

Medication Safety from Purchase to Disposal

Charles W. Wilson, Jr., RPh.



Charles W. Wilson, Jr., RPh.

- Chuck received his degree in Pharmacy from The University of Georgia, 1982. He is currently co-owner of The Medicine Shoppe of Dunwoody Pharmacy.
- The Pharmacy specializes in compounding , immunization, general retail, and ambulatory surgery services.
- He helped develop policies and procedures for one of the first Multi specialty outpatient ambulatory surgery centers in Atlanta and currently works with 35 centers throughout the Metro Atlanta area.
- Chuck is an active member of ASCP (American Society of Consultant Pharmacy), APHA (American Pharmacy Association), and GPHA (Georgia Pharmacy Association).

Hot Issues for Pharmacy

- Availability of surgery medications (FDA is putting pressure on manufacturers and closing plants, which is causing many shortages).
- Summary report published at:
<http://www.ashp.org/drugshortages/summitreport>
- DEA is monitoring narcotic usage and is putting pressure on all aspects of healthcare. Manufacturers, wholesalers, pharmacies, doctors, hospitals, and ambulatory centers are scrutinized for the amount of usage.
- 797 Guidelines.
- Medication errors and safe practices.
- Healthcare reform.



<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>

Drug Shortages



- 260 drug shortages in 2011 including injectables, chemotherapy, analgesic, antibiotics, and ADD medications.
- Fentanyl, midazolam, propofol, emergency cart medications such as furosemide, sodium bicarbonate, mannitol, epinephrine, rocuronium, succinylcholine, etc.

Causes of Drug Shortages

- Strict FDA oversight of manufacturing processes.
- Manufacturer negligence and bad practices.
- Government policies forcing manufacturers to reduce inventory and production due to reduced reimbursement of low cost generics.
- Drug industry consolidation.
- DEA monitoring of control drugs at all levels including manufacturer, wholesaler, and pharmacy.



Causes of Drug Shortages

- Limited raw materials.
- Closing of several manufacturing plants.
- Manufacturers keeping smaller inventories and having shorter production runs.
- Hoarding by hospitals and outpatient centers.
- View drug shortages on FDA website: FDA.gov/drugs/drug_safety/drug_shortages
- Healthcare reform.

What Can We Do About It?

- Review alternatives with QI committee.



- Find alternate sources for purchase such as a pharmacy or secondary wholesaler.
- Break up larger vials into smaller doses (Must use proper 797 guidelines).

DEA Diversion

- DEA is monitoring all control drug use.
- Limiting manufacturers on production.
- Limiting wholesalers on distribution.
- Monitoring pharmacy usage at all levels.
- Setting large fines on all of above if they do not monitor drug use.
- Closing down wholesalers, clinics, and pharmacies.



Narcotic Documentation

- Narcotic security and documentation are essential in the ambulatory surgery center setting.
- Narcotic abuse among highest with healthcare professionals due to access. Anyone **could be** abusing medication in your center.
- Make sure you protect yourself by following proper protocol.



Narcotic Documentation

- Must be able to track narcotics from time of ordering and receipt in the center until time of administration and charting.
- Master Control Log.
- Narcotic Count Sheets.
- Narcotic Administration Logs.
- C222 form documentation.
- Charts (should match administration logs).



Narcotic Ordering

- C222 forms are required for C2 drugs such as fentanyl, morphine, hydromorphone, meperidine, and oxycodone/apap.
- Control 3,4, and 5 drugs can be ordered along with legend drugs as long as the center/medical director have a DEA certificate allowing C2-C5 drug ordering.
- C3 drugs include hydrocodone/apap products.
- C4 drugs include midazolam, diazepam products.

DEA Form C222

- Used to order Control 2 drugs for the center or used to transfer Control drugs out of center.
- Set up a Master Control 2 Log for blank C222 order forms. (List C222 order form #, date used, and initials of person who fills out form).
- C222 forms need to be properly filled out and cannot show any cross outs or changes to form or it will have to be **VOIDED**.

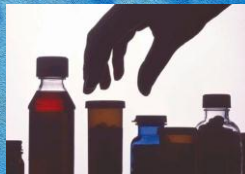
Waste Disposal

- Utilize a Reverse Wholesaler* to remove expired drugs from your center.
- Contact your wholesaler about expired drug returns.
- EPA is asking everyone to not dispose medications into sinks or toilets to prevent entering our water systems.
- Control drug waste should be handled per state and federal requirements.
- Use specialized container or bio-waste containers .
- Use diaper, underpads, kitty litter, or coffee grinds as a lining of container to absorb meds.

www.epa.gov/efc
www.fda.gov/oc
www.cdph.ca.gov/Programs/OPA/Pages/P080001.aspx

Narcotic Record Keeping (Cont.)

- At the end of the day count, always add up your drug administrations and compare to your counts.
- Any discrepancies should be handled immediately and involve all staff handling medications to determine cause. If the cause is not readily found, notify Administration and pharmacist .



Prevent Problems!!!

