



Healthcare-Associated Viral Hepatitis: Considerations for Healthcare Practitioners and Public Health Management



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Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

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**“Patients deserve effective infection control
wherever they receive health care.”**

- Macedo de Oliveira et al.

**“Health care organizations must develop up-
to-date infection control practices, not just in
hospitals but in all [...] facilities.”**

-Wenzel and Edmond

Annals of Internal Medicine, 2005, (142)11

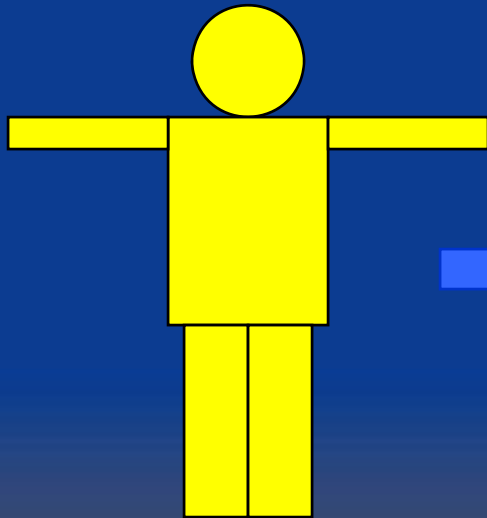
Background: Healthcare-Associated Viral Hepatitis Transmission, United States

- Decreased transfusion and occupational risks
- Increasing recognition of outbreaks
 - Detection is haphazard (“hit or miss”)
 - Asymptomatic infections
 - Long incubation periods/ low index of suspicion
 - Various settings, primarily those providing outpatient (ambulatory) care
 - Unsafe injection practices / aseptic technique

