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HEALTH-CARE- ASSOCIATED INFECTIONS

HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers



GAO

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Highlights of [GAO-09-213](#), a report to congressional requesters

Why GAO Did This Study

Health-care-associated infections (HAI) are a leading cause of death. Recent high-profile cases of HAIs in ambulatory surgical centers (ASC) due to lapses in recommended infection control practices may indicate a more widespread problem in ASCs, but the prevalence of such lapses is unknown.

The Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services (CMS) and other entities collect data on HAIs, including process data on the use of recommended practices and outcome data on HAI incidence. CMS conducts standard surveys on about half of ASCs every 3 to 4 years, assessing compliance with its standard on infection control. In this report, GAO examines the availability of data on HAIs in ASCs nationwide. GAO interviewed subject-matter experts, agency officials, and trade and professional group officials.

What GAO Recommends

To collect nationally representative and standardized information on ASC compliance with infection control practices that reduce HAIs, GAO recommends that the Acting Secretary of HHS develop and implement a written plan to use the data collection instrument and methodology tested in the ASC pilot to conduct recurring periodic surveys of randomly selected ASCs. In response, CMS concurred with the recommendation.

To view the full product, including the scope and methodology, click on [GAO-09-213](#). For more information, contact Cynthia A. Bascetta at (202) 512-7114 or bascettac@gao.gov.

HEALTH-CARE-ASSOCIATED INFECTIONS

HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers

What GAO Found

Disparate sources of data on HAIs in ASCs are available, but none provide information on the extent of the problem nationwide. Such data are useful for guiding federal policies aimed at preventing the lapses in infection control practices—such as reusing syringes and drawing medication to be injected into multiple patients from single-dose vials—that can lead to increased risk of HAIs for patients. GAO identified five data sources—two operated by HHS, two by professional organizations, and one by a state government—all of which differ from one another in the type of HAI information they collect.

In order to make nationwide estimates of HAIs and lapses in related infection control practices in ASCs, a data source would need to collect its data from a nationally representative random sample of ASCs. However, none of the five sources does so. The two professional organizations and the state source collect data from narrowly defined subsets of ASCs. The most detailed data are provided by the two federal sources, one of which collects outcome data and the other process data. Experts GAO interviewed said it was more feasible for ASCs to collect process data than outcome data. The Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network collects detailed, standardized data on HAI outcomes that are comparable across hospitals and other health care facilities, but it has only recently begun to collect data on ASCs and it is not set up to collect nationally representative data. The other HHS data source, a CMS ASC pilot study conducted in three states, collects detailed process data on practices that affect the risk of HAIs.

The pilot study tested the application of two innovations—a CDC-developed infection control assessment tool and direct observation by the surveyor of a single patient's care from start to finish of the patient's stay—during the course of CMS's standard surveys of selected ASCs. These innovations allowed surveyors to identify serious lapses in CDC-recommended infection control practices that would not have been detected during CMS's standard surveys of selected ASCs. A CMS official told GAO that CMS officials would consider making changes to CMS's standard survey process after reviewing planned CMS and CDC analyses of the pilot study results but did not expect to collect standardized quantitative data on the extent of compliance with specific infection control practices using a data collection instrument, as was done with the assessment tool for the pilot. Even if CMS were to continue the pilot's data collection methods, the data would not be generalizable to ASCs nationwide—and thus could not provide information on the extent of the lapses—because ASCs are selected for surveys on the basis of their perceived risk for quality issues and the length of time since they were last surveyed, rather than through random selection. A random sample—the size of which CMS could determine—could generate national estimates that would identify those infection control practices where lapses by ASCs across the country were most likely to put their patients at risk of contracting HAIs.

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Abbreviations

| | |
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| AAAASF | American Association for Accreditation of Ambulatory Surgery Facilities, Inc. |
| ASC | ambulatory surgical center |
| CDC | Centers for Disease Control and Prevention |
| CMS | Centers for Medicare & Medicaid Services |
| HAI | health-care-associated infection |
| HHS | Department of Health and Human Services |
| NHSN | National Healthcare Safety Network |
| SSI | surgical site infection |

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United States Government Accountability Office
Washington, DC 20548

February 25, 2009

Congressional Requesters

Health-care-associated infections (HAI) are 1 of the top 10 leading causes of death in the United States, according to the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC), and can cause needless suffering and expense. HAIs are infections that patients may acquire in a health care setting while receiving treatment for other conditions.¹ One such setting is ambulatory surgical centers (ASC), which are freestanding outpatient facilities where surgical procedures such as endoscopies and orthopedic or plastic surgery are performed.² Both the number of ASCs and the number of surgeries performed in ASCs have increased substantially since 1990. Currently, there are over 5,100 ASCs nationwide that provide services to Medicare beneficiaries. In 2007, more than 6 million surgeries were performed in ASCs and paid for by Medicare.³

Because patients in ASCs tended to be healthier than those in hospitals and the procedures performed in ASCs were less invasive and less complex, experts in infection control traditionally have considered the risk of infection in outpatient settings such as ASCs to be low.⁴ However, in recent high-profile cases of HAIs in ASCs, large numbers of patients were put at risk and recommended to be tested for health-care-associated HIV and hepatitis infections. In one such case, approximately 40,000

¹In general, HAIs are distinct from community-acquired infections, that is, infections acquired before entering the health care setting. The term health-care-associated infection is often used synonymously with the terms hospital-acquired infection and nosocomial infection.

²In this report, we are concerned exclusively with freestanding ASCs that participate in Medicare. These ASCs do not include hospital outpatient departments or physicians' offices where surgeries are performed. Some freestanding ASCs may be affiliated with a hospital, however.

³Medicare is a federal health insurance program that serves over 42 million elderly and disabled beneficiaries and pays for certain health care services. Approximately 85 percent of all ASCs in the United States are approved to provide services to Medicare beneficiaries. While there are other ASCs that do not treat Medicare beneficiaries, in this report we focus on those approximately 5,100 ASCs that serve Medicare beneficiaries.

