



Keeping the Infection Out of the Injection

Barbara Montana, MD MPH FACP

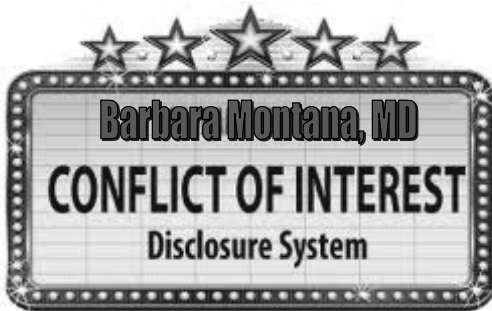
Medical Director

Communicable Disease Service

New Jersey Department of Health and Senior Services



No conflicts to report



Overview

- What is injection safety?
- Investigations linked to unsafe injection practices
- Common injection safety breaches
- Recommended injection and medication practices
- Injection safety resources

Injection Safety

- Measures taken to perform injections in a safe manner for patients and providers
- Prevent harms such as needlestick injuries
- Prevent transmission of infectious diseases from:
 - Patient to provider
 - Provider to patient
 - Patient to patient

<http://www.cdc.gov/injectionsafety/>

Guidelines

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

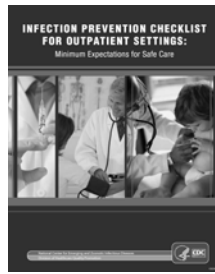
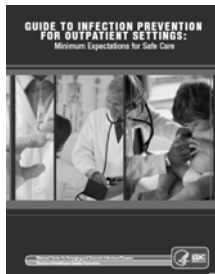
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Committee

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

Suggested citation: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection
Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing
Transmission of Infectious Agents in Healthcare Settings.
<http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions2007.pdf>

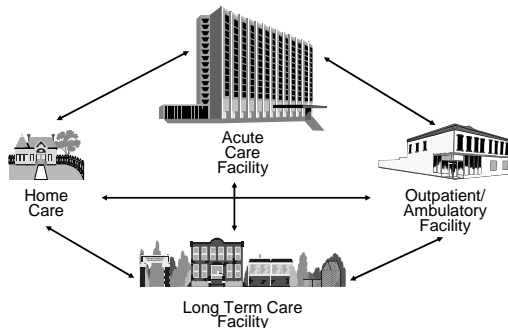
<http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html>

Guidelines for Outpatient Settings



<http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html>

Attention to Basic Infection Control Needs to Extend Across the Entire Healthcare Continuum

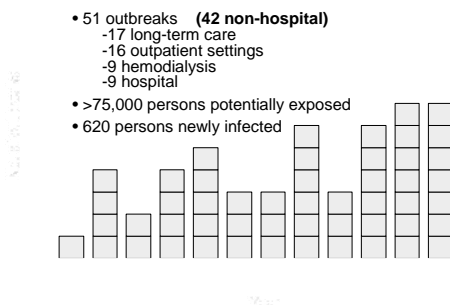


Transition of healthcare delivery

- Growth and shifts in care to settings where infection control infrastructure and oversight may be lacking
 - Doctor's Offices
 - 2007: ~1 billion visits to office-based physicians¹
 - Hemodialysis
 - 2008: 354,600 maintenance hemodialysis patients in the U.S.²
 - 2008: 5240 dialysis centers (82% increase since 1996)
 - Ambulatory Surgical Centers
 - 2009: 5175 (240% increase since 1996)
 - Outpatient procedures represent ¾ of all U.S. surgical operations³
 - Nursing Homes
 - 2008: 3.2 million Americans resided in nursing homes⁴
 - Assisted Living Facilities
 - 2004: 975,000 beds (>2x growth since 1990s)

1.National Ambulatory Medical Care Survey; 2007 Summary available at: <http://www.cdc.gov/nchs/data/ambulatory07.pdf>
 2.2010 USRDS Annual Data Report. Available at: <http://www.usrds.org/2010>
 3.Baile PS. Infection Control Practices in Ambulatory Surgical Centers. JAMA. 2010;303:2295-7
 4.Nursing Home Data Compendium available at: http://www.cms.gov/CertificationandCompliance/Downloads/nursinghomedatacompendium_2008.pdf

Healthcare-associated HBV/HCV outbreaks by year reported – July 1998 to June 2009



Thompson et al. Annals of Int Med, 2009; and unpublished data

HBV/HCV Outbreaks (n=16) in Outpatient Settings due to Unsafe Injection Practices, 2001-2010