TRANSMISSION OF BLOODBORNE PATHOGENS VIA CONTAMINATED EQUIPMENT OR MEDICATIONS

SOURCE

Infectious person,
e.g. chronic, acute

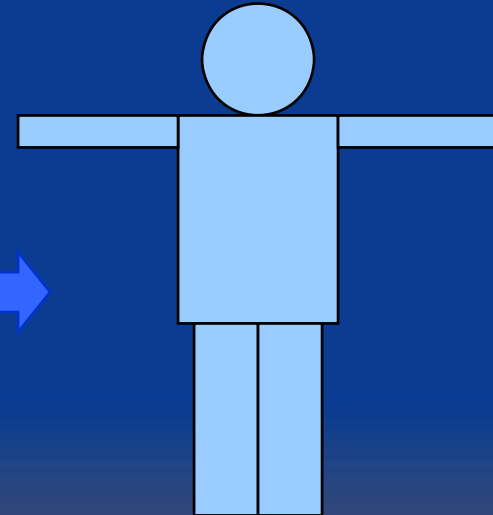


CONTAMINATED EQUIPMENT OR MEDICATION OR HANDS



CASE

Susceptible,
non-immune person

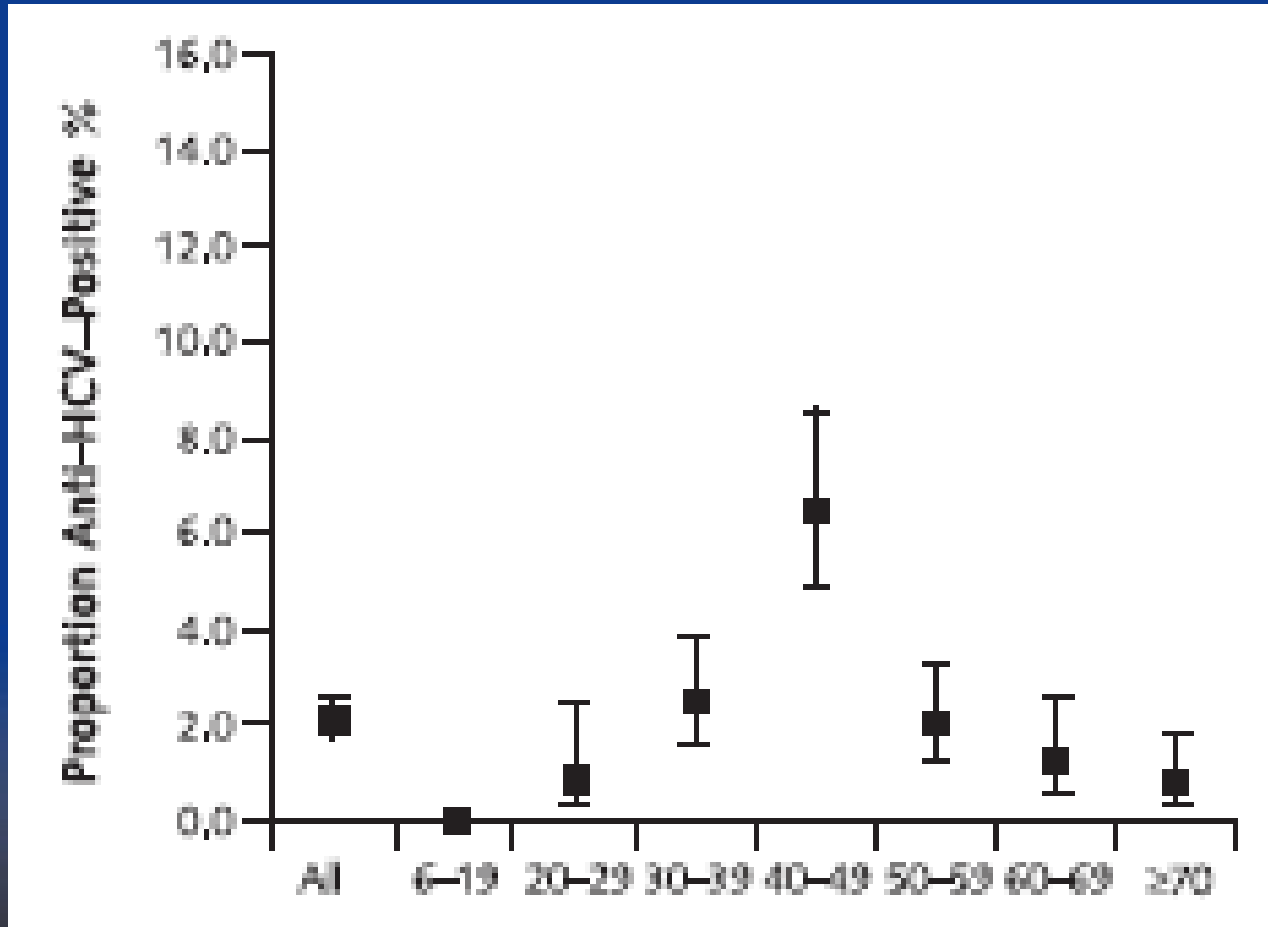


Characteristics of HBV and HCV

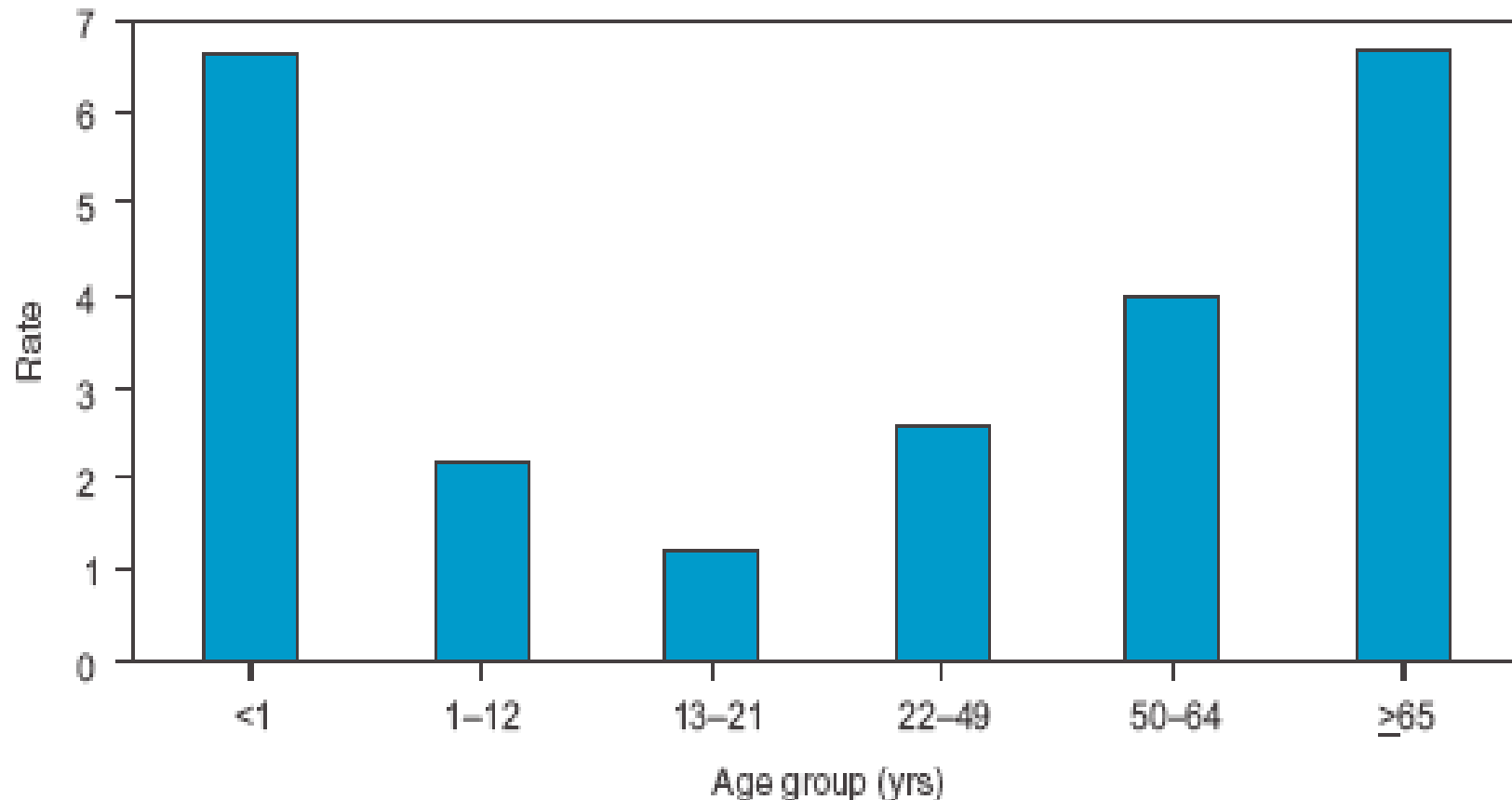
<u>Characteristic</u>	<u>HBV</u>	<u>HCV</u>
Titer (per ml)*	10 ⁸⁻⁹	10 ⁶
Environmental stability	>week	days
Reservoir size (U.S.)	1.3M	2.7M

* Blood, acute infection

Prevalence of Anti-HCV, United States, Males, 1999-2002 (NHANES)