⁴C. Friedman *et al.*, "Requirements for Infrastructure and Essential Activities of Infection Control and Epidemiology in Out-of-Hospital Settings: A Consensus Panel Report," *American Journal of Infection Control* (27:418-30), 1999.

patients in Nevada were potentially exposed to hepatitis C and other infectious diseases over a 4-year period because of lapses in adherence to basic infection control practices. These lapses included reusing syringes and drawing medication to be injected into multiple patients from single-dose vials. Subsequent inspections of other ASCs in the state found similar problems, suggesting that such lapses are not isolated events but indicate a larger, more widespread problem. However, the prevalence of such unsafe practices is unknown.

Two federal agencies have established standards and conducted other activities aimed at controlling and preventing HAIs in health care settings, including ASCs. CDC has issued evidence-based guidelines containing recommended practices, such as proper hand hygiene, to prevent HAIs. HHS's Centers for Medicare & Medicaid Services (CMS) has developed health and safety standards⁵ with which ASCs must comply in order to be certified as suppliers of Medicare-covered services. One of the health and safety standards covers infection control and requires each ASC to establish an infection control program for identifying and preventing infections and maintaining a sanitary environment.⁶ CMS oversight of certified ASCs includes a provision for conducting on-site standard surveys of facilities to assess their compliance with the standards.⁷ State survey agencies select ASCs for these surveys based on policies set by CMS. About half of ASCs are surveyed every 3 to 4 years.

⁵CMS calls these ASC standards "conditions for coverage."

⁶In response to the dramatic growth since 1990 in the number of ASCs participating in Medicare and in the volume of procedures that they perform, CMS issued a revised set of standards for ASCs in November 2008. See 73 *Fed. Reg.* 68502, 68719-20, 68813 (Nov. 18, 2008) (Adding 42 C.F.R. § 416.51). In addition to requiring ASCs to maintain a sanitary environment and an infection control program, the infection control standard requires ASCs to document that they have considered nationally recognized infection control guidelines and implemented those they have determined to be most relevant to their own operations. It also requires that the infection control program be directed by a designated and qualified professional with training in infection control. Discussion in this rule states that ASC clinical staff such as nurses and pharmacists could fill this role without additional training specific to infection control, as long as they received approximately 4 hours of continuing education in infection control each year. This rule is effective May 18, 2009.

⁷There are several types of CMS surveys, including standard and validation surveys, initial certification, complaint investigations, and revisits. In this report, we discuss only standard surveys.

Other activities in HHS aimed at addressing the problem of HAIs include maintaining several databases in different HHS agencies, such as the database of CDC's National Healthcare Safety Network (NHSN) program. In response to demands for more public information on HAIs, at least 23 states have begun to develop and implement HAI public reporting systems—with 17 using CDC's NHSN—to collect and disseminate HAI data from hospitals.⁸ In addition, some states plan to include HAI data from ASCs in these reporting systems, with Missouri beginning to collect data in 2006. These data sources collect information related to HAIs, including process and outcome measures. Process measures record the use of procedures or practices, such as hand hygiene and safe injection practices, designed to reduce the incidence of infections. Outcome measures record actual incidence of an active infection such as a surgical site infection (SSI), or the transmission of an infectious agent such as hepatitis following a procedure.

Previously, we reported that the extent of the HAI problem, while significant, was unknown because the data that CDC and other HHS agencies collect on HAIs in hospitals are limited in scope and lack integration across multiple databases.⁹ We also found that resource and technological challenges have affected the implementation of states' HAI public reporting systems.¹⁰ Data on the extent of the problem of HAIs nationwide are useful for guiding federal actions and policies aimed at preventing the lapses in infection control practices that can lead to increased risk of infection for patients in medical facilities. Given your continuing concern regarding HAIs and recent incidents involving HAIs in ASCs, in this report we (1) examine the extent to which data are available to understand the problem of HAIs in ASCs nationwide and (2) compare the feasibility of collecting outcome versus process data on HAIs in ASCs.

To examine the extent to which data are available to understand the problem of HAIs in ASCs nationwide, we interviewed subject-matter experts and agency and organization officials knowledgeable about this

⁸GAO, *Health-Care-Associated Infections in Hospitals: An Overview of State Reporting Programs and Individual Hospital Initiatives to Reduce Certain Infections*, [GAO-08-808](#) (Washington, D.C.: Sept. 5, 2008), 2, 20.

⁹GAO, *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*, [GAO-08-283](#) (Washington, D.C.: Mar. 31, 2008).

¹⁰[GAO-08-808](#), 24.

topic. We identified six subject-matter experts by conducting a literature search to systematically find individuals who have published studies related to HAIs in ASCs. We interviewed the six subject-matter experts using a standard set of interview questions and received responses from all six. We also interviewed officials from the three main accrediting organizations;¹¹ the ASC trade association; CDC and CMS; three professional organizations and one advocacy organization identified as having knowledge related to our research objectives;¹² and three state survey agencies that were identified by CMS officials as participating in a pilot project involving infection control in ASCs.¹³ To compare the feasibility of collecting outcome versus process data on HAIs in ASCs, we asked all experts and CMS and CDC officials we interviewed to identify the challenges in collecting such data and how these challenges can be addressed. We conducted this performance audit from June 2008 through December 2008, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

Disparate sources of data on HAIs in ASCs are available, but none provide information on the extent of the problem nationwide. We identified five sources of data on HAIs in ASCs—two administered by HHS, two by professional organizations, and one by a state government—all of which differ from one another in the type of HAI information that they collect. In order to make nationwide estimates of HAIs and lapses in related infection control practices in ASCs that could be used in developing federal actions and policies designed to prevent these infections, a data source would need to collect its data from a nationally representative random sample of ASCs. However, none of the five sources does so. The two professional organizations and the state source collect data only from member ASCs or

¹¹These three accrediting organizations are the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., the Accreditation Association for Ambulatory Health Care, and The Joint Commission.

