

National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination

CHAPTER 5. AMBULATORY SURGICAL CENTERS

I. Introduction

In response to increasing concerns about the public health impact of healthcare-associated infections (HAIs), the U.S. Department of Health & Human Services (HHS) developed an Action Plan to Prevent Healthcare-Associated Infections (Action Plan).¹ The initial Action Plan, released in January 2009, focused on a first phase of six high priority HAI-related areas within the acute care hospital setting. These areas include surgical site infection, central-line associated bloodstream infection, ventilator-associated pneumonia, catheter-associated urinary tract infection, *Clostridium difficile* infection, and methicillin-resistant *Staphylococcus aureus* infection. The Action Plan utilized subject matter experts to identify key actions in HAI prevention in hospitals, and included recommendations for surveillance, research, communication, and metrics for measuring progress towards national goals.

While the initial focus of the Action Plan was on acute care, inpatient settings, the HHS Steering Committee for the Prevention of Healthcare-Associated Infection acknowledged the need for addressing HAI prevention across the healthcare continuum, including outpatient settings. As part of Phase II of the Action Plan, ambulatory surgical centers (ASCs) and end-stage renal disease facilities were selected as focus areas. The following document represents a culmination of many months of deliberation by subject matter experts across HHS – with input from key stakeholders – that summarizes HAI prevention issues specific to ASCs and present key actions needed to assure safe care in these settings.

II. Background

Healthcare-associated infections are a leading cause of death in the United States, and can cause needless suffering and expense. At any given time, about one in every 20 patients has an infection related to their hospital care. One setting which has demonstrated tremendous growth both in the volume and complexity of procedures being performed is ASCs. Ambulatory surgical centers are defined by the Centers for Medicare & Medicaid Services (CMS) as distinct entities that operate exclusively to provide surgical services to patients who do not require hospitalization and are not expected to need to stay in a surgical facility longer than 24 hours (42 C.F.R. §416.2).² Many of the services performed in these facilities extend beyond procedures traditionally thought of as

¹ Department of Health and Human Services. HHS Action Plan to Prevent Healthcare-Associated Infections. Available at: <http://www.hhs.gov/ophs/initiatives/hai/draft-hai-plan-01062009.pdf>. Accessed June 27, 2010.

² Medicare program: changes to the ambulatory surgical center payment system and CY 2009 payment rates: final rule [November 18, 2008]. Federal Register, 73(223):68714. <http://edocket.access.gpo.gov/2008/pdf/E8-26212.pdf>. Accessed May 10, 2010.

surgery, including endoscopy, and injections to treat chronic pain.³ Currently, there are over 5,300 Medicare-certified ASCs in the U.S., which represents a greater than 54% increase since 2001. In 2007 more than six million surgeries were performed in these facilities and paid for by Medicare at a cost of nearly \$3 billion.^{4,5}

Oversight of Medicare-certified ASCs

Oversight of Medicare-certified ASCs to assure compliance with the Conditions for Coverage (CfCs), which include minimum health and safety standards, falls to the State Survey Agencies (SSAs) or any of the four accrediting organizations (AOs) that have approved Medicare accreditation programs.^{3,6} These are Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities, American Osteopathic Association, and The Joint Commission. Ambulatory surgical centers that are accredited by an AO are exempt from routine surveys conducted by SSAs. However, a notable exception to this rule is the surveys conducted by the SSA in response to a complaint. Similarly, a relatively small number of validation surveys are conducted by SSAs to verify the equivalency of the AO's survey process to that of CMS and the SSA. Currently, approximately 25% of Medicare-certified ASCs have relied upon an accrediting organization for their certification.

Data on HAI Risks in ASCs is Lacking

National estimates regarding the number of HAIs originating in ASCs are not available and little is known about infection control and prevention practices in these settings. Current data related to surgical site infections (SSIs) and other HAIs come primarily from hospitals, which have an established infrastructure with personnel dedicated to infection control and prevention and HAI surveillance. This infrastructure is largely absent in ASCs. Much of what is known about adverse events and HAIs in these settings is based on outbreak investigations conducted by State Health Departments and the Centers for Disease Control and Prevention (CDC). Recent steps to better assess and summarize infection control and prevention practices in ASCs occurred in the context of an enhanced inspection pilot activity that was led by CMS and supported by CDC. In 2008, SSAs in each of three states (Maryland, North Carolina, and Oklahoma) incorporated an infection control audit tool, based upon CDC guidelines (e.g., Standard Precautions),⁷ into their routine ASC survey process. Over two-thirds of the facilities surveyed in the pilot had lapses in infection control and prevention

³ Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan. https://www.cms.gov/ASCPayment/Downloads/C_ASC_RTC%202011.pdf. Accessed October 26, 2011.

