and create no new legal obligations for health care facilities. Rather, in this context and arising from existing ethical principles,[8] codes of medical ethics,[13,14] and patient preferences,[9,12] triggers for notifying patients (or their surrogate decision maker if the patient or resident lacks decision-making capacity) include when patients: (1) have experienced harm, (2) require information to identify and/or mitigate a potential harm, or (3) their care is altered. The following actions would address these 3 triggers.

1 Notify patients when they have experienced harm, including explaining how the harm or change to their health care status likely occurred.

Within the context of this framework, harm refers primarily to developing an infection; we have extended it more broadly, here, to include becoming colonized with an emerging highly antibiotic-resistant pathogen (eg, carbapenem-resistant *Enterobacteriaceae* [CRE]). This type of notification often takes the form of a conversation with the patient or their surrogate, as part of routine clinical care.

2 Provide information patients need to identify and/or mitigate a potential harm, including available information regarding the breach or outbreak.

When an outbreak or infection control breach is first suspected or identified, the extent of patient harm is usually not evident. At-risk patients might have already developed signs or symptoms of infection but either have not sought care or have presented at a facility other than the index facility. Alternatively, at-risk patients might need to undergo screening (eg, surveillance cultures or bloodborne pathogen testing) or be made aware of signs and symptoms that could indicate infection. Signs and symptoms of infection with nontuberculous mycobacteria (NTM), for example, may take a long time to manifest following exposure. Further, most patients with newly acquired hepatitis B virus or hepatitis C virus (HCV) infection do not manifest signs or symptoms of acute infection; likewise, early signs and symptoms of acute human immunodeficiency virus (HIV) infection may be mistaken for a self-limited viral illness. In situations where bloodborne pathogen risk is present, patient notification is important so patients can obtain appropriate testing.[15] For some pathogens, testing before the development of signs and symptoms of infection might not be reliable; however, notification remains advisable so patients can be counseled about monitoring for signs and symptoms and the action(s) to take if they develop. In either situation (ie, proactive testing, counseling for signs and symptoms), patients should receive plain language information explaining why they are being contacted as well as any actions they might need to take to protect others (eg, advising patients with respiratory infection to practice respiratory hygiene and cough etiquette). This outreach might also be important early in an investigation to support case finding, helping to confirm the presence of an outbreak or better define its magnitude and scope. Of note, identifying at-risk patients can be challenging compared with identifying those who have been harmed (trigger 1) or those who have experienced an alteration in care (trigger 3) when relevant exposures are not well documented in patient charts or billing records.

3 Notify patients when they have experienced an alteration in care that results from an outbreak or infection control breach.

Patients who develop an infection and, often, patients who become colonized with an antibiotic-resistant pathogen will experience an alteration in care. This might include receipt of antibiotics that they would not otherwise have received or use of additional infection control precautions (eg, the use of gowns or masks, restricting the patient to their room) during the current or future health care encounters. Further, alterations in care might not be isolated only to patients who develop infection or colonization; in a long-term care facility, for example, outbreak control measures may include decisions to restrict visitors or limit group activities, which could affect all facility residents.[16]

PATIENT NOTIFICATION SCENARIOS

The scenarios that follow describe application of our patient notification triggers in a variety of real-world (Scenarios 1,2,4–6,11) and hypothetical situations (Scenarios 3,7–10,12) that reflect some of the breaches and considerations raised during notification consultations. The scenarios do not necessarily take into account any jurisdictional requirements[17,18] that might influence decisions regarding patient notification.

OUTBREAKS

1 Outbreak in an oncology clinic:

A local hospital infection preventionist notified the health department of 4 patients admitted to the hospital with *Pseudomonas aeruginosa* bloodstream infection (BSI); 2 of these patients also had *Klebsiella pneumoniae* BSI.[19] All 4 patients had an indwelling infusion port and were receiving infusion services at a physician-owned outpatient oncology clinic. As the health department's investigation began, 4 additional clinic patients were admitted to the hospital with catheter-associated BSIs; the clinic was closed under a public health order. All current patients receiving infusion services at the clinic were contacted by the health department, informed of the outbreak, and assessed for symptoms of infection; their primary care physicians were also notified of the risk and asked to monitor for and report any infections. Communication was also maintained with area hospitals to identify additional hospital admissions for these patients. An assessment of infection control practices identified serious longstanding breaches in handling of injectable medications, including overt reuse of syringes for more than 1 patient. A letter was sent to all patients who had ever received care at the clinic informing them of their potential exposure to unsafe injection practices and advising them to seek bloodborne pathogen testing, which was offered for free at county health clinics. All 3 notification triggers applied in this scenario.

