Keeping the Infection Out of the Injection

April 16, 2014
• Rachel has more than 20 years of experience in patient safety, quality, and risk management — both as an internal leader and as an external consultant. Her healthcare industry customers have included multi-hospital systems, large acute hospitals, long-term acute care facilities, critical access hospitals, healthcare services, and managed care organizations.

• Rachel has extensive experience in standards preparation and compliance, strategic organizational improvement planning and implementation, quality measurement, patient satisfaction, and medical staff quality and peer review.

• Rachel is a graduate of Ball State University with a bachelor of science degree in nursing, and she earned a master of science degree in nursing administration from Indiana University. Rachel is a member of the American Society for Healthcare Risk Management and the Indiana Society for Healthcare Risk Management.
Do you know...

- All of the risk resources available to you as a MedPro insured?
- How to contact your clinical risk consultant?
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Today's faculty, as well as CME planners, content developers, editors, committee members and Clinical Risk Management staff at Medical Protective have reported that they have no relevant financial relationships with any commercial interests.
Barbara Montana, MD, MPH, FACP is the Medical Director for the Communicable Disease Service at the New Jersey Department of Health. Dr. Montana earned her medical degree at New York University School of Medicine and has a Master of Public Health from the Rutgers University-School of Public Health. She is board certified in Internal Medicine and Infectious Diseases and is an Adjunct Assistant Professor in the Division of Epidemiology, Rutgers University-School of Public Health.

Dr. Montana has expertise in vaccine-preventable diseases, injection safety, and healthcare-associated infections. She has extensive experience with outbreak investigations including the 2012 – 2013 multistate outbreak of fungal meningitis and other infections associated with contaminated steroid injections, and the serogroup B meningococcal outbreak associated with a New Jersey University.
Keeping the Infection Out of the Injection

Barbara Montana, MD, MPH, FACP
Medical Director
Communicable Disease Service
No conflicts to report

This presentation is for educational purposes only. Consult references and regulations for detailed information.

Many of the slides used in this presentation were provided by the Centers for Disease Control and Prevention
Overview

- Discuss increased focus on healthcare-associated infections (HAI) and injection safety
- Discuss safe injection practices and common breaches of infection prevention practices
- Review outbreaks linked to poor infection prevention practices
- Provide infection prevention resources
Why is injection safety on the radar?

- Healthcare-associated infections (HAI) have been identified by the Centers for Disease Control and Prevention (CDC) as a winnable battle

- Goals:
  - Improve adherence to infection prevention guidelines
  - Improve national surveillance
  - Improve capacity at the state and local level to address HAI
Transition of healthcare delivery

- **Growth and shifts in care to non-acute care settings**
  - **Doctor’s Offices**
    - 2007: ~1 billion visits to office-based physicians
    - >1 million patients with cancer receive outpatient chemotherapy and/or radiation each year
      - 67% of Medicare recipients receive chemotherapy in private physician’s office
  - **Ambulatory Surgical Centers**
    - 2009: 5175 (240% increase since 1996)
    - Outpatient procedures represent ¾ of all US surgical operations
  - **Nursing Homes**
    - 2009: 3.3 million Americans resided in nursing homes
  - **Residential Care Facilities (assisted living and personal care)**
    - 2010: 971,900 beds in 31,100 facilities

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Concerns about outpatient care

- **Expansion of services without proportionally expanded infection control oversight**
  - Infection control practices vary greatly
  - Some facilities lack written infection control policies and procedures for patient protection

- **Outpatient settings are not routinely inspected for infection control practices**

- **Lack systematic surveillance to detect infections originating in outpatient settings**
GUIDELINES
2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD; Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory Committee

Acknowledgement: The authors and HICPAC gratefully acknowledge Dr. Larry Strausbaugh for his many contributions and valued guidance in the preparation of this guideline.


Guidelines for outpatient settings

Other guidelines


William A. Rutala, Ph.D., M.P.H.\textsuperscript{1,2}, David J. Weber, M.D., M.P.H.\textsuperscript{1,2}, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)\textsuperscript{3}

http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html
Other guidelines

United States Pharmacopeia (USP) Chapter <797>

Applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). USP 797 requirements affect all disciplines involved in sterile compounding, including physicians, nurses, pharmacists, and pharmacy technicians.
INJECTION SAFETY
Standard Precautions

- Hand hygiene
- Use of personal protective equipment
- Respiratory hygiene and cough etiquette
- Safe injection practices
- Safe handling of potentially contaminated equipment or surfaces in the patient environment
What are safe injection practices?

