



**Medication Management:
From Cradle to Grave
Including Narcotics**

Objectives

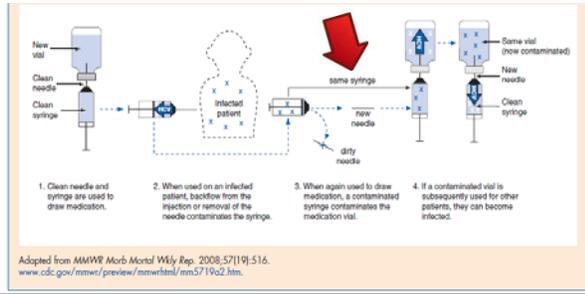
The participant to be able to:

- Identify areas where oversight or perceptions of cost saving may put patients at risk for an unsafe practice
- Understand correct processes that are non negotiable
- Know where to go to get the supporting details you will need

Ramifications

- Patients/employees exposed to illness or even death
- \$\$\$ spent in testing
- Lawsuits
- Criminal charges
- Loss of licensure
- Facility closures

July 25, 2007



2009

Colorado Hospital Based Surgery Facility

- 8000 patients screened (3 facilities)
- 26 confirmed associated infections
- Drug diversion (fentanyl) by HCV-infected surgical tech

Fentanyl

- 2016 - 64,000 drug overdose deaths (58,200 entire Vietnam War)
- Opioid overdoses were 75% of the total
- Fentanyl sharp increase, up 103% compared to heroin with an increase of 17%



2011

Mississippi Clinic

- 470 patients screened
- 16 confirmed associated infections
- Reuse of same needle on multiple patients

2015

Michigan Pain Management Facility

- 122 patients screened
- 2 confirmed associated infections
- Syringe reuse contaminating vials used for more than 1 patient

West Virginia Cardiology Clinic

- 2000 patients screened
- 5 confirmed associated infections
- Use of SDV for more than one patient

United States Pharmacopeial Convention (USP)

- Independent non-profit - sets the bar for manufacturing and distributing safe and effective medications

- 2/5/18 WHO grants USP official relations as a trusted expert around the world



USP-NF General Chapter <797>
Pharmaceutical Compounding—
Sterile Preparations

USP <797> Update Information

Below is the timeline associated for the proposed revisions <797> and opportunities to engage with USP and provide input.

- July 27, 2018 - Web pre-posting in Pharmacopeial Forum
- Sept 5, 2018 - Public comment period
- Nov 30, 2018 - Close of public comment period
- June 1, 2019 - Intended Publication
- Dec 1, 2019 - Intended Official Date

ISO Class 5 – Clean Room



USP <797>

- CSP = compounded sterile preparations (1)
- No more than 3 commercially manufactured packages of sterile products involving not more than two entries into any one container (4 & 7)
- Administration begins not less than one hour after preparation (7)

USP <797>

- Opened or needle punctured single-dose containers shall be used within 1 hour of opening (7)



- USP 797 states for purposes of this chapter, CSP's include ophthalmic drops and ointments (11)



APIC

Point of Care Devices

- Hand Hygiene
- Aseptic technique
- Store, access, and prepare in a clean area
- Use single-use auto-retracting lancing devices
- Never use finger stick device for more than one patient
- EPA disinfectant per IFU



APIC

Point of Care Devices

- Avoid handling test strip containers with soiled gloves
- Clean visible dirt before disinfecting
- Hand Hygiene



APIC

- Drug Diversion
- Transporting medications
- Storage of needles and syringes
- Injectables in the operating room
- Decapping

AST

Follow the 6 rights of medication handling:

1. Right Patient
2. Right Drug
3. Right Dosage
4. Right Route
5. Right Time
6. Correct Documentation



AST

Sterile technique when dispensing onto sterile field

Vial Method:

1. Decanters are NO longer the go to
2. Circulator draws up
3. CST draws up
4. Discard in regular trash



AST

Sterile technique when dispensing onto sterile field

Ampule Method:

1. Circulator draws up
2. CST draws up
3. Discard in sharps container



* Correlation of actual to preprinted labels!!

SDV

- Approved for single use
- Typically lack antimicrobial preservative
- Discard after every use
- Clinical proof microbial growth after one hour



MDV



- A multiple-dose vial (MDV) is indicated by it's FDA approved label
- Although MDVs can be used for more than one patient when aseptic technique is followed, **ideally even MDVs are used for only one patient**
- **MDVs typically contain an antimicrobial preservative to help limit the growth of bacteria.** The preservatives have no effect on bloodborne viruses
- Discard MDVs when the beyond-use date has been reached or any time the sterility of the vial is in question

Beware.....

