INFECTION PREVENTION STRATEGIES FOR THE ASC PHARMACY - 2015

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With a Little Other Compliance Added In

Biography

- Christopher M. Dembny R.Ph.
- Licensed pharmacist in Texas for 30 years
- Consultant pharmacist for surgery centers for 20 years
- Exclusively practicing in surgery centers and surgical hospitals and ERs for 15 years
- Currently consulting for > 70 ASCs
- Current Board Member Texas State Board of Pharmacy

Question #1: T or F

- The United States Pharmacopiea authored USP 797 and has regulatory oversight of surgery centers.

Question #2: T or F

- Compounding pharmacies are your best option to provide you compounded sterile products.

Question #3: T or F

- DEA requires two licensed personnel to witness waste of controlled substances.

Question #4: T or F

- Per DEA, you may dispose of controlled substance waste by mixing with objectionable substances (ipecac) or absorbents (kitty litter).

Question #5: T or F

- DEA requires controlled substances to be stored in double locking cabinet.

Infection Control

- Infection control is a hot topic among all of the regulatory and accreditation agencies
- Infections are a major problem in hospitals
- Hospital-Acquired Infections Cost $10 Billion a Year: Study --- US News 9/3/13
- One out of every 20 patients who are admitted to a hospital will fall victim to an infection they pick up while there, according to the U.S. Centers for Disease Control and Prevention
- --- (US News 9/3/13)

Hospital?

- Four surgeons performed more than 10,000 orthopaedic surgeries in a multispecialty and single specialty ambulatory setting over 8 years. These procedures were reviewed for postoperative deep infection within one year of initial operation.

- RESULTS:
- The post-surgical deep infection rate in a multi-specialty ASC was 0.81% for 2867 operations compared with a rate of 0.38% for 7311 operations performed in a single specialty ASC ($p = 0.007$).
- PubMed: J Orthop 9/5/13

Who Has Oversight?

- FDA
- CMS
- Department of State Health Services
- State Board of Pharmacy (some states)
- **The Joint Commission**
- **AAAHC**
- **AAAASF – DNV - others**
- **Why green? $$$$**

Single-Dose Vial

- A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/procedure/injection. (AAAHC)

Single-Dose Vial

- Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.
- (AAAHC)
- (Single-dose; single-patient; preservative-free; PF; MPF)

Multiple-Dose Vial

- A multiple-dose vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multiple-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria (AAAHC), not fungi or virus.

Single-Dose Vial

- Use a single-dose/single-use vial for a single patient during the course of a single procedure.
- Discard the vial after this single use; used vials should never be returned to stock on clinical units, drug carts, anesthesia carts, etc. (TJC)
- Identify SDV/MDV

Single-Dose Vial

- If a single-dose/single-use vial must be entered more than once during a single procedure for a single patient to achieve safe and accurate titration of dosage, use a new needle and new syringe for each entry. (TJC)

Single-Dose Vial

- 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. (CMS)
- ------propofol -

Single-Dose Vial

- Administering drugs from one SDV to multiple patients without adhering to USP <797> standards is not acceptable under CMS infection control regulations. (CMS)
- Must be done in an ISO class 5 environment by someone compliant with USP 797. [compounding pharmacy-outsourcing facility] check your state rules.

Multiple-Dose Vials

- Only vials clearly labeled by the manufacturer for multiple-dose use can be used more than once.
- Limit the use of a multiple-dose vial to only a single patient, whenever possible, to reduce the risk of contamination. (TJC)

Multiple-Dose Vials

- Disinfect the vial's rubber septum before piercing by wiping (and using friction) with a sterile 70 percent isopropyl alcohol "ethyl/ethanol alcohol, lodophor" or other approved antiseptic swab.
- Allow the septum to dry before inserting a needle or other device into the vial. (TJC)

Multiple-Dose Vials

- Once a multiple-dose vial is punctured, it should be assigned a "beyond-use" date. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer. (TJC)

Multiple-Dose Vials

- Multiple-dose medications used for more than one patient are stored and accessed away from the immediate areas where direct patient contact occurs. (CMS infection control worksheet) http://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

Compounded Sterile Products

Definition: Low Risk Compounding

- (I) Single volume transfers of sterile dosage forms from ampules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter (filter needle) to remove any particles. (TSBP Rules)

Compounded Sterile Products

- (II) Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions. (TSBP Rules)

Compounded Sterile Products

- Always use aseptic technique and all of the techniques described earlier.
- USP 797 is a long and detailed tome which you don't want to study enough to comprehend and can't comply with in the ASC.
- EXCEPT:
  - (CMD)

Compounded Sterile Products

- Immediate Use Exemption
- Compounded sterile products are exempted from all other requirements of USP 797 if administration is begun to *the patient* within 1 hour and continues no longer than 24 hours.
- (CMD)

Immediate Use Exemption

- IMMEDIATE USE COMPOUNDED STERILE PRODUCTS (CSPs)
- For the purpose of emergency or immediate patient care, CSPs are exempted from the requirements described in this chapter for Low-Risk Level, Medium-Risk Level, and High-Risk Level CSPs when all of the following criteria are met:

Immediate Use Exemption

1. Only simple aseptic measuring and transfer manipulations are performed with not more than three (3) sterile nonhazardous commercial drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution.

