Infection Prevention Challenges in the Ambulatory Surgery Center: Strategies for a Successful CMS Survey

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Program Objectives

• Discuss common challenges and frequently asked questions regarding the infection prevention requirements in the CMS ASC survey.
• Present practical suggestions to improve the IP program in an ASC.

Note: because CMS uses “infection control” the terms infection control (IC) and infection prevention (IP) will be used interchangeably throughout this presentation.

The 2009 Nevada ASC Outbreak as a Catalyst for Major Change

• State of Nevada, CDC and CMS conducted an intensive investigation of Las Vegas HCV outbreak; eventually extended throughout the state.
• ICWS tool developed; tested in 3 pilot states.
• ICWS then expanded to 12 volunteer states.
• ICWS mandatory in all CMS ASC surveys in Q 4 2009; voluntary use by some accrediting organizations.
• Compilation of first ASC IP database (in progress); results expected 2011.

Results of the 3 State Pilot Were Published in JAMA, June 2010

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%)
- lapses in handling of blood glucose monitoring equipment (25/54; 46.3%; 95% CI, 33.4%-59.6%).

Schaefer, MK. Infection control assessment of ambulatory surgical centers. JAMA 2010 Jun 9; 303(22):2273-9

Changes in the ASC Survey Process

- Emphasis on observation and interview
- Tracer methodology (similar to process used by accrediting organizations)
- Direct observation in procedure room or OR
- Increased total survey time and number of surveyors present on-site
  - New emphasis on infection control!

Priority Areas Described in the CMS ICWS

- The ASC’s infection control program
- Hand hygiene and use of PPE
- Medication use and safe injection practices
- Cleaning, disinfection and sterilization of reusable equipment
- Environmental cleaning
- Point of care testing (glucometers)
Risk Assessment is the Basis for Your Successful Program!

Facility Specific IP Risk Assessment

- Program Planning, Priorities and Goal Setting
- Staff Education and Training
- Surveillance and Reporting Activities
- Link to AQC quality (QAPI) program

The IP Program: Identifying Your Risks

Sample criteria:

- High risk for infectious complications
- New procedure; risks not yet fully understood
- Tracking & trending of cases with infections
- Follow up on “near miss” events
- Follow up on adverse/sentinel events

The Infection Control Program

- **Select guidance documents**
  1. Current
  2. Accessible
  3. Consistent with policy & procedure
  4. Consistent with staff education
- **Designate the responsible person**
  1. Must be licensed
  2. Must be qualified to manage IP program
  3. Time allotment for IP is stated
IP Program Requirement: Educating Your Staff
There is no one "formula" for success

FAQs related to staff training
• Does everyone need education? Are physicians and/or surgeons exempt?
• Must inservices be provided via live, on site training?
• Are programs provided by vendors acceptable?
• How much training must I provide?
• Who is an acceptable provider?

Challenge Staff with Realistic Scenarios
• You discover a "wet pack" in the last load sterilized for the day. What do you do?
• You learn that the scope used during the colonoscopy earlier in the day had not been cleaned per manufacturer instructions. What should steps must you take?
• You are in pre op for a pediatric case when you discover that the child has a rash on the torso and a low grade fever. What do you do first?

Take a Closer Look at How Employees are Being Oriented and Trained
Are you relying on the see one-do one-teach one method? If so, to what extent?

This method for on the job training can communicate incorrect information and reinforce deficient practices.
Program Requirement: Surveillance and Reporting of Infections

ASC Surveillance Systems Must Address Multiple Challenges

- Wide variation in methods and statistical tools
- Self reporting may be included
- Patient follow up/tracking difficult, especially if > 30 days
- Definitions and criteria may not always be aligned with surveillance systems in ASCs
- Electronic surveillance programs and IT support lacking or very limited for most ASCs
- Baseline data absent or difficult to obtain

Example: Surgical Site Infection (SSI) Surveillance

In ASCs should SSI surveillance include:
- Deep incisional and organ space infections only?
- Or should superficial incisional infections also be included?
- In the absence of baseline data, who should decide – and how?
How to Maximize Your Compliance with Surveillance Requirements

1. Include facility leadership, including physicians, in every phase.
2. Think big but start small.
3. Use available resources and pursue those that you need.
4. Use basic IP tools such as line lists and spreadsheets; train staff to use these tools.
5. Share your results and . . .
6. Use your results to make improvements

IP Program: Start with the Basics
A quick way to find your starting point!

• Show me how you wash your hands
• How do you take off your dirty gloves?
• What type of sterilizer are you using?
• What do you do with red biohazard containers when they are full?
• Explain how you prevent “clean” items from being mixed up with “dirty” ones
• What would you do if you found a used needle & syringe on the floor?

Lapses in ASC Infection Control Practices
Why Do They Occur?

Behavior:
adaptive skills or “human factors” are the most common cause in most adverse events

Technology:
May sometimes be implicated in adverse events but usually is not the primary cause
Hand Hygiene and PPE
Examples of Lapses Based on Behavior

- Double gloving to avoid washing hands
- Applying alcohol hand rub to gloves rather than removing them
- Wearing gloves outside patient care areas but insisting “it's OK – they're clean”
- Reusing gowns because they do not appear soiled
- Wearing the same gown all day even when visibly soiled

When Monitoring Hand Hygiene
Be Sure to Remember . . .

- How often do staff clean their hands? Are gloves being used correctly along with hand hygiene?
- Is the cleaning technique adequate? Are all surfaces being cleaned?
- Are hand/wrist accessories used per your ASC policy? Include nail polish, artificial nails, decals, rings, bracelets, watches etc. Do staff know the policy?

