SSI Prevention, Surveillance and Reporting

Challenges in Hospitals and Ambulatory Surgery Centers

Tom Jordan, RN, BS
Director, Infection Prevention
Sentri7
Impact of SSIs

SSI Burden-US
~300,000 SSIs/yr (17% of all HAI; second to UTI)
2%-5% of patients undergoing inpatient surgery

Mortality
3 % mortality
2-11 times higher risk of death
75% of deaths among patients with SSI are directly attributable to SSI

Morbidity
long-term disabilities

Impact of SSIs


http://www.hhs.gov/ash/initiatives/hai/introduction.html
Impact of SSIs

Length of Hospital Stay

~7-10 additional postoperative hospital days

Cost

$3000-$29,000/SSI depending on procedure & pathogen

Up to $10 billion annually

Most estimates are based on inpatient costs at time of index operation and do not account for the additional costs of rehospitalization, post-discharge outpatient expenses, and long term disabilities

Impact of SSIs

• 174,425 patients underwent hip or knee replacement in 2007

• 2,134 (1.2 percent) were hospitalized for a surgical site infection (SSI) within one year following their procedure (in 2008).

• Of those, 267 (12.5 percent) re-hospitalized in the year after the initial SSI hospitalization (in 2009) specifically due to SSI-related issues, for a total of 384 hospitalizations

• Subsequent rehospitalizations for SSI were associated with an average hospital stay of 8.6 days, costing on average $26,812.

Impact of HAIs

Scribbled note from a patient on a ventilator...

“When will this horror end?”
The attributable impact of MRSA on outcomes of surgical patients is substantial.

Preventing a single case of SSI due to MRSA can save hospitals as much as $60,000.

MRSA was associated with:

1. 5.5 days of additional hospitalization

1. $24,113 of additional charges
Pathogenic Sources

Endogenous

Patient flora
Skin
Mucous membranes
GI tract
Seeding from a distant focus of infection

http://www.cdc.gov/HAI/ssi/ssi.html#prev
Pathogenic Sources

Exogenous

Surgical Personnel (surgeon and team)
Soiled attire
Inadequate hand hygiene
OR physical environment and ventilation
Tools, equipment, materials brought to the operative field
Breaks in aseptic technique
Cleaning/Sterilization Failure

http://www.cdc.gov/HAI/ssi/ssi.html#prev
Emerging Challenges

Challenges in detecting SSIs
Lack of standardized methods for post-discharge/outpatient surveillance
  Increased number of outpatient surgeries
  Shorter postoperative inpatient stays

Antimicrobial Prophylaxis
Increasing trend toward resistant organisms may undermine the effectiveness of existing recommendations for antimicrobial prophylaxis

http://www.cdc.gov/HAI/ssi/ssi.html#prev
Whether a SSI occurs is dependent upon a complex interaction between numerous factors including:

1. The nature and number of organisms contaminating the surgical site
2. The health of the patient
3. The skill and technique of the surgeon
Risk Factors

Other defined risk factors include:
• Diabetes
• Obesity
• Cigarette smoking
• Systemic corticosteroids or treatment with other immunosuppressive drugs
• Malnutrition

Modifiable Risk Factors

Excessive OR traffic

Inadequate wound dressing protocol

Improper glucose control

Colonization with preexisting microorganisms

Inadequate intraoperative oxygen levels

http://www.cdc.gov/HAI/ssi/ssi.html#prev
Risk Factors

• Preoperative nasal carriage or colonization at other sites with S. aureus
• The presence of a remote focus of infection

• Duration of preoperative hospitalization

• The preoperative severity of illness of the patient

• Contamination of the surgical site by flora from the operating room environment or personnel.

• Anal, vaginal, or nasopharyngeal carriage of group A streptococci by operating room personnel
Modifiable Risk Factors

Antimicrobial prophylaxis

- Inappropriate choice (procedure specific)
- Improper timing (pre-incision dose)
- Inadequate dose based on body mass index, procedures >3h, or increased blood loss

Skin or site preparation ineffective

- Removal of hair with razors

Colorectal procedures

- Inadequate bowel prep/antibiotics
- Improper intraoperative temperature regulation

http://www.cdc.gov/HAI/ssi/ssi.html#prev
Proud Parents of Hand Hygiene

Ignaz Semmelweis
Philadelphia - 1993 Movie - Tom Hanks Won Oscar
•1847 - Friend of Semmelweis incurred BBP Exposure during autopsy

•Died of pathology similar to women dying of puerpal fever

•Semmelweis made the contamination connection
Puerperal fever mortality rates for the First and Second Clinic at the Vienna General Hospital 1841–1846. (Data for more years are available.)