2 Outbreak in a neonatal intensive care unit:

A cluster of 4 patients with infections caused by *Staphylococcus aureus* strains that had a similar morphology and antibiogram were identified in a 7-day period.[20] An investigation was launched by the facility and steps were taken to limit further spread within the unit, including use of screening cultures; cohorting; Transmission-Based Precautions for patients found to be colonized or infected; and mupirocin treatment for patients and staff. Parents of patients in the neonatal intensive care unit were given a letter notifying them of the outbreak and outlining the rationale for screening cultures, cohorting, and mupirocin treatment. They were also advised regarding recommended infection prevention practices (eg, hand hygiene) to prevent transmission on the unit. All 3 notification triggers applied in this scenario.

3 Outbreak in a nursing home:

A nursing home identified acute respiratory illness among 4 residents on the same unit. The cause of the infections was unknown. The nursing home immediately contacted the health department and implemented measures to prevent further transmission. Infected residents were placed on Contact and Droplet Precautions (including eye protection to be worn by health care personnel caring for infected residents), in either a single room or cohorted with other infected residents. All residents and health care personnel were notified, in person and through posted signs, about the emergence of respiratory infections in the facility and the need to monitor for and immediately report any signs or symptoms of respiratory infection. Active surveillance for new infections was also implemented. Although the source of the outbreak was unknown, unvaccinated residents and staff were offered influenza vaccine. New admissions to the unit were suspended and group activities were cancelled, including meals in the dining hall. Signs and supplies emphasizing respiratory hygiene and cough etiquette were posted throughout the facility; letters were sent to family members informing

them about the outbreak and reminding them not to visit when ill. All 3 notification triggers applied in this scenario.

4 Outbreak associated with contaminated medication:

The health department received a report of a single case of fungal meningitis in an immunocompetent adult after an epidural steroid injection at an outpatient clinic.[21] Initially, the health department conducted outreach to the clinic and area hospitals to search for additional cases and determine if an outbreak existed or if this was an isolated infection. A multistate outbreak was ultimately confirmed and the source of the infections (contaminated pharmacy-compounded steroid medication) was identified. Early information suggested that presenting symptoms of fungal meningitis were often vague, leading to delayed diagnosis and high risk of mortality and other severe outcomes. An aggressive effort was then undertaken by health departments and the facilities that administered the contaminated medications to directly contact exposed patients (eg, by telephone), informing them of the signs and symptoms of infection that should prompt them to seek care. In addition, public health investigators provided physicians with guidance that would allow them to properly diagnose and treat the infections. Notification of patients who had already developed infection was also critical to ensure they and their physicians knew their infection was likely fungal in origin and to direct them to treatment guidance. Notification triggers 1 and 2 primarily applied in this scenario.

5 Outbreak associated with heater-cooler devices:

A cluster of invasive NTM infections among open-heart surgery patients at a single hospital was reported to public health.[22] The ensuing investigation identified an association between the infections and exposure to the LivaNova 3T heater-cooler device used during cardiac surgery procedures requiring cardiopulmonary bypass (consistent with a recent report from Switzerland). The hospital notified approximately 1,300 open heart-surgery patients who were exposed to the device over the preceding four years. Patients were counseled about the signs and symptoms that could signal the presence of NTM infection; similar guidance was provided to area physicians. The facility also contacted patients who had been previously diagnosed with an NTM infection, along with the family members of case-patients who had died, to notify them about the infections and provide additional information. The likely source of the NTM, *Mycobacterium chimaera*, was later found to be contamination of the 3T heater-cooler device at the manufacturing site, suggesting that additional cardiac surgery patients at other facilities using the same device were at risk. Patients infected with *M. chimaera* through open-chest cardiac surgery can develop general or nonspecific symptoms that can take months to years to develop; diagnosis of these infections can be missed or delayed, making these infections more difficult to treat. Ultimately, CDC recommended that all facilities in the United States using 3T heater-cooler devices (whether or not they had a documented case) notify (by letter) all patients potentially exposed to these devices to counsel them about signs and symptoms of infection to ensure prompt recognition and treatment of these serious infections.[23] Notification triggers 1 and 2 primarily applied in this scenario.

