HEALTHCARE ASSOCIATED INFECTION OUTBREAK INVESTIGATIONS IN AMBULATORY CARE SETTINGS, LOS ANGELES COUNTY, 2000 – 2012

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BACKGROUND

Healthcare services are increasingly delivered in outpatient, ambulatory care settings (ACSs) rather than inpatient, acute care settings. Nationwide, there are nearly 1.2 billion outpatient visits per year.[1] ACSs encompass a broad array of facilities, such as primary care clinics, ambulatory surgery centers, pain clinics, oncology clinics, imaging facilities, dialysis centers, urgent care centers, and other specialized facilities. The types of procedures performed in ACSs are also diverse, including podiatry (e.g., nail clipping, wound care, podiatric surgery), surgery, endoscopy (e.g., gastrointestinal, urological, arthroscopic), pain injections, and more.

Ambulatory surgery centers, a subset of ACSs, have seen an astounding growth. In 1985, the number of ambulatory surgery centers participating in Medicare was 336; the number boomed to approximately 5368 in 2011.[2,3] Sixty-three percent of all surgeries in 2005 were outpatient, compared with 51 percent in 1990 and only 16 percent in 1980.[4] Explanations for this shift in delivery of healthcare services include lower costs, increased patient satisfaction, and convenient scheduling[5]; however, there are also a number of concerns.

Often, the procedures performed in ACSs are invasive, putting patients at high risk of infection. Further, many procedures currently performed in ACSs were previously performed in hospitals where infection control oversight is regulated. Despite the surge in ambulatory care, there has not been a corresponding increase in infection control oversight in ACSs, and there are insufficient data on the rates of infections resulting from procedures performed in ACSs. In fact, only 20 ambulatory surgery centers reported data to the National Healthcare Safety Network (NHSN) for 2006 through 2008, compared to 1545 hospitals that reported data during the same period.[6]

At the same time, the amount of literature demonstrating a need for infection control oversight in ACSs is growing. For example, from 2001 through 2011, at least 18 outbreaks of viral hepatitis were associated with unsafe injection practices in ACSs, such as physician offices or ambulatory surgery centers.[7] Additionally, an infection control audit performed by the Centers for Medicare and Medicaid Services (CMS) in 2008 found that 46 of 68 ambulatory surgery centers surveyed had at least one lapse in infection control; 12 had lapses identified in three or more of five infection control categories.[8] As such, CMS now requires adherence to its Infection Control Surveyor Worksheet for participation in CMS.[9] However, many ACSs do not fall into the category of licensed surgery or dialysis center or do not participate in CMS, and are thus not held to the same infection controls standards.

Recognizing the infection control concerns associated with ACSs, the Los Angeles County (LAC) Department of Public Health (DPH) Acute Communicable Disease Control Program (ACDC) conducted an analysis to characterize healthcare associated infection (HAI) outbreaks in LAC in ACSs.

METHODS

Adapting the CMS definition for ambulatory surgery centers, ACDC defined an ACS as a distinct healthcare entity, either hospital-based or non-hospital-based, that operates exclusively on an outpatient basis for patients who do not require hospitalization and who are expected to stay less than 24 hours.[10] ACSs affiliated with a hospital are under the common ownership, licensure, or control of a hospital.[11] Ophthalmology offices, hospital clinics, urology offices, radiology offices, pain clinics, orthopedist offices, oncology offices, OB/GYN clinics, and medical spas were grouped together into offices/clinics.

LAC DPH relies on passive surveillance, the receipt of reports of infections from hospitals, laboratories, clinics, and other healthcare facilities and professionals required to submit such reports as defined by

regulation. In California, all outbreaks, confirmed or suspected, are mandated under Title 17 of the California Code of Regulations § 2500 to be reported to the local health department. At LAC DPH, reported outbreaks are documented in the LAC DPH Disease Control Outbreak Log. For this analysis, ACDC reviewed the LAC DPH Disease Control Outbreak Log database, LAC DPH Special Studies Reports where many outbreak investigations are described for ACDC's annual report, and personal correspondence with LAC DPH employees involved in investigations of reported suspected and confirmed HAI outbreaks in ACSs that occurred from January 2000 through November 2012.

