The Future of Infection Surveillance at Ambulatory Surgical Centers

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Funding The authors received no financial support for the research, authorship, and publication of this article.

Conflict of Interest The authors report no conflicts of interest.

ABSTRACT

Background: The Centers for Medicare and Medicaid (CMS) has begun mandating infection surveillance at surgical sites, which started in hospitals and is now in ambulatory surgical centers (ASCs). We found a 0.1% increase in infection rate between 2005 and 2007, which prompted us to examine the issue further. The purpose of the current study was to summarize the results of an investigation after an outbreak of infection at our ASC, specifically attempting to identify a common pathogen, vector, or unknown lapses in infection prevention. Additionally, we relate our experience to current trends in infection prevention at ASCs by examining the most recent CMS infection surveillance requirements.

Methods: We performed a retrospective review of patients with infections after orthopaedic procedures at our ASC from 2005 to 2008. Infections were identified by the Centers for Disease Control and Prevention surveillance definitions, with a total of 17 patients included in the study. We also reviewed the site inspection and documented the resultant interventions.

Results: No common pathogen was found in the 17 patients. The results of the site review noted a contaminated tendon-stripper used in half of the cases, poor disassembly of instruments before cleaning, overuse of "flash" sterilization, and poor ventilation in the operating suites. In 2011, infection rates returned to 1.3%.

Conclusions: An ongoing infection surveillance program, periodic site inspections, and process reviews are essential to prevent surgical site infections at ASCs.

Keywords: Ambulatory Surgery, Outpatient Surgery, Arthritis, Infectious, Arthroscopy

INTRODUCTION

According to the Centers for Medicare and Medicaid Services (CMS), an ambulatory surgical center (ASC) is defined as: "a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission."[1] As of 2010, there were 5316 Medicare-certified ASCs, representing more than a 54% increase from 2001. In 2007, an estimated 6 million surgical procedures were performed at ASCs, with a $3 billion cost to Medicare.[2] As the number of ACSs and number of procedures continues to grow, few data are available regarding the complications of procedures performed in these settings, specifically surgical site infections (SSIs).

To participate in the CMS "Pay for Performance" program beginning January 2012, acute care hospitals were required to perform surveillance on SSIs (specifically infections in patients undergoing colectomies and abdominal hysterectomies) and enter the data into the National Healthcare Safety Network, a secure database of the Centers for Disease Control and Prevention (CDC).[3,4] Although currently voluntary, surveillance and data entry efforts are anticipated to extend to more procedures and settings such as ASCs.

SSI rates after outpatient orthopaedic procedures tend to be less than 1%.[5-15] Some studies have reported a lower SSI rate at single-specialty ASCs.[16] A 2010 article from Edmonston and Foulkes[17] reviewed more than 11,000 cases during a 5-year period at a single orthopaedic ASC. They found the overall infection rate to be 0.33%. Infection rates after anterior cruciate ligament (ACL) reconstructions are estimated to be between 0.14% to 0.78%.[10] Similarly, infection rates after orthopaedic arthroscopic procedures are estimated to be between 0.10% to 1.1%.[7,18]

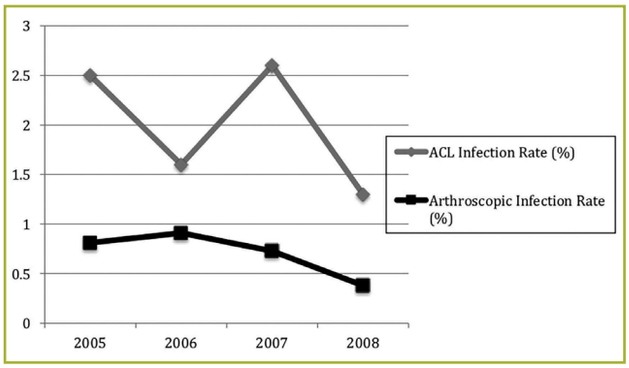

Figure 1. *Arthroscopic and anterior cruciate ligament (ACL) infection rates between 2005 to 2008.*

