

Infection Control Assessment of Ambulatory Surgical Centers

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OVER THE LAST SEVERAL DECADES, health care delivery in the United States has shifted toward the outpatient setting; ambulatory surgery in particular has been an area of immense growth. Ambulatory surgical centers (ASCs) are defined by the Centers for Medicare & Medicaid Services (CMS) as facilities that operate exclusively to provide surgical services to patients who do not require hospitalization or stays in a surgical facility longer than 24 hours.¹

Between 2001 and 2008 there was a greater than 50% increase in the number of Medicare-certified ASCs in the United States; currently more than 5000 ASCs participate in the Medicare program.^{2,3} In 2007, these facilities performed more than 6 million procedures with services extending beyond what is traditionally considered surgery to include endoscopy, pain injections, and dental procedures among others.²

For editorial comment see p 2295.

Context More than 5000 ambulatory surgical centers (ASCs) in the United States participate in the Medicare program. Little is known about infection control practices in ASCs. The Centers for Medicare & Medicaid Services (CMS) piloted an infection control audit tool in a sample of ASC inspections to assess facility adherence to recommended practices.

Objective To describe infection control practices in a sample of ASCs.

Design, Setting, and Participants All State Survey Agencies were invited to participate. Seven states volunteered; 3 were selected based on geographic dispersion, number of ASCs each state committed to inspect, and relative cost per inspection. A stratified random sample of ASCs was selected from each state. Sample size was based on the number of inspections each state estimated it could complete between June and October 2008. Sixty-eight ASCs were assessed; 32 in Maryland, 16 in North Carolina, and 20 in Oklahoma. Surveyors from CMS, trained in use of the audit tool, assessed compliance with specific infection control practices. Assessments focused on 5 areas of infection control: hand hygiene, injection safety and medication handling, equipment reprocessing, environmental cleaning, and handling of blood glucose monitoring equipment.

Main Outcome Measures Proportion of facilities with lapses in each infection control category.

Results Overall, 46 of 68 ASCs (67.6%; 95% confidence interval [CI], 55.9%-77.9%) had at least 1 lapse in infection control; 12 of 68 ASCs (17.6%; 95% CI, 9.9%-28.1%) had lapses identified in 3 or more of the 5 infection control categories. Common lapses included using single-dose medication vials for more than 1 patient (18/64; 28.1%; 95% CI, 18.2%-40.0%), failing to adhere to recommended practices regarding reprocessing of equipment (19/67; 28.4%; 95% CI, 18.6%-40.0%), and lapses in handling of blood glucose monitoring equipment (25/54; 46.3%; 95% CI, 33.4%-59.6%).

Conclusion Among a sample of US ASCs in 3 states, lapses in infection control were common.

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Despite this shift in health care delivery, attention to infection control in ASCs might be lacking, as evidenced by the increased identification of outbreaks of health care-associated infections (HAIs) and patient notifications resulting from lapses in infection control in these and other outpatient settings.⁴⁻¹¹ The recent outbreak of hepatitis C virus infections and large-scale patient notification resulting from unsafe injection practices at

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a licensed ASC in Las Vegas, Nevada, highlight this issue.¹²

State Survey Agencies are primarily responsible for periodically inspecting and assessing ASC compliance with Medicare health and safety standards. However, inspections have not previously required observations of procedures or standardized assessments of infection control practices. The Las Vegas ASC with the hepatitis C outbreak had not undergone a full inspection by state surveyors in 7 years.¹² To ensure that similar infection control lapses were not occurring in other facilities, surveyors from the Nevada Board of Licensure and Certification conducted focused inspections of all 51 of the state's ASCs using an infection control audit tool developed by the Centers for Disease Control and Prevention (CDC) based on nationally recognized guidelines. Lapses in infection control identified in 28 of these ASCs, which were also subjected to federal inspections, prompted CMS to conduct similar inspections in a sample of ASCs in 3 additional states.

The objectives of the assessment were to describe compliance with basic infection control practices as well as with other Medicare health and safety standards in ASCs and to determine whether use of the audit tool and patient tracer methodology improved inspection effectiveness.

METHODS

Data Collection

On March 28, 2008, CMS notified all State Survey Agencies that they were seeking 1 to 4 volunteer states to conduct inspections in ASCs incorporating the infection control audit tool used in Nevada. Incentives for participation included 1-time supplemental funding to cover the cost of these inspections and the assurance that all inspections performed as part of this activity would count in CMS' assessment of each state's performance for the fiscal year. Participating states were asked to have a sufficient number of qualified surveyors available to complete 20 to 30 ASC inspections by

September 30, 2008, in addition to their regular inspection workload. Seven states volunteered to participate in the pilot. Maryland, North Carolina, and Oklahoma were selected for participation based on geographic dispersion, number of inspections proposed, and cost considerations.