These suspected and confirmed HAI outbreaks in ACSs were classified by public health activities undertaken by ACDC, infection control breaches, duration of investigation, and number and outcome of cases. Data were analyzed using SAS 9.3.

Public health activities were separated into 15 categories, including site visit(s), medical record review, epidemiologic studies, patient notification, active surveillance, recommendations to facility, sample collection, laboratory analysis, and environmental investigation. Epidemiologic analyses included case control, retrospective cohort, prospective cohort, and comparison studies. Patient notification refers to the process of informing patients about potential exposures through mailed notification letters or postage of a letter in the facility. Active surveillance, as opposed to passive surveillance, is surveillance in which ACDC proactively solicited infection reporting (e.g., analyzed current patient medical records from facilities for case finding or surveying patients to identify additional cases). Sample collection involved the ascertainment of biological specimens from patients (e.g., from blood, wound, urine), environmental samples (e.g., water, air), medication samples, and samples from equipment (swabs from inside or outside of equipment). Laboratory analyses included genetic typing, pulsed-field gel electrophoresis for DNA fingerprinting, and genomic sequencing. Laboratory analysis was conducted by either LAC DPH Public Health Laboratory or sent to the Centers for Disease Control and Prevention (CDC) laboratory or California Department of Public Health (CDPH) laboratory for testing. Environmental investigations were conducted in conjunction with LAC DPH Environmental Health Division and involved evaluating facility layouts, monitoring staff compliance with environmental infection control standards, and collecting and laboratory testing air, water, or equipment samples.

Infection control characteristics were classified into ten categories, including breaches in hand hygiene, use of personal protective equipment (PPE), injection safety, medication documentation, equipment processing and sterilization, written infection control policies and procedures, and staff credentials.

RESULTS

Characterization of Outbreak Investigations

Twenty-eight investigations of suspected or confirmed HAI outbreaks in ACSs in LAC met the inclusion criteria. The majority of identified outbreak investigations were in facilities not affiliated with a hospital (71.4%). The most common settings for outbreak investigations were ambulatory surgery centers (21.4%) and dialysis centers (21.4%). The distribution of settings by outbreak investigations is shown in Table 1.

Table 1: Distribution of outbreaks by hospital affiliation and setting type

Setting type	Number of outbreak investigations (% of total)	Total number of cases (% of total)
Hospital Affiliation		
Yes	8 (28.6)	42 (25.0)
No	20 (71.4)	126 (75.0)
Setting type		
Office/ clinic	11 (39.3)	53 (31.5)
Ambulatory surgery center	6 (21.4)	26 (15.5)
Dialysis center	6 (21.4)	70 (41.7)
Contracted home health agency	5 (17.9)	19 (11.3)

Outbreaks were reported 0 to 1160 days after exposure of the first case (median: 69 days). The total case count was 168 (mean: 6; range: 0–36); 59 cases were hospitalized and five cases died. The types of implicated agents included bacterial, viral, fungal, ectoparasitic, toxin, and chemical. Bacterial agents were implicated in 50% of identified outbreak investigations. One investigation found no cases and did not implicate an agent. The distribution of agent types by outbreak investigations is shown in Table 2.

Table 2: Types of implicated agents

Agent type	Number of outbreak investigations (% of total)	Examples
Bacterial	14 (50)	*Enterobacter*, *Klebsiella*, *Pseudomonas*, *Stenotrophomonas*, *Staphylococcus*, *Mycobacterium*
Viral	6 (21.4)	Hepatitis B, Hepatitis C
Fungal	3 (10.7)	*Fusarium*
Ectoparasitic	1 (3.6)	Scabies
Toxin	1 (3.6)	
Multiple	1 (3.6)	Adenovirus and *Streptococcus*
Unknown	1 (3.6)	
Not applicable	1 (3.6)	

Public Health Activities

Investigations lasted a median of 36 days (range: 7–94 days). The mean number of control activities undertaken by ACDC during the investigations was 6.8. The most common actions taken by ACDC were: conducting one or more site visits (78.6% of investigations); providing written recommendations to the facility (78.6%); medical record reviews of cases and other patients (75%); formal interviews of facility staff (64.3%); and laboratory analysis (60.7%). ACDC also often consulted CDC (50.0%) and CDPH (35.7%) during investigations. Other partners consulted included the Food and Drug Administration, the Medical Board of California, the California Board of Pharmacy, and internally, LAC Public Health Laboratory (PHL) and LAC Environmental Health Division. Non-case patients were notified of possible risk in 7.1% of investigations. In one investigation, nearly 2,300 patients were notified of possible exposure. Public health activities performed by LAC DPH are summarized in Table 3.