State	Setting	Year	Type
NY	Private MD office	2001	HCV
NY	Private MD office	2001	HBV
NE	Oncology clinic	2002	HCV
OK	Pain remediation clinic	2002	HBV+HCV
NY	Endoscopy clinic	2002	HCV
CA	Pain remediation clinic	2003	HCV
MD	Nuclear imaging	2004	HCV
FL	Alternative medicine clinic	2005	HBV
CA	Alternative medicine clinic	2005	HCV
NY	Endoscopy/surgery clinics	2006	HBV+HCV
NY	Pain remediation clinic	2007	HCV
NV	Endoscopy clinic	2008	HCV
NC	Cardiology clinic	2008	HCV
NJ	Oncology clinic	2009	HBV
FL	Alternative medicine clinic	2009	HCV
CA	Pain remediation clinic	2010	HCV+HBV

Over the past decade, over 125,000 patients have had to be notified in the context of more than two dozen incidents and outbreaks involving unsafe injections...



Guh et al 2010. <http://shea.confex.com/shea/2010/webprogram/Paper1789.htm>

Outbreaks of bacterial and parasitic infections associated with unsafe injections, United States, 1999-2009

- **17 outbreaks: 16 bacterial, 1 malaria**
 - 7 pain clinics; 4 oncology centers, 3 dialysis clinics
 - Joint/spine injections (8 outbreaks)
 - Saline/heparin flush procedures (7 outbreaks)
 - 74% of case-patients required hospitalization for medical or surgical treatment



*MacCannell et al. 2010, <http://shea.confex.com/shea/2010/webprogram/Paper2113.html>

New York City – Private Medical Practice,
December 2001



Two patients aged >75
years developed acute
hepatitis B

- Admitted same hospital
- Attended same private
medical practice

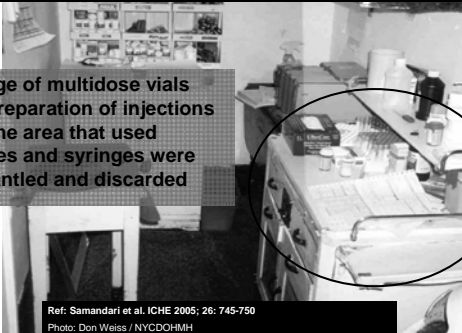
New York City – Private Medical Practice

- 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
- Associated with injection of vitamins and
steroids
 - 2 or 3 medications together in one syringe
 - Needles and syringes were NOT reused

Samandari et al. ICHE 2005 26(9):745-50

**FACT: Medication should not be prepared in areas that are
potentially contaminated**
**FACT: Multidose vials should only be used when no
alternative is available and should be patient dedicated**

Storage of multidose vials
and preparation of injections
in same area that used
needles and syringes were
dismantled and discarded

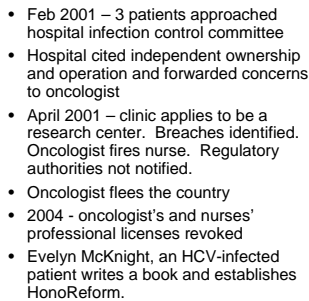


Ref: Samandari et al. ICHE 2005; 26: 745-750
Photo: Don Weiss / NYCDOHMH



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Macedo de Oliveira et al., *Annals of Internal Medicine*, 2005, 142:898-902



Nebraska – Oncology Clinic



- Outcomes
 - 6 deaths from HCV, *not* cancer
 - 33 antiviral therapy, 28 achieved sustained response
 - 1 sexually acquired HCV
 - 89 lawsuits, \$16M paid from Nebraska Excess Liability Fund

Mailliard ME, et al. Hepatology 2009 Aug;50(2):361-8

Nevada – Endoscopy Center, 2007

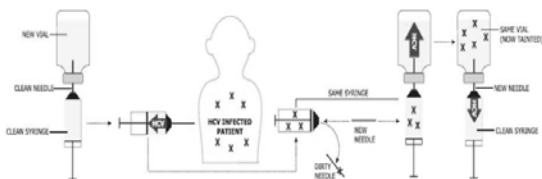


Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic — Nevada, 2007

On January 2, 2008, the Nevada State Health Division (NSHD) contacted CDC concerning surveillance reports received by the Southern Nevada Health District (SNHD) regarding two persons recently diagnosed with acute hepatitis C. A third person with acute hepatitis C was reported.