- Limit access to narcotics.
- One person in charge of narcotic keys and allocation of narcotics will prevent problems.
- Document allocation of narcotics to anesthesia staff and other nursing staff.
- Document return of narcotics from anesthesia and other nursing staff.
- Do not allow staff to leave until all administrations are documented and counts are verified at end of day.



Propofol

- New state regulations changing status to control drug status.
- Need to account for drug on narcotic count log and use narcotic administration forms.
- Keep locked up at all times and limit access .
- Check with your state on status.
- Abuse among healthcare professionals.



Maintenance of Medications

- All medications must be stored and utilized based on **manufacturer guidelines** and /or **federal 797 guidelines**.
- Temperature, humidity, light, drug stability, and possible contamination will affect where and how drugs are used.



Manufacturing Guidelines

- Manufacturers will determine the best stability of a drug with regard to temperature, humidity, and light.
- Expiration dates are determined following manufacturer guidelines for proper storage.
- If a drug is not stored under manufacturer guidelines, the expiration date on the drug cannot be utilized in determining when to discard the drug.
- Manufacturers may not determine stability of sterile drug after it is opened.

797 Guidelines

- 797 Guidelines were established in 2004 for proper use of Compounded Sterile products.
- 797 sets standards to reduce the chance for contamination and reduce the spread of infection.
- 797 Guidelines are utilized because manufacturers do not routinely research stability of drugs past 28 days after opening.
- www.ashp.org/s_ashp/docs/files/discguide797-2008.pdf reference or online order at www.usp.org/products/797Guidebook/
- [ASHP/discguide797-2008](#)

797 Guidelines

- Involves all sterile manufactured products.
- Involves all sterile injectables.
- Sets standards for use of single dose and multidose vials.
- Single dose vials must be used within 1 hour of withdrawal from vial.
- Multidose vials must be used within 28 days of needle puncture of vial unless manufacturer documents alternative dating.
- [ASHP/discguide 797-2008](#)

797 Guidelines

- **Immediate Use CSP** (Compounded or manufactured sterile products).
- Does not use ISO 5 Environment (IV Hood).
- Most common use in ambulatory care.
- Must use within **one hour** of preparation.
- Aseptic technique must be used.
- Cannot combine more than three products.
- No more than two entries into a product.
- Discard product if not used within one hour.

797 Guidelines

- CSP microbial contamination risk levels.
- All products in these levels require preparation in an ISO 5 level environment such as an IV Hood/Clean Room or IV Glove Box.
- Low Risk CSPs.
- Medium Risk CSPs.
- High Risk CSPs.

Low Risk CSPs

- Prepared in ISO 5 environment.
- BUD – Beyond Use Date:
 - Product stable for **48 hours** at room temp.
 - Product stable for **14 days** at frig temp.
 - Product stable for **45 days** at freezer temp.
- No more than 3 drugs combined.
- Examples: Propofol repackaged into smaller vials.

Medium Risk CSPs

- Prepared in ISO 5 environment.
- Involves more than 3 drugs.
- Example: parenteral nutrition iv fluids.
- BUD (Beyond Use Date):
 - **48 hours** at room temp.
 - **14 days** at frig temp.
 - **45 days** at freezer temp.

High Risk CSPs

- Prepared in ISO 5 environment.
 - Involves use of **non-sterile** products.
 - Requires sterilization of finished product by autoclave or filtration process.
 - BUD:
 - 48 hours at room temp.
 - 14 days at frig temp.
 - 45 days at freezer temp.
- Example: Hyaluronidase (Wydase)- made from raw materials.

Single Dose Drugs

- Single dose drugs do not contain preservatives.
- Single dose drugs are designed for **one use** and **one patient**.
- Discard drug after one use.
- Single dose drugs are useful when preservatives are prohibited such as in epidural procedures.
- Single dose vials are useful in preventing overdose of medications.
- V solutions are single dose.



Multi Dose Drugs

- Multi Dose drugs have preservative to maintain stability and resist contamination.
- If anyone suspects improper handling such as not utilizing aseptic technique, exposure to other drugs, or possible contamination, discard the medication.
- **Usually** more cost effective.
- Once a multi dose drug is opened, it must be discarded within 28 days if properly handled. (Make sure to date and initial vial when opened).
- Always observe vial for discoloration and/or precipitate.



IV Solutions

- Store in bins with outer wrapper intact off floor.
- If outer wrapper is removed, use within same day.
- IV solutions stored in warmer must be dated and used with 14 days.



Refrigerated Medications

- Manufacturer recommends storage of drug between 36 to 46°F or 2-8°C.
- Once a medication is removed from frig, the stability of the drug has changed. (Cannot use expiration date as a guideline. Follow manufacturer recommendations).
- Succinylcholine is stable for 14 days after removal from frig unopened.
- Zemuron is stable for 60 days after removal from frig unopened.
- If you remove these from frig, add OOF dating to vial.
- If you open vial, use shortest date (OFF or 28 day dating guideline).

Refrigerator Logs

- Check refrigerator and freezer temps daily and record on log.
- Use a thermometer with an alarm to determine if temperature deviates.
- Adjust temperature as needed daily.
- Clean refrigerator and freezer monthly using proper cleaning/disinfectant solution.
- No food allowed in medication frig.

