

Keeping the Infection Out of the Injection

April 16, 2014

Today's host



Rachel Rosen, RN, MSN, Sr. Clinical Risk Management Consultant

- 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.



Today's speaker



Barbara Montana, MD, MPH, FACP Medical Director for the Communicable Disease Service New Jersey Department of Health

- 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 vaccinepreventable 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 physicians¹
 - >1 million patients with cancer receive outpatient chemotherapy and/or radiation each year
 - 67% of Medicare recipients receive chemotherapy in private physician's office²
 - Ambulatory Surgical Centers
 - 2009: 5175 (240% increase since 1996)
 - Outpatient procedures represent ¾ of all US surgical operations ³
 - Nursing Homes
 - 2009: 3.3 million Americans resided in nursing homes⁴
 - Residential Care Facilities (assisted living and personal care)
 - 2010: 971,900 beds in 31,100 facilities⁵

^{1.} National Ambulatory Medical Care Survey: 2007 Summary available at: http://www.cdc.gov/nchs/data/nhsr/nhsr027.pdf

^{2.} Milliman's analysis of Medicare 5% Sample, 2006-2009.

^{3.}Barie PS. Infection Control Practices in Ambulatory Surgical Centers. JAMA. 2010;303:2295-7

^{4.} Nursing Home Data Compendium available at: https://www.cms.gov/CertificationandComplianc/Downloads/nursinghomedatacompendium_508.pdf

^{5.}NCHS Data Brief, (78) Dec 2011 available at http://cdc.gov/nchs/data/databriefs/db78.pdf

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.

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/ncidod/dhqp/pdf/isolation2007.pdf

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

Guidelines for outpatient settings

GUIDE TO INFECTION PREVENTION FOR OUTPATIENT SETTINGS: Minimum Expectations for Safe Care

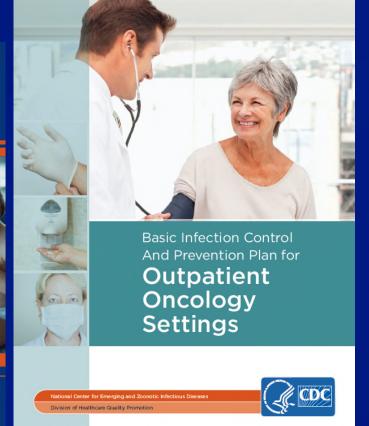


INFECTION PREVENTION CHECKLIST FOR OUTPATIENT SETTINGS:

Minimum Expectations for Safe Care







http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html http://www.cdc.gov/hicpac/basic-infection-control-prevention-plan-2011/index.html



Other guidelines

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

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.



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-todeliver 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
- Limit use of multi-dose vials and dedicate them to a single patient whenever possible
- Never administer medications from the same syringe to multiple patients
- Prepare medications in clean areas
- Do not reuse a syringe to enter a medication vial/solution
- Remove needles/syringes from sterile package at time of use, fill at time of use
- Do not administer medications from a single-dose vial or intravenous solution bag to more than one patient
- Follow guidelines for assisted blood glucose monitoring and other point-of-care testing



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

Thompson ND, Perz JF, Moorman AC, Holmberg SD. Ann Intern Med. 2009 Jan 6;150(1):33-9. Review.

*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

Unsafe injection practices: US alerts since 2001

- > 150,000 patients have required notification to advise bloodborne pathogen testing following potential exposure to unsafe injections¹
- 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

Examples of HBV/HCV outbreaks in outpatient settings due to unsafe injection practices since 2001

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

Outbreaks associated with outpatient oncology settings

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



Published: Wednesday, September 14, 2011, 9:51 PM Updated: Wednesday, September 14, 2011, 9:51 PM

By Megan DeMarco/Statehouse Bureau

glucose sampling, and now officials say dozens of people might be at risk for contracting serious diseases.