6 Outbreak associated with contaminated duodenoscopes:

Six patients with a history of admission to the same hospital had New Delhi metallo-β-lactamase (NDM)-producing CRE isolated from clinical cultures over a 5-month period.[24] An investigation to identify the source of the organism and to assess for transmission within the facility was launched. Patients epidemiologically linked to case-patients (eg, roommates, patients admitted to the same ward where the first patient was treated) were notified and offered CRE rectal screening. A history of endoscopic retrograde cholangiopancreatography procedures involving a duodenoscope was strongly associated with being a case-patient. Review of reprocessing procedures did not identify protocol lapses; however, NDM-producing *Escherichia coli* and *Klebsiella pneumoniae* carbapenemase-producing *K. pneumoniae* were isolated from cultures obtained from the duodenoscope used on several case-patients. Based on these findings, the facility notified all patients who underwent a procedure with any duodenoscope at the hospital during the outbreak period. Patients were informed about the potential exposure to CRE and offered CRE rectal screening and bloodborne pathogen testing. Testing identified an additional 27 patients colonized with CRE; bloodborne pathogen testing did not identify previously undiagnosed infections among patients who returned for screening. Notification triggers 1 and 2 primarily applied in this scenario.

BREACHES WITH DEVICE REPROCESSING

7 Breaches in bronchoscope reprocessing:

A nurse noticed debris at the biopsy-port cap of a bronchoscope that had been reprocessed and was about to be used for a patient procedure in a hospital bronchoscopy suite. This prompted a review of bronchoscope reprocessing procedures, which identified several infection control breaches. The bronchoscope channel was not brushed as part of manual cleaning by a reprocessing technician who had been working in the suite for the last month. Further, the facility had recently purchased a new automated endoscope reprocessor (AER). The AER connectors were not compatible with the bronchoscope, which meant the scope channel was not flushed with glutaraldehyde disinfectant solution or rinsed. The water filter in the new AER had not been changed at the interval recommended by the manufacturer. The facility contacted the health department for assistance with a risk assessment, which concluded there could be risk of both bacterial and bloodborne pathogen infections. The facility sent letters to all patients who had undergone a bronchoscopy over the prior 8 months, which was when the new AER had been purchased. Patients were informed about the breaches in reprocessing and counseled that the breaches may have put them at risk of infection. Patients were informed about the signs and symptoms of respiratory infection and were also advised to return to the hospital for bloodborne pathogen testing. Notification trigger 2 applied in this scenario.

8 Breaches in cystoscope reprocessing:

A routine assessment of infection control at an outpatient urology clinic identified multiple breaches in cystoscope reprocessing. The facility failed to soak the cystoscope in cleaning solution for the recommended length of time; they did not immerse the entire cystoscope in the glutaraldehyde solution that was used to perform high-level disinfection; the cystoscope

was rinsed in a bath of initially sterile water that was only replaced when it became cloudy or began to smell. The facility contacted the health department to discuss the risks posed by identified breaches; the health department recommended a patient notification be performed. The facility sent letters to all patients who had undergone cystoscopy at the clinic since the last routine assessment had occurred (6 months prior). Patients were informed that the identified breaches could have placed them at increased risk of developing a bacterial infection following their procedure. They were instructed to contact the clinic if they developed signs and symptoms of a urinary tract or BSI. Patients who had undergone cystoscopy in the prior 2 weeks were also contacted by phone as, if infection were to occur, it would most likely manifest within 2 weeks following the procedure. The infection control breaches were not believed to pose risk of bloodborne pathogen transmission; however, the clinic agreed to provide such testing if a patient requested it. Notification trigger 2 applied in this scenario.

9 Breaches in a dental clinic:

A patient filed a complaint with the state dental board about concerning practices at a dental clinic. The dental board, in collaboration with the health department, conducted a site visit at the clinic. During the site visit, they observed multiple breaches in infection control including: the autoclave that was reportedly used to sterilize dental instruments was broken —the dentist could not provide maintenance records for the autoclave to demonstrate when it had last been properly working and there were no logs to show that equipment had been sterilized; in lieu of the autoclave, dental staff wiped the used dental equipment with a bleach wipe; “clean” dental equipment was stored, unwrapped, next to the sink where dirty equipment was cleaned. Based on findings from the site visit, the dental clinic was closed and the dentist’s license was suspended. At this point, the dentist refused to cooperate further with the investigators or turn over patient records. Because of the delay in obtaining patient records, the health department elected to move forward with a public notification through the local media advising any patient who had ever received care from the dentist to seek bloodborne pathogen testing from their primary care physician. Guidance on recommended tests was posted on the health department website. In addition, patients who did not have a primary care provider were offered testing at the local health department. Notification trigger 2 applied in this scenario.