After the 3 pilot states were identified, CMS set a sample size for each state based on the number of ASCs each state committed to inspecting. All of the ASCs in each state were categorized into 3 areas based on the types of procedures performed (multispecialty, endoscopy, and other). For each state, the proportion of Medicare-certified ASCs in each of the 3 procedure categories was determined, and using a random number generator, CMS selected a stratified random sample from each subgroup for inspection. For example, 40% of Maryland's ASCs were in the category "other." Therefore, CMS randomly selected 40% of the Maryland pilot ASCs from that category.

State surveyors conducted full, unannounced on-site assessments of compliance with all Medicare ASC health and safety standards, excluding those related to life safety code (ie, fire safety), in each selected facility. In addition to adhering to standard inspection protocols, surveyors were instructed to use the infection control audit tool and to apply a case tracer methodology. The case tracer methodology required surveyors to follow at least 1 patient throughout the entire stay in the ASC while observing practices (eg, documentation, infection control) to assess compliance with regulatory standards. This included observation of part or all of the patient's procedure. Additionally, surveyors observed infection control practices throughout the ASC (eg, preoperative and postoperative areas). Although the inspection was unannounced, once surveyors entered the facility, staff were notified that an inspection was being conducted. When procedures were observed by surveyors, consent was obtained from both the patient and physician performing the procedure.

To help standardize infection control assessments by surveyors, health care epidemiologists from the CDC traveled to each of the participating states and spent a day with surveyors discussing infection control elements included on the audit tool, including how best to assess them in the facility. Staff from the CDC then accompanied surveyors on initial ASC inspections to further assist with incorporation of the audit tool into the inspection process. Staff from the CDC also consulted when surveyors had additional questions about infection control observations and findings during the remainder of the pilot.

Data collected with the infection control audit tool included basic information about the ASC (eg, types and number of procedures performed) in addition to adherence to important infection control activities. Five general categories of infection control were assessed: hand hygiene and use of personal protective equipment, injection safety and medication handling, equipment reprocessing (eg, sterilization and high-level disinfection), environmental cleaning, and handling of blood glucose monitoring equipment. Given the proportion of procedures performed in ASCs that are not considered traditional surgery (eg, endoscopy, dental, pain injections), particular emphasis was placed on elements beyond those targeting primary surgical site infection prevention.

Surveyors observed moments when staff should be performing hand hygiene, including before and after invasive procedures and after contact with blood, body fluids, or contaminated surfaces. They further evaluated whether staff wore gloves for contact with blood and body fluids or contaminated surfaces and whether gloves were removed before moving to new tasks. Surveyors assessed if staff used new sterile needles and syringes for each patient and for each entry into medication vials that were used as a source of supply for multiple patients. They further assessed if injections were prepared in a clean work area and if single-dose medications were

appropriately dedicated to a single patient. Surveyors evaluated whether equipment was precleaned prior to sterilization or high-level disinfection, facilities adhered to manufacturer instructions regarding recommended steps for reprocessing, equipment was appropriately stored after reprocessing, and single-use devices were discarded after use. They evaluated whether disinfectants registered by the Environmental Protection Agency were used by the facilities to adequately clean operating and procedure areas between patients. Finally, they assessed whether blood glucose meters were cleaned and disinfected after each use and whether, contrary to labeling, spring-loaded lancing penlet devices were used for multiple patients.

Surveyors were instructed to collect data primarily through observations, supplemented with interview findings. Attention for each component of the audit tool focused on staff members appropriate for each section (eg, the staff member who performed sterilization of equipment was observed and interviewed regarding sterilization practices). Lapses in each infection control category were documented by surveyors, although surveyors did not document the frequency with which lapses were identified. For example, on the audit tool, multiple lapses in hand hygiene would be documented in the same manner as a single lapse observed by surveyors and are reported in the results as a general lapse in that category.

On completion of the inspection, the surveyors conducted a routine exit meeting with the facility summarizing preliminary findings from the inspection. Facilities were then sent an official notice of the findings. Deficiencies were identified via the Form CMS 2567, "Statement of deficiencies and plan of correction," describing all deficiencies noted during the inspection. Facilities were required to develop a plan of correction addressing all deficiencies and to submit the plan to the State Survey Agency for review. Serious deficiencies, as determined by

CMS, required a follow-up inspection to determine whether the ASC had come into compliance. Failure to adequately address and correct all citations could result in termination of the ASC's participation in the Medicare program.

At the conclusion of all federal inspections conducted by state surveyors, data from the Form CMS 2567 is entered into a national database maintained by CMS. After the conclusion of the pilot, this database was queried and the number of pilot inspections with deficiencies cited by surveyors related to medication handling and infection control were compared with the numbers reported to CMS for all ASC inspections conducted nationally in the previous fiscal year.

