The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Purpose

To review the ASC Chapter of the National Action Plan and work on moving forward with proposed metrics and outcome measures, with feedback and suggestions on alternate data sources and methodologic options.
I. INTRODUCTION

• Ambulatory surgical centers (ASCs) were selected as a focus area for Tier 2 of the HHS HAI Action Plan

• HHS interagency workgroup was formed, including
  – Centers for Medicare and Medicaid Services (CMS)
  – Centers for Disease Control and Prevention (CDC)
  – Agency for Healthcare Research and Quality (AHRQ)
  – Indian Health Service (IHS)

• Draft Action Plan: update on progress made, remaining gaps, and recommendations for next steps
  – Initially released in Sept 2010, with subsequent revisions in response to stakeholder comments
  – Current version posted April 2012
II. BACKGROUND

• ASCS are defined by CMS as distinct entities that exclusively 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

• Currently, >5,300 U.S. Medicare-certified ASCs
  – 54% increase since 2001

• 2007: over 6 million procedures performed in ASCs and paid for by Medicare at a cost of nearly $3 billion
  – Wide variety of care with >70% of claims for endoscopy, eye procedures (e.g., cataract removal), and spinal/lower back injections
  – Facilities are also heterogeneous re size, staffing, ownership type, chain or hospital affiliation, electronic health records
II. 1. Oversight of Medicare-Certified ASCs

- ASCs are surveyed to measure compliance with Conditions for Coverage (CfCs)
  - State Survey Agencies (SSA)
  - Accrediting Organization (AO) deemed by CMS
    - The Joint Commission (TJC)
    - Accreditation Association for Ambulatory Health Care (AAAHC)
    - American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
    - American Osteopathic Association (AOA)

- A minority (~25%) of ASCs are accredited by an AO
  - Exempt from surveys conducted by SSA, except for:
    - Complaint surveys
    - Validation surveys
II. 2. Data on HAI Risks in ASCs is Lacking

• National estimates regarding HAI risks associated with care provided in ASCs are not available
  – Surveillance infrastructure remains largely under-developed
  – Outbreak reports (e.g., 2008 Las Vegas NV hepatitis C virus)

• Traditionally, little was known about infection control practices
  – To better assess practices, an enhanced inspection pilot activity was led by CMS with support from CDC*
  – In 2008, State Survey Agencies in Maryland, North Carolina, and Oklahoma) incorporated an infection control audit tool, based upon Standard Precautions, into their routine ASC survey process
  – Over two-thirds of the facilities surveyed in the pilot had lapses in infection control identified by surveyors

* Schaefer et al. JAMA, June 9, 2010
Infection Control Assessment of Ambulatory Surgical Centers

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

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

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

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

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

JAMA
JAMA. 2010;303(22):2273-2279
"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."
III. PROGRESS MADE
Improved Inspection Frequency / Methodology

• Routine survey process modified to use tracer methodology and new Infection Control Worksheet
  – Section 1 – ASC characteristics
    • Type of ASC, scopes of services, organization of its infection control program, training/qualifications, use of nationally recognized standards and/or guidelines, surveillance methods
  – Section 2 – Infection Control Practices Assessment
    – Specific practices in five critical areas of infection control (e.g., hand hygiene, injection safety, equipment reprocessing, and environmental cleaning)
III. PROGRESS MADE
Expanded CfCs for Infection Control / Prevention

- Revised ASC Conditions for Coverage, Interpretive Guidelines and Survey Procedures (2009)

- For the first time, the CfCs for ASCs specifically addressed the need for infection control programs, including:
  - Maintain an infection control program based upon nationally recognized infection control guidelines
  - The infection control program be under the direction of a designated healthcare professional with training in infection control
  - The infection control program be integrated into the ASC’s Quality Assessment and Performance Improvement Program (QAPI)
  - Prevent, identify and manage HAIs through its infection control program activities conducted in accordance with recognized infection control surveillance practices
§416.51(b) Standard: Infection Control Program – Surveillance Aspects

As part of this ongoing program, the ASC must have an active surveillance component that covers both ASC patients and personnel working in the facility. Surveillance includes infection detection through ongoing data collection and analysis.

Identifying Infections

- The ASC must conduct monitoring activities throughout the entire facility in order to identify infection risks or communicable disease problems.
- The ASC should document its monitoring/tracking activities, including the measures selected for monitoring, and collection and analysis methods.
- Activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC’s National Healthcare Safety Net (NHSN).
- Monitoring includes follow-up of patients after discharge, in order to gather evidence of whether they have developed an infection associated with their stay in the ASC.
§416.44(a) Standard: Physical Environment – Surveillance Aspects

Te ASC must establish a program for identifying and preventing infections [...] and reporting the results to appropriate authorities.