<table>
<thead>
<tr>
<th>Year</th>
<th>First clinic</th>
<th>Second clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year</td>
<td>Births</td>
</tr>
<tr>
<td>1841</td>
<td>3,036</td>
<td>237</td>
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<tr>
<td>1842</td>
<td>3,287</td>
<td>518</td>
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<tr>
<td>1843</td>
<td>3,060</td>
<td>274</td>
</tr>
<tr>
<td>1844</td>
<td>3,157</td>
<td>260</td>
</tr>
<tr>
<td>1845</td>
<td>3,492</td>
<td>241</td>
</tr>
<tr>
<td>1846</td>
<td>4,010</td>
<td>459</td>
</tr>
</tbody>
</table>
April 1847 - Mortality = 18.3%
May - handwashing introduced
June = 2.2%
July = 1.2%
1. Appropriate Use of Prophylactic Antibiotics
   - Prophylactic antibiotic received within 1 hour prior to surgical incision*

   - Prophylactic antibiotic selection for surgical patients consistent with national guidelines (as defined in JC/CMS Specification Manual and SCIP for Measure SCIP-Inf-2)

   - Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac patients)

*Due to the longer infusion time required for Vancomycin, it is acceptable to start this antibiotic (e.g., when indicated because of beta-lactam allergy or high prevalence of MRSA) within 2 hours prior to incision.


Use preprinted or computerized standing orders specifying antibiotic, timing, dose, and discontinuation.

- Develop pharmacist- and nurse-driven protocols that include preoperative antibiotic selection and dosing based on surgical type and patient-specific criteria (age, weight, allergies, renal clearance, etc.).

- Change operating room drug stocks to include only standard doses and standard drugs, reflecting national guidelines.
Timely Antibiotic Administration - Process

Use preprinted or computerized standing orders specifying antibiotic, timing, dose, and discontinuation.

- Assign dosing responsibilities to anesthesia or designated nurse (e.g., pre-op holding or circulator) to improve timeliness.

- Involve pharmacy, infection control, and infectious disease staff to ensure appropriate timing, selection, and duration.

- Verify administration time during –time-out or pre-procedural briefing so action can be taken if not administered.

1. Appropriate Hair Removal

Ensure adequate supply of clippers and train staff in proper use.

- Use reminders (signs, posters).
- Educate patients not to self-shave preoperatively.
- Remove all razors from the entire hospital.
- Work with the purchasing department so that razors are no longer purchased by the hospital.
Perioperative Glucose Control

The degree of hyperglycemia in the postoperative period in cardiac procedures has been correlated with the rate of SSI in patients undergoing major cardiac surgery.

*Glucose control is defined as serum glucose levels below 200 mg/dl, collected at or closest to 6:00 AM on each of the first two postoperative days.*
Implement one standard glucose control protocol for cardiac surgery.

- Regularly check preoperative blood glucose levels on all patients to identify hyperglycemia

- Assign responsibility and accountability for blood glucose monitoring and control.
Clinical hypothermia during surgery can result from:

- Anesthesia
- Anxiety
- Wet skin preparations
- Skin exposure in cold operating rooms
Prevention of Perioperative Hypothermia

Prevent hypothermia at all phases of the surgical process.

- Use warmed forced-air blankets preoperatively, during surgery, and in PACU.
- Use warmed fluids for IVs and flushes in surgical sites and openings.
- Use warming blankets under patients on the operating table.
- Use hats and booties on patients perioperatively.
- Adjust engineering controls so that operating rooms and patient areas are not permitted to become excessively cold overnight, when many rooms are closed.
- Measure temperature with a standard type of thermometer.
The evidence suggests that preoperative antiseptic showers reduce bacterial colonization and may be effective at preventing SSIs

**Preop Skin Prep for Preventing Surgical Site Infections**
*Infection Control and Hospital Epidemiology, June 29, 2012*
## Parameters for Controlled Environments During Sterilization

<table>
<thead>
<tr>
<th>Functional area</th>
<th>Airflow</th>
<th>Minimum number of air exchanges per hour</th>
<th>All air exhausted directly to the outdoors</th>
<th>Temperature</th>
<th>Relative humidity</th>
</tr>
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<tbody>
<tr>
<td>Soiled/decontaminated</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
<td>60°F to 65°F (16°C to 18°C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Sterilizer equipment access</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
<td>75°F to 85°F (24°C to 29°C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Sterilizer loading/unloading</td>
<td>Positive (out)</td>
<td>10</td>
<td>Yes</td>
<td>68°F to 73°F (20°C to 23°C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Restrooms/housekeeping</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
<td>≤ 75°F (≤ 24°C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Preparation and packaging</td>
<td>Positive (out)</td>
<td>10 (downdraft type)</td>
<td>No</td>
<td>68°F to 73°F (20°C to 23°C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Textile packaging room</td>
<td>Positive (out)</td>
<td>10 (downdraft type)</td>
<td>No</td>
<td>68°C to 73°F (20°C to 23°C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Clean/sterile storage</td>
<td>Positive (out)</td>
<td>4 (downdraft type)</td>
<td>No</td>
<td>≤ 75°F (≤ 24°C)</td>
<td>≤ 70%</td>
</tr>
</tbody>
</table>

### Reference
A True Story
A True Story

5 Post Spinal Fusion SSIs with readmission in 7 months

3 cases required return to surgery
Peri-operative Processes

Preadmission Testing

• MRSA Screens

• Chlorhexedine Showers for Total Joint

• Shaving at home
Operative Processes

Day of Surgery:

• Pre-op

• Holding
Central Sterilization

Operating Room

Multi-disciplinary Observations and Interviews

Learn, Observe, Interview, Research
Operative Processes

The OR:

Neutral Observers (IP, Risk Management, CQO, CMO)

Cleaning of room from prior case

Antibiotic administration process and timing
Operative Processes

The OR:

Temp/humidity

Room set up

Hand scrub technique

Patient skin prep
Operative Processes

The OR:

Number of people in room during case
Technique

Equipment

Room traffic
Observations - Standardization?
Manufacturers’ Written Instructions

Not having or following manufacturer’s written instructions for processing devices is a significant and common misstep.

