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Outpatient Settings Policy Options for Improving Infection Prevention

Licensing

Training

Reporting

Investigating

Key Policy Elements for Best Practices

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

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Abbreviations List

ASC	Ambulatory surgical center
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
FDA	Food and Drug Administration
HAI	Healthcare-associated infections
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCW	Healthcare worker
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human immunodeficiency virus
NHSN	National Healthcare Safety Network

Executive Summary

Recent experiences with newly emerging and highly infectious diseases have spotlighted the importance of robust public health and healthcare delivery systems. These needs extend across all healthcare settings and jurisdictions. Efforts to define and apply basic standards of infection control in outpatient healthcare settings[1] require bolstering at state, local, territorial and federal levels.

Current policies are highly variable, leaving many gaps in patient protection from infectious diseases (e.g., healthcare-associated infections or HAIs). For example, only a minority of outpatient facilities are certified by the Centers for Medicare and Medicaid Services (CMS) and few are licensed by states or maintain accreditation status. As a result, many of these facilities are opened and operated without being held to minimum safety standards for infection control or other aspects of patient care, potentially putting patients at risk. States and their supporting HAI multidisciplinary advisory groups who are interested in more effective and proactive oversight of outpatient facilities may consider addressing four key elements: (1) facility licensing/accreditation requirements, (2) provider-level training, licensing and certification, (3) reporting requirements, and (4) establishment and effective application of investigation authorities.

This document is designed to assist state, local, and territorial health departments and policymakers at various levels to analyze current policies in outpatient settings, review proposed changes, and inspire possible changes to improve programs.

The following sections outline the four key elements recommended by the workgroup and reflect CDC and health department encounters with outbreak investigations,[2] as well as feedback from workgroup members based on their experiences and expertise. Each section contains an explanation of the element and its components, sample scenarios highlighting the need for effective practices or strategies, potential options to improve programs, examples of existing state policies, and other aids designed to help states and territories identify gaps and pursue potential solutions at the state, territorial, local, and facility levels.

1. Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care; http://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html

2. Outbreaks and Patient Notifications in Outpatient Settings; http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

Introduction

Over the past several decades, healthcare delivery has shifted from the acute, inpatient hospital setting to a variety of ambulatory and community-based settings. CDC recognizes the critical role of public health in patient safety and is interested in identifying barriers and facilitators, including policies that show early promise in reducing HAIs in outpatient settings. To accomplish this goal, CDC formed a workgroup to obtain input and facilitate the sharing of experiences from state, territorial, local, and tribal health departments that are considering, or have existing policies that address infection control or HAI prevention in outpatient settings.

Ambulatory care is provided in hospital-based outpatient clinics, nonhospital-based clinics and physician offices, ambulatory surgical centers, and many other specialized settings. Americans frequently receive care in ambulatory settings, with over three-quarters of all operations in the United States occurring in an outpatient setting.[3] Vulnerable patient populations rely on frequent and intensive use of ambulatory care to maintain or improve their health. For example, each year more than one million cancer patients receive outpatient chemotherapy, radiation therapy, or both.[4] It is critical that all of this care be provided under conditions designed to protect patients and save lives by minimizing or eliminating the risk of HAIs or other adverse events.

Compared to inpatient acute care settings, ambulatory care settings have traditionally lacked infrastructure and resources to support infection control and surveillance activities. Physician licensure, while beneficial, is not enough to ensure quality healthcare is delivered and patients are effectively protected. Dual licensure of both facilities and healthcare providers has the ability to ensure that healthcare is provided in a safe environment and the quality of care is held to the same standards throughout the state. While data describing risks for HAIs are lacking for most ambulatory settings, numerous outbreak reports[5, 6] have described transmission of gram-negative and gram-positive bacteria,[7] mycobacteria, viruses[8], and parasites.[9] This highlights the need for more consistent surveillance data.[10]

3. Barie PS. Infection Control Practices in Ambulatory Surgical Centers. JAMA. 2010;303:2295-2297.

4. Halpern MT, Yabroff KR. Prevalence of Outpatient Cancer Treatment in the United States: Estimates from the Medical Panel Expenditures Survey (MEPS). Cancer Investigation. 2008;26:647-651.

5. Guh, et al. Patient Notification for Bloodborne Pathogen Testing due to Unsafe Injection Practices in the US Health Care Settings, 2001–2011; Medical Care: September 2012 - Volume 50 - Issue 9 - p 785–791. doi: 10.1097/MLR.0b013e31825517d4

6. Kuehn, Bridget. Unsafe Injection Practices Plague US Outpatient Facilities, Harm Patients. JAMA. 2012;308(24):2551-2552. doi:10.1001/jama.2012.114239.

7. Anderson, et al. Invasive Staphylococcus aureus Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, 2012; Morbidity and Mortality Weekly Report: July 13, 2012 / 61(27);501-504; http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm

8. Greeley, et al. Hepatitis B outbreak associated with a hematology-oncology office practice in New Jersey, 2009; AJIC: American Journal of Infection Control Volume 39, Issue 8 , Pages 663-670, October 2011. doi:10.1016/j.ajic.2010.11.011

9. Outbreaks and Patient Notifications in Outpatient Settings; http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

10. United States Government Accountability Office. HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action Is Needed; http://www.gao.gov/assets/600/592406.pdf

In many instances, outbreaks and other adverse events[11] were associated with breakdowns in basic infection control procedures (e.g., reuse of syringes leading to transmission of bloodborne viruses[12]).

Outpatient settings in particular warrant increased attention from local, territorial, and state health agencies, which are well-positioned to ensure that basic standards of infection control[13] are understood and observed consistently across the healthcare system.

All outpatient healthcare facilities, including physician offices and specialty clinics, might be expected to follow these basic infection control practices at a minimum, regardless of licensure and accreditation status.

