

## **PART 4: PHASE TWO – OUTPATIENT SETTINGS AND INFLUENZA VACCINATION OF HEALTH CARE PERSONNEL**

### **CHAPTER 5: AMBULATORY SURGICAL CENTERS**

#### **I. INTRODUCTION**

In response to increasing concerns about the public health impact of health care-associated infections (HAIs), the U.S. Department of Health & Human Services (HHS) developed an action plan to prevent HAIs.<sup>1</sup> 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: 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 called for 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.

Although the initial focus of the action plan was on acute care in inpatient settings, the Federal Steering Committee for the Prevention of Health Care-Associated Infection acknowledged the need for addressing HAI prevention across the health care continuum, including in outpatient settings. As part of Phase Two 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 key actions needed to assure safe care in these settings.

#### **II. BACKGROUND**

HAIs are a leading cause of death in the U.S. and can cause needless suffering and expense. At any given time, about 1 in every 20 hospitalized patients has an HAI, and more than one million HAIs occur across health care settings every year. ASCs have demonstrated tremendous growth in both the volume and the complexity of procedures being performed. ASCs 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).<sup>2</sup> Many of the services

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<sup>1</sup> Department of Health and Human Services. HHS Action Plan to Prevent Health Care-Associated Infections. Available at: [http://www.hhs.gov/ash/initiatives/hai/actionplan/hhs\\_hai\\_action\\_plan\\_final\\_06222009.pdf](http://www.hhs.gov/ash/initiatives/hai/actionplan/hhs_hai_action_plan_final_06222009.pdf). Accessed February 27, 2013.

<sup>2</sup> 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.

performed in these facilities extend beyond procedures traditionally thought of as surgery.<sup>3</sup> In fact, endoscopy procedures, injections to treat chronic pain, and eye procedures (e.g., cataract removal) account for approximately 70% of Medicare claims from ASCs. Currently, there are more than 5,300 Medicare-certified ASCs in the U.S., which represents an increase of more than 54% since 2001. In 2007, more than 6 million surgeries were performed in these facilities and paid for by Medicare at a cost of nearly \$3 billion.<sup>4,5</sup>

### **A. 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 ASC accreditation programs.<sup>6,7</sup> These are the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, the American Osteopathic Association, and The Joint Commission. ASCs that are accredited by an AO may be deemed by CMS to be in compliance with Medicare health and safety standards and are exempt from routine surveys conducted by SSAs. A notable exception to this rule is the surveys conducted by the SSA in response to a complaint. Similarly, SSAs conduct a relatively small number of validation surveys to verify the equivalency of an AO's survey process to that which CMS requires for SSAs. Currently, approximately 25% of Medicare-certified ASCs have relied upon an accrediting organization and are "deemed" for certification purposes.

### **B. Data on HAI Risks in ASCs Are Lacking**

No national estimates regarding the number of HAIs originating in ASCs are available, and little is known about infection control and prevention (ICP) 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 ICP and HAI surveillance. Traditionally, this infrastructure was lacking in ASCs. Much of what is known about adverse events and HAIs in outpatient settings, including ASCs, is based on outbreak investigations conducted by state and local health departments and the Centers for Disease Control and Prevention (CDC).<sup>8,9,10</sup> Recent steps to better assess and summarize ICP practices in ASCs

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<sup>3</sup> Schaefer MK, Jung M, Dahl M, et al. Infection Control Assessment of Ambulatory Surgical Centers. *JAMA* 2010; 303(22):2273-2279.

<sup>4</sup> U.S. 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://www.gao.gov/new.items/d09213.pdf>. Accessed February 27, 2013.

<sup>5</sup> 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.

<sup>6</sup> Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan. [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C\\_ASC\\_RTC-2011.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C_ASC_RTC-2011.pdf). Accessed October 26, 2011.

<sup>7</sup> 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.

<sup>8</sup> 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

occurred in the context of an enhanced inspection pilot activity that was led by CMS and supported by CDC. In 2008, SSAs in three states (Maryland, North Carolina, and Oklahoma) incorporated an infection control audit tool, based upon CDC guidelines (e.g., Standard Precautions),<sup>11</sup> into their routine ASC survey processes. More than two-thirds of the facilities surveyed in the pilot had lapses in ICP identified by surveyors Table 8, and half of the facilities had not undergone a full inspection in more than five years.<sup>12</sup> At the time of the pilot, limited resources did not allow for more frequent surveys of ASCs. American Recovery and Reinvestment Act (ARRA) funding was used, starting in fiscal year 2010, to significantly increase the frequency of ASC surveys, and CMS has continued to maintain funding to support full surveys of 25% of ASCs each year.

