Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care
Dr. Melissa Schaefer, CDC, Atlanta
Teleclass broadcast sponsored by Virox Technologies Inc (www.virox.com)

Objectives
- Describe the spectrum of care provided in outpatient settings
- Describe infection control lapses being identified in outpatient settings
- Discuss current prevention activities and materials targeting infection prevention needs in outpatient settings

Outpatient settings
- Settings that provide healthcare to patients who do not remain overnight
- Examples include:
  - Physician offices
  - Hospital-based outpatient clinics
  - Urgent care centers
  - Cancer clinics and infusion centers
  - Imaging centers
  - Alternative medicine clinics
  - Ambulatory surgical centers
  - Hemodialysis clinics


Transition of healthcare delivery to settings outside the hospital
- Physician offices
  - 2007: ~1 billion visits to office-based physicians
- Hemodialysis
  - 2008: 354,600 maintenance hemodialysis patients in the U.S.
- Outpatient procedures represent >3/4 of all operations performed
  - Ambulatory surgical centers
    - 2011: >5,300 (>54% increase since 2001)
    - 2007: > 6 million procedures performed in ASCs and paid by Medicare (~$3 billion)
    - 10 states have more ASCs than hospitals
      - MD, DE, WA, NJ, CA, FL, AZ, GA, OR and RI


Outpatient settings
- Provide similar services as hospitals
- Surgery, injections, infusions (chemotherapy, antimicrobials, contrast)
- Increasingly vulnerable patient populations
  - Age extremes
  - Immunocompromised
- Expansion of services without proportionally expanded infection control infrastructure and oversight

Oversight in outpatient settings
- Outpatient healthcare settings subject to little oversight or regulation
  - Medicare is a Federal insurance program that has oversight of a subset of outpatient settings (e.g., hemodialysis facilities)
  - Medicare-certified facilities are subject to inspections by state survey agencies (or accrediting organizations) to determine compliance with minimum health and safety standards
  - Majority of outpatient settings operate only under the physician’s medical license +/- business license unless state laws specify otherwise
  - Not subject to routine survey/inspections (vs. restaurants)
  - Accreditation of outpatient facilities that are not part of hospital systems is uncommon
    - The Joint Commission recently announced accreditation of its 2,000th ambulatory care facility
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HAI Risks in Outpatient Settings

- National estimates of number of healthcare-associated infections originating in outpatient settings lacking
- Rely on information obtained from outbreak investigations and patient notifications
  - >40 recognized outbreaks in outpatient settings resulting from unsafe injection practices during the last 10 years
  - Wide range of infections, many life-threatening
  - >117,000 patients notified they were potentially exposed to unsafe injection practices in outpatient settings
- Common theme of outbreaks and notification events
  - Breakdowns and violations in standard procedures
  - Preventable with basic infection control practices
  - Healthcare personnel not aware of their errors

The Las Vegas outbreak

May 16, 2008; Vol. 57 / No. 19
Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic — Nevada, 2007

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

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

Injection safety breaches

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

Outbreaks and Patient Notifications in Outpatient Settings

<table>
<thead>
<tr>
<th>Setting</th>
<th>Year investigated</th>
<th>Pathogens(s)</th>
<th>Infections(s)</th>
<th>Infections notified performed</th>
<th>Infections notified reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urology Clinic (L)</td>
<td>2013</td>
<td>HCV*</td>
<td>HCV*</td>
<td>Yes (103)</td>
<td>1</td>
</tr>
</tbody>
</table>


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


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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)

Infection Control Assessment of Ambulatory Surgical Centers

- 68% of ASCs had at least 1 lapse in infection control
- 18% had lapses identified in 3 or more of the 5 categories.

Recent Outbreaks and Patient Notifications

- 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
  - Pediatric Clinic
    - Children told to be tested for HIV after flu vaccines reused
      - April 12, 2011
- CDC Recommendations
  - Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)

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

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Injection safety – Patient notification

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

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

- "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

PPE / Injection safety – Outbreak

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

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

Equipment reprocessing – Patient notification

- Urology clinic re-used single-use-only endocavitary needle guides during performance of prostate biopsies
- "Needle guides used on average 3-5 times before being discarded after becoming too bloody"
- ~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.