10 Breach in surgical instrument reprocessing:

As part of an accreditation survey, surveyors found that a hospital’s newly acquired satellite clinic was not performing biologic indicator testing as part of their instrument sterilization process. This raised concerns that the lack of testing meant that sterility of instruments could not be guaranteed and was reported to the state health department. The health department assisted with a risk assessment and performed a detailed review of the clinic’s sterilization practices. Following a surgical procedure, instruments were immediately transported in a closed container to the reprocessing room. Appropriate manual cleaning with a brush and enzymatic cleaner was performed; instruments were rinsed, wrapped, and steam sterilized following recommended parameters (eg, time, temperature); mechanical and chemical indicators were used to monitor the sterilization process. The facility had never used biologic indicators. During the health department visit, a typical sterilization cycle was run

with a biological indicator; the biologic indicator was negative. The facility was instructed to commence using biologic indicators at least weekly. Based on the infection control assessment, a risk to patients was not identified. The facility was advised, for transparency, they could consider notifying patients; however, they elected not to perform a patient notification. No notification triggers were clearly met in this scenario.

BREACHES INVOLVING MEDICATION SAFETY (IE, SYRINGE REUSE AND DRUG TAMPERING)

11 Breach involving syringe reuse:

A hospital telemetry unit nurse was observed to frequently leave a partially filled syringe of saline flush near a computer work station.[25] The hospital questioned the nurse about this practice and she reported reusing syringes for more than 1 patient over the previous 6 months. She erroneously believed this was a safe, cost-saving measure if no fluids were withdrawn into the syringe before injection. At the time the breach was identified, the facility was unaware of any infections associated with the practice. The hospital notified all potentially exposed patients (by both certified and registered mail) and provided free bloodborne pathogen testing. As a result of the outreach, HCV transmission was documented as having occurred on at least one occasion from a patient with known chronic infection to a susceptible patient whose stay overlapped with the source patient. Notification trigger 2 applied in this scenario.

12 Identification of drug tampering:

An operating room nurse observed a surgical technician taking a syringe filled with fentanyl and replacing it with a syringe containing a similar appearing liquid. The technician was immediately confronted and the incident was reported to law enforcement and public health authorities. The technician admitted he had been stealing syringes of fentanyl and swapping them with syringes of saline over the prior month. He stated he always replaced the fentanyl syringes with new syringes that he filled with sterile saline from a multidose vial he kept in his locker. He was asked to undergo bloodborne pathogen testing and was found to be immune by vaccination to hepatitis B virus but negative for HCV and HIV. The hospital elected to contact all patients who had surgery on the dates the technician was working since he was hired (4 months prior). The notification letter informed patients that drug tampering by an employee had been identified and, because of the employee’s behavior, they may not have received fentanyl during their procedure. Patients were advised that the technician had tested negative for bloodborne pathogens and, based on his reported method of diversion, there was not believed to be a risk of infection. However, because they were relying on self-reported, unconfirmed behavior, they could not be certain there was not a risk (eg, patient-to-patient transmission of bloodborne pathogens from reused syringes or bacterial infections from nonsterile saline). Patients were encouraged to contact the hospital if they developed any possible signs or symptoms of bacterial infection (eg, fever, chills, pain, or redness at the injection site) and advised that, if they had concerns, the hospital would provide bloodborne pathogen testing at no charge. The hospital also adjusted patient bills to remove charges for

sedating medications used during their procedures. Notification triggers 1 and 2 applied in this scenario.

DISCUSSION

Decisions about patient notification are often not straightforward and can be subject to differing interpretations. In presenting this expanded framework, we have described triggers for patient notification in the context of a possible health care-associated outbreak or infection control breach that arise from existing ethical principles, codes of medical ethics, and patient preferences.[8–14] These include situations when patients have experienced harm (Trigger 1); when patients require information to identify and/or mitigate a potential harm (Trigger 2); or when a patient's care has been altered (Trigger 3).