This document is designed to assist state, local, and territorial health departments and policymakers at various levels to analyze current policies in outpatient settings, review proposed changes, and inspire possible changes to improve programs. The following sections outline key considerations and elements that have been recommended by the workgroup as possible effective policy or practice strategies to improve the oversight of outpatient healthcare settings. These sections reflect CDC and health department experiences with outbreak investigations, as well as feedback from workgroup members based on their experiences and expertise. Each section contains:

- An explanation of the element and its components
- Sample scenarios that highlight the need for effective practices or strategies (additional examples of outbreaks in outpatient settings available on the CDC website)[14]
- Potential options to improve programs
- Examples of existing state policies representative of the elements
- Aids designed to help states identify gaps and pursue potential solutions at the state, local, territorial, and facility levels

11. Robyn, et al. Notes from the Field: Adverse Events Associated with Administration of Simulation Intravenous Fluids to Patients — United States, 2014; Morbidity and Mortality Weekly Report: March 6, 2015 / 64(08);226-227; http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6408a6.htm

12. Guh, et al. Patient Notification for Bloodborne Pathogen Testing due to Unsafe Injection Practices in the US Health Care Settings, 2001–2011; Medical Care: September 2012 - Volume 50 - Issue 9 - p 785–791. doi: 10.1097/MLR.0b013e31825517d4

13. Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care; http://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html

14. Outbreaks and Patient Notifications in Outpatient Settings; http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

1. Facility Licensing/Accreditation

Facility licensure and accreditation requirements can help maintain public safety and ensure quality of healthcare delivery. In addition, they also can provide states with the number and type of facilities within their borders and additional influence over these facilities and their activities. In some states, facility licensing also acts as a source of revenue for the state health department, and is used to support infection control activities for these facilities.

Only a minority of outpatient healthcare facilities are certified by CMS and relatively few are licensed by states or maintain accreditation status. As a result, many outpatient facilities are opened and operated without being held to minimum safety standards for infection control or other aspects of patient care, apart from sanctions and penalties following investigations into the practice. This leads to gaps in the ability of state, territorial, and local health departments to monitor and improve healthcare quality and prevent adverse events. Regardless of licensure or accreditation, all outpatient healthcare facilities, including physician offices and specialty clinics, might be expected to follow, at a minimum, basic infection control practices outlined in Standard Precautions, as summarized in the CDC Outpatient Guide.[15] More detailed requirements may be applied to certain types of outpatient settings based on their scope of practice.

Outpatient facilities may offer surgical and other invasive procedures without being subject to national infection control standards or any form of on-site inspections. In the following example, the absence of facility licensing and accreditation results in a delay in discovering an outbreak, potentially placing patients at risk.

A plastic surgery center chain, which does not participate in Medicare or accept other health insurance payments, is unlicensed and unaccredited in the two states where its facilities are located. A physician, who is not a board-certified surgeon, performs liposuction procedures at two of the facilities in the chain with two assistants. The team transports equipment between facilities and has deficient infection control practices (e.g., failure to wear face masks consistently during surgical procedures). A hospital notifies the health department after admitting several of the physician's patients with invasive group A Streptococcus infections, and one patient dies.[16, 17]

15. Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care; http://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html

16. Beaudoin, Amanda L., et al. "Invasive Group A Streptococcus Infections Associated With Liposuction Surgery at Outpatient Facilities Not Subject to State or Federal Regulation"; http://archinte.jamanetwork.com/article.aspx?articleid=1876675

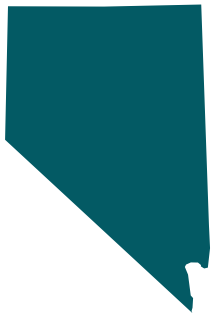
17. Morgan, Daniel J., et al. "The Gap in Patient Protection for Outpatient Cosmetic Surgery"; http://archinte.jamanetwork.com/article.aspx?articleid=1876672

To better protect patients and save lives from lapses illustrated by the above example, states may consider the following actions:

- Maintaining accurate information on the locations, numbers, and types of outpatient facilities within the state
  - ❒ Documenting which types of outpatient facilities are able to operate under a physician's license instead of a facility license
- Requiring all outpatient healthcare facilities be registered
  - ❒ Requiring all outpatient healthcare facilities to identify a licensed healthcare professional to serve as the infection control coordinator
  - ❒ Requiring that all outpatient healthcare facilities adopt standard requirements for record keeping and record sharing practices, such as documentation of medications given, procedure logs, personnel training and certification, healthcare provider vaccination information (e.g., hepatitis B and seasonal influenza vaccination), and environmental cleaning practices
- Enhancing collaboration between the medical boards that license healthcare providers, the licensure agencies that license healthcare facilities, other state agencies, and accrediting agencies
  - ❒ Documenting which agency or licensing board is responsible for the issuance and review of the physician's licenses and facility licenses
  - ❒ Ensuring that accrediting agencies report adverse events or unsafe conditions identified during an accreditation survey to the appropriate local and/or state agency
  - ❒ Requiring accrediting bodies to incorporate basic infection control practices in their initial accreditation, subsequent inspections, and applications for renewed accreditation
  - ❒ Ensuring that pharmacy board requirements are communicated and monitored for any outpatient facility that is engaged in on-site drug compounding activities
  - ❒ Requiring licensure for staffing agencies that place healthcare providers
- Designating license fees or fines for the support of education, technical assistance, and inspection/monitoring activities by the appropriate state/local agency
- Working with medical liability and healthcare insurance companies to encourage them to assess the infection control practices used by insured or participating healthcare providers and facilities
- Using standard approaches such as state agency survey protocols to measure adherence to Standard Precautions (e.g., use CDC-developed survey tools for expanded on-site assessments not limited to CMS-certified facilities or state-licensed surgery centers)

Examples of existing facility licensing or accreditation policies:

New York state[18] – full accreditation from a nationally recognized agency must be obtained and maintained by licensed physicians performing any surgical or invasive procedure requiring anesthesia or other sedation or any outpatient liposuction procedure, where the procedure is performed outside of a hospital. The licensed physician may only perform these procedures in a facility that has obtained and maintained full accreditation from a nationally recognized agency.