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

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How often are lapses in reprocessing occurring?

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

- ASC 3-state pilot:
  - 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:
  - 9000 patients notified of potential exposure to bloodborne pathogens

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

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
  - 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

Outbreaks of HBV infection associated with blood glucose monitoring - 1990 to 2011, US

- Hospital (2)
- Nursing Home (8)
- Assisted Living Facility (17)

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

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
**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 disinfection, the testing meter should not be used for >1 patient

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**Outpatient Settings**

  - Outpatient Guide
  - Outpatient Checklist
  - List of outbreaks and patient notification events

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**CDC Guide to Infection Prevention in Outpatient Settings**

- 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


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**CDC Guide to Infection Prevention in Outpatient Settings**

- Administrative Measures
  - Assure at least one individual with training in infection prevention is employed by or regularly available to the facility
- Educate and Train Healthcare Personnel
- Monitor and Report Healthcare-associated Infections
- Adhere to Standard Precautions
  - Hand Hygiene
  - Personal Protective Equipment
  - Injection Safety
  - Environmental Cleaning
  - Medical Equipment
  - Respiratory Hygiene/Cough Etiquette
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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

<table>
<thead>
<tr>
<th>Infection Prevention Checklist: Section 1: Administrative Policies and Facility Practices</th>
<th>Was Practice Performed?</th>
<th>Was Practice Confirmed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Have written policies and procedures in place regarding infection control, including medical, dental, and ambulatory surgical facility policies; infection control training, and definitions of facility personnel roles and responsibilities</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

CMS Inspection Tool for ASCs

Outpatient Oncology Settings

Basic Infection Control And Prevention Plan for Outpatient Oncology Settings

Hemodialysis Facilities
- [http://www.cdc.gov/dialysis/collaborative/tool-resources/index.html]

- Audit tools and protocols for prevention of bloodstream infections

CDC Evidence-based Guidelines
- [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/injection/]

- Guidelines
- Links to freely accessible publications
- FAQs
- Medscape video – Free CME
- [http://www.oneandonlycampaign.org/]

- Injection safety campaign led by CDC
- Injection safety training video for healthcare personnel

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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
  - Summarizes HAI prevention issues specific to ASCs and presents key actions needed to assure safe care in these settings
  - Infection prevention training for ASCs - Free CME

Summary
- Significant portion of healthcare in the United States provided in outpatient settings
  - Variable oversight
- Outbreaks and patient notification events continue to identify infection prevention concerns/opportunities in outpatient settings
  - Highlight lapses in basic infection control
- Multiple ongoing activities and resources available to facilities

Thank you

HHS Action Plan for ASCs
- Summarizes HAI prevention issues specific to ASCs and presents key actions needed to assure safe care in these settings
  - Infection prevention training for ASCs - Free CME

Coming Soon
- 05 June (Free Teleclass – Broadcast Live from APIC Conference): MDR Gram-Negative Infections: Across the Continuum of Care
  Speaker: Prof. Keith Kaye, Wayne State University
- 06 June (Free WHO Teleclass – Europe): Economic Impact of Healthcare-Associated Infections in Low and Middle Income Countries
  Speaker: Dr. A. Nevzat Yalcin, Akdeniz University, Turkey
  Sponsored by WHO First Global Patient Safety Challenge – Clean Care is Safer Care
- 13 June (Free South Pacific Teleclass): Hand Hygiene Initiatives in Australia
  Speaker: Phil Russo, Hand Hygiene Australia
- 18 June (Free Teleclass – Broadcast Live from CHICA Conference): Safety in the Field: Making Decisions About Cleaning, Disinfection, and Sterilization in Long Term Care
  Speaker: Colette Ouellet, Public Health Ontario

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