Immediate Use Exemption

2. Unless required for the preparation, the preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.

Immediate Use Exemption

3. At no point during preparation and prior to administration are critical surfaces and ingredients of the CSP directly exposed to contact contamination such as human touch, cosmetic flakes or particulates, blood, human body substances (excretions and secretions e.g., nasal and oral), and non-sterile inanimate sources.

Immediate Use Exemption

4. Administration begins not later than one (1) hour following the start of preparing the CSP.

Immediate Use Exemption

- When the CSP is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the CSP shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond-use time and date.

Immediate Use Exemption

- If administration has not begun within one (1) hour following the start of preparing the CSP, the CSP is promptly and safely discarded. Immediate Use CSPs shall not be stored for later use.
- (USP 797)

Safe Injection Practices

- 1. Use aseptic technique to avoid contamination of sterile injection equipment.
- 2. Needles, cannulae, and syringes are sterile, single-use items. They should never be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.

Safe Injection Practices

- 3. Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed.
- 4. Use fluid infusion and administration sets for one patient only and dispose appropriately after use. Consider a syringe or needle/cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set.

Safe Injection Practices

- 5. Use single-dose vials for parenteral medications whenever possible.
- 6. Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use.
- 7. If multiple-dose vials must be used, both the needle or cannula and syringe used to access the multiple-dose vial must be sterile.

Safe Injection Practices

- 8. Do not keep multiple-dose vials in the immediate patient treatment area. Store multiple-dose vials in accordance with the manufacturer's recommendations. Discard multiple-dose vials if sterility is compromised or questionable.
- 9. Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients. (these are not MDV)
- (CDC)

Questions?

- Questions on sterile products??????

Compounding Pharmacies?

- Solution or more problems?

Are Compounding Pharmacies a Viable Answer?

- **Maybe???**
- **But choose carefully.**
- **Get approval from Med Exec.**
- **The cheapest isn't always the best.**
- **The cheapest isn't always the cheapest -- Ask those who used NECC.**

Outsourcing Facilities?

- FDA now says that pharmacies may no longer compound items for "office use compounding" without being patient specific.
- Many state boards of pharmacy consider "office use" compounding part of the practice of pharmacy.

Picking a Good Compounder

A. Look for accreditation:

- Pharmacy Compounding Accreditation Board (PCAB)
- An independent accreditation organization
- FDA registration (outsourcing facility)
- Can't ensure everything is perfect

Picking a Good Compounder

B. Independent assessment

- Consultant pharmacist can be a resource
- International Association of Compounding Pharmacists (IACP) http://www.iacprx.org/
- http://www.iacprx.org/associations/13421/files/CPAQ%20REV%20with%20updated%20member%20number%20October%202012.pdf
- This is the assessment tool from IACP

Picking a Good Compounder

C. Consultant Pharmacist Assessment

D. I would use in-state compounders

Picking a Good Compounder

E. Ask for independent analysis
1. Sterility
   a.Bacterial
   b.Fungal
2. Quantitative Analysis

Outsourcing Facilities

- Also known as 503 B Pharmacies
- Must comply with CGMP requirements
- Will be inspected by FDA according to a risk-based schedule
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound

Outsourcing Facilities

Outsourcing Facilities

- At this time (11/14), there are 55 of these listed on the FDA web site
- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm
- Only 37 of these have been inspected at this time

Outsourcing Facilities

- All but two of the inspected facilities received a FDA-483 (notice of deficiencies)
- Range from 3 to 20 pages (or more)

Outsourcing Facilities

- Outsourcing facilities may soon be your only choice for compounded sterile products
- This is an ongoing issue that could be a turf war between FDA and Boards of Pharmacy
- No clear direction at this point
- Questions on outsourcing facilities?

Drugs

Controlled Substances

Required Documentation:

- 1. Biannual controlled substance inventory (once every two years) (TX-annual)
- 2. CII invoices with DEA 222… or CSOS In separate file (signed by person receiving)
- 3. Power of attorney to sign DEA 222
- 4 CIII-V invoices (separate) (signed)
- 5. Controlled substance ***reproducible*** audit trail

Controlled Substances

BLANK DEA FORM 222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

McKesson Medical Surgical	4250 Patriot Drive, Suite 100
Grapevine, TX	5/2/03

No. of Packages	Size of Package	Name of Item	Packages Shipped	Date Shipped
2	100	Percocet 7.5/500		
3	100	Codeine Phos. 30mg tab		
5	25x1ml	Demerol 50mg 1ml amp		
5	10/BX	Fentinyl 100 mcg/2ml		

4 LAST LINE COMPLETED

Valid Signature

MM/DD/YYYY	XXXXXXX
1,2,3,3N,4,5	
XXXXXXXXXX	XXXXXXX

Your Business
123 Main Street
Anywhere, USA 12345

Note: The graphic illustrated above is only a depiction of the DEA Form 222. It is not intended to be used as an actual order form.