Safe Injection Practices

- Article in the American Journal of Infection Control, December 2010. "Injection practices among clinicians in United States Health Care settings".
- Survey of what clinician awareness of injection safety.
- Shows what clinicians deem acceptable or unacceptable.
- 5446 clinician respondents included.

Am J Infect Control 2010; 38:7

Acceptable Practices

(with Aseptic Technique Included):

- Administration from syringe prepared by someone else (71% clinicians said never).
- Single dose vial used multiple times for same patient (Must use new needle and syringe to prevent contamination). Discard vial at end of procedure (70% clinicians said never).
- Multiple dose vial for more than one patient (Must use aseptic technique and use new needle and syringe each time) - 34% said never.

Am J Infect Control 2010; 38:7

Unacceptable Practices

- Use of a single dose vial for more than one patient (6% of clinicians said it was ok). Example – Sodium Bicarbonate 8.4% 50ml vial has resulted in numerous bacterial and viral infections.
- Reuse syringe for additional doses from same multi-dose vial (15% clinicians said ok).
6.5% saved vial for use on another patient.
52% in Hospital and
48% Non Hospital
28% from anesthesia department.

Am J Infect Control 2010; 38:7



Unacceptable Practices (Cont.)

- Syringes, needles, lancets, and cannulae are single use devices only.
- Never enter multi dose vials with previously used needle or syringe.
- Discard multi dose vials if aseptic technique is under question.
- Use of a bag or bottle of IV solution for medication diluent for more than one patient –IV solutions are single dose only and never reenter bag.

• Am J Infect Control 2010; 38:7

Mistaken Beliefs

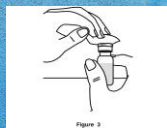
- Contamination is limited to the needle of the syringe-needle unit.
- Syringe is not contaminated if plunger is only pushed and not pulled to aspirate.
- No risk of contamination during IV administration if injection is given into the fluid path of the tubing that does not contain visible blood.



• Am J Infect Control 2010; 38:7

Prevention from Unsafe Practice

- Educate all staff on your safe practices policies.
- Notify administration if you see someone not following safety policies and procedures.
- Make patient care the highest priority in your center!!!



Security of Medications

- All medications should be stored in a lockable cabinet or drawer to prevent access to non authorized personnel.
- Syringes, needles, and Rx Pads should also be kept in a locked cabinet or drawer.
- Narcotics should be kept in a double lock cabinet with box permanently attached to wall.
- Refrigerator should be lockable.
- Emergency carts require a lock seal accessible when necessary in an emergency.



Emergency Cart Drugs

- Emergency carts need to be readily accessible to authorized personnel.
- Review drugs utilized in cart with Anesthesiologist and Pharmacist.
- Check cart **daily** to verify lock seal is not compromised.
- Check drugs and dating monthly or whenever the cart is utilized.
- Replace expired meds and meds used during a code within 24 hours or soon as possible.
- All multi dose drugs should be replaced if opened.
- Make sure to update your emergency log when drugs are replaced.
- Maintain a notebook on the emergency cart with emergency procedures, codes sheets, drug expiration drug log, daily lock seal check, and defibrillator test log.

Chart Review

- Review your follow up calls to determine any patient care concerns.
- Nausea and pain issues should be reviewed to determine any changes in protocol and medication use.



- Improve outcomes and patient care.

Cost Controls



- Utilize your pharmacist in formulary development.
- Many new generic forms are becoming available.
- Avoid ordering large quantities of drugs when only 1 or 2 are needed.
- Review par levels to avoid excess quantities and prevent drugs from going expired before use.
- Reduce duplications of drug therapy.

HEALTH CARE REFORM

How Will It Effect Us?????



- Reduced reimbursements.
- Increased drug costs.
- Unknowns.....

Pharmacist- Your Healthcare Provider

- Utilize your pharmacist for medication information. We are the experts in that field!
- Your pharmacist knows Drug interactions, Drug dosing, Drug Compatibility, and Drug alternatives when you need it.
- Utilize your pharmacist for medication supplies.
- Your pharmacist can provide medications when your center is in need. Ask for emergency meds or other meds if you need small quantities. You don't have to order 25 of an item from a wholesaler when you only need one.
- When you cannot get a particular medication, ask your pharmacist if they can find it.
- Specially Compounded medications such as Hyaluronidase and other discontinued manufactured products may be available.
- Some products can be repackaged into smaller doses to reduce waste.

Pharmacy Consultant Responsibilities in an Ambulatory Setting

- Establish and review Pharmacy Policies and Procedures for the center.
- Regular Audits of center for proper maintenance of Pharmacy Policies and Procedures.
- Make recommendations for Quality Improvements in the center.
- Provide Training and In-Services to staff of center.



Quality of Care

- All decisions made in how we provide services in our centers should be about **“providing the best possible care to our patient.”**
- In managing our medication usage in a proper manner, we can protect ourselves and our centers, work more efficiently, be more cost effective, and provide the **best possible care to our patients.**

Questions???

If you would like to contact me for any additional information:

Chuck Wilson, R.Ph.
(770) 455-1144
dunwoodyrx@gmail.com