¹²These four organizations are the American Association of Nurse Anesthetists, the American Society for Gastrointestinal Endoscopy, HONOReform, and the Association for Professionals in Infection Control and Epidemiology, Inc.

¹³These are the Maryland, North Carolina, and Oklahoma state survey agencies.

from ASCs within a certain geographical area, respectively. The most detailed data are provided by the two federal sources. CDC's NHSN—the most widely recognized source of data on HAIs—collects detailed, standardized data on HAI outcomes that are comparable across facilities, but it has only recently begun to collect data on ASCs and it is not set up to collect nationally representative data. The other HHS data source, a CMS ASC pilot study conducted in three states, collected detailed process data on practices that affect the risk of HAIs in ASCs. The pilot study tested the application of two innovations—a CDC-developed infection control assessment tool and direct observation by the surveyor of a single patient's care from start to finish of the patient's stay. These innovations allowed surveyors to identify serious lapses in CDC-recommended infection control practices. These lapses would not have been detected during the course of CMS's standard surveys of selected ASCs. CMS officials told us that they intended to consider making changes to CMS's standard survey process after reviewing planned CMS and CDC analyses of the pilot study results but did not expect to collect standardized quantitative data on the extent of compliance with specific infection control practices using a data collection instrument, as was done with the assessment tool for the pilot. Even if CMS were to continue the pilot study's data collection methods, those data would represent only the ASCs actually surveyed under CMS's current selection policies. The data would not be generalizable to ASCs nationwide—and thus could not provide information on the extent of the problem—because ASCs are selected for surveys on the basis of their perceived risk for quality issues and the length of time since they were last surveyed, rather than through random selection. A random sample—the size of which HHS could determine—could generate meaningful national estimates to help identify where lapses in infection control practices by ASCs across the country were most likely to be putting patients at risk of contracting HAIs.

Experts we interviewed stated that it was more feasible for ASCs to collect process data than outcome data. They noted that collecting outcome data in ASCs was challenging because patients were typically in ASCs for a relatively short period of time and would be more likely to seek follow-up care at a physician's office or hospital emergency room than to return to the ASC. Therefore the ASC might never know that an HAI occurred, and so would be unable to report it. Several experts said that it was more feasible to collect process data to detect unsafe practices that might lead to HAIs than to track outcomes such as the transmission of HAIs to individual patients. They added that process data might also be more useful by pointing out areas for specific remedial training.

To obtain nationally representative and standardized information on the extent to which ASCs implement specific infection control practices that reduce the risk of transmitting HAIs to their patients, we recommend that the Acting Secretary of HHS develop and implement a written plan to use the data collection instrument and methodology tested in the ASC pilot study, with appropriate modifications based on the CDC and CMS analyses of that study, to conduct recurring periodic surveys of randomly selected ASCs.

We provided a draft of this report to HHS for comment. In written comments submitted by CMS, the agency concurred with our recommendation. CMS stated that it would use the results from the pilot study to determine whether it should incorporate the infection control assessment tool into the standard ASC survey process. The agency stated that if it decided to use the tool, then it would examine the potential to draw on CDC to provide training on the use of the tool and data analysis of the completed tools on an ongoing basis. Given such support, CMS stated its willingness to begin random selection of at least some ASCs in each state for ASC surveys.

Background

An ASC patient may acquire an HAI from bacteria or viruses contaminating, for example, the hands of a health care worker or a needle or tube used to deliver medicine, fluids, or blood. These bacteria or viruses may include those responsible for such illnesses as staphylococcus infections and hepatitis.

Two agencies in HHS have activities under way to prevent, control, or monitor HAIs. CDC—a key HHS agency for research and programs designed to prevent HAIs—has issued 13 guidelines relevant to infection control and prevention in health care settings. In these guidelines, which are based on scientific evidence, CDC recommends practices for implementation to prevent HAIs.¹⁴ Practices recommended to prevent or control HAIs include, for example, appropriate isolation of infected patients in health care facilities, proper sterilization of equipment, appropriate provision of antibiotics to patients before surgery, annual vaccination of health care personnel for influenza, and hand washing or the use of alcohol-based hand rubs.

¹⁴[GAO-08-283](#), 12.

CMS is responsible for ensuring that ASCs that are certified as suppliers of Medicare-covered services comply with its requirements for infection control. For most ASCs, this occurs through the state-administered standard survey process conducted by state survey agencies under contract with CMS. ASCs may choose instead to undergo accreditation by a CMS-approved accrediting organization.¹⁵ CMS-approved accreditation programs for ASCs have standards that meet or exceed Medicare's standards. Accrediting organizations are to conduct periodic surveys of ASCs to assess their compliance with the standards established by the accrediting organization, including those related to infection control. The state survey agency or accrediting organization assesses compliance through direct observation of activities in the facility and review of its policy documents. If an ASC opts for the CMS state-administered survey process, a state surveyor uses CMS's survey guidance to conduct the state's compliance review of the ASC.

Disparate Sources of Data on HAIs in ASCs Are Available, but None Provide Information on the Problem Nationwide

We identified five disparate sources of HAI data, all of which differed from one another in the types of HAI information they collected. However, none obtained its data from a nationally representative random sample of ASCs, and therefore none could be used to develop national estimates of HAI outcomes or compliance with infection control practices that affect the risk of acquiring HAIs in ASCs. Two federal data sources—CDC's NHSN and CMS's ASC pilot study—provided the most detailed information on HAI outcomes and infection control practices, respectively.

Five Sources of Data for Separate, Non-Nationally-Representative Patient Populations Provide Different Types of Information on HAIs in ASCs

We identified five disparate data sources that currently collect data on HAIs in ASCs. HHS operates two of these data sources—CDC's NHSN and CMS's ASC pilot study. Two are maintained by professional associations—the Ambulatory Surgery Center Association's Outcomes Monitoring Project and the American Association for Accreditation of Ambulatory Surgical Facilities, Inc. (AAAASF) Internet-based Quality Assurance and Peer Review Reporting System. Finally, the state of Missouri collects data on HAIs in ASCs through its Missouri State HAI Reporting System. (See table 1.)

