The Nuts and Bolts of Safe Injection and Infusion Practices

APIC "Heart of New York" Chapter 118
March 30, 2017

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No Disclosures

Objectives

- Describe outbreaks related to unsafe injection and infusion practices.
- Describe APIC Position Paper contents r/t safe injection and infusion practices.
- Identify current resources for safe injection practices.

Dear "patient,"

Rose Medical Center is sending you this letter because a terminated employee – a surgical scrub technician – may have put some surgery patients at risk for exposure to hepatitis C. We are working closely with the Colorado Department of Public Health and Environment in its investigation of this situation. Hepatitis C is a virus that can potentially cause serious damage to the liver.

Our records indicate that you had surgery at Rose between October 21, 2008 and April 13, 2009 – either in the hospital or the outpatient surgery department in the Wolf Building. If this is correct, we believe, as does the State Health Department, that you **should take a free, confidential blood test**. This test may help determine if you were exposed to hepatitis C as a result of your surgery.

We first learned of this when the State Health Department contacted us about a cluster of cases with hepatitis C who had surgery at Rose between the dates listed above. We do not know at this point if those patients were exposed to the virus at our hospital, but we are cooperating with the State Health Department to try to get the facts.

SOURCE
Infectious person,
e.g. chronic, acute

CONTAMINATED INJECTABLE EQUIPMENT OR PARENTERAL MEDICATION

CASE(S)
Susceptible,
non-immune person(s)

TRANSMISSION OF BLOODBORNE PATHOGENS VIA UNSAFE INJECTION PRACTICES

What happens when Safe Injection Practices (SIP) are not followed?

- Patient notification
  - exposure/infection
  - testing for HCV, HBV, and HIV.
- Patient infections
  - bloodborne viruses
  - bacterial pathogens
- Licensing board
  - disciplinary action
- Legal actions
  - malpractice suits

LAS VEGAS REVIEW-JOURNAL

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

Lawyers: 100 fear infection

Health official: PUBLIC HEALTH CRISIS

Outbreaks: Tip of the Iceberg?

- 2001 to 2009 – 15 Outbreaks
  - Outpatient setting
  - 50% anesthesia/sedation

- 2008-2015 – 59 Outbreaks
  - 55 - <u>non-hospital settings</u>
    - 23 *Hepatitis B* (17 in LTC)
      - >10,700 notified
      - 175 infected
      - Blood glucose monitoring
    - 33 *Hepatitis C* (13 outpatient 18 hemodialysis , 2 drug diversion)
      - ~100,000 notified
      - >239 infected

http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

Fungal Bloodstream Infections Associated with a Compounded Intravenous Medication at an Outpatient Oncology Clinic — New York City, 2016

- January 1–May 31, 2016
  - 17 IV pts met case definition –
    - *Exophiala dermatititis and/or*
    - *Rodotorula mucilaginosa*
    - 2 deaths (?)
- Failure to meet:
  - CDC IC standards for outpatient oncology settings
  - USP 797 and 800 standards for sterile medication compounding and handling of hazardous drugs as outlined by U.S.P 797 and 800 Pharmacopeia chapters 797 and 800 (4,5)
  - FDA standards for medications (section 503A)
- IV flush bags containing saline, heparin, vancomycin, and ceftazidime had been compounded under substandard conditions
  - Stored in a refrigerator, and accessed daily for multiple patients over approximately 4–8 weeks until the solution was depleted.

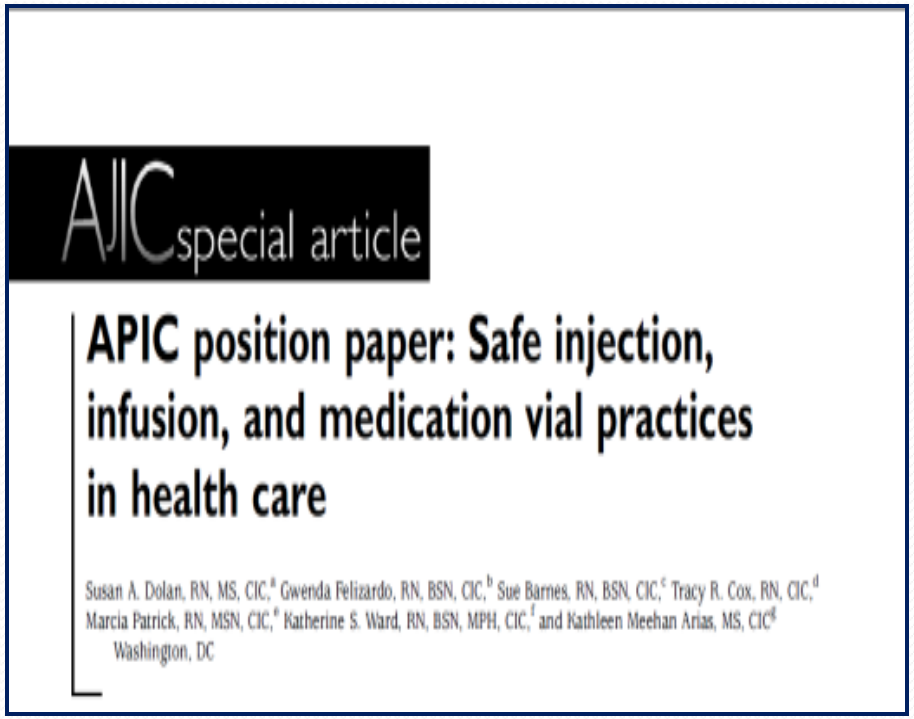
Weekly / November 18, 2016 / 65(45);1274–1275

Hepatitis C Transmission from Inappropriate Reuse of Saline Flush Syringes for Multiple Patients in an Acute Care General Hospital — Texas, 2015

- Hospital telemetry unit nurse had been reusing saline flush prefilled syringes in the intravenous (IV) lines of multiple patients
  - Believed it was a safe, cost-saving measure if no fluids were withdrawn into the syringe before injection of the saline flush
- 392 potentially exposed over 18 months
  - 262 pts identified tested
    - 4 w/ newly diagnosed BBP (2 HBV, 2 HCV)

MMWR/ March 10, 2017 / 66(9);258–260

2010



AJIC special article

APIC position paper: Safe injection, infusion, and medication vial practices in health care

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2016

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Practice Forum

APIC position paper: Safe injection, infusion, and medication vial practices in health care

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APIC Position Paper – Update 2016