One copy should be placed in the decontamination area to reference cleaning protocols.

One copy should go in the prep/packaging area for reference how to prepare/sterilize the device.

Nancy Chobin, RN, AAS, ACSP, CSPDM, a consultant and CS/SPD educator for the Saint Barnabas Health Care System in New Jersey
Common Mistakes in Central Sterilization

“As a ‘manufacturing center’, the Central Sterilization Department must ensure that all employees follow the stated policies to enhance consistency in all processes.

Examples of some of the types of audits that should be performed include (but are not limited to):

- Tray audits
- Sterilization record audits
- Instrument preparation audits, etc.”

Operation of equipment and machines

Parameters
Common Mistakes in Central

Common SPD Mistakes and How to Solve Them  4/29/09 - ICT

1. Temperature and humidity not recorded daily or controlled properly for staff comfort and to limit microbial growth. Decontamination should be controlled between 60 degrees F and 65 degrees F (16 degrees C to 18 degrees C), general work areas between 68 degrees F to 73 degrees F (20 degrees C to 23 degrees C) and sterile storage not to exceed 75 degrees F (24 degrees C). Relative humidity should be controlled between 30 percent and 60 percent.

2. Not wearing a face mask to protect against aerosols when manually cleaning soiled items in the decontamination department.

3. Improper loading of mechanical washers, i.e., layered trays, inserts and rigid container filter plates not separated to allow full contact with cleaning/disinfection solution.
4. Lack of individual instrument inspection for cleanliness and function during tray assembly.

5. Paper/plastic peel pouches and/or count sheets placed inside wrapped sets or rigid containers. The plastic side of pouches can inhibit proper sterilization or drying of the set, and the chemicals inside the paper or ink of count sheets may be toxic. Cytotoxicity testing can validate the safety of count sheets.

6. Incorrect sterilizer parameters selected for processing complex devices and/or heavy instrument sets, i.e., orthopedics. Many healthcare facilities do not maintain each manufacturer’s validated reprocessing instructions to teach staff the proper cycle selection. This is true in the SPD as well as operating rooms where flashing occurs.
Common SPD Mistakes and How to Solve Them 4/29/09 - ICT

7. Sterilized items are not allowed to cool properly before handling/distribution. A minimum of 30 minutes is recommended, with some heavy trays needing one to two hours. Handling processed items before they have cooled can compromise the integrity of the package’s barrier system.

8. Wrapped trays being stacked on top of each other in sterile storage. Rigid containers may be stacked during storage, but the compression of heavy wrapped trays can compromise sterility of both trays.

9. Lack of daily cleaning and disinfection of floors, work stations and frequently touch items, i.e., telephone, door handles; and lack of any cleaning schedule for sterilizers, vents, walls, ceilings as well as storage bins, racks and carts.

10. SPD personnel not 100 percent certified and/or actively involved in local SPD chapters.
Cleaning & Decontamination

Manufacturer Instructions for:
• Type of water; compressed air
• Cleaning equipment
• Accessories (eg, adaptors) for creating connection between instrument and equipment
• Accessories for cleaning lumens, ports, internal and cannulated parts
• Cleaning agents
• Lubricants
• Processing methods
Sharp Safety in Central

Segregate Sharps from other instruments.

Ensure staff members are not using hands to search for sharps.
Loaner Instruments/Trays

Should be:

1. Examined
2. Cleaned
3. Decontaminated
4. Sterilized

By the receiving health care organization before use, according to manufacturer’s written instructions.
Ultrasonic Cleaners

Ultrasonic Cleaner (UC) in the cleaning of instruments and devices should be determined by the health care facility.

UC cleans, but does not disinfect or sterilize the items.

Check manufacturer recommendations for cleaning solvent to be included.
Ultrasonic Cleaners

Use a process called cavitation that facilitates removal of small particles and debris from instrument:
- Joints
- Crevices
- Hard to reach places such as lumens.

Should only be used after gross soil has been removed.

Instruments with lumens should be fully submerged and filled with cleaning solution to remove air from within channel.

Instruments should be thoroughly rinsed after ultrasonic cleaning.

UC should be emptied, cleaned, rinsed with water and chamber wiped with manufacturer-recommended disinfectant.

Fluid in UC can harbor gram-negative bacteria. This can result in production of endotoxins, which:
- are heat-resistant
- can survive steam sterilization

Endotoxins from contaminated eye instruments have caused toxic anterior segment syndrome (TASS), an acute inflammation of the anterior segment of the eye.
Automated Washer Decontaminators

Cycles process instruments and equipment to a level that renders them safe to handle by persons who will inspect and prepare them for terminal sterilization.