- January 2008 – cluster of 3 acute HCV infections identified in Las Vegas
- All 3 patients underwent procedures at the same endoscopy clinic (ECSN) during the incubation period

The Nevada outbreak: mechanism



- **Two breaches contributed to transmission:**
 - Re-entering propofol vials with used syringes
 - Using contents from these single-dose vials on more than one patient

MMWR 2008 57(19):513-517

Nevada - Endoscopy Center

- Clinic immediately advised to stop unsafe injection practices (reuse of syringes and propofol vials)
- Unsafe practices had been commonly used by some staff at the clinic for at least 4 years
 - Health department began notifying 40,000 persons to recommend HBV, HCV, HIV screening
- A total of 8 cases were directly linked to ECSN; an additional 101 were possibly linked



MMWR; May 16, 2008;57:19

<http://www.southernnevadahealthdistrict.org/download/outbreaks/final-hepc-investigation-report.pdf>

FACT: Vials should never be entered with a used needle or syringe
FACT: Single-dose vials or bags of intravenous fluid should never be used for more than one patient



Single dose vial used for multiple patients

8 NEWSNOW
LAS VEGAS
THU, FEB 4, 2010 (midnight)

Insurance Company for Dr. Desai Denies Liability
Two major decisions Tuesday in the civil lawsuit surrounding the hepatitis crisis. One decision concerns whether attorneys can sue the company that insures the doctors. They also made a decision about whether a class action lawsuit can go forward.

Police recommend criminal charges hepatitis outbreak
By BRIAN HAYNES
LAS VEGAS REVIEW-JOURNAL
Posted: Nov. 19, 2009 | 3:23 p.m.

The thousands of Southern Nevadans who want to see the doctor and others in his medical clinics for their roles in the hepatitis C outbreak blamed on unsafe injection practices.

Anatomy of a travesty: The Dipak Desai colonoscopy scandal
Two years later, there is still no resolution - or punishment

Desai, Dipak MD
Colonoscopy Center of Nevada
2000 W. Sahara Avenue, Suite 300
Las Vegas, Nevada 89102

Subject: NOTICE OF RESCINDMENT OF BUSINESS LICENSE NUMBER 20700420

Attention: Counselor

2/24/2010
The Nevada State Board of Medical Examiners accepted the surrender of Dr. Desai's Nevada medical license. The surrender was made based on Dr. Desai not being competent to safely practice medicine due to physical and mental impairments arising from a series of strokes. The surrender is absolute and irrevocable and was done in accordance with NAC 639.240. The surrender of Dr. Desai's medical license will not preclude the Board from proceeding on the pending disciplinary complaint filed on April 25, 2008, involving the hepatitis C outbreak at the Endoscopy Center of Southern Nevada.

Nevada State Board of Medical Examiners
1800 Terminal Way, Suite 300
Reno, Nevada 89502
E-mail: admin@nsbmed.org

Feds' blitz: 30 days, 50 clinics
Teams of investigators swooping into Nevada to get all...

HBV Transmission Associated with Assisted Blood Glucose Monitoring

Officials Release Findings In GlenCare Investigation

By NBC17 Staff



Published November 16, 2010



Inspectors looking into what caused a first Hepatitis B outbreak at a Wayne County assisted living facility have released their findings.

A statement of deficiencies was released to GlenCare of Mount Olive by the N.C. Division of Health Service Regulation after a two-week investigation.

According to the findings, the facility violated resident rights and some staff members were not properly trained on caring for diabetic residents, specifically relating to blood glucose monitoring.

State health officials said the virus was inadvertently spread by blood monitoring meters that GlenCare staffers used for diabetes testing when reused blood made its way into or on to the devices.

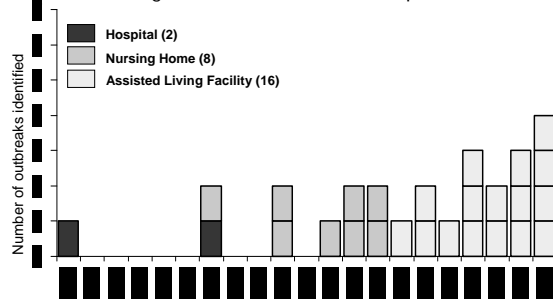
MMWR / February 18, 2011 / Vol. 60 / No. 6

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

Outbreaks (n=26) of HBV infection associated with Assisted Monitoring of Blood Glucose - 1990 to present, US

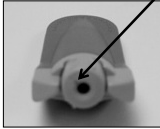


Thompson, Perz. Journal of Diabetes Science and Technology 2009; 3:283-88. CDC unpublished data (2009-2010).