¹⁵The three primary accrediting organizations for ASCs are the American Association for Accreditation of Ambulatory Surgical Facilities, Inc., the Accreditation Association for Ambulatory Health Care, and the Joint Commission. The American Osteopathic Association also accredits a small number of ASCs.

Table 1: Sources of Data on HAIs from ASCs

| Data sources | Number of ASCs; time period | Patient population | Data collection method | Outcomes recorded | Process/practices recorded | Data analysis |
|---|--|---|---|--|---|--|
| CDC National Healthcare Safety Network (NHSN) | Unknown; data from 2006 to present | Patients undergoing selected procedures in enrolled facilities, some of which may be ASCs; ^a some facilities enroll in NHSN voluntarily and others are required to do so under state law | HAIs are detected by facility staff through prospective and post-discharge surveillance, which may include patient examination, medical record review, and/or communication with a patient or physician ^b | Procedure-specific SSIs ^b | Central line insertion practices ^c | Rates of SSIs, controlling for procedure type and patient risk factors |
| CMS ASC Pilot Study | Approx. 68; ^d data from June through October 2008 | Patients in ASCs certified for Medicare participation in Maryland, North Carolina, and Oklahoma | Surveyors use a CDC-developed instrument to collect data during on-site inspections through interviews, document inspection, and observation | None | Training policies; procedures used to detect infections; practices for hand hygiene, injection, sterilization, and environmental cleaning | Facility compliance with specified infection control practices |
| Ambulatory Surgery Center Association Outcomes Monitoring Project | Approx. 650; data from the mid-1990s to present | Patients treated in ASCs that are members of the Ambulatory Surgery Center Association and choose to submit data | ASCs report quarterly the total number of patients who match specified descriptions, such as experiencing wound infections or receiving antibiotics prior to surgery | Aggregate number of post-procedure wound infections per quarter | Aggregate number of patients for whom antibiotics were ordered and who received them within specified time frames prior to surgery to prevent infection | Performance benchmarking compared to other ASCs |
| American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) Internet-based Quality Assurance and Peer Review Reporting System | 105 multi-specialty or Medicare-certified ASCs; ^e data from 2001 to present | Patients treated in facilities accredited by AAAASF ^f | Facilities are obligated to report all infections; ^g a physician peer reviews each of these cases and extracts from the patient's medical record key information, such as type of infection, management, and outcome | Aggregate number and rate ^h of infections plus eventual resolution of infection | Antibiotics administered, wound management, length of stay if hospitalized | Overall rate of infections and modes of treatment |

| Data sources | Number of ASCs; time period | Patient population | Data collection method | Outcomes recorded | Process/practices recorded | Data analysis |
|-------------------------------------|---------------------------------------|--|---|--------------------------------------|----------------------------|--|
| Missouri State HAI Reporting System | 26 in 2006; data from 2006 to present | Patients undergoing hernia or breast surgery in Missouri ASCs that performed at least 20 of those procedures during the previous calendar year | HAIs are detected by facility staff during 30-day follow up, which may include patient exam, medical record review, or patient or physician survey ^b | Procedure-specific SSIs ^b | None | Rates of SSIs, controlling for procedure type and patient risk factors |

Sources: Interviews, documents, and contacts with agency and organization officials.

^aUntil recently, enrollment in NHSN had been limited to hospitals and outpatient hemodialysis centers. CDC officials nonetheless stated that they believed some ASCs had enrolled and entered HAI data into NHSN but they could not determine how many. NHSN includes, under the ASC category, surgical units within a hospital outpatient department. CDC has initiated a new survey of facilities enrolled in NHSN that will identify which are ASCs and distinguish between those located within hospitals and those that are freestanding. By February 2009, all enrolled facilities should have completed this survey.

^bDatabase uses standard CDC definitions.

^cAlthough central lines, which are intravenous lines inserted into a large vein typically in the neck or near the heart, are commonly used in hospitals, particularly in intensive care units, they can also be used in ASCs.

^dMaryland agreed to survey 32 ASCs, North Carolina 16, and Oklahoma 20. The ASCs surveyed were randomly selected by CMS.

^eThese numbers do not reflect the total number of facilities in the AAAASF database, which includes both ASC and office-based surgery facility data. The majority of AAAASF's accredited facilities are office-based surgical facilities that do not fall under Medicare's ASC classification.

^fIn 1992 the American Association for Accreditation of Ambulatory Plastic Surgery Facilities expanded the scope of its accrediting activities to include facilities operated by physicians from other specialties and became the AAAASF. However, facilities performing plastic surgery remain a majority of the approximately 1,200 facilities accredited by AAAASF.

^gInfections are one of the unanticipated sequelae that facilities participating in this system are obligated to report.

^hThese data are collected only on patients with identified infections. Overall infection rates are calculated by dividing the aggregate number of identified infections by the total number of procedures performed.

The five data sources do not provide nationally representative information on HAIs in ASCs. In order to provide a basis for a nationwide estimate of risks of HAIs in ASCs, a data source would need to collect its data from a nationally representative random sample. None of the five data sources does so, and therefore it is not possible to generalize from their results to the nationwide population of ASCs or patients that they treat. Consequently, each of these data sources provides information only about the facilities that actually submit data to it and cannot reliably be used to describe other facilities.¹⁶

In terms of their coverage across ASCs, each of these data sources collects information on HAIs from a relatively small proportion of the 5,100 ASCs in the United States. The coverage ranges from the 26 ASCs that most recently reported data to the state of Missouri to about 650 ASCs reporting to the Ambulatory Surgery Center Association's database. Moreover, which ASCs are included in each of the databases is determined by highly variable criteria.¹⁷ They include, depending on the database, a decision by the individual ASC to voluntarily participate, membership of the ASC in a particular professional association, and selection of an ASC based on its geographic location in a particular state. For example, all the ASCs in the ASC pilot study are from Maryland, North Carolina, or Oklahoma because those states volunteered to participate in the study, and the ASCs covered by the two professional organizations and the state source are taken from narrowly defined subsets of ASCs, that is, from member ASCs or from ASCs within a certain geographical area, respectively.

