CMS
Infection Control Worksheet (ICWS)
Question

Raise your hand if you are familiar with the ICWS
Objectives

- Understand the elements of infection prevention and control in the settings surveyed by CMS.
- Identify common problems, gaps and practice deficiencies related to infection prevention detected via the ICWS.

Disclaimer
References to specific brands of products and supplies are for illustration only and do not represent an endorsement of the product by the speaker.
Development of the ASC ICWS*

- Initial tool developed by CDC as part of Nevada outbreak investigations.
- $10 million ARRA funding made it possible to increase ASCs surveys & implement ICWS nation-wide.
- CMS was surveying 1/3 of all nonaccredited ASCs, although budget cuts impacted the number of surveys.
- Some accrediting organizations are also using the ICWS.
- Original goal: collect ICWS from 1500 ASCs.

*Infection Control Worksheet for CMS surveyors
Locating the ICWS on the CMS Web Site

Search:
“CMS ASC Infection Control Worksheet”
CMS Survey Outcomes

- No Deficiency
- Standard Level Deficiency
- Condition Level Deficiency
- Immediate Jeopardy

Terminology used in CMS ICWS
Includes instructions to surveyors regarding when/at what level to cite specific deficiencies
ICWS Part 1 – General Information

Examples

• Facility Name
• Location
• CMS Certification Number
• Year opened for operation
• Date of most recent federal survey
• Does ASC participate in Medicare via accredited “deemed” status?
• By: AAAHC; AAAASF; AOA; TJC; AAACN

You will probably need to provide some of these details to the surveyor.
## How are Your Services Provided?

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<th>Service</th>
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<th>Employee</th>
<th>Other</th>
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Infection Control Program: ICWS Required Elements

- Written IC program plan
- Qualified, licensed professional to direct the program
- Selection of nationally recognized guidelines
- Evidence of compliance with selected guidelines
- Surveillance system, including notifiable disease reporting per State requirements
- Staff education & training
Qualified Professional

- If the facility cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) must be cited.

- Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.
National Guidelines

- Guideline for Isolation Precautions (CDC)
- Guideline for Hand Hygiene (CDC or WHO)
- Disinfection & Sterilization in Healthcare Settings (CDC)
- Environmental Infection Control in Healthcare Settings (CDC)
- Perioperative Standards & Recommended Practices (AORN)
- Specialty Guidelines (SGNA*, Ortho, etc.)
- Other

*sgna.org

Reminder: staff must have easy access to any guidelines you use and reference in the description of your facility program.
National Guidelines

- If the facility neither selected (and documented) any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, they should be cited for a condition-level deficiency related to 42 CFR 416.51.
How Many IC Hours per Week?

- On average, how many IC hours per week?
- Note: §416.51(b)(1) does not specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.
What is Your System to Identify and Track Infections? Surveillance Method?

- ASC sends emails or survey forms to patient home post procedure
- ASC follows-up with primary care provider
- Physician/surgeon obtains infection information at post-op visit and notifies ASC
- ASC call patients post-op
- Others?
- Supporting documentation required
Infection Identification System

- If the facility does not have a documented identification system, a deficiency related to 42 CFR 416.51(b)(3) must be cited.
- If the facility does not have supporting documentation, a deficiency related to 42 CFR 416.51(b)(3) must be cited.
Notifiable Disease Reporting

- If the ASC does not have a reporting system, a deficiency **must** be cited related to 42 CFR 416.51(b)(3).
Infection Control Staff Education

**Frequently Asked Questions**

- Does everyone need training?
- How often must I provide education?
- Who can I use for education program and product support? Are web-based programs acceptable?
- Is it OK if I train my own employees even if I’m not an IP or experienced in infection control?
- Does CMS approve or endorse education programs?
Infection Control Education: CMS Documentation Requirement

- Is training documented?
- If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency must be cited in relation to 42 CFR 416.51(b) and (b)(3).
- If training is completely absent, then consideration should be given to condition-level citation, particularly when the ASC’s practices fail to comply with infection control standards of practice.
Infection Control Training

- If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC’s practices fail to comply with infection control standards of practice.
Infection Control Training

- NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency must be cited in relation to 42 CFR 416.51(b) and (b)(3).
- All levels of staff included, appropriate to job and ed level
Hand Hygiene

- After removing gloves
- Before direct patient contact
- After direct patient contact
- Before invasive procedures
- After contact with blood, body fluids or contaminated surfaces even if gloves are worn
Gloves Worn

- For procedures that might involve contact with blood or body fluids
- When handling potentially contaminated patient care equipment
- Gloves removed before going to the next task or patient
Surveyors are expected, as much as possible, to base their findings on observation. Staff interview and documentation review will also be included.