University of New Mexico School of

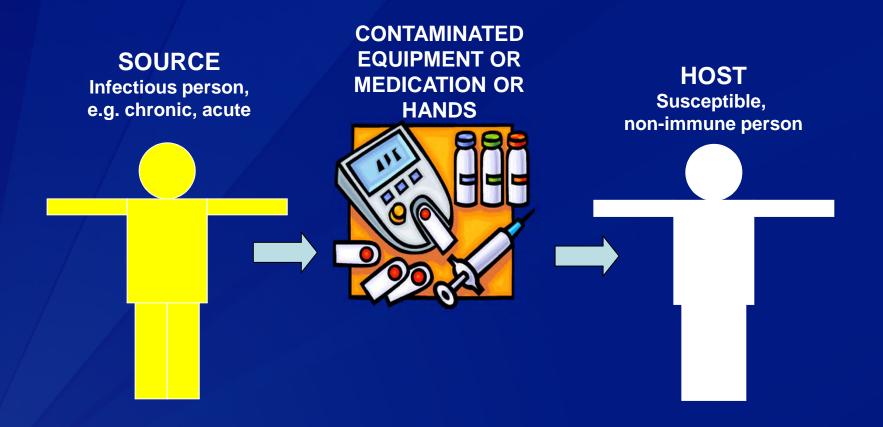
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Risks of medical injections in the US *outside* of recognized outbreaks

- 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 cased 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), unjections (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



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*

- +Kamili S, Krawczynski K, McCaustland K, et al. Infectivity of hepatitis C virus in plasma after drying and storing at room temperature. Infect Control Hosp Epidemiol. 2007;28:519-24.
- * Bond WW, Favero MS, Petersen NJ, et al. Survival of hepatitis B virus after drying and storage for one week. Lancet 1981;317:550-1.

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*

^{*}Katzenstein TL, Jorgensen LB, Permin H, et al. Nosocomial HIV-transmission in an outpatient clinic detected by epidemiological and phylogentic analyses. AIDS. 1999;13:1737-44.



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



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

The New Hork Times

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January 13, 2002

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 hepatitis B, hepatitis C and H.I.V. as part of an investigation into the possible impre administration of injections at his medical practice.

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

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

imp Business information > Business articles > New York Law Journal



Decision of Interest.

Newspaper Article from: New York Law Journal | May 28, 2004 | Copyright

Lachterman v. Halpern - Defendant Dr. Seymour Halpern has moved herein for summary judgment dismissing plaintiff's request for treble and punitive damages in this medical malpractice action. As to treble damages, defendant contends that the requisite statutory basis has not been established. As to punitive damages, defendant contends that insufficient evidence exists to support such an

Plaintiff does not dispute that the requisite statutory basis for treble damages has not been stated. Springer v. Viking Press, 90 AD2d 315 (1st Dep't 1982), aff'd 60 NY2d 916 (1983). Therefore, that part extraordinary claim. of defendant's motion which seeks to strike the demand in plaintiff's complaint for treble damages is granted. However, plaintiff vigorously disputes defendant's contention that no basis exists for punitive damages as a matter of law. On that point, this Court agrees with the plaintiff.

The instant action is one of seven actions against the same physician Dr. Seymour Halpern which have been assigned to this Court.[1] All involve the same central fact pattern. Many of the relevant The Hepatitis Outbreak facts 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.



Press Release

New York City Department of Health Office of Public Affairs

FOR IMMEDIATE RELEASE CONTACT: Sandra Mullin/Andrew Tucker Friday, January 11, 2002 (212) 295-5335/5336

NYC DEPARTMENT OF HEALTH INVESTIGATING HEPATITIS B CASES AMONG PATIENTS TREATED BY DOCTOR'S OFFICE IN MANHATTAN All Patients who Received Injections at this Practice are Being Notified of Potential Risk

The New York City Department of Health (DOH) today announced that it is working with the New York State Department of Health to investigate the occurrence of hepatitis B in twenty patients who receive care from a medical practice operated by Dr. Seymour Halpern. DOH has been contacting all individuals who currently receive medical care at the practice located at 146 Central Park West in Manhattan, and is advising them to seek testing. Dr. Halpern is participating fully in this investigation and has been very

STATE BOARD FOR PROFESSION

IN THE MATTER

OF

SEYMOUR HALPERN, M.D.

