Title: Medication Safety Pearls

ACCREDITATION The Illinois Council of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The intended audience is pharmacy technicians.

This program will provide 2.5 contact hours of patient safety continuing pharmacy education credit for pharmacy technicians. ACPE Universal Activity Number: 0121-0000-15-057-H05-T | Type of Activity: Knowledge-based. Release Date: 12/04/15 | Expiration Date: 12/31/17.

Instructions: Please download all handouts, including the Post Test, for the bonus CPE and refer to them while listening to the audio recording and viewing the slides to make notes. Once you have completed listening to all recordings, you may complete the post-test and evaluation as usual.

Recording Subtitles

Part 1

Technicians: Keeping Pharmacy Safe

Faculty: Arpit Mehta, PharmD, MPH
Pharmacy Operations Manager
HSHS St. John’s Hospital (at time of presentation)

Part 2

Keeping Kids Safe: Quality and Safety in the Pediatric Pharmacy

Faculty: Daniel E. Hickman, CPhT
Lead Pharmacy Technician
OSF St. Francis Medical Center
Children’s Hospital of Illinois

Part 3

Paralyzing Danger: Safety Strategies for Neuromuscular Blocking Agents

Faculty: Peggy S. Bickham, PharmD
Assistant Director
Specialty and Support Services
University of Illinois Hospital

(Please note, the recording for Part 3 is missing the first 4 introductory slides – please refer to the PDF handout to review those slides.)
Pharmacy Tech Topics Bonus CPE Instructions and Guide

Part 4

Danger, Will Robinson! Overview of USP Chapter <800>

Faculty: Patricia C. Kienle, RPh, MPA, FASHP
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions

Learning Objectives for pharmacy technicians

I. Identify the role of pharmacy technicians in ensuring safe medication practices in the pharmacy.

II. Explain quality measures and safety practices used to help reduce medication errors in the Pediatric Pharmacy.

III. List neuromuscular blocking agents (NMBs) that are commonly used in hospitals.

IV. Describe at least five error prevention strategies for preventing errors involving neuromuscular blocking agents (NMBs).

V. List the three categories of hazardous drugs (HDs).

VI. List the types of personal protective equipment (PPE) that need to be used with hazardous drugs (HDs).
Post Test

Technicians: Keeping Pharmacy Safe – recording

1. According to the IOM report, which of the following statements is TRUE?
   a. 98,000 people are killed from unpreventable medical errors
   b. One person dies every hour from a medication error in the US
   c. The estimated total cost of medication errors is $1.5 billion
   d. Approximately 500,000 preventable adverse drug events occur every year

2. Which of the following models is used to explain the concept of barriers in preventing medication errors from occurring?
   a. Tie Model
   b. Swiss Cheese Model
   c. Button Model
   d. Cheddar Cheese Model

3. The Pharmacy Practice Model Initiative (PPMI) promotes the following related to technicians EXCEPT:
   a. Complete standardized training, certification and licensure
   b. Increase the role of the technician in drug distribution
   c. Require that technicians counsel patients about over-the-counter medication use
   d. Expand technician roles into more non-traditional, advanced positions

4. One error reduction strategy is to question if you have to open more than how many vials/ampules when preparing an intravenous bag for an adult patient?
   a. 1
   b. 2
   c. 3
   d. 5

Keeping Kids Safe: Quality and Safety in the Pediatric Pharmacy - recording

5. What kind of quality measures are used in the Children’s Hospital of Illinois Pharmacy?
   a. Missed medication scorecard
   b. Data from the pediatric pharmacy medication safety committee
   c. Taste testing of flavored medication
   d. A and B are correct

6. The role of the Safety Coach is to:
   a. Improve individual and team performance.
   b. Recognize good behaviors
   c. Correct unsafe, unproductive behaviors
   d. All of the above are correct
7. A technician can help to improve safety by doing which of the following EXCEPT?
   a. Create work-arounds
   b. Tell someone if you see something that is “an accident waiting to happen”
   c. Be aware of unsafe practices is the first step to eliminating them
   d. Encourage all employees to be aware of unsafe practices

8. A safe culture can be established through trust by:
   a. Discussing safety concerns
   b. Taking non-punitive actions on safety issues
   c. Creating action items on identified issues
   d. All of the above

Paralyzing Danger: Safety Strategies for Neuromuscular Blocking Agents – recording

9. Which of the following drug groups are all neuromuscular blocking agents (NMBs)?
   a. succinylcholine, rocuronium, Narcan
   b. Peptavlon, mivacurium, acetylcholine
   c. rocuronium, Nimbex, succinylcholine
   d. atracurium, vecuronium, cyclobenzaprine