All 3 notification triggers typically come into play in the context of a confirmed outbreak or an infection control breach where pathogen transmission has been confirmed. In those scenarios, there are patients who have experienced harm; there are often additional exposed patients who require information to identify and/or mitigate a potential harm; and there are usually patients who have experienced alterations in their care as a result of the exposure (eg, receipt of antibiotics). Trigger 2 typically applies when investigating a potential outbreak and in the context of an infection control breach, absent initial reports of pathogen transmission. In those scenarios, it may not be clear if an infection is part of a larger outbreak or if the identified breach or contaminated medication posed risk of pathogen transmission. Risk to patients can often only be ascertained through active outreach to potentially exposed patients to identify harm (ie, case finding). Notifications in these situations might initially focus on the highest risk groups. For example, initial outreach might focus on patients who received similar procedures on the same day as the index patient or underwent procedures in the days spanning when a breach was first identified. If done in a timely manner, this action can generate information that helps confirm the presence of an outbreak, clarifies the need to notify additional patients, and informs the evidence base and recommended standard approach for similar events in the future.

In our experience, there are 3 concerns that are often raised regarding the need for patient notification. First, there may be concern about the anxiety the notification process could cause affected patients, particularly when the risk is small, exposure is uncertain, or there is not a recommended action for them to take. Second, there may be concern that the notification will result in negative publicity or loss of trust in the health care facility or willingness of patients to seek medical care in the future; liability and financial repercussions might also be factors here. Third, there may be concern about the resources needed to perform a patient notification. While these concerns may have validity, experience and research increasingly favor full transparency and notification regarding medical errors and adverse events.[9–14]

Even if harm was unlikely and there is not an action to recommend, patients have a reasonable expectation to be informed when their health care provider or health care facility failed to meet standards of care.[9–12] Further, even if a patient is already aware of their infection or colonization status (and receiving appropriate follow-up and management), they

should still be informed if they are believed to be part of a larger outbreak. This is a step that, if overlooked, can result in damaged reputations and loss of trust in the facility or provider.[26] Patients surveyed following a notification conducted in response to a breach in endoscope reprocessing felt they had a right to know about anything that might impact the quality of their care and that such communication is important to maintain confidence in a particular institution.[9] While approximately 28% of respondents agreed it would make them nervous to be told about an error in their health care, more than 90% agreed that facilities should tell patients about any error in their care, even if the chance of harm was extremely low. Following the notification, the majority of patients surveyed had an improved perception of the facility's honesty and integrity. Other research has not identified long-term reductions in patients seeking care at hospitals where quality concerns were publicly reported.[27]

In addition, while patients will often have been counseled that infection is a known risk of a procedure and to watch for and report signs of infection as part of the routine consent process for their medical procedures, this does not obviate the need to perform a patient notification. The risk of infection communicated to the patient during the consent process assumes that the provider will meet the expected standard of care. Even if the actions recommended as part of the original consent process are unchanged (ie, watch for and report signs and symptoms of infection), patients want to know if their risk of infection has changed as the direct result of deviations from standard care practices or if they are part of a larger outbreak.[9,12]

The possibility of bloodborne pathogen transmission is a frequent consideration during the evaluation of infection control breaches. If an infection control breach is believed to pose risk of bloodborne pathogen transmission, patients should be counseled about the need for proactive testing; in some situations, postexposure prophylaxis may also be warranted, making timely notification critical. A strong recommendation for testing should accompany exposures to breaches where there is a clear and well-established risk (eg, in the context of a health care-associated hepatitis C outbreak, Category A breach, Category B breaches where neither cleaning nor high-level disinfection or sterilization were performed; see Scenarios 1, 7, 9, and 11). On the other hand, for breaches believed to pose low or uncertain risk, it may be appropriate and reasonable to forego a firm recommendation for testing and instead offer counseling and testing if requested by the individual patient (see Scenarios 6, 8, and 12). The strength of a recommendation for bloodborne pathogen testing or testing for other pathogens should be clearly communicated to patients along with the rationale for the recommendation.

As demonstrated in the scenarios, the mode of patient notification can vary from an individual notification (eg, phone call, letter, or in the moment conversation with a patient if a breach is identified as part of their health care encounter), group notification (eg, a notice at the entrance to a facility or unit), or a public notification (eg, press release or notice on a facility or health department website). While patients prefer individual notification, ideally through a face-to-face visit or phone call,[12,28] this is not always possible or practical. In certain circumstances, such as when patient records are not complete or there is an urgent need to broadly disseminate guidance to health care personnel on how to diagnose and manage exposed patients, public notification may be the preferred initial route of

communication. For example, in Scenario 9, which involved breaches in sterilization of dental equipment and concerns for bloodborne pathogen transmission, patient records were not immediately available so the health department elected to move forward with a broader public notification via a press release followed by letters if/when the records were obtained.