Can have a single chamber for rinsing, cleaning and drying or can use multiple chambers.

Phases include:
• An initial cool-water rinse to remove protein debris
• An enzymatic rinse
• Detergent wash
• Ultrasonic cleaning
• Sustained hot-water rinse
• Lubrication rinse
• Liquid chemical germicide rinse
• Drying cycle
Table 7. Minimum cycle times for steam sterilization cycles

<table>
<thead>
<tr>
<th>Type of sterilizer</th>
<th>Item</th>
<th>Exposure time at 250°F (121°C)</th>
<th>Exposure time at 270°F (132°C)</th>
<th>Drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity displacement</td>
<td>Wrapped instruments</td>
<td>30 min</td>
<td>15 min</td>
<td>15-30 min</td>
</tr>
<tr>
<td></td>
<td>Textile packs</td>
<td>30 min</td>
<td>25 min</td>
<td>15 min</td>
</tr>
<tr>
<td></td>
<td>Wrapped utensils</td>
<td>30 min</td>
<td>15 min</td>
<td>15-30 min</td>
</tr>
<tr>
<td>Dynamic-air-removal (e.g., prevacuum)</td>
<td>Wrapped instruments</td>
<td></td>
<td>4 min</td>
<td>20-30 min</td>
</tr>
<tr>
<td></td>
<td>Textile packs</td>
<td>4 min</td>
<td>5-20 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wrapped utensils</td>
<td>4 min</td>
<td>20 min</td>
<td></td>
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</table>
Case Cart Wash
Cleaned surgical instruments should be organized for packaging in a manner to allow the sterilant to contact all exposed surfaces.
Assembly

Instruments should be placed in a container tray or basket that is large enough to evenly distribute the metal mass in a single layer.

Broad-surfaced instruments and those with concave surfaces (malleable retractors, hips skids) should be placed on edge.

Instruments with hinges should be opened and those with removable parts should be disassembled when placed in trays.
Assembly

Sterilization only occurs only on surfaces that have direct contact with the sterilant.

Disassembly of multiple-part instruments and those with sliding parts (retractors) enables the sterilant to contact all surfaces.

Instruments should be kept in the open and unlocked position using instrument stringers, racks, etc.

Heavy instruments should be positioned on the bottom of trays.

Stylets should be removed from lumens to enable sterilant contact with the inside of lumens.
Powered surgical instruments and all attachments should be decontaminated, lubricated, assembled, sterilized and tested before use according to manufacturer’s written instructions.
## Controlled Environments for Sterilization

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<tr>
<td>Sterilizer equipment access</td>
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<td>Yes</td>
<td>75° F to 85° F (24° C to 29° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Sterilizer loading/unloading</td>
<td>Positive (out)</td>
<td>10</td>
<td>Yes</td>
<td>68° F to 73° F (20° C to 23° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Restrooms/housekeeping</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
<td>≤ 75° F (≤ 24° C)</td>
<td>30% to 60%</td>
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<td>Clean/sterile storage</td>
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<td>4 (downdraft type)</td>
<td>No</td>
<td>≤ 75° F (≤ 24° C)</td>
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</tr>
</tbody>
</table>

**Reference**

Table 12. Suggested protocol for management of positive biological indicator in a steam sterilizer.

1. Take the sterilizer out of service. Notify area supervisor and infection control department.
2. Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective. As soon as possible, repeat biological indicator test in three consecutive sterilizer cycles. If additional spore tests remain positive, the items should be considered nonsterile, and supplies processed since the last acceptable (negative) biological indicator should be recalled. The items from the suspect load(s) should be recalled and reprocessed.
3. Check to ensure the sterilizer was used correctly (e.g., verify correct time and temperature setting). If not, repeat using appropriate settings and recall and reprocess all inadequately processed items.
4. Check with hospital maintenance for irregularities (e.g., electrical) or changes in the hospital steam supply (i.e., from standard ≥97% steam, <3% moisture). Any abnormalities should be reported to the person who performs sterilizer maintenance (e.g., medical engineering, sterilizer manufacturer).
5. Check to ensure the correct biological indicator was used and appropriately interpreted. If not, repeat using appropriate settings.

If steps 1 through 5 resolve the problem
6. If all three repeat biological indicators from three consecutive sterilizer cycles (step 2 above) are negative, put the sterilizer back in service.

If one or both biological indicators are positive, do one or more of the following until problem is resolved.
7. A. Request an inspection of the equipment by sterilizer maintenance personnel.
   B. Have hospital maintenance inspect the steam supply lines.
   C. Discuss the abnormalities with the sterilizer manufacturer.
   D. Repeat the biological indicator using a different manufacturer’s indicator.

If step 7 does not resolve the problem
   Close sterilizer down until the manufacturer can assure that it is operating properly. Retest at that time with biological indicators in three consecutive sterilizer cycles.