- Measures taken to perform injections in a safe manner for patients and providers

- Prevent transmission of infectious diseases from:
  - Patient to provider
  - Provider to patient
  - Patient to patient

http://www.cdc.gov/injectionsafety/
Injections without infections

- **Safe Production**: Sterile medication for injection/infusion
- **Safe Preparation**: Right-sized dose in a ready-to-deliver format (typically a syringe)
- **Safe Administration**: Adherence to Standard Precautions to minimize risk of infection to patients and healthcare personnel
- **Safe Disposal**: Minimize risk of harm to patients and healthcare personnel
Safe injection practice highlights

- Use aseptic technique and safety technology
- Never administer medications from the same syringe to multiple patients
- Do not reuse a syringe to enter a medication vial/solution
- Do not administer medications from a single-dose vial or intravenous solution bag to more than one patient
- Limit use of multi-dose vials and dedicate them to a single patient whenever possible
- Prepare medications in clean areas
- Remove needles/syringes from sterile package at time of use, fill at time of use
- Follow guidelines for assisted blood glucose monitoring and other point-of-care testing
OUTBREAKS
Bacterial and parasitic infections associated with contaminated injectable medications, United States 1999 - 2009

17 outbreaks

- 15 (88%) occurred in outpatient facilities
  - 7 pain clinics
  - 4 oncology centers
  - 3 hemodialysis centers
  - 1 primary care center
- 73.8% of case patients were admitted for medical or surgical treatment
- Procedures associated with contamination
  - Joint or spine injections (47.1%)
  - Saline or heparin flushes (41.2%)
  - *S. aureus* identified in 6 outbreaks, gram-negative rods in 8

“Never Events” - HBV/HCV* outbreaks in nonhospital settings due to unsafe injection practices, 1998 - 2008

- **Outpatient**
  - 12 outbreaks
  - 58,000 persons at risk
  - 16,074 persons screened
  - 311 outbreak-associated infections

- **Hemodialysis**
  - 6 outbreaks
  - 492 persons at risk
  - 490 person screened
  - 40 outbreak-associated infections

- **Long-term care**
  - 15 outbreaks
  - 1701 persons at risk
  - 919 persons screened
  - 97 outbreak-associated infections

**TOTALS:**
- 33 OUTBREAKS
- 60,193 PERSONS AT RISK
- 17,483 PERSONS SCREENED
- 448 OUTBREAK-ASSOCIATED INFECTIONS


*Hepatitis B Virus (HBV)/Hepatitis C Virus (HCV)*
“Never Events” – HBV/HCV outbreaks in nonhospital settings due to unsafe injection practices, 2008 - 2013

- **Outpatient**
  - 16 outbreaks
  - > 77,000 patients notified
  - 73 outbreak-associated cases

- **Hemodialysis**
  - 7 outbreaks
  - 1419 patients notified
  - 68 outbreak-associated case

- **Long-term care**
  - 15 outbreaks
  - > 1850 patients notified
  - 159 outbreak-associated cases

**TOTALS:**
- 38 OUTBREAKS (36 non-hospital)
- > 101,050 PERSONS NOTIFIED
- 385 OUTBREAK-ASSOCIATED INFECTIONS

http://www.cdc.gov/hepatitis/outbreaks/healthcarehepoutbreaktable.htm
Unsafe injection practices: US alerts since 2001

- > 150,000 patients have required notification to advise bloodborne pathogen testing following potential exposure to unsafe injections\(^1\)

- **From 2001 – 2011: 35 patient alerts in 17 states**
  - 29 (83%) involved outpatient settings
  - 26 (74%) events occurred since 2007

- **2012 – 13: numerous alerts including:**
  - 8,000 patients of a Colorado oral surgeon due to syringe reuse
  - 12,777 patients involving hospitals in multiple states due to a radiology technician suspected of tampering with narcotics
  - 7,000 patients of an Oklahoma oral surgeon due to poor injection and sterilization practices
  - Alerts have occurred for breaches without identified disease

\(^1\)Guh et al. Medical Care 2012
### Examples of HBV/HCV outbreaks in outpatient settings due to unsafe injection practices since 2001