10. Which of the following error prevention strategies is recommended by ISMP to reduce the risk of error with NMBs?
    a. Segregate all products in specially labeled containers or bins wherever they are stored
    b. Require bedside attendance during initial administration
    c. Implement IV workflow technology utilizing barcode scanning of all ingredients used in sterile compounding
    d. All of the above

11. Which of the following technologies has the potential to eliminate wrong-ingredient errors in pharmacy sterile compounding if used properly?
    a. BCMA (bar code medication administration)
    b. Remote pharmacist verification of compounded sterile products utilizing cameras in the laminar airflow workstation (hood)
    c. IV workflow technology utilizing barcode scan verification only when chemotherapy and high alert drugs are compounded
    d. IV workflow technology utilizing barcode scan verification of all ingredients used in all sterile compounding

12. What is the mechanism of action of NMBs?
    a. An antagonist of acetylcholine
    b. An agonist of acetylcholine
    c. An antagonist of norepinephrine
    d. An agonist of norepinephrine

Page 4 of 6
13. Which of the following is TRUE regarding NMBs?
   a. They result in depression of the central nervous system (CNS)
   b. They cause muscle paralysis only
   c. They reduce pain
   d. They do not require intubation first

**Danger, Will Robinson! Overview of USP Chapter <800> - recording**

14. The purpose of USP 800 is to promote:
   a. Patient safety
   b. Worker safety
   c. Environmental protection
   d. All of the above

15. What gloves are worn to prepare hazardous drugs?
   a. Same as for non-hazardous compounding
   b. One pair of chemo gloves
   c. Two pairs of chemo gloves
   d. Compounder can decide which to wear

16. Pharmacy mixes IV chemo for the health-system’s inpatients and attached oncology clinic. Vials of antineoplastic HDs may be stored:
   a. Intermingled with regular stock since the vial is a final dosage form
   b. Intermingled with regular stock since the health-system does not identify it as a HD
   c. In the positive pressure anteroom
   d. In the negative pressure buffer room

17. HDs are sorted into which three groups?
   a. Oral antineoplastic, parenteral antineoplastic, reproductive hazards only
   b. Antineoplastic, non-antineoplastic, reproductive hazards only
   c. Antineoplastic, injectable reproductive hazards, other
   d. Antineoplastics, other oral HDs, other injectable HDs

18. Which of the following documents is the basis for the HDs identified in USP <800>?
   a. ASHP Drug Information
   b. EPA list of hazardous materials
   c. NIOSH list of hazardous drugs
   d. The Joint Commission Medication Management standards

19. A supplier follows the shipping recommendations in <800>. A tote with a HD indicator is received from the supplier. Can the tote be opened in the general pharmacy area?
   a. Yes, because it will have a sealed impervious wrapper around the HDs in the tote
   b. Yes, because all HDs may be unwrapped as long as the outside packaging of the vial or box is not opened
   c. No, because the tote must be taken into the positive pressure anteroom to open it
   d. No, because the tote must be taken into the negative pressure chemo hood to open it
20. What does <800> say about the use of Closed System Drug-Transfer Devices (CSTDs)?
   a. Must be used when compounding and should be used when administering
   b. Should be used when compounding and must be used when administering
   c. Should be used for both compounding and administering
   d. Must be used for both compounding and administering
Technicians – Keeping Pharmacy Safe

Arpit Mehta, Pharm.D., MPH
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arpit.mehta@hshs.org

Objectives

• Define the importance of medication safety in hospitals
• Identify the role of pharmacy technicians in ensuring safe medication practices in the pharmacy

Disclosure

• Arpit has nothing to disclose

To Err is Human

• Institute of Medicine (IOM) report
• 98,000 people are killed each year from a preventable medical error

IOM – Medication Error

• One person dies every hour from a medication error in the US (IOM, 1999)
  – 1.5 million preventable ADEs every year
• Estimated total cost: $8.5 – $17 Billion

Would you fly if you saw this?

CNN breaking news: A new study shows that…

Airlines expect 1-2 jets to crash daily

Over 1000 deaths expected weekly
Patients in US health care system

- Comparing annual deaths due to medical errors to airlines

- 44,000 – 98,000 deaths annually due to medical errors
- Airlines expect 1 – 2 jets to crash daily
- Over 1000 deaths expected weekly

Mortality causes

- Heart 616,067
- Cancer 562,875
- Stroke 135,952
- Lung 127,924
- Accidents 123,706
- Medical Errors ~100,000
- Alzheimer’s 74,632
- Diabetes 71,382

Health Care is Dangerous!