Modified from Bryce.
Flash Sterilization

“Whoa. Watch where that things lands, we’ll probably need it!”
Flash Sterilization

a. Do not flash sterilize implanted surgical devices unless doing so is unavoidable. *Category IB. 849, 850*

b. Do not use flash sterilization for convenience, as an alternative to purchasing additional instrument sets, or to save time. *Category II. 817, 962*
c. When using flash sterilization, make sure the following parameters are met:

1) clean the item before placing it in the sterilizing container (that are FDA cleared for use with flash sterilization) or tray
2) prevent exogenous contamination of the item during transport from the sterilizer to the patient
3) monitor sterilizer function with mechanical, chemical, and biologic monitors. *Category IB. 812, 819, 846, 847, 962*
# Flash Steam Sterilization Parameters

<table>
<thead>
<tr>
<th>Type of sterilizer</th>
<th>Load configuration</th>
<th>Time</th>
<th>Exposure Temperature</th>
<th>Drying Times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity displacement</td>
<td>Metal or nonporous items only (i.e., no lumens)</td>
<td>3 min</td>
<td>270° F–275° F (132° C–135° C)</td>
<td>0 to 1 min</td>
</tr>
<tr>
<td></td>
<td>Metal items with lumens and porous items (e.g., rubber, plastic) sterilized together</td>
<td>10 min</td>
<td>270° F–275° F (132° C–135° C)</td>
<td>0 to 1 min</td>
</tr>
<tr>
<td>Dynamic air-removal (prevacuum)</td>
<td>Metal or nonporous items only (i.e., no lumens)</td>
<td>3 min</td>
<td>270° F–275° F (132° C–135° C)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Metal items with lumens and porous items sterilized together</td>
<td>4 min</td>
<td>270° F (132° C)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 min</td>
<td>275° F (135° C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- The sterilizer manufacturer’s instructions for use of express cycles should be followed. One sterilizer manufacturer provides an express flash cycle that permits flash sterilization with a single-ply wrapper to help contain the device to the point of use. This cycle is not recommended for devices with lumens. Express cycles should only be used if the sterilizer is designed with this feature.
- Steam-flush pressure-pulse: See manufacturers’ written instructions for time and temperature.
- This table does not include specific instructions for rigid flash sterilization containers. The container manufacturer’s instructions should be followed.

**Reference**

Integrity of Sterile Wrap
Value Based Purchasing

• Centers for Medicare and Medicaid Services (CMS) has aggressively embraced a Value Based Purchasing (VBP) model.

• CMS transformed from a passive payer for services to a prudent (pay for performance) purchaser of services

• Paying for Quality of Services AND cost effectiveness AND Patient Outcomes
Value-based Purchasing

The concept of value-based health care purchasing...

“Buyers should hold providers of health care accountable for both cost and quality of care”

Meyer, Rybowski, and Eichler, 1997
Pay for Performance is a type of value-based purchasing that provides an incentive-based reimbursement system.

Financial incentives reward providers for achieving a range of payer objectives.
Proliferation of ASCs

Between 1999 and 2005, Medicare payments (facility fees) to ASCs increased from $1.2 billion to $2.8 billion,

An annualized rate of growth of 15.3% reflecting a more than 3-fold increase in the number of procedures performed in the outpatient setting.

Some evidence also suggests that cases of higher complexity are now being performed in the ASC setting and involving patients with greater comorbidities.
The number of Medicare-certified ASCs:

1999 = 2786 ASCs
2005 = 4506 ASCs
2008 = 5174 ASCs

Annual Growth Rate from 1999 to 2005 = 8.3%
Annual Growth Rate from 2001 to 2008 = 6.3%

Barie, P. Infection Control Practices in Ambulatory Surgical Centers JAMA. 2010;303(22):2295-2297
However, total Medicare payments to ASCs increased by only 4.6% between 2007 and 2008 ($3 billion in 2008).

In part due to a provision in the Deficit Reduction Act of 2005, which capped the ASC rate for each service at the outpatient prospective payment rate.

61% of ASCs are exclusively physician-owned

96% operate on a for-profit basis
In 2008, SSAs in Maryland, North Carolina, and Oklahoma incorporated an infection control audit tool, based upon CDC guidelines (e.g., Standard Precautions), into their routine ASC survey process.

Over two-thirds of the facilities surveyed in the pilot had lapses in infection control and prevention identified by surveyors and half of the facilities had not undergone a full inspection in more than five years.
46 of 68 ASCs were impacted by at least 1 lapse in infection control

12 of 68 ASCs 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 of 64; 28.1%); failing to adhere to recommended practices regarding reprocessing of equipment (19 of 67; 28.4%), and lapses in handling of blood glucose monitoring equipment (25 of 54; 46.3%).
### Table 3. Types of Lapses Identified in the Pilot Ambulatory Surgical Centers by Facility Type