<table>
<thead>
<tr>
<th>Setting site</th>
<th>Year</th>
<th>Virus</th>
<th># notified</th>
<th># infected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians office (NY)</td>
<td>2001</td>
<td>HBV</td>
<td>1,042</td>
<td>38</td>
</tr>
<tr>
<td>Pain management clinic (OK)</td>
<td>2002</td>
<td>HBV/HCV</td>
<td>908</td>
<td>102</td>
</tr>
<tr>
<td>Hematology/oncology clinic (NE)</td>
<td>2002</td>
<td>HCV</td>
<td>613</td>
<td>99</td>
</tr>
<tr>
<td>Alternative medicine (FL)</td>
<td>2005</td>
<td>HBV</td>
<td>253</td>
<td>7</td>
</tr>
<tr>
<td>Endoscopy/surgery clinics (NY)</td>
<td>2006</td>
<td>HBV/HCV</td>
<td>4,490</td>
<td>12</td>
</tr>
<tr>
<td>Pain management (NY)</td>
<td>2007</td>
<td>HCV</td>
<td>9,000</td>
<td>3</td>
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<tr>
<td>Endoscopy clinic (NV)</td>
<td>2008</td>
<td>HCV</td>
<td>63,000</td>
<td>9</td>
</tr>
<tr>
<td>Cardiology clinic (NC)</td>
<td>2008</td>
<td>HCV</td>
<td>1,205</td>
<td>5</td>
</tr>
<tr>
<td>Alternative medicine (FL)</td>
<td>2009</td>
<td>HCV</td>
<td>163</td>
<td>9</td>
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<tr>
<td>Hematology/oncology (NJ)</td>
<td>2009</td>
<td>HBV</td>
<td>4,600</td>
<td>29</td>
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<tr>
<td>Endoscopy clinic (NY)</td>
<td>2009</td>
<td>HCV</td>
<td>3,287</td>
<td>2</td>
</tr>
<tr>
<td>Pain management clinic (CA)</td>
<td>2010</td>
<td>HBV/HCV</td>
<td>2,293</td>
<td>2</td>
</tr>
<tr>
<td>Radiology clinic (FL)</td>
<td>2010</td>
<td>HCV</td>
<td>3,929</td>
<td>5</td>
</tr>
<tr>
<td>Pain management (NY)</td>
<td>2011</td>
<td>HCV</td>
<td>466</td>
<td>2</td>
</tr>
</tbody>
</table>
# Outbreaks associated with outpatient oncology settings

<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Predominant Infection Type(s)</th>
<th>No. of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>NE</td>
<td>2002</td>
<td>Hepatitis C infection</td>
<td>99</td>
</tr>
<tr>
<td>CA</td>
<td>2002</td>
<td><em>Alcaligenes xylosoxidans</em> bloodstream infection</td>
<td>12</td>
</tr>
<tr>
<td>IL</td>
<td>2004</td>
<td><em>Klebsiella oxytoca</em> and/or <em>Enterobacter cloacae</em> bloodstream infection</td>
<td>27</td>
</tr>
<tr>
<td>GA</td>
<td>2004</td>
<td><em>Burkholderia cepacia</em> bloodstream infection</td>
<td>10</td>
</tr>
<tr>
<td>GA*</td>
<td>2007</td>
<td>Polymicrobial bloodstream infection</td>
<td>13</td>
</tr>
<tr>
<td>NJ</td>
<td>2009</td>
<td>Hepatitis B infection</td>
<td>29</td>
</tr>
<tr>
<td>NJ</td>
<td>2011</td>
<td><em>K. pneumoniae</em> bloodstream infection</td>
<td>12</td>
</tr>
<tr>
<td>MS</td>
<td>2011</td>
<td><em>K. pneumoniae</em> and/or <em>Pseudomonas aeruginosa</em> bloodstream infection, skin/soft tissue infection</td>
<td>17</td>
</tr>
<tr>
<td>WV</td>
<td>2011</td>
<td><em>Tsukamurella</em> spp. bloodstream infection</td>
<td>15</td>
</tr>
</tbody>
</table>

*Outpatient Bone Marrow Transplant Facility*
Children At Fort Collins Clinic Tested After Syringe Mix-Up

Toms River oncologist's license revoked following hepatitis B outbreak among patients
Risks of medical injections in the US *outside* of recognized outbreaks

- Case-control study of hepatitis B and hepatitis C
- 48 reported cases of symptomatic acute hepatitis B or C
  - Persons aged 55 years and older – NY and OR
  - Excluded nursing home residents and cases identified as a result of outbreak investigation
- 3 matched controls per case
  - Age group (55 – 59, 60 – 69, and 70 years) and residential postal code
- In a multivariate model, behavioral risks (17% attributable risk), injections (37% attributable risk), and hemodialysis (8% attributable risk) were associated with case status
- Conclusion: Healthcare exposures may represent an important source of new HBV and HCV infections among older adults

Perz et al. Hepatology 2013
Indirect transmission of pathogens via contaminated equipment or medications

**SOURCE**
Infectious person, e.g. chronic, acute

**CONTAMINATED EQUIPMENT OR MEDICATION OR HANDS**

**HOST**
Susceptible, non-immune person
Infectious Risks of Unsafe Injections

- **Hepatitis C virus**
  - Stable in the environment for at least 16 hours

- **Hepatitis B virus**
  - High viral load
  - Stable in the environment (and infectious) for 1 week or longer


Infectious Risks of Unsafe Injections

- HIV
  - Generally does not survive well in the environment
  - Can survive (and be infectious) in syringes for several days
  - Has been transmitted from patient-to-patient in modern medical settings though rare
    - In one case, mode of transmission was suspected to be contamination of multi-dose vials of saline*

INVESTIGATIONS
HBV Outbreak – New York City, 2001
Private medical practice

- 2 patients aged >75 years developed acute hepatitis B associated with injection of vitamins and steroids
  - 2 or 3 medications together in one syringe
  - Needles and syringes were NOT reused
- Notification of >1000 patients; >200 tested
- 38 patients with acute HBV infection
- HBV sequenced from 28 patients was identical
- All staff members negative for HBV markers

Samandari et al. ICHE 2005 26(9):745-50
Storage of multidose vials and preparation of injections in same area that used needles and syringes were dismantled and discarded

Recommendations:
• Prepare medication in clean areas away from potentially contaminated items
• Use single dose vials when available

Ref: Samandari et al. ICHE 2005; 26: 745-750

Photo: Don Weiss / NYCDOHMH
Doctor's Patients Urged to Get Hepatitis Tests

By DEAN E. MURPHY

City health officials are urging more than 1,000 patients of a Manhattan doctor to be tested for hepatitis B, hepatitis C and H.I.V. as part of an investigation into the possible improper administration of injections at his medical practice.