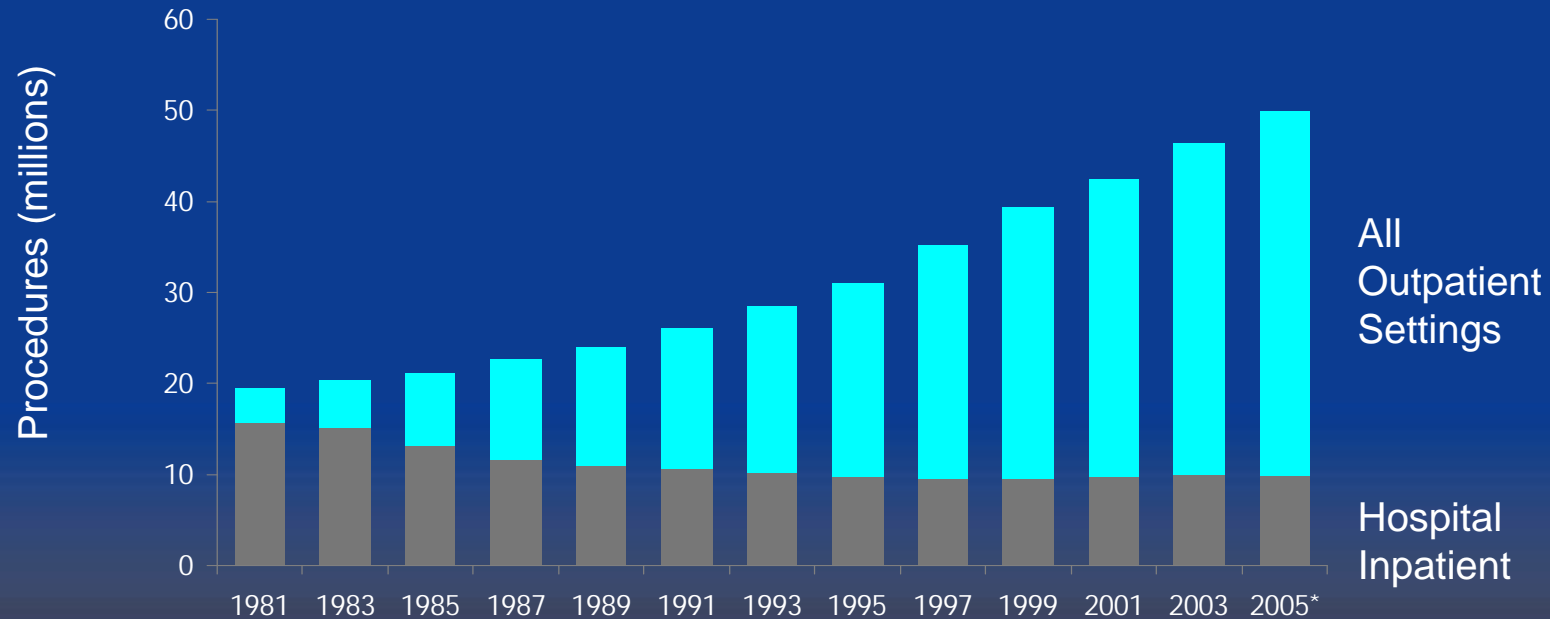
Annual Rate of Visits per Person to Physician Offices, by Patient Age Group — United States, 2003



Growth in Outpatient Care

- Shift in healthcare delivery from acute care settings to ambulatory care, long term care and free standing specialty care sites
 - Infection control oversight often lacking
- Approximately 1.2 billion outpatient visits / year
- Dialysis Centers
 - 2008: 4,950 (72% increase since 1996)
- Ambulatory Surgical Centers
 - 2009: 5100 (240% increase since 1996)
- Assisted Living Facility Beds
 - 2004: 934,000 (53% increase since 1998)

Increasing numbers of surgical procedures are moving from the inpatient to the outpatient setting



Source: Slide provided by AHA, based on Avalere Health analysis of Verispan's Diagnostic Imaging Center Profiling Solution, 2004, and American Hospital Association Annual Survey data for community hospitals, 1981-2004. *2005 values are estimates.

Emerging Threat to Patient Safety

- Outbreaks associated with unsafe injections and other breakdowns in basic infection control
- Large public health patient notifications advising testing for hepatitis B virus, hepatitis C virus, and HIV





MMWR™

Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

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

May 16, 2008 / Vol. 57 / No. 19

CDC

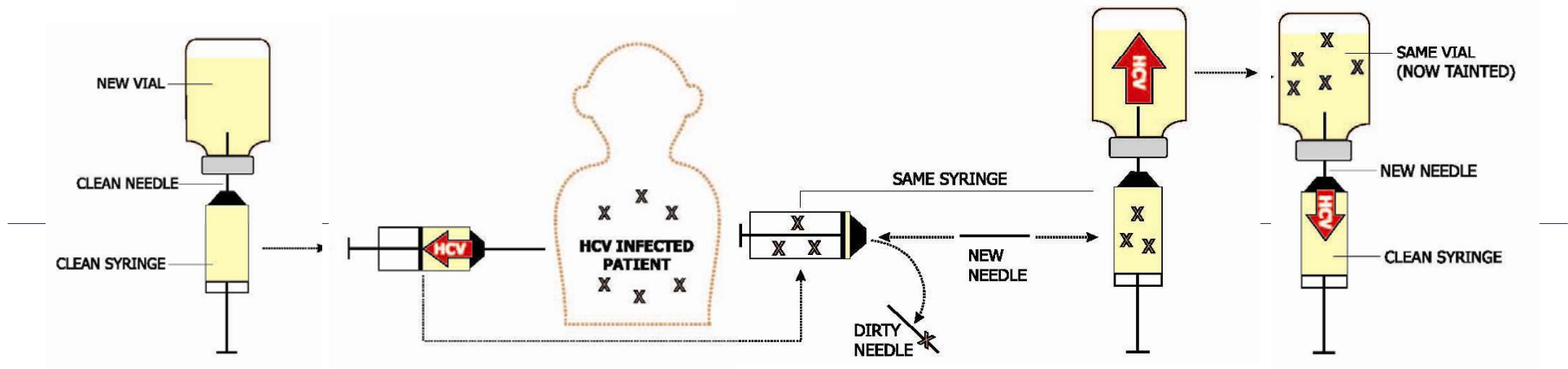
Nevada Hepatitis C Outbreak

- January 2008 – cluster of 3 acute hepatitis C cases identified in Las Vegas
- All 3 patients underwent procedures at the same endoscopy clinic during the incubation period
- Clinic performed upper and lower endoscopies
 - 50-60 procedures/day
- Reviews of surveillance records, laboratory records and a physician report identified 3 additional clinic-associated cases