⁴ US Government Accountability Office. Healthcare-associated infections: HHS action needed to obtain nationally representative data on risk in ambulatory surgical centers [GAO-09-213, February 25, 2009]. Available at: http://nueterrahealthcare.com/building_partnerships/documents/GAOHAIreport02-09.pdf. Accessed May 10, 2010.

⁵ A data book: healthcare spending and the Medicare program [June 2009]. Medicare Payment Advisory Commission. Available at: <http://www.medpac.gov/chapters/Jun10DataBookSec8.pdf>. Accessed May 10, 2010.

⁶ Medicare program: changes to the ambulatory surgical center payment system and CY 2009 payment rates: final rule [November 18, 2008]. Federal Register, 73(223):68714. <http://edocket.access.gpo.gov/2008/pdf/E8-26212.pdf>. Accessed May 10, 2010.

⁷ Centers for Disease Control and Prevention. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings. Available at: <http://www.cdc.gov/hicpac/2007IP/2007IsolationPrecautions.html>. Accessed October 21, 2009.

identified by surveyors and half of the facilities had not undergone a full inspection in more than five years.⁸

A February 2009 report from the Government Accountability Office (GAO) highlighted the lack of information related to health outcomes and process measures in ASCs⁹:

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.

In the report, GAO further recommended the utilization of existing regulatory infrastructure, such as the inspections performed in the 2008 CMS pilot, to collect data on infection control practices in ASCs to help describe current practices and target infection control prevention strategies.

This report is an update on progress made, remaining gaps, and recommendations for next steps related to reducing the risks of HAI transmission in ASCs. Although similar surgical procedures are performed in physician offices and hospital-based surgery centers, this report focuses on Medicare-certified ASCs of which assessment and enforcement of CMS standards falls primarily to SSAs and AOs.

III. Progress Made

ASC Conditions for Coverage Expanded to Include Infection Control and Prevention

CMS revised the ASC CfCs and the interpretive guidelines and survey procedures, which became effective in 2009.¹⁰ Previously, the survey methodology, set out in Appendix L of the State Operations Manual, had not been updated in at least ten years.¹¹ In 2008, CMS revised the CfCs for ASCs to specifically address the need for infection control and prevention programs (set out at 42 C.F.R. § 416.51), including the following requirements:

⁸ Schaefer MK, Jhung M, Dahl M, et al. Infection Control Assessment of Ambulatory Surgical Centers. *JAMA* 2010; 303(22):2273-2279.

⁹ US Government Accountability Office. Healthcare-associated infections: HHS action needed to obtain nationally representative data on risk in ambulatory surgical centers [GAO-09-213, February 25, 2009]. Available at: http://nueterrahealthcare.com/building_partnerships/documents/GAOHAIreport02-09.pdf. Accessed May 10, 2010.

¹⁰ Medicare program: changes to the ambulatory surgical center payment system and CY 2009 payment rates: final rule 73 Fed. Reg. 68502, 68813 [November 18, 2008]. <http://edocket.access.gpo.gov/2008/pdf/E8-26212.pdf>. Accessed May 10, 2010.

¹¹ Centers for Medicare & Medicaid Services. State operations manual (SOM) appendix L, ambulatory surgical centers (ASC) comprehensive revision. Available at: http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf. Accessed April 30, 2010.

- The ASC must maintain an infection control and prevention program based upon nationally recognized infection control and prevention guidelines;
- The infection control and prevention program must be under the direction of a designated healthcare professional with training in infection control and prevention;
- The infection control and prevention program must be integrated into the ASC's Quality Assessment and Performance Improvement Program; and,
- The ASC must prevent, identify, and manage HAIs through its infection control and prevention program.

Improved Inspection Frequency and Methodology

As noted above, historically, surveys of ASCs have been infrequent (the median interval between inspections has been more than five years) and surveyors did not formally assess infection control and prevention practices as part of the inspection process. However, in response to a 2008 outbreak of hepatitis C virus infections at a Nevada ASC, national attention quickly focused on ASCs and triggered questions related to their performance, safety and oversight.^{12,13} CDC tools used in outbreak investigation were further adapted to develop a checklist for assessing infection control and prevention practices in ASCs. CMS, with support from CDC, endeavored to strengthen and expand the infection control and prevention component of the survey to include direct observation of healthcare personnel practices using the CDC checklist. As a result, there has been a notable increase in overall awareness of the needs for infection control and prevention activities in ASCs, where SSAs and AOs are primarily responsible for assessment and enforcement of CMS standards. There has also been increased emphasis on the process measures necessary to measure compliance and to examine findings and patterns across surveys. This has been a critical first step toward the goals of valid and reliable surveillance systems and patient-centered outcome measures related to decreasing HAI risks among ASC patients.

