Infection Prevention in Outpatient Surgery Centers

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Nothing to Disclose
Objectives

- Describe the spectrum of settings where surgery is performed
- Describe infection control lapses being identified in outpatient settings
- Discuss current prevention activities and materials targeting infection prevention needs in outpatient settings
Increasing numbers of surgical procedures are moving from inpatient to outpatient settings

Inpatient vs. Outpatient Surgery Volume, 1981-2005


Source: American Hospital Association;
Ambulatory surgical centers (ASCs)

- “Distinct entities that operate exclusively to provide surgical services to patients who do not require hospitalization and are not expected to need to stay in a surgical facility > 24 hours”

- Currently, >5,300 ASCs are certified for Medicare participation
  - >54% increase since 2001

- 2007: >6 million ASC procedures were paid for by Medicare at a cost of nearly $3 billion
  - >70% of claims are for endoscopy or eye procedures (e.g., cataract removal) and spinal / lower back injections

http://www.hhs.gov/ash/initiatives/hai/tier2_ambulatory.html
Surgery not just performed in “ASCs”

Ambulatory Care Settings

Outpatient Surgery

CMS-certified ASCs
Where is outpatient surgery being performed?

Chart 2: Percent of Outpatient Surgeries by Facility Type, 1981-2005

Source data: Verispan’s Diagnostic Imaging Center Profiling Solution, 2004. *2005 values are estimates

Source: American Hospital Association;
Oversight in outpatient settings

- **Variable**
  - CMS-certified ASCs are subject to CMS Conditions for Coverage and periodic inspections
  - Physician-offices operate under the physician’s medical license +/- business license unless state laws specify otherwise

- **Examples of increasing state requirements**
  - **NY**: Practices that perform office-based surgery required to be accredited
  - **NV**: Doctor’s offices that provide sedation/anesthesia subject to state inspections + new “injection safety pledge” law
  - **NJ**: Outpatient endoscopy and surgical centers required to retain services of a licensed Infection Control Practitioner

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3. [http://www.oneandonlycampaign.org/partner/nevada](http://www.oneandonlycampaign.org/partner/nevada)
HAI Risks in Outpatient Settings
Outbreaks and Patient Notifications in Outpatient Settings

The following table includes examples of recent outbreaks and patient notification events occurring in a variety of outpatient settings including primary care clinics, pediatric offices, ambulatory surgical centers, pain remediation clinics, imaging facilities, oncology clinics, and health fairs. This is not an exhaustive list but it serves as a reminder of the serious consequences that can result when healthcare personnel fail to follow the basic principles of infection control. Such consequences include: infection transmission to patients, notification of thousands of patients of possible exposure to bloodborne pathogens, referral of providers to licensing boards for disciplinary action, and malpractice suits filed by patients.

These events are preventable, yet they continue to occur. Facilities and healthcare personnel are urged to review the Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care and its accompanying Infection Prevention Checklist to assess the policies and procedures in their facility as well as their own personal practices to assure they are in accordance with evidence-based guidelines and to prevent patient harm.

<table>
<thead>
<tr>
<th>Setting</th>
<th>Year Investigated</th>
<th>Pathogen(s)</th>
<th>Infection(s)</th>
<th>Patient notification performed (# notified)</th>
<th>Infection Control Breaches Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urology Clinic [1]</td>
<td>2011</td>
<td>N/A*</td>
<td>N/A*</td>
<td>Yes (101)</td>
<td>1) Single-use needle guides (for prostate biopsy) used for &gt;1 patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1) Syringe reuse (i.e.,...</td>
</tr>
</tbody>
</table>
Outbreaks in outpatient settings associated with unsafe injections, United States, 2001-2011

- **At least 41 outbreaks**
  - 18 viral hepatitis (HBV and/or HCV)
    - >50% involved administration of anesthetic/analgesic
  - 23 bacterial
    - 30% in pain remediation clinics
    - >50% of case-patients required hospitalization

- **Common breaches:**
  - Reuse of syringes and/or needles for >1 patient or to reenter medication vials used for >1 patient
  - Use of single-dose vials or saline bags for >1 patient
  - Low adherence to hand hygiene and aseptic technique

The Las Vegas outbreak

- Licensed ASC
- Had not undergone a full inspection by state surveyors in 7 years
- Serious breaches in injection safety identified during outbreak investigation

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm
Injection safety breaches

Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.