Review of Anesthesia Delivery

- Started induction with syringe filled with lidocaine (1cc) and propofol (9ccs)
 - Clean needle and syringe used to inject directly through intravenous catheter
- If patient needed more anesthesia, some providers:
 - Removed needle from syringe and replaced with a new one
 - Used old syringe w/ new needle to draw more propofol
- Medication remaining in the vial was used to sedate the next patient

Unsafe Injection Practices that Likely Led to HCV Transmission



1. Clean needle and syringes are used to draw medication

2. When used on an HCV-infected patient, backflow from the injection or removal of the needle contaminates the syringe

3. When again used to draw medication, contaminated syringe contaminates the medication vial

4. Contaminated vial that is reused exposes subsequent patients to risk of HCV infection

MMWR; May 16, 2008; 57:19

CDC

Nevada Outbreak – Epilogue

- Clinic immediately advised to stop unsafe injection practices
 - License revoked and clinic was closed
- Unsafe practices had been commonly used by some staff at the clinic for at least 4 years
 - Health department began notifying ~40,000 persons to recommend HBV, HCV, HIV screening
- CDC assisted with infection control assessments at all Nevada ambulatory surgical centers
 - CMS pilot conducted in OK, NC, and MD
 - Infection control tool incorporated into routine surveys



Was Nevada an Isolated Incident?

Viral Hepatitis Outbreaks - Outpatient Settings

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	Chelation therapy	2005	HBV
CA	Alternative medicine infusion	2005	HCV
NY	Endoscopy/surgery clinics	2006	HBV+HCV
NY	Anesthesiologist office	2007	HCV
NV	Endoscopy clinic	2008	HCV
NC	Cardiology clinic	2008	HCV
NJ	Oncology clinic	2009	HBV

Thompson et al. *Ann Intern Med.* 2009;150:33-39.

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CA	Alternative medicine infusion	2005	HCV
NY	Endoscopy/surgery clinics	2006	HBV+HCV

→ Breaks in aseptic handling of parenteral medications

NV	Endoscopy clinic	2008	HCV
NC	Cardiology clinic	2008	HCV
NJ	Oncology clinic	2009	HBV

Thompson et al. *Ann Intern Med.* 2009;150:33-39.

Syringe Reuse Incidents, 2007-08

Notification and Testing for Hepatitis B Virus, Hepatitis C Virus, and HIV

- New York City – Endoscopy clinic – Hepatitis C virus transmission → 4,500 patients notified
- Long Island, NY – Pain Management Clinic – Hepatitis C virus transmission → 10,400 patients notified
- Michigan – Dermatologist – Fraud investigation → 13,000 patients notified
- Las Vegas, NV – Endoscopy clinic – Hepatitis C virus transmission → 40,000 patients notified



John Mangan



What should happen if the Jets broke the rules?
Talk about it at newsday.com



Patricia Binkley

Newsday

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Project** A3



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Stole His
Christmas
Lights** A6



THE SYRINGE MESS

**8,500
More
At Risk**

Every patient doc treated for 5 years
should be tested, health officials say A5

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What are some of the incorrect practices that have resulted in transmission of pathogens?

- Using the same syringe to administer medication to more than one patient, even if the needle was changed or if injected into IV tubing
- Reuse of syringe to draw medication or flush solution from a container that is then used for other patients
- Using single dose vials or a common bag of saline or other IV fluid for more than one patient
- Injections prepared in immediate patient treatment areas or other contaminated area