- 12% of physicians and 3% of nurses reuse same needle and/or syringe on multiple patients
- SDV's and MDV's can come in any shape and size, beware.....

Best Practices

- Hand Hygiene
- Use of PPE
- Respiratory hygiene and cough etiquette
- Safe handling of equipment and surfaces

Best Practices

- Adequately swab the vial with friction and air dry
- Filter needles for glass ampules
- Sterile product prep in the OR



Purchasing

- www.ashp.org/drugshortages/current/
- www.ashp.org/shortages
- <https://www.fda.gov/Safety/Recalls/ucm563383.htm>
- Try small volume wholesalers
- Identify weekly and monthly needs
- Consider alternative drugs
- Consider alternative dosages
- Contact manufacturers directly

Purchasing

- Review compounding pharmacies
- Have your orders in the “que”
- Shelf Life Extension Program (SLEP)
- <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm563360.htm>

Atropine Sulfate Injection, USP 0.1 mg/mL; 5 mL ABBOJECT syringe

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
54322DK00	1-Jun-2017	1-Dec-2017
54373DK00	1-Jun-2017	1-Dec-2017
54424DK00	1-Jun-2017	1-Dec-2017
58236DK00	1-Oct-2017	1-Apr-2018
63183DK00	1-Mar-2018	1-Sep-2018
64293DK00	1-Apr-2018	1-Oct-2018
67331DK00	1-Jul-2018	1-Jan-2019

Storage

- Calculate the expiration date, NOT the open date on MDV
- Signature list (Name, Initials, Signature)
- Tracer thermometer, fridge on generator?
- Assure high alert and look alike sound alike meds are flagged in storage
- Secure drug samples if you have them

Storage

- Avoid "intermingling"
- Avoid stocking various strengths together
- Date succinylcholine and rocuronium and use per IFU
- Do not label syringes "en mass"
- No spiking bags for multiple patients
- Store IV bags in their outer wrapper
- Date IV's put in the warmer

Storage

- Watch for rust on your carts
- Wire racks off the floor 8-10 inches with a plastic liner on lower shelf and 18 inches from the ceiling (if you have sprinklers) & 2 inches from outside wall
- Separate clean from sterile

Storage

5 conditions that can compromise sterility

- Moisture
- Soil
- Physical damage
- Handling
- Pests

Controlled Drugs

- Properly executed power of attorney
- MUST have validation am and pm
- Assure there is an accurate paper trail for withdrawals from cabinet to OR if doing trays, bags, etc.
- Keep records for 3 years (invoices, packing slips, 222 blue form with signature)

Controlled Drugs

- No erasures or White-Out
- Discards done in REAL TIME, witnessed, completely expelled
- Correlate anesthesia record to controlled drug record for consistency
- Fully empty waste and render "irretrievable"

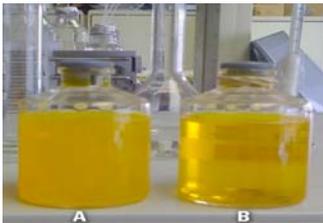
Controlled Drugs



Emergency/MH Cart

- Check at least monthly for expiration dates
- Dantrolene 36 vials
 - * mix with sterile water for injection without a bacteriostatic agent and NOT normal saline, you will need 22 100 mL vials

Dantrolene



A = mixed with 60 ml normal saline
B = mixed with 60 mL of water for injection

Emergency/MH Cart

- Have a list of drugs on the outside of the cart
- Pediatric dosage guidelines
- Breakable locks used to secure carts

Pharmacy Waste

- DOT – 49 CFR 173
 - EPA – 40 CFR 262.11 and 261.3
 - OSHA - 1910
 - DEA – State & Federal
 - NIOSH/CDC - Hazardous Drugs VS Hazardous waste pharmaceutical
- Preparing, transferring, and disposing of hazardous waste.....

OSHA

- 1910.1030 (d)(2)(v) – wash hands
- 1910.1030(d)(2)(vii)(A) – No recapping or removal of needles
- 1910.1030(d)92)(viii)(A) – Sharps containers

Hazardous Drugs



- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs that have previously been determined to be hazardous

P-List



- P042 Epinephrine
- P075 Nicotine
- P081 Nitroglycerin
- P204 Physostigmine
- P188 Physostigmine salicylate
- P001 Warfarin >0.3%

U LIST



- U044 Chloroform
- U058 Cyclophosphamide
- U059 Daunomycin
- U075 Dichlorodifluoromethane
- U089 Diethylstilbestrol
- U122 Formaldehyde
- U129 Lindane
- U150 Melphalan
- U151 Mercury
- U010 Mitomycin C
- U182 Paraldehyde
- U188 Phenol
- U200 Reserpine
- U201 Resorcinol
- U202 Saccharine
- U205 Selenium
- U206 Streptozotocin
- U237 Uracil mustard
- U248 Warfarin <0.3%