At our inpatient institution, SSI surveillance began in 2003 and has evolved from a retrospective review of single procedures to a prospective program of multiple procedures. In 2005, surveillance was expanded to include our affiliated ASC. There was a noted increase in postoperative infections after outpatient orthopaedic procedures seen in the Outpatient Parenteral Antimicrobial Therapy Clinic. Because of this, surveillance on orthopaedic SSIs was instituted for ACL reconstructions and eventually expanded to include all arthroscopic knee and shoulder procedures. Retrospective review of orthopaedic SSIs between 2005 and 2008 indicated an increased infection rate of 2.5% in 2005 and 2.6% in 2007 (Figure 1). These results prompted an outbreak investigation at the facility to determine if there was a common pathogen or vector contributing to the increased infection rate.

The purpose of this paper was to first summarize the results of the outbreak investigation, specifically looking for a common pathogen, vector, or other lapse in infection control. Secondly, we wanted to relate our experience to current requirements in infection prevention at ASCs, referencing the most recent "Guidance for Surveyors" document for ASCs from CMS.[17]

METHODS

We received approval from our Human Research Review Committee (HRRC #19-127). With the assistance of the Division of Epidemiology, Biostatistics and Preventive Medicine at The University of New Mexico Hospital, we reviewed medical records of patients to determine SSIs after orthopaedic procedures at our ASC between May 2005 to December 2008. Specifically, we reviewed medical records of patients with infections identified by the hospital infection control program, which reviewed all orthopaedic arthroscopic procedures performed at our ACS. Ultimately, 17 patients were identified and included in the study. Additionally, we completed a review of the site inspection, resultant interventions, and infection rates all through 2011.

Criteria for Surgical Site Infections

CDC surveillance definitions were used to identify SSIs. At the time of our investigation, SSIs were defined as infections that occurred within 30 days of the index procedure (with the exception of procedures involving implants, which were monitored for 1 year).[19] For this investigation, surveillance was limited to organ space SSIs which correlates to a clinical diagnosis of septic arthritis. Diagnosis of an organ space SSI required at least one of the following factors to be documented in the medical records: purulent drainage from a drain that is placed through a stab wound into the organ or space; organisms isolated from an aseptically obtained culture of fluid or tissue in the organ or space; an abscess or other evidence of infection involving the organ or space that is found on direct examination, during reoperation, or by histopathological or radiological examination; or diagnosis of an organ or space SSI by a surgeon or attending physician.

Diagnosis of Septic Arthritis

Clinical diagnosis of septic arthritis is based on physical examination findings such as joint swelling, warmth, or positive joint aspiration.[6] Other factors include pain, difficulty, or inability to bear weight in conjunction with elevated inflammatory markers during laboratory examination.[6] At our facility, we consider the following levels to be elevated: erythrocyte sedimentation rate (ESR), > 20 mm/hr; C-reactive protein (CRP), > 0.4 mg/dL; and white blood cell count (WBC), > 10.6 x 103 cells/mm^3. There are two gold standards for the diagnosis of septic arthritis. The first is a joint aspiration with a positive gram stain or culture, and the second is a total nucleated cell count greater than 50,000 WBC/mL in a native joint or greater than 2500 WBC/mL in a prosthetic joint.[6,20] Although a CDC definition for septic arthritis has been developed along with an orthopaedic definition for periprosthetic joint infections, no surveillance definition specifically addresses infections of arthroscopic joint infections.[21] Notably, there is considerable morbidity with superficial infections but we focused on the commonalities between patients who had septic arthritis.