27

Practices Associated with HBV Transmission During Assisted Monitoring of Blood Glucose

Use of multi-use fingerstick devices 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

220

MMWR

March 11, 2005

Transmission of Hepatitis B Virus Among Persons Undergoing Blood Glucose Monitoring in Long-Term-Care Facilities — Mississippi, North Carolina, and Los Angeles County, California, 2003–2004

BOX 1. Recommended practices for preventing patient-to-patient transmission of hepatitis viruses from diabetes-care procedures in long-term-care settings

Diabetes-care procedures and techniques

- Prepare medications such as insulin in a centralized medication area; multidose insulin vials should be assigned to individual patients and labeled appropriately.

FACT: Fingerstick devices must be dedicated to one person

FACT: Whenever possible, blood glucose meters should not be shared; if shared, the device should be cleaned and disinfected (with bleach) after every use

FACT: Insulin pens must be dedicated to one person; pens for multiple patients should be stored separately

FACT: Staff must engage in hand hygiene and remove gloves after each patient

MMWR 2005; 54:220-3 www.cdc.gov/injectionsafety

Too Close to Home



New Jersey Investigations

New Jersey – Oncology Office, 2009



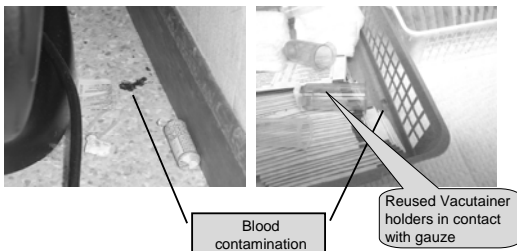
- February 2009 – 2 patients, 60 and 77 years of age, reported to local health department with acute HBV infection
 - Both received care at the same oncology practice
 - Neither had traditional risk factors
- Review of NJ Communicable Disease Reporting and Surveillance System (CDRSS) revealed 3 additional cases linked to the oncology practice
 - None had traditional risk factors
- Office inspected on March 3 & 10
- 60 – 80 patients seen per day; 12 - 15 received infusions

New Jersey – Oncology Office



FACT: Medication should not be prepared in areas that are potentially contaminated
FACT: Syringes should not be unwrapped or filled in advance

New Jersey – Oncology Office



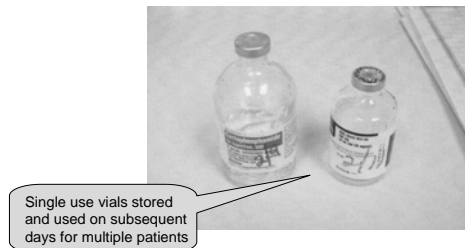
FACT: Environmental surfaces must be kept clean
FACT: Vacutainer holders should not be reused
FACT: Potentially contaminated items should not come in contact with other patient-care items (i.e.; gauze)

New Jersey – Oncology Office



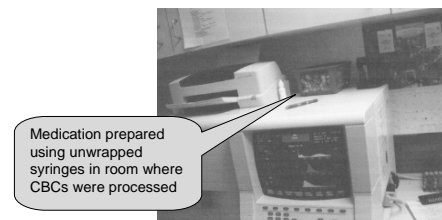
FACT: IV bags should not be opened or spiked in advance
FACT: IV bags should not be used a source of fluid for multiple patients

New Jersey – Oncology Office

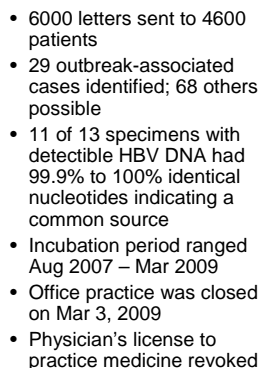


FACT: Single use vials do not have preservative and should not be used for more than one time or for more than one patient

New Jersey – Oncology Office



FACT: Syringes should not be unwrapped prior to use
FACT: Medication should not be stored or prepared in potentially contaminated areas



New Jersey – Acute Care Hospital, 2010



- 1 patient, 65 years of age, diagnosed with acute hepatitis C infection
 - No traditional risk factors elicited
 - Had ambulatory gynecologic surgery during the incubation period

New Jersey – Acute Care Hospital

- Chart review performed of patients who had surgery performed on the same day
- Chart review identified a patient with known chronic HCV who had surgery prior to index case
- Commonalities included 2 surgical nurses, 1 anesthesiologist, the anesthesia cart, and propofol
- Only the anesthesiologist performed invasive procedures on both patients, only common medication was propofol, anesthesia cart was used for both