The five data sources also vary in the type and level of detail of the information they collect. NHSN, AAAASF, and Missouri's system collect data on individual patients, and the ASC pilot study and the Ambulatory Surgery Center Association's database collect data that are aggregated to the facility level. Four of the five data sources—all but the ASC pilot study—collect information on patient outcomes, specifically rates of SSIs. However, of those four, only the federal NHSN and state of Missouri databases employ standard CDC definitions to identify cases with SSIs

¹⁶An exception applies to the three states that participated in the ASC pilot. CMS officials reported that the ASCs surveyed as part of the pilot were randomly selected by CMS in each of the three states. In principle, this would make the findings from these surveys generalizable to the ASCs in each of these states, but not to ASCs in any other state.

¹⁷It is possible that some ASCs are included in more than one data source.

based on these criteria.¹⁸ The two professional association databases leave identification of SSIs to individual physician judgment. Both professional association databases also collect information on one or more process measures. One of these databases focuses on a practice intended to prevent SSIs—the routine use of antibiotics prior to surgery—and the other collects information on the treatment of SSIs. The ASC pilot study collects data solely on process measures. The most detailed data are provided by the two federal data sources, NHSN—the most widely recognized source of outcome data on HAIs—and the ASC pilot study. The pilot study collects data on a broad range of process measures assessing the implementation of infection control practices, such as those intended to prevent the transmission of infections through appropriate hand hygiene, injection, and sterilization procedures.

NHSN Collects Clinically Sophisticated and Standardized Data on HAI Outcomes in ASCs, but It Is Not Set Up to Collect Nationally Representative Data

A key feature of NHSN is that it collects clinically sophisticated and standardized data on HAI outcomes. Facilities that participate in NHSN, including ASCs, agree to collect and submit information on HAI outcomes, such as SSIs, according to defined protocols and standardized definitions. CDC developed detailed protocols for NHSN that specify the medical record and laboratory data needed to identify and categorize HAIs in accordance with CDC's standardized definitions. These protocols are widely accepted by infection control professionals because they make the data in NHSN clinically relevant and comparable across the facilities submitting data to NHSN. At the same time, the data collection procedures used by NHSN can be labor intensive and technically complex for some users. For example, one expert reported that ASCs found data submission to NHSN to be time-consuming and that an ASC might opt out of the program if its demands on staff time and other resources became excessive.

Although the number of ASCs currently submitting data to NHSN is unknown, it is likely to be small. NHSN has national open enrollment for multiple types of facilities. However, until September 2008 only hospitals

¹⁸Although the Missouri state database uses definitions based on CDC criteria, it collects its data over the Internet through a separate, state-developed system rather than NHSN.

and outpatient hemodialysis centers could enroll in NHSN.¹⁹ In September 2008, CDC launched a new release of NHSN that enabled freestanding ASCs that were separate from hospitals to enroll. Enrollment of ASCs may increase over time, especially if more states enact programs mandating public reporting of HAIs by ASCs using NHSN. According to a CDC official, CDC has a facility survey under way that will enable it to determine the number of ASCs that enroll in NHSN, but this official does not expect to have results available from this survey until spring 2009.

Nonetheless, independent of the number of ASCs that participate in NHSN, the processes by which ASCs enroll make NHSN data nonrepresentative of ASCs nationwide. Some ASCs enroll in NHSN voluntarily, and others are required to enroll by mandate of their state government. Because NHSN uses voluntary and mandatory selection procedures, the selection of ASCs for participation in NHSN is nonrandom. This lack of random selection precludes a projection of its results to any ASCs that do not participate and generalization to the national population of ASCs.

ASC Pilot Study Collected More Detailed Information on HAIs in ASCs Than CMS's Standard Survey Process Alone, but Did Not Collect Nationally Representative Data

The ASC pilot study examined the potential for using CMS's standard surveys to collect information on ASCs' implementation of specific infection control practices.²⁰ Under the pilot study, CMS modified the standard survey process by introducing two innovations—the incorporation of a CDC-developed infection control assessment tool and direct observation by the surveyor of a single patient's care from start to finish of the patient's stay. CDC officials also provided training for state surveyors on using the tool and developed plans to analyze the infection control data obtained with the tool. A CMS official told us that CMS would consider making changes to CMS's standard survey process for ASCs after reviewing planned CMS and CDC analyses of the pilot study results.

¹⁹According to CDC officials, a modest number of ASCs were enrolled in NHSN when enrollment was limited to hospitals and outpatient hemodialysis centers. These were ASCs within hospitals that had enrolled and entered HAI data into NHSN, but CDC cannot determine how many there were. The definition of ASCs that we use for this report does not include such surgical units within a hospital.

²⁰The pilot study was not solely focused on infection control, as the surveys conducted under the pilot study examined ASCs' compliance with all Medicare health and safety standards except for the life safety standards.