Error – System Failure

- Health care delivery is a system
- A system is a set of integrated components working together towards a goal
- System Failure:
  - Addresses route cause of the error
  - Starting point for redesigning the system and reducing errors

Swiss Cheese Model

- Slices of cheese are defences or safeguards
- Holes are weaknesses
- A potential hazard or “accident”
- Policies & procedures
- Technology, equipment
- Staff & teams
- Organizational structure & culture

Adopted from: www.ahrq.gov

Swiss Cheese Model

- Pharmacist checks the incorrect medication
- Pharmacist verifies an order for an oral medication
- System Failure
- Technician bypass scan & picks incorrect medication from the shelf
- Nurse bypass scan & administers the incorrect medication

Patient receives the incorrect medication

Adopted from: www.ahrq.gov
Swiss Cheese Model

Pharmacist checks the correct medication
Pharmacist verifies an order for an oral medication
Technician scans and picks correct medication from the shelf
Nurse scans at bedside & administers the correct medication
Patient receives the correct medication

Adapted from www.ahrq.org

Medication Distribution Process

Conception
Order Processing
Evaluation
Documentation
Administration
Dispensing

Medication Distribution Process

• Follow the Standard Operating Procedures (SOP)
• Important to use checks and balances of processes or procedures
• Avoid bypassing safe guards
  – Barcode scanning
• Do not work around the processes; rather help improve the processes

HighAlert Medications

• Increased risk of causing significant patient harm when used in error
• Mistakes are not necessarily more common
• Independent double check

High Alert Medications

• T- tPA (Alteplase)
• A- argatroban
• P- PCA (Patient Controlled Analgesia)
• S- Saline, Hypertonic (3% Sodium Chloride)
• C- Chemotherapy
• H- Heparin IV
• I- Insulin
• N- Neuromuscular Blockers
• Detailed list can be found here: http://www.ismp.org/tools/highalertmedications.pdf

Look Alike Sound Alike Medications (LASA)

• Examples:
  – Keppra, keflex, kaletra
  – Glipizide, glyburide
• Some drugs have two brand names
  – Sildenafil → Viagra and Revatio
• Suffixes
  – Wellbutrin SR vs Wellbutrin XL
  – Depakote ER vs Depakote DR
• OTC products
  – Maalox Total Stomach Relief: bismuth subsalicylate, NOT aluminum or magnesium hydroxide
Look Alike Sound Alike Medications (LASA)

What’s in your SALAD bowl??
Sound-Alike/Look-Alike Drugs

<table>
<thead>
<tr>
<th>Prevent Error:</th>
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<tbody>
<tr>
<td>Use bar-code scanning.</td>
</tr>
<tr>
<td>Recognize ICU medications</td>
</tr>
<tr>
<td>Double-check independently high alert items.</td>
</tr>
<tr>
<td>Read size drug and medication as a metric.</td>
</tr>
<tr>
<td>Check parents and brand names of medications.</td>
</tr>
<tr>
<td>Pay attention to when a child is small or 3.</td>
</tr>
<tr>
<td>Infants: Needs 2 liters, when measuring from medication to syringe, when comparing to MAP, ensure volume is correct.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HPHEDrine</th>
<th>ZPINE/Frine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydromorphone</td>
<td>Morphine</td>
</tr>
<tr>
<td>HydroALZIDE</td>
<td>HydroXYLone</td>
</tr>
<tr>
<td>Insulin: Humalog, Humulin, Humulin: Humalog, Humulin</td>
<td></td>
</tr>
<tr>
<td>Amphetaminic: Liquid, Amphetaminic: conventional</td>
<td></td>
</tr>
<tr>
<td>MPH:</td>
<td></td>
</tr>
<tr>
<td>Ox CONTIN</td>
<td>OxCOCOONE immediate release</td>
</tr>
<tr>
<td>Morphine oral liquid, conventional concentrations</td>
<td></td>
</tr>
<tr>
<td>Motorrola, ConMed, ConMed, ConMed, ConMed, ConMed</td>
<td></td>
</tr>
<tr>
<td>Zantac</td>
<td>Ranitidine</td>
</tr>
<tr>
<td>Heparin</td>
<td>Verify concentrations</td>
</tr>
</tbody>
</table>

Error Reduction Strategies

• Rule of Thumb:
  – Need more than 3?
  – NICU: Need more than 1 mL?