In 2009, American Recovery and Reinvestment Act (ARRA) funding supported a 120% increase in the number of non-accredited ASC surveys conducted by SSAs, enabling surveys of one-third of all such ASCs. (Accredited ASCs are not included in the intensified survey schedule since they are inspected by their respective AO, which is required to survey the ASC at least every three years.) Simultaneously, the survey process was modified by CMS. A case tracer methodology was incorporated into the overall survey process to facilitate a more complete evaluation of an individual patient's experience while under the care of an ASC. By following a patient through his or her ASC admission, the CMS surveyor is able to more accurately determine how well the actual provision of care and services are aligned with the CfCs. In addition, a modified version of the infection control worksheet (ICWS) that was developed for use

¹² Centers for Disease Control and Prevention. Acute hepatitis C virus infections attributed to unsafe injection practices at an endoscopy clinic: Nevada, 2007. *Morbidity and Mortality Weekly Report (MMWR)* 2008; 57(19):513-517.

¹³ Schaefer MK, Jhung M, Dahl M, et al. Infection Control Assessment of Ambulatory Surgical Centers. *JAMA* 2010; 303(22):2273-2279.

in the 2008 three state pilot activity has been adopted for routine use in the survey process. The current version of the ICWS was released in May 2009 for national implementation during all SSA surveys, beginning October 1, 2009.¹⁴ Use of the tool was also required by CMS of the four AOs that accredit ASCs.

The ICWS is divided into two sections:

Section one, ASC Characteristics – This section captures descriptive information about the type of ASC, its scopes of services, the organization of its infection control and prevention program and any training it provides. The use of nationally recognized standards and/or guidelines, surveillance methods used by the ASC, and qualifications of the healthcare professional responsible for the infection control and prevention program are included in section one.

Section two, Infection Control and Prevention Practices Assessment – This section is based upon evidence-based recommendations and standards from CDC and other nationally recognized guidelines. Here, the focus is on specific practices in five areas of infection control and prevention that are critical elements for a successful infection control and prevention program and assuring safe care. These are: hand hygiene and use of personal protective equipment, injection safety and medication handling, equipment reprocessing (e.g., sterilization and high-level disinfection), environmental cleaning, and handling of point-of-care devices, specifically use of blood glucose monitoring equipment.

In FY 2010, after the implementation of the case tracer methodology and the ICWS in one third of non-deemed ASCs, there was an almost fourfold increase (61%) in the percentage of ASCs surveyed that were found to have infection control and prevention deficiencies. Further, 21% of ASCs surveyed were found to have condition-level (i.e. very serious) infection control deficiencies. Each facility cited for noncompliance at the condition level is not only required to submit a corrective plan of action, but also receives a follow-up visit by the SSA to assure that compliance has been achieved. In FY 2011 the preliminary results indicate that fewer infection control deficiencies were found, and that fewer of those rose to the condition level. Based on the preliminary data, 51% of ASCs surveyed had an infection control deficiency, and 11% were at the condition-level. Since the same survey methodology was used by the SAs in both FY 2010 and FY 2011, it is possible that the FY 2011 results reflect increased awareness by the ASC industry of infection control requirements and standard practices.

The first national database of ASC infection control and prevention practices captured on the ICWS is in development with new data being submitted by the SSAs regularly.

¹⁴ Centers for Medicare & Medicaid Services. State operations manual (SOM) appendix L, ambulatory surgical centers (ASC) comprehensive revision. Available at: http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf. Accessed April 30, 2010.

Analysis of this data is expected to begin in late 2011 and findings will be disseminated to help further target infection prevention and educational needs in ASCs.

Education and Training

Another important achievement has been the increase in both the number and types of resources available to support HAI prevention initiatives in ASCs. Joint efforts between HHS Operating Divisions, professional associations and consumer advocates have resulted in closer scrutiny of key infection related issues such as injection safety, blood glucose monitoring and sterilization and disinfection practices.