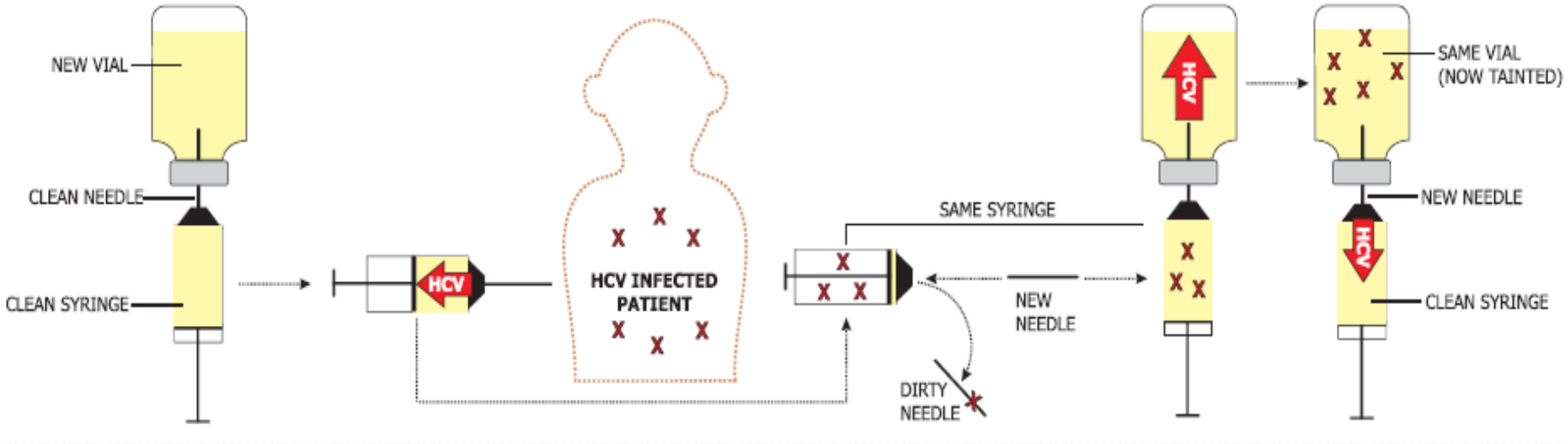
- **Literature review of Outbreaks**
  - Medical Handling and Administration Practices
  - Point of Care testing (e.g. Blood glucose monitoring)
  - Drug Diversion
- **Issues**
  - Training and Competency
  - USP <797> Compounding clarifications
  - Immediate Use CSPs
  - Dispensing devices
  - Transporting Medications
- **Recommendations**
  - Aseptic Technique
  - Transporting Medications
  - IV solutions
  - Injectables in the Operating Room
  - Syringes and Needles
  - Medication Vials
  - Drug Diversion
  - Point of Care Devices
  - Blood Glucose Management
  - Healthcare Personnel
  - Oversight and Enforcement

Syringes and Needles

- Use needle free systems, whenever possible.

Nevada - Indirect Syringe Reuse

Endoscopy center HCV outbreak investigation



- Syringes reused to withdraw multiple doses for individual patients
- Remaining volume in single dose propofol vials used for subsequent patients
- Vial became vehicle for HCV spread
- 40,000 patients at risk (HCV - 9 pts. linked, 106 possibly linked)
- ~ $20 Million investigation costs

6/15/2011 >> Nevada State Leg. Passed Safe Injection Practices Bill (eff. 10-1-11)

Syringes & Needles

- New sterile syringe and needle for each entry into vial or IV bag
- Never store needles or syringes unwrapped
  - Sterility cannot be ensured
- In the clinical setting: Avoid using bulk packaged, sterile unwrapped syringes whenever possible
  - Intended for ISO Class 5 environment compounding
  - If used in mass immunization clinics or allergy testing, open a new, sterile package and discard any remaining syringes at the conclusion of the activity, do not save for later use.
- Do not prepare med in one syringe and transfer to another syringe (e.g. via open barrel or bevel of syringe)
- Do not draw medication from carpuject style syringe into another syringe

What is the time limit for use between prefilling a syringe and administering the injection?

1. 12 hours
2. 8 hours
3. 1 hour

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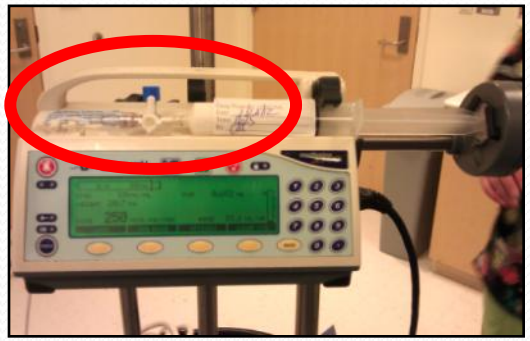
1. 12 hours
2. 8 hours
3. **1 hour**

Common Syringe concern

Issue: Propofol syringe for multiple pts and change microbore tubing between pts?

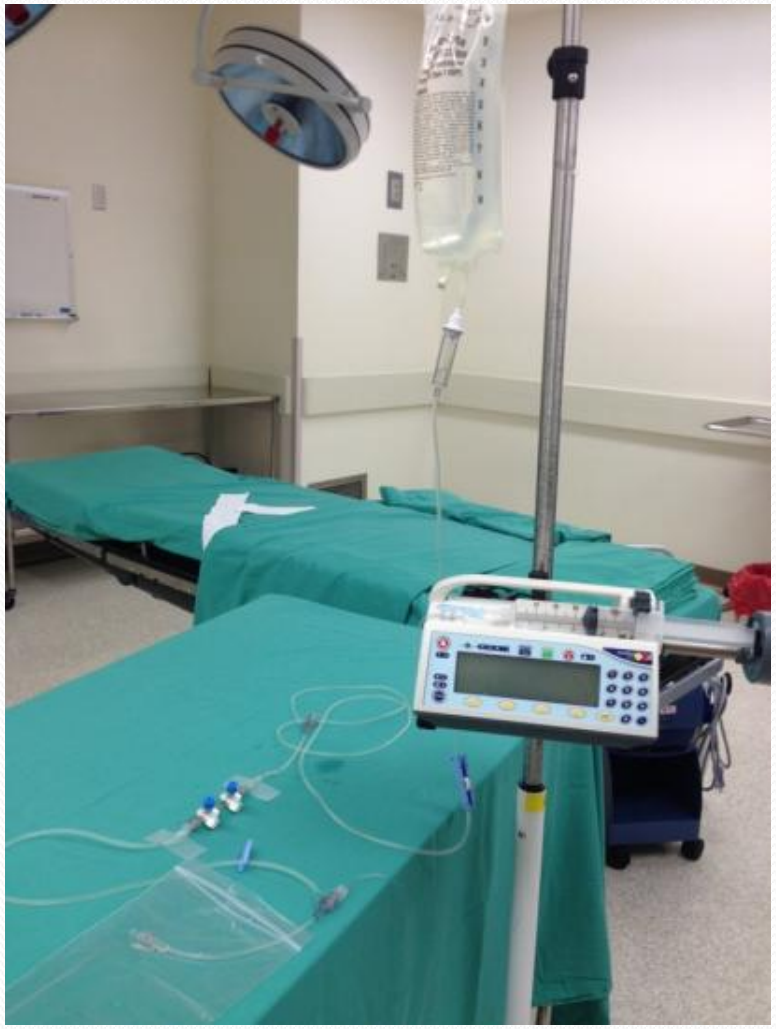


- ***Contamination can occur:***
  - Handling
  - Fluid splatter
  - Retrograde flow
    - Specific gravity Blood > IV solutions = backflow against forward flowing fluid possible.
  - Lack of visible blood
    - Blood contamination found in 3.3% of tubing injection sites
      - Only 33% visible to naked eye[1]