Data Analysis

At the conclusion of the pilot study, all infection control audit tools were deidentified and transmitted to CDC for analysis. Data were entered into an Access database (Microsoft Corporation, Redmond, Washington) and analysis was conducted using SAS version 9.2 (SAS Institute Inc, Cary, North Carolina). The proportion of facilities with lapses in each of the 5 infection control categories was calculated. Associations between presence of a lapse and state, and between presence of a lapse and facility type (single-purpose endoscopy or other), were assessed for each infection control category using χ^2 tests; Fisher exact tests were substituted where appropriate. Association between presence of a lapse and number of procedures performed per month was assessed for each infection control category using the Wilcoxon rank sum test. Significance was set at $P < .05$.

The sample size varied for each infection control lapse identified because not all of the questions were applicable to each facility or able to be assessed in every inspection. For example, facilities that did not perform blood glucose monitoring were not included in calculation of lapses related to handling of blood glucose monitoring equipment. Additionally, if the

unannounced inspections were inadvertently conducted on days when procedures were not being performed, surveyors might not have been able to directly assess or question appropriate staff members about specific practices.

RESULTS

Demographics

A total of 68 ASCs were assessed during the pilot inspections; 32 in Maryland, 16 in North Carolina, and 20 in Oklahoma. This reflects 9.4% of all CMS-certified ASCs at the time of the pilot in Maryland (N=342), 21.1% in North Carolina (N=76), and 39.2% in Oklahoma (N=51). Each inspection took a median of 2 days to complete (range, 1-3 days), and surveyors observed a median of 1 procedure during the inspections (range, 0-6 procedures). A median of 5.4 years had elapsed between the pilot inspection and most recent prior inspection (range, 0.6-12.6 years).

Ambulatory surgical centers inspected during the pilot performed a median of 210 procedures per month (range, 3-1260 procedures). Thirty-one of 68 ASCs (45.6%; 95% confidence interval [CI], 34.1%-57.5%) performed procedures on both adults and children. The types of procedures performed are summarized in TABLE 1. More than half of the ASCs (37/67; 55.2%; 95% CI, 43.2%-66.8%) performed only 1 type of procedure. At these single-procedure ASCs, endoscopic (21/37; 56.8%, 95% CI, 40.6%-71.9%) and ophthalmologic (6/37; 16.2%, 95% CI, 6.8%-30.7%) procedures were the most common procedures performed.

Infection Control Lapses

Overall, 46 of 68 pilot ASCs (67.6%; 95% CI, 55.9%-77.9%) had at least 1 lapse in infection control noted by surveyors. Specific lapses in each of the categories are summarized in TABLE 2. Twelve of 62 facilities (19.4%; 95% CI, 10.9%-30.6%) were noted to have a lapse in adherence to hand hygiene or appropriate use of personal protective

Table 1. Types of Procedures Performed at the Pilot Ambulatory Surgical Centers^a

Procedure Type	No. (%) [95% Confidence Interval]			
	Maryland (n = 32)	North Carolina (n = 15) ^b	Oklahoma (n = 20)	All (n = 67)
Dental	4 (12.5) [4.1-27.5]	4 (26.7) [9.1-52.5]	5 (25.0) [9.8-47.0]	13 (19.4) [11.2-30.2]
Endoscopy	15 (46.9) [30.2-64.1]	7 (46.7) [23.2-71.3]	13 (65.0) [42.7-83.2]	35 (52.2) [40.3-64.0]
General	4 (12.5) [4.1-27.5]	5 (33.3) [13.4-59.2]	10 (50.0) [28.9-71.1]	19 (28.4) [18.6-40.0]
Gynecology	7 (21.9) [10.1-38.6]	3 (20.0) [5.4-45.4]	10 (50.0) [28.9-71.1]	20 (29.9) [19.8-41.6]
Ophthalmology	5 (15.6) [6.0-31.3]	7 (46.7) [23.2-71.3]	13 (65.0) [42.7-83.2]	25 (37.3) [26.4-49.3]
Orthopedics	7 (21.9) [10.1-38.6]	6 (40.0) [18.1-65.5]	13 (65.0) [42.7-83.2]	26 (38.8) [27.7-50.8]
Otolaryngology	6 (18.8) [8.0-35.0]	4 (26.7) [9.1-52.5]	9 (45.0) [24.6-66.7]	19 (28.4) [18.6-40.0]
Pain	7 (21.9) [10.1-38.6]	6 (40.0) [18.1-65.5]	13 (65.0) [42.7-83.2]	26 (38.8) [27.7-50.8]
Plastic surgery	7 (21.9) [10.1-38.6]	7 (46.7) [23.2-71.3]	7 (35.0) [16.8-57.3]	21 (31.3) [21.1-43.2]
Podiatry	7 (21.9) [10.1-38.6]	6 (40.0) [18.1-65.5]	8 (40.0) [20.6-62.1]	21 (31.3) [21.1-43.2]
Other ^c	4 (12.5) [4.1-27.5]	5 (33.3) [13.4-59.2]	4 (20.0) [6.7-41.5]	13 (19.4) [11.2-30.2]