**Table 8. Infection Control Lapses Identified during Three-State Pilot Activity**

Infection Control Category Assessed	Number of Facilities with Lapses Identified (%)
Hand hygiene and use of personal protective equipment	12/62 (19%)
Injection safety and medication handling	19/67 (28%)
Equipment reprocessing	19/67 (28%)
Environmental cleaning	12/64 (19%)
Handling of blood glucose monitoring equipment	25/54 (46%)

A February 2009 report from the Government Accountability Office (GAO) highlighted the lack of information related to health outcomes and process measures in ASCs<sup>13</sup>:

*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.*

<sup>9</sup> Centers for Disease Control and Prevention. Outbreaks and Patient Notifications in Outpatient Settings available at: <http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html>

<sup>10</sup> U.S. Government Accountability Office. Patient Safety: HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action is Needed [GAO-12-712, July 13, 2012]. Available at: <http://www.gao.gov/assets/600/592406.pdf>

<sup>11</sup> 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.

<sup>12</sup> Schaefer MK, Jhung M, Dahl M, et al. Infection Control Assessment of Ambulatory Surgical Centers. *JAMA* 2010; 303(22):2273-2279.

<sup>13</sup> 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](http://nueterrahealthcare.com/building_partnerships/documents/GAOhAIreport02-09.pdf). Accessed May 10, 2010.

In the report, GAO further recommended using 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 ICP 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, for which assessment and enforcement of Medicare standards falls primarily to SSAs and AOs.

### **III. PROGRESS MADE**

#### **A. ASC Conditions for Coverage Expanded to Include Infection Control and Prevention**

CMS revised the ASC Medicare CfCs and the interpretive guidelines and survey procedures; the survey procedures became effective in 2009.<sup>14</sup> Previously, the survey methodology, set out in Appendix L of the State Operations Manual, had not been updated in at least 10 years.<sup>15</sup> In 2008, CMS revised the CfCs for ASCs to specifically address the need for ICP programs (set out at 42 C.F.R. § 416.51), including the following requirements:

- The ASC must maintain an ICP program based upon nationally recognized infection control and prevention guidelines.
- The ICP program must be under the direction of a designated health care professional with training in ICP.
- The ICP program must be integrated into the ASC's quality assessment and performance improvement program.
- The ASC must prevent, identify, and manage HAIs through its ICP program.

#### **B. 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 use a consistent, structured process to assess ICP 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.<sup>16,17</sup> CDC tools used in outbreak investigation were further adapted to develop a checklist for observing and

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<sup>14</sup> 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.

<sup>15</sup> 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](http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf). Accessed April 30, 2010.

<sup>16</sup> 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.

<sup>17</sup> Schaefer MK, Jhung M, Dahl M, et al. Infection Control Assessment of Ambulatory Surgical Centers. *JAMA* 2010; 303(22):2273-2279.

assessing ICP practices in ASCs. CMS, with support from CDC, endeavored to strengthen and expand the ICP component of the survey using the CDC checklist. As a result, overall awareness of the needs for ICP activities in ASCs, where SSAs and AOs are primarily responsible for assessment and enforcement of Medicare standards, has increased. 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, ARRA funding supported a 120% increase in the number of surveys of non-accredited, non-deemed ASCs conducted by SSAs, enabling surveys of one-third of all such ASCs. (Accredited ASCs are not included in the intensified survey schedule because they are inspected by their respective AOs, which are required to survey the ASCs at least every three years.) Simultaneously, the survey process was modified by CMS.

The overall survey process was revised to incorporate a case tracer methodology; i.e., surveyors follow a patient through his or her ASC admission, from registration and pre-operative preparation, through the procedure and to post-operative recovery and discharge. This method facilitates a more complete evaluation of an individual patient's experience while under the care of an ASC and permits surveyors 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 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.<sup>18</sup> CMS also required the four AOs with approved Medicare ASC accreditation program to use the tool.

The ICWS is divided into two sections:

#### Section One, ASC Characteristics

This section captures descriptive information about the type of the ASC, its scopes of services, the organization of its ICP program, and any training it provides. The ASC's use of nationally recognized standards or guidelines, surveillance methods used by the ASC, and qualifications of the health care professional responsible for the ICP 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.<sup>19,20</sup> Here, the focus is on specific

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<sup>18</sup> 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](http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf). Accessed April 30, 2010.