In October 2009, after a ten year lapse, CMS hosted a two-and-a-half day training program for ASC surveyors, an event attended by over 200 participants, supported by CDC staff, and made available through electronic media to surveyors that were unable to attend in person. Surveyors and SSA personnel currently have expanded access to experts in infection control and prevention, including CMS Regional Medical Officers, other CMS personnel with infection control and prevention expertise, and CDC officials. Further, CMS, with input from CDC, is developing a web-based training course for ASC surveyors that will include modules addressing assessment of infection prevention practices in ASCs. In addition, CDC has led development of educational videos (e.g., hand hygiene, safe injection practices) and other materials for training of front-line healthcare personnel, including, a new web-based Continuing Medical Education (CME) course available at no-cost on Medscape. The Agency for Healthcare Research and Quality (AHRQ) has initiated a “Questions Are the Answer” campaign to encourage patients to ask questions about their healthcare. In 2011, HHS launched a national media campaign to raise consumer awareness about HAIs.

The impetus for improvement and collaboration has extended beyond HHS as well. Increasingly, other federal departments, such as Department of Veterans Affairs and Department of Defense are involved. Professional organizations, such as the Association for Professionals in Infection Control and Epidemiology (APIC) and the Association of periOperative Registered Nurses, have developed education programs and conference content designed to address HAI prevention needs within ASCs. In August 2011, CMS sponsored the attendance of, in total, 130 state surveyors, Regional Office surveyors, and Regional Chief Medical Officers at the two-day APIC training “Infection Prevention for ASCs: Meeting CMS Conditions for Coverage.” Private providers of continuing education have followed the lead of the associations and are beginning to promote their own web-based programs. In addition, the ASC Quality Collaboration has developed and posted several toolkits for infection control and prevention.

Interagency Collaboration

Across HHS, information exchange, consultation, and collaboration between the Operating Divisions, including CMS, CDC, AHRQ, the Indian Health Service, and the Food and Drug Administration, in the area of HAI prevention among ASC patients has

increased substantially since the release of the Action Plan in January 2009. In 2009, CMS and CDC entered into an interagency agreement to enhance CMS expertise and capacity to provide oversight of infection control and prevention activities within Medicare-certified institutional providers and suppliers of healthcare services, with an initial focus on ASCs. CDC provided funding for CMS to create a new position for an infection preventionist to assist with this work. AHRQ has also identified ambulatory care as a high-priority area for HAI prevention and surveillance research, as demonstrated by recent funding initiatives.¹⁵

IV. Remaining Needs and Prevention Opportunities

Unmet needs pertaining to HAI prevention in ASCs fall into three main categories:

1. The need for proactive HAI Prevention at the clinic level;
2. The need to sustain and expand improvements in oversight and monitoring; and,
3. The need to develop meaningful HAI surveillance and reporting procedures.

Need for Proactive HAI Prevention at the Clinic Level

While significant progress has been made toward improving oversight in ASCs, ultimately, accountability for HAI prevention and safe care rests with the ASC itself. The new infection control and prevention requirements set forth by CMS in the updated CfCs will help assure that ASCs develop infection control and prevention policies based upon nationally-recognized guidelines and that those policies are under the direction of someone with training in infection control and prevention. However those updates, alone, will not be sufficient. ASCs need to proactively embrace a culture of safety and make allocation of resources and education of personnel for HAI risk reduction a priority, without the threat of an impending survey or citation from CMS. Understanding where and in what ways risks and hazards associated with infections are embedded in the process and structure of care within ASCs is vital to the development of safe practices for HAI prevention. Once the risks and hazards are understood and modeled, using such techniques as Socio-Technical Probabilistic Risk Assessment (ST-PRA), new safe practices can be developed using a risk-informed design approach. One such practice has already been developed and tested in the inpatient setting. The Comprehensive Unit-based Safety Program, which was developed for use in hospital settings, provides one possible model that can be modified and applied to the ASC setting.¹⁶

¹⁵ AHRQ's 2009 Funded Projects to Prevent Health Care-Associated Infections. Available at: <http://www.ahrq.gov/qual/haify09.htm>. Accessed June 27, 2010.

¹⁶ Pronovost PJ, Berenholtz SM, Goeschel CA, et al. Creating High Reliability in Health Care Organizations. *Health Services Research* 2006;41:1599-1617.

Based on the number of ASCs that have been issued infection control and prevention citations by state surveyors since the new survey process and ICWS were implemented, clearly there are educational needs that are still not being met. The survey process is not designed to address these education gaps. Additional educational resources and training opportunities are needed to assist facilities with development of infection control and prevention policies and plans of correction when lapses are identified as well as to support ongoing training of personnel.