The physician, Dr. Seymour Halpern, has been cooperating with the authorities, his office said. Though Dr. Halpern, an internist, continues to treat patients at his office on Central Park West, he has stopped giving injections, according to Sandra Mullin, a spokeswoman for the city's Health Department.

Health officials sent letters to 1,040 of Dr. Halpern's patients advising them to get tested after health investigators determined that at least 20 of Dr. Halpern's patients were infected with hepatitis B. It is not clear how the 20 people were exposed to the virus, or if they had received injections at Dr. Halpern's office, the officials said.

The Health Department said it was trying to contact anyone who might have been exposed to the hepatitis B virus. Anyone who received injections at Dr. Halpern's office within the past three years was considered exposed, he said.

Decision of Interest.

Justice Schlesinger

Lachterman v. Halpern - Defendant Dr. Seymour Halpern has moved herein for summary judgment on the ground that the statutory basis for the defendant's motion to dismiss his complaint for treble damages is without merit. The plaintiff, Dr. Seymour Halpern, has moved for summary judgment on the ground that the defendant's motion to dismiss his complaint is without merit. The defendant has moved for summary judgment on the ground that the plaintiff's complaint is without merit.

The Hepatitis Outbreak

The instant action is one of several actions against the same physician. The physician, Dr. Seymour Halpern which have been assigned to this Court.[1] All have been assigned to this Court. The facts and issues are documented in the October 25, 2002 report of the New York City Department of Health and Mental Hygiene (DOH), a copy of which is attached to defendant's moving papers. A summary follows.
HCV Outbreak – Nebraska, 2002
Outpatient hematology/oncology practice

- 2001 – gastroenterologist reported to state health department a cluster of 4 HCV infections
  - Patients all received care at the same oncology practice
  - All genotype 3a

- Oncology practice was located inside hospital complex, but independently owned
  - Single physician; small staff

HCV Outbreak – Nebraska, 2002

Outpatient hematology/oncology practice

- 613 patients notified to be tested for HCV
- At least 99 patients with HCV identified
  - Lacked previous evidence of HCV infections
  - Genotype 3a in all available samples \( n = 95 \)
  - All received care at the practice before July 2001
    - Nurse dismissed in July 2001 due to infection control breaches
    - Transmission period at least March 2000 – July 2001

HCV Outbreak – Nebraska, 2002

Outpatient hematology oncology practice

- Nurse reused syringes to access saline bag for flushes
  - After syringes were used to withdraw blood from patients’ catheters
  - Patient recalled seeing blood in saline bag

- Saline bag used as common-source supply for multiple patients
  - Contaminated bag could have served up to 25 – 50 patients

- Breaches identified in 2001, but never reported to public health or licensing authorities

HCV Outbreak – Nebraska, 2002
Outpatient hematology/oncology practice

- Oncologist fled the country
- 2004 – oncologist’s and nurses’ professional licenses revoked
- 89 lawsuits, $16 million paid from Nebraska Excess Liability Fund
- Patient outcomes
  - 6 deaths from HCV, not cancer
  - 33 underwent antiviral therapy, 28 achieved sustained response
  - 1 sexually acquired HCV

Following the Nebraska HCV outbreak: One survivor’s response

Evelyn’s Story

Dr. Evelyn McKnight is a nationally recognized patient safety advocate and survivor of one of the largest viral outbreaks in America’s medical history. Dr. McKnight turned her own personal tragedy into a mission to save lives.

Evelyn is co-founder and president of HONOReform and co-founder of the HONOReform Foundation. She is co-author of A Never Event: Exposing the Largest Outbreak of Hepatitis C in American Healthcare History, in which she documents the 2001 Nebraska outbreak. Evelyn presents at local, regional, and national conferences; she recently presented at conferences for the American Public Health Association (APIC), the CDC, and the CDC Foundation, and she presented at the Vaccine Congress, among many others. All honoraria she receives support the efforts of HONOReform.
HCV Outbreak – Nevada, 2007
Endoscopy center

- January 2008 – cluster of 3 acute HCV infections identified in Las Vegas
- All 3 patients underwent procedures at the same endoscopy center during the incubation period
- Health department investigated the clinic and identified injection safety breaches
- Unsafe practices had been commonly used by some staff at the clinic for at least 4 years
HCV Outbreak – Nevada, 2007