- Hand hygiene (including glove use)
- Proper use of PPE (bloodborne pathogens)
- Safe injection practices (including use of medication vials)
- Disinfection and sterilization
- Environmental infection control
- Safe use and handling of POC testing devices
Surveyor Observations

- The surveyor is required to examine more than just ASC documentation
- How many procedures were observed?
- Can the ASC refuse to allow the surveyor to observe in the OR?
ICWS: Hand Hygiene

What is the compliance in your ASC?

- Measured by observation, interview, both
- Soap and water available
- Alcohol-based hand rubs available
- ABHR installed correctly 42 CFR 416.44(b)(5)
- Need more information on installation?
  See NFPA Life Safety Code®
Gloves: Some Common Mistakes Seen in CMS Surveys

- Failure to clean hands after removing gloves
- Moving from patient to patient without changing gloves and cleaning hands
- Using ABHR on gloves (rather than changing gloves)
- Thinking double gloving protects against puncture injury
- Not having gloves accessible in locations where they are needed/used
ICWS: Safe Injection Practices are a Survey Priority!

The surveyor will inspect injectable medications, saline, other infusates to make sure that

- Needles are used for only one patient
- Syringes are used for only one patient
- Medication vials are always entered with new needle and syringe
- MDV labeled with expiration date 28 days after opening.
Injection Practices

The Surveyor Will Also Check:

- Single use vials used on only one patient
- Manufacturer pre-filled syringes used only on one patient
- Bags of IV solution used on only one patient
- Medication administration tubing and connectors used on only one patient
- Med vials & IV ports swabbed prior to each entry

Reminder: if the product or device is labeled “single use” it CANNOT be used again.
A Persistent Misconception – and *Dangerous* Practice!

The lack of a needle does NOT make a syringe reusable. A safety syringe with a blunt cannula (tip) or a luer connector must be used only once.

A syringe is never protected against contamination by changing the needle or by using needleless systems.

**Example:** 5cc needleless blunt plastic cannula syringe
DO CMS & CDC Permit Incremental Dosing? Yes, *but only when* . . .

- Same syringe, same drug
- Required intraoperatively
- No opportunity to reuse with another patient
- Most common scenario: anesthesia
Labeling Requirements are Strictly Enforced!

• ICWS: Medications that are pre-drawn are labeled with the time of draw, initials of the person drawing, medication name, strength and expiration date or time.

Reminder: There are NO acceptable “work arounds” or substitute practices to avoid using a label.
Inspection of Multi Dose Vials

- Multidose vials used on > 1 patient
  - Vial septum disinfected with alcohol before each entry
  - New needle and syringe used for each access
  - Vials are dated when first penetrated and discarded in 28 days or manufacturer’s expiration date, whichever comes first
  - Vials are not stored or accessed in immediate vicinity of the patient

Reminder: single dose and multi dose vials are not interchangeable. Drug cost/availability does not justify doing so.
CMS Memo 6.15.12

- Administering drugs from one SDV to multiple patients without adhering to USP <797> standards is not acceptable under CMS infection control regulations.

- Healthcare facilities that do not adhere to USP <797> standards but reuse SDVs for multiple patients must be cited for deficiencies under the applicable infection control standards.
Surveyors Will Look in More Than One Place for Injection Safety Deficiencies

Important Reminders

- Per CDC, medications should be drawn up as close to the time of use as possible (USP 797: 1 hour)
- Do not “carry over” pre drawn syringes from one day to the next; discard at the end of the day
- Do not spike & prime IV bags & sets the day before they will be used (USP 797: 1 hour)
- NEVER use a bag of saline for flush solution on multiple patients
- NEVER combine the “leftover” contents in partially used vials
Required Report to Public Health

- Use of the same needle for > one individual
- Use of the same (pre-filled /manufactured/ insulin or any other) syringe, pen or injection device for more than one individual
- Re-use of a needle or syringe that has been used to administer medications to an individual that is then entered into another medication container for the contents to be used for another individual
- Use of the same lancing/fingerstick device for more than one individual, even if the lancet is changed
Sharps Disposal

- Sharps disposed of in puncture-resistant sharps containers placed at point of use
- Containers are replaced when fill line is reached
- NIOSH/OSHA: Mounted 52-56” from floor to slot for standing use
- Biohazard labeled
- Located at point of use

http://www.cdc.gov/niosh/docs/97-111/
Disinfection and Sterilization

A Problem Prone Area in Many ASC Surveys!