Need to Sustain and Expand Improvements in Oversight and Monitoring

Despite recent improvements to the survey process, including increased attention to infection control and prevention and a commitment by CMS to inspect one-quarter of all CMS-certified ASCs nationwide during each fiscal year after FY 2010, surveys are still infrequent and only represent information from a single snapshot in time.

Need to Develop Meaningful HAI Surveillance and Reporting Procedures

The progress previously described related to updates in the CfCs and improvements in the survey process focus primarily on process measures. While process measures are critically important to assuring safe care and these updates by CMS were much needed, surveillance of patient outcomes following procedures in ASCs and other outpatient settings remains challenging. The advantages and disadvantages of some of the currently available options for HAI surveillance in ASCs are summarized in Table 9. Currently, there is no national data source describing HAIs that originate in ASCs. Thus, there is no standardized mechanism in ASCs to tie compliance with process measures to improved outcomes or reductions in HAIs.

Post-discharge surveillance remains an area where additional guidance is needed. Currently, there is a great deal of heterogeneity and a lack of standardization of post-discharge HAI surveillance data in ASCs. This exists for a number of reasons. First, given the diversity of procedures performed in ASCs, many of which extend beyond what is traditionally considered surgery, guidance is lacking as to which procedures should be prioritized for surveillance activities. Moreover, there are no standardized surveillance definitions for many of the higher volume procedures performed in ASCs.

There is no “one size fits all” HAI surveillance solution for ASCs. For example, many ASCs perform only endoscopy, for which SSI definitions are not applicable. Other ASCs specialize in orthopedic and/or general surgical procedures; existing SSI definitions exist for some of these procedures, but research is needed to understand how definitions and surveillance protocols that have been developed for use in hospital settings can be translated for the ASC environment. State Health Departments and CDC continue to investigate outbreaks at ASCs and track infections across the spectrum of healthcare settings, including sentinel surveillance for viral hepatitis. CDC’s National Healthcare Safety Network (NHSN), which is currently used by facilities in all 50 states to collect HAI data, including 13 states that require reporting of data on SSIs, is primarily targeted toward procedures performed in acute care

hospitals. Colorado¹⁷, Massachusetts, Nevada, and New Hampshire, have state mandates for SSI reporting in ASCs; the aforementioned states are using NHSN to report SSIs in ASCs. Evaluation of these states' experiences will be needed to determine how the system might be tailored to better fit the needs of outpatient settings.

An additional challenge to effective routine HAI surveillance for ASCs pertains to the difficulty in tracking patients after they are discharged. They present to the ASC for the procedure itself but typically do not return to the ASC for routine post-operative care or if there are complications with the procedures. Instead, they may present to an area hospital or their personal physician for evaluation and treatment. These visits are not necessarily reported back to the ASC and, in some cases, patients may not be given sufficient education regarding where and to whom adverse events (e.g., development of infection, hospitalization, bleeding) following their procedure should be reported. ASCs have employed a variety of methods to track infections in patients following procedures including direct follow-up with patients and/or their surgeons. However, experience with these methods has been marked by poor response rates from both patients and providers, significant variability in terms of how long after surgery follow-up occurs, and low sensitivity (Table 9).

Several efforts are currently underway that are aimed at overcoming the lack of standardized or validated methods to identify SSIs resulting from procedures performed at ASCs, but which are diagnosed in hospitals or other healthcare settings. AHRQ is funding work that will use all-payer administrative data from AHRQ's Healthcare Cost and Utilization Project (HCUP) to develop quality indicator specifications for HAIs originating in surgical care settings. This work is being conducted in collaboration with CMS. In a related AHRQ-funded project, these specifications will be tailored for use in identifying SSIs that originate in the ASCs. This effort will involve: enhancements to HCUP data to facilitate linkage of patients across time and setting in the HCUP database; development of a pilot national ambulatory surgery database; and estimation of HAI prevalence and incidence in ambulatory surgery settings. CDC is funding a Prevention Epicenters Program study that is examining SSIs following ambulatory surgery. One group of investigators is using automated data from a managed care organization to focus on the CMS Hospital Outpatient Quality Reporting Program and additional high volume procedures. The second group is using the HCUP state ambulatory surgery databases to focus on spine procedures. The project's goal is to provide a descriptive epidemiology of select ambulatory procedures resulting in SSIs that require a subsequent ambulatory procedure or an acute care hospitalization for treatment within 60 days of the index procedure and to assess the usefulness of coding and ambulatory pharmacy dispensing data in identifying SSIs.

¹⁷ State of Colorado Status Report on the Health Facility Acquired Infections Disclosure Initiative. Available at <http://www.cdphe.state.co.us/hf/PatientSafety/2010%20Annual%20HAI%20Report%20Final%201.19.10.pdf>. Accessed October 12, 2011.