<table>
<thead>
<tr>
<th>Infection Control Category</th>
<th>Single-Purpose Endoscopy ASCs With Lapses Identified</th>
<th>All Other Facility Types With Lapses Identified</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand hygiene and personal protective equipment</td>
<td>4/20 (20.0) [6.7-41.5]</td>
<td>8/41 (19.5) [9.5-33.7]</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Injection safety and medication handling</td>
<td>6/21 (28.6) [12.5-50.2]</td>
<td>13/45 (28.9) [17.1-43.3]</td>
<td>.98</td>
</tr>
<tr>
<td>Equipment reprocessing (eg, sterilization and high-level disinfection)</td>
<td>5/21 (23.8) [9.3-45.2]</td>
<td>14/45 (31.1) [18.9-45.7]</td>
<td>.54</td>
</tr>
<tr>
<td>Environmental cleaning</td>
<td>1/21 (4.8) [0.2-21.3]</td>
<td>11/42 (26.2) [14.6-41.0]</td>
<td>.05</td>
</tr>
<tr>
<td>Handling of blood glucose monitoring equipment</td>
<td>5/17 (29.4) [11.7-53.7]</td>
<td>19/36 (52.8) [35.6-68.6]</td>
<td>.11</td>
</tr>
</tbody>
</table>

Abbreviation: ACSs, ambulatory surgical centers.
Table 1. Types of Procedures Performed at the Pilot Ambulatory Surgical Centers<sup>a</sup>

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>No. (%)</th>
<th>[95% Confidence Interval]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maryland (n = 32)</td>
<td>North Carolina (n = 15)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Dental</td>
<td>4 (12.5) [4.1-27.5]</td>
<td>4 (26.7) [9.1-52.5]</td>
</tr>
<tr>
<td>Endoscopy</td>
<td>15 (46.9) [30.2-64.1]</td>
<td>7 (46.7) [23.2-71.3]</td>
</tr>
<tr>
<td>General</td>
<td>4 (12.5) [4.1-27.5]</td>
<td>5 (33.3) [13.4-59.2]</td>
</tr>
<tr>
<td>Gynecology</td>
<td>7 (21.9) [10.1-38.6]</td>
<td>3 (20.0) [5.4-45.4]</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>5 (15.6) [6.0-31.3]</td>
<td>7 (46.7) [23.2-71.3]</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>7 (21.9) [10.1-38.6]</td>
<td>6 (40.0) [18.1-65.5]</td>
</tr>
<tr>
<td>Otolaryngology</td>
<td>6 (18.8) [8.0-35.0]</td>
<td>4 (26.7) [9.1-52.5]</td>
</tr>
<tr>
<td>Pain</td>
<td>7 (21.9) [10.1-38.6]</td>
<td>6 (40.0) [18.1-65.5]</td>
</tr>
<tr>
<td>Plastic surgery</td>
<td>7 (21.9) [10.1-38.6]</td>
<td>7 (46.7) [23.2-71.3]</td>
</tr>
<tr>
<td>Podiatry</td>
<td>7 (21.9) [10.1-38.6]</td>
<td>6 (40.0) [18.1-65.5]</td>
</tr>
<tr>
<td>Other&lt;sup&gt;c&lt;/sup&gt;</td>
<td>4 (12.5) [4.1-27.5]</td>
<td>5 (33.3) [13.4-59.2]</td>
</tr>
</tbody>
</table>

<sup>a</sup>Column totals do not equal 100% as facilities might perform more than 1 procedure type.

<sup>b</sup>One audit tool from North Carolina did not include information regarding types of procedures performed.

<sup>c</sup>Procedures in this category included dermatology and urology.
CMS is now requiring all states to use the infection control audit tool and case tracer method for ASC inspections.

ASCs cited for deficient practices are required to correct them; ASCs that fail to correct serious deficiencies risk termination of their participation in Medicare.

CMS and CDC have provided in-depth infection control training sessions for surveyors, making CMS Regional Office physicians available to accompany surveyors on inspections, and arranging consultations with experienced personnel when questions arise.
State-mandated reporting - ASCs

HAI Reporting in Ambulatory Surgical Centers

State HAI Laws that Include Reporting by ASCs

No HAI reporting required
HAI reporting required

Last updated 3/12

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/Amb_map.gif
Timing of Prophylactic Antibiotics in ASCs

Percentage of ASC admissions with antibiotics ordered who received antibiotics on time

<table>
<thead>
<tr>
<th>Reporting Period</th>
<th>1Q2011</th>
<th>2Q2011</th>
<th>3Q2011</th>
<th>4Q2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Participating ASCs</td>
<td>877</td>
<td>1,035</td>
<td>1,034</td>
<td>1,029</td>
</tr>
<tr>
<td>Number of ASC Admissions Represented</td>
<td>906,691</td>
<td>1,099,661</td>
<td>1,030,200</td>
<td>1,046,623</td>
</tr>
<tr>
<td>Percentage of ASC Admissions with antibiotic ordered who received antibiotic on time</td>
<td>97 %</td>
<td>98%</td>
<td>98%</td>
<td>98%</td>
</tr>
</tbody>
</table>

Represents the experience of 1,046,623 ASC admissions with antibiotics ordered seen at 1,029 facilities between October 1 and December 31, 2011

The data trends for this measure over the last four quarters are presented below in both tabular and graphical formats.