• Oral Syringes for oral liquids

• Independent verification

• Standardize
  – Instead of “Workarounds” – help to improve the process

Use of Technology for Medication Dispensing

• Barcode Scanning
• Pharmacy Information Systems
• Robot, Medication Carousel, High Speed Packager, Sterile Product Compounding, Automated Dispensing Cabinets (ADC)

PPMI and Technician Role

• Goal:
  – Develop and disseminate a futuristic practice model that supports the effective use of pharmacists as direct patient care providers

• Major Themes:
  – Move pharmacists closer to the patient
  – Responsibility for safe use of medications and ensuring quality
  – Well-developed technician workforce
  – Wide-spread use of technology

Expanding Role of Technicians within PPMI

• Need for standardized technician training, certification, licensure
• Push for increased role of technicians in drug distribution
• Expanded roles into non-traditional, advanced activities
• Clear recognition of importance of technician role in future practice models
Josie King

Meet Josie King

Assessment Question 1
• According to the IOM report, one person dies every hour from a medication error in the US
  A. True
  B. False

Assessment Question 2
• Which of the following models is used to explain the concept of barriers in preventing medication errors from occurring?
  A. Tie Model
  B. Swiss Cheese Model
  C. Button Model
  D. Cheddar Cheese Model

Assessment Question 3
• The PPMI pushes for increased technician roles in distribution and other non-traditional advanced activities
  A. True
  B. False

Questions?
Keeping Kids Safe: Quality and Safety in the Pediatric Pharmacy

Daniel Hickman CPhT
OSF St. Francis Medical Center,
Children’s Hospital of Illinois

The speaker has no conflicts of interest to disclose in relation to this presentation.

Learning Objectives
1. Explain quality measures used in the Pediatric Pharmacy
2. Discuss safety practices to help reduce medication errors in the Pediatric Pharmacy

As many as 1 in 10 hospitalized children are impacted by a medication error.
Up to 35% of these errors are serious or life threatening.
The goal is to learn from these events and to adopt effective strategies to prevent harmful errors from happening again.

References

Children’s Hospital of Illinois (CHI)
• Established August 2010
• 126 bed hospital
• General Peds, PICU, PIC, NICU
• Pediatric Surgery
• St. Jude affiliate

CHOI Pharmacy
• Opened August 2010
• 16 Pharmacists
• 8 Technicians
• Averages 350 drawn up oral doses daily
• Averages 100 report IV doses daily
**Missing Medication Project**

- Reduce the amount of missing meds in the CHOI Hospital
- Benchmarked at 12.08 missing meds per month
- Working with the Nursing Leaders of the floors to see how Nursing can help reduce missing meds

**What we have changed**

- We have changed the General Peds report times to print twice a day
- DC’ed IV medications are retrieved during the next round of delivery to try and reuse them if possible
- Using the proper redispense reason in EPIC when investigating missing meds
- Investigating the missing med to find them or correct the problem of why they are missing

**Wasted Medication Project**

- Reduce oral medication waste from cart fill to decrease cost and increase efficiency in the pharmacy
- Split General Pediatric cart fill to twice a day
- Getting stop dates on IV’s

**Pediatric Pharmacy Medication Safety Committee**

- PPMSC started in December 2012
- Committee looks at all medication error events, safety issues, and procedures within the Pediatric Pharmacy to increase patient safety
Safety Coach Program

• Improve individual and team performance
• Recognize good behaviors
• Correct unsafe, unproductive behaviors

Safe Culture Through TRUST

• Safe environment to discuss safety concerns
• Non-punitive actions on safety issues
• Issues identified now have action items which allow closure
• Safety coach voice is heard, valued, and responded to

Goals of Observations

• Be the EYES of the unit regarding safety
• Provide ‘real-time’ feedback to co-workers
• Provide an effective feedback loop to increase awareness of proven safety practices
• Identify coaching/affirming opportunities
  – Use of TeamSTEPPS techniques (read back, clarifying questions, effective handoffs)
  – Identify strategy used
  – Highlighting opportunities for improvement
  – Quality of the coaching/affirmation vs. Quantity of Observations

Bottom Line:

• We all need to be aware of unsafe practices
• Being aware of the unsafe practices is the first step to eliminating them
• If you see something that is an “accident waiting to happen,” tell someone
• Investigate “work arounds”

Conclusion

• Medication Errors happen
• Learn from your mistakes
• Make changes from the mistakes that are made

What kind of Quality Measures are used in the CHOI Pharmacy?

A. Missing Medication Scorecard
B. Data from the Pediatric Pharmacy Medication Safety Committee
C. Taste testing of flavored medication
D. A and B
The role of the Safety Coach is?

A. Improve individual and team performance.
B. Recognize good behaviors
C. Correct unsafe, unproductive behaviors
D. All of the above
Paralyzing Danger: Safety Strategies for Neuromuscular Blocking Agents

Peggy Bickham, PharmD
Assistant Director
Hospital Pharmacy Specialty and Support Services
University of Illinois Hospital
Chicago, IL

I have no conflict of interest to declare.

Which one of the following drugs is a neuromuscular blocking agent (NMB)?