- Surveyors will observe CDS practices
- Precleaning must always be performed
- Surgical instruments (entering normally sterile sites or vascular system) must be sterilized
- High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as flexible endoscopes, laryngoscope blades, vaginal specula, etc.)
ICWS: Sterilized Items

- Appropriately maintained and handled throughout the process
- Stored in designated clean areas
- Packages inspected for integrity, reprocessed if not intact
- No “wet packs”
Precleaning: Often Incomplete or Incorrect

- Instruments are precleaned per manufacturer’s or evidence-based guidelines
- Enzymatic cleaners often used
- Devices and instruments are inspected for residual soil and recleaned as necessary
- Proper cleaning tools are available, in good repair, e.g. scope brushes
- Appropriate PPE worn

Reminder: precleaning is essential because you cannot sterilize organic matter, debris or dirt!
When Instruments are Rinsed, is the Process Adequate?

Adequate rinsing is NOT a “bird bath” technique!

Surveyors know the difference. Make sure your techs do too!
Sterilization of Instruments

Surveyors will look for documentation that shows . . .

- Each load monitored with **mechanical indicators** for time, temperature, pressure
- **Chemical indicator** used in each load
- **Biological indicator** run at least weekly and with each load containing implants
- **Documentation** maintained for each load for each piece of sterilizing equipment
- Equipment has routine maintenance/preventive checks, documented

**Hint:** if staff think the autoclave works more or less like a microwave, you are probably NOT ready for your next survey.
“Immediate Use” Sterilization

What will trigger a deficiency? What is NOT acceptable?

• Performed routinely
• To avoid purchasing additional instruments
• To minimize instrument processing times or for staff convenience

The surveyor will look for evidence of

• Performing IUS often or every load
• Instruments are always or usually unwrapped
• Instruments are steam sterilized in open trays or not contained/covered in any way

Reminder: an unwrapped instrument must be protected from the time it is removed from the sterilizer until it is delivered to the sterile field.
Single Use Devices (SUDs)

- If reprocessed, the **device** is approved by FDA for reprocessing;
- Device is reprocessed by an **FDA-approved reprocessor**
- No ambulatory care facilities or ASCs have been approved by the FDA to reprocess

Reminder: if you are reprocessing any single use/disposable items **in your facility**, you are not only in violation of CMS CfCs, you are violating FDA law.
High-Level Disinfection

- Semi-critical equipment is high-level disinfected
- Performed on site or via contract service
- Items are precleaned, inspected, recleaned if necessary
- Documentation (log) supports that processes are safe and accurate
High-Level Disinfection

- HLD equipment is maintained per manufacturer’s instructions
- AERs: Do NOT skip precleaning
- Make sure specific reprocessing protocols are in place for each type of scope that you use
- Documentation of preventive maintenance of AERs and scopes

Remember: ECRI ranked cross-contamination from flexible endoscopes the #1 health technology hazard in 2010!
Chemicals in High Level Disinfection

- Prepared per manufacturer’s instructions
- Tested for appropriate concentration per manufacturer’s instructions (dipstick)
- Replaced according to manufacturer’s instructions
- Documentation of above
- Neutralize chemical before discarding (EPA)

**Remember:** Adverse respiratory reactions and skin sensitivities have resulted from staff exposure to some HLD chemicals. Know the directions for use and warnings specific to the chemical you use.
High-Level Disinfection of Endoscopes

The surveyor will investigate . . .

• Scopes are soaked for length of time specified on product label
• If using AER, proper connectors used
• Appropriate temperature maintained
• Scopes adequately dry before used again
• Scopes correctly stored (per manufacturer directions)

Reminder: are manufacturer instructions on file and available to staff if/when needed?
Environmental Infection Control

- Surveyors will observe cleaning
- ORs cleaned with EPA-registered disinfectant between cases/procedures
- ORs terminally cleaned daily (includes endoscopy suites)
- Special attention to high-touch surfaces
- Procedure for cleaning gross blood spills

**Reminder:** if you are using a vendor for cleaning, including terminal cleaning of ORs, how do you assure that their services meet infection control standards?
Point of Care Testing Devices

Most Common Example: **Blood Glucose Monitors**
- Labeled for multi-patient use
- New, auto-disabling lancet used each time
- Meter cleaned, disinfected after each use:
  - Follow manufacturer’s instructions
  - If no instructions, cannot be used on > 1 patient
  - Disinfectant must be effective against HBV & HIV
  - Dilute bleach solution is also effective but may be too corrosive for some equipment.

**ALCOHOL** is NEVER an acceptable disinfectant in shared-use situations!
Summary

• The ASC ICWS is proving to be an important survey tool in identifying actual and potential threats to patient safety.
• Use of the ICWS is expected to continue.
• CMS is currently modifying the ICWS for use in other provider/supplier surveys.
• Based on preliminary and recent findings, infection control practices in ASCs may be deficient and require rigorous attention and enforcement to protect patients.
Questions?
Thank you!

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