Data Summary: Prophylactic IV Antibiotic Timing

http://www.ascquality.org/qualityreport.cfm#Antibiotic
State Operations Manual - ASCs

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51 Condition for Coverage – Infection control

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

Interpretive Guidelines: §416.51

State Operations Manual
Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

(Rev. 76, 12-22-11)

Transmittals for Appendix L

Part I - Ambulatory Surgical Center Survey Protocol

National Action Plan to Prevent HAIs:

Roadmap to Elimination
AMBULATORY SURGICAL CENTERS

Oversight of Medicare-certified ASCs

To assure compliance with the Conditions for Coverage (CfCs), which include minimum health and safety standards oversight is provided by the State Survey Agencies (SSAs) or any of the four accrediting organizations (AOs) that have approved Medicare accreditation programs.

http://www.hhs.gov/ash/initiatives/hai/ambulatory_surgical_centers.html
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 endorsed and are applicable to ASCs;

Identify areas where 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 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 SSI definitions and methods should be developed; and,
- Establish a multi-year plan and phased approach to support their routine surveillance.
Roadmap to Elimination
AMBULATORY SURGICAL CENTERS

Broad Financial Incentives
Congress authorized a 2.0% payment linkage for ASC’s to report quality data in Section 109(b) of the Tax Relief and Health Care Act of 2006.

In the CY 2012 OPPS/ASC final rule with comment period, CMS finalized its proposal to implement an ASC Quality Reporting Program beginning with the CY 2014 payment determination and finalized measures for the CYs 2014, 2015, and 2016 payment determinations (76 FR 74494, 74504, 74509, 74510, Nov. 30, 2011).
Roadmap to Elimination
AMBULATORY SURGICAL CENTERS

Broad Financial Incentives

For the CY 2016 payment determination, CMS adopted Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), with data collection beginning on October 1, 2014 and continuing through March 31, 2015 (76 FR 74510)
National Action Plan to Prevent HAIs:

Roadmap to Elimination
AMBULATORY SURGICAL CENTERS

Broad Financial Incentives

CMS also adopted “Prophylactic Intravenous (IV) Antibiotic Timing” (NQF #0264) for the CYs 2014, 2015, and 2016 payment determinations.
Tracer Methodology

A minimum of one surgical procedure must be observed during the site visit, unless the ASC is a low volume ASC with no procedures scheduled during the site visit.

The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices.

I. Hand Hygiene

II. Injection Practices (injectable meds, saline, other infusates). Observations of ... anesthesiologists, CRNAs, Nurses

III. Single Use Devices, Sterilization, and High Level Disinfection

IV. Environmental Infection Control

V. Point of Care Devices (e.g., blood glucose meter)

INFECTION CONTROL PROGRAM

15. Does the ASC have an explicit infection control program?
   ☐ YES ☐ NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 must be cited.

16. Does the ASC’s infection control program follow nationally recognized infection control guidelines? ☐ YES ☐ NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) must be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.
18. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC?  
○ YES  
○ NO

18a. If YES, how does the ASC obtain this information?  
○ The ASC sends e-mails to patients after discharge  
○ The ASC follows-up with their patients’ primary care providers after discharge  
○ The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC  
○ Other (please *print*):

18b. Is there supporting documentation confirming this tracking activity?  
○ YES  
○ NO
III. Single Use Devices, Sterilization, and High Level Disinfection

Pre-cleaning must always be performed prior to sterilization and high-level disinfection.

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments).

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 reusable flexible endoscopes, laryngoscope blades).

Observations are to be made of staff who perform equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.
# Ambulatory Surgical Center

## INFECTION CONTROL SURVEYOR WORKSHEET

<table>
<thead>
<tr>
<th><strong>STERILIZATION</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Critical equipment is sterilized</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Yes</td>
<td>○ Observation</td>
<td></td>
</tr>
<tr>
<td>○ No</td>
<td>○ Interview</td>
<td></td>
</tr>
<tr>
<td>○ N/A</td>
<td>○ Both</td>
<td></td>
</tr>
</tbody>
</table>

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Are sterilization procedures performed on-site?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(If NO, skip to “F”)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Yes</td>
<td>○ Observation</td>
<td></td>
</tr>
<tr>
<td>○ No</td>
<td>○ Interview</td>
<td></td>
</tr>
<tr>
<td>○ N/A</td>
<td>○ Both</td>
<td></td>
</tr>
</tbody>
</table>

(A “No” answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.)