Data Gathered

We reviewed the ESR, CRP, WBC, and joint aspiration results. Additionally, we collected data regarding patient age, date of index procedure, preoperative diagnosis, index procedure, graft used, number of days from surgical procedure to diagnosis of infection, subsequent procedures (ie, type and number), antibiotic treatment (ie, type and duration), and preoperative antibiotic administration.

We also examined infection control records on facility inspections, findings, and interventions. In the medical records, several aspects of patient care and safe practices were evaluated on the basis of multiple visits. These included patient preoperative preparation, perioperative antibiotic administration, instrument processing and sterilization, operating room ventilation, and personnel adherence to the best infection control practices.

Table 1. *Age and diagnosis details of the 17 patients with surgical site infections*[a]

Patient Age, Years	Diagnosis	Surgical Procedure	Graft	Days to Infection	Laboratory Results[b]	Cultures Results
22	ACLt, MMt,	ACLr, MMd	BPTB autograft	21	WBC, 7.4, ESR, 84 CRP, 25.7, TNC, 96,160	No growth
45	ACLt, MCLt, PCLt,	ACLr, MCLr PCLr	HS autograft and allograft	29	WBC, 9.7, ESR, 123 CRP, 15.8, TNC, --	*Pseudomonas aeruginosa, Enterobacter cloacae, Corynebacterium lipophiloflavum*
19	ACLt	ACLr	HS autograft	19	WBC ,11.8, ESR, 73 CRP, --, TNC, 121,400	*Staphylococcus epidermidis*
60	RCT, SLAP, ACA	RCTr, SLAPr, SAD,	--	14	WBC, 13.8, ESR, 56 CRP, 27, TNC, --	*Methicillin-sensitive Staphylococcus aureus*
56	Shoulder synovitis	Synovectomy	--	8	WBC, 14.3, ESR, 6 CRP, 2.8,, TNC, 57,000	*Methicillin-sensitive Staphylococcus aureus*
15	ACLt	ACLr	HS autograft	26	WBC, 10.5, ESR, -- CRP, 13.7, TNC, 38,000	*Staphylococcus haemolyticus*[a]
51	ACLt, MMt	ACLr, MMd	HS autograft	30	WBC, 7.7, ESR, 68 CRP, 1.4, TNC, 41,400	*Staphylococcus epidermidis*
21	ACLt, MMt, LMt	ACLr, MMd, LMd	HS autograft	25	WBC, 10.1, ESR, 90 CRP, 4.6, TNC, 80,840	*Staphylococcus epidermidis*
54	MMt	MMd	--	13	WBC, 7.0, ESR, 51 CRP, 11.3, TNC, 81,100	*Enterococcus faecalis, Staphylococcus capitis*[a]
48	PLCi	PLCr	Achilles and TA allografts	27	WBC, 8.2, ESR, 29 CRP, 9.5, TNC, 87,990	No growth
34	ACLt	ACLr	HS autograft	20	WBC, 9.7, ESR, 30 CRP, 3.6, TNC, 47,640	No growth
14	ACLt	ACLr	HS autograft	17	WBC, 7.9, ESR, 45 CRP, 6.4, TNC, 46,000	No growth
54	Loose body	Loose body removal	--	12	WBC, 8.8, ESR, 5 CRP, 2.6, TNC, 18,360	*Enterobacter cloacae*
29	ACLt, LMt	ACLr, LM repair	HS autograft	140	WBC, 8.6, ESR, 107 CRP, 12.6, TNC, 73,370	No growth
19	Knee synovitis	Synovectomy	--	14	WBC, 10.2, ESR, 44 CRP, 14.3, TNC, 73,370	*Staphylococcus capitis, Staphylococcus epidermidis, Corynebacterium*
53	ACLt, MMt	ACLr, MMd	HS autograft	36	WBC, 7.3, ESR, 42 CRP, 11.5, TNC, 37,140	No growth
58	LMt	LMd	--	22	WBC, 6.3, ESR, 29 CRP, 3.8, TNC, 37,140	*Staphylococcus epidermidis*