Interpretive Guidelines §416.44(a)(3)

- ASCs are required to have a program to follow up on each patient after discharge, in order to identify and track infections associated with the patient’s stay in the ASC.
- ASCs are not expected to establish routine post-surgical laboratory testing for infectious diseases, but if it learns of an infection in the post-discharge period from the patient or patient’s physician, the ASC might consider inquiring whether there is a lab confirmation of an infectious disease, and, if there are indications that the infection was associated with the patient’s stay in the ASC, report the case to the appropriate State authorities if the disease is a reportable disease under State law (including regulations).
- ASCs may delegate portions of this follow-up responsibility to the physicians on the ASC’s staff who will see the patients in their office post-discharge only if the ASC’s program includes a mechanism for ensuring that the results of the follow-up are reported back to the ASC and documented in the patient’s medical record.
IV. REMAINING NEEDS AND PREVENTION OPPORTUNITIES

• Unmet needs pertaining to HAI prevention in ASCs fall into three main categories:
  – Proactive HAI prevention at the clinic level
  – Sustain and expand improvements in oversight and monitoring
  – Develop meaningful HAI surveillance and reporting procedures
IV.3. Develop meaningful HAI surveillance and reporting procedures

– Build on progress made in process measurement to move toward surveillance of patient outcomes
  • Link process measure compliance with improved outcomes

– Challenges
  • No “one size fits all solution”
  • Uptake of electronic health records has lagged
  • Variable post-discharge follow-up methods including surgeon or patient reporting
    – Contact patient’s primary care provider
    – Contact patient by telephone (e.g., @ 24 or 48 hours)
    – Rely on the physician performing the procedure to obtain this information (e.g., at a follow-up visit after discharge)
The Incidence and Cost of Unexpected Hospital Use After Scheduled Outpatient Endoscopy

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Background: Data on complications of gastrointestinal endoscopic procedures are limited. We evaluated prospectively the incidence and cost of hospital visits resulting from outpatient endoscopy.

Methods: We developed an electronic medical record-based system to record automatically admissions to the emergency department (ED) within 14 days after endoscopy. Physicians evaluated all reported cases for relatedness of the ED visit to the prior endoscopy based on predetermined criteria.

Results: We evaluated 6383 esophagastroduodenoscopies (EGDs) and 11,632 colonoscopies (7392 for screening and surveillance). Among these, 419 ED visits and 266 hospitalizations occurred within 14 days after the procedure. One hundred thirty-four (32%) of the ED visits and 76 (29%) of the hospitalizations were procedure related, whereas 31 complications were recorded by standard physician reporting (P < .001). Procedure-related hospital visits occurred in 1.07%, 0.84%, and 0.95% of all EGDs, all colonoscopies, and screening colonoscopies, respectively. The mean costs were $1403 per ED visit and $10,123 per hospitalization based on Medicare standardized rates. Across the overall screening/surveillance colonoscopy program, these episodes added $48 per examination.

Conclusions: Using a novel automated system, we observed a 1% incidence of related hospital visits within 14 days of outpatient endoscopy, 2- to 3-fold higher than recent estimates. Most events were not captured by standard reporting, and strategies for automating adverse event reporting should be developed. The cost of unexpected hospital visits postendoscopy may be significant and should be taken into account in screening or surveillance programs.

Arch Intern Med. 2010;170(19):1752-1757
IV.3. Develop meaningful HAI surveillance and reporting procedures

(continued)

- Many high volume ASC procedures lack standardized HAI surveillance definitions
- For some procedures that are under surveillance in hospitals, need research on translation to ASC setting
  - Several states requiring ASCs to report SSIs using NHSN
    - Colorado: hernia procedures, hip/knee replacements
    - Nevada: breast, gallbladder, hernias, open reductions
    - New Hampshire: breast, hernias, open reductions
    - Massachussets: hernias
  → Between <10 and <50% of ASCs per state perform applicable procedures under these mandates
IV. 3. Develop meaningful HAI surveillance and reporting procedures (continued)

Novel approaches using electronic data sources to identify potential SSI events originating in ambulatory settings

- Identify and describe ambulatory procedures resulting in surgical site and/or healthcare-associated infections based on a subsequent procedure or acute care hospitalization

- E.g., AHRQ-funded study in collaboration with CMS using administrative data from HCUP (Healthcare Cost and Utilization Project)
  - Pilot national ambulatory surgery database

- E.g., CDC-funded studies using automated data from a managed care organization and HCUP state ambulatory surgery databases
  - Pharmacy dispensing data
V. NEXT STEPS: COLLABORATIONS FOR SHARED SOLUTIONS

1. Engage stakeholders to facilitate collaboration and promote a culture of safety
2. Identify needs and opportunities for HAI reduction through improvements in the process of care
3. Disseminate evidence-based guidelines and training for infection control
4. Improve and expand process measures
5. Establish surveillance criteria and associated strategies for outcomes measurement
6. Measurable goals
7. Broad financial incentives
8. Extend HAI prevention actions developed for ASCs to other outpatient surgery venues
Measurable Goals – Process Measures

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.