Table 3: Public health activities conducted during outbreak investigations

Public health activity	Number of outbreak investigations (% of total)
Site visit	22 (78.6)
Medical record review	21 (75.0)
Formal staff interviews	18 (64.3)
Epidemiologic study[±]	9 (32.1)
Sample collection	13 (46.4)
Environmental sample[¥]	9 (32.1)
Biological specimen	6 (21.4)
Medication sample	4 (14.3)
Laboratory analysis	17 (60.7)
LAC PHL	14 (50.0)
CDC	9 (32.1)
Environmental health investigation	7 (25.0)
Patient interviews	6 (21.4)
Patient notification	2 (7.1)
Active surveillance	8 (28.6)
Sought outside consultation	17 (60.7)
CDC	14 (50.0)
CDPH	10 (35.7)

Review of facility policies and procedures	15 (53.6)
Written recommendations to facility	22 (78.6)
Special report published by ACDC	10 (35.7)
Other publications×	5 (17.9)

±Epidemiologic study includes case control (5), retrospective cohort (2), prospective cohort (1), and comparison (1)
¥Environmental samples include air, water, and equipment isolates
×Other publications include CDC's Morbidity and Mortality Weekly Reports, the American Journal of Infection Control, Emerging Infectious Diseases, and an abstract for the Society for Healthcare Epidemiology of America (SHEA) conference

Infection Control Breaches

Of the 28 outbreak investigations included, 22 (78.6%) cited at least one infection control breach. The mean number of infection control breaches identified by LAC DPH during the outbreak investigations was 2.4 (range: 0 – 8). The most common breaches recorded were associated with injection safety (35.7%), equipment processing and sterilization (35.7%), medication documentation (25.0%), and environmental cleaning (21.4%). Injection safety violations included reuse of single-dose medication and not using aseptic technique to enter multi-dose vials. Breaches in equipment processing and sterilization included incomplete disinfection of reusable dialyzers following dialysis and use of incorrect cleanser and disinfection method for endoscopes. Infection control breaches are summarized in Table 4.

Table 4: Infection control breaches noted in outbreak investigations

Infection control breach	Number of outbreak investigations (% of total)
Hand hygiene	5 (17.9)
Personal protective equipment (PPE)	3 (10.7)
Proper glove use	2 (7.1)
Injection safety	10 (35.7)
Injection preparation technique and environment	7 (25.0)
Single-use medication policies	2 (7.1)
Logging exposure events	2 (7.1)
Single-use equipment (e.g., blood glucose meters)	4 (14.3)
Medication documentation	7 (25.0)
Dosage or lot number	3 (10.7)
Open date or expiration date	5 (17.9)
Equipment processing and sterilization	10 (35.7)
Log of equipment maintenance	2 (7.1)
Documentation or manuals for equipment	2 (7.1)
Documentation of infection control policies and procedures	5 (17.9)
Knowledge and adherence to policies and procedures	4 (14.3)
Credentials of staff	5 (17.9)
Environmental cleaning	6 (21.4)

Outbreak investigations in which infection control breaches were identified required significantly more public health activities than those that did not find infection control breaches (7.5 actions versus 3.7 actions; $p<0.05$). When a site visit was part of the outbreak investigation, significantly more infection control breaches were identified than when there was no site visit conducted (3.0 breaches versus 0.2 breaches; $p <0.0001$).

Suspected Sources of Outbreaks

Lapses in infection control were suspected as the source for 16 (57.1%) of the outbreak investigations reviewed. Suspected causes included single-use medication used on multiple patients, reuse of finger stick blood glucose meters on multiple patients, deficiencies in dialyzer reprocessing, and improper equipment cleaning and disinfection. Two outbreak investigations identified externally contaminated medication as the suspected source (7.1%). Nine investigations did not identify a source of the outbreak (32.1%). One investigation found no cases and thus identified no source.