ACA, acromioclavicular arthritis; ACLt, anterior cruciate ligament tear; ACLr, anterior cruciate ligament reconstruction; BPTB, bone-patellar tendon-bone; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; HS, hamstrings; MCLt, medial collateral ligament tear; MCLr, medial collateral ligament reconstruction; MMd, medial meniscus debridement; MMr, medial meniscus repair; MMt, medial meniscus tear; LMd, lateral meniscus debridement; LMr, lateral meniscus repair; LMt, lateral meniscus tear; PLCi, posterolateral corner injury; PLCr, posterolateral corner reconstruction; RCRi, rotator cuff repair; RCRr, rotator cuff tear repair; SAD, subacromial decompression; SLAP, superior labrum anterior to posterior; TA, tibialis anterior; TNC, total nucleated cells; WBC, white blood cell count; --, not applicable.
All patients diagnosed with septic arthritis had purulence in the joint with the exception of this patient who was diagnosed with a superficial wound infection.
[a]Considered to be contaminants.
[b]At our facility, the following levels are elevated and suggestive of infection: erythrocyte sedimentation rate, > 20 mm/hr; C-reactive protein, > 0.4 mg/dL; white blood cell count (WBC), > 10.6 x 10^3 cells/mm^3; and total nucleated cell count, > 50,000 WBC/mL.

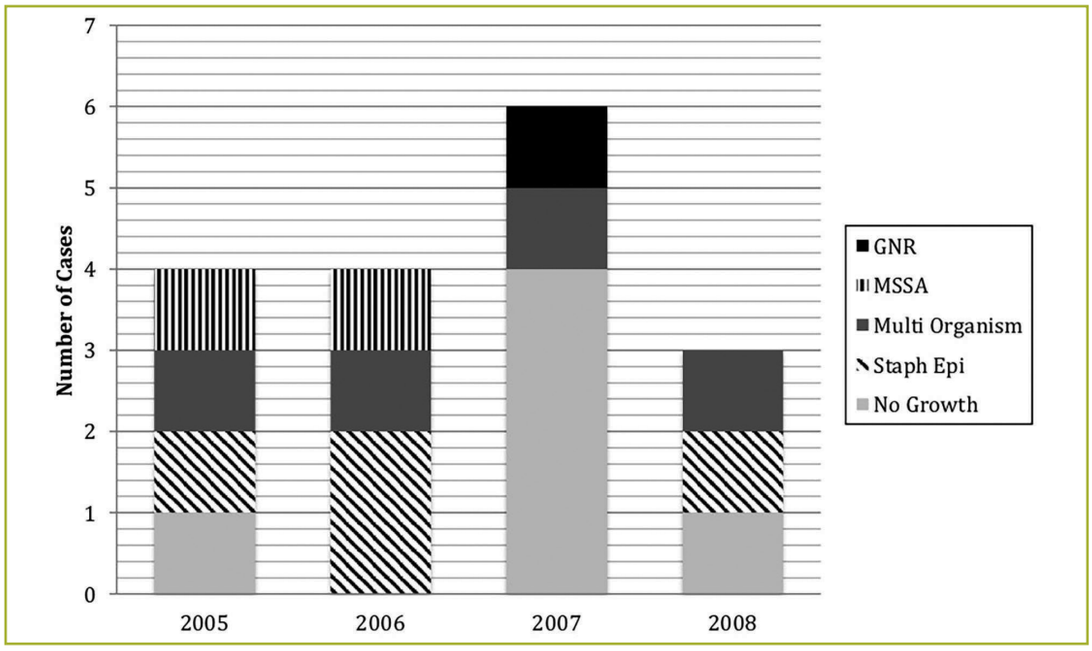

Figure 2. *Pathogens by the number of cases and year between 2005 and 2008. GNR, gram negative rods. MSSA, methicillin-sensitive Staphylococcus aureus. Staph Epi, Staphylococcus epidermidis.*