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.

Current National Quality Forum (NQF)-Endorsed Measures Applicable to ASCs

- Six ASC Quality Collaboration-sponsored measures
  - Appropriate Surgical Site Hair Removal
  - Hospital Transfer/Admission
  - Patient Burn
  - Patient Fall in the ASC
  - Prophylactic IV antibiotic timing
  - Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

- CDC-sponsored Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431)

http://www.ascquality.org/
Hospital Transfer/Admission

Measure Type: Outcome

Intent:
• To capture any ASC admissions (patients) who are transferred or admitted to a hospital upon discharge from the ASC.

Numerator/Denominator:
• Numerator: Ambulatory Surgery Center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.
• Denominator: All ASC admissions.

Inclusions/Exclusions:
• Numerator Inclusions: ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.
• Numerator Exclusions: None.
• Denominator Inclusions: All ASC admissions.
• Denominator Exclusions: None.

Data Sources:
• ASC medical records, incident/occurrence reports and variance reports are potential data sources.

Definitions:
• Admission: completion of registration upon entry into the facility.
• Hospital transfer/admission: any transfer/admission from an ASC directly to an acute care hospital including hospital emergency room.
• Discharge: occurs when the patient leaves the confines of the ASC.

Improve and Expand Process Measures

• Potential for reporting ASC inspection measures and/or metrics based on facility self-audit
• Potential to adapt CMS’ Surgical Care Improvement Project (SCIP) for procedures that are being performed in ASCs
• Potential for additional measures that address HAI prevention
  – e.g., endoscopy and other equipment reprocessing
Establish Surveillance Criteria and Associated Strategies for Outcomes Measurement

- Efforts needed to inform how HAI surveillance can most effectively be conducted among ASC patients
- Determine which procedures are the highest priority for tracking of infectious complications
- Current and next steps:
  - Robust estimates of #s and types of ASC procedures
  - Research into SSI and other HAI surveillance methods including electronic data mining and clinical validation
  - Improve capacities for identifying, reporting, and investigating potential infections and outbreaks among ambulatory surgery patients
# Top ASC Surgical Procedures by Volume, 2009

<table>
<thead>
<tr>
<th>Claims Rank</th>
<th>Procedure Short Descriptor</th>
<th>Claims Volume</th>
<th>% of Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cataract removal with IOL lens insert, 1 stage</td>
<td>1,150,342</td>
<td>20.6%</td>
</tr>
<tr>
<td>2</td>
<td>Upper Gastrointestinal (GI) endoscopy with biopsy</td>
<td>441,591</td>
<td>7.9%</td>
</tr>
<tr>
<td>3</td>
<td>Colonoscopy with biopsy</td>
<td>341,161</td>
<td>6.1%</td>
</tr>
<tr>
<td>4</td>
<td>Colonoscopy, diagnostic</td>
<td>290,385</td>
<td>5.2%</td>
</tr>
<tr>
<td>5</td>
<td>Laser surgery (lens)</td>
<td>272,248</td>
<td>4.9%</td>
</tr>
<tr>
<td>6</td>
<td>Colonoscopy with lesion ablation or removal</td>
<td>232,258</td>
<td>4.2%</td>
</tr>
<tr>
<td>7</td>
<td>Injection spine: lumbar, sacral (caudal)</td>
<td>229,137</td>
<td>4.1%</td>
</tr>
<tr>
<td>8</td>
<td>Injection foramen epidural: lumbar, sacral</td>
<td>207,053</td>
<td>3.7%</td>
</tr>
<tr>
<td>9</td>
<td>Inject paravertebral f jnt l/s, 1 lev</td>
<td>125,918</td>
<td>2.3%</td>
</tr>
<tr>
<td>10</td>
<td>Colorectal cancer screening; high-risk individual</td>
<td>92,715</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

Measurable Goals

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:

• Identify a set of ASC procedures for which surveillance definitions and methods should be developed; and,

• Establish a multi-year plan and phased approach to support their routine surveillance.
Feedback and Suggestions on Alternate Data Sources and Methodologic Options

1. What are the merits of a “mixed methods” approach to outpatient procedure surveillance that permits a focus on specific procedures/infections as well as broader outcomes (e.g., hospitalization) which encompass infections and other adverse outcomes?

2. For outpatient procedures, what combination of traditional and electronic methods of case finding and reporting should be pursued? In the near term? In the long term?
Thank you

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www.hhs.gov/ash/initiatives/hai/actionplan/#tier2