A. Cyclobenzaprine
B. Succinylcholine
C. Hydralazine
D. Clozapine
E. Carbamazepine

NMB Prototype: Curare
- Natural curare comes from a woody vine found in South America (Chondodendron tomentosum)
- First used by indigenous South American people as poison for arrow or dart tips
- Animals became paralyzed and died
- Not effective when orally ingested, so meat could be eaten safely

- Described in 1516 by Pietro Martire d’Anghere in his book “De Orbo Novo”
- Spanish soldiers and explorers in Central and South America died when hit by poisoned arrows blown at them by natives
- Described by Sir Walter Raleigh in 1596
- Brought to Europe in 1745 by French explorers (Charles Marie de la Condamine) on scientific expedition to Ecuador
- Extensively studied and experimented with over the next 200 years


How NMBs Work
- Acts at neuromuscular junction (motor endplate)
- Competitive antagonist of acetylcholine (ACh)
- Classified as
  - polarizing (succinylcholine)
  - nondepolarizing (everything else in clinical use today)

Historical Impact on Medicine
- Before NMBs were available, deep levels of anesthesia were required for intra-peritoneal surgeries
  - Caused cardiovascular and respiratory depression
  - High incidence of morbidity and mortality
- NMBs allowed development of “balanced anesthesia”
  - Lower, safer doses of anesthetic agents possible
- NMB as important to advancing the practice of anesthesia as ether, nitrous oxide, endotracheal intubation, and local anesthetics


Clinical Use Today
- Produce skeletal muscle relaxation (including the diaphragm)
  - During surgery of intubated patient
  - During tracheal intubation
  - To facilitate mechanical ventilation of critically ill patients in ICU and decrease O2 requirement
- More rarely: to treat muscle spasms due to tetanus, epilepsy, drug overdose, black widow spider bite
Important FACTS!

- NMBs cause muscle paralysis ONLY!
- CNS is not affected
  - Consciousness and full awareness remain intact
  - Patient still senses pain

Therefore, it is essential to:
- Intubate (artificial ventilation)
- Administer anesthesia
- Administer pain medication

Meet the NMBs!

Ultra-Short-acting
- Duration 4-6 minutes
  - succinylcholine *
Short-acting
- Duration 15-30 minutes
  - mivacurium
Intermediate-acting
- Duration 20-60 minutes
  - vecuronium **
  - cisatracurium
  - atracurium
Long-acting
- Duration 60-100 minutes
  - pancuronium *

Get To Know the NMBs!

...for the safety of our patients!

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Confused Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>succinylcholine</td>
<td>Quelicin, Anectine</td>
<td></td>
</tr>
<tr>
<td>vecuronium</td>
<td>Norcuran</td>
<td>Narcan (naloxone), vancomycin</td>
</tr>
<tr>
<td>rocuronium</td>
<td>Zemuron</td>
<td></td>
</tr>
<tr>
<td>atracurium</td>
<td>Tracrium</td>
<td>Ativan</td>
</tr>
<tr>
<td>cisatracurium</td>
<td>Nimex</td>
<td></td>
</tr>
<tr>
<td>pancuronium</td>
<td>Pavulon</td>
<td>Peptavlon</td>
</tr>
<tr>
<td>mivacurium</td>
<td>Mivacron</td>
<td></td>
</tr>
</tbody>
</table>

Reports of Inadvertent Administration

- Pancuronium was misplaced among heparin flush stock...a nurse inadvertently administered 5ml to a non-intubated patient (recovered after 10 hours on ventilator). 2000
- Verbal order for “Narcan” was misinterpreted by nurse to be ‘Norcuron’, obtained from cabinet and administered to patient, who experienced respiratory and cardiac arrest, was resuscitated, placed on ventilator and sent to ICU. 1998
- ED physician mistakenly entered orders for midazolam and vecuronium for a trauma patient he was intubating into an oncology patient’s record. Another ED nurse relieving for break administered to the patient, not realizing the patient must be intubated. She left the room and the patient arrested, could not be resuscitated. 2005


Inadvertent Administration

- Atracurium was administered subcutaneously instead of hepatitis B vaccine to seven infants. Within 30 minutes all experienced respiratory distress. Five recovered, one sustained permanent injury, one died. Anesthesiologist had stored a vial in the refrigerator for convenience and it was similar in appearance to the vaccine vial. 2002
- ED physician ordered NMB to sedate a combative patient. Nurse administered the drug too soon, before intubation. Patient arrested and suffered permanent anoxic injury.
- ED nurse prepared saline flush syringes each day. Left-over unlabeled vecuronium syringes from a trauma patient were inadvertently mixed in with the saline syringes. One was used to flush the line of a 3 year old child, who became flaccid and developed respiratory arrest. She was quickly intubated and ventilated and recovered. 2005


Predominant Medication Error Event Types Associated with NMB (n=120)