Endoscopy center

Clean needle and syringe used to draw medication

Syringe contaminated when used on HCV-infected patient

Reused syringe contaminates medication vial

Contaminated single-use vial used for subsequent patient
> 50,000 patients were notified of potential exposure and advised to seek testing

A total of 8 cases were directly linked to the endoscopy center; additional 101 were possibly linked
Drug maker to pay $285 million to settle hepatitis outbreak

Ex-Vegas MD guilty of murder in wide Hepatitis C outbreak

Police recommend criminal charges in hepatitis outbreak

Feds’ blitz: 30 days, 50 clinics
Outpatient hemodialysis unit

- **July 2008 – 3 patients with HCV seroconversions reported to Health Department**
  - All received hemodialysis at same unit in prior 6 months
  - Hemodialysis unit was a large, for-profit, outpatient facility
  - 30 dialysis stations, 70 – 100 patients daily
  - 162 patients were receiving hemodialysis at the time of the investigation
    - 20 (18%) had chronic HCV at the time of admission
    - 90 (82%) were negative at admission

- **Investigation revealed 9 cases seroconverted over 8 years**
  - Patients had not been informed of seroconversion


Outpatient hemodialysis unit

- **Multiple infection prevention breaches**
  - Inadequate cleaning and disinfection practices
    - Visible blood remained on dialysis chairs, dialysis machine surfaces, and surrounding floor between patient treatments
  - Direct care staff failed to wear gloves, change gloves between patients, or perform hand hygiene after contact with patients and soiled surfaces
- **Facility surrendered its operating certificate and paid $300K civil penalty**
Whenever possible, blood glucose meters should not be shared. If meters are shared, they must be approved for multi-patient use and have cleaning instructions.

Insulin pens and lancet devices must be patient dedicated. Items for multiple patients must not be stored together.

Insulin vials should be patient dedicated. If not dedicated, insulin injections should be prepared in medication prep room.

http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html#bgMeters
Practices associated with HBV transmission during assisted monitoring of blood glucose

- Use of fingerstick devices or insulin pens on multiple persons
- Failure to clean and disinfect blood glucose testing meters between each use
- Failure to change or use gloves, or perform hand hygiene between procedures

Patel et al. ICHE 2009; 30:209-14
Thompson et al. JAGS 2010
MMWR 2005; 54:220-3 www.cdc.gov/injectionsafety
Outbreaks of HBV infection associated with blood glucose monitoring - 1990 to 2010, US

Number of outbreaks identified


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

Insulin Pen Reuse Incidents

- Pen-shaped injector devices for insulin that are designed to permit self-injection and are intended for single-person use

- 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 outpatient clinics, 2011: 2,345 patients notified
  - NY veteran’s hospital, 2013: 716 patients notified
  - NY hospital, 2013: 1,900 patients notified
Deaths from Acute Hepatitis B Virus Infection Associated with Assisted Blood Glucose Monitoring in an Assisted-Living Facility — North Carolina, August–October 2010

Sharing of blood glucose monitoring equipment in assisted-living facilities has resulted in at least 16 outbreaks of hepatitis B virus (HBV) infection in the United States since 2004 (1,2).

- Eight cases, six deaths
- The investigation identified unsafe practices, including sharing of reusable fingerstick lancing devices approved for single patient use only and shared use of blood glucose meters without cleaning and disinfection between patients
Hepatitis B Virus Outbreak – New Jersey, 2009
Private hematology/oncology practice

- **February 2009** – gastroenterologist reported to local health department 2 patients with acute HBV infection, ages 60 and 77
  - No traditional risk factors
  - Both received care at same hematology/oncology clinic
- **Freestanding private hematology/oncology practice**
  - Small number of clinical staff
  - Throughput of 60 – 80 patients per day; 12 – 15 infusions
- **Review of NJ Communicable Disease Reporting and Surveillance System revealed 3 additional cases**
- **State and local health department investigated; site visits March 2009**

HBV Outbreak – New Jersey, 2009
Private hematology/oncology practice

Recommendations:
• “Each patient is an island”
• Appropriately space patient care areas
• Do not share IV poles or chair-side tables
• Perform good hand hygiene; use gloves appropriately
Uncapped syringes for flushing IVs unwrapped and prefilled in advance
Syringes filled in advance
Blood drawing equipment in area of medication preparation
Uncapped syringes for flushing IVs unwrapped and prefilled in advance
Medication prepared in hood in patient treatment area
Medication prepared using unwrapped syringes in room where CBCs were processed

**Recommendations:**
- Medication should not be prepared or stored in areas that are potentially contaminated
- Syringes should not be unwrapped or filled in advance
Recommendations:
• Environmental surfaces must be kept clean
• Vacutainer holders should not be reused
• Potentially contaminated items should not come in contact with other patient-care items (i.e.; gauze)
IV bags with stoppers removed