Nevada[19] – physician offices and clinics providing medical care that includes general anesthesia, conscious sedation or deep sedation and surgical centers for ambulatory patients must obtain and maintain accreditation by a state approved accrediting agency. The Division of Public and Behavioral Health of the Department of Health and Human Services inspects each of these facilities prior to issuing a license and performs annual unannounced inspections focused on infection control practices. Deficiencies found must be corrected by the facility under penalty of licensure or fines.

West Virginia[20] – all pain management clinics are required to obtain a license that must be annually renewed and are subject to annual inspection. Application for licensure must include criminal background checks on all current and expected employees and licensure may be denied or revoked based on information submitted.

Massachusetts[21] – clinics designated as ambulatory surgical centers are required to document that all staff, including contractors, students, volunteers, or other temporary personnel, have received a seasonal influenza vaccination unless they meet exclusion criteria. The Commissioner of Public Health may issue guidelines for the type of vaccine to be administered and required dates for vaccination each year.

18. Laws of New York PBH Public Health, Title 2-A, Section 230d

19. Nevada Revised Statute NRS 449.443 – NRS 449.448

20. West Virginia Code §16-5H

21. Code of Massachusetts Regulations 105 CMR 140, Licensure of Clinics

Questions to consider in your state:

- Do you know which types of outpatient healthcare facilities in your state or jurisdiction require licensure or accreditation and which regulatory body oversees this licensure/accreditation?
- Are any types of physician offices required to be licensed or accredited?
- Are there infection control training requirements for physician offices and other outpatient healthcare facilities in your state?
- Are there established lines of communication between the medical boards that license healthcare providers and the licensure agencies that license healthcare facilities?
- Are medical boards that license healthcare providers and the licensure agencies that license healthcare facilities engaged effectively with your state's HAI program?

2. Healthcare Provider Training, Licensure, and Certification

Appropriate healthcare provider training ensures that healthcare professionals, in addition to maintaining their own licensing standards, keep pace with constantly updating information, evolving techniques, technology, and the increased demands of an ever-expanding and aging population. Lack of sufficient healthcare knowledge and skills can directly affect patient safety and quality of care, increasing patient morbidity and mortality. Additionally, consistently high turnover among healthcare workers stresses the need for maintaining a high level of healthcare knowledge within the industry.

Requirements for healthcare provider training, licensure, and certification are highly variable across the United States. While licensure requirements are generally clear for all physicians and registered nurses, requirement for continuing education and other forms of training vary greatly, as do licensing/certification requirements for allied health professionals. In addition to state licensure requirements, this may also include requirements by an employing facility. Physicians, nurses, and others who are employed by hospitals generally receive more frequent and standardized infection control training relative to their independent or outpatient-based colleagues.

Allied health professionals, particularly those working in doctor's offices and other outpatient settings that are not licensed, accredited or CMS-certified, may have received minimal formal pre-service training, with on-the-job training that may be minimal or incomplete. For many medical/dental technicians and assistants, annual OSHA-mandated bloodborne pathogen training may represent their only exposure to formal continuing education addressing infection control issues. Delegation of activities, including preparing and sometimes administering injections, is loosely governed by state physician and/or nurse practice standards, meaning that patients may receive care from staff with little training or without direct oversight. Additionally, outpatient facilities that are engaged in drug compounding may be doing so with unqualified personnel who lack appropriate training, credentials, and equipment.

It is critical that all employees receive infection control training that reflects best practices and is appropriate for their duties to ensure patients are protected from adverse events. Training on injection safety is especially critical for unlicensed healthcare workers who may be involved in preparing or delivering vaccinations or other injections. In the following example, unsafe practices due to a lack of proper training resulted in a patient notification.

A medical technician in a busy pediatric clinic is administering influenza vaccine to children. Instead of using an appropriate pre-filled pediatric dose, the technician takes a pre-filled adult dose, administers half to the child, removes the needle and saves the half-filled syringe, storing it in a cardboard box in the refrigerator, unlabeled. Children who receive an injection using the leftover contents are placed at risk of bloodborne pathogen transmission. This also places the technician at risk for a needlestick injury. Once this practice is uncovered, the state and local health departments help oversee a patient notification effort which generates significant media attention.[22]

22. CBS Denver – "Children told to be tested for HIV after flu vaccines reused"; http://www.9news.com/news/article/193134/180/Children-told-to-be-tested-for-HIV-after-flu-vaccines-reused

To better protect patients and save lives from problems illustrated by the above example, states may consider the following actions:

- Requiring HAI prevention and infection control training as a condition of licensure for physicians, nurses, medical assistants, technicians, and others
- Requiring a minimum level of periodic continuing education credits related to infection control training for all licensed healthcare personnel
- Requiring every facility infection control coordinator to participate in an infection control continuing education training program approved by the state
- Expanding licensure and/or certification requirements for all healthcare providers, with mechanisms for checking compliance
- Maintaining a list of all licensed or certified healthcare providers that have practiced or are currently practicing in the state, including any punitive actions against them, in a manner that would allow its use by medical facilities to validate employee licenses or certifications
- Ensuring that healthcare provider information pertaining to drug theft, tampering, or other misconduct is shared
- Requiring state-approved basic infection control training for anyone engaged in healthcare work under the supervision of a licensed healthcare professional, including workers not licensed by the state
- Enacting licensure and/or certification requirements for all providers, including health professionals working in short-term or temporary assignments
- Communicating healthcare worker vaccination recommendations to healthcare workers on a regular basis

Examples of existing healthcare provider training, licensure and certification policies:"

Colorado[23] – surgical assistants and surgical technologists employed or contracted to work at a healthcare facility (e.g. ambulatory surgical facilities), a physician's office where surgery is performed, or a staffing or contracting agency for surgical assistants and surgical technologists are required to register with the state Director of Registrations. This information is compiled into a publicly available database and includes: education and training qualifications; all current employers and employers within previous five years; current certification by a nationally accredited certifying organization; and any civil, criminal, or administrative action relating to their performance of the duties of a surgical assistant or surgical technologist.