NONDISCIPL STIPULATION & ORDER OF CONDITIONS **PURSUANT TO 6230 OF THE** PUBLIC HEALTH LAW

Upon the Stipulation and Application of SEYMOUR HALPERN M.D. (Licensee) for an Order Of Conditions Pursuant to §230 of the Public Health Law, which application is made a

part hereof, it is agreed to and

ORDERED, that the application and the provisions thereof are hereby adopted and so ORDERED; and it is further

ORDERED, that this order shall take effect as of the date of the issuance of this order and shall remain in effect as set forth in the Stipulation and Application.

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



Macedo de Oliveria A et al. Ann Intern Med 2005;142:898-902.

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

Macedo de Oliveria A et al. Ann Intern Med 2005;142:898-902.

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

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

Following the Nebraska HCV outbreak: One survivor's response

HONORe form dation

Evelyn's Story

<u>Dr. Evelyn McKnight</u> is a nationally recognized patient safety advocate and survivor of one of the largest viral outbreaks in Amer history. Dr. McKnight turned her own personal tragedy ir save lives.

Evelyn is co-founder and president of HONOReform and I-Foundation. She is co-author of A Never Event: Exposing to Outbreak of Hepatitis C in American Healthcare History, in vithe 2001 Nebraska outbreak. Evelyn presents at local, renational conferences; she recently presented at conferer APIC, the CDC and the CDC Foundation, and she present Vaccine Congress, among many others. All honoraria she

"Patient turns a harsh light on dangerous medical error."
—as seen in USA Today **Exposing the Largest** Outbreak of Henatitis C in American Healthcare History McKnight T. Bennington

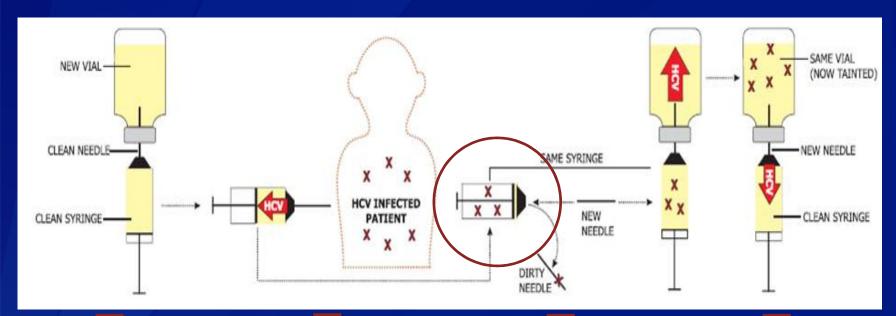


HCV Outbreak – Nevada, 2007 Endoscopy center

- 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

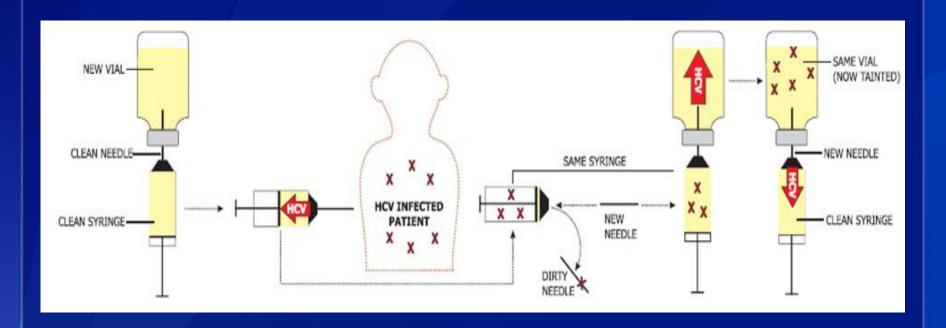
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Contaminated singleuse vial used for subsequent patient

MMWR; May 16, 2008; 57:19 HCV: hepatitis C virus

45

HCV Outbreak – Nevada, 2007 Endoscopy center



- > 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





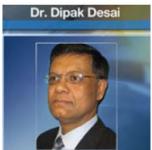


Ex-Vegas MD guilty of murder in wide Hepatitis C outbreak

Insurance Company for Dr. Desai Denies Liability

UPDATED: JUL 22, 2008 10:00 PM EDT

EDWARD LAWRENCE, REPORTER



Two major decisions Tuesday in the civil lawsuit surrounding the hepatitis-C crisis. One decision concerns whether attorneys can sue the company that insures the doctors. They also made a decision about whether a class action

First, the Company Southern because (

'Sometin careful al

reviewjournal.com

lawsuit can go forward.



