“Strategies to Reduce Dispensing Errors in Hospitals Using Automated Dispensing Cabinets (ADCs)”

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Disclosure Statements

“The presenter wishes to disclose that he was employed by Cardinal Health from 1998 to 2006 and that he has a 401K Savings Plan from this employment. This information was disclosed to the New York State Commission on Public Integrity on May 12, 2009.”


“The presenter has established the right to use the service mark for ‘Safe-T-Pack’ in commerce and has registered the mark with the U.S. Patent and Trademark Office”
Goals of this Presentation

- To review the magnitude of the ADEs in the US
- To highlight the benefits and limitations of ADCs
- To focus on one possible cause of sentinel events
- To review the root cause analysis of heparin overdoses that caused sentinel events in babies
- To describe a study underway at Upstate University Hospital to reduce filling and dispensing errors associated with the ADC batch-fill process
- To consider other strategies that may help to reduce ADEs in hospital pharmacies
The Problem

- Estimated 380,000 to 450,000 preventable ADEs occurring in hospitals annually (2)
- Most of the fatal medication errors (46.7%) occur in hospitals (2)
- High volumes of medication dispensed in a busy hospital pharmacy department may contribute to 100 or more undetected errors a day (4)

Prevention of Medication Errors Using Automation and Technology

- Computerized Prescriber Order Entry (CPOE)
- Bar-code enabled point-of-care (BPOC)
- “Smart” infusion pumps
- Automated dispensing systems (ADCs)
- “Robust” pharmacy order entry system

Automated Dispensing Cabinet Benefits

- ADCs offer sub-inventories of medications which are readily available.
- The batch-fill process is completed once or twice a day in condensed period of time.
- Electronic audit trails are available to identify who was involved in errors or discrepancies.
Automated Dispensing Cabinets (ADCs)

“More than 75% of all hospitals in the United States use ADCs to support a decentralized drug distribution model.”

How safe are they?
Automated Dispensing Systems Concerns

- The batch fill process does not support bar-code verification of more than one dose or label during the dispensing process.
- Multiple doses of medication are usually checked by the bag full using packaging size and color as a differentiator.
- ADCs do not allow bar-code verification of more than one dose (or label) during the replenishment process.
- ADC calculate reorder quantities by subtracting quantity on hand from a pre-determined par level for each drug resulting in a larger number of loose doses.
Safer ADC Validation Process Needed?

- ISMP recommendation - “ADCs must include the ability to use bar-coding technology for the restocking process to prevent medication errors”

- In a study of more than 250,000 doses of medication, Poon EG, Cina, JL, Churchill W, et al concluded that “each dose should be bar-code scanned to insure accuracy”

1 “Medication dispensing errors and potential adverse drug events before and after implementation bar code technology in the pharmacy” Ann Inter Med 2006; 145:426-34.
Bedside Scanning

- Although bar-code scanning at the point-of-care (BPOC) will ultimately reduce the potential for medication errors, the large investment of time and money during difficult economic times will delay widespread adoption of this improvement.
Impact of Current Economic Challenges


- Hospital cutbacks due to the economy - 90%
- Cuts in administrative expenses - 80%
- Reduction in staff - 48%
- Decreased services - 22%

AHA Survey; 1078 responses received; March 27, 2009
Impact of Current Economic Challenges


- Reduction in Drug Expenditures – 66%
- Reduced Budgets – 37%
- Reduction in pharmacy services – 20%
- Reduction in hours of pharmacy services – 7%

David Chen, RPh, MBA, Director, Pharmacy Practice Sections; 541 responses; March 26, 2009
Impact of Current Economic Challenges

American Society of Health-System Pharmacists – "Impact of the Current Economy on Pharmacy Services in Hospitals and Health Systems (2009)"

Diminished Resources have forced cancellation, reduction, or delay in the implementation of pharmacy improvements:

- Bar code medication and administration - 26%
- Electronic med and administration records - 16%
- Computerized provider order entry – 24%
- Facility improvement to comply with USP 797- 29%

David Chen, RPh, MBA, Director, Pharmacy Practice Sections; 541 responses; March 26, 2009
The Swiss Cheese Model:

Dr. Joseph Reason established that adverse events occur when multiple safety-checks fail in a process.
Root-Cause Analysis of Fatal Heparin Error

- Infant dies after receiving 10x overdose of heparin
- Nurse placed heparin 10,000 unit / ml vial in
- ADC had two strengths of heparin in the inventory location
- Nurse labeled drug label before administering heparin
Med Event -> Risk Assessment -> Innovation

- Heparin overdoses in infants have motivated health-systems pharmacists to develop safer processes

- Decentralized pharmacy distribution systems using automated dispensing cabinets (ADCs) introduce new challenges in maintaining safe dispensing practices

- Can we improve filling and dispensing accuracy and improve pharmacy efficiency and productivity by utilizing “controlled packaging”? 
Study Details

- Study the number of dispensing errors that occur in the pharmacy department during the ADC batch fill and verification process comparing two different packaging systems (conditions).