Private Medical Practice: New York City, 2001

Injection Preparation and Disposal

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

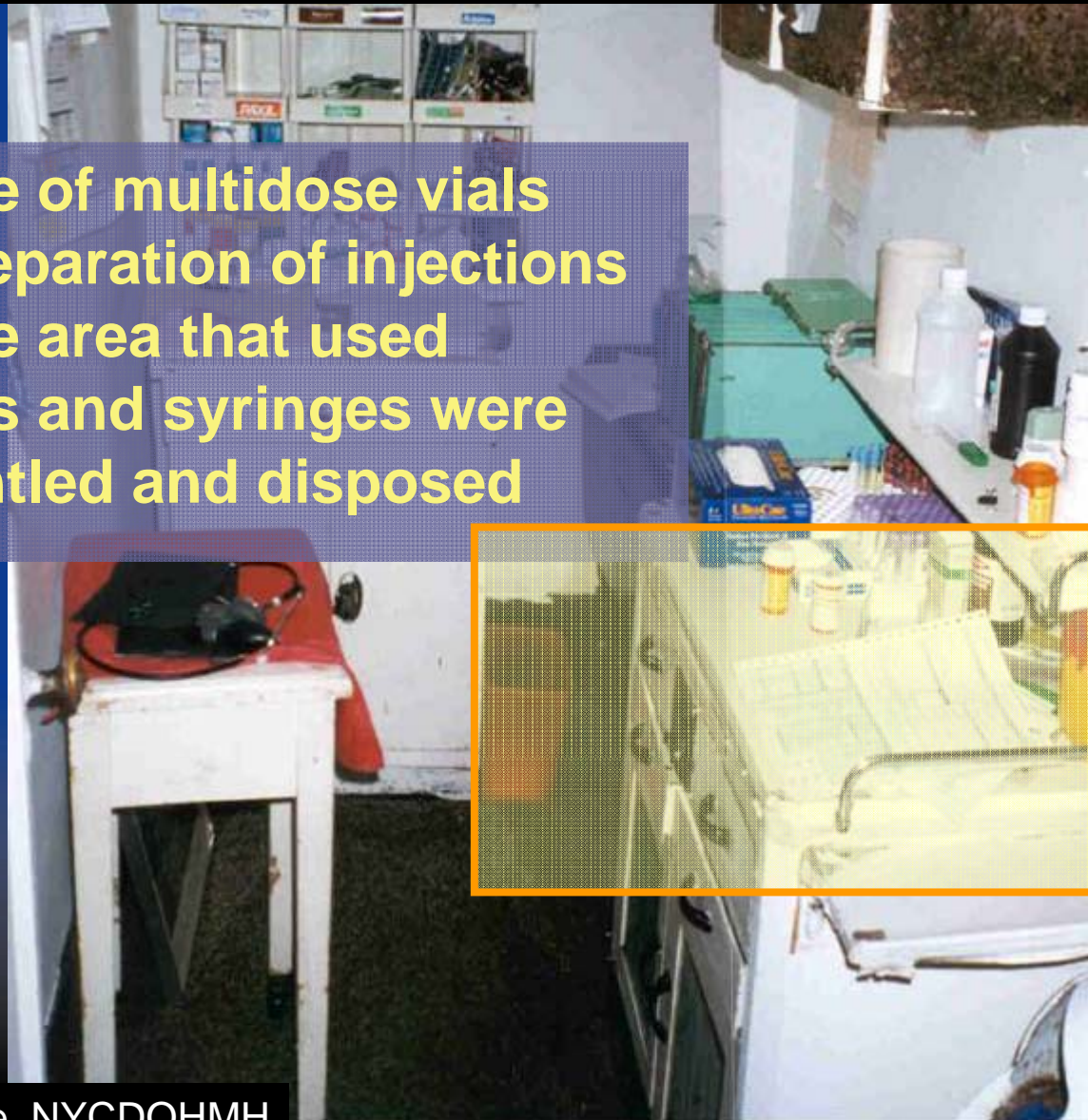


Photo: D. Weise, NYCDOHMH

CDC

Insulin Pen Reuse Incidents

- Incidents in which insulin pens were reused for multiple patients, reportedly after changing needles
- NY hospital, 2008
- TX hospital, 2009
 - 16 HCV+ patients





FDA News

FOR IMMEDIATE RELEASE

March 19, 2009

Media Inquiries:

Karen Riley, 301-796-4674

Consumer Inquiries:

888-INFO-FDA

FDA: Insulin Pens and Insulin Cartridges Must Not Be Shared

The U.S. Food and Drug Administration today issued an alert to health care professionals reminding them that single-patient insulin pens and insulin cartridges should not be used to administer medication to multiple patients due to the potential risk of transmitting blood-borne pathogens such as HIV and the hepatitis viruses.

Insulin pens are pen-shaped injector devices that contain a disposable needle and either an insulin reservoir or an insulin cartridge. The devices typically contain enough insulin for a patient to self-administer several doses of insulin before the reservoir or cartridge is empty. All insulin pens are approved only for single-patient use (one device for only one patient).

The FDA is aware of incidents at two undisclosed hospitals involving more than 2,000 people in which the cartridge component of the insulin pens were used to administer insulin to multiple patients, although the disposable needles were reportedly changed among patients.

"Insulin pens are designed to be safe for one patient to use one pen multiple times with a new, fresh needle for each injection," said Amy Egan, M.D., deputy director of safety

“Although the incident leading to this FDA alert occurred with insulin pens, the same risk may exist with shared use of any reusable injection device.”

Diabetes Care and Risks for Bloodborne Pathogen Transmission



Photo courtesy of the Statewide Program for Infection Control and Epidemiology (SPICE) at the University of North Carolina