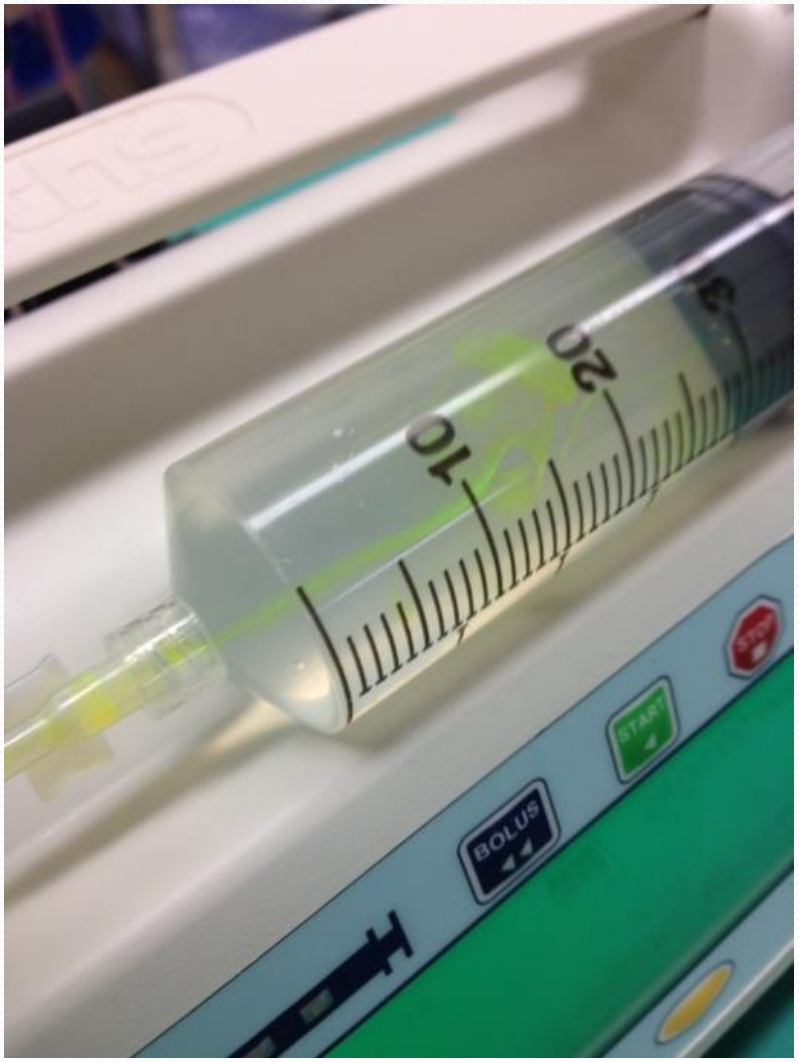
[1]*Greene ES. ASA Newsletter. 2002;66(12):22-23*

Common Syringe concern

Photo simulation

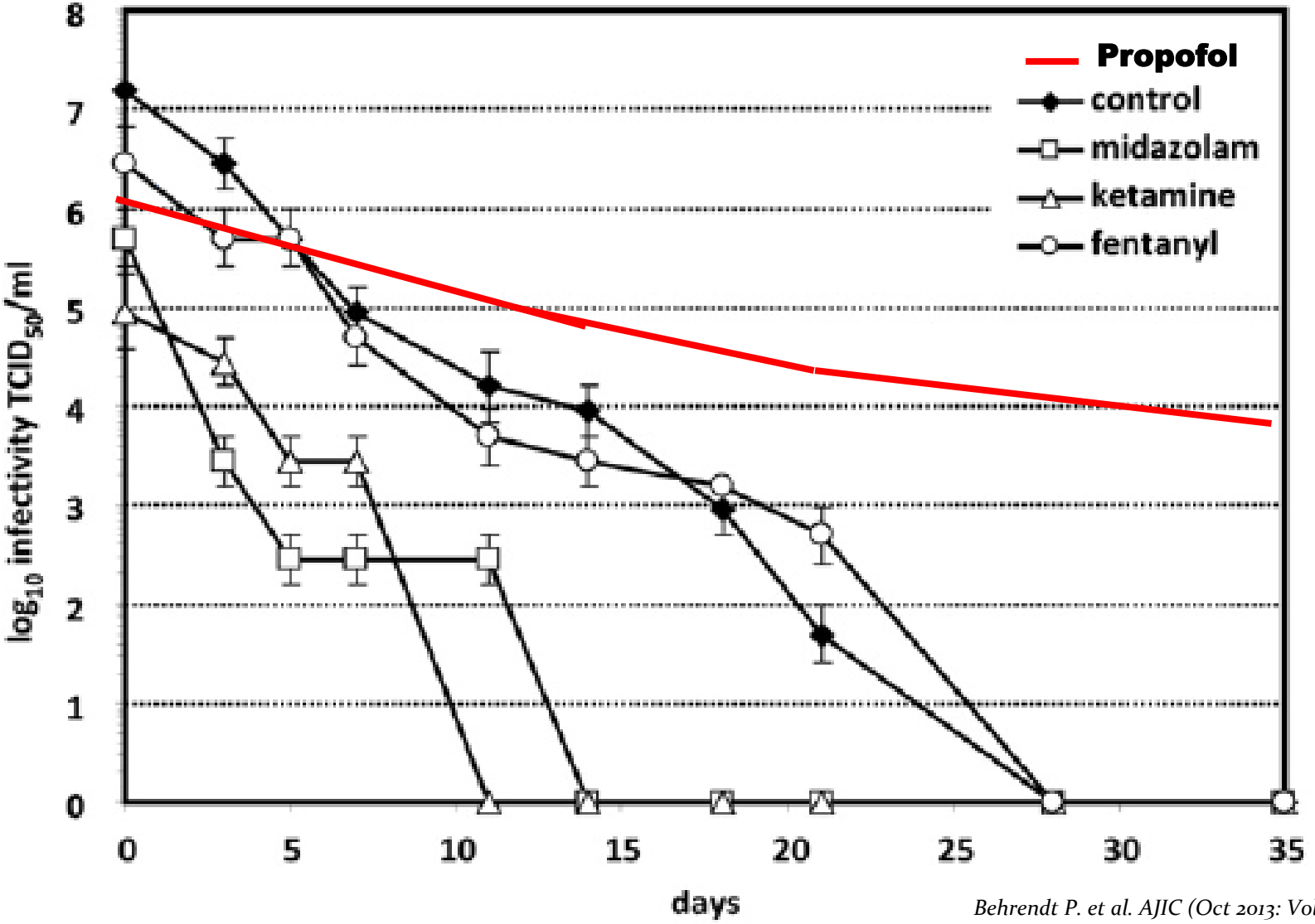


Courtesy Robin Stackhouse, MD – UCSF Department of Anesthesiology



Courtesy Robin Stackhouse, MD – UCSF Department of Anesthesiology

Stability/transmission of HCV in different anesthetic agents



Behrendt P. et al. AJIC (Oct 2013: Vol 41 No10)

Clinical Infectious Diseases (Vol 53) November 1, 2011 p. 963-4

Pre-filled syringes

- Only terminally sterilized (after packaging) syringes can be put onto a sterile field after opening.
  - “sterile field ready”
- Do not use to further dilute meds
  - Contamination
  - Dosing errors
  - Drug diversion
  - Needlestick injuries
- Pharmacy should prepare and dispense meds that require further dilution
  - If not feasible, provide single-dose vials of drug and diluent together

Investigation of Hepatitis C Virus Transmission Associated with Injection Therapy for Chronic Pain – CA 2015

- Repeat blood donor
  - Acute hepatitis C virus (HCV) infection
    - Detected on routine donor screening
  - No risk factors
- Prolotherapy (regenerative injection therapy for pain relief)
- Pain clinic
  - reentering MDV with used syringe
  - SDV use for multiple patients
  - poor hand hygiene and inconsistent glove use
  - lack of aseptic technique when handling injection equipment and medication.
- 400 notified
  - 5 new + HCV with no risk factors
    - 4 had a procedure on the same day

MMWR June 3, 2016 / 65(21);547–549

Medication Vials

- 1991-1993, 7 hospitals experienced outbreaks traced to mishandling of propofol
- Six different bacterial pathogens
- Wide variety of lapses in aseptic technique
- "...the larger vials look like multidose vials, and our investigations revealed that the vials are sometimes being used for an extended period of time, for more than one patient or procedure, and to refill syringes meant to be used only once."

The Problem is….