Recommendations:
• IV bags should be opened/spiked as close to time of use as possible
• IV bags should not be used as a source of fluid for multiple patients
• Single use vials do not have preservative and should not be used for more than one time or for more than one patient

Single use vials stored and used on subsequent days for multiple patients

HBV Outbreak – New Jersey, 2009
Private hematology/oncology practice
HBV Outbreak – New Jersey, 2009
Private hematology/oncology practice

- 4600 patients notified to be tested
- At least 29 outbreak-associated HBV cases; 68 others possible
- Incubation period August 2007 – March 2009

Molecular Testing:
HBV sequence analysis

HBV Outbreak – New Jersey, 2009
Private hematology/oncology practice

- Office practice closed March 3, 2009
- Physician’s license to practice medicine revoked by the New Jersey Board of Medical Examiners
- Nurses disciplined by New Jersey Board of Nursing

Hepatitis B outbreak associated with a hematology-oncology office practice in New Jersey, 2009

Rebecca C. Gantley, MPH; Shereene Soumillon, MS; Nicole D. Thompson, PhD, MS; Patricia High, MPH, CHES; Ellen Rodowski, RN, MSN, APN; Elizabeth Handelhor, MPH; Guo-Rong Xia, MD, LL; Lilia Garcia-Bauer, PhD; Jennifer Crawford, MPH, CHES; Courtney Robertson, MD, MPH, FACP; Christine Tan, MD, MPH; and Barbara Montesano, MS, MPH, FACP
Trenton and Toms River, New Jersey; and Atlanta, Georgia

**Background:** Transmission of bloodborne pathogens due to breaches in infection control is becoming increasingly recognized as a greater emphasis is placed on reducing health care-associated infections. Two women, aged 60 and 77 years, were diagnosed with acute hepatitis B virus (HBV) infection, both received chemotherapy at the same physician’s office. Due to suspicion of health care-associated HBV transmission, a multidisciplinary team initiated an investigation of the hematology-oncology office practice.

**Methods:** We performed an onsite inspection and environmental assessment, staff interviews, records review, and observation of office practices. Patients who visited the office practice between January 1, 2009, and March 7, 2009 were advised to seek testing for bloodborne pathogens. Patients and medical providers were interviewed. Specimens from HBV-infected patients were sent to the Centers for Disease Control and Prevention for HBV DNA testing and phylogenetic analysis.

**Results:** Multiple breaches in infection control were identified, including inadequate policies and procedures, improper hand hygiene, medication preparation in a blood processing area, incorrect suture bag, and reuse of single-use tools. The office practice was closed, and the physician’s license was suspended. Out of 2,700 patients notified, 264 (9.6%) returned results; 182 (33.4%) of these were HBV-related.

**Conclusion:** Systematic breaches in infection control led to ongoing transmission of HBV in various procedures in the office practice. This investigation underscores the need for improved infection control and infection safety education for health care providers, and the development of mechanisms for ongoing communication and cooperation among public health agencies.

Am J Infect Control 2011;39:663-70
Doctor in N.J. hepatitis outbreak fights for license

Another Lawsuit Filed Claiming Hepatitis B Infection Came from Doctor’s Office

New Jersey Doctor's License Suspended After 5 Patients Test Positive for Hepatitis B

Monday, April 06, 2009
Associated Press

State regulators on Friday temporarily suspended the license of a New Jersey doctor who contracted hepatitis B after being treated for prostat...
Klebsiella pneumoniae Outbreak - New Jersey, 2011
Private hematology/oncology practice

- June 2011 – hospital infection preventionist reported cluster of *Klebsiella pneumoniae* blood stream infections
  - All received care at the same oncology practice

- Oncology office located on hospital campus, but independently owned and operated
  - No oversight by hospital infection preventionist
  - Throughput of 40 – 70 patients per day; 991 infusions performed June 2011; 28 infusion stations

- State and local health department investigated; site visit July 11, 2011
K. pneumoniae Outbreak – New Jersey, 2011

Case-Finding

- 12 cases with *K. pneumoniae* bacteremia
- 11 cases had indwelling subcutaneous central venous access ports which were removed following bacteremia

PFGE of *K. pneumoniae* clinical specimens
**K. pneumoniae Outbreak – New Jersey, 2011**

Private hematology/oncology practice

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**Recommendations:**
- IV bags should not be used as a source of fluid for multiple patients
- Medication should be prepared in a clean dedicated medication preparation area

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IV bags used as sources of fluid to prepare medication for multiple patients
K. pneumoniae Outbreak – New Jersey, 2011
Private hematology/oncology practice

Recommendations:
• Syringes should not be unwrapped or filled in advance
• For immediate use compounded sterile products, administration must begin not later than 1 hour following the start of the preparation of compounded sterile product (USP<797>)
**Recommendations:**

- Follow USP <797> and NIOSH guidelines regarding appropriate medication preparation
- Single-use/Single dose vials should not be reused
Single dose/Single Use vs Multidose