The surveys conducted under the pilot study collected more detailed information on practices that affect the risk of HAIs in ASCs than have previous surveys of ASCs. CMS's current survey process requires surveyors to ascertain whether an ASC's written policies and procedures address certain general topics pertaining to infection control.²¹ In doing so, surveyors assess the implementation of these policies and procedures and an ASC's overall maintenance of a sanitary environment through direct observation and interviews with ASC staff. If surveyors find that either the content of those policies and procedures or their implementation by ASC staff is insufficient to meet CMS's infection control standard, they submit a deficiency report to CMS that provides a detailed narrative describing the particular conditions or activities in the ASC that created that deficiency.²² In contrast, the pilot study's infection control assessment tool focused on specific CDC-recommended infection control practices. The tool is a 12-page document that includes dozens of specific infection control practices, involving such topics as environmental cleaning, disinfection, sterilization, and injection safety. CDC researchers who developed the tool included those practices that they had found were most critical for the prevention of HAIs in the ASC setting. CMS modified the tool to indicate when responses to the tool's questions identified a violation of the ASC health and safety standards for infection control. During the course of the pilot study, surveyors recorded on the tool itself whether or not ASC staff appropriately implemented each of those practices, based on a combination of on-site interviews and observation. For each survey in the pilot, surveyors submitted a completed tool to CMS, along with the usual statements of deficiency for those ASCs where the surveyors found inadequate compliance with the infection control or other standards. Collecting completed tools for every surveyed ASC made it possible to produce standardized quantitative data on the extent of compliance with each of the practices assessed by the tool across all ASCs surveyed for the pilot study. The tool provides detailed guidance to surveyors on how to assess the implementation of these practices. In addition, the training provided by CDC officials on how to use the tool included the principles of disease transmission to prepare the state surveyors to observe ASC

²¹These topics include methods to minimize sources and transmission of infection, including adequate surveillance techniques, sterilizing techniques for supplies and equipment, procedures for isolation, procedures for orienting new employees in infection control and personal hygiene, and aseptic techniques.

²²The ASC in turn must submit a corrective action plan that describes how it will remedy those deficiencies.

practices with a “sharp eye” for serious mistakes that could lead to the transmission of HAIs. State officials from the pilot states reported positive assessments of the pilot survey process and noted that during the pilot surveyors observed unsafe practices that they would not have detected using the current survey guidance. These practices included ASC staff using single-use medication vials for multiple patients and failing to properly sterilize equipment.

State officials reported that surveys conducted under the pilot study took additional time and staff resources, although specific amounts varied. In all three states, surveyors conducted a standard survey for a given ASC in addition to completing the infection control assessment tool and observing a patient’s care from start to finish. For the two states that had previously conducted standard surveys of ASCs, one found that implementing the pilot study’s two innovations required substantial additional staff resources, and the other found that, with practice, only a modest amount of additional resources was needed.²³

CMS and CDC officials reported that they intended to separately analyze the results of the pilot study, each agency having a different focus. Specifically, a CMS official reported that CMS would analyze the effect of the pilot study’s innovations on CMS’s ability to assess the level of compliance of ASCs in the pilot states with Medicare’s health and safety standards, including the standard pertaining to infection control. In addition, from its interviews with state officials, CMS has obtained information on what techniques were effective for using the infection control assessment tool and related CDC training. CMS’s review would identify where lapses in infection control practices were found by surveyors in the pilot states and use these data to strengthen CMS’s ASC survey guidance, which CMS is currently in the process of updating. CDC officials reported that their analysis of the pilot study would focus on deriving a baseline understanding of how safely care was being delivered in ASCs, by determining the prevalence of lapses in specific infection control practices. These officials stated that CDC would use the analysis to identify “hot spots” for infection control errors for which it could target future recommendations and trainings.

²³Officials from the remaining state’s survey agency reported that although the state had conducted standard surveys of ASCs seeking enrollment for the first time in Medicare, it had not previously resurveyed any existing ASCs due to a lack of available resources.

Neither CDC nor CMS officials have determined a timeline for the completion of their respective activities. As of October 2008, surveyors in the pilot states had finished their surveys and submitted the information they collected to CMS to be analyzed separately by CMS and CDC. Officials from both agencies estimated that their analyses of the survey results would be available in fiscal year 2009, but said they did not have any written plan or timeline for completing their analyses.

A CMS official reported that agency officials planned to consider making some changes to CMS's standard survey process for ASCs after reviewing the CMS and CDC analyses but did not intend to continue the pilot study's data collection. This official reported that CMS was considering adopting the practice of directly observing patients from start to finish that was tested in the pilot study. This official also stated that CMS was considering whether to use the infection control assessment tool simply as a prompt for surveyors in assessing compliance with its infection control standard. The official noted that the tool provided precise guidance that had previously been lacking on specific practices that surveyors should examine in assessing compliance with the infection control standard. Under the pilot study, the assessment tool allowed surveyors to record ASC compliance with specific infection control practices in a quantifiable manner. In contrast, if the tool is used as a prompt, the surveyors would report only the instances where ASCs were found to be out of compliance with the standard as a whole, giving a narrative description of the reasons why, as they currently do under the standard survey process. CMS officials told us that they did not intend to continue using the tool to collect data, as was done in the pilot study.

Even if CMS were to continue the pilot study's data collection methods, it still would not be able to use these data to make estimates about the prevalence of safe and unsafe infection control practices in ASCs nationwide. CMS's current policy for selecting ASCs to survey eschews random selection in favor of an approach that seeks to maximize the impact of limited survey resources, including targeting ASCs considered most likely to represent a greater risk for quality issues and selecting those

that have not been surveyed within a given time interval.²⁴ Specifically, in selecting ASCs for these surveys, CMS requires state survey agencies to give highest priority to ASCs that have not been surveyed in 6 years or more or that have had recent compliance problems. State survey agencies survey about half of ASCs every 3 to 4 years, but some ASCs go much longer between surveys—20 percent more than 6 years and 8 percent more than 10 years. CMS officials told us they were concerned that the level of ASC survey activity in recent years had not been sufficient to provide meaningful and current data on ASC performance across the board, including infection control issues. As a result, for fiscal year 2009 CMS increased the number of highest-priority surveys that it funded states to conduct on ASCs from 5 to 10 percent of ASCs each year. However, because this larger number of surveys does not include randomly selected ASCs, the results would still not provide information that could be generalized to ASCs nationwide.

