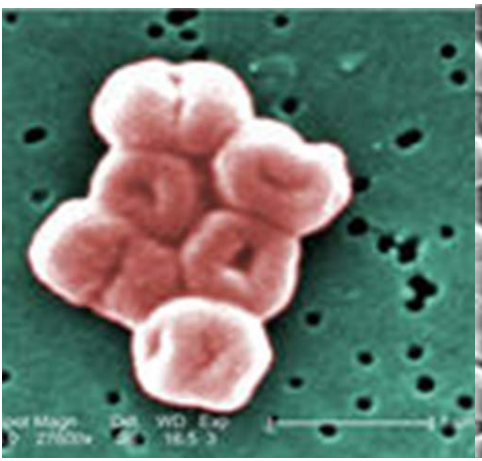
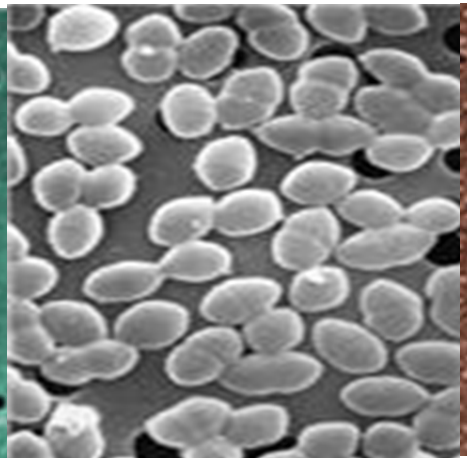
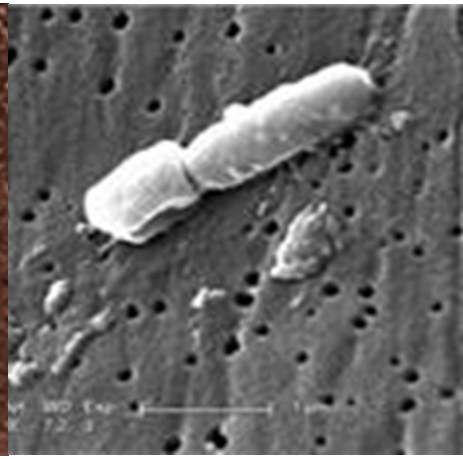
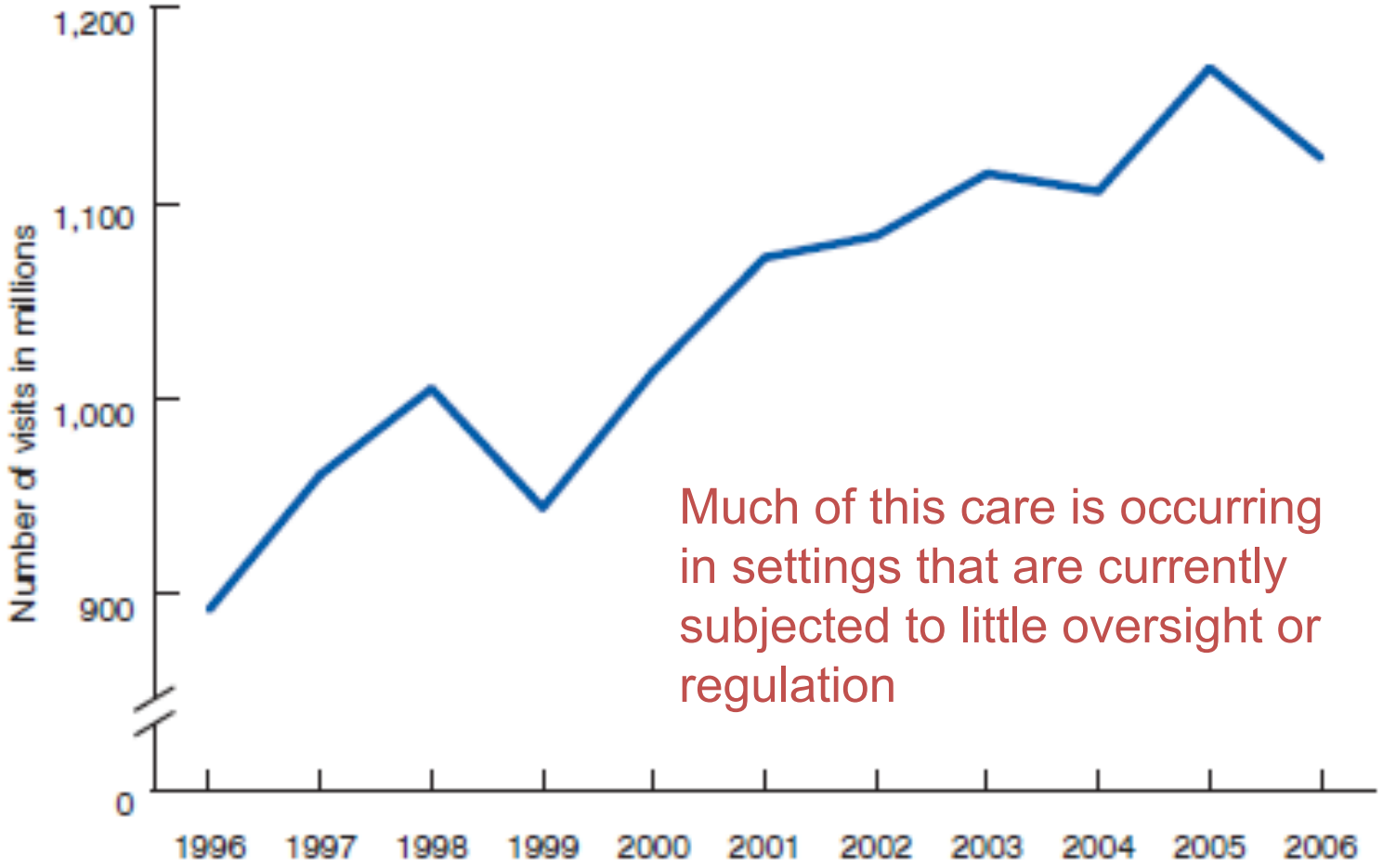
# Outpatient Care Settings and Infection Risks