1. A clean syringe and needle are used to draw the sedative from a new vial.
2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). Backflow into the syringe contaminates the syringe with HCV.
3. The needle is replaced, but the syringe is reused to draw additional sedative from the same vial for the same patient, contaminating the vial with HCV.
4. A clean needle and syringe are used for a second patient, but the contaminated vial is reused. Subsequent patients are now at risk for infection.

- Re-entered medication vials with a used syringe
- Used single-dose vials for more than one patient

Investigation outcomes

- Clinic immediately advised to stop unsafe practices
  - Business license revoked and clinic was closed
- Unsafe practices had been commonly used by some staff at the clinic for at least 4 years
  - Health department began notifying >50,000 former patients to recommend testing
- Transmission clearly identified on 2 separate dates
- Cost to health department >$800,000
- Legal action
  - Physicians and CRNAs at the clinic, Manufacturers of propofol, Insurance companies
- Led to assessment of remaining ASCs in Nevada using infection control checklist
  - Checklist subsequently adopted by CMS for use in ASC inspections
Inspection of CMS-certified ASCs

- Prior to 2009, inspections did not require observations of procedures or standardized assessment of infection control

- After 2009
  - Case-tracer methodology
    - Follow at least 1 patient throughout their entire stay in the ASC while observing practices (e.g., documentation, infection control)
  - Use of standardized checklist
    - Systematic assessment of infection prevention practices
Infection control worksheet (ICWS) components

- **Elements from CDC/HICPAC Guidelines**
  - Emphasis on Standard Precautions

- **Hand hygiene and glove use**

- **Injection safety and medication handling**

- **Instrument reprocessing**
  - High-level disinfection (e.g., endoscope reprocessing)
  - Sterilization

- **Environmental cleaning**

- **Point-of-care devices (e.g., blood glucose meters)**
68% of ASCs had at least 1 lapse in infection control
18% had lapses identified in 3 or more of the 5 categories.
Overall results of 3-state pilot infection control assessments

<table>
<thead>
<tr>
<th>Infection Control Category Assessed</th>
<th>Number of Facilities with Lapses Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Hygiene and Use of Gloves</td>
<td>12/62 (19%)</td>
</tr>
<tr>
<td>Injection Safety and Medication Handling</td>
<td>19/67 (28%)</td>
</tr>
<tr>
<td>Equipment Reprocessing</td>
<td>19/67 (28%)</td>
</tr>
<tr>
<td>Environmental Cleaning</td>
<td>12/64 (19%)</td>
</tr>
<tr>
<td>Handling of Blood Glucose Monitoring Equipment</td>
<td>25/54 (46%)</td>
</tr>
</tbody>
</table>

Schaefer et al. JAMA 2010;303:2273-2279
Recent Outbreaks and Patient Notifications
Injection safety – Patient notification

- Medical assistant administered flu vaccine from the same syringe to >1 patient
  - *Children between age 6 months and 35 months put at risk*

- Patient notification conducted and bloodborne pathogen testing advised

- **CDC Recommendations**
  - *Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)*

[Children told to be tested for HIV after flu vaccines reused](http://www.9news.com/news/article/193134/180/Children-told-to-be-tested-for-HIV-after-flu-vaccines-reused)
Injection safety – Patient notification

- Diabetes educator used insulin pens for >1 patient
- 2,345 patients notified and recommended to undergo bloodborne pathogen testing

Outpatient Clinic

Thousands of Wisconsin clinic patients possibly exposed to HIV

August 30, 2011

CDC Recommendations

- Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)

Injection safety – Outbreak and Patient notification

- 16 patients with bloodstream infections
- Clinic closed for “unsafe infection control practices”
- 470 patients notified and advised to undergo bloodborne pathogen testing

JACKSON, Miss. (AP) — A clinic in south Mississippi gave cancer patients less chemotherapy or cheaper drugs than they were told and reused the same needles on multiple people as part of a multimillion-dollar Medicare and Medicaid fraud, a 15-count indictment alleges.