<sup>19</sup> Schaefer MK, Jung M, Dahl M, et al. Infection Control Assessment of Ambulatory Surgical Centers. *JAMA* 2010; 303(22):2273-2279.

practices in five areas of ICP that are critical elements for a successful ICP program and assuring safe care: 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 fiscal year 2010, after the implementation of the case-tracer methodology and the ICWS in one-third of non-accredited ASCs, there was an almost fourfold increase (61%) in the percentage of ASCs surveyed that were found to have ICP 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 it has achieved compliance. The preliminary results from fiscal year 2011 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. Because the same survey methodology was used by the SSAs in both fiscal years 2010 and 2011, the fiscal year 2011 results could reflect increased awareness by the ASC industry of infection control requirements and standard practices.

The first national database of ASC ICP practices captured on the ICWS has been developed. In accordance with recommendations made by GAO, findings from analysis of these data will be used to help further target infection prevention and educational needs in ASCs.<sup>21</sup> Although SSAs are no longer required to submit an ICWS for each survey they conduct, starting in fiscal year 2013 and at periodic intervals thereafter CMS will randomly select a sample of ASCs in each state for which an ICWS must be submitted to the national database.

### **C. Education and Training**

Another important achievement has been the increase in both the number and the 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 10-year lapse, and again in September 2012 CMS hosted a two-and-a-half-day training program for ASC surveyors, supported by CDC staff with each event attended by surveyors from SSAs around the nation. Starting in December 2012, an online ASC surveyor training course is available on a monthly basis to SSAs. The course includes a module addressing assessment of infection control practices in ASCs. Surveyors and SSA personnel also currently have expanded access to experts in ICP, including CMS Regional Medical Officers, other CMS

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<sup>20</sup> U.S. 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://www.gao.gov/new.items/d09213.pdf>. Accessed August 27, 2012.

<sup>21</sup> U.S. Government Accountability Office. PATIENT SAFETY HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action Is Needed. Available at <http://www.gao.gov/assets/600/592406.pdf>. Accessed August 27, 2012

personnel with ICP expertise, and CDC officials. In addition, CDC has led development of educational videos (on topics such as hand hygiene and safe injection practices) and other materials for training of front-line health care 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 health care. 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 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 ICP.

#### **D. 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 ICP activities within Medicare-certified institutional providers and suppliers of health care 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 identified ambulatory care as a high-priority area for HAI prevention and surveillance research, as demonstrated by recent funding initiatives.<sup>22</sup>

### **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
- (3) The need to develop meaningful HAI surveillance and reporting procedures

#### **A. Need for Proactive HAI Prevention at the Clinic Level**

Although 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 ICP

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<sup>22</sup> AHRQ’s 2009 Funded Projects to Prevent Health Care-Associated Infections. Available at: <http://www.ahrq.gov/qual/haify09.htm>. Accessed June 27, 2010.

requirements set forth by CMS in the updated Medicare CfCs will help ensure that ASCs develop ICP policies based upon nationally recognized guidelines and that those policies are under the direction of someone with training in ICP. However those updates alone will not be sufficient. ASCs need to proactively embrace a culture of safety and make allocation of resources (e.g., ensuring supplies necessary for adherence to Standard Precautions are available and allowing sufficient time to adequately reprocess reusable medical devices) 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 model that is being modified and applied to the ASC setting with development of the Surgical Unit-based Safety Program — Ambulatory Surgery.<sup>23</sup>

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

## **B. Need to Sustain and Expand Improvements in Oversight and Monitoring**

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

## **C. 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. Although 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. Currently, there is no national data source describing HAIs that originate in ASCs. Thus, ASCs have no standardized mechanism to tie compliance with process measures to improved outcomes or reductions in HAIs.

Additional guidance is needed in post-discharge surveillance. Currently, there is a great deal of heterogeneity and a lack of standardization of post-discharge HAI surveillance data in ASCs.

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<sup>23</sup> Pronovost PJ, Berenholtz SM, Goeschel CA, et al. Creating High Reliability in Health Care Organizations. *Health Services Research* 2006;41:1599-1617.

This is the case 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, eye, or interventional pain procedures for which SSI definitions are not applicable. Other ASCs specialize in orthopedic 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 and local health departments and CDC continue to investigate outbreaks in outpatient settings, including ASCs, and track infections across the spectrum of health care 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. Colorado,<sup>24</sup> Massachusetts, Nevada, and New Hampshire have state mandates for SSI reporting in ASCs; these states use NHSN to report SSIs in ASCs. Evaluation of these states’ experiences is under way to determine how the system might be tailored to better fit the needs of outpatient settings. In addition, there is ongoing interest from HHS and stakeholders in developing measures applicable to all ASCs, including those that perform procedures not captured by existing NHSN SSI definitions.