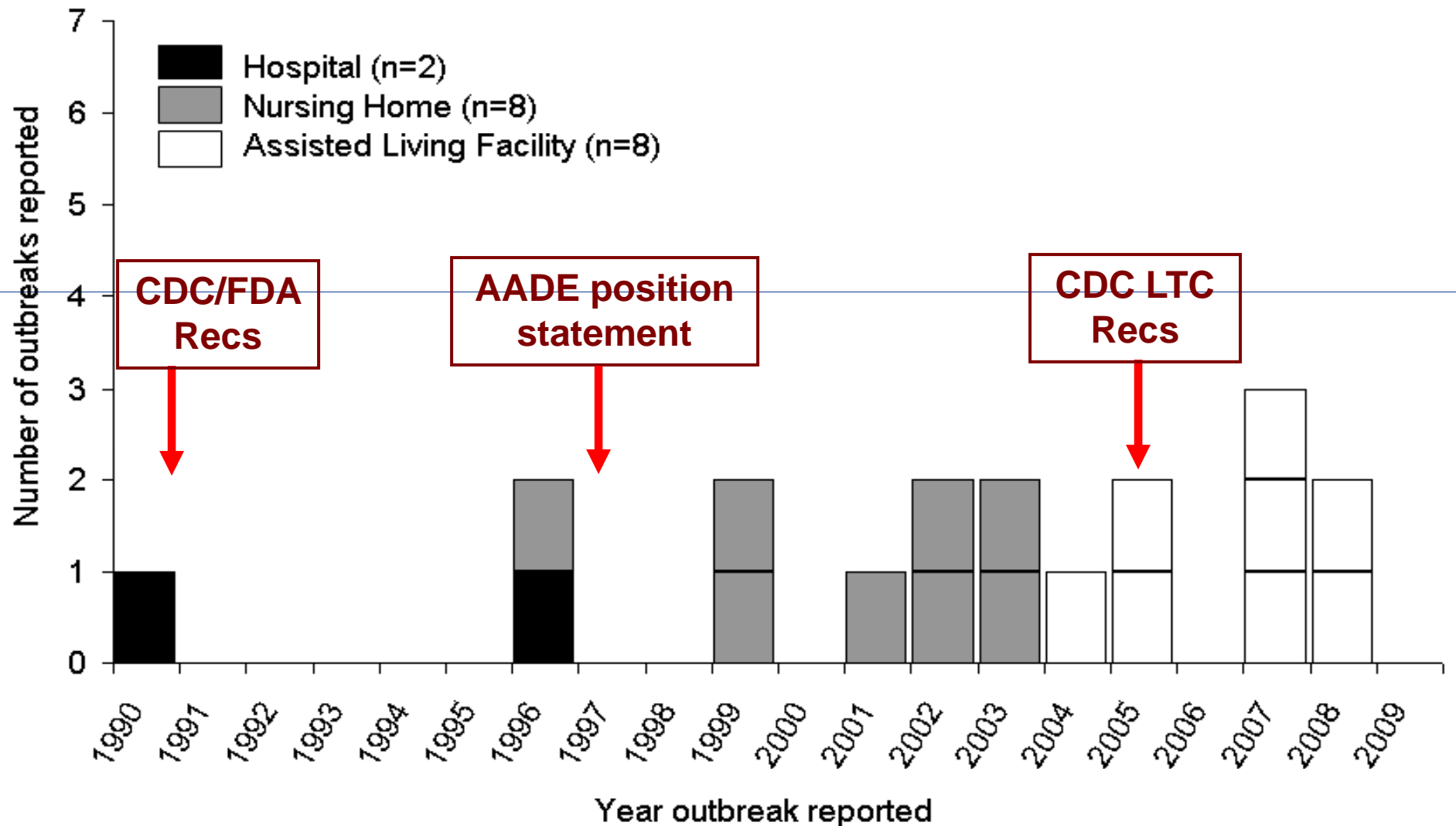
Blood Glucose Monitoring



- Fingersticks = Percutaneous Exposures
- Risks for bloodborne pathogen transmission
 - Settings in which multiple persons require FS
- Long-term care settings
 - Diabetes prevalence ~20-25%
- First outbreak occurred in Sweden shortly after insulin was introduced in 1922*

* Flaum et al. *Eine noscomiale Ikterus-Epidemie*. 1926.
Actas Medica Scandinavica

Reported outbreaks of HBV infection among persons monitoring blood glucose, US – 1990-2008



Thompson and Perz. Eliminating the Blood: Ongoing Outbreaks of Hepatitis B Virus Infection and the Need for Innovative Glucose Monitoring Technologies. *Journal of Diabetes Science and Technology* 2009;3:283-8.

Most Outbreaks Associated w/ Spring-loaded Penlet-type Lancing Devices



Disposable
cap w/
lancet



Reusable
barrel



**Single use, safety lancet –
lancet retracts after use,
disposable**

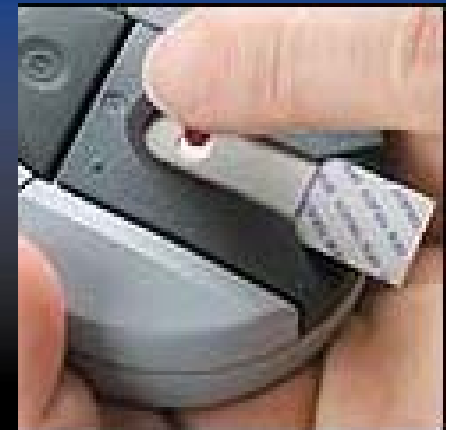


**Point of care blood glucose
testing meter (Glucometer)**

Shared Glucometer as Potential Vehicles for HBV Transmission

- Glucometers are the most widely used point-of-care testing device
- Multicenter hospital survey found that 30% of glucometers had blood contamination*
 - Most facilities lack schedule for cleaning meters or specify only daily cleaning
 - On-meter test strip dosing format associated with higher contamination risk
- Failure to clean and disinfect between patients may lead to glove contamination / inoculation

* Louie et al. *Point of Care* 2005, 4(4)158-163





How common are some of these practices?



- Survey of 50 Virginia ALFs* after outbreaks and an educational mailing found:
 - 7 (14%) shared penlets w/o cleaning
 - 8 (16%) shared glucometers (w/o cleaning)
- Survey of 38 Florida Nursing Homes and ALFs:
 - 4 (11%) shared penlets w/o cleaning
 - Sharing glucometers was common; only 27% of NHs reported cleaning devices between patients

* *A Patel et al. Infect Control Hosp Epidemiol 2009; 30:209-214*



Recommended Infection Control Practices

MMWR 2005; 54:220



- Never reuse lancets
 - Single-use safety lancets that retract and disable
- Assign separate glucometers to individual patients
- If glucometers must be shared
 - Clean and disinfect the device between patients
 - Select device designed for institutional use and which does not require test strip to be inserted while blood is applied



HCV & HBV in Hemodialysis

■ HCV

- Prevalence: 8-10% (vs. 1.6% in general US population)
- Isolation not recommended, no vaccine
- Prevention requires strict attention to infection control practices

■ HBV

- Prevalence has declined due to:
 - Infection control & isolation practices
 - Vaccination

Viral hepatitis outbreaks - hemodialysis centers

State	Year	Type	Cases
MD	1998	HCV	7
OH	2000	HCV	5
WI	2000	HCV	3
IL	2001	HCV	11
NY	2006	HCV	8
VA	2006	HCV	7
NY	2008	HCV	9

Thompson et al. *Ann Intern Med.* 2009;150:33-39.