CBS NEWS

Tuesday, 2 July 2013 (1 week ago)

2nd-degree murder was among 27 counts against Dipak Desai; At least 9 cases were linked to his clinics, 63,000 patients were tested in 2008



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 630,240. 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 1105 Terminal Way, Suite 301

> Reno, Nevada 89502 E-mail: nsbme@medboard.nv.gov

Police recommend criminal charges hepatitis outbreak

By BRIAN HAYNES LAS VEGAS REVIEW-JOURNAL Posted: Nov. 19, 2009 | 3:23 p.m.

Feds' blitz: 30 days, 50 clinics

The thousands of Southern Nevadans who want to Teams of investigators swooping into Nevada to get an

In their final report submitted to prosecutors, Las Vegas police recommended criminal charges for the doctor and others in his medical clinics for their roles in the hepatitis C outbreak blamed on unsafe injection practices.

HCV Outbreak – New York, 2001 – 2008 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

HCV Outbreak – New York, 2001 – 2008 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

March 6, 2009 / Vol. 58 / No. 8



Hepatitis C Virus Transmission at an Outpatient Hemodialysis Unit — New York, 2001–2008

Assisted blood glucose monitoring



Centers for Disease Control and Prevention

CDC 24/7: Saving Lives. Protecting People.™

SEARCH

Injection Safety

Injection Safety

CDC's Role

CDC Statement

Information for Providers

Information for Patients

Preventing Unsafe Injection Practices

Infection Prevention during Blood Glucose Monitoring and Insulin Administration

FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration

CDC Clinical Reminder: Fingerstick Devices

Clinical Reminder: Insulin Pens

Recent Publications

Recent Meetings

The One & Only Campaign

Patient Notification Toolkit

Related Links

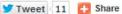
One & Only Campaign &

Injection Safety









Infection Prevention during Blood Glucose Monitoring and Insulin Administration

On this Page

- Summary
- Blood Glucose Monitoring and Insulin Administration
- Unsafe Practices
- Best Practices
- Fingerstick Devices

- Blood Glucose Meters
- Insulin Administration
- Recommended Practices
- Additional Information
- References

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other infectious diseases during assisted blood glucose (blood sugar) monitoring and insulin administration.

CDC is alerting all persons who assist others with blood glucose monitoring and/or insulin administration of the following infection control requirements:





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Contact Us:



Centers for Disease Control and Prevention 1600 Clifton Rd Atlanta, GA 30333

800-CDC-INFO (800-232-4636)

TTY: (888) 232-6348 Contact CDC-INFO

Glucose monitoring facts

Whenever possible, blood glucose meters should not be shared. If meters are shared, they must be approved for multipatient 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

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

Outbreaks of HBV infection associated with blood glucose monitoring - 1990 to 2010, US



Thompson J Diabetes Sci Technol 2009; 3:283-88. Thompson JDST 2011;5:1396-1402. CDC unpublished data.

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



HBV Outbreak – North Carolina, 2009 Assisted living facility

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).

Officials Release Findings In GlenCare Investigation

By NBC17 Staff





Published: November 16, 2010

Inspectors looking into what caused a fatal 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 tainted blood made its way into or on to the devices.