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Samia Nasr 301-796-3409, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010, or (CDRH) Office of Communication and Education, 800-638-2041 or 301-796-7100.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Combination Products

October 2015
Pharmaceutical Quality/CMC

- ***Single-Dose Container/Single-use vials**
  - Not required to meet antimicrobial effectiveness testing
  - Use with a single patient as a single injection/infusion.
  - Vial, ampule, prefilled syringe
- ***Single-use: (FDA is retiring this term)***
- **Multi-Dose Container**
  - Meets antimicrobial effectiveness testing
  - Intended to contain more than one dose of the drug product (≤30ml)
  - Vial
- **Single-Patient-Use Containers**
  - Intended to be used multiple times for a single patient
  - Examples: patient controlled analgesia cartridges and certain pens for injection

- FDA – Draft Guidance Document ***"Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use."***
  See APIC Comments submitted to FDA 12-2015

TJC FAQs: When do multi-dose vials that have been punctured or opened need to be discarded?

- Discard 28 days after first use unless manufacturer specifies otherwise
  - *Rationale:* Per USP, manufacturers only required to test effectiveness of bacteriostatic agent in multi-dose vial for period of 28 days
  - Label with new beyond use date
  - **Labeling multi-dose vial with date opened will NOT meet requirement**
  - Manufacturers allowed by FDA to provide extended dating in package insert if they have conducted testing beyond 28 days
  - Includes multi-dose pens for single patient

https://www.jointcommission.org/standards_information/jcfaq.aspx?ProgramId=0&ChapterId=0&IsFeatured=False&IsNew=False&Keyword=vials *(Accessed 7-2016)*

When is it permissible to use single-dose containers (e.g. vials) for more than one patient?

1. Never
2. When proper aseptic technique is used in a separate medication prep area
3. Only under certain defined circumstances

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3. **Only under certain defined circumstances**

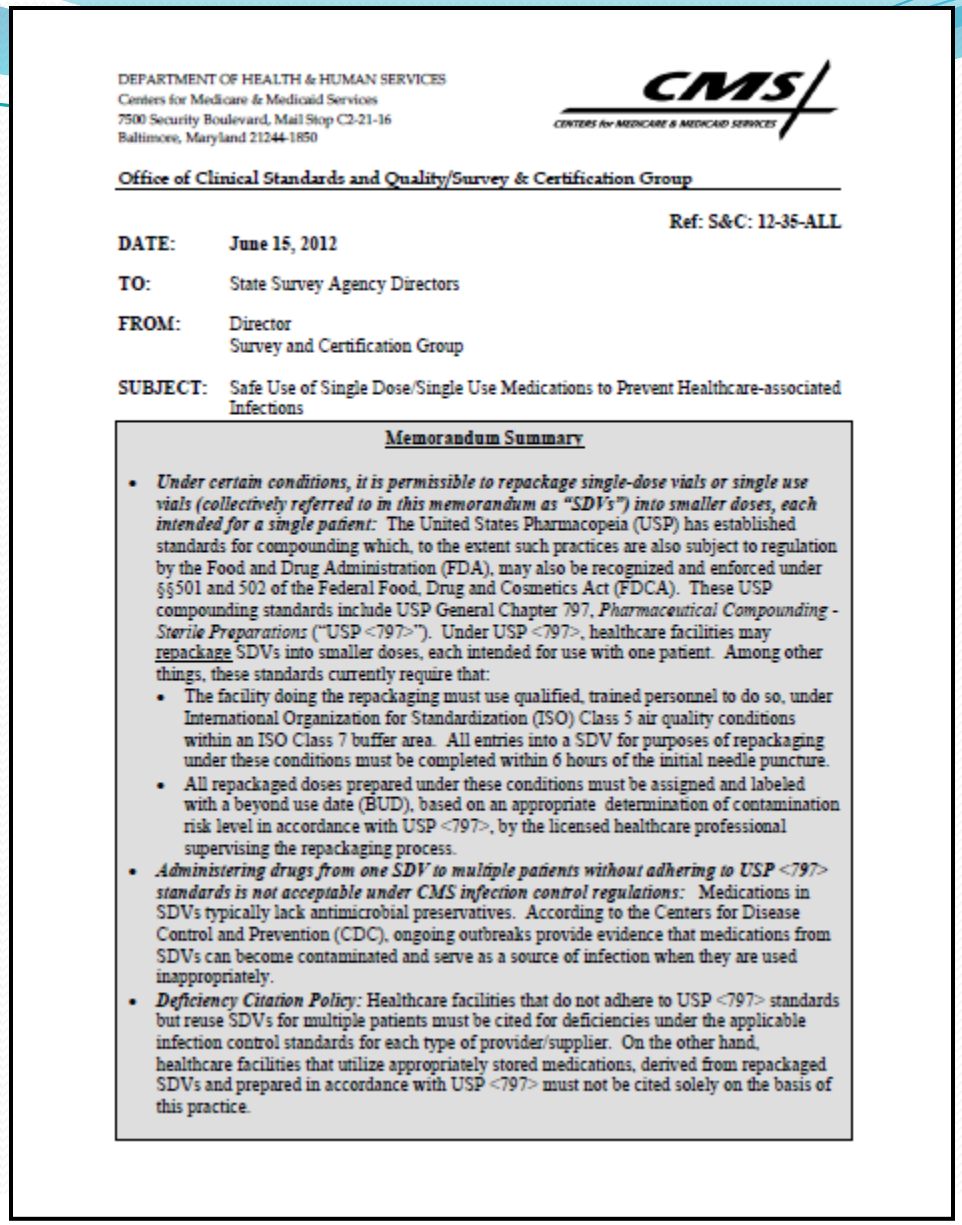
CMS

Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

June 15, 2012

Deficiency Citation Policy

- Healthcare facilities that do not adhere to USP <797> standards but reuse SDVs for multiple patients must be cited for deficiencies under the applicable infection control standards for each type of provider/supplier



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS/ CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

DATE: June 15, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

Memorandum Summary

- ***Under certain conditions, it is permissible to repackage single-dose vials or single use vials (collectively referred to in this memorandum as "SDVs") into smaller doses, each intended for a single patient:*** The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, *Pharmaceutical Compounding - Sterile Preparations* ("USP <797>"). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.
- ***Administering drugs from one SDV to multiple patients without adhering to USP <797> standards is not acceptable under CMS infection control regulations:*** Medications in SDVs typically lack antimicrobial preservatives. According to the Centers for Disease Control and Prevention (CDC), ongoing outbreaks provide evidence that medications from SDVs can become contaminated and serve as a source of infection when they are used inappropriately.
- ***Deficiency Citation Policy:*** Healthcare facilities that do not adhere to USP <797> standards but reuse SDVs for multiple patients must be cited for deficiencies under the applicable infection control standards for each type of provider/supplier. On the other hand, healthcare facilities that utilize appropriately stored medications, derived from repackaged SDVs and prepared in accordance with USP <797> must not be cited solely on the basis of this practice.

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-35.pdf

Medication Shortages

- In times of “critical need”, contents from unopened single-dose/single-use vials can be repackaged for multiple patients.
  - performed by qualified healthcare personnel
  - USP General Chapter <797>Pharmaceutical Compounding – Sterile Preparations.
- Healthcare facilities can proactively arrange for these doses to be split, in accordance with USP standards, when necessary.

http://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html

"Do you have a recommendation about instilling/injecting air into a vial prior to withdrawing a medication? We are being advised by our safety committee that the CDC recommends against this practice."