Michael Bell, MD
Deputy Director, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

# Trends in Outpatient Care Visits, United States, 1996-2006




Much of this care is occurring in settings that are currently subjected to little oversight or regulation

[1] http://www.cdc.gov/nchs/data/nhsr/nhsr008.pdf

# Outpatient Care – Growth, Concerns

- **Approximately 1.2 billion outpatient visits / year**
  - **The average person makes four visits annually to physician offices**
- **Increasingly complex procedures, vulnerable patients**
  - **Each year more than one million cancer patients receive outpatient chemotherapy and/or radiation therapy**
- **Expansion of services without supporting increases in infection control and related services**
- **Challenges in detecting infections originating in outpatient settings**

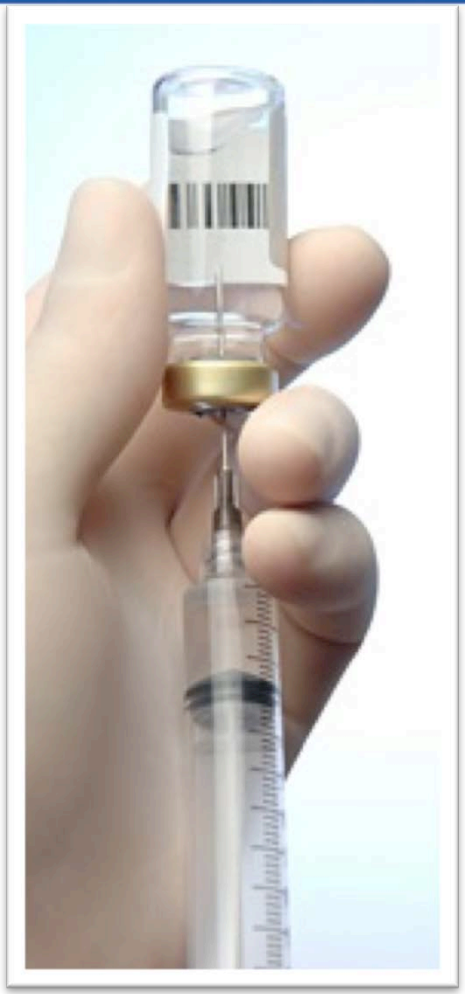
# Summary of Patient Notification Events due to Unsafe Injection Practices, 2001-2011

- 35 notification events in at least 17 states

  >130,000 patients notified
- 26 (74%) notification events occurred since 2007

  Including 4 largest events (>5000 patients per event)
- 22 (65%) notification events in the context of viral hepatitis outbreaks
- 13 (37%) notification events prompted by discovery of lapses, absent evidence of disease transmission

# Basic Safe Practices



- Injections and infusions of parenteral medications are the most common invasive procedure across all of healthcare
  - Sedation/anesthesia for surgical procedures and imaging/diagnostic studies
  - Spinal and intrarticular steroid injections
  - Chemotherapy

## HIV, Hepatitis tests urged for **7000 Oklahoma dental** patients

The Saratogian - Apr 2, 2013

Even so, a complaint filed by the **Oklahoma Dental** Board cites Harrington for an array of safety and health violations that created contamination risks for his patients. He is scheduled to appear before a **dental** board hearing on April 19 and has voluntarily **...**

## Thousands still need HIV test as **dentist** faces charges

NBCNews.com (blog) - 4 hours ago

Citing the scope of a public health scare involving thousands of patients of an **Oklahoma** oral surgeon, the head of the state's **dentistry** board said Monday she wants prosecutors to consider pursuing criminal charges. Nearly 1,000 of Dr. W. Scott Harrington's **7,000** patients have now been tested in Tulsa for hepatitis B and C as well as HIV, the virus that causes AIDS. About 400 people showed up at a clinic north of downtown Saturday, the first day the free tests were offered, and nearly 560 people showed up Monday.