- Formal power analysis using Fisher’s exact test requires $\geq 11,000$ doses of each condition.

- Study will target “SVP” drugs that are in vials $\leq 10$mls.
Conditions Studied

- Measure the different error rates between two packaging systems (conditions)
  - Condition 1 – “Zip-lock Pack” (open packaging system)
  - Condition 2 – “Safe-T-Pack®” (controlled packaging system)
Controlled Packaging Definition

- Packaging takes place in controlled environment
- Insures contents are consistent with labeling
- Package labeling includes drug name, strength, concentration, vial size, expiration date, quantity, and a bar-code product identifier
- Packaging prepared by an FDA licensed facility using current Good Manufacturing Practices (cGMP)
Controlled Packaging for Study Purposes

- **Safe-T-Pack® Controlled Package** - a multiple dose module (i.e. a bag of 5 vials) repackaged by an FDA licensed packager into a sealed plastic bag that contains descriptive labeling and a barcode.

- **Manufacturer’s Controlled Package** - multiple dose module (i.e. a tray of 25 vials) dispensed in the original sealed container.
Zip-lock Packaging
Safe-T-Pack® Packaging
Manufacturer’s Controlled Packaging
Study Goals/Objectives

- Determine if “Safe-T-Pack” reduces errors
- Identify best SVPs to package in Safe-T-Pack®
- Make recommendations for label formats
- Measure workflow and productivity metrics
- Estimate value (cost/benefit ratio)
Why Small Volume Parenterals (SVPs)

- Pharmacokinetic and pharmacodynamic properties – difficult to reverse ADEs
- Many “high-alert” drugs are SVPs
- SVP drugs are often included in the batch fill process
- SVP are often purchased and/or stored as single dose vials
- Small print size on vials is difficult to read
SVP Selection Process

- Omnicell's 30 Day Batch
- Study Team's Trial Drug
- Omnicell's Daily Batch Fill Report

SVP Short List

- High-alert drugs
- LASA drugs
- Large quantity

Targeted SVP List
Medication Review Process

- Review each dose of random sample for accuracy (Pharmacist Reviewer)
- Filling & dispensing errors targeted:
  - Wrong medication
  - Wrong strength or dose
  - Wrong formulation
  - Expired drug product
1. Med containers are labeled whenever meds are prepared but not immediately administered
2. Info on med labels is displayed in a standard format in accordance with law/regulations and standards of practice
3. Labels include med name, strength and amount
4. Labels include expiration date when not used in 24 hours
Safe-T-Pack® Design Process

- Informal test determined approximate font size used on SVP vials

- Design for Patient Safety by National Patient Safety Agency (UK) & Royal College of Art

Heparin 10,000 units/mL (Arial 16)
Heparin 10,000 units/mL (Arial 13)
Heparin 10,000 units/mL (Arial 12)
Heparin 10,000 units/mL (Arial 6)
Heparin 10,000 units/mL (Arial 5)
Heparin 10,000 units/mL (Arial 4)
Safe-T-Pack® Design

- Large font size – 13 to 16 point
- Spacing for legibility
- Room for carousel label
- Bar code symbology depicting UUH’s Med Id number
- Clear plastic on one side to visualize contents
Safe-T-Pack® Inventory Management

- Safe-T-Pack® inventory counted daily
- Safe-T-Pack® supplies ordered weekly
- Safe-T-Pack® orders received, tagged, stocked like regular orders
Safe-T-Pack® Training for Pharmacy Technicians

- **Medication order filling:**
  - Orders ≤ 9 vials -> fill exact # of vials ordered
  - Orders ≥ 10 vials -> use “Rule of Five” (round down to nearest multiple of five (5) & use controlled packaging only)

- **ADC loading:**
  - Remove vials from Safe-T-Pack® before filling ADC
Number of Vials Reviewed in Each Conditions

<table>
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<tr>
<th>Months</th>
<th>Total # Vials</th>
<th>Vials in Ziploc</th>
<th>Vials in Safe-T-Pack</th>
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<tr>
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<td>2300</td>
<td>1500</td>
<td>800</td>
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<td>Sep-09</td>
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<td># of Vials Reviewed</td>
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Total Vials Reviewed: 26,796
Conclusion Other “Food” for Thought

- Can not reveal results of the Study until after Pharmacy Safety Forum in Albany on June 9th
- Further analysis required to determine possible benefits associated with expanding the controlled packaging strategy to solid oral drugs
- Study the feasibility of using “Universal Medication ID” (UMID) numbers
- Lobby manufacturers of ADCs to allow automatic rounding when batch orders are processed
Questions?