- CDC does not specifically address this practice in their injection safety materials
- CDC "Pink Book"
  - "Instilling air into a multidose vial prior to withdrawing a vaccine dose may not be necessary. It could cause a "spritz" of vaccine to be lost the next time the vial is entered, which through time can decrease the amount of vaccine in the vial and lead to the loss of a dose (e.g., obtaining only 9 full doses from a 10-dose vial)."
- Some manufacturers actually do recommend injection of air into the vial (e.g. insulin)
  - http://www.bd.com/resource.aspx?IDX=11020&CMP=PIG

Flushing

- Never use a container of IV solution (e.g. bag or bottle) to obtain flush solutions for > 1 patient
- Single-dose containers recommended
  - One time use for single patient
- Multi-dose vials – for one patient and discard
  - New needle and unused sterile syringe for each entry

Nebraska: Evelyn's Story…

- Audiologist, breast cancer in 2000 Nebraska oncology clinic
- State and CDC investigation
  - Syringe reuse/common flush bag
  - 99 infected – 6 died
- 89 lawsuits, $16M paid from NELF *(Nebraska Excess Liability Fund)*
  - Settlement used to start HONOReform

An Outbreak of Hepatitis C Virus Infections among Outpatients at a Hem/Onc Clinic. Ann Intern Med. 2005;142:898-902; Outcomes of a patient to patient outbreak of genotype 3a hepatitis C. Hepatology 2009

Spiking/priming IV bags “in advance”

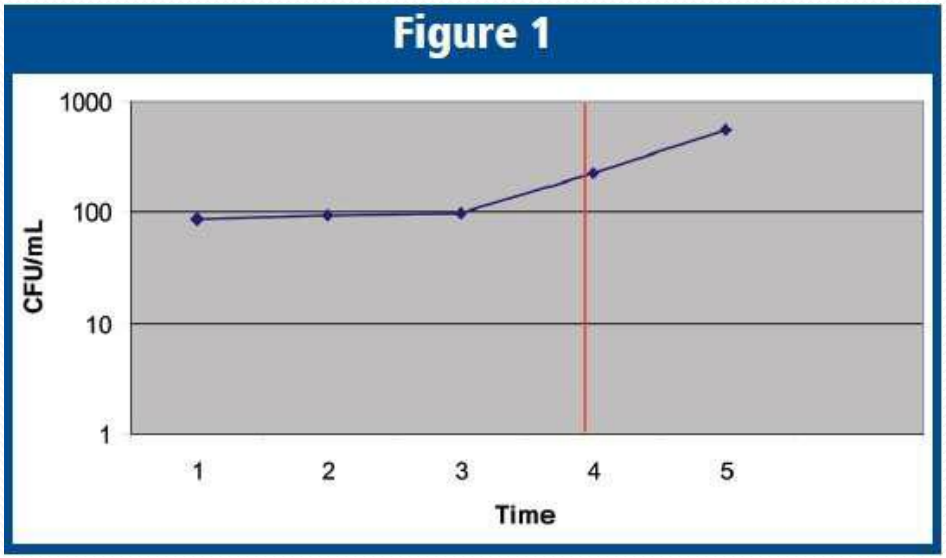
- **APIC supports USP in most clinical settings/scenarios**
  - 1 hour time limit from preparation (spiking bag) until beginning administration if not prepared in a *ISO 5 environment
    - Precludes microbial growth in the event of contamination
    - Organism replication can occur within 1-4 hours
      - Exponential ↑ thereafter
  - Longer timeframes if primed by pharmacy in *ISO 5 environment

*International Organization for Standardization (laminar flow, air quality, ventilation , personnel and surface sanitation requirements)

Challenges

- Cost
- Technique in busy setting
- ? Higher risk of contamination due to breaks in technique
- Many settings don’t have ISO 5 environments
- Difficult to comply
- Limited data on actual contamination in real practice

FDA NDMSA



Time	Microbial Count (CFU/mL)	Log of Microbial Count
1	88	1.9
2	95	2
3	98	2
4	220	2.3
5	552	2.7

Metcalfe, JW, **Microbiological Quality of Drug Products after Penetration of the Container System for Dose Preparation Prior to Patient Administration.** American Pharmaceutical Review, Feb 1, 2009

APIC supports Risk Assessment for rare exceptions

(non ISO 5 environment)

- Prepare as close as possible to time of administration
  - Not night before, 4 hour limit?
- Educate designated staff
  - Tactile learning environment
  - Verify competency
  - Periodic monitoring
- Clean, dry workspace
- Controlled setting
- Properly labeled bag/tubing. Date/time/initials
- Facility P&P

TJC FAQ's - Spiking of IV bags "in advance"

July 30, 2010

What would a Joint Commission surveyor look for?

- **A:** Joint Commission standards do not specifically address this issue. However, IC.01.05.01 EP 1 requires that, "When developing infection prevention and control activities, the hospital uses evidence-based national guidelines or, in the absence of such guidelines, expert consensus."
- Therefore, The Joint Commission does not require that an organization place a specific time restriction on IV fluids (other than those specified in **CDC IX.C.1-3). However, if an accredited organization has a policy that specifies a hang time, or delineates how quickly fluids must be hung after being spiked, a surveyor may issue a **R**equirement **F**or **I**mprovement related to compliance with the organization's own policy.

- ***Additional guidance can be obtained from the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) or U.S. Pharmacopeia. State health departments, pharmacy boards or hospital licensing acts may also contain further regulations.***

***** CDC/HICPAC "Guidelines for the Prevention of Intravascular Catheter-Related Infection."***

HCV Transmission during CT Scan with Contrast Media

- Several hospitals; 6 cases; all had recently undergone CT scan with contrast
- Equipment used:
  - Contrast injector with automatic load from 500-mL bottle shared by >4 persons (different manufacturers)
  - All connected to patient through extension tube with non-return valve (only part of equipment changed for each patient)

Panella H, et al. Emerg Infect Dis 2008;4(2):333-336

HCV Transmission during CT Scan with Contrast Media

- Investigation:
  - One maneuver involving risk of contamination of extension tube identified in all hospitals
  - Could have occurred through hands of personnel manipulating extension tube by disconnecting tube from patient first and then from equipment without changing gloves between these manipulations

Q & A: *Multi-dosing for contrast media in CT*

- Recently, manufacturers are providing Diagnostic Imaging Departments with information* that changing an extension tubing (that has 2 back check valves) after each patient permits the remainder of the IV delivery system to be re-used for multiple patients.
- After a procedure that requires contrast media (depending on the facility) the extension tubing is cut or the end is dropped in a garbage can (*cutting and garbage help remind staff to change before next patient*) OR a new extension tubing is attached in readiness for the next patient requiring contrast media.

**The concept and products are being marketed to MRI departments, cardiac cath labs, and recently an anesthesiology group studied whether it would be safe to use for anesthetic delivery (propofol was test solution).*

APIC

(not specifically addressed in Position Paper)

- Multiple patient use is the issue
  - Product and accessory equipment (e.g. tubing)
- APIC Practice Guidance Committee SBAR
  - PBP should not be used for multi patient use. http://www.apic.org/Resource_/TinyMceFileManager/Bulk_Package_of_Contrast_Material_SBAR_Final.pdf
- FDA – 2014
  - Imaging Bulk Package **(IBP)** vs. Pharmacy Bulk Package **(PBP)** https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=89

Is it necessary to disinfect the rubber stopper on a medication vial if it has a flip-top cover?

1. No
2. Yes

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1. No
2. **Yes**

Accessing vials

- Always use a new sterile syringe and new needle/cannula when entering a vial.
- Never enter a vial with a syringe or needle/cannula that has been previously used.
- Disinfect the rubber stopper of med vials (and the neck of glass ampuls) with sterile 70% alcohol before entering.

"Barrier protection capacity of flip-top pharmaceutical vials"

Anesthesiology, Oregon Health and Science University – Portland, OR

Table 1

Survey responses to Question 1: "Prior to removing the plastic flip-top cover, is the rubber stopper on a propofol vial sterile under routine clinical conditions?"