An additional challenge in achieving effective routine HAI surveillance for ASCs pertains to the difficulty in tracking patients after they are discharged. Patients present to the ASC for procedures but typically do not return to the ASC for routine postoperative care or to address complications from the procedures. Instead, they may present to an area hospital or their personal physician for evaluation and treatment. These visits are not necessarily reported 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 procedures should be reported. ASCs have employed a variety of methods to track infections in patients following procedures, including direct follow-up with patients or their surgeons. However, experience with these methods has been marked by low sensitivity, reflecting poor response rates from both patients and providers, as well as significant variability in terms of how long after surgery follow-up occurs.<sup>25,26,27</sup>

Several efforts currently under way are aimed at overcoming the lack of standardized or validated methods to identify SSIs that result from procedures performed at ASCs but are diagnosed in hospitals or other health care settings. An AHRQ-funded project is identifying SSIs

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<sup>24</sup> State of Colorado Status Report on the Health Facility Acquired Infections Disclosure Initiative. Available at <http://www.colorado.gov/cs/Satellite/CDPHE-HF/CBON/1251590876310>. Accessed February 27, 2013.

<sup>25</sup> Manian FA. Surveillance of surgical site infections in alternative settings: Exploring the current options. *Am J Infect Control* 1997;25:102-5.

<sup>26</sup> Yokoe DS, et al. Enhanced identification of postoperative infections among inpatients. *Emerging Infectious Diseases* 2004;10:1924-1930.

<sup>27</sup> Michelson J. Improved detection of orthopaedic surgical site infections occurring in outpatients. *Clin Orthop Rel Research* 2005; 433:218-224.

that originate in ASCs. This effort will involve enhancements to Healthcare Cost and Utilization Project (HCUP) data to facilitate linkage of patients across time and settings 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. Another group is using the HCUP state ambulatory surgery databases to focus on spine procedures. The project's goals are (1) 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 (2) to assess the usefulness of coding and ambulatory pharmacy dispensing data in identifying SSIs.

## **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.

### **A. 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 chapter and further prioritize next steps for HAI prevention in ASCs. In October 2010, CDC and the Office of the Assistant Secretary for Health (OASH) in the HHS Office of the Secretary (OS) hosted an HAI Recovery Act Grantee Meeting, which brought 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 discussed how these groups can better collaborate to promote uptake of best practices and assist in the development of stronger ICP infrastructure in ASCs. In March 2011, HHS convened a stakeholder meeting 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 (1) implement guidance included in the ASC section of the draft *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* (HAI Action Plan) and (2) plan and coordinate efforts to enhance ICP-related education, communication, and outreach activities. The ASC Association hosted a follow-up meeting in May 2011 to continue the dialogue with an expanded set of partners. In May 2012, HHS hosted an HAI Data Summit with a section focused on ASCs in which participants provided feedback and suggestions on alternate data sources and methodologies. 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 and local 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 and optimized ICP 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
- Identifying additional strategies to involve consumers and others on an ongoing basis, including discussions regarding how patients can be better educated about identifying adverse events resulting from outpatient procedures and empowered to report them

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

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

Reviews of ICP 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 ICP procedures. Similarly, AHRQ has funded 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 health care safety and human factors specialists from the engineering field may lead to innovative and scalable process of care, device, or facility design improvements.

### **C. Disseminate Evidence-Based Guidelines and Training Materials for Infection Control and Prevention in ASCs**

As described in Section III, the CfCs for ASCs now include a requirement that each facility's ICP program must be under the direction of a designated health care professional with training in ICP. This represents a significant step toward meeting the goal of having ICP 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 appear to be lacking. In 2011, CDC developed and released a publication called *Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care* along with an infection prevention

checklist.<sup>28</sup> These documents summarize ICP recommendations for ambulatory care settings, including ASCs, and will help educate health care providers and communicate expectations for ICP 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 ICP with a focus on ambulatory care settings; CDC-funded injection safety activities are under way in a growing number of states.

Several states are providing regional training opportunities to meet the educational needs of health care 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 ICP 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 the Region II 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 OASH sponsored a promotion package<sup>29</sup> to more widely disseminate materials from the Region II HAI ASC Training Workshop, which will provide opportunity for free CME credits. In addition, New York, New Jersey, Nevada, and North Carolina are instituting specific training and oversight requirements related to ICP for settings such as ASCs where invasive procedures are performed or sedation is administered.