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Number</th>
<th>% of Total Reports (n=154)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong drug</td>
<td>57</td>
<td>37%</td>
</tr>
<tr>
<td>Wrong dose / overdose</td>
<td>25</td>
<td>16.2%</td>
</tr>
<tr>
<td>Prescription / refill delayed</td>
<td>7</td>
<td>4.5%</td>
</tr>
<tr>
<td>Wrong technique</td>
<td>6</td>
<td>3.9%</td>
</tr>
<tr>
<td>Extra dose</td>
<td>6</td>
<td>3.9%</td>
</tr>
<tr>
<td>Other</td>
<td>19</td>
<td>12.3%</td>
</tr>
</tbody>
</table>

Contributing Factors

- Unsafe storage or products
- Look-alike labeling and packaging
- Look-alike drug names
- Unlabeled syringes
- Inadequate knowledge of drug action
- Failure to ensure ventilator support
- Ordering errors

Inattentional Blindness

A type of confirmation bias

- Failure to notice a fully visible but unexpected object because attention was engaged on another task, event, or object.
- The person performing the task fails to see what should have been plainly visible, and later, they cannot explain the lapse.
- Vials and labels look similar to what we expect to see, so we tend to see what we expect.

Error Prevention Strategies

- Limit access
  - Allow floorstock only in OR, ED, critical care units where patients can be properly ventilated and monitored.
- Segregate storage
  - Pharmacy should maintain a distinct sealed box with warnings affixed, in med area or refrigerator.
- Warning labels
  - Affix fluorescent red labels on each vial, syringe, bag, and storage box.

Error Prevention Strategies

- Safeguard storage in the pharmacy
  - Sequester NMB stored in the pharmacy.
  - Affix warming labels to vials.
- Standardize prescribing
  - Establish order sets and alerts to avoid misinterpretation.
  - Include requirement or cross-check for ventilator support and discontinuation after extubation.
  - Do not allow “Resume previous meds” orders.
  - Refer to “paralyzing agents”, not “muscle relaxants”.
  - Do not allow “prn” orders.

Error Prevention Strategies

- Redundancies
  - Consider requiring independent double check before dispensing and administering.
  - Double check against original order.
- Require bedside attendance during initial administration
  - Licensed practitioner with experience in intubation and airway management.

Error Prevention Strategies

- Prompt removal of discontinued products
  - Discard or sequester vials, IV bags, and syringes with NMB for immediate pharmacy pickup after discontinuation/exubation.
- Increase awareness
  - Educate staff about risks.
  - Provide list of generic and brand names for all NMBs available at facility.
In what areas do the errors involving NMBs most usually originate (in order of most-least)?

A. OR  B. ICU  C. ED  D. Pharmacy  E. Pediatrics

In which of the following scenarios might “inattentional blindness” have played a role?

1. Cisatracurium infusion prepared for a ventilated infant. Delivered by accident to adult unit with 3 bags of antibiotics. Nurse verified the first 3 bags of antibiotics, but was interrupted and did not check the 4th (cisatracurium). Label similar in color and so the bag was hung. Patient experienced respiratory arrest and required ventilation for several hours.

2. Pancuronium was misplaced among heparin flush stock...a nurse inadvertently administered 5ml to a non-intubated patient (recovered after 10 hours on ventilator).

3. Anesthesiologist ordered trial supply of mivacurium infusion from a drug rep. Product was delivered to pharmacy, was stocked next to metronidazole. Infusion was in foil wrapper like metronidazole. Tech labeled several bags as metronidazole, pharmacist did not catch, nurse did not catch, 4 patients received mivacurium. All arrested; two recovered, one suffered permanent harm, one died.

Pharmacy Errors

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3. Anesthesiologist ordered trial supply of mivacurium infusion from a drug rep. Product was delivered to pharmacy, was stocked next to metronidazole. Infusion was in foil wrapper like metronidazole. Tech labeled several bags as metronidazole, pharmacist did not catch, nurse did not catch, 4 patients received mivacurium. All arrested; two recovered, one suffered permanent harm, one died.

What Happened?

- Pharmacy received order for fosphenytoin for seizures
- Pharmacy prepared the IV solution, but accidentally added rocuronium instead of fosphenytoin
- The bag was dispensed labeled as fosphenytoin
- After the bag was hung, a code red was announced. The door to the patient room was closed to protect from fire.
- When the nurse re-entered, the patient was Paralyzed

Oregon hospital admits mistake led to patient death

Sisters woman, 65, given paralyzing agent in ER

An Oregon hospital’s fast-out admission that a medication error resulted in a 65-year-old woman’s death this week serves as a reminder of hospitals’ efforts to increase transparency and communication when such incidents occur.

The patient went to the emergency room Monday with anxiety and concerns about the medications she was taking after recent brain surgery at a different hospital. Staff members determined she needed an intravenous anti-seizure medication called fosphenytoin. Instead, she was given the wrong medication, a paralyzing agent called rocuronium, which caused her to stop breathing and go into cardiac arrest, leading to irreversible brain damage. The patient was on life support until Wednesday morning.