Florida[24] – ambulatory surgical centers must establish an internal risk management program that includes risk management and risk prevention education and training of all non-physicians as part of their orientation and annual training. Additionally *unlicensed* healthcare providers may assist or participate in a surgical procedure only if the following conditions are met:

- Not an activity that may only be performed by a licensed health care practitioner
- Facility authorizes the person to do so following competency assessment
- Done under the direct and immediate supervision of a licensed physician

North Carolina[25] – all healthcare organizations shall ensure that all of their healthcare workers are trained in the principles of infection control and the practices required by the organization's infection control policy, shall require and monitor compliance with the policy, and update the policy as needed. Healthcare workers and emergency responders shall, with all patients, follow CDC Guidelines on blood and body fluid precautions incorporated by reference in 10A NCAC 41A .0201. The healthcare organization shall develop an infection control plan and designate one on-site staff member for each facility to direct infection control activities, who must complete a course in infection control approved by the Department of Health and Human Services.

23. CO Revised Statutes Title 12, Article 43.2 - Surgical Assistants and Surgical Technologists

24. Florida Statutes Title XXIX, Section 395.0197

25. NC Administrative Code 10A 41A.0206

New York State[26] – all dental hygienists, dentists, licensed practical nurses, optometrists, physicians, physician assistants, podiatrists, registered professional nurses, specialist assistants, medical students, medical residents, and physician assistant students must complete an initial health department approved training course in infection control practices to prevent transmission of HIV and hepatitis B and C, as well as refresher training every four years. The law also requires the Department of Health to consult medical and infection control professionals on a regular basis to review the training program and revise its content as needed.

Washington[27] – ambulatory surgical facilities are required to develop a coordinated quality improvement program in order to obtain and maintain a license. The program must include the following items related to the maintenance of medical staff and is contained within their relevant personnel files:

- Periodic review of credentials, professional conduct, and competence in healthcare delivery of all medical staff and all persons employed by/associated with the facility
- Training in quality improvement, patient safety, medication errors, injury prevention, responsibility to report professional misconduct, the legal aspects of patient care, improved communication with patients, and causes of malpractice claims for staff personnel engaged in patient care activities

Questions to consider in your state:

- What are the requirements for licensing or certification of outpatient healthcare personnel and what entities are responsible for each type?
- In your state, are the licensure and certification fees paid by healthcare providers used to support training and education, or other public health programs?
- Which types of outpatient healthcare providers are subject to mandatory infection control training requirements?
- What types of healthcare providers are allowed to perform certain invasive procedures, such as injections?
- Who ensures that adequate training on delegated tasks has taken place whenever provision of medical care (such as delivery of injections) is delegated down to a technician or assistant?

26. Laws of New York, PBH Public Health, Article 2, Section 239

27. Revised Code of Washington 70.230

3. Reporting Requirements

Monitoring reported infection data enables public health authorities to detect changes in disease occurrence and distribution, identify changes in causes of disease, and detect changes in healthcare practices. Prompt reporting by facilities and healthcare providers protects patients and saves lives. Requirements and systems for HAI reporting improve healthcare quality and patient safety by ensuring unsafe practices are discovered, identified, and corrected before further infections or disease outbreaks can occur. HAI reporting requirements for outpatient settings have lagged behind requirements for acute care settings, and vary by infection or event type and reporting system (e.g., National Healthcare Safety Network[28] or NHSN).

The process of updating these requirements is also variable. For example, in Texas[29] the state may change the HAI reporting requirements for ambulatory surgical centers by giving official notice 90 days before the start of reporting. In other states like New Hampshire,[30] the state must go through the rule-making process to change HAI reporting.

General infectious disease reporting requirements (i.e., under each state or territory's notifiable diseases and conditions listings) are applicable to outpatient settings. However, there may be different requirements depending on the types of a) facilities, b) healthcare providers, and c) laboratories performing clinical specimen testing. These reporting requirements are important for the state to be able to identify and track emerging infectious disease threats in order to provide the appropriate response. The ability to revise reportable disease lists when necessary helps the state keep pace with emerging diseases. Additionally, the definition of an outbreak — or potential outbreak — may be variable and not well-defined. Certain infectious diseases, for which even a single healthcare-associated case may signal a more widespread or serious problem, may require special attention. Reporting requirements for adverse events other than infections are also highly variable. Commonly, these are reported to state, territorial, and/or local health departments as patient complaints, which in turn may prompt investigations for unsafe medical practices or unsafe facility conditions.

28. CDC's National Healthcare Safety Network (NHSN); http://www.cdc.gov/nhsn/

29. Texas Administrative Code Title 25 Part 1 Chapter 200 Subchapter A

30. New Hampshire Revised Statute Title XI Chapter 151 Section 151:33

Healthcare providers may or may not know when to involve the health department regarding lapses in infection control practices. Healthcare providers may benefit from receiving clear direction from the state, territorial, local, and tribal health department regarding their responsibility and the appropriate process to report possible outbreaks of infection and reports of reportable diseases or other adverse events. In the following two examples, timely reporting by healthcare providers could have led to outbreak discovery earlier, mitigating the potential harm to patients and saving lives.

Healthcare providers may or may not know when to involve the health department regarding lapses in infection control practices. Healthcare providers may benefit from receiving clear direction from the state, territorial, local, and tribal health department regarding their responsibility and the appropriate process to report possible outbreaks of infection and reports of reportable diseases
or other adverse events. In the following two examples, timely reporting by healthcare providers could have led to outbreak discovery earlier, mitigating the potential harm to patients and saving lives.