V. Next Steps: Collaborations for Shared Solutions

The remaining needs surrounding HAI prevention in ASCs, as outlined in the previous section, serve as an opportunity for HHS to set forth a proposed series of next steps, priority areas, and actions, as follows.

1. Engage Stakeholders to Facilitate Collaboration and Promote a Culture of Safety

In September 2010, HHS hosted a meeting of stakeholders including professional organizations, consumer groups, trade associations, accrediting organizations, and government partners to discuss this module and help further prioritize next steps for HAI prevention in ASCs. Further, in October 2010 CDC in conjunction with Office of the Assistant Secretary for Health (OASH) in the HHS Office of the Secretary (OS) hosted a HAI Recovery Act Grantee Meeting bringing together HAI Coordinators from all 50 states to define next steps related to state HAI activities funded through ARRA. As part of this meeting, work related to HAI elimination in ASCs was presented and representatives from communicable disease, regulatory and quality improvement organizations came together to discuss how these groups can better collaborate to promote uptake of best practices and assist in the development of stronger infection control and prevention infrastructure in ASCs. In March 2011, a stakeholder meeting was convened by HHS including accrediting organizations, professional organizations, and various federal agencies. The purpose of the meeting was to continue to build a multi-sectoral collaborative and provide a communication structure to: implement guidance included in the ASC section of the draft “HHS Action Plan to Prevent Healthcare-Associated Infections” and plan and coordinate efforts to enhance infection control and prevention related education, communication, and outreach activities. Likewise, the ASC Association hosted a follow-up meeting in May 2011 to continue the dialogue with an expanded set of partners.

Additional areas that have been identified as priorities for stakeholder collaboration and engagement include:

- Working with AOs to identify best practices to promote HAI prevention initiatives; measure benefits of accreditation in terms of HAI risk reduction; and assure timely and appropriate communication with SSAs, State Health Department officials, and CMS regarding ICWS and related inspection findings;
- Working with CMS Quality Improvement Organizations, State HAI Programs, State Hospital Associations, AOs, and other stakeholders to develop and promote a patient-centered Culture of Safety in the ASC setting;
- Using the AHRQ Medical Office Survey on Patient Safety Culture to obtain baseline cultural assessments by working with stakeholders to specifically adapt the survey for ASCs and developing a related ASC Patients’ Perspectives of Care Survey.

- Promoting development and uptake of safe work practices, optimized infection control and prevention procedures and engineering controls to prevent transmission of HAIs in the ASC environment;
- Working with CDC and the public health system to specifically address ASCs within the State Action Plans to Prevent HAIs; and,
- Identifying additional strategies to involve consumers and others on an ongoing basis, including discussions regarding how patients can be better educated and empowered about identification and reporting of adverse events resulting from outpatient procedures.

Collaboration and ongoing engagement with stakeholders will be needed to successfully implement the activities and goals that are outlined in the sections that follow.

2. Identify Needs and Opportunities for HAI Reduction through Improvements in the Process of Care within ASCs

Reviews of infection control and prevention deficiencies identified through inspections and other assessments or consultations have the potential to identify needs and opportunities to reduce the risk of infection within ASCs. For example, CDC and other stakeholders have promoted access to the services of infection prevention specialists to perform on-site assessments aimed at optimizing infection control and prevention procedures. Similarly, AHRQ is currently funding a risk assessment approach to SSI prevention in the ASC setting using ST-PRA to prepare models of risks and hazards associated with HAIs. From these risk models, new safe practices might be developed through a risk-informed design process. Coupling these efforts with healthcare safety and human factors specialists from the engineering field may lead to innovative and scalable process of care, device, or facility design improvements.

3. Disseminate Evidence-Based Guidelines and Training for Infection Control and Prevention in Ambulatory Surgery Centers

As described above (Section III), the CfCs for ASCs now include a requirement that each facility's infection control and prevention program must be under the direction of a designated healthcare professional with training in infection control and prevention. This represents a significant step toward meeting the goal of having infection control and prevention expertise and prevention activities that are tailored to the specific needs of individual facilities.

The ASC ICWS and CfCs are in many respects founded on Standard Precautions, yet understanding and uptake of these guidelines and underlying principles in ASCs currently appear to be lacking. In 2011, CDC developed and released a Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care along with an infection prevention checklist, <http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html>

summarizing infection control and prevention recommendations for ambulatory care settings including ASCs. These documents will help educate healthcare providers and communicate expectations for infection control and prevention in a convenient and practical format. In addition, CDC and the Safe Injection Practices Coalition are leading the “One and Only Campaign” to promote safe injection practices and basic infection control and prevention with a focus on ambulatory care settings; CDC-funded injection safety activities are currently underway in a growing number of states.