Three staff members involved in the patient’s care are on administrative leave, and are receiving counseling through the hospital’s caregiver assistance program. The Chief Clinical Officer declined to say what their jobs are but said they’re “devastated by this.”

What Happened?

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Tragic error with neuromuscular blocker should prompt risk assessment by all hospitals. ISMP Medication Safety Alert, Dec 14, 2014.

www.ismp.org/newsletters/acute/article.aspx?id=97
Reflection:
How could this tragedy have been prevented? Which of the strategies discussed might have made a difference?

ISMP Recommendations
• Limit neuromuscular blockers in formulary
• Segregate or eliminate storage from active pharmacy stock when possible
  – Highly visible storage container
  – Bright warning labels
• Regularly review storage areas to assess potential for mix-ups
• Thoroughly examine the entire pharmacy IV admixture process
  – Review ISMP IV Sterile Compounding Guidelines (www.ismp.org/sc?id=461)
  – Consider implementing IV workflow technologies


Future State (Why Not NOW?)
• IV workflow technologies utilize barcode scanning of products during IV admixture
• Double checks the accuracy of the ingredients of each compounded product (if utilized correctly)
• A number of systems are available on the market
• Potential to eliminate errors due to inattentional blindness

Consider implementing IV workflow technologies!!!

IV workflow systems “that utilize barcode scanning support can assure proper drug selection, but only if the systems are fully integrated with the pharmacy and hospital information systems. Without full integration between the IV workflow technology and the order entry system, errors can still be introduced into the process. Although some hospitals have chosen to limit use of these systems [IV workflow technology] for focused areas like admixture of chemotherapy or high-alert drugs, there’s no telling when someone might accidentally introduce a high-alert drug when preparing other drug classes that wouldn’t ordinarily be scanned. Therefore, to be maximally effective, the system must be utilized for all compounded admixtures.”

What was the first department in the hospital to adopt barcode scanning?
A. The pharmacy  
B. The operating room  
C. Nursing – BCMA  
D. The gift shop

http://jerryfahrni.com/2015/01/a-missed-opportunity-for-safety-why-scanning-a-limited-formulary-in-the-i-v-room-is-a-mistake/ (Paraphrased from blog comment by Ray Vrabel)
Danger, Will Robinson!
Overview of USP Chapter <800>

Patricia C. Kienle, RPh, MPA, FASHP
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions

Disclosure

• Patricia Kienle is an employee and stockholder of Cardinal Health
• She is an elected member of the USP Compounding Expert Committee, but is not speaking as a USP representative
• All conflicts resolved through peer review

Objectives

• Cite the document that defines hazardous drugs (HDs)
• List the three categories of HDs
• Explain the containment strategies related to HDs.
• Identify elements that could be used for an Assessment of Risk
• List the types of PPE that need to be used with HDs

Patti’s Wish

• Identify three things that you can improve the next day you are at work

What’s All the Fuss?

Why <800>?

• To promote patient safety, worker safety, and environmental protection when handling hazardous drugs (HDs)
• Addresses, but is not limited to
  – Receipt
  – Dispensing
  – Storage
  – Administration
  – Compounding
  – Disposal
• Applies to all healthcare personnel who handle HDs
• Applies to all healthcare entities that store, prepare, transport, or administer HDs
What Regulations Exist?

- USP <795>
  Pharmaceutical Compounding – Nonsterile Preparations
- USP <797>
  Pharmaceutical Compounding – Sterile Preparations
- OSHA regulations
- State regulations

Is your site compliant with the hazardous drug part of <797>?
A. Yes
B. Partially
C. No

What are the Upcoming Regulations?

- Proposed USP <800>
  – Federally-enforceable regulation
- Applies to both sterile and nonsterile compounding
- State regulations
  – Enforcement

HDs in Your Facility

- Receiving
- Storing
- Compounding
- Administering

Hazardous Drug Definition

- Carcinogens
- Genotoxins
- Teratogens
- Reproductive toxins
- Organ toxicity at low doses
- Structure or toxicity similar to drugs classified as hazardous

NIOSH 2014 List of Hazardous Drugs

NIOSH 2014
List of Hazardous Drugs

• Antineoplastic
• Non-antineoplastic
• Reproductive hazard only

• Drugs that are hazardous to personnel
  – Different from EPA-hazardous, which are hazardous to the environment

Show Me the Science

www.cdc.gov/niosh/topics/hazdrug/

Your HD List

• Review the NIOSH list
• Identify the meds you stock
• Determine the containment strategies

Your Handling Options

Treat all HDs the same
  • Use all the containment strategies in <800>

Assess risk and stratify
  • Identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or are not API

Assessment of Risk

• Drug
• Dosage form
• Risk of exposure
• Packaging
• Manipulation
• Documentation of alternative containment strategies and/or work practices
• Review annually and document

Can you identify HD packages when they are delivered?