## Charges possible for **Oklahoma dentist** in health scare

Chicago Sun-Times - Apr 1, 2013

(AP) — The head of **Oklahoma's dental** board said Monday her office wants prosecutors to pursue criminal charges against a Tulsa oral surgeon at the center of a public health scare involving at least **7,000** of his patients. Susan Rogers, the executive director **...**

## **7000** US patients at HIV risk

Dentistry.co.uk - 9 hours ago

Health officials in the US state of **Oklahoma** have warned **7,000** patients their **dentist** may have exposed them to HIV and hepatitis B and C. Patients of Dr W Scott Harrington's practice in Tulsa were advised to test themselves at a free clinic set up by the state, **...**

# Unsafe Injection Practices Resulted In…

- Patients placed at risk for life-threatening infections
  - Outbreaks and Patient Alerts
- Referral of providers to licensing boards for disciplinary action
- Legal actions including class action suits

LAS VEGAS REVIEW-JOURNAL

www.reviewjournal.com

50 CENTS ONE DOLLAR NEVADA'S LARGEST NEWSPAPER ★★★★ MARCH 14, 2008

**Lawyers: 100 fear infection**

Health official · By ANNETTE WELLS and BRIAN HAYNES · PUBLIC HEALTH CRISIS · sents about 25 such clients. Most of the positive tests were · officials say, at least six people contracted hepatitis C because

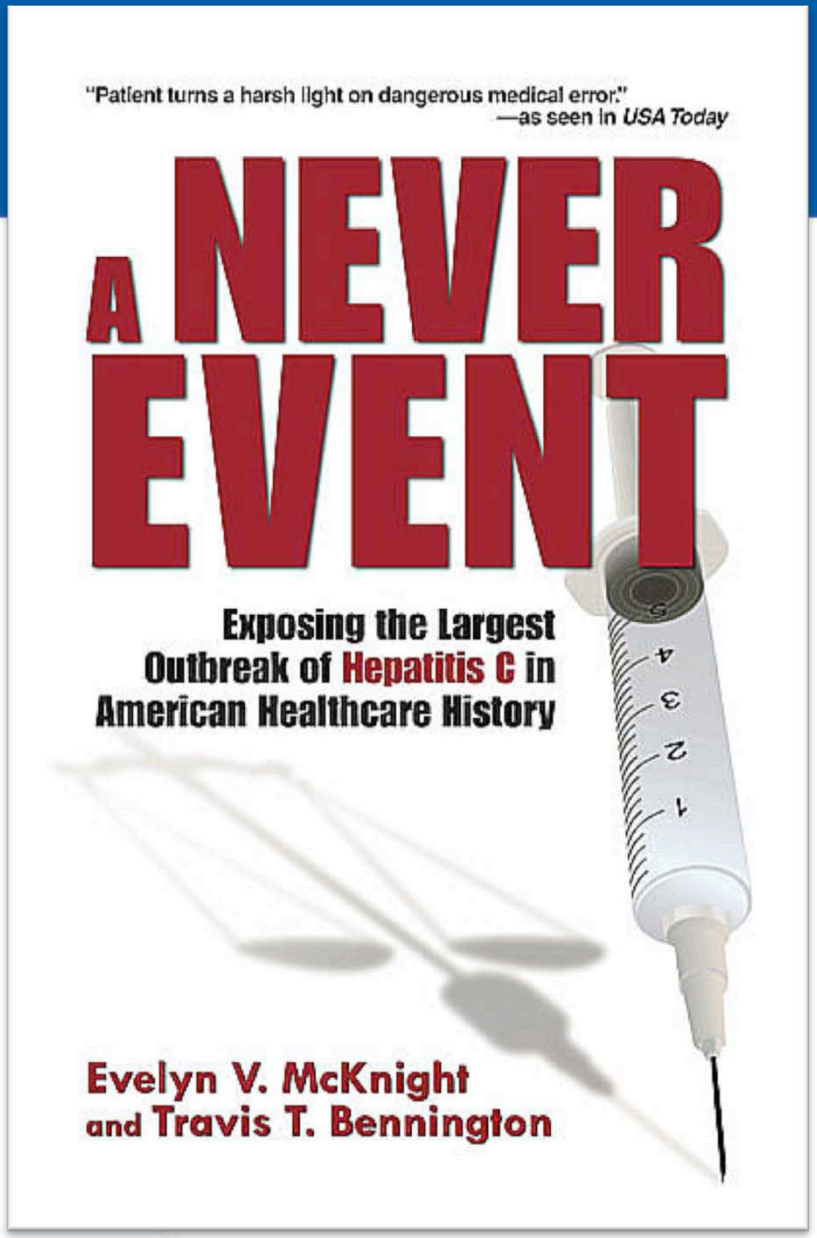
# Three things every provider needs to know about injection safety

1. Needles and syringes are single use devices. They should not be used for more than one patient or reused to draw up additional medication.