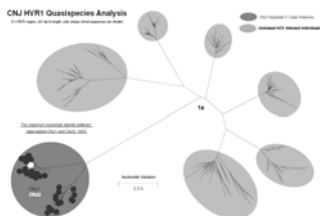
FACT: Medication should not be prepared in areas that are potentially contaminated or on potentially contaminated surfaces
FACT: Single-dose vials or bags of intravenous fluid should never be used for more than one patient



Inspection revealed:

- No policies for stocking or cleaning carts between cases
- No pharmacy accounting system to ensure appropriate use of single-dose vials
- Preparation of medication in patient care area on top of cart

New Jersey – Acute Care Hospital



- CDC quasispecies analysis revealed maximum nucleotide identities of 100% indicating common source
- ~ 80 patients of anesthesiologist notified to be tested
- No additional cases identified
- Facility policies amended; litigation pending

Other NJ Experiences



- Healthcare-associated HBV in a patient of a residential healthcare facility undergoing podiatry procedure at a private office, 2010
 - Inspections revealed breaches at both the residential facility and the podiatry office
 - > 1,000 patients notified
- Outbreak of HCV at a dialysis center, 2009
 - 16 cases identified from 2005 - 2009
- Staph infections associated with knee arthroscopy in an ambulatory surgery center, 2009
- Outbreak of *Klebsiella* associated with a private hematology-oncology practice, 2011
- *Strep salivarius* meningitis following epidural injection, 2011

Why are there lapses in **basic** infection control?

- Lack of awareness
- Poor/insufficient training
- Economics
- Lax or nonexistent policies and procedures



Common Themes and Findings

- **Investigations were resource-intensive and disruptive**
 - Notification, testing, and counseling of hundreds of patients
- **Delayed recognition and missed opportunities**
 - Prolonged transmission
 - Growing reservoirs of infected patients
- **IC programs lacking or responsibilities unclear**
 - Clinic space rented from a hospital (NE)
- **Entirely preventable**
 - Standard precautions + aseptic technique



MMWR 2003 52:901-6 / CID 2004; 38:1592-8

Injection practices among clinicians in United States health care settings

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

Pugliese et al 2010. AJIC.
Available at: <http://www.cdc.gov/injectionsafety> or
<http://www.ajicjournal.org/article/PIIS0196655310008539/abstract>

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 on an ambulatory basis.

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 ASCs 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, injection 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

JAMA. 2010;303(22):2273-2279

Multi-state ASC evaluation

- Objectives
 - Describe infection control practices in a sample of ASCs in additional states
 - Determine whether use of an infection control work sheet (ICWS) improved survey effectiveness
- Methods
 - Inspections in a sample of 68 ASCs in Maryland, North Carolina, and Oklahoma from June-October 2008
 - Used ICWS
 - Emphasis on observations
 - Focus on staff who performed procedures of interest
 - Case tracer methodology
 - Presence of infection control lapses in each of the infection control areas assessed was documented

Results of multi-state pilot infection control assessments

- 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

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

Infection control lapses

- 28% of ASCs used single-dose vials for multiple patients

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

- patient's intravenous infusion bag or administration set ⁴⁰⁹.
- Category IB
- IV.H.4. Use single-dose vials for parenteral medications whenever possible ⁴⁰³ Category IA
- IV.H.5. Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use ^{369 453, 1005} Category IA
- IV.H.6. If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile ^{453, 1002} Category IA

<http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

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Handling of Blood Glucose Monitoring Equipment	25/54	(46%)



Infection control lapses just as important.....

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008



Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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

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

- Tailor infection-control measures to individual practice setting
- Clearly designate responsibility for oversight and monitoring
- Periodically review staff practices (e.g., at least annually)
- Establish procedures and responsibilities for reporting and investigating breaches in infection-control policy

Prepare medications in areas physically separated from those with potential blood contamination.

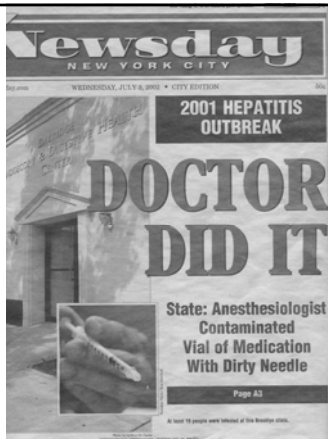
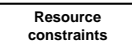
Use barriers to protect surfaces from blood contamination when blood samples are obtained.