RESULTS

Table 1 shows patient demographics and diagnosis details. Of the 17 patients, two had undergone shoulder arthroscopies and 15 had undergone knee arthroscopies. Of the 15 knee arthroscopies, there were nine ACL reconstructions (ie, four meniscal debridements and one meniscal repair), two meniscal debridements, one multiligament reconstruction, one posterolateral corner reconstruction, one loose body removal, and one synovectomy. There were nine hamstring autografts, one bone-patella tendon-bone autograft, and three allografts used for reconstruction. Of the two patients with shoulder arthroscopies, one involved a rotator cuff and SLAP (ie, superior labral tear from anterior to posterior) repair and the other involved synovectomy.

Diagnosis and Treatment

The average time to diagnosis and treatment of infection was 28 days from the index procedure. One patient who was identified with a late infection was treated at 140 days. Culture results were negative for infection in 6 of the 17 patients. The remaining patients developed *Staphylococcus epidermidis*, multiple organisms, methicillin-susceptible *Staphylococcus aureus*, and gram-negative rods (Figure 2).

All patients were treated with irrigation and debridement in the operative suite, with 16 of the 17 patients treated arthroscopically and one patient treated with open debridement. Subsequent debridements were required for five patients. Hardware and grafts were removed in three patients, and three patients had antibiotic beads placed and subsequently removed. Perioperative antibiotics were given to 14 of the 17 patients. In 16 patients, septic arthritis was treated with intravenous antibiotics. The two remaining patients were treated with oral antibiotics. There were various combinations of medications, route, and duration of the treatments (Table 2).

Two surgeons performed 16 of the 17 index procedures. The remaining index procedure was performed by a different surgeon. It should be noted that one surgeon performed six of the eight ACL reconstructions that developed infection.

Infection Rates

Infection rates by year are reviewed in Figure 3. SSI rates after all arthroscopic procedures from 2005 to 2011 were 0.81%, 0.91%, 0.73%, and 0.38% for each sequential year. Infection rates after ACL reconstruction were 2.5%, 1.6%, 2.6% and 1.3% for each sequential year.

Site Investigation Findings

Results of the site investigation revealed important deficiencies in infection control, with most issues being in sterile processing. On one site visit, positive airflow in the operating rooms was found to be inadequate. Interviews with the sterile processing department revealed a lack of understanding of instrument disassembly and cleaning, brushes being re-used and not cleaned, and employees running short cycles during the pre-sterilization wash process at the end of the day. At that time, none of the sterilization technicians were certified.

Three patients did not receive perioperative antibiotics. During the study period, a povidone-iodine mixture was used for skin preparation on all patients. Additionally, a tendon-stripper commonly used by the two surgeons in this study was not being completely disassembled before cleaning. After properly disassembling the tendon-stripper, it was found to have visible adherent debris.

Table 2. Treatment details of the 17 patients with surgical site infections[a]

Patient age, years	No. postoperative procedures and details	Antibiotic treatment (type, method)	Antibiotic duration, weeks	Peri-op antibiotic
22	1 - AD	Ceftriaxone IV Levofloxacin PO	5	Yes
45	3 - AD, HWR, GR, antibiotic beads	Ciprofloxacin PO, Zosyn IV, Linezolid PO	18	Yes
19	3 – AD, GR, HWR, antibiotic beads	Vancomyocin IV, Clindamycin IV, Rifampin PO	8	Yes
60	3 – AD, antibiotics beads	Nafcillin IV, Rifampin PO, Linezolid PO	16	Yes
56	2 - AD	Cefazolin IV, Bactrim PO	6	Yes
15	1 – AD	Cephalexin PO	2	Yes
51	1 – AD	Nafcillin/Cefazolin IV[b] Ciporofloxacin PO, Rifampin PO	18	Yes
21	1 – AD	Nafcillin IV	6	No
54	1 – AD	Ceftriaxone IV, Amoxicillin PO	5	No
48	1 – open I&D, HWR, GR	Linezolid PO	4	Yes
34	1 – AD	Vancomycin IV, Rifampin PO, Linezolid PO	6	No
14	1 – AD	Cefazolin IV	6	Yes
54	2 – AD	Vancomycin IV, Ciprofloxacin PO, Rifampin PO, Linezolid PO	6	Yes
29	1 – AD	Vancomycin IV, Ciprofloxacin PO, Rifampin IV	6	Yes
19	1 – AD	Nafcillin IV, Cephalexin PO	6	Yes
53	2 – AD	Linezolid PO	4	Yes
58	1 – AD	Vancomycin IV	4	Yes