A gastroenterologist diagnoses a new acute case of Hepatitis C (HCV) in a patient who lacks the traditional risk factors for HCV. In reviewing the medical record, the physician determines that the patient underwent a colonoscopy procedure at physician's clinic during the incubation period. Two weeks later, a second patient presents with acute HCV with no traditional risk factors and a medical history of colonoscopy during the incubation period. While concerned, the physician does not report at this time.[31]

An ophthalmology clinic is performing intraocular injections using compounded products, including a blue dye and repackaged Bevacizumab (Avastin®). Patients begin to return to the clinic with severe eye infections with a week after receiving injections. While the initial cases are concerning to clinic staff, they choose to follow cases closely and conduct an internal investigation but do not report this to any local, state, or federal authorities (e.g. FDA's MedWatch)[32]. The clinic calls the health department after 9 such cases present over the course of 8 weeks.[33]

To better protect patients and save lives from problems illustrated by the above example, states may consider the following actions:

- Developing standards and criteria for publically reporting outbreaks and investigations
- Educating outpatient healthcare facilities and healthcare personnel regarding appropriate mechanisms for reporting reportable diseases and adverse events

31. Gutelius B, Perz JF, Parker MM, et al. "Multiple Clusters of Hepatitis Virus Infections Associated with Anesthesia for Outpatient Endoscopy Procedures". Gastroenterology 2010;139(1):163-170; http://www.ncbi.nlm.nih.gov/pubmed/20353790

32. MedWatch: The FDA Safety Information and Adverse Event Reporting Program; http://www.fda.gov/Safety/MedWatch/default.htm

33. Mikosz CA, et al. Fungal endophthalmitis associated with compounded products. Emerging Infectious Diseases. 2014 Feb.; http://wwwnc.cdc.gov/eid/article/20/2/13-1257_article

- Clarifying the conditions (e.g., numbers and types of infections) which may constitute a potential outbreak and trigger reporting requirements for an outpatient facility
- Pursuing additions to reportable diseases list to include HAIs, or other serious or life threatening events, such as unsafe injection practices
- Encouraging reporting of unsafe healthcare practices, including consideration of whistleblower protections
- Using regulations or other official policy instead of legislation for listing reportable diseases instead of legislation in order to allow the state health department to more readily make changes to emerging threats and pathogens
- Educating clinicians and state agencies regarding application of HIPAA protections to public health reporting[34, 35]

Examples of existing reporting policies:

California[36] – outpatient facilities are required to report adverse event data to California Department of Public Health no later than 5 days after detection. Adverse events are defined in accordance with California Health and Safety Code § 1279.1. Proposed legislation will expand these to include events related to infection control, including:

- Unusual wound infection (i.e., rare or emerging disease or syndrome of uncertain origin believed to be caused by a transmissible infectious agent or microbial toxin)
- Suspect bloodborne pathogen transmission or other disease outbreak
- Any other serious or life-threatening event

Florida[37] – ambulatory surgical centers must establish an internal risk management program that includes a system for monitoring and investigating the frequency and cause of adverse incidents (event within control of health care personnel to prevent) within the facility. It must also include a system for informing a patient or a patient representative that the patient was the subject of an adverse incident, and that it be given by an appropriately trained person as soon as possible minimize damage or injury to the patient. Additionally, certain adverse incidents occurring in the facility must be reported to the state's Agency for Health Care Administration (AHCA). AHCA in turn must publicly release aggregated data on adverse incidents and malpractice claims quarterly and annually.

34. CSTE Position Statement 13-ID-09 Communication of Possible Healthcare-Associated Infections across Healthcare Settings, Appendix 3; http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/13-ID-09.pdf

35. HHS HIPAA FAQ, Health Information Privacy; http://www.hhs.gov/ocr/privacy/hipaa/faq/public_health_uses_and_disclosures/397.html

36. California Health and Safety Code Section 1248-1248.85

37. Florida Statutes Title XXIX, Section 395.0197

New York City[38] – facilities, labs, and providers are required to immediately report by telephone and provide a written report within 24 hours to the NYC Department of Health and Mental Hygiene regarding:

- An outbreak or suspected outbreak of any disease, condition of public health interest or syndrome of known or unknown etiology, that may be a danger to public health and occurs in three or more persons. An outbreak may be detected based on clinical, laboratory, or epidemiologic evidence.
- Any unusual manifestation of a disease or condition of public health interest in an individual or an unusual disease defined as a newly apparent or emerging disease or a syndrome of uncertain etiology that could possibly be communicable.

New York State[39, 40, 41] – licensed physicians performing any surgical or invasive procedure requiring anesthesia or other sedation or any liposuction procedure, where the procedure is performed outside of a hospital, are required to report adverse events to the Department of Health's patient safety center within one business day. Physicians are also required to report transmission of bloodborne reportable disease between patients or between provider and patient(s) within one business day of becoming aware of transmission. Both of these reporting requirements include confidentiality provisions.

Tennessee[42] – outpatient diagnostic centers are required to report all cases of communicable disease identified to the Department of Health; failure to do so can be cause for revoking the facility's license.

Washington[43] – information received by the Department of Health from reports, inspections, or complaint investigations may be publically disclosed upon request after the ambulatory surgical facility has received any resulting reports or documents. Information about complaints that did not warrant an investigation shall only be disclosed to the ambulatory surgical facility and the complainant. Any information disclosed shall not include names or other identifiers.

38. New York City Health Code Article 11, Section 3c

39. Laws of New York, PBH Public Health, Title 2-A, Section 230d

40. Office-Based Surgery - Adverse Event Report; http://www.health.ny.gov/forms/doh-4431.pdf

41. New York State Department of Health, Office-based Surgery Adverse Event Reporting 2010-2013, August 2014; http://www.crainsnewyork.com/assets/pdf/CN96029821.PDF

42. TN Rules of Dept. of Health Chapter 1200-08-35

43. Revised Code of Washington 70.230

West Virginia[44] – the state health department may provide the identity of any healthcare facility under investigation for an outbreak or disease cluster if necessary to prevent additional infections or to request assistance from other providers and medical laboratories in identifying additional cases. Aggregate data on outbreaks and investigations may be publically released on a regular basis and may identify the county or region where the facility is located.

Questions to consider in your state:

- How are expectations and requirements pertaining to disease reporting communicated to physicians and other healthcare providers working in outpatient facilities?
- Are there consequences for a physician or other healthcare provider's failure to report outbreaks in a timely manner?
- How are reporting requirements for physicians, healthcare providers, and outpatient healthcare facilities enforced?