A. Yes
B. No
HD Receipt

• Your supplier should mark containers
• Your receiving personnel need to be inserviced to assess the integrity of the container
• You must provide
  – Chemo gloves
  – Chemo spill kit

HD Storage

• Shall be stored separately from other inventory
• Shall be in
  – Negative pressure room
  – Vented to the outside
  – At least 12 air changes per hour
• Take the plastic-wrapped package into the negative pressure storage area to unwrap it

Where are your HDs mixed?

A. BSC or CACI in negative pressure cleanroom
B. BSC or CACI in positive pressure cleanroom
C. BSC or CACI in normal pressure room
D. Outside of BSC or CACI

HD Preparation

• Shall be in physically separate space
  – Negative pressure room
  – Vented to the outside
  – Appropriate number of air changes per hour

Engineering Controls

• Primary
  – Biological Safety Cabinet (BSC)
  – Compounding Aseptic Containment Isolator (CACI)
• Secondary
  – The room in which the PEC is placed
• Supplemental
  – Closed system drug-transfer devices

Two Tenets of Safety

• Containment
• Dilution
Why Negative Pressure?

**PEC**
Positive Pressure

**CPEC**
Negative Pressure

Nonsterile Compounding

<table>
<thead>
<tr>
<th>C-PEC</th>
<th>C-SEC Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Externally vented (preferred) or redundant HEPA-filtered in series</td>
<td>• 12 ACPH</td>
</tr>
<tr>
<td>• Examples: CVE, Class I or II BSC, CACI</td>
<td>• Externally vented</td>
</tr>
<tr>
<td></td>
<td>• Negative pressure between 0.01 and 0.03&quot; w.c.</td>
</tr>
</tbody>
</table>

CPE or BSC
Negative Pressure
12 ACPH

Sterile Compounding

**Configuration**

<table>
<thead>
<tr>
<th>ISO Class 7 Buffer Room</th>
<th>C-PEC</th>
<th>C-SEC</th>
<th>Maximum BUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Externally Ventied</td>
<td>• Externally Ventied</td>
<td>• 30 ACPH</td>
<td>As described in &lt;797&gt;</td>
</tr>
<tr>
<td>• Examples: Class II BSC or CACI</td>
<td>• Externally Ventied</td>
<td>• Negative pressure between 0.01 and 0.03&quot; w.c.</td>
<td></td>
</tr>
</tbody>
</table>

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Containment Segregated Compounding Area

- Not currently allowed in <797>
- Not acceptable for high-risk

CSTDs

- Closed system drug-transfer devices
- Mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system

Administering HDs

- Requires Supplemental Engineering Controls
- Why?
CSTD Resources

USP <797> and <800> Requirements

- Didactic
- Overseen by experts
- Monitored
- Media fill test
  - Initial
  - Requalifying
- Gloved fingertip test
  - Initial
  - Requalifying
- Surface sampling

Training Materials Available

- Policies and procedures
- Device manufacturers
- NIOSH
- ASHP
- Critical Point

What gloves are worn to prepare hazardous drugs?

A. Same as for non-hazardous compounding
B. One pair of chemo gloves
C. Two pairs of chemo gloves
D. Compounder can decide which to wear

PPE Requirements in <800>

- Gloves
- Gowns
- Hair covers
- Shoe covers
- Face protection
- Respirators

Gloves for Handling HDs

- Chemo gloves tested to ASTM D6978
- Non-powdered
- Two pairs
- Outer gloves must be sterile when compounding sterile preparations
Gowns for Handling HDs

- Tested and shown to resist permeability by HDs
- Disposable
- Polyethylene-coated polypropylene or other laminate
- Close in back (no open front)
- Long-sleeved
- Elastic or knit closed cuffs
- No seams or closures that could allow HDs to pass through

Other Garb Issues

- Eye protection
  - BSC/CACI provide eye protection
  - Use goggles when working outside a PEC
- Respirators
  - Use when outside a PEC
- All garb is required when using a CACI

Cleaning Process

- Deactivation and decontamination
- Use of detergent
- Disinfecting surfaces

Chemo hoods are cleaned with ...

A. Sterile alcohol
B. Germicidal detergent
C. Bleach
D. Commercial product for hazardous drugs

PPPMag – January 2015

Are Gloves and Gowns Safe for Handling Chemotherapy?

PPPMag Articles

September 2013 October 2014
Environmental Monitoring

- USP <797> requirements
- Wipe samples

How close to <800> compliant is your site?

A. Less than half-way there
B. Between 50-90%
C. Close to compliant

Your Action Plan