Responses n=878	Yes	No	Unsure
Anesthesiologist (%)	247 (48)	171 (33)	96 (19)
CRNA (%)	73 (48)	70 (46)	10 (6)
Resident (%)	140 (66)	41 (20)	30 (14)
Total (%)	460 (52)	282 (32)	136 (16)

National survey – 878 responses

Hilliard et al. J Clin Anesthesia 2013;25:177-180

48 vial tops cultured

(propofol, pancuronium, sterile saline w/ flip-top covers)

- 12 vials - routine handling but before use
  - Flip-top was removed and cultured
  - 2/12 positive were contaminated
- Other vials
  - Aerosol contaminant
    - 0 positive
  - Liquid submersion
    - 7 of 15 vials positive

Hilliard et al. J Clin Anesthesia 2013;25:177-180

Accessing catheter hubs, needleless connectors, and injection ports

- Options:
  - Antiseptic containing port protector cap
  - Vigorous mechanical friction with a swab
    - CHG/alcohol
    - Sterile 70% isopropyl alcohol
    - Or, other approved disinfectant swab
- Institutional policy on wiping method re: time
  - Studies:
    - 3-15 seconds
    - Product and/or device specific
- Allow adequate dry time
  - unless directed otherwise by manufacturer's instructions

Injectables in the Operating Room Setting

- ***Whenever possible,***
  - Prepare injections that require compounding (2 or more meds combined) in an ISO Class 5 environment
    - Reduce post op bleeding and pain
    - Injected into intra-articular spaces
  - Single medications for injection
    - Draw up just prior to use
    - ISO Class 5 is not required per USP <797>

Injectables in the Operating Room Setting

Multidose Medication Vials

- Do not store in the immediate patient care area (e.g. surgery/procedure room, anesthesia cart, patient rooms or bays, etc).

- If used in the immediate patient care area, they must be dedicated for single patient use and discarded immediately after use.

http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

Injectables in the Operating Room Setting

Decapping Device

- Do not use to open vial to pour onto the sterile field
  - Vials are not designed for aseptic pouring
- Use a commercially available sterile transfer device
  - The circulator holds the vial so the scrubbed person can withdraw the med or solution using a sterile syringe and needleless adapter
    - Remove the transfer device after each use as they are not intended for multiple uses

Injectables in the Operating Room Setting

Sequential Dosing *(e.g. by anesthesia)*

- Draw the entire contents for 1 patient into sterile syringe
- Use the same syringe for sequential doses in only that patient
- Do not leave syringe unattended

OR

- Obtain sequential doses individually from the same vial using new needle/cannula/syringe each time
- Discard vial when empty or no later than the end of the case

Narcotics Theft a.k.a. "Diversion"

- 1 in 10 HCP struggling with addiction
- Leading cause of provider to patient HCV transmission
  - Other bloodborne and bacterial pathogens
- Prevention needs extend beyond traditional "infection control"
  - Limit opportunities for access or deception
  - Safety-engineered solutions and systems approach
  - Legislation/regulations/licensing

https://www.cdc.gov/injectionsafety/drugdiversion/

Swedish Medical Center – Colorado

- August 2015 – January 2016
- HIV + Surgical technician – Fentanyl syringes
  - replaced with syringes containing another substance
- Notified 3000 pts for testing
  - No evidence of disease transmission to date
- Deficient practices – pharmacy (drug auditing procedures), infection control and surgical services.
- Charged with 1 count each: tampering with a consumer product, 1 obtaining a controlled substance by deceit and subterfuge
- Had been fired from 4 hospitals in other states & “diverting” while serving in Afghanistan
- Colorado legislation enhances current regulation
  - effective 8-10-16
  - adds background check and fingerprinting to Colorado applicants for Surgical Techs

Nurse may have stolen drugs, infected patients

Minn. nurse diverted drugs from IVs for personal use, possibly spreading bacteria

REUTERS

March 16, 2011

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MINNEAPOLIS — A nurse is suspected of inadvertently tainting intravenous painkillers at St. Cloud Hospital while seeking drugs, spreading bacterial infections to 23 patients since October, the hospital said on Wednesday.

- 23 patients
- The nurse was identified as the common factor linking the patients via patient and medication access records.
- *Klebsiella oxytoca* and *Ochrobactrum anthropi*

Narcotics Diversion

- Prevention efforts
  - Drug monitoring systems
  - Security measures
  - Licensing and hiring practices
  - Staff education
  - Recognize signs of diverter behaviors
- Appropriate response to drug diversion events
  - Exposure investigation
  - Assessment of harm to patients
  - Consultation with public health officials when tampering with injectable medications is suspected
  - Prompt reporting to enforcement agencies.

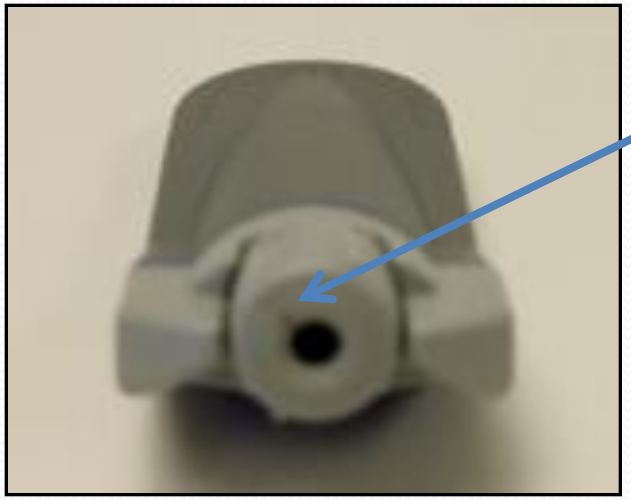
- Controlled meds securely stored
- Secure medication waste system
- Pharmacy reconciliation
- Testing of waste for authenticity of medication

Outbreaks Associated with Blood Glucose Monitoring

- Most in nursing homes and assisted living facilities, resulting from:
  - Using fingerstick devices for more than one person
  - Using blood glucose meter for more than one person without cleaning/disinfecting between uses
  - Using insulin pens for more than one person
  - Failing to change gloves and perform hand hygiene between fingerstick procedures

http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

Device-associated HBV transmission among persons with diabetes



Blood contamination of **finger stick device** used for multiple persons

Blood contamination of shared **glucose testing meters**

Challenge: increased point of care testing and use of over-the-counter personal care devices

An emerging problem: the new generation of devices

Multi-lancet fingerstick device

Sharing of **multi-lancet** fingerstick devices reported as cause of HBV infection outbreak in Nursing Home[1]

Sharing of **multidose insulin pens** reported[2,3]

- Should be single patient use

Multi-dose Insulin Pens

1: Gotz et al. Eurosurveillance 2008;13:1-4
2: www.newsinferno.com/archives/3066 3. www.lcsun-news.com/ci_11670031

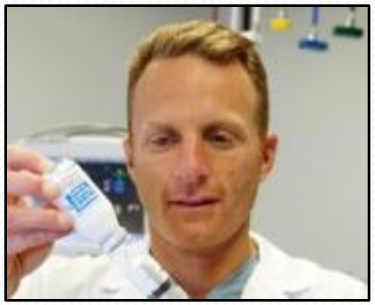
Injection practices among clinicians in United States health care settings