DISCUSSION

ACDC documented considerable morbidity and mortality associated with the 28 suspected and confirmed HAI outbreak investigations in ACSs included in this review. Cumulatively, over one-third of cases associated with these investigations were hospitalized; there was a 3% mortality rate among the cases. The analysis revealed diversity in types of ACSs and outbreak settings in LAC. A dozen different types of outbreak settings were identified, ranging from complex surgery centers with multiple operating rooms to small medical spas and pain clinics, all performing a variety of services. Additionally, the review demonstrates that outbreak investigations require substantial public health resources. The 28 investigations required many public health activities including site visits, laboratory analysis, and patient notification; our investigations lasted, on average, over one month. Interestingly, outbreak investigations that uncovered infection control breaches were associated with a greater number of public health activities than those without infection control breaches.

The most common infection control lapses identified in this analysis are consistent with those found by a national audit of ambulatory surgery centers nationwide.[8] Notably, injection safety violations and equipment cleaning issues were most frequent, both of which are preventable through taking Standard Precautions and practicing basic infection control. These findings highlight a need for better reporting from ACSs as well as more infection control oversight of ACSs.

There were some limitations to this analysis. This retrospective review relied on the availability and completeness of investigation documents. It is possible that some investigations were not documented in the LAC DPH Disease Control Outbreak Log or recalled by ACDC personnel and were not included in this review. Another limitation is delayed reporting to LAC DPH. Surveillance of HAIs in ACSs is passive in LAC, relying on facilities to recognize and report outbreaks and reportable conditions to LAC DPH. Among the 28 investigations included in this review, the median time between exposure of first case and report to LAC DPH was 69 days, with some situations reported years following the first exposure. Delayed reporting may be due in part to difficulty in tracking infections in outpatient populations; ACSs may have minimal patient follow-up. The difficulty in tracking infections also reduces the ability of public health officials to attribute infections to ACSs, especially if the infection is identified in an acute care setting after exposure at an ACS. In many cases, ACSs were unaware of the reporting requirements for outbreaks and other notifiable conditions. As a result of reporting issues, the findings of this review may be an underestimation of the true morbidity and mortality associated with HAIs in ACSs in LAC.

The difficulty in tracking infections in ACSs is concerning, especially in the case of acute communicable diseases, because delayed reporting can have serious consequences for public health intervention and patient safety. To improve reporting, ACSs should be encouraged to utilize NHSN reporting tools when applicable. NHSN is a useful system for both active and passive surveillance of HAIs and can be applied to ambulatory settings. NHSN recently launched a module for dialysis facilities to track infections; ambulatory surgery centers can already report infections to NHSN in the same way as hospitals.[6]

In addition to enhanced reporting, there are several potential opportunities to improve infection control practices and guidelines in ACSs through more oversight. While more research is needed to identify common infection control errors in ACSs and how to prevent them, state policies for oversight through licensure, incorporating training requirements, infection control standards, and regular inspection may be an approach for reducing HAIs in ACSs. As an example, the New York State Department of Health requires all office-based surgery practices to be accredited, mandates infection control training for every licensed healthcare provider, and requires providers in these facilities to report adverse events within one day.[12] Furthermore, much like following the CMS Infection Control Surveyor Worksheet is mandatory for CMS participation, requiring site visits, infection prevention programs and adherence to nationally recognized infection control guidelines for licensure may be appropriate for ACSs.[9] In our analysis, we found that site visits made by ACDC were helpful in identifying infection control breaches during the investigation process, as opposed to when no site visits are made. With regular inspection, infection control violations can be detected and addressed. The CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) created the *Guide to infection prevention in outpatient settings: Minimum*

expectations for safe care, which is intended to provide infection control and prevention recommendations to ACSs. Included in the recommendations are the development of an infection prevention program in the facility, specific infection prevention education and training of healthcare personnel, surveillance of HAIs, and adherence to Standard Precautions.[13] This document should serve as a guide to ACSs in LAC for infection prevention practices.

CONCLUSION

HAI outbreaks in ACSs occur frequently, in diverse settings, and require substantial public health resources. The reviewed outbreak investigations were associated with considerable morbidity and mortality, as more than one-third of affected patients were hospitalized. Infection control standards and appropriate event reporting should be promoted, enhanced, and enforced in ACSs to ensure patient safety.

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