44. West Virginia Code of State Rules §64-7-7

4. Investigation Authorities

Health departments require a firm legal foundation to respond to, request information from, and investigate potential disease outbreaks, cases of reportable diseases, or other breakdowns in care delivery which may pose risks of serious infection risks. Public Health authority should clearly apply to all types of outpatient healthcare facilities including clinics, medical office practices, and dental office practices. In order to improve healthcare quality and patient safety, health departments must have the ability and resources to investigate facilities in response to disease reports and consumer complaints or other adverse events to ensure that the root cause of an outbreak or unsafe medical practice is appropriately addressed and corresponding corrective actions are pursued, including an inspection to evaluate the facility and healthcare provider qualifactions and practices.

Generally, each state health department has broad authorities for HAI prevention and response activities. To improve the effectiveness and timeliness for investigations of outbreaks or other related adverse events, all public health agencies and state licensing boards should be fully aware of which local, territorial, state, or federal agency or board has or shares authority for investigation of different facility type, including triggers, inspection protocols, and regulatory enforcement/punitive activities (*Appendix II*).

Investigational authority is necessary for responding to potential outbreaks, and other types of adverse events which may pose serious infection risks and endanger patients' lives. Sometimes, this authority is the only way for the state to review conditions within unlicensed facilities that are not subject to initial or periodic inspections. The following scenarios illustrate issues that arise when investigation authorities are not clearly established or known.

A repeat blood donor has documented HCV seroconversion and is reported to the health department. Interview of the patient indicates an absence of behavioral risk factors to explain the new infection and appears credible. Six weeks prior to the blood donation, which resulted in the positive HCV test, the patient underwent oral surgery. The health department attempts a site visit but encounters resistance from the oral surgeon, who places a call to the state dental board, which temporarily halts the investigation.[45]

A staff member at a cancer clinic contacts CDC to report that another clinic employee has been reusing syringes when performing saline flush procedures. CDC relays this information to the state health department, which agrees that this practice, if it is in fact occurring, must be corrected immediately. Delays occur as the state and local health departments attempt to sort out jurisdictional and procedural issues related to contacting and investigating the clinic.[46]

In a multi-state investigation related to contaminated injectable steroid products from a compounding pharmacy, CDC and state health departments advised affected clinics that received and administered potentially contaminated product to contact selected groups of patients. While the majority completed notification, some states reported that several office practices had not yet initiated or completed notification of patients many weeks after the initial recall and CDC and health department outreach. In some cases, the physician-owner was reluctant to turn over patient lists or otherwise cooperate.[47]

To better protect patients and save lives from problems illustrated by the above example, states may consider the following actions:

- Developing a positive and cooperative relationship between state, local, and territorial health agencies" to "Developing a positive and cooperative relationship between public health agencies
- Proactively communicating and coordinating at multiple levels, (e.g., between state agencies/boards or between state and local health departments) to facilitate a mutual understanding of roles and authorities related to investigating communicable disease reports and threats involving different types of outpatient settings/providers

45. Oklahoma State Department of Health, Public Health Investigation of Tulsa Dental Practice; http://www.ok.gov/health/Organization/Office_of_Communications/News_Releases/2013_News_Releases/Public_Health_Investigation_of_Tulsa_Dental_Practice.html

46. CDC unpublished data. For similar outbreak related to syringe reuse in oncology clinics, please see the following: Macedo de Oliveira A, et al. An outbreak of hepatitis C virus infections among outpatients at a hematology/oncology clinic (NE), Annals of Internal Medicine, 2005 Jun 7;142(11):898-902; http://www.ncbi.nlm.nih.gov/pubmed/15941696

47. Multistate Investigation of Suspected Infections Following Steroid Injections; http://www.cdc.gov/hai/outbreaks/TN-pharmacy/

- Assuring the ability to investigate facility complaints from the public or medical personnel, especially in regards to suspect practices that have not resulted in documented infections or other adverse events but which the agency or board deems as a threat to patient safety due to the potential risk of a serious or life-threatening infection
- Developing a sample "Commissioner's Order" that states may present to a physician or clinic manager which explains the health department's authority to perform on-site investigation, observations, and record review
- Developing communication tools that states may present to a physician or clinic manager which explains the application of HIPAA protections to public health investigations[48, 49]

Examples of existing investigative authority policy:

California[50] – outpatient settings that are accredited must be inspected by the accreditation agency no less than every 3 years, in response to complaints against an agency, or complaints against one or more outpatient settings accredited by an agency that indicate agency noncompliance with the standards approved by the Medical Board of California. Additionally, the board must ensure that accreditation agencies inspect outpatient settings facilities and facilities may also be inspected by the board and the department, as specified.

Illinois[51] – licensed ambulatory surgical treatment centers are to post details on how to file complaints with the Department of Public Health along with the facility license in a location visible to staff, patients, visitors, and the general public. The Department of Public Health is required to investigate all complaints received, referring items outside of their jurisdiction as appropriate.

Maryland[52] – requires ambulatory care facilities to be open for inspection during business hours or while treating patients for the purpose of verifying compliance to licensure regulations or for the investigation of complaints. This includes all records for the facility and copies may be requested via written request from the Department of Health. Additionally, if a complaint concerns the performance of a healthcare practitioner or standards of practice, the policy specifically requires that the Department of Health refer it to the appropriate licensing board that authorizes the healthcare provider.

48. CSTE Position Statement 13-ID-09 Communication of Possible Healthcare-Associated Infections across Healthcare Settings, Appendix 3; http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/13-ID-09.pdf

49. HHS HIPAA FAQ, Health Information Privacy; http://www.hhs.gov/ocr/privacy/hipaa/faq/public_health_uses_and_disclosures/397.html

50. California Health and Safety Code Section 1248-1248.85

51. IL Administrative Code Section 77.I.b.205

52. Code of Maryland Regulations Title 10, Sections 10.05.01.05 and 10.05.01.12

Washington[53] –all licensed ambulatory surgical facilities within the state are surveyed every eighteen months by the department, CMS, or an accrediting agency. This survey includes the submission of data related to the quality of care provided to patients within the facility. Based on this data, data related to facility and/or practitioner performance, or the receipt of a complaint against the facility, the Department of Health may perform an inspection or investigation of the practices in the facility.