Collecting Process Data on HAIs in ASCs Is More Feasible Than Collecting Data on Outcomes

Experts we interviewed noted that the ASC environment presented challenges to the feasibility of collecting outcome data. Some of these challenges relate to the difficulties in identifying ASC patients who develop HAIs. The experts told us that patients tend to be in outpatient facilities for a relatively short time because ASC procedures generally take little time to perform. Because HAIs are not likely to develop until after a patient leaves an ASC, the opportunity to observe patients and collect HAI data is limited. The experts also told us that the opportunity to collect HAI outcome data might be further limited because rather than returning to the ASC if a complication develops following a procedure, patients often seek follow-up care from their primary care physician, a hospital emergency department, or an urgent care center. Consequently, the ASC might never know that an HAI occurred, and so would be unable to report it.

Experts noted that a general lack of infection control professionals in ASCs presents a challenge to the feasibility of collecting either outcome or process data. According to the experts, ASCs rarely have a designated

²⁴There is, however, one group of ASCs that are selected through a generally random process. State survey agencies conduct surveys on a CMS-selected sample of accredited ASCs to validate the accrediting organizations' survey results. According to CMS officials, approximately 18 percent of Medicare-certified ASCs are accredited, which means they are inspected by the accrediting organizations rather than the state survey agencies to determine compliance with Medicare requirements. Accreditation surveys take place approximately every 2 to 3 years, depending on the accrediting organization.

infection control professional, which is a health care worker trained to lead infection control efforts in a health care facility.²⁵ CDC officials told us that, as with NHSN, data collection for HAIs has been historically designed for hospitals with the understanding that, unlike most ASCs, hospitals have infection control professionals responsible for collecting such data. The lack of such an individual presents a challenge to the feasibility of collecting either type of data, especially when such data are technically complex or the data collection processes are labor intensive. Employing an infection control professional would require ASCs to devote time and resources to an area that they have traditionally thought to be low risk.

The experts we interviewed generally agreed that collecting process data on HAIs in ASCs is more feasible and potentially more useful than collecting data on outcomes. Several experts said it was more feasible to collect data on HAIs by focusing on process measures rather than outcome measures because unsafe practices may be observed with less effort and technical training than is needed to identify individual cases of HAIs. A CMS official reported that because of the relatively short time that patients are in the facility, the ASC environment lends itself well to the methodology of tracing a patient through his or her entire experience at the ASC as a means for observing specific practices, such as those related to infection control. The experts also noted that gathering such process data could provide useful guidance to ASCs. For example, such data could point to areas for specific remedial training on preventive activities, such as training on the proper use of single-dose vials and the appropriate procedures for sterilizing equipment.

Conclusions

The increasing volume of procedures and evidence of infection control lapses in ASCs create a compelling need for current and nationally representative data on HAIs in ASCs in order to reduce their risk. Because HAIs generally only occur after a patient has left an ASC, data on the occurrence of these infections—outcome data—are difficult to collect. But data on the implementation of CDC-recommended infection control practices—process data—in ASCs can be collected more easily and can provide critical information on why HAIs are occurring and what can be done to help prevent them.

²⁵Infection control professionals identify cases of HAIs and promote infection control practices to help reduce the occurrence and spread of HAIs.

One federal data source, the ASC pilot study, has shown the potential for using process data to increase the understanding of HAIs in ASCs. The pilot study tested the addition of an infection control assessment tool to collect detailed data on recommended practices during the course of a CMS standard survey. With the tool, specially trained state surveyors were able to identify serious lapses in recommended practices. Such lapses, which increased patients' risks of developing HAIs, had not previously been detected through CMS's standard surveys. The pilot study had the added benefit of not relying on ASCs to submit HAI data themselves with their limited staff resources.

The results of the ASC pilot study demonstrate the feasibility of collecting data on the prevalence of specific infection control practices while conducting surveys of ASCs. Although detailed analyses of the data obtained during the pilot by CDC and CMS are pending, officials in the three pilot states and at CMS uniformly reported positive assessments of the process developed by CMS and CDC to collect these data during the course of standard ASC surveys by state surveyors. However, CMS has no plans to continue collecting such data following the completion of the ASC pilot surveys. If CMS and CDC do not build on their experiences with and analyses of the pilot to continue collecting such data from a subset of ASC surveys using an instrument such as the infection control assessment tool, then HHS is losing an opportunity to take advantage of the existing ASC survey process to collect information on the prevalence of infection control practices on an ongoing basis.

Collecting detailed data on the prevalence of infection control practices is only part of what is needed to increase the understanding of the problem of HAIs in ASCs nationwide. The ability of HHS to use CMS's standard survey process to collect nationally representative process data on infection control practices in ASCs and to make estimates about the prevalence of safe and unsafe infection control practices in ASCs nationwide also depends on introducing random selection for ASC surveys. The larger the number of randomly selected ASCs surveyed, the greater the precision that would be achieved for those results. For standard surveys, CMS currently selects those ASCs deemed most likely to have quality problems or that have not been surveyed within a given time interval and does not select any randomly from the national population of ASCs. However, CMS has recently expanded the number of ASC surveys that it conducts, and HHS could choose to have CMS select some ASCs randomly for standard surveys while continuing to target others. In determining the number of ASCs to be randomly selected, HHS could weigh the value of obtaining more precise information from a larger

number of randomly selected ASCs against the value of targeting surveys to those ASCs that may be more likely to have quality deficiencies. HHS could determine the number of ASCs it would need to select at random to generate meaningful national estimates to help identify where lapses in infection control practices by ASCs across the country were most likely to be putting patients at risk of contracting HAIs.

Recommendation for Executive Action

To obtain nationally representative and standardized information on the extent to which ASCs implement specific infection control practices that reduce the risk of transmitting HAIs to their patients, we recommend that the Acting Secretary of HHS develop and implement a written plan to use the data collection instrument and methodology tested in the ASC pilot study, with appropriate modifications based on the CDC and CMS analyses of that study, to conduct recurring periodic surveys of randomly selected ASCs.

Agency Comments

We provided a draft of this report to HHS for comment. In response, the Acting Administrator of CMS provided written comments, and we have reproduced these comments in appendix I. CMS also provided technical comments, which we have incorporated as appropriate.