HCV Transmission in Dialysis Centers



- Mechanism of transmission
 - Blood contamination of the environment, medication vials, and medical devices
- Implicated practices
 - Not routinely cleaning dialysis machines / station between patients
 - Use of mobile medication or supply carts
 - Preparation of injected medications in potentially contaminated areas
 - Re-entry and re-use of medication vials

N. Thompson. NKF Spring Meeting. Grapevine, TX. April 3, 2008



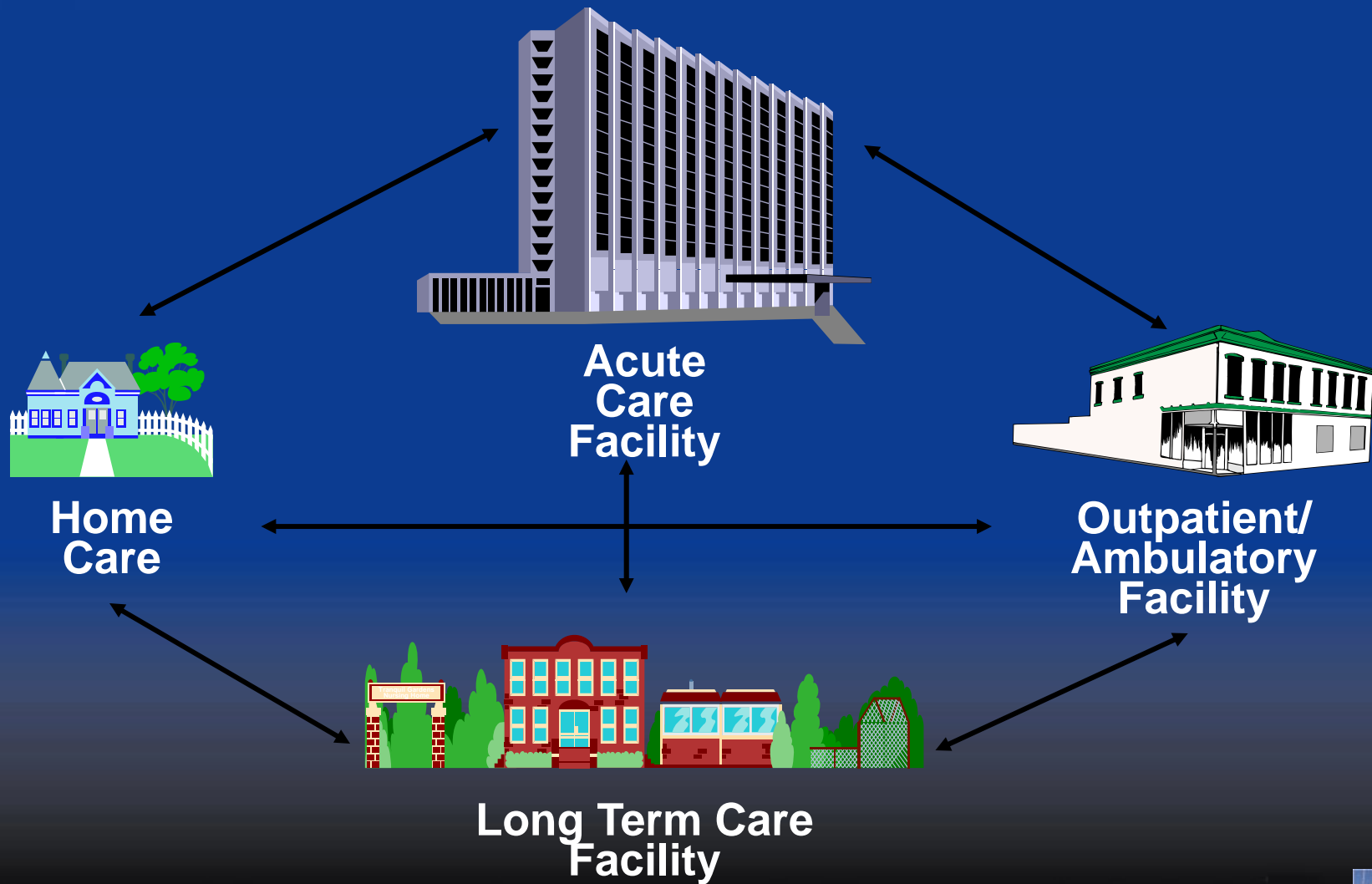


Medication Handling Issues in Dialysis Settings

- Pooling of medication
 - from several single-dose vials into one vial for subsequent administration
- Re-use of single-dose medication vials
 - to obtain doses for > 1 patient
- Medication preparation performed at patient station or other contaminated area
- Updated CMS Conditions for Coverage incorporate CDC Infection Control Guidelines*

* MMWR August 15, 2008 / 57(32);875-876

Increasing Public Health Needs Across the Continuum of Care





Basic Patient Protections



- Healthcare should not provide any avenue for transmission of bloodborne viruses
 - Basic patient safety / “red flag”
 - Risks of patient-to-patient spread on par with HCW and blood safety efforts
- Entirely preventable: **Standard Precautions**
 - Aseptic techniques for handling parenteral medications, administering injections, and sampling blood

Comprehensive Approach is Needed...

- **Public health surveillance and case-investigation**
- **Healthcare provider education and training**
- **Improvements in medical devices and medication packaging**
- **Professional oversight, licensing, and public awareness**



1. Public health surveillance and case-investigation

Core Public Health Functions

Surveillance and response are vital to recognize and contain transmission

Communication of findings helps establish evidence base and define issues/problems

Transmission of Hepatitis B in the Health Care Setting: The Elephant in the Room ... or the Mouse?