AD, arthroscopic debridement; GR, graft removal; HWR, hardware removal; IV, intravenous; peri-op, perioperative; PO, oral.
[a]All treated with repair/reconstruction, meniscal debridement, synovectomy or loose body removal as indicated by the diagnosis with the exception of one who underwent lateral meniscal repair and anterior cruciate ligament reconstruction.
[b]Increased creatinine, switched to Cefazolin.

DISCUSSION

Before the start of this study, we observed an increase in orthopaedic SSIs at our ASC between 2005 and 2008 (ie, 2.5% in 2005 and 2.6% in 2007). Results of a thorough review of medical records and a site investigation indicated that most patients with infections had undergone knee ligament reconstructive procedures (primarily ACL reconstruction) performed by two orthopaedic surgeons. Additionally, the SSIs were likely the result of a lack of standardization in sterile processing.

In the current study, there were 17 patients diagnosed with deep SSI. Of these patients, nine received hamstring autografts and four received hamstring allografts. Although there is an increased risk of SSI with both hamstrings autograft and allograft, our infection rate was far greater than what could be explained by graft choice alone.[22] For reconstructions, we used nine hamstring autografts, one bone-patella tendon-bone autograft, and three allografts. Although it appeared that the inappropriately handled tendon-stripper may have contributed to some of the infections, there was no common infectious agent found indicating one source. Additionally, the povidone-iodine mixture used on all patients primarily used for skin preparation. One prospective randomized controlled study found that a chlorhexidine-alcohol mixture is superior to iodine for prevention of SSIs; however, these findings have not yet been incorporated into formal guidelines.[23] Among our patients with negative culture findings, there was a low-grade yet persistent inflammatory reaction. It was suggested that it may have been a reaction to the sterile debris in contaminated instruments.

Healthcare-associated infections are a leading cause of death in the United States, with an estimated 1.7 million healthcare-related infections and 99,000 deaths attributed to these infections in 2002.[23,24] These data, however, do not reflect the burden of infections acquired in ambulatory settings and day-time surgical procedures. In response to the growing concerns surrounding healthcare-associated infections, the United States Department of Health and Human Services released an action plan in January 2009 to help prevent healthcare-associated infections.[24] The first phase of recommendations focused on six related areas of healthcare-associated infections such as SSIs at acute inpatient facilities. However, it did not focus on ASCs.