West Virginia[54] – during the course of an outbreak or disease cluster investigation at any healthcare facility, the Health Commissioner is required to contact patients if it is determined that they may have been exposed to an infectious disease (e.g. HBV, HCV, HIV) and that the patient or those around them are at risk. Patients will be notified of the possible exposure and appropriate steps to take to prevent infection risk. The patient may be given information regarding the facility or healthcare provider that was the source of the outbreak if necessary.

Questions to consider in your state:

- Does the state, territorial, local, or tribal health department's ability to perform a site visit and conduct an investigation depend on the presence of a confirmed case of a reportable disease?
- Who has authority to investigate and follow-up on reports of unsafe practices in a doctor's office or clinic?
- If a doctor's office or clinic is not licensed at the facility level, what agencies or entities have authority/responsibility for investigating clusters of illness?
- Are there established lines of communication with your state's health facility licensure bodies and individual provider licensure bodies, including clear understanding of the circumstances in which one of these entities should engage the other, prior to, during, or after an investigation?

53. Revised Code of Washington 70.230

54. West Virginia Code of State Rules §64-7-7

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Appendix I - Policies referenced in key element sections

The following list compiles the state policy examples provided within the document. These examples were presented to the workgroup and chosen based on input from the members. It is meant to provide a sample of the current policy landscape and is not a comprehensive list of state policies regarding the administration of outpatient facilities or the related operations of state, local, and territorial health departments.

State	Policy Code/Name
Alabama	Administrative code 420-5-2
California	Health and Safety Code, 1248-1248.85
Colorado	Colorado Revised Statutes Title 12, Article 43.2 - Surgical Assistants and Surgical Technologists
Florida	Florida Statutes Title XXIX, Section 395.0197
Illinois	Administrative code 77.I.b.205
Maryland	Code of Maryland Regulations – Title 10, Sections 10.05.01.05 and 10.05.01.12
Massachusetts	Code of Massachusetts Regulations – 105 CMR 140, Licensure of Clinics
Nebraska	Administrative code Title 175 Chapter 7
Nevada	Adopted regulation R179-09
Nevada	Nevada Revised Statutes 449.443-449.448
New Hampshire	He-P 300, Parts 301 and 309
New Jersey	New Jersey Revised statutes 26:2H-5.1e
New York	Laws of New York, PBH – Public Health, Title 2-A, Section 230d
New York	Laws of New York, PBH – Public Health, Title 2-E, Article 2, Section 239
North Carolina	Administrative code 10A 41A.0206
Oregon	Administrative Rule 333-076
Tennessee	Rules of Dept. of Health, Chapter 1200-08-35
Washington	Revised Code of Washington – 70.230
West Virginia	West Virginia Code of State Rules §64-7-7
West Virginia	West Virginia Code of State Rules §16-5H

Appendix II - Outpatient settings worksheets

The following worksheets are intended to increase awareness within public health agencies of the authorities currently in place in their state and identify gaps presented in the "Questions to consider" within each of the four key elements. Each worksheet lists outpatient settings that may exist within states and is not meant to be all-inclusive (note that some states may have different names for some of the listed facilities). For each worksheet, answer the corresponding question from the key element.

Worksheet 1: Facility Licensing and/or Accreditation

Setting Type	Number of Facilities	Facility License/ Accreditation Required	Provider License/ Accreditation Required	Infection Control Training Required
Alternative Medicine Clinics				
Ambulatory Surgical Centers				
Chiropractic clinics				
Dental Offices				
Dental Surgery Practices				
Dialysis Centers				
Free-Standing Emergency Rooms				
Imaging Centers				
Infusion Centers				
Oncology Clinics				
Orthopedic Clinics				
Ophthalmology/ Eye Clinics				
Pain Clinics				
Physical Therapy Facilities				
Physician Offices				
Plastic Surgery Practices				
Podiatry Clinics				
Radiology Clinics				
Urgent Care Clinics				

Worksheet 2: Healthcare Provider Training, Licensure, and Certification

Healthcare Provider Type	Licensing/ Certification Requirements	Mandatory Infection Prevention and Control Training	Allowed to Perform Certain Invasive Procedures (e.g. Injections)	Ensures Adequate Training for Technicians and Assistants to Perform Delegated Tasks
Acupuncturist				
Chiropractor				
Cleaning / Environmental Services Staff				
Dental Assistant				
Dental Hygienist				
Dentist				
Equipment Sterilization Staff				
Infection Preventionist				
Laboratory Technician				
Licensed Practical Nurse				
Medical Technician				
Nurse				
Nurse Practitioner				
Nursing Technician				
Office/ Administrative Staff				

Healthcare Provider Type	Licensing/ Certification Requirements	Mandatory Infection Prevention and Control Training	Allowed to Perform Certain Invasive Procedures (e.g. Injections)	Ensures Adequate Training for Technicians and Assistants to Perform Delegated Tasks
Oncologist				
Oncology Technician				
Ophthalmologist				
Optometrist				
Pharmacist				
Pharmacy Technician				
Physical Therapist				
Physician				
Physician – Surgical				
Physician's Assistant				
Podiatrist				
Radiology Technician				
Specialist Assistant				
Surgical Technician				
Surgical Technologist				
Volunteers				
Others				

Worksheet 3: Reporting Requirements

Setting Type	How Reporting Requirements Conveyed to Facility/ Providers	Enforcement for Failure to Follow Reporting Requirements	If Enforcement Applicable, Agency or Board that Enforces
Alternative Medicine Clinics			
Ambulatory Surgical Centers			
Chiropractic clinics			
Dental Offices			
Dental Surgery Offices			
Dialysis Centers			
Free-Standing Emergency Rooms			
Imaging Centers			
Infusion Centers			
Oncology Clinics			
Ophthalmology/Eye Clinics			
Orthopedic Clinics			
Pain Clinics			
Physical Therapy Facilities			
Physician Offices			
Plastic Surgery Practices			
Podiatry Clinics			
Radiology Clinics			
Urgent Care Clinics			