- 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



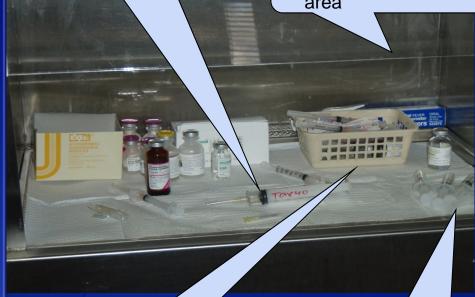
- "Each patient is an island"
- Appropriately space patient care areas
- Do not share IV poles or chair-side tables
- Perform good hand hygiene; use gloves appropriately

HBV Outbreak - New Jersey, 2009

Private hematology/oncology practice

Syringes filled in advance

Medication prepared in hood in patient treatment area



Blood drawing equipment in area of medication preparation

Uncapped syringes for flushing IVs unwrapped and prefilled in advance



Medication prepared using unwrapped syringes in room where CBCs were processed

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





Blood contamination

Reused Vacutainer holders in contact with gauze

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

IV bags used as sources of fluid to flush catheters for multiple patients



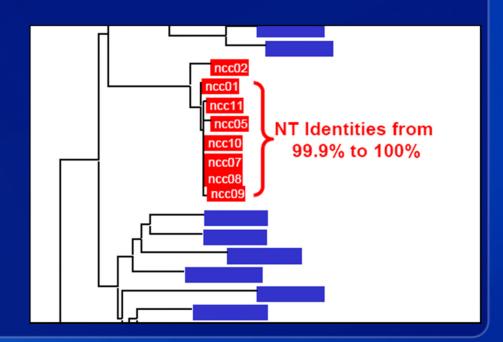
IV bags with stoppers removed

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

- IV bags should be opened/spiked as close to time of use as possible
- IV bags should not be used 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

- 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



Greeley RD et al. Am J Infect Control 2011; Oct;39:663-70.

- 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 D. Greeley, MPH. A.b. Shereen Semple, MS. Nicola D. Thompson, PhD, MS. Patricia High, MHS, CHES, Ellen Rudowski, RN, MSN, APN. Piziabeth Handschur, MPH. Guo-liang Xia, MD, Ellia Ganova-Raeva, PhD, Elennifer Crawford, MPH, CHES, Corwin Robertson, MD, MPH, FACP, Christina Tan, MD, MPH, PACP, and Barbara Montana, MD, 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 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 staff practices. Patients who visited the office practice between January 1, 2006 and March 3, 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 Diesaes Control and Prevention for HBV DNA testing and phylogenic analysis.

Results: Multiple breaches in infection control were identified, including deficient policies and procedures, improper hand hygiene, medication preparation in a blood processing area, common-use saline bags, and muse of single-dose vials. The office practice was closed, and the physician's license was suspended. Out of 2,700 patients notified, the results were available for 1,304 (5) 601. The processing of the physician's license was suspended. Out of 2,700 patients notified, the results were available for 1,304 (5) 601. The processing of the physician's license was suspended. Out of 2,700 patients notified.

(51.6%). Twenty-nine outbreak-associated HBV cases were identified. Specimens from 1 100% nucleotide identity on phylogenetic analysis.
Conclusion: Systematic breaches in infection control led to ongoing transmission of HBV in

Am J Infect Control 2011;39:663-70

vasive procedures at the office practice. This investigation underscores the need for improved regulatory oversignt or outpatient health care settings, improved infection control and of injection safety education for health care providers, and the development of mechanisms for ongoing communication coperation among public health agencies.

Rev Woods Capacity Needless needless: health care, associated infection; infection control beaches; injection safety.

Key Words: Cancer; bloodborne pathogen; health care-associated infection; infection control breaches; injection safety.

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Doctor in N.J. hepatitis outbreak fights for license

Attorneya

LEGAL TOPICS BREAKING NEWS

NJ Oncologist Sued by Patient for Spreading Hepatitis B

Updated 4/5/2009 1:46 PM

he contracted hepatitis B after being treated for prost

Spension / Programs / Units

Other News Pages

Consumer Affairs (Division of

Criminal Justice (Christon of) Garning Entwoment (Civ. of)

Highway Traffic Safety (Division of)

Insurance Fraud Presposter (Office of)

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Governor's Office Civil Rights (Division on)