Several states are providing regional training opportunities to meet the educational needs of healthcare professionals working in ASCs. HHS Region II, representing more than 450 ASCs in New York, New Jersey and Puerto Rico, used supplemental HAI funding from OS/OASH to conduct infection control and prevention training targeted to providers in ASCs and engaged various professional organizations to promote enrollment in these activities. HHS funding also supported further development and packaging of these materials for wider distribution, including for Spanish speaking populations, and an evaluation of their usability with direction from CDC and other HHS partners. Also in 2011, the Office of Healthcare Quality sponsored a promotion package, <http://www.hhs.gov/ash/initiatives/hai/resources/index.html> to more widely disseminate materials from the Region II HAI ASC Training Workshop, which will provide opportunity for free CME credits. In addition, states including New York, New Jersey, Nevada, and North Carolina are instituting specific training and oversight requirements related to infection control and prevention for settings such as ASCs where invasive procedures are performed and/or sedation is administered.

4. Improve and Expand Process Measures

Infection control and prevention process measures as described in the ICWS represent basic expectations for ASC personnel. Individual ASCs are encouraged to conduct their own reviews to assure ongoing compliance, determine additional practices for which process measurement and internal auditing may be warranted, and to identify other areas for improvement. An expanded conception of process measurement and quality improvement is warranted, as illustrated by the following examples.

The CMS Surgical Care Improvement Project (SCIP) is a national quality partnership of stakeholders committed to improving surgical care by reducing surgical complications. SCIP measures have primarily targeted improvement measures in hospital settings. Given that many similar procedures are being performed on an outpatient basis, measure development should focus on specific procedures for application across setting types. Currently, SCIP-Inf-1 and SCIP-Inf-2 are measures included in the Hospital Inpatient Quality Reporting Program.

In addition, there are six National Quality Forum-endorsed measures adopted by the ASC Quality Collaboration including: patient burn; prophylactic intravenous antibiotic timing; patient fall in the ASC; wrong site, side, patient, procedure, or implant; hospital transfer/admission; and appropriate surgical site hair removal.¹⁸ Additional measures that address HAI prevention in ASCs beyond SSIs are needed along with further evaluation and stakeholder input. For example, equipment reprocessing including high-level disinfection and sterilization, with a particular emphasis on endoscope reprocessing deserves specific attention. Other areas that would benefit from quality/process measure development include provider and patient education, safety culture, and prevention activities.

5. Expand Current Knowledge of Surveillance to Include ASC-Specific Measures and Associated Strategies for Outcomes Measurement

Further research is needed to help inform how HAI surveillance can most effectively and efficiently be conducted in ASCs and, as importantly, which procedures should receive the highest priority for tracking of infectious complications. There are several activities needed to explore surveillance options in ASCs, some of which are currently underway:

- Establish robust estimates of the numbers and types of procedures that are currently being conducted in support of identifying prevention needs, surveillance priorities, and benchmarks for higher volume, higher risk procedures;
- Continue and expand research into SSI and other HAI surveillance methodologies for ASCs, with an emphasis on electronic data mining across hospital and outpatient settings and clinical validation procedures;
- Include ASCs in local, state, and national efforts to promote adoption of electronic health records and explore other information technology options to support enhanced, consistent HAI-related process/outcome data collection and reporting; and,
- Identify options for improving State Health Department capacity for outbreak detection and reporting, including development of systems to identify clusters of ASC patients requiring hospital admission for HAI-related complications and establishing protocols and other requirements for reporting and investigation of potential bloodborne pathogen transmission among ASC patients.

6. Measurable Goals

¹⁸ ASC Quality Measures: Implementation Guide. Available at: <http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf>. Accessed June 27, 2010.