2. Do not administer medications from a single-dose vial or IV bag to multiple patients.

3. Limit the use of multi-dose vials and dedicate them to a single patient whenever possible.

Source: Centers for Disease Control and Prevention (CDC).
http://www.cdc.gov/injectionsafety/providers/provider_faqs.html




**99 cancer patients** in Nebraska became **infected with hepatitis C virus** in the early 2000's as a result of **syringe reuse to access a shared bag of saline** for flush procedures

To Prevent Transmission of Infections in Healthcare

# 1

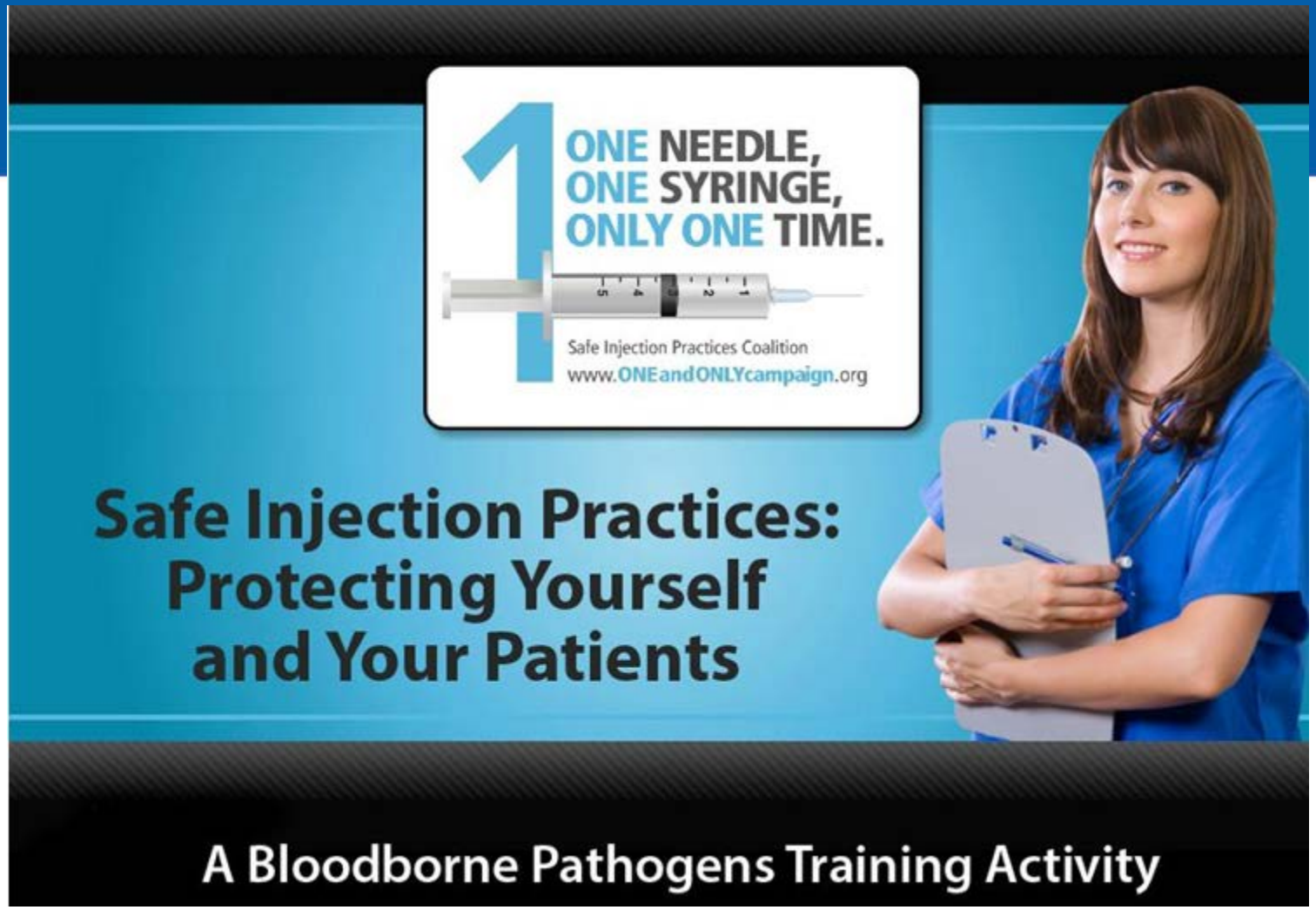
## ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.


Safe Injection Practices Coalition

www.ONEandONLYcampaign.org

**Injection Safety is Every Provider's Responsibility**

Centers for Disease Control and Prevention
Office of the Director




http://www.oneandonlycampaign.org/content/bloodborne-pathogens-training

# Injection Myths

**"I'm preventing contamination and infection transmission as long as I'm…"**

"…changing the needle between patients."

"…injecting through intervening lengths of intravenous tubing."

"…maintaining pressure on the plunger to prevent backflow."

"…not able to observe contamination or blood."