(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a. If YES to B, please indicate method of sterilization:</td>
<td></td>
</tr>
<tr>
<td>○ Steam autoclave</td>
<td></td>
</tr>
<tr>
<td>○ Peracetic acid</td>
<td></td>
</tr>
<tr>
<td>○ Other <em>(please write)</em></td>
<td></td>
</tr>
</tbody>
</table>

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Items are pre-cleaned according to manufacturer’s instructions or evidence-based guidelines prior to sterilization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Yes</td>
<td>○ Observation</td>
<td></td>
</tr>
<tr>
<td>○ No</td>
<td>○ Interview</td>
<td></td>
</tr>
</tbody>
</table>
## Ambulatory Surgical Center
### INFECTION CONTROL SURVEYOR WORKSHEET

<table>
<thead>
<tr>
<th>Practices to be Assessed</th>
<th>Was Practice Performed?</th>
<th>Manner of Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>D.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization</td>
<td>○ Yes</td>
<td>○ Observation</td>
</tr>
<tr>
<td></td>
<td>○ No</td>
<td>○ Interview</td>
</tr>
<tr>
<td></td>
<td>○ N/A</td>
<td>○ Both</td>
</tr>
<tr>
<td>b. A chemical indicator is placed in each load</td>
<td>○ Yes</td>
<td>○ Observation</td>
</tr>
<tr>
<td></td>
<td>○ No</td>
<td>○ Interview</td>
</tr>
<tr>
<td></td>
<td>○ N/A</td>
<td>○ Both</td>
</tr>
<tr>
<td>c. A biologic indicator is performed at least weekly and with all implantable loads</td>
<td>○ Yes</td>
<td>○ Observation</td>
</tr>
<tr>
<td></td>
<td>○ No</td>
<td>○ Interview</td>
</tr>
<tr>
<td></td>
<td>○ N/A</td>
<td>○ Both</td>
</tr>
<tr>
<td>d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)</td>
<td>○ Yes</td>
<td>○ Observation</td>
</tr>
<tr>
<td></td>
<td>○ No</td>
<td>○ Interview</td>
</tr>
<tr>
<td></td>
<td>○ N/A</td>
<td>○ Both</td>
</tr>
<tr>
<td>e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load</td>
<td>○ Yes</td>
<td>○ Observation</td>
</tr>
<tr>
<td></td>
<td>○ No</td>
<td>○ Interview</td>
</tr>
<tr>
<td></td>
<td>○ N/A</td>
<td>○ Both</td>
</tr>
</tbody>
</table>

### Ambulatory Surgical Center

#### INFECTION CONTROL SURVEYOR

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Observation</th>
<th>Interview</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>G. Sterile packages are inspected for integrity and compromised packages are reprocessed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H. Additional breaches in sterilization practices not captured by the questions above were identified (If YES, please specify further in comments)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
National Action Plan to Prevent HAIs:

Roadmap to Elimination
AMBULATORY SURGICAL CENTERS

Instructional letter is available on-line at:
Injection Safety
Every Provider’s Responsibility

Evelyn McKnight’s Story

Dr. Evelyn McKnight, mother of three, was battling breast cancer and was infected with hepatitis C during treatment because of syringe reuse to access saline flush solution.

Along with Evelyn, a total of 99 cancer patients were infected in what was one of the largest outbreaks of hepatitis C in American healthcare history.

Evelyn co-founded HONOReform, a foundation dedicated to improving America’s injection safety practices, and was the catalyst of the formation of the Safe Injection Practices Coalition.

Three Things Every Provider Needs to Know About Injection Safety

1. Needles and syringes are single use devices. They should not be used for more than one patient or reused to draw up additional medication.

2. Do not administer medications from a single-dose vial or IV bag to multiple patients.

3. Limit the use of multi-dose vials and dedicate them to a single patient whenever possible.
U.S. Outbreaks Associated with Unsafe Injection Practices, 2001-2011
Over 125,000 patients were notified as a result of incidents and outbreaks involving unsafe injections practices.

City alerts 450 patients of Hylan Boulevard clinic to hepatitis C concern
June 17, 2011

Nurse accused of stealing pain meds gets probation
September 20, 2011

NJ doctor loses license after hepatitis B outbreak
September 15, 2011

Injection Practices Among Clinicians in United States Health Care Settings

- Survey of 5,500 U.S. healthcare professionals
- 1 percent “sometimes or always” reuse a syringe on a second patient
- 1 percent “sometimes or always” reuse a multidose vial for additional patients after accessing it with a used syringe
- 6 percent use single-dose/single use vials for more than one patient

Insulin Pen Reuse Incidents

- Reuse of insulin pens for multiple patients, reportedly after changing needles has resulted in large notifications
  - NY hospital, 2008: 185 patients notified
  - TX hospital, 2009: 2,114 patients notified
  - WI hospital and outpatient clinic, 2011: 2,401 patients notified
Materials Available for Order

One & Only Campaign Materials For Order Via CDC-INFO

- Safe Injection Practices DVD: Item 22-0087
- Na for Safe Injection Poster: Item 22-0098
- It's Elementary Poster: Item 22-0097
- Provider Brochure: Item 22-0702
- Patient Brochure: Item 22-0701
- Injection Safety Pocket Card: Item 22-0713
- Logo Poster for Providers: Item 22-0780
- Logo Poster for General Public: Item 22-0099
- Injection Safety Healthcare Provider Checklist: Item 22-1579
- Injection Safety Healthcare Provider Toolkit: Item 22-1599

How to Order

SCAN
Scan with your Smartphone to access the ordering page

CALL
1-800-CDC-INFO

CLICK
http://www.cdc.gov/pubs/dhqp.aspx

1-800-CDC-INFO