Worksheet 4: Investigation Authorities

Setting Type	Authority to Investigate and Follow-up on Confirmed Reportable Disease Case	Authority to Investigate and Follow-up on Complaint or Report of Unsafe Practices	Established Line of Communication between Licensing Agency/Board and Health Department in Case of Investigation
Alternative Medicine Clinics			
Ambulatory Surgical Centers			
Chiropractic clinics			
Dental Offices			
Dental Surgery Offices			
Dialysis Centers			
Free-Standing Emergency Rooms			
Imaging Centers			
Infusion Centers			
Oncology Clinics			
Ophthalmology/Eye Clinics			
Orthopedic Clinics			
Pain Clinics			
Physical Therapy Facilities			
Physician Offices			
Plastic Surgery Practices			
Podiatry Clinics			
Radiology Clinics			
Urgent Care Clinics			

Appendix III - Outbreaks and patient notifications in outpatient settings, selected examples, 2010-2014

The following table includes selected examples of recent outbreaks and patient notification events. These events occurred in a variety of outpatient settings including primary care clinics, pediatric offices, cosmetic surgery centers, pain remediation clinics, imaging facilities, cancer (oncology) clinics, dental clinics, and health fairs. This is not an exhaustive list but it serves as a reminder of the serious consequences that can result when healthcare personnel fail to follow basic principles of infection control[1]. Such consequences include: infection transmission to patients, notification of thousands of patients of possible exposure to bloodborne pathogens, referral of providers to licensing boards for disciplinary action, and malpractice suits filed by patients.

These events are preventable, yet they continue to occur. In order to prevent patient harm, facilities and healthcare staff members are encouraged to review practices to assure they are in accordance with CDC's evidence-based guidelines.[2]

Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2014	N/A*	N/A*	Yes (1,100)	1) Reuse of syringes to access medication vials used for >1 patient† 2) Failure to properly reprocess reusable medical equipment
2013	Staphylococcus aureus	Septic Arthritis	No	1) Complex preparation/ compounding of injection materials involved extensive manipulations in the procedure room, with opportunities for contamination
2013	N/A*	N/A*	Yes (415)	1) Reuse of syringes to access medication vials that may have been used for >1 patient†

1. Centers for Disease Control and Prevention. http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

2. Centers for Disease Control and Prevention. Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care

Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2013	Hepatitis B Virus	Hepatitis	Yes 534)	1) Multiple procedural and infection control breaches were identified
2013	Hepatitis C Virus	Hepatitis	Yes (5,810)	1) Mishandling of injectable medications including reuse of single-dose vials of propofol 2) Improper reprocessing of dental instruments
Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2013	Nontuberculous mycobacteria, Other	Surgical Site Infection	No	1) Off-label use of lubricating gel directly on sterile tissues 2) Reuse of single-use breast implants as sizers
2013	N/A*	N/A*	Yes (100)	1) Suspected tampering with injectable controlled substances by a healthcare provider
2012	Hepatitis C Virus	Hepatitis	Yes (>300)	Specific lapses in infection control not identified at the time of the investigation

Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2012	Group A Streptococcus	Necrotizing Fasciitis	No	1) Failure to wear surgical masks and gowns consistently 2) Visibly dirty equipment 3) No logs of autoclave use, maintenance, or performance checks
2012	Staphylococcus aureus	Septic Arthritis or Bursitis	No	1) Contents from single-dose vials used for >1 patient
2012	Methicillin-resistant Staphylococcus aureus	Mediastinitis, Meningitis, Epidural Abscess, Sepsis	No	1) Contents from single-dose vials used for >1 patient 2) Healthcare personnel did not wear facemasks when performing spinal injections
2012	N/A*	N/A*	Yes (~8,000)	1) Overt syringe reuse from one patient to another
2011	Tsukamurella species	Bloodstream Infections	No	1) Use of common-source bag of saline to prepare saline flush 2) Suboptimal procedures for central line access and preparation of chemotherapy
Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2011	N/A*	N/A*	Yes (2,345)	1) Overt reuse of insulin demonstration pen from one patient to another

Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2011	Staphylococcus aureus	Skin and Soft Tissue Infections	No	1) Failure to follow aseptic technique when preparing injections 2) Undated, open multi-dose vials and single-dose vials were kept in patient areas
2011	Hepatitis C Virus	Hepatitis	Yes (466)	1) Suspected syringe reuse contaminating medication vials†
2011	Pseudomonas aeruginosa and Klebsiella pneumoniae	Bloodstream Infections	Yes (623)	1) Overt syringe reuse from one patient to another 2) Reuse of syringes to access medication containers used for >1 patient†
2011	N/A*	N/A*	Yes (101)	1) Single-use needle guides for prostate biopsy used for >1 patient
2011	N/A*	N/A*	Yes (171)	1) Overt syringe reuse from one patient to another
2010	N/A*	N/A*	Yes (250)	1) Overt syringe reuse from one patient to another
2010	N/A*	N/A*	Yes (25)	1) Suspected overt syringe reuse from one patient to another
2010	N/A*	N/A*	Yes (~60)	1) Same fingerstick device used on >1 patient to obtain blood samples for blood glucose monitoring

Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2010	Streptococcus salivarius	Meningitis	No	1) Healthcare personnel did not wear facemasks when performing spinal injection procedures 2) Contents from single-dose vials used for >1 patient
Year Investigated	Pathogen(s)	Infection(s)	Patient Notification Performed (# notified)	Infection Control Breaches
2010	Hepatitis B and C Viruses	Hepatitis	Yes (2,293)	1) Syringe reuse contaminating medication vials used for >1 patient[†] 2) Mishandling of medication preparation

* Infection control breach, not infections, prompted patient notification. It is not known if any infections resulted from the unsafe practices. For more information, please see reference 14.

† Double Dipping: When a syringe that had been used to inject medication into a patient, is then reused to enter a medication vial. The syringe is discarded but contents from that vial, which were contaminated through reuse of the syringe, are then used for subsequent patients. This can lead to transmission of infections if the contents from that vial, which were contaminated through reuse of the syringe, are then used for subsequent patients. For more information, please visit www.cdc.gov/injectionsafety.

Footnotes

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