# U.S. Experience – Outbreaks

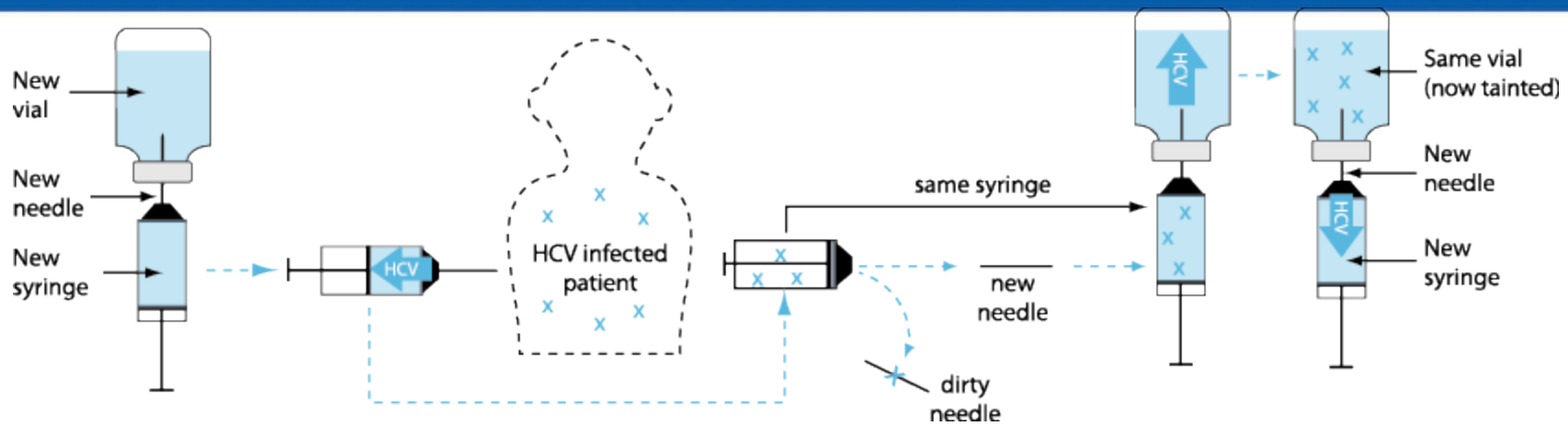
**49 recognized outbreaks, 2001—2012**

- **Viral hepatitis (n=21)**
- **Bacterial infections (n=28)**

- **90% (n=44) occurred in outpatient settings**


Guh et al. Medical Care 2012

# Las Vegas, Nevada Outbreak, 2008




- Syringes were reused to withdraw multiple doses for individual patients
- Remaining volume in single dose propofol vials was used for subsequent patients
- >50,000 patients notified to seek testing

# Corning Hospital nurse reused syringes; tests urged for 236 patients

Photos Zoom

Leader Files

**By John Zick**
**Corning Leader**
Posted Feb 07, 2013 @ 03:31 PM
Last update Feb 07, 2013 @ 04:24 PM



**Business News**

DFS Force-Placed Insurance Legislation is a Joke

With Payroll Tax Back, Consumers Look to Refunds for Basic Needs

CORNING — Nearly 250 people who were treated at Corning Hospital between mid-October and late January may have been exposed to disease by a nurse who reused saline syringes.

The hospital has notified 236 people who were patients between Oct. 15 and Jan. 29 that they were potentially exposed to HIV and Hepatitis B

# BE AWARE
# DON'T SHARE

Insulin pens that contain more than one dose of insulin are only meant for one person.

They ***should never be used for more than one person***, even when the needle is changed.

## ONE INSULIN PEN, ONLY ONE PERSON

**The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.**

**For more information, please visit:**
**www.ONEandONLYcampaign.org**

# Insulin Pen Reuse Incidents

- Reuse of insulin pens for multiple patients, reportedl changing needles has resulted in large notifications
  - NY hospital, 2008: 185 patients notified
  - TX hospital, 2009: 2,114 patients notified
  - WI hospital and outpatient clinic, 2011: 2,401 patients notified
  - 2013: multiple incidents involving NY and NC, including 2 VA Medical Centers and a private hospital

- Fingerstick devices and misuse of glucose meters present a related hazard with well-established risks of transmitting hepatitis B (and other bloodborne pathogens)

Infection Prevention during Blood Glucose Monitoring and Insulin Administration (2012). Retrieved March 9, 2012 from http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
Important Patient Safety Notification (2011). Retrieved March 9, 2012 from http://www.deancare.com/about-dean/news/2011/important-patient-safety-notification/

# U.S. Experience – Patient Alerts

- **>150,000 patients have required notification to advise bloodborne pathogen testing following potential exposure to unsafe injections[1]**
  - **From 2001-2011: 35 Patient Alerts**
    - **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**
    - **7,000 patients of a Oklahoma oral surgeon due to poor injection and sterilization practices**
    - **12,777 patients involving hospitals in multiple states due to a radiology technician suspected of tampering with narcotics**

[1] Guh et al. Medical Care 2012

# Emerging Issue: Narcotics Tampering

**Reuse of syringes ("swaps") and contamination of medications/infusates**

**2004-2012: outbreaks of HCV (TX, CO, FL, NH…)**

Fentanyl theft resulted in transmission of hepatitis C virus to patients from infected personnel due to syringe reuse

**2011: outbreak of bloodstream infections (MN)**

Annals of Internal Medicine | ORIGINAL RESEARCH

## Health Care–Associated Hepatitis C Virus Infections Attributed to Narcotic Diversion

Walter C. Hellinger, MD; Laura P. Bacalis, RN; Robyn S. Kay, MPH; Nicola D. Thompson, PhD, MS; Guo-Liang Xia, MD, MPH; Yulin Lin, MD; Yury E. Khudyakov, PhD; and Joseph F. Perz, DrPH

**Background:** Three cases of genetically related hepatitis C virus (HCV) infection that were unattributable to infection control breaches were identified at a health care facility.