CDC Recommendations
- Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)


September 9, 2011
Injection safety – Outbreak and Patient notification

- “Double dipping” – syringe that has been used to inject IV medication into a patient, reused to enter a medication vial that was used for subsequent patients
- >2000 patients notified and bloodborne pathogen testing recommended

CDC Recommendations
- Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient

http://www.publichealth.lacounty.gov/acd/HepInfo.htm
PPE / Injection safety – Outbreak

- Healthcare personnel did not wear facemasks when necessary for spinal injections and used single-dose vials for multiple patients

**Post-Myelography Bacterial Meningitis Among Patients at an Outpatient Radiology Facility — Missouri, 2010**


- CDC Recommendations
  - HCP wear a surgical mask when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)
  - Single dose (single-use) medication vials, ampules, and bags or bottles of IV solution are used for only one patient

Injection safety recommendations

- Use aseptic technique when preparing and administering medications
- Never administer medications from the same syringe to multiple patients
- Do not reuse a syringe to enter a medication vial or solution
- Do not administer medications from a single-dose vials or intravenous solution bags to more than one patient
- Limit the use of multi-dose vials and dedicate them to a single patient whenever possible
- Wear a surgical mask for when placing a catheter or injecting material into the epidural or subdural space

Equipment reprocessing – Patient notification

- Urology clinic re-used single-use-only endocavitary needle guides during performance of prostate biopsies¹
  - “Needle guides used on average 3-5 times before being discarded after becoming too bloody”²
  - ~100 patients notified

- CDC Recommendations
  - Single-use devices (SUDs) are discarded after use and not used for more than one patient
    • If the facility elects to reuse SUDs, these devices must be reprocessed prior to reuse by a 3rd-party reprocessor that is registered with the FDA as a 3rd-party reprocessor and cleared by the FDA to reprocess the specific device in question.

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How often are lapses in reprocessing occurring?

- **January 1, 2007-May 11, 2010 - FDA identified\(^1\):**
  - 80 reports of inadequate reprocessing filed with the Agency
    - 28 reports of infection that may have occurred from inadequate reprocessing

- **ASC 3-state pilot\(^2\):**
  - 28% with lapse in reprocessing of medical equipment
    - 5.8% inappropriately reprocessed single-use devices
    - 6.7% failed to adequately pre-clean instruments
    - 16.7% did not prepare, test, or replace high-level disinfectant appropriately

- **December 2002-December 2006 - 17 healthcare facilities requested assistance from California Dept Health Services regarding inadequately reprocessed endoscopes\(^3\):**
  - >9000 patients notified of potential exposure to bloodborne pathogens

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1. [Statement of Anthony D. Watson to the House Committee on Veteran’s Affairs available at:](http://veterans.house.gov/prepared-statement/prepared-statement-anthony-d-watson-bs-ms-mba-director-division-anesthesiology)
2. [Schaefer et al. Infection Control Assessment of Ambulatory Surgical Centers. *JAMA* 2010;303(22):2273-2279.](#)
Equipment reprocessing recommendations

- Facilities should ensure that reusable medical equipment (e.g., point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient.

- Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer’s instructions.
  - *If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use.*
  - *Not all equipment is reusable (it must be FDA-approved as such).*
    - *In ASC pilot, 6% of facilities inappropriately reprocessed/reused single-use devices.*
Equipment reprocessing recommendations

- Assign responsibilities for reprocessing of medical equipment to HCP with appropriate training
  - Maintain copies of the manufacturer’s instructions for reprocessing of equipment in use at the facility; post instructions at locations where reprocessing is performed
  - Observe procedures to document competencies of HCP responsible for equipment reprocessing upon assignment of those duties, whenever new equipment is introduced, and on an ongoing periodic basis (e.g., quarterly)

- Assure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment
Point-of-Care Devices - Outbreak

- HBV outbreak in an assisted-living facility
  - 8 patients acutely infected with HBV; 6 deaths
- Fingerstick devices used for >1 patient
- Did not clean and disinfect meters between patients

CDC Recommendations
- A new single-use, auto-disabling lancing device is used for each patient
- The glucose meter is cleaned and disinfected after every use

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6006a5.htm
Outbreaks of HBV infection associated with blood glucose monitoring - 1990 to 2010, US

- Hospital (2)
- Nursing Home (8)
- Assisted Living Facility (16)

Point-of-Care Devices – Patient notification

- Physician Assistant student trainees used the same multi-lancet fingerstick device for >1 person
- ~ 50 individuals tested with this device and recommended to undergo bloodborne pathogen testing

Indian Health Service
Press Release

FOR IMMEDIATE RELEASE
Contact: (301) 443-3593, FAX (301) 443-0507

New Mexico Health Fair Participants Urged to Seek Additional Testing

CDC Recommendations
- A new single-use, auto-disabling lancing device is used for each patient