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

Posted on 06. Dec, 2009 in News Stories



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

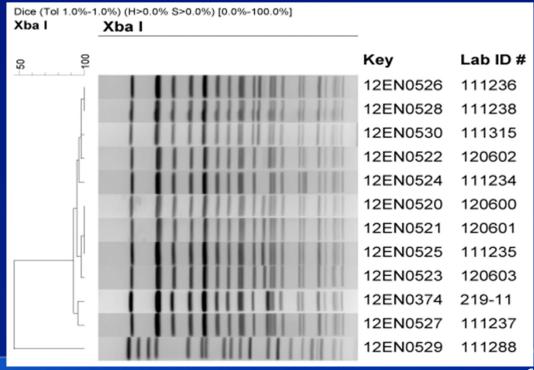
K. pneumoniae Outbreak – New Jersey, 2011 Case-Finding

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



IV bags used as sources of fluid to prepare medication for multiple patients

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

K. pneumoniae Outbreak – New Jersey, 2011 Private hematology/oncology practice





- 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>)

K. pneumoniae Outbreak – New Jersey, 2011 Private hematology/oncology practice



- 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

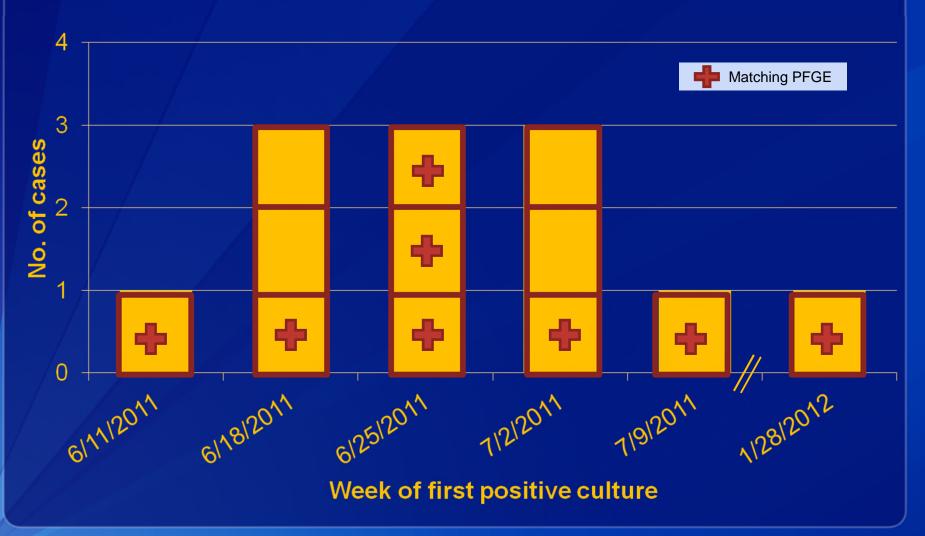




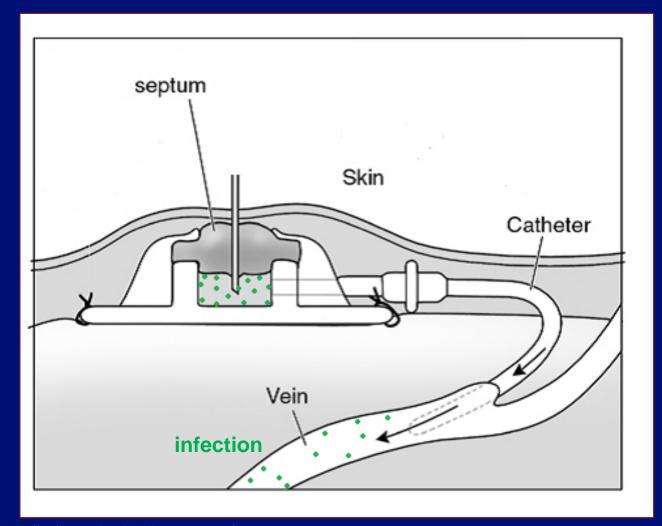


Single dose/single use vials do not contain preservative

K. pneumoniae Outbreak – New Jersey, 2011Cases by week of first positive (n=12)



Ports and Late-Onset Bloodstream Infection



Adapted from http://usfbreasthealth.blogspot.com/

Acute hepatitis B - Los Angeles, 2008 Long term care

ARTICLE IN PRESS

Outbreak of acute hepatitis B virus infections associated with podiatric care at a psychiatric long-term care facility

Matthew E. Wise, PhD, MPH, a,b 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.