**Objective:** To investigate HCV transmission from an HCV-infected health care worker to patients through drug diversion.

**Design:** Cluster and look-back investigations.

*NS5B* sequence homology with the HCV strains of the 3 case patients. Quasi-species analysis showed close genetic relatedness with variants from each of the case patients and more than 97.9% nucleotide identity. The employee acknowledged parenteral opiate diversion. An investigation identified 6132 patients at risk for exposure to HCV because of the drug diversion. Of the 3929 living patients, 3444 (87.7%) were screened for infection. Two additional

# Boston to tell 57 they may have been infected by paramedic

By Kay Lazar | GLOBE STAFF OCTOBER 01, 2012



Boston health officials over the weekend began notifying 57 people who, they say, may have been exposed to blood-borne illnesses in the summer of 2011 when they were treated by a city ambulance paramedic now believed to have tampered with vials of painkillers and sedatives.

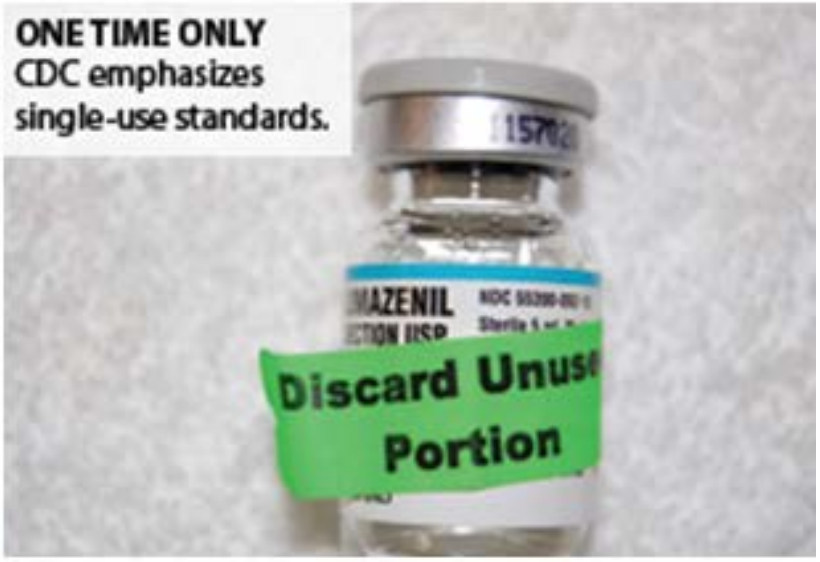

DIPRIVAN
DIPRIVAN
DIPRIVAN
LIDOCAINE HCl
1%
10 mg/mL

Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, 2012

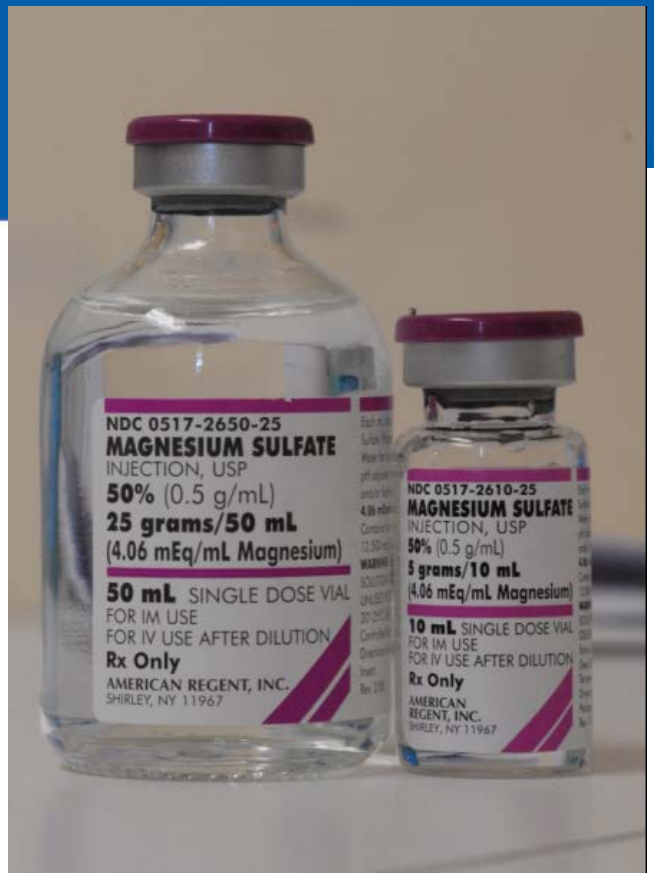
Centers for Disease Control and Prevention
MMWR
Weekly / Vol. 61 / No. 27

# MRSA Outbreaks Blamed on Unsafe Injection Practices

A new CDC report detailing 2 MRSA outbreaks reiterates the CDC's recommendation for using single-use and single-dose vials for 1 patient only, even when facing medication shortages.