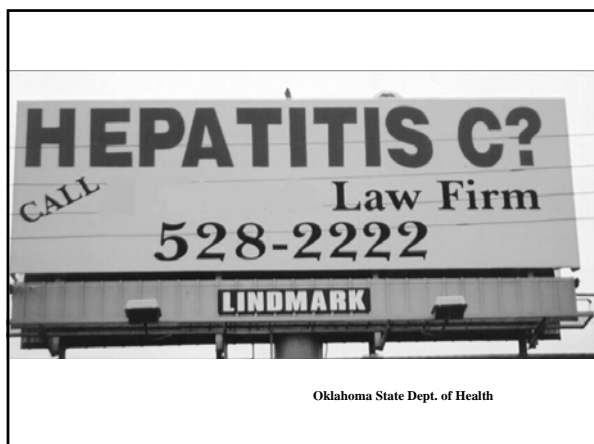
Clean and disinfect blood-contaminated equipment and surfaces in accordance with recommended guidelines.

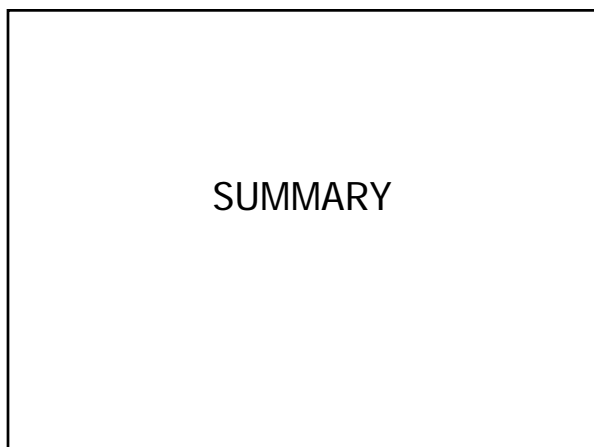
Hand hygiene and gloves

Perform hand hygiene (i.e., hand washing with soap and water or use of an alcohol-based hand rub) before preparing and administering an injection, before and after donning gloves for obtaining blood samples, after immediate blood contamination, and between patients.

Clinical Infectious Diseases 2004; 38:1592-8
www.cdc.gov/hepatitis








SUMMARY

Improper use of syringes, needles, and medication vials can result in:

- Transmission of life-threatening infections to patients
- Notification of patients of possible exposure to bloodborne pathogens and recommendation for testing
- Referral of providers to licensing boards for disciplinary action
- Malpractice suits filed by patients



Key Take-Home Messages

- All healthcare providers are urged to carefully review their infection control practices and the practices of all staff under their supervision. Healthcare providers must understand disease reporting requirements and have good working relationships with local public health agencies
- Public health professionals need to be aware of the possibility of healthcare-associated infections when investigating reportable diseases and outbreaks
- Healthcare consumers need to be advocates for safe injection practices









<http://www.state.nj.us/health/cd/reporting.shtml>

Thank You

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Some Frequently Asked Questions

Q: Is it OK to use the same syringe to give intramuscular (IM) or subcutaneous (SC) injections to more than one patient if I change the needle between patients?

A: NO. Once they are used, the syringe and needle are both contaminated and must be discarded. Use a new sterile syringe and needle for each patient.



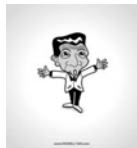
Q: If I used a syringe only to infuse medications into an IV tubing port that is several feet away from the patient's IV catheter site, is it OK to use the same syringe for another patient?

A: NO. Everything from the medication bag to the patient's catheter is a single interconnected unit



Q: Are these recommendations new?

A: NO. These recommendations are part of established guidance.



Q: How can healthcare providers ensure that injections are performed correctly?

A: To help ensure that staff understand and adhere to safe injection practices, consider the following:

- Designate someone to provide ongoing oversight for infection control issues
- Develop written infection control policies
- Provide training
- Conduct quality assurance assessments

Q: Can I reuse a syringe during a procedure for a patient who requires additional medication as long as the vial will not be used for another patient?

A: It is preferable to always use a new sterile syringe to withdraw medications, even if the medication will only be used for one patient. This provides an extra layer of protection for patients and is encouraged

Q: Why can't I just visually inspect syringes to determine whether they are contaminated or can be used again?

A: Pathogens including HCV, HBV, and human immunodeficiency virus (HIV) can be present in sufficient quantities to produce infection in the absence of visible blood. Just because you don't see blood or other material in a used syringe or IV tubing, e.g., does not mean the item is free from potentially infectious agents.