#### **D. Improve and Expand Process Measures**

ICP 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 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. Currently, SCIP-Inf-1 and SCIP-Inf-2 measures: antibiotics within 1 hour before incision or within 2 hours if vancomycin or quinolone is used and received prophylactic antibiotics consistent with recommendations, respectively are included in the Hospital Inpatient Quality Reporting Program. Because many similar procedures are being performed on an outpatient basis, additional work is needed to focus development of similar measures for specific ASC procedures.

In addition, six National Quality Forum (NQF)–endorsed measures have been adopted by the ASC Quality Collaboration: 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.<sup>30</sup> Additional measures that address HAI prevention in ASCs beyond SSIs are needed along with further evaluation and stakeholder input. For example,

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<sup>28</sup> <http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html>

<sup>29</sup> <http://www.hhs.gov/ash/initiatives/hai/resources/index.html>

<sup>30</sup> ASC Quality Measures: Implementation Guide. Available at: <http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf>. Accessed June 27, 2010.

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.

### **E. 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. Several activities are needed to explore surveillance options in ASCs, some of which are currently under way:

- Establish robust estimates of the numbers and types of procedures that are currently being conducted to identify 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.
- Identify options for improving state and local 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.

### **F. Adopt Measurable Goals**

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

- Currently, all Medicare-certified ASCs are expected to demonstrate 100% adherence to all measures contained within the ICWS used by surveyors during the inspection process. Facilities not subject to Medicare certification, including office-based practices and other settings not subject to routine inspections, are encouraged to conduct regular self-audits to assure ongoing compliance. The ICWS, used by SSAs and AOs during facility inspections, is available online at [http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09\\_37.pdf](http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf). The CDC checklist and guide for outpatient settings, including ASCs, is available at <http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html>. By December 31, 2013, HHS, with stakeholder input, will develop a plan for analysis of process measure data that are collected using the ICWS as part of ASC inspections and dissemination of these findings.
- By December 31, 2013, HHS, with stakeholder input, will perform the following:
  - Identify existing quality measures (e.g., serious reportable events, SCIP measures) that have been NQF-endorsed and are applicable to ASCs.

- Identify areas in which additional quality measures are needed for ASCs.
- Establish a timeline and methods for adoption and implementation of select measures within ASCs.
- Currently, all certified ASCs are expected, as part of the Medicare CfCs, to have a system in place to actively identify infections that may have been related to procedures performed in the ASC, including a mechanism to comply with state notifiable disease reporting requirements (e.g., reporting of outbreaks). To support a consistent approach to HAI surveillance in ASCs, by December 31, 2013, HHS, with stakeholder input, will perform the following:
  - Identify a set of ASC procedures for which HAI definitions and methods should be developed.
  - Establish a multi-year plan and phased approach to support the routine surveillance of HAIs in a resource-efficient manner that can be implemented consistently across facility types.
  - Identify requirements and standards for ASCs to report notifiable diseases and potential outbreaks.

### **G. Establish Broad Financial Incentives**

Sections 1833(i)(2)(D)(iv) and (i)(7) of the Social Security Act authorize, but do not require, the Secretary to implement the revised ASC payment system in a manner so as to provide for a 2.0 percentage point reduction in any annual update for failure by an ASC to report on quality measures. In the calendar year 2012 Outpatient Prospective Payment System (OPPS)/ASC final rule with comment period, CMS finalized its proposal to implement an ASC Quality Reporting Program beginning with the 2014 payment determination and finalized measures for the 2014, 2015, and 2016 payment determinations (76 FR 74494, 74504, 74509, 74510, Nov. 30, 2011).<sup>31</sup> For the 2016 payment determination, CMS adopted a HAI measure, Influenza Vaccination Coverage Among Health-Care 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 Antibiotic Timing (NQF #0264) for the 2014, 2015, and 2016 payment determinations. In the calendar year 2013 OPPS/ASC final rule with comment period, CMS established a policy for reducing the payment rates in calendar year 2014 and in subsequent calendar years for ASCs that fail to meet the ASC Quality Reporting Program requirements (77 FR 68499-00, Nov. 15, 2012).

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<sup>31</sup> Federal Register Final Rule With Comment Period: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements, <http://www.gpo.gov/fdsys/pkg/FR-2011-11-30/pdf/2011-28612.pdf>. November 30, 2011.

## **H. Extend HAI Prevention Actions Developed for ASCs to Other Outpatient Surgery Venues**

This chapter 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. Although little is known about ICP 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, must be mindful of this group.

## **VI. CONCLUSION**

This chapter 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 HAI 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 chapter continues to evolve.