Based upon feedback received during the September 2010 stakeholder meeting and from public comments, HHS proposes the following HAI Prevention Goals for ASCs.

i. Currently, all CMS-certified ASCs are expected to demonstrate 100% adherence to all measures contained within the ICWS used by surveyors during the inspection process. Facilities, including office-based practices and other settings not subject to routine inspections, are encouraged to conduct regular self-audits to assure ongoing compliance. The worksheet is available on-line at: http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf

ii. By December 31, 2013, HHS, with stakeholder input, will perform the following:

- a) Identify existing quality measures (e.g., serious reportable events, SCIP measures) that have been endorsed and are applicable to ASCs;
- b) Identify areas where additional quality measures are needed for ASCs; and;
- c) Establish a timeline and methods for adoption and implementation of select measures within ASCs.

iii. Currently, all certified ASCs are expected, as part of the CMS CfCs, to have a system in place to actively identify infections that may have been related to procedures performed in the ASC. To support a consistent approach to HAI surveillance in ASCs, by December 31, 2013, HHS, with stakeholder input, will perform the following:

- a) Identify a set of ASC procedures for which SSI definitions and methods should be developed; and,
- b) Establish a multi-year plan and phased approach to support their routine surveillance.

7. Broad Financial Incentives

Congress authorized a 2.0% payment linkage for ASC's to report quality data in Section 109(b) of the Tax Relief and Health Care Act of 2006. This subsection modified sections 1833(i)(2)(D)(iv) and (i)(7) of the Social Security Act, and provided the Secretary the authority to require ASCs to report quality data to receive their full annual fee schedule update. In the CY 2012 OPPS/ASC final rule with comment period, CMS finalized its proposal to implement an ASC Quality Reporting Program beginning with the CY 2014 payment determination and finalized measures for the CYs 2014, 2015, and 2016 payment determinations (76 FR 74494, 74504, 74509, 74510, Nov. 30, 2011). For the CY 2016 payment determination, CMS adopted a HAI measure, Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), with data collection beginning on

October 1, 2014 and continuing through March 31, 2015 (76 FR 74510); CMS also adopted “Prophylactic Intravenous (IV) Antibiotic Timing” (NQF #0264) for the CYs 2014, 2015, and 2016 payment determinations.

8. Extend HAI Prevention Actions Developed for ASCs to Other Outpatient Surgery Venues.

This module centers on defining current issues and making recommendations on how to ensure safe care in ASCs. However, ASCs represent only a subset of the ambulatory care facilities performing surgical procedures. Physician-run, office-based surgical practices perform procedures that are identical or similar to those conducted in ASCs, but many of these facilities are not subject to any regulatory oversight beyond physician licensure and are not being evaluated through any type of inspection process. While little is known about infection control and prevention and HAI rates in ASCs, even less is known about what is occurring in these types of facilities. Future efforts directed toward ASCs, particularly related to educational outreach, need to be mindful of this group.

VI. Conclusion

The above Action Plan reflects feedback from stakeholders that was obtained during the initial public comment period and during subsequent stakeholder meetings. Multiple stakeholders expressed a desire to be engaged and collaborate with HHS on continued development of the Action Plan and generation of the measurable goals. HHS welcomes this collaboration and will continue to reach out to these groups for further explanation, discussion, and partnership development as the draft module continues to evolve.

TABLE 9. Summary of Literature Review of Surgical Site Infection Surveillance Practices Conducted in Non-Acute Care Settings*

Method	Potential Advantages	Potential Disadvantages
Routine wound examination by trained professional	High sensitivity and specificity	Labor intensive, prospective only
Outpatient chart review by trained professionals	High sensitivity and specificity	Labor intensive
Surgeon Reporting		
Self Initiated	High specificity, resource efficient	Poor sensitivity
Mail Survey	Acceptable specificity, relatively resource efficient	Suboptimal sensitivity
Patient reporting		
Mail Survey	Relatively resource efficient	Unreliable sensitivity and specificity
Telephone Survey	Good public relations	Labor intensive, unreliable sensitivity and specificity
Microbiological data	Relatively resource efficient, may “flag” potential SSIs	Unreliable sensitivity and specificity.
Claims data algorithm incorporating discharge diagnosis codes, procedure codes, pharmacological Rx date*	Electronically available, increased sensitivity and positive predictive value	Changes in coding practices with changes in pay for performance practices, applicable in a limited, managed care type setting where patients follow up in the same system that they received operative treatment; poor sensitivity
Clinic notes text searching **	Can be individualized to discipline	No widely accepted benchmark for f/u rates, definitions would need to be standardized by discipline, rate of f/u influenced by multiple factors, attrition bias (f/u response not representative of the original population)

Key References/Notes:

- Manian FA. Surveillance of in alternative settings: Exploring the current options. *Am J Infect Control* 1997;25:102-5.
- *Yokoe DS, et al. Enhanced identification of postoperative infections among inpatients. *Emerging Infectious Diseases* 2004;10:1924-1930.
- **Michelson J. Improved detection of orthopaedic surgical site infections occurring in outpatients. *Clin Orthop Rel Research* 2005; 433:218-224.