Controlled Substances

***Reproducible* Audit Trail**

- A. Track in --- all invoices
- B. Monthly summary from wholesaler
- C. Valid administration records
- D. Witness of Waste
  - 1. DEA non-retrievable
  - 2. OSHA – EPA – transport – destruction

Controlled Substances

***Reproducible* Audit Trail**

- E. Transfer of drug to another registrant (5% rule) proper documentation****
- F. Documentation of destruction (reverse management) *******
- **Document everything in and everything out – cradle to grave *********

Controlled Substances

- **Controlled substance administration records**
- Date and time of administration
- Patient name
- Drug and dose administered
- **Signature** of person administering ***
- Amount of Waste (if any) and **signature** of person witnessing waste
- Name of ordering practitioner
- **Must be maintained separately from chart**

Controlled Substances

- Ordering:
- CII --- DEA 222 or CSOS (power of attorney)
- CIII-V --- order like dangerous drugs
- Files for invoices --- signed
- Continual inventory – (counts?)
- Administration records

Controlled Substances

Date___________

Patient or sheet #	time		Demerol 50mg amp	Morphine 10mg	Fentanyl 2ml amp	Fentanyl 5ml amp			Amount given	waste	Administered by (signature) **Or signed out by**	Waste witness if necessary (signature)	Ordered by
Beginning count													
Ending count													

Amount given and waste, signature of person administering, waste witness, and ordered by only necessary on this sheet for meds not on sedation admin record

Controlled Substances

Controlled Substance Administration Record

Date: ___________ sheet # ________________

Start of day removal Signed out by: ___________________________	# Fent 2ml checked out		# Midaz 5mg checked out	# Midaz 2mg checked out	Checked out to whom

Patient Sticker	Time of admin	Fent dose	dose	Midaz dose	Midaz dose	Admin by (signature)
		Fent waste	waste	Midaz waste	Midaz waste	Waste witness (signature)
Patient Sticker	Time of admin	Fent dose	dose	Midaz dose	Midaz dose	Admin by (signature)
		Fent waste	waste	Midaz waste	Midaz waste	Waste witness (signature)
Patient Sticker	Time of admin	Fent dose	dose	Midaz dose	Midaz dose	Admin by (signature)
		Fent waste	waste	Midaz waste	Midaz waste	Waste witness (signature)
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		Fent waste	waste	Midaz waste	Midaz waste	Waste witness (signature)
Patient Sticker	Time of admin	Fent dose	dose	Midaz dose	Midaz dose	Admin by (signature)
		Fent waste	waste	Midaz waste	Midaz waste	Waste witness (signature)
Patient Sticker	Time of admin	Fent dose	dose	Midaz dose	Midaz dose	Admin by (signature)
		Fent waste	waste	Midaz waste	Midaz waste	Waste witness (signature)

End of day return	# Fentanyl 2ml returned	# returned	# Midaz returned	# Midaz returned	Return to stock witnessed by:

Controlled Substances

- **Theft or loss**
- DEA 106 – now online only
- Theft or "significant loss"
- Check state and local requirements
- TX - DEA, DPS, TDSHS, TSBP, local police

Controlled Substances

- **Adequate Security**
- Double locked?
- Bolted to wall?
- Security system? (camera)
- Metal cabinet?
- Steel safe?

Controlled Substance Questions??????

Pharmacy Compliance

- A. All drugs are secured to prevent unauthorized access.
- B. Licenses available and up to date
- C. Storage temperature adequate – thermometer (Recording? Accurate?)
- D. No expired medications
- E. Invoices

Pharmacy Compliance

- F. Recall notices
- G. Drug storage (MDV)
- H. Pharmacy Policies and Procedures
- I. Chart review

Pharmacy Compliance

- **Chart Review**
- A. Allergies – current and consistent and what reaction
- B. Potential for allergic reaction
- C. Potential for drug interaction
- D. Potential for adverse reaction

Pharmacy Compliance

- **Chart Review**
- E. Valid orders for drugs administered
- F. Documentation of administration or drugs that were ordered
- G. Anesthesia/sedation record matches controlled substance administration record

Miscellaneous

- A. Hydrocodone CII
  - Make sure to order UD on DEA 222

  B. Tramadol is CIV
  - Make sure to inventory on biennial inventory

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Review Questions

- All answers are False

Questions?????

Contact Information

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Thank you!