The third concern raised regarding need for patient notification relates to the resources needed. Patient notifications can be both resource and labor-intensive, particularly for free-standing outpatient clinics or other settings that might not have ready access to the risk management or communication infrastructure available in larger hospital systems. Under prevailing ethical and professional practices,[8–14] however, this does not obviate the need to perform patient notification when one is warranted. However, not all breaches pose the same level of risk to all patients and there may be opportunities to balance the desire for transparency with the potential to divert resources and attention from other initiatives and pressing matters. For example, if patient notification was performed every time an opportunity for hand hygiene was missed, the majority of patients could require notification after each health care encounter. While all infection control breaches warrant correction and education of health care personnel at the facility to prevent future occurrences, formal patient notification might not be warranted for every instance of an infection control breach (as was described in Scenario 10, in which biological indicators were not used but all other aspects of instrument sterilization were deemed adequate).

While this paper focused on triggers for notifying patients, this process always entails engagement of additional stakeholders including health care personnel, facility leadership, and public health. Regulatory authorities such as the state survey agency, medical, nursing or pharmacy boards, and law enforcement—as well as accrediting organizations—may also need to be included in the notification process depending on the event. Health care personnel are the first line of communication with patients and also need to understand the event and messaging to properly address questions raised by patients and their families. In some instances, such as Scenario 3, which involved an undiagnosed respiratory illness outbreak in a nursing home, health care personnel may also be at risk and need to be informed about signs and symptoms of infection or recommended actions to protect themselves and patients. They also require information about recommended infection prevention practices to prevent further transmission (eg, implementing Transmission-Based Precautions). Depending on the events, communications may need to extend beyond health care personnel working at the affected facility. For example, in Scenario 4, notification efforts extended broadly to the medical community caring for exposed patients. Because presenting symptoms were often vague and there was limited experience in diagnosing and treating the fungus, physicians required guidance on how to effectively evaluate and care for exposed patients. Further, as part of a response to multidrug-resistant organisms, interfacility communication is critical to ensure receiving facilities are aware of a patient’s multidrug-resistant organisms’ status and the level of Transmission-Based Precautions necessary to prevent transmission in the facility.[29]

By working with internal (eg, facility leadership, risk management) and external stakeholders (eg, public health) prior to conducting a notification, facilities can ensure that infrastructure is in place to manage the process. In addition to crafting appropriate

messaging for the initial outreach (eg, letter, phone call), there is a need to establish a mechanism to address patient questions and concerns (eg, call center). There may also be a need to arrange for laboratory testing or other evaluation of exposed patients. Identifying how or why the event occurred (eg, lack of training of health care personnel; lack of access to necessary patient care supplies) is critical for preventing future occurrences. While the primary responsibility for patient notification rests with the health care facility/provider, the health care-associated infections program in the health department is an important partner that can provide useful guidance, particularly for notifications associated with outbreaks, which are required to be reported in most states.[30,31] They can offer expertise with investigation and risk assessment and assist with best practices for conducting patient notification. CDC is also available for consultation in conjunction with the health department. For example, in 2018, CDC/DHQP provided technical assistance for more than 300 health care-associated outbreaks and infection control breach assessments, including on the ground investigative support for 10 of these events (CDC, unpublished data). CDC and partners, including the Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens have also developed an array of patient notification resources including toolkits, sample patient notification letters, scripts for communicating information to patients, and guides for defining and investigating outbreaks.[29,32–34]

Ultimately, a strong infection prevention and control program that includes education of health care personnel, methods to prevent and monitor for diversion of controlled substances, and a process to verify ongoing adherence to recommended practices can help avoid a large-scale patient notification.[35] Such activities can help prevent the infection control breaches or other unsafe practices that contribute to outbreaks and health care-associated infection risks. Regular auditing of practices and encouraging staff to promptly report concerns can also be helpful in limiting the timeframe and scope for a potential notification. For example, in Scenario 8, breaches in cystoscope reprocessing were identified as part of a routine assessment of infection control in the facility. When determining the timeframe for a patient notification, the facility notified all cystoscopy patients over the prior 6 months, which was when the last infection control assessment documenting appropriate practices had been performed. This notification could have been avoided or the timeframe could have been narrowed if the facility had performed more frequent assessments. CDC has developed a number of setting-specific resources health care facilities can use to routinely assess infection prevention practices.[36]

This expanded framework clarifies triggers for patient notification in the context of health care-associated outbreaks and breaches in infection control. Application of these triggers may result in a more consistent, less arbitrary approach to patient notifications. Ensuring transparency in these situations is important to ensure patients have the information they need to protect their health and make informed decisions about their care and helps build trust in their providers.

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