In 2008, an outbreak at one Nevada ASC prompted

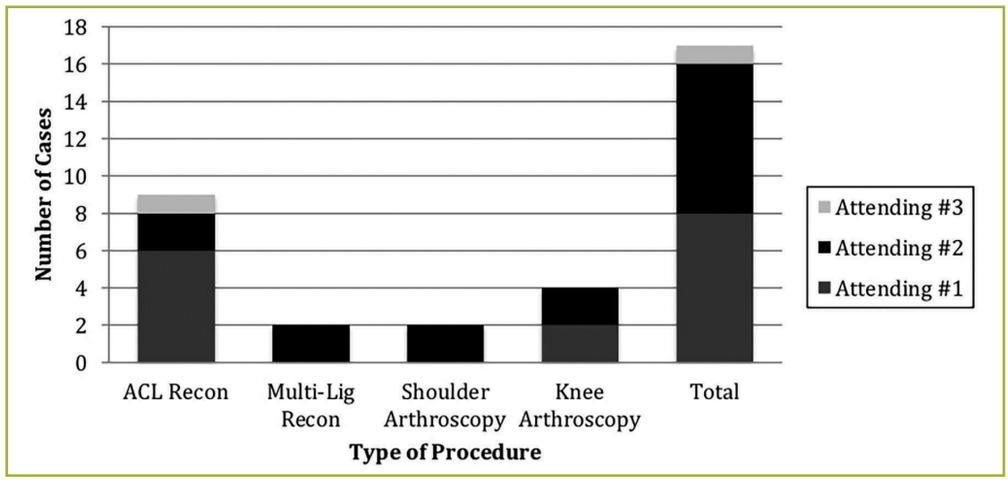

Figure 3. *Arthroscopic infections by attending and type of case. ACL, anterior cruciate ligament; Recon, reconstruction; Multi-Lig, multiligament.*

an investigation into infection control at all 51 ASCs in Nevada. The investigation used an audit tool developed by the CDC[25] and found lapses in infection control in 28 of the ASCs. These findings prompted CMS to conduct further investigation in three additional states (Maryland, North Carolina, and Oklahoma) and found that 46 of the 68 facilities surveyed had at least one major lapse in infection control.[26] Subsequently, the United States Department of Health and Human Services recognized the need to address the prevention of healthcare-associated infections. This therefore led to the second phase of planning, which includes the prevention of healthcare-associated infections at ASCs.[24] CMS current conditions of participation include: an infection control program based on nationally recognized infection control guidelines that is under the direct control of trained infection control personnel; integration of the infection control program into the ASC's quality improvement program; and documentation that the ASC is controlling and monitoring infections using this program.[1]

Infection surveillance at ASCs can pose particular challenges. Post-discharge surveillance from ASCs requires various methods of tracking patients (eg, follow-up calls, surgeon surveys, and medical record review).[6] Unfortunately, high sensitivity is difficult to achieve outside integrated healthcare systems with common electronic records.[27] Patients with infections are typically admitted for diagnosis, debridement, and initiation of antimicrobial therapy at acute care facilities. Yet, there is a lack of communication in acute care facilities that makes identifying cases difficult. Therefore, a good working relationship with infection professionals in local acute care hospitals is essential. In some states, such as Texas, acute care hospitals are required to notify the originating facility when any patient is found to have a healthcare-associated infection, which is now a requirement for acute care facilities due to efforts by the Joint Commission.[16,28]

In response to the observed infection outbreak at our ASC, several changes were enacted. First, the ventilation system was updated. Additionally, the sterile processing technicians are now certified and all instrumentation assembly and disassembly instructions are readily available in the processing room. A continuous improvement program is in place for immediate-use sterilization (previously known as "flash" sterilization). Furthermore, we continued to perform prospective surveillance on all arthroscopic procedures performed in our ASC; notably, this ended in 2011 when a temporary reallocation of resources was required by new CMS requirements and a change in the electronic health record.

The current study is a retrospective review and therefore has some inherent limitations. First, there is the potential of selection bias. The patients were identified by medical records, and thus accuracy of report was dependent on the clinical notes. Also, the patients who experienced SSIs did return to our healthcare system. It is possible that they sought treatment for SSI elsewhere, but that was not noted in the record. On the basis of these limitations, it is impossible to draw definitive conclusions; however, this review does give insights about the increased infection rate that was found at our ASC.

Ultimately, our infections were recognized and corrected because of a close partnership with infectious diseases clinicians, our hospital epidemiologist, and certified infection prevention specialists. ASCs may require expert consultation to ensure that appropriate infection surveillance and preventive processes are put in place to meet the evolving standards of patient safety.

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