Red Sharps Container

- Needles, syringes, lancets, broken glass with blood on it
- Suture needles, scalpel blades, butterflies (both traditional and safety)
- Vacutainer tubes (both plastic and glass)
- Phlebotomy needles with vacutainer tube holder attached
- Capillary tubes (both plastic and glass)
- IV catheters
- Dental anesthetic carpules with blood
- Dental wires and endodontic files
- Other sharp objects contaminated with blood such as box cutters and broken glass



Red Sharps Container

- What should you **avoid** putting in a sharps container? All of the following should not be disposed of through a sharps container:

- Medication and Medication Wrappers
- Aerosols or inhalers
- Garbage or liquids of any kind
- Batteries of any type
- Cauterizers
- Fluorescein
- Hazardous, chemical, radioactive or red bag waste (non-sharps regulated medical waste)
- Fixatives and preservatives



WASTE DISPOSAL

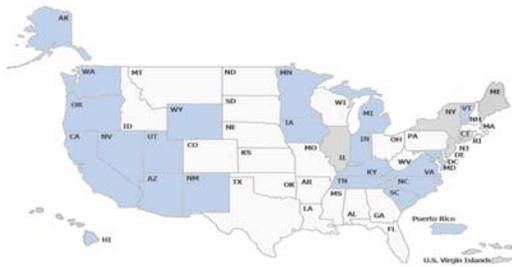
Regular Waste: Clear Bag • Empty IV bags and tubing • Empty medication vials or containers • Empty syringes without needles • Non-hazardous dressings • Diapers • Food • Gloves • Sphygmans • Empty bag tags & other charge tags • Safety needles 	Biohazardous Waste: Red Bag • Blood and all other potentially infectious material • Blood culture/transport/transporter • Pleurocentesis • Soiled or dripping body coverings • Suction lines with heavily soiled or other potentially infectious material • All disposables: items soiled or dripping with blood or other potentially infectious material	Chemical Waste: Yellow Bag • Toxic Chemicals: includes all supplies used to make and administer chemotherapeutic agents • Examples: tubing, empty bags, bottles, vials, syringes, gloves, pads, masks, gowns, wipes etc. Return to pharmacy at once in original bag. Do not place in sharps container.	Pharmaceuticals: Blue Box • Partially used or residual prepackaged or over the counter medications: IV bags, pads, gel, cream or patch. • Residual or residual narcotics and/or controlled substances • MUST BE UNLABLED: equat into container or cut patches. Return to pharmacy at once in original bag. Do not place in sharps container.	Pharmaceuticals: R.C.R.A. * • R.C.R.A. pharmaceuticals are controlled hazardous waste. • Includes unused or residual drugs: • Insulin (if empty place in regular sharps) • Acetaminophen • Cefazolin • Digoxin • Chemotherapy Return to pharmacy at once in original bag for proper disposal. *Federal Resource Conservation and Recovery Act (RCRA)	Sharps: Red Box • Non-Crimo vials: empty • Non-Crimo syringes with needles empty • Broken medication vials • Sewer • Sink • Bloodlines • Laminated filters • IV drip

Pharmacy Waste -EPA

- <https://www.epa.gov/hwgenerators/links-hazardous-waste-programs-and-us-state-environmental-agencies>



Pharmacy Waste - OSHA



AAAASF



- Very specific about what emergency meds must be on hand at the facility
- Controlled substance inventory must be sequentially numbered and bound
- 12 vials of Dantrolene and IV bag of preservative free H2O ok

AAAHC



- Pharmacy contractors have contract and proof of license
- Expired items are disposed of in a manner that prevents unauthorized access.

IMQ



- Verbal orders signed within 24 hours
- If state law permits, a medical assistant with special training may do narcotic counts if on job description

TJC



2018 National Patient Safety Goals

- NPSG.03.04.01 Before a procedure, label medicines that are not labeled
- NPSG.03.05.01 Take extra care with patients who take medications to thin their blood
- NPSG.03.06.01 Record and pass along correct info about a patients meds

TJC



- Emergency back up plan for medication dispensing equipment and medication refrigerators (EC Chapter)
- Plan to review overrides if you are using automatic dispensing cabinets (MM.08.01.01)
- Have a policy on "wasting" (MM Chapter)
- Policy on signed and held orders indicating date and time actually give (MM.04.01.01)

Medication Management

Please email your questions and comments to:

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