Ban Mishu Allos and William Schaffner

Division of Infectious Diseases, Department of Medicine, and Department of Preventive Medicine, Vanderbilt University School of Medicine, Nashville, Tennessee

“We suggest that the current burden of health care–acquired bloodborne infection is largely unknown because only modest efforts have been made to identify such cases and quantify the risk.”

→ Raise awareness and build capacity among health departments to investigate cases and clusters that are potentially healthcare related



2. Healthcare provider education and training

Establish / Reinforce Standards...

“Foundations of Safe Care”



Foundations of Safe Care



- Standard Precautions remain the cornerstone for prevention in all healthcare settings
 - Recommended for care of all patients regardless of suspected or confirmed infection in any healthcare setting and by all healthcare personnel


- Includes the appropriate use of
 - Hand hygiene
 - Personal protective equipment
 - Respiratory hygiene and cough etiquette
 - **Safe injection practices**




BOX. Injection safety recommendations

- Never administer medications from the same syringe to more than one patient, even if the needle is changed.
- Consider a syringe or needle contaminated after it has been used to enter or connect to a patients' intravenous infusion bag or administration set.
- Do not enter a vial with a used syringe or needle.
- Never use medications packaged as single-use vials for more than one patient.
- Assign medications packaged as multi-use vials to a single patient whenever possible.
- Do not use bags or bottles of intravenous solution as a common source of supply for more than one patient.
- Follow proper infection-control practices during the preparation and administration of injected medications.

Adapted from: CDC. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007. Atlanta, GA: US Department of Health and Human Services, CDC; 2007. Available at http://www.cdc.gov/ncidod/dhqp/gl_isolation.html.



Minimizing the use of shared medications affords an extra layer of protection to reduce patient risk



- Use single-dose medication vials whenever possible
- Single-dose vials should not be used for more than one patient
- Assign multi-dose vials to a single patient whenever possible
- Do not use bags or bottles of intravenous solution as a common source of supply for more than one patient

Adapted from: CDC. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007.
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Department of Health and Human Services

Centers for Disease Control and Prevention

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Injection Safety

Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Injection safety, or safe injection practices are measures taken to perform injections in an optimally safe manner for patients, healthcare providers, and others. 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. Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and healthcare provider, and also to prevent harms such as needlestick injuries.

- > [Injection Safety for Providers](#)
- > [Injection Safety Facts](#)
- > [Safe work practices to prevent HCW exposure to bloodborne pathogens](#)
Excerpted from [Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007](#).
- > [A Patient Safety Threat – Syringe Reuse](#)

<http://www.cdc.gov/ncidod/dhqp/injectionsafety.html>

CDC



3. Improvements in medical devices and medication packaging



Technological Trends and Solutions



- Intravenous delivery of injections/infusions
 - False sense of safety regarding IV lines?
- Needleless systems
 - Inherent safety benefit with respect to sharps injuries
 - Potential for contamination of shared vials remains
- Explore improvements and innovations in medication packaging



4. Professional oversight, licensing, and public awareness...



Western Queens Gazette

Vol. 27 No. 8 February 20, 2008

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Vials Transmitted Hepatitis

Multi-Dose Vials: An Unacceptable Health Risk

75 Vial-Related Hepatitis Outbreaks

Borough	Number of Outbreaks
Manhattan	52
Brooklyn	19
Queens	4
Bronx	0

Photo courtesy Rep. Anthony Weiner

Congressmember Anthony Weiner (D-Brooklyn/Queens), a member of the House Subcommittee on Health, released data on Sunday, February 17 showing that multi-dose vials have infected 75 New Yorkers, including 19 people from Brooklyn and four from Queens, with hepatitis.



Hepatitis C Danger In Your MD's Office?

Outbreaks Of Dangerous Infection Coming From An Unlikely Place

NEW YORK, Feb. 25, 2008

Comments 53

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At Risk At The Doctor's?

Doctor's offices and other outpatient settings have recently been under fire for spreading insidious infections like hepatitis. Dr. Emily Senay reports. | [Share/Embed](#)

(CBS) During treatment for breast cancer in 2002, Evelyn McKnight was floored to learn that she would have to fight a second serious disease: Hepatitis C, CBS News medical correspondent Dr. Emily Senay reports.

"We were completely confounded," McKnight said. "We had no idea where I could have gotten that."

Soon her husband Tom, a family physician in Fremont, Neb., discovered some of *his* patients had also been infected.

"The only common denominator was that we were all cancer patients," McKnight said.

And they all were receiving chemotherapy at the same cancer-treatment center.

In the end, 99 people were infected, the largest outbreak of its kind in North American history. The

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RSS

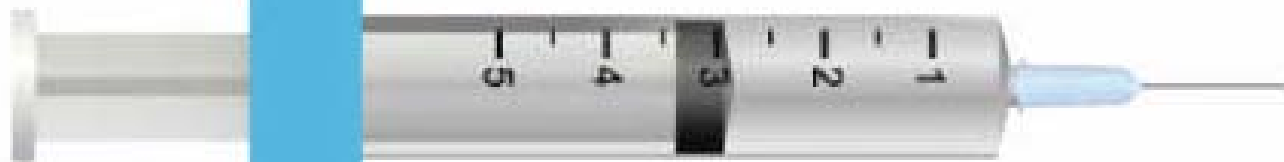
TOP



For Pre

1

**ONE NEEDLE,
ONE SYRINGE,
ONLY ONE TIME.**



Safe Injection Practices Coalition

www.ONEandONLYcampaign.org



Thank you

www.CDC.gov

JPERZ@CDC.GOV

The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention.