SURVEY - 5,446 health-care practitioners

- **1 %** - sometimes or always reusing a syringe on more than one patient after only changing the needle.
- **6 %** - sometimes or always using single-use vials for multiple patients. These vials lack preservatives, so they can support growth of contaminants between uses.
- **15%** - use the same syringe to re-enter a multiple-dose vial numerous times;
  - 7 % - Save these multiple-dose vials for use with other patients.
- **9%** - sometimes or always use a common bag or bottle of IV solution as a diluting agent for drugs for multiple patients or to clear IV tubing.
  - *These solutions also lack preservatives*

Pugliese G. et al AJIC Dec 2010 pp789-798

Survey Finds 'Discouraging' Injection Habits Among Anesthesiologists



- 49% - same vial for > 1 patient
- 31% - use Propofol on > 1 patient
- ~25% don't always use a new needle or syringe when drawing from a vial
- ~25% use an open vial w/o knowing who accessed it prior
- Reused syringes on different patients
  - 8% residents
  - 2% anesthesiologists

Gounder P. et.al. Journal of Clinical Anesthesia 2013;25:521–528

Challenges in Safe Injection and Infusion Practices

- Cost containment and the drive for efficiency
- Ingrained behaviors – “unthinking force of habit”
- “Culture of complacency” vs. “safety culture”
- Trend toward patient care settings where infection control programs are lacking (hospital ⇨ ambulatory)

Personnel training and competency

- Implement programs for:
  - Training
  - Competency evaluation
- Personnel must have:
  - Knowledge
  - Skills and ability

Periodically assess competency and compliance

Infection control survey tool

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).

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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

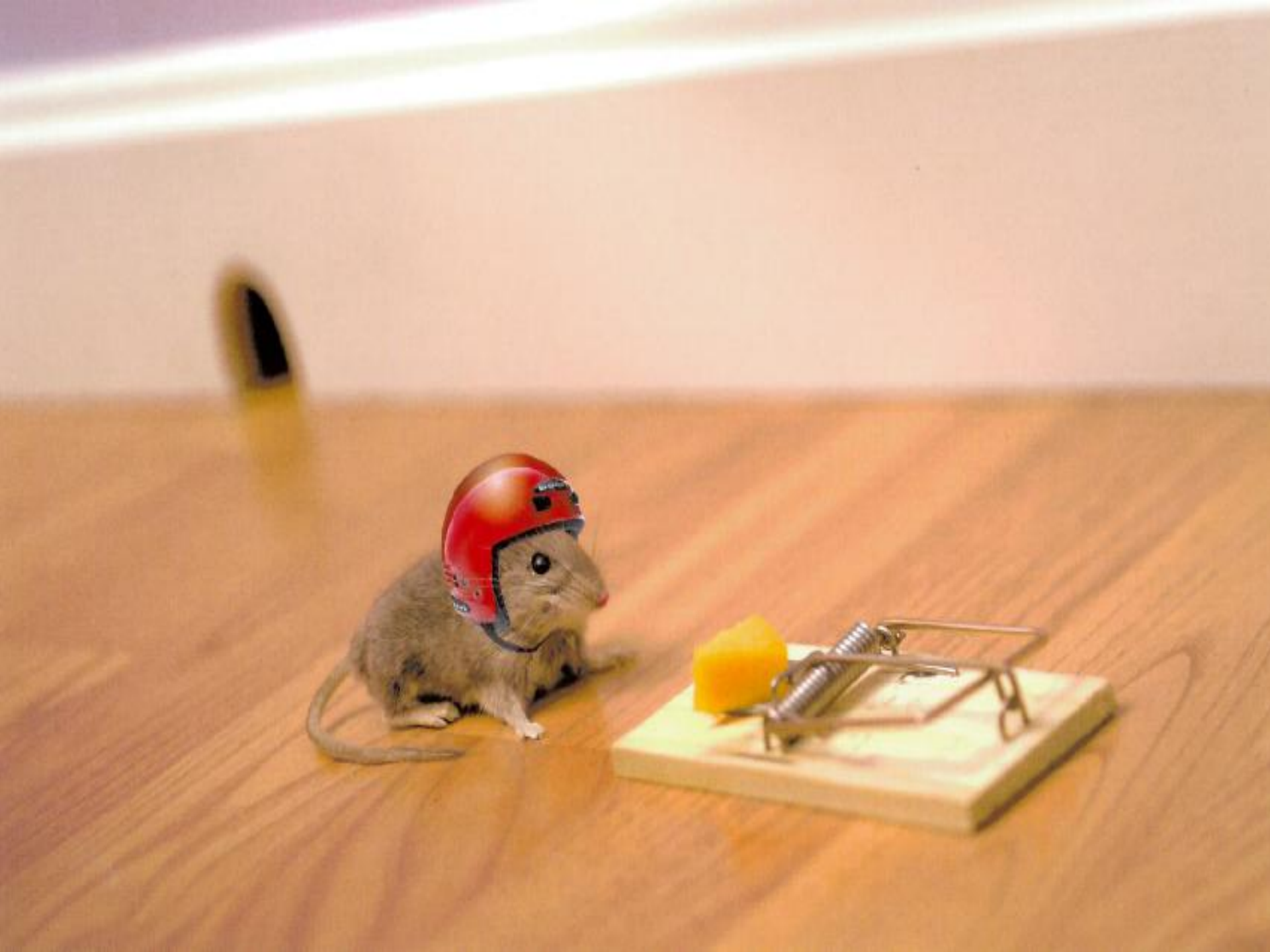
"New" in 2016

Oversight and Enforcement

- Need policies and mechanisms that:
  - Support use of safe practices
  - Ensure compliance with safe practices
  - Mandate corrective action when lapses identified
- Enforce absolute adherence
- Hold personnel accountable for compliance
- Do surveillance to identify HAIs potentially related to injection/medication practices

Summary

- Many outbreaks resulting from unsafe practices
- Safe practices are key to prevention
- Need professional awareness and accountability
- Infection preventionists play critical role
  - Implement healthcare provider education, training, competency assessment and oversight mechanisms
  - Provide surveillance and investigation capacity
  - Promote culture of patient safety



Allergens and BUD

- Manufacturer vials of allergens used for diagnostic testing
  - 28 day BUD
  - New needles/new syringe and not in immediate use area
- Patient specific compounded vials of multiple allergens used in desensitization (treatment for allergies)
  - 1 year BUD
    - Or sooner based on the expiration date of each allergen (if any are sooner, then that is the BUD)
  - Often given weekly/monthly to same pt.

AAAAI – American Academy of Allergy, Asthma and Immunology

http://www.aaaai.org/ask-the-expert/usp-compounding-guidelines

USP 797 Compounding Guidelines

Beyond Use Dating - 28 Day Shelf Life for Compounded Products?

- There has been some controversy over applying the United States Pharmacopeia (USP) shelf life rules for compounded pharmaceutical products to *allergen* extract mixes.

  These rules require that all compounded (mixed) materials be disposed of every **28 days** due to sterility concerns. The allergy industry has successfully challenged this requirement and made the case that allergen extract mixes are an exception to this rule.

- It has been agreed that the manufacturer's assigned expiration dates apply to compounded allergen extracts so long as proper sterility procedures are in place at your facility and the extracts contain a preservative, such as phenol (0.4%), that inhibits bacterial growth.

- Besides following routine sterile handling (aseptic) procedures, compounding (mixing) personnel are also required to pass a Media Fill Test at least annually. This is a test of aseptic technique. A written test is also recommended. ALK does not sell nor specifically endorse any Media Fill Test product on the market but can make suggestions upon request.

- The written test, as well as the guidelines for handling allergenic extracts, are available from www.JCAAI.org. An abbreviated list of guidelines is also printed in the most recent update of the Allergen Immunotherapy Practice Parameters (2011).