^aColumn totals do not equal 100% as facilities might perform more than 1 procedure type.
^bOne audit tool from North Carolina did not include information regarding types of procedures performed.
^cProcedures in this category included dermatology and urology.

equipment (ie, gloves). Nineteen of 67 facilities (28.4%; 95% CI, 18.6%-40.0%) had deficiencies related to injection practices or medication handling, primarily through use of single-dose vials for more than 1 patient (28.1%; 95% CI, 18.2%-40.0%). Nineteen of 67 facilities (28.4%; 95% CI, 18.6%-40.0%) failed to adhere to recommended practices regarding reprocessing of surgical equipment. Twelve of 64 facilities (18.8%; 95% CI, 10.6%-29.7%) did not appropriately clean high-touch surfaces in patient care areas. Twenty-five of 54 facilities (46.3%; 95% CI, 33.4%-59.6%) had lapses in appropriate handling of equipment used for blood glucose monitoring. Twelve of 68 facilities (17.6%; 95% CI, 9.9%-28.1%) had lapses identified in 3 or more of the 5 infection control categories evaluated by surveyors.

There was no significant association between presence of a lapse and number of procedures performed per month in the categories of hand hygiene ($P = .54$), injection safety and medication handling ($P = .57$), equipment reprocessing ($P = .85$), environmental cleaning ($P = .90$), or handling of blood glucose monitoring equipment ($P = .34$). Nor was there a significant association between presence of a lapse and type of facility in any of the 5 categories (TABLE 3). However, pres-

ence of lapses related to environmental cleaning varied significantly among the 3 states, with only surveyors in Oklahoma documenting lapses in this category ($P < .001$) (Table 2).

Citations

Thirty-nine of 68 pilot ASCs (57.4%; 95% CI, 45.4%-68.7%) were ultimately cited for deficiencies in infection control and 20 of 68 ASCs (29.4%; 95% CI, 19.5%-41.0%) were cited for deficiencies related to medication administration, including use of single-dose medications for multiple patients. The percentage of inspections with deficiencies related to infection control during this pilot was more than 6-fold greater than the number reported to CMS nationally during the 12-month period from October 1, 2006, to September 30, 2007, when 78 of 957 facilities (8.2%; 95% CI, 6.5%-10.0%) were cited for infection control deficiencies and 88 of 957 (9.2%; 95% CI, 7.5%-11.2%) were cited for medication administration deficiencies.

COMMENT

Results from this study suggest that infection control practices in ASCs might be lacking and were not specific to a given state. Two-thirds of the pilot ASCs had lapses in infection control identified during the inspections. Further-

more, 18% of ASCs had lapses extending across 3 or more areas of infection control. Results also suggest that the audit tool likely enhanced surveyor attention to infection control, resulting in an increased number of facility citations related to infection control and medication handling compared with national numbers from the previous year.

Some of the more concerning lapses noted on the audit tool were related to medication handling and equipment reprocessing. Twenty-eight percent of facilities used medications in single-dose vials for multiple patients. These medications do not contain preservatives to inhibit bacterial growth and are only meant for use on a single patient for a single procedure.^{11,13} Reuse of these vials, as well as bags of saline also labeled for single-patient use, for multiple patients has resulted in previous outbreaks of bloodstream infections.^{5,14-16} In what could be a cost-saving measure, facilities have purchased single-dose medications in packaging larger than that required for single-patient use and then used the contents for multiple patients.^{14,15}

Six percent of all pilot facilities were noted to inappropriately reprocess and reuse items that were packaged and labeled as single-use devices. Examples of such devices included bite blocks and syringes used to flush the endoscope during endoscopy procedures. Reprocessing of single-use devices is regulated by the Food and Drug Administration (FDA), and such reprocessing can only be performed by third-party or hospital reprocessors that have received clearance from FDA and are registered with FDA as reprocessing facilities.¹⁷ None of the ASCs cited for reprocessing single-use devices used third-party reprocessors; instead, they elected to inappropriately create their own procedures for reprocessing devices and when these devices should be discarded.

Twenty-one percent of facilities that performed blood glucose testing used a single lancing penlet device for multiple patients. Labeling on package inserts usually states that these devices