Point-of-Care Devices

- **3-state pilot:**
  - 46% of ASCs at some type of lapse in handling of blood glucose monitoring equipment
    - 32% (17/53) of ASCs failed to clean and disinfect the blood glucose meter between patients
    - 21% (11/53) used the same fingerstick device for >1 patient
Point-of-Care Device Recommendations

- New single-use, auto-disabling lancing device is used for each patient
  - Lancet holder devices are not suitable for multi-patient use

- If used for >1 patient, the point-of-care testing meter is cleaned and disinfected after every use according to manufacturer’s instructions
  - If the manufacturer does not provide instructions for cleaning and disinfections, then the testing meter should not be used for >1 patient

http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
Infection prevention resources for outpatient surgical settings
Outpatient Settings

  - Outpatient Guide
  - Outpatient Checklist
  - List of outbreaks and patient notification events
These recommendations are not new

- Summary of existing evidence-based guidelines produced by the CDC and the Healthcare Infection Control Practices Advisory Committee
- Based primarily upon elements of Standard Precautions
  - Infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting where healthcare is delivered
- Users should consult the full guidelines for more detailed information and recommendations concerning specialized infection prevention issues (e.g., multi-drug resistant organisms)
- Does not replace existing detailed guidance for hemodialysis centers or dental practices

Represent minimum infection prevention expectations for safe care in ambulatory care settings

Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care


- **Checklist should be used:**
  - To ensure that the facility has appropriate infection prevention policies and procedures in place and supplies to allow healthcare personnel to provide safe care
  - To systematically assess personnel adherence to correct infection prevention practices

### Infection Prevention Checklist

#### Section I. Administrative Policies and Facility Practices

<table>
<thead>
<tr>
<th>Facility Policies</th>
<th>Practice Performed</th>
<th>If answer is No, document plan for remediation</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Written infection prevention policies and procedures are available, current,</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>and based on evidence-based guidelines (e.g., CDC/HICPAC), regulations, or</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>standards (Note: Policies and procedures should be appropriate for the services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>provided by the facility and should extend beyond OSHA bloodborne pathogen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>training)</td>
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<td></td>
</tr>
</tbody>
</table>
### II. Injection Practices (injectable medications, saline, other infusates)
Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

<table>
<thead>
<tr>
<th>Practices to be Assessed</th>
<th>Was Practice Performed?</th>
<th>Manner of Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Needles are used for only one patient</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>

| B. Syringes are used for only one patient | ○ Yes | Observation |
|                                          | ○ No | Interview |
|                                          | ○ N/A | Both |
CDC Evidence-based Guidelines

- [http://www.cdc.gov/HAI/prevent/prevent_pubs.html](http://www.cdc.gov/HAI/prevent/prevent_pubs.html)
- These include the following:
  - Guideline for Disinfection and Sterilization
  - Guidelines for Environmental Infection Control
  - Guidelines for Hand Hygiene
  - Guideline for Isolation Precautions
    - Standard Precautions
    - Injection Safety
Injection Safety Resources

- [http://www.cdc.gov/injectionsafety/](http://www.cdc.gov/injectionsafety/)
  - Guidelines
  - Links to freely accessible publications
  - FAQs
  - Medscape video – **Free CME**

  - Injection safety campaign led by CDC
  - Injection safety training video for healthcare personnel
Point-of-Care Device resources

  - Infection prevention recommendations
  - Clinical alerts
    - Fingerstick devices
    - Insulin pens
  - FAQs including
    - “How can Hepatitis B virus be transmitted through the meter?”
    - “What products are acceptable for cleaning and disinfection of blood glucose meters?”
HHS Action Plan for ASCs

- [http://www.hhs.gov/ash/initiatives/hai/tier2_ambulatory.html](http://www.hhs.gov/ash/initiatives/hai/tier2_ambulatory.html)
  - Summarizes HAI prevention issues specific to ASCs and presents key actions needed to assure safe care in these settings

- [http://www.hhs.gov/ash/initiatives/hai/resources/index.html](http://www.hhs.gov/ash/initiatives/hai/resources/index.html)
  - Infection prevention training for ASCs - Free CME
Summary

- Surgical/Invasive procedures being performed in a variety of outpatient settings
  - Variable oversight

- Outbreaks and patient notification events continue to identify infection prevention concerns/opportunities in outpatient settings

- Multiple ongoing activities and resources available to facilities
Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.