- Single dose/single use vials do not contain preservative
K. pneumoniae Outbreak – New Jersey, 2011
Cases by week of first positive (n=12)
Ports and Late-Onset Bloodstream Infection

Adapted from [http://usfbreasthealth.blogspot.com/](http://usfbreasthealth.blogspot.com/)
Outbreak of acute hepatitis B virus infections associated with podiatric care at a psychiatric long-term care facility

Matthew E. Wise, PhD, MPH, Patricia Marquez, MPH, Umid Sharapov, MD, Susan Hathaway, RN, MPH, Kenneth Katz, MD, MSCE, Scott Tolan, MD, Alina Beaton, MD, Jan Drobeniuc, MD, PhD, Yury Khudyakov, PhD, Dale J. Hu, MD, MPH, Joseph Perz, DrPH, Nicola D. Thompson, PhD, and Elizabeth Bancroft, MD, SM

Atlanta, Georgia; and Los Angeles, California

Background: Effective measures exist to prevent health care-associated hepatitis B virus (HBV) transmission, yet outbreaks continue to occur. In 2008, the Los Angeles County Department of Public Health identified an outbreak of HBV infections among psychiatric long-term care facility residents.

Methods: Residents underwent HBV serologic testing and were classified as acutely infected, chronically infected, susceptible, or immune. Persons residing in the facility during 2008 were enrolled in a retrospective cohort study to identify risk factors for acute HBV infection. We assessed infection control practices at the facility.

Results: Nine of 81 residents (11%) enrolled in the cohort study had acute HBV infection. Five of 15 residents (33%) undergoing podiatric care on a single day subsequently developed acute infection (rate ratio, 4.33; 95% confidence interval, 1.18-15.92). Infection control observations of the consulting podiatrist revealed opportunities for cross-contamination of instruments with blood. Other potential health care and behavioral modes of transmission were identified as well. Residents were offered HBV vaccination, and infection control recommendations were implemented by the podiatrist and facility.

Conclusions: Of the multiple potential transmission modes identified, exposure to HBV during podiatry was likely the dominant mode in this outbreak. Long-term care facilities should ensure compliance with infection control standards among staff and consulting health care providers.

Key Words: Viral hepatitis; nursing homes; disease outbreaks; podiatry.

Published by Elsevier Inc. on behalf of the Association for Professionals in Infection Control and Epidemiology, Inc. (Am J Infect Control 2011; 39:1-7.)
Sept – Nov, 2008 – 5 residents diagnosed with acute HBV infection reported from single facility

None of the 5 residents underwent blood glucose monitoring

Investigation revealed 9 of 81 residents enrolled in study were found to be acutely infected
Fig 1. Links between resident C-1 and residents who developed acute HBV infection.
Breaches identified

- Cross-contamination of equipment and surfaces during routine procedures
- Used equipment placed adjacent to clean items
- Potential for contamination during transport of items by private provider
- Inappropriate procedures related to assisted blood glucose monitoring leading to environmental contamination
Corrective action

- All residents and staff offered HBV vaccine
- Appropriate storage of clean and dirty equipment by private providers
- Renovated treatment room to facilitate infection control and hand hygiene
- Institute proper procedures for cleaning and disinfection of surfaces
- All HBV-infected patients with diabetes were provided dedicated glucometers
- Oversight by infection preventionist
Spinal Injections

- Multiple outbreaks among patients who have received spinal injection procedures

- Nearly all spinal infections were performed by a provider who was not wearing a facemask

Spinal Injections

- CDC recommends anyone performing a spinal injection procedure should:
  - Always wear facemasks when injecting material or inserting a catheter into the epidural or subdural space
  - Always use aseptic technique and other safe injection practices (e.g., using a single-dose vial of medication or contrast solution for only one patient) should always be followed for all spinal injection procedures

What are the common themes and findings?

- Investigations are resource-intensive and disruptive
- There is delayed recognition and missed opportunities
- Infection prevention programs and lacking or responsibilities unclear
- The disease transmission is entirely preventable
  - Standard precautions and aseptic technique
- Events result in actions against professional licenses and malpractice suits
How much can we see?

- Asymptomatic infection
- Under-reporting of cases
- Under-recognition of healthcare as risk
- Difficulty identifying single healthcare exposure
- Barriers to investigation
- Resource constraints
WHY DOES THIS KEEP HAPPENING?
<table>
<thead>
<tr>
<th>Myth</th>
<th>Truth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changing the needle makes a syringe safe for reuse.</td>
<td>Once they are used, both the needle and syringe are contaminated and must be discarded. A new sterile needle and a new sterile syringe should always be used for each patient and to access medication vials.</td>
</tr>
<tr>
<td>Syringes can be reused as long as an injection is administered through an intervening length of IV tubing.</td>
<td>Everything from the medication bag to the patient’s IV catheter is a single interconnected unit. Distance from the patient, gravity, or even infusion pressure do not ensure that small amounts of blood won’t contaminate the syringe once it has been connected to the unit. Syringes should never be reused for more than one patient or to access medication vials.</td>
</tr>
<tr>
<td>If you don’t see blood in the IV tubing or syringe, it means that those supplies are safe for reuse.</td>
<td>Pathogens including hepatitis C virus, hepatitis B virus, and HIV can be present in sufficient quantities to produce infection without any visible blood.</td>
</tr>
<tr>
<td>Single-dose vials with large volumes that appear to contain multiple doses can be used for more than one patient.</td>
<td>Single-dose vials should not be used for more than one patient regardless of the vial size.</td>
</tr>
</tbody>
</table>
Why are there lapses in *basic* infection prevention practices?