In its written comments, CMS stated that it concurred with our recommendation to HHS. CMS stated that it would use the results from the pilot study to evaluate the value and feasibility of incorporating the infection control assessment tool into the standard ASC survey process. The agency stated that if its evaluation resulted in a decision to use the infection control survey tool on an ongoing basis, then it would explore with CDC whether CDC would be able to continue to provide training and data analysis of the completed infection control assessment tools, as CDC did for the pilot study. Given such support from CDC, CMS stated that it would be willing to establish a process for randomly selecting at least some ASCs in each state for ASC surveys. We agree that implementing our recommendation requires analysis of the pilot study to determine appropriate modifications to the data collection tool and collaboration within HHS. However, given the risks of HAIs in ASCs and the compelling need for current and nationally representative data on them, it is important that the department follow our recommendation to develop and implement a written plan to ensure that it collects such data using recurring periodic surveys of randomly selected ASCs.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Acting Secretary of HHS and other interested parties. The report also will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or bascettac@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.



Cynthia A. Bascetta
Director, Health Care

List of Congressional Requesters

The Honorable Henry Waxman
Chairman
Committee on Energy and Commerce
House of Representatives

The Honorable Frank Pallone, Jr.
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Shelley Berkley
House of Representatives

Appendix I: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JAN 26 2009

Cynthia A. Bascetta
Director, Health Care
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Ms. Bascetta:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "HEALTH-CARE-ASSOCIATED INFECTIONS: HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers (GAO-09-213).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

Appendix I: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

JAN 26 2009

DATE:

TO: Barbara Pisaro Clark
Acting Assistant Secretary for Legislation
Office of the Secretary

FROM: Charlene Frizzera
Acting Administrator

A handwritten signature in black ink that reads "Charlene Frizzera".

SUBJECT: Government Accountability Office (GAO) Draft Report: "Health-Care-Associated Infections: HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers" (GAO-09-213)

Thank you for the opportunity to comment on the subject GAO draft report. The purpose of the report was to examine the availability of data on health-care-associated infections (HAIs) in ambulatory surgical centers (ASCs) nationwide. The report notes that recent high-profile cases of HAIs in ASCs due to lapses in recommended infection control practices may indicate a more widespread problem in ASCs, but that the prevalence of such lapses is unknown.

The Centers for Medicare & Medicaid Services (CMS) recognizes that the ASC segment of the health care delivery system has been growing very rapidly and now represents a significant portion of the surgical services provided to Medicare beneficiaries and other patients. We also have been concerned about strengthening the Medicare Conditions for Coverage for ASCs, which establish health and safety standards for these entities, in order to better assure the quality of ASC services.

On November 18, 2008, we adopted comprehensive revisions to these standards, including introducing more stringent requirements in the area of infection control (73 Fed. Reg. 68502, 68813, November 18, 2008). These rule changes will take effect on May 18, 2009. At the same time as we revised the ASC requirements, we also have sought to strengthen our oversight of ASC compliance with Medicare's standards. Unfortunately, due to resource limitations and competing statutorily mandated survey priorities, we have not been able to fund periodic routine resurveys of ASCs by State Survey Agencies as frequently as we would like, with the result that enforcement of ASC conditions for coverage is largely complaint driven. For fiscal year 2009, however, CMS doubled the minimum percentage of annual resurveys the States are expected to complete, from 5 percent of all Medicare-certified ASCs to 10 percent. Additionally, in the aftermath of the Nevada HAI case referenced in the report and our subsequent determination that there were widespread compliance problems in ASCs throughout the State, we concluded that

Page 2 – Cynthia A. Bascetta

more information on the prevalence of compliance problems in Medicare-certified ASCs was required in order to further refine our ASC oversight policy.

On very short notice, the State Survey Agencies in Maryland, North Carolina, and Oklahoma volunteered to participate in a pilot program under which they agreed to survey a significant number of the ASCs in their State within a compressed timeframe. CMS made available funds to cover these additional surveys in the three States. The Centers for Disease Control and Prevention (CDC) also volunteered, again on short notice, to refine the infection control surveyor tool it had pioneered in Nevada for use in the pilot and provided training to the pilot State surveyors on the use of the tool. CMS and CDC also entered into an agreement whereby copies of the tools completed for each pilot survey would be furnished to CDC for data entry and analysis. Although the evaluation of the pilot study is still underway, we have already found the experience of this pilot to be very instructive. We appreciate the GAO's recognition of the valuable information that is being developed through this pilot.

The GAO report makes one recommendation for the Department of Health and Human Services (HHS) consideration. This recommendation and our response to it are discussed below.

GAO Recommendation

To obtain nationally representative and standardized information on the extent to which ASCs implement specific infection control practices that reduce the risk of transmitting HAIs to their patients, HHS should develop and implement a written plan to use the data collection instruments and methodology tested in the ASC pilot study, with appropriate modifications based on the CDC and CMS analyses of that study, to conduct recurring periodic surveys of randomly selected ASCs.

CMS Response

We concur. CMS will use the results of the pilot study to evaluate the value and feasibility, given the increased costs associated with them, of incorporating the instrument and methodologies employed in the pilot into the standard ASC survey process. If that evaluation results in a decision to use the infection control survey tool on an ongoing basis, CMS will explore with CDC whether CDC has the interest and resources to continue its coding, data entry, and analysis of completed infection control survey tools on an ongoing basis, as well as to provide training at regular intervals to surveyors in the use of the tool. In the event that CDC is able to continue this work, then CMS would be willing to establish within the annual ASC resurvey target for each State Survey Agency a component for a random sample of ASCs within each State. The exact size of the component sample remains to be determined.

We thank the GAO staff for their work in this important area of Federal health care oversight.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Cynthia A. Bascetta at (202) 512-7114 or bascettac@gao.gov

Acknowledgments

In addition to the contact named above, key contributors to this report were William Simerl, Assistant Director; Jennel Harvey; Eric Peterson; Roseanne Price; and Andrea E. Richardson.

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