- If you encounter any issues with the USP 797 shelf life guidelines for compounded products, please contact your allergen extract supplier for assistance.

https://extractopedia.com/use-of-allergen-extracts/mixing-allergens/aseptic-procedures-sterility/usp-797-compounding-guidelines

Special CSP Types: Allergen Extracts

- Collaboration with American Academy of Otolaryngic Allergy (AAOA) and Joint Council of Allergy, Asthma, and Immunology (JCAAI)
- Preparation Guidelines at www.jcaai.org
- Preservative-free allergen extracts must fully comply with all aspects of USP <797>.
- Preserved intradermal and subcutaneous SDVs and MDVs are exempt from personnel, environmental and storage requirements if all criteria are met.
  - **For single patient only; labeled; not stored**
  - **Compounded by simple aseptic transfer**
  - **Hand hygiene is performed**
  - **Garb: hair/beard covers, gown, mask, sterile gloves**
  - **Gloves are intermittently disinfected w/ sterile IPA**
  - **Vial stoppers and ampule necks are disinfected**

http://www.rld.state.nm.us/uploads/files/Overview%20of%20Chapter%20797%20for%20Surveyors%20Inspectors.pdf

Is it okay for anesthesia providers to store medication syringes in their pocket?

"Meds in pockets"

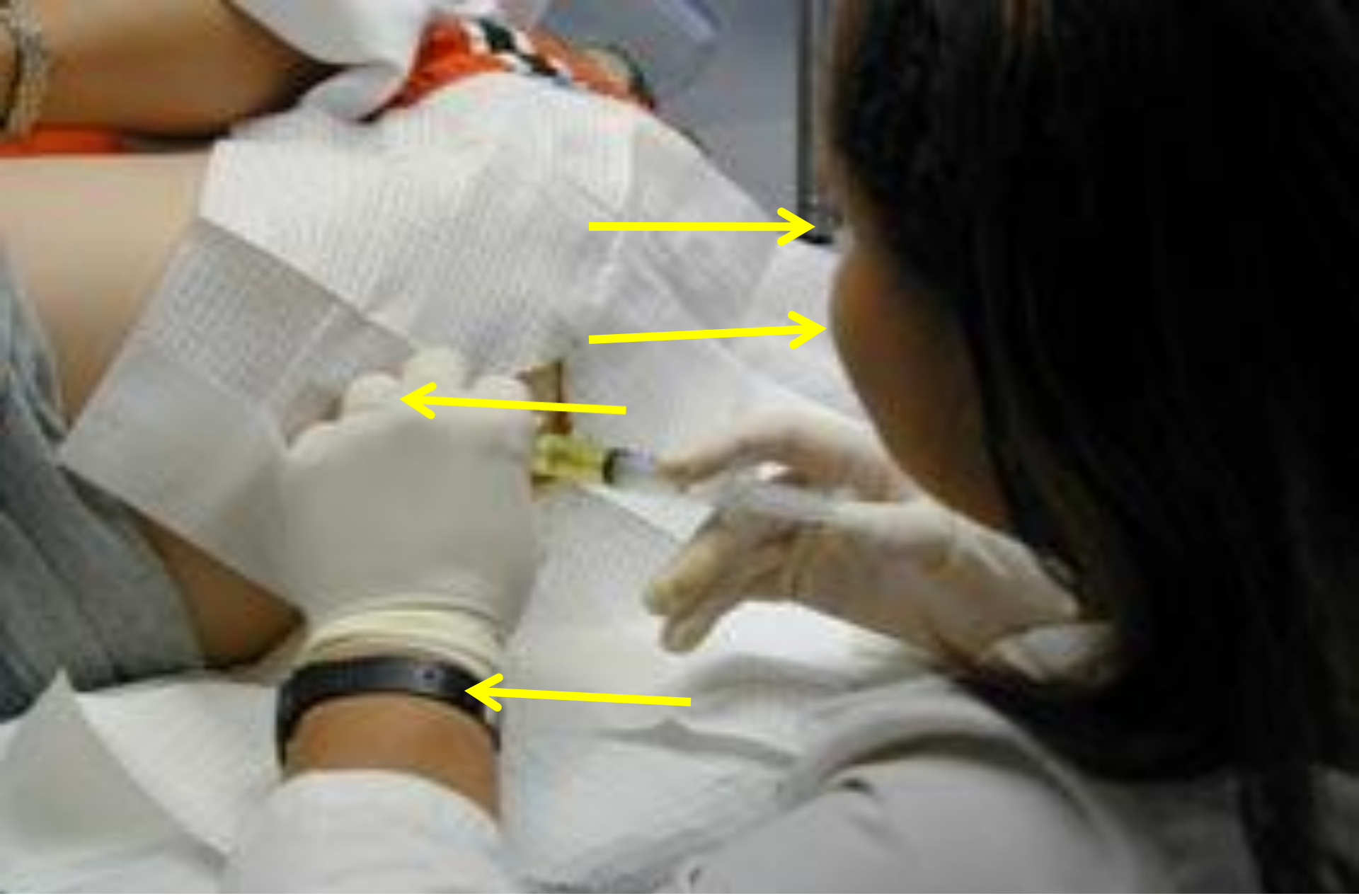
- ASA: transport meds to the pt. for premedication and to have rescue medications during pt. transport
- *TJC changed it's stringency on this:*

Allowing carrying of medication in accordance with institutional policy – The issue of anesthesia professionals (or anyone for that matter) carrying a medication is left to the individual health care organization. As long as the organization has written policies on storage of medication, which includes carrying medication, and those policies are followed, the practice is accepted by The Joint Commission.

http://www.asahq.org/For-Members/Advocacy/Washington-Alerts/The-Joint-Commission-Adopts-ASA-Recommendations-on-Medication-Management-Issues.aspx

Neuraxial Procedures

What is the recommended PPE to be worn by anesthesia when performing Neuraxial procedures (e.g. spinal anesthesia)?



Practice Advisory - Neuraxial procedures

- Epidural anesthesia, lumbar puncture
  - epidural, spinal, or combined spinal– epidural administration of anesthetics, analgesics, or steroids; lumbar puncture or spinal tap; epidural blood patch; epidural lysis of adhesions; intrathecal chemotherapy; epidural or spinal injection of contrast agents for imaging; lumbar or spinal drainage catheters; or spinal cord stimulation trials

- Infection
  - epidural abscess
    - 50-60% *Staph aureus*
    - *15-20% Streptococcus species*
  - meningitis
    - 49% *Viridans Streptococcus*
      - 16% *Strep. Salivarius*

Bacterial Meningitis After Intrapartum Spinal Anesthesia New York and Ohio, 2008--2009

- **5 cases of bacterial meningitis**
  - Post partum women
  - Intrapartum spinal anesthesia
  - Rapid onset of meningitis (<24hrs)
  - 4 w/ CSF – *Streptococcus salivarius*
  - 1 death – meningoencephalitis caused by *Streptococcus salivarius*

- **Investigation**
  - Hospital A
    - Same anesthesiologist – reported routinely using a mask
    - Others in room did not (including visitors)
    - Indistinguishable PFGE in 2 of the pts.
  - Hospital B
    - Same anesthesiologist – did not routinely use a mask
    - Cultures negative but had been prophylaxed. PCR positive for *Strep. Salivarius*
  - *Droplet Transmission most likely*

- What to wear:
  - CAP
  - MASK
  - STERILE GLOVES

    …and Eye protection!
- *Remove rings/watches*
- *Skin prep w/ dry time*
- *Sterile drape*
- *Sterile occlusive dsg.*
  - *Newer types are clear*

- *Limit opening line*
- *Remove unwitnessed disconnects*

Practice Advisory…Anesthesiology 2010;112:530-545