- Lack of awareness
- Poor/insufficient training
- Economics
- Lax or non-existent policies and procedures
How common are these breaches?

- Anonymous survey of 5,500 US healthcare professionals (primarily RNs)
  - 1% “sometimes or always” reuse a syringe on a second patient
  - 1% “sometime or always” reuse a multidose vial after accessing it with a reused syringe
  - 6% use single dose/single use vial for more than one patient

Pugliese, et al 2010. AJIC.
Available at: [http://www.cdc.gov/injectionsafety](http://www.cdc.gov/injectionsafety) or [http://www.ajicjournal.org/article/PIIS0196655310008539/abstract](http://www.ajicjournal.org/article/PIIS0196655310008539/abstract)
Injection practices among anesthesiologists

- Survey of 595 residents and attending anesthesiologists in NY State (26% response rate)
- 49% used the same vial of medication for more than one patient
- 25% said they did not always use a new needle and syringe when drawing medication from a vial
- 8% of residents, 2% of attendings reuse syringes on different patients

Anesthesiology News, Clinical Anesthesiology; January 2012; 38(01). Available at: http://www.anesthesiologynews.com
Infection Control Assessment of Ambulatory Surgical Centers

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OVER THE LAST SEVERAL DECADES, health care delivery in the United States has shifted toward the outpatient setting; ambulatory surgery in particular has been an area of immense growth. Ambulatory surgical centers (ASCs) are defined by the Centers for Medicare & Medicaid Services (CMS) as facilities that operate exclusively to pro-

Context More than 5000 ambulatory surgical centers (ASCs) in the United States participate in the Medicare program. Little is known about infection control practices in ASCs. The Centers for Medicare & Medicaid Services (CMS) piloted an infection control audit tool in a sample of ASC inspections to assess facility adherence to recommended practices.

Objective To describe infection control practices in a sample of ASCs.

Design, Setting, and Participants All State Survey Agencies were invited to participate. Seven states volunteered; 3 were selected based on geographic dispersion, number of ASCs each state committed to inspect, and relative cost per inspection. A stratified random sample of ASCs was selected from each state. Sample size was based on the number of inspections each state estimated it could complete between June and October 2008. Sixty-eight ASCs were assessed; 32 in Maryland, 16 in North Carolina, and 20 in Oklahoma. Surveyors from CMS, trained in use of the audit tool, assessed compliance with specific infection control practices. Assessments focused on 5 areas of infection control: hand hygiene, infection safety and medication handling, equipment reprocessing, environmental cleaning, and handling of blood glucose monitoring equipment.

Main Outcome Measures Proportion of facilities with lapses in each infection control category.

Results Overall, 46 of 68 ASCs (67.6%; 95% confidence interval [CI], 55.9%-77.9%) had at least 1 lapse in infection control; 12 of 68 ASCs (17.6%; 95% CI, 9.9%-28.1%) had lapses identified in 3 or more of the 5 infection control categories. Common lapses included using single-dose medication vials for more than 1 patient (18/64; 28.1%; 95% CI, 18.2%-40.0%), failing to adhere to recommended practices regarding reprocessing of equipment (19/67; 28.4%; 95% CI, 18.6%-40.0%), and lapses in handling of blood glucose monitoring equipment (25/54; 46.3%; 95% CI, 33.4%-59.6%).

JAMA. 2010;303(22):2273-2279
Results of multi-state pilot infection control assessments

- Inspections in a sample of 68 ASCs in Maryland, North Carolina, and Oklahoma from June-October 2008
  - Median of 5.4 years between pilot and most recent inspection (0.6-12.6 years)
  - 68% (46/68) of ASCs had at least one lapse in infection control
  - 18% (12/68) had lapses in 3 or more of the 5 infection control categories assessed
## Infection control lapses

<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>
RESOURCES
Injection Safety

Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the World Health Organization, a safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. Visit the page on CDC's role in safe injection practices.
Single-Dose and Multi-Dose Vial Infographic

Is that a single-dose or multi-dose vial? The Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC) urge all healthcare providers to recognize the differences between vials. A new dynamic infographic from the One & Only Campaign helps. This information can literally save a life. The click here to access the web-based infographic.

Award-Winning Safe Injection Practices Video – How to Do It Right

View graphic
Thank you!

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What questions do you have?

Thank You!
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