Safe Injection Practices

These practices are a survey priority because

- Lapses have been shown to transmit blood borne diseases, especially hepatitis.
- Current surveys of clinicians (self report) indicate that deficient practices are still occurring.
- Beliefs that deficient practices save the ASC time and/or money persist.
- Deficient practices justified by the belief “I've always done it this way and nothing has ever gone wrong” are difficult to eradicate.
Unsafe Practices May Occur at Many Points During Drug Delivery

Some examples
- Single use med vial used more than once
- Multidose vial not used aseptically, dated when opened or stored securely
- Med syringe used for multiple patients
- Bags of normal saline used to prefill syringes
- Med syringes not labeled, left on top of carts or stands, carried in pocket
- IV bags spiked and tubing primed many hours prior to use

Products Must Be Used Consistent with Their FDA Label

A common – and dangerous! - misconception

Injection Safety: Enforce a Zero Tolerance Approach to Unsafe Practices

Help reinforce staff training and awareness by asking basic questions . . .
When is it OK to use a single-use med vial?
If a med is extremely expensive, is it OK to use the "leftovers" even if labeled for single patient use?
What information must be included on a syringe label?
When does a syringe NOT need a label?
What should you/do you do if you observe an unsafe practice?

Repeat . . . Reinforce . . .Repeat
Survey Tip: OSHA and Bloodborne Pathogens

- CMS does not conduct OSHA inspections or enforce OSHA regulations.
- However, certain OSHA regulations correspond to CMS standards for prevention of disease transmission.
- The primary overlap in content focuses on bloodborne pathogens.

Survey readiness should include an evaluation of the ASC’s compliance with OSHA BBP
Infection Prevention and Reusable Equipment

Cleaning: Required For All Equipment

Disinfection
Destroys or renders inert pathogenic organisms

Sterilization
Destroys all organisms

Are you using the appropriate chemicals? In the correct dilution?

Are you following manufacturer DFUs for each piece of equipment?

Cleaning: One Method is Not Appropriate for All Items

Some common problems:

• Multiple steps and components increase risks in cleaning/disinfecting scopes.
• "Quick rinse" a common error in cleaning surgical instruments.
• Belief that steam sterilization makes pre-cleaning unnecessary is a persistent misconception.
• Must follow manufacturer DFU for cleaning as well as disinfection or sterilization.

Common Obstacles to Thorough Disinfection

• Complete disassembly and cleaning of all components.
• Correct preparation, testing and disposal of high level disinfectants.
• Adequate testing of equipment integrity and function.
• Satisfactory rinsing and drying.
• Safe storage (including separation of "clean" and "dirty")
Common Obstacles to Sterilization

- Incorrect instrument prep and/or loading of trays
- Missing or incorrect use of indicators
- Missing or incomplete documentation
- Overutilization of “flash sterilization”
- Manufacturer instructions for sterilizer not found; staff unfamiliar with requirements
- Staff not trained to read/use printouts from sterilizers
- Staff response to alarms not clear
- Incorrect reprocessing of single use items, especially surgical instruments

Sterilization: Changing Terminology

- In the professional literature, the term “flash sterilization” is slowly being replaced by “immediate use sterilization."
- However, as of December 2010 the terminology used by CMS does not yet reflect this change.

As you prepare for your survey, you should expect to hear these terms used interchangeably.

ASC Environmental Cleaning Checklist

Who – What – When - Where

EPA registered disinfectants) are used
Criteria for routine cleaning are identified
Criteria for terminal cleaning are identified
Frequency for all types of cleaning is described, tracked and evaluated (including contract service, if used)
High touch surfaces are identified and cleaned per procedure
Cleaning protocols for non critical equipment are implemented
Survey Tip: Environmental Cleaning
Includes . . .

Does your ASC use privacy curtains? If so, they must be taken down and cleaned regularly.

Studies have shown that privacy curtains are high touch surfaces that can harbor pathogens, especially MRSA.

Point of Care Testing in ASCs

- POC (or POCT) allows lab testing to be performed as close to the patient as possible.
- It is the fastest growing segment of laboratory testing worldwide.
- Same quality expectations and standards as a traditional laboratory.
- In ASCs, focus is on glucometer use.

ASC Compliance with the CMS CLIA Requirements

- ASCs performing POCT with glucometers are required to have a CLIA certificate.
- The Clinical Laboratory Improvement Amendments Division (CLIA) is part of the Survey and Certification Group at CMS.
- ASCs must be able to produce their CLIA certificate during the survey.
If You Need More Information . . .

For instructions on how to apply for a CLIA certificate or details about the program, visit the CMS web site:

www.cms.gov/clia

Survey Tips for Glucometers
When Meters Are Shared Among Patients

- Glucometer must be approved for multi-patient use. (If in doubt, contact the manufacturer)
- Single use, retractable lancing devices are strongly preferred.
- Must be cleaned and disinfected after each use with appropriate disinfectant.
- ASC responsible for all quality controls specified by the manufacturer.
- Glucometer must be stored in a secure location when not in use.

ASC Regulations are Available at www.cms.gov

- For regulations and interpretive guidance, see State Operations Manual (SOM) Appendix L
- For a copy of the ICWS, go to Survey & Certification General Information, Policy and Memos to States. Search for Memo 09-37. ICWS is attached to this memo.
IP in ASCs: Looking Ahead

- IP is ASCs is an evolving and dynamic field.
- More information about IP practices in ASCs will be available when the findings from the first year of ICWS national data collection are released in 2011.
- The new ASC Module (in final development now) will help establish new goals and priorities for IP when it is added to the HHS HAI Action Plan in 2011.