Rey 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;■1-7.)

Acute hepatitis B - Los Angeles, 2008 Long term care

□ 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

Acute hepatitis B - Los Angeles, 2008 Long term care

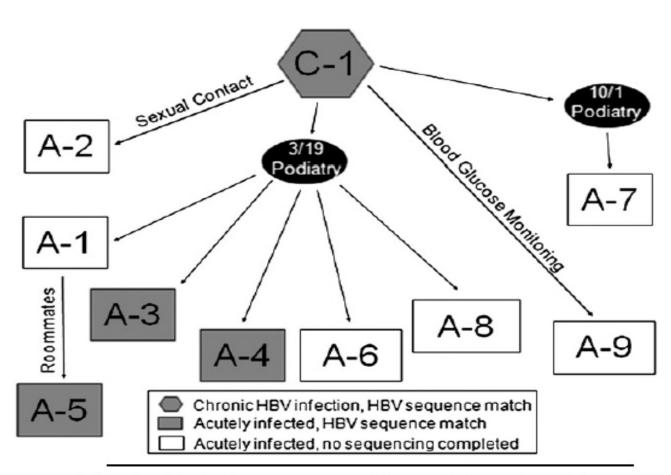


Fig 1. Links between resident C-1 and residents who developed acute HBV infection.

Acute hepatitis B - Los Angeles, 2008

Long term care 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

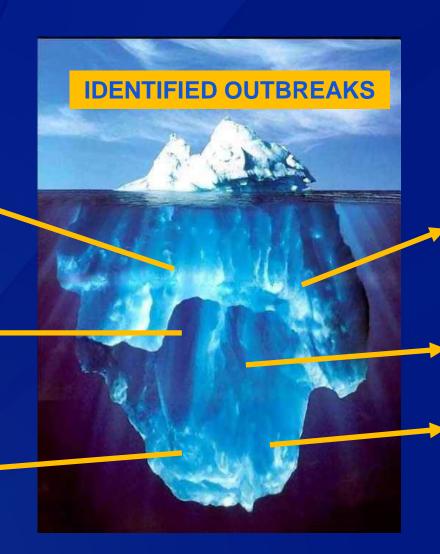


How much can we see?

Asymptomatic infection

Underreporting of cases

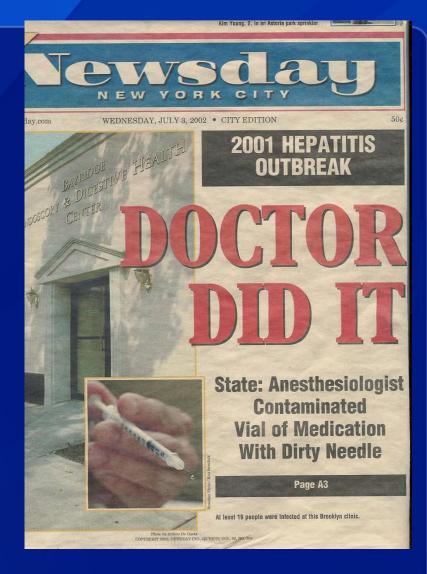
Underrecognition of healthcare as risk



Difficulty identifying single healthcare exposure

Barriers to investigation

Resource constraints



WHY DOES THIS KEEP HAPPENING?

Dangerous Misperceptions

Myth

Changing the needle makes a syringe safe for reuse.

Syringes can be reused as long as an injection is administered through an intervening length of IV tubing.

If you don't see blood in the IV tubing or syringe, it means that those supplies are safe for reuse.

Single-dose vials with large volumes that appear to contain multiple doses can be used for more than one patient.

Truth

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.

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.