According to the report, at least 10 patients contracted life-threatening staph or MRSA infections and had to be hospitalized as a result of providers using medication from single-dose or single-use vials on multiple patients in a pain management center in Arizona and an orthopedic center Delaware. Another patient died, and while a multiple-drug overdose was reported as the cause of death, an invasive MRSA infection couldn't be ruled out, says the CDC. In both investigations, clinicians reported difficulty obtaining the medication type or vial size






Read the label – unless it is a *manufactured* vial with the term "multi-dose vial" printed on it, it is not a multi-dose vial

# Propofol

- […] failure to use aseptic technique when handling propofol […] associated with microbial contamination of the product and with fever, infection/sepsis, other life-threatening illness, and/or death
- Propofol should be prepared for single-patient use only. Any unused portions of propofol, reservoirs, dedicated administration tubing and/or solutions containing propofol must be discarded…
- Guidelines for Aseptic Technique
  - Propofol should be prepared for single-patient use only.

http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=6337

# Right-sized vials and prefilled syringes


Limit the use of multi-dose vials and dedicate them to a single patient whenever possible

# Injection Practices Among Clinicians in US Healthcare Settings

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

Pugliese G., Gosnell C., Bartley J., & Robinson S. (December 2010). Injection practices among clinicians in United States health care settings. *American Journal of Infection Control, 38* (10), 789-798. Retrieved from http://www.ajicjournal.org/article/PIIS0196655310008539/abstract.

# Risks of Injections Outside of Recognized Outbreaks

Case-Control Study of Hepatitis B and Hepatitis C

48 reported cases of symptomatic acute hepatitis B or C

- Persons aged 55 years and older – NY and OR
- Excluded nursing home residents and cases identified as a result of outbreak investigations

3 matched controls per case

- age group (55-59, 60-69, and 70 years) and residential postal code

**In a multivariate model, behavioral risks (17% attributable risk), injections (37% attributable risk), and hemodialysis (8% attributable risk) were associated with case status**

**Conclusion:**

**Healthcare exposures may represent an important source of new HBV and HCV infections among older adults.**



Perz et al. Hepatology 2013

The Washington Post

# Woman who had liposuction in Baltimore County dies from infection

By Lena H. Sun, Published: September 19

A woman who had liposuction at a Baltimore County cosmetic surgery center has died after contracting a bacterial infection, Maryland health officials said Wednesday. Two other women who had liposuction at the same center were also hospitalized with the same infection.

State health officials shut down the facility, Monarch Med Spa, in Timonium, Md., on Wednesday as part of an investigation to determine the possible sources of infection and to limit further spread. State and county investigators found "probable deviations from standard infection control practices," among other deficiencies, according to the state order shutting the facility.

http://www.washingtonpost.com/national/health-science/woman-who-had-liposuction-in-baltimore-county-dies-from-infection/2012/09/19/bb8991de-027d-11e2-9b24-ff730c7f6312_story.html

# Investigation of Monarch MedSpa Expanded

by System Account on 10/2/2012 2:56 PM

***DHMH seeking public comment on potential oversight of outpatient surgical facilities***

**BALTIMORE (October 2, 2012)** – During the week of Sept 17, 2012, The Maryland Department of Health and Mental Hygiene (DHMH) and the Baltimore County Department of Health began investigating a cluster of three severe invasive Group A *Streptococcus* (GAS) infections in persons who recently had liposuction at a cosmetic surgery center, Monarch MedSpa, in Timonium, Maryland. As reported previously, the procedures occurred in mid-August to mid-September. All three patients were hospitalized; one subsequently died. DHMH and Baltimore County ordered the facility closed on September 18.

Because there are also Monarch MedSpa facilities in other states, the investigation has expanded. A coordinated effort with Pennsylvania, Delaware and the Centers for Disease Control and Prevention (CDC) is underway. The status of the Maryland investigation is ongoing, and to date, no additional Maryland cases have been identified.

Cosmetic surgery centers in Maryland are not currently subject to state licensure. DHMH is seeking public comment on potential approaches to oversight of these facilities.

Over the last five years, an average of 189 cases of invasive GAS were reported annually in Maryland. About 9,000 to 11,500 cases of invasive GAS disease occur each year in the United States, resulting in 1,000 to 1,800 deaths annually.

For more information, visit http://www.cdc.gov/ncidod/dbmd/diseaseinfo/groupastreptococcal_g.htm.

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# *New Laws Will Strengthen Patient Protections in Maryland*

May 2, 2013

ANNAPOLIS (May 2, 2013) – Governor Martin O'Malley today signed three new laws that will provide critical protections for patients in M Department of Health and Mental Hygiene advocated in favor of the new laws, which will allow for greater oversight and protection in a settings.

"These new laws will strengthen protections for Maryland patients," said Dr. Joshua M. Sharfstein, Secretary of DHMH.