Pathogens including hepatitis C virus, hepatitis B virus, and HIV can be present in sufficient quantities to produce infection without any visible blood.

Single-dose vials should not be used for more than one patient regardless of the vial size.

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

Injection practices among clinicians in United States health care settings

Gina Pugliese, RN, MS, ^a Cathie Gosnell, RN, MS, MBA, ^b Judene M. Bartley, MS, MPH, CIC, ^c and Scott Robinson, MA, MPH

Charlotte, North Carolina

Background: Improper use of syringes, needles, and medication vials has resulted in patient-to-patient transmission of bloodborne pathogens, including hepatitis C virus. This study examined the injection practices of health care providers to identify trends and target opportunities for education on safe practices.

Methods: An on-line survey was conducted in May and June 2010 of clinicians in US health care settings that prepare and/or administer parenteral medications.

Results: The majority of the 5446 eligible respondents reported injection practices consistent with current recommendations. However, the following unsafe practices were identified: 6.0% "sometimes or always" use single-doselsingle-use vials for more than 1 patient; 0.9% "sometimes or always" reuse a syringe but change the needle for use on a second patient; 15.1% reuse a syringe to enter a multidose vial and then 6.5% save that vial for use on another patient (1.1% overall).

Conclusion: Unsafe injection practices represent an ongoing threat to patient safety. Ensuring safe injection practices in all health care settings will require a multifaceted approach that focuses on surveillance, oversight, enforcement, and continuing education.

Key Words: Injection safety; bloodborne pathogens; survey needlestick injuries; safety practices; reuse syringes; reuse vials; propofol.

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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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Joseph F. Perz, DrPH, MA

VER 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, 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. 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

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%))



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



A-Z Index A B C D E F G H I] K L M N O P Q R S I U Y W X Y Z #

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.



Preventing Unsafe

Assisted Monitoring of



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SEARCH

www.oneandonlycampaign.org







About the Campaign

The One & Only Campaign is a public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices.



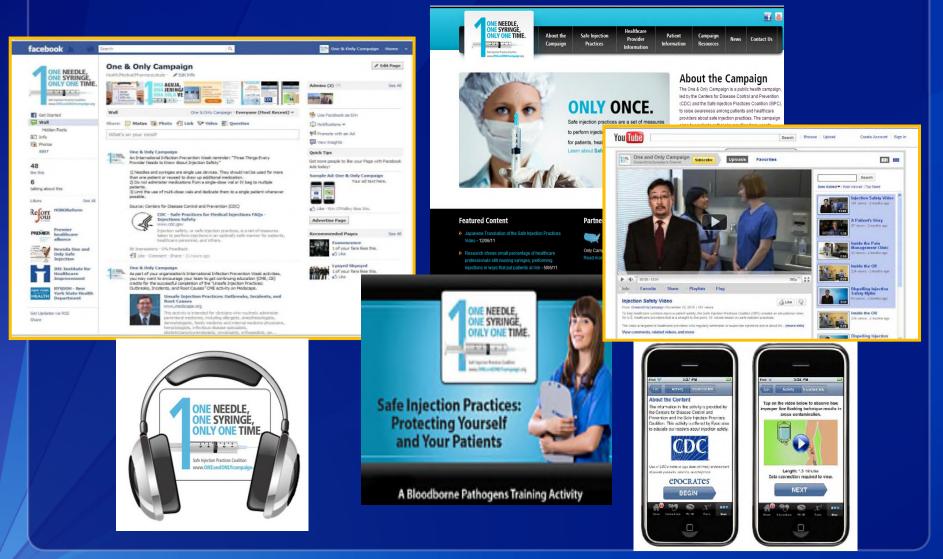
Featured Content

Partner States

Campaign Resources

Launch of Free Continuing Education Activity on Safe

www.ONEandONLYcampaign.org







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.



Recognize the differences between singledose and multiple-dose vials and understand appropriate use of each container type.

View graphic

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





Thank you!



Barbara Montana, MD, MPH, FACP Medical Director, Communicable Disease Service Barbara.Montana@doh.state.nj.us



What questions do you have?



Thank You!



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