House Bill 1009 authorizes DHMH to adopt regulations to oversee cosmetic surgical facilities, including "medical spa" facilities. The leg proposed after three patients contracted severe invasive Group A Streptococcus infections following liposuction procedures at a cosm center in Baltimore County in 2012. An investigation found the facility lacked adequate infection control procedures. The new law will al Department the authority to license such facilities, investigate complaints and hold facilities accountable. The law takes effect October

House Bill 986 will require facilities and practitioners who either create or distribute pharmaceuticals created using sterile compounding acquire a permit from the Maryland Board of Pharmacy. The legislation was proposed in the wake of a nationwide outbreak of fungal m to contaminated steroid injections that came from a Massachusetts compounding pharmacy. In Maryland, 26 individuals contracted fu and three died, as a result of the infected injections. The law takes effect July 1, 2013.

Senate Bill 1057 requires all health care staffing agencies operating in Maryland to be licensed by the Office of Health Care Quality. Cu nursing staffing agencies must be licensed, but agencies that place other health professionals are not required to be licensed. The age health professionals on a temporary basis in hospitals and healthcare facilities around the state. The legislation was introduced after a worker who was infected with Hepatitis C was arrested in New Hampshire on suspicion of unlawful drug diversion activity that transmit to patients. The individual worked in several states, including Maryland. Laboratory testing has now found seven Maryland patients infe Hepatitis C virus who were found to have virus closely related to infections linked to the case.

The Department conducted a thorough review of the case and released recommendations for strengthening legal and regulatory prote prevent similar cases in the future. Senate Bill 1057 was a result of one of those recommendations. The new law takes effect October

###

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# **Infection Control Standards:**
## Oversight and Regulation

- Expanded infection control requirements for outpatient settings including hemodialysis and ambulatory surgical centers (**CMS**)
- Periodic infection control training requirements for licensed healthcare providers (**NY**)
- Requirement for outpatient endoscopy and surgical centers to retain a licensed Infection Preventionist (**NJ**)
- Increased licensing, accreditation, and/or inspection requirements for physician offices and clinics based on levels of anesthesia or sedation provided (**NY, NV**)

# Infection control survey tools to aid inspection of CMS-certified Ambulatory Surgical Facilities

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

**II. Injection Practices (injectable medications, saline, other infusates)**

**Additional Instructions:**

**Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).**

.

| Practices to be Assessed | Was practice performed? | Manner of confirmation |
|---|---|---|
| A. Needles are used for only one patient | 1 Yes 2 No 3 N/A | 4Observation 5Interview 6Both |
| B. Syringes are used for only one patient | 1 Yes 2 No 3 N/A | 4Observation 5Interview 6Both |
| C. Medication vials are always entered with a new needle | 1 Yes 2 No 3 N/A | 4Observation 5Interview 6Both |
| D. Medication vials are always entered with a new syringe | 1 Yes 2 No 3 N/A | 4Observation 5Interview 6Both |

Ref: Schaefer et al. JAMA. 2010; 303:2273-79 and http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf

# CDC Guide to Infection Prevention in Outpatient Settings:
# Minimum Expectations for Safe Care

## Outpatient Settings

## Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care

Download the printable Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care [PDF - 620 KB] May 2011

### Note to Readers

The following document is a summary guide of infection prevention recommendations for outpatient (ambulatory care) settings. The recommendations included in this document are not new but rather reflect existing evidence-based guidelines produced by the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee. This summary guide is based primarily upon elements of Standard Precautions and represents the minimum infection prevention expectations for safe care in ambulatory care settings. Readers are urged to consult the full guidelines for additional background, rationale, and evidence behind each recommendation. All guidelines are available at: Guidelines and Recommendations


www.cdc.gov/HAI/settings/outpatient/

# Injection Safety Checklist

## INJECTION SAFETY CHECKLIST

The following Injection Safety checklist items are a subset of items that can be found in the *CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care.*

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare personnel to safe injection practices. (Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.)

| Injection Safety | Practice Performed? | If answer is No, document plan for remediation |
|---|---|---|
| Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment | Yes No | |
| Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens) | Yes No | |
| The rubber septum on a medication vial is disinfected with alcohol prior to piercing | Yes No | |
| Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient | Yes No | |
| Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient | Yes No | |
| Medication administration tubing and connectors are used for only one patient | Yes No | |
| Multi-dose vials are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial<br>Note: This is different from the expiration date printed on the vial. | Yes No | |
| Multi-dose vials are dedicated to individual patients whenever possible. | Yes No | |
| Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g,. operating room, patient room/cubicle)<br>Note: If multi-dose vials enter the immediate patient treatment area they should be dedicated for single-patient use and discarded immediately after use. | Yes No | |

**RESOURCES**

*Checklist:* **http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf**

*Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care:*
**http://www.cdc.gov/HAI/pdfs/guidelines/standatds-of-ambulatory-care-7-2011.pdf**

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

www.oneandonlycampaign.org

Centers for Disease Control and Prevention
Office of the Director

www.cdc.gov/injectionsafety

# More Information

www.cdc.gov/hai

Thank you!