Turning a Personal Tragedy into a Dedication: International Research on Designing a Peelable and Point-of-Use Labeling System for Injectable Medicines

Presented By: Miriam Klein, B.S., Pharm.D.
Medication Safety Fellow
Kingsbrook Jewish Medical Center (KJMC)
Turning A Personal Tragedy Into A Passion For Avoiding Medication Errors

EVENT
- Infant seen by newly licensed woman pediatrician
- Regular pediatrician on vacation
- Treated for high fever with antibiotic

COMMENT
- Regular Pediatrician reviewed medication dose
- Told Parent (Father): “You should have gotten the dose, not the baby”

CONJECTURE
- Probable drug was erythromycin
- One prominent side effect:
  - Ototoxicity (hearing loss)

AHFS Drug Information 2007
- “Ototoxicity consisting of bilateral hearing loss, in at least one case irreversible, has been reported rarely with erythromycin lactobionate, stearate, or ethylsuccinate”
- “Ototoxicity has generally occurred in patients with impaired renal or hepatic function and/or in those who were receiving high dosages of erythromycin (e.g., 4g/day or more)”

DEDICATION...
- Life-long disability impetus fuels my passions for helping others to avoid such errors

Disclosure: Conference travel and accommodation sponsored by Schreiner MediPharm (Label Producers) which enables me to continue my research in designing a safer labeling system for injectable medicines.
International Research

- Working with various pharmaceutical manufacturers to design a “peelable” and/or “point of use” labels for high risk injectable medicines in the United Kingdom and Canada
  - Reasons for research on labels:
    - Many errors reported globally on high risk injectable medicines
- Finalizing label designs will be approved by health care professionals
- In the UK a pilot study is being planned to measure, in a secondary care setting, the potential benefits of a transferable label both in risk reduction terms and also in economic terms
Global Background Medication Errors

- Focus on errors from injectable medicines
  - Reports on medication errors involving injectable medications published
  - Various alerts on injectable medications issued
  - Error prone stages of medication errors involving injectables
  - High-alert medications errors reported
  - Unlabeled syringes common in health care facilities
  - Current label designs for syringes unsuitable
United Kingdom/USA: Injectable Medication Errors

- In the United Kingdom (UK), National Patient Safety Agency Alert #20: *Promoting Safer Use of Injectable Medicines* (March 2007)

- In the US, the Institute for Safe Medication Practice (ISMP) issue in one of its Medication Safety Alert about unlabeled syringes
  - “...significant risk associated with preparations of injectable products in clinical areas”

- U.S. PHARMACOEPIA MEDMARX ® Data Reports
Risks from Injectable Medications

- United Kingdom’s National Patient Safety Agency (NPSA) received 800 incident reports a month regarding injectable medicines from January 2005 through June 2006

- Analysis of Deaths & Severe Harm:
  - From NPSA’s report of injectable medicines incidents regarding degree of harm from January 2005 through June 2006:
    - 25 incidents of death
    - 28 of serious harm

Top 3 Error Prone Stages of Medication Process

<table>
<thead>
<tr>
<th>Stage of Medication Process</th>
<th>Number</th>
<th>Per cent of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration (which may include preparation)</td>
<td>10,394</td>
<td>73.1</td>
</tr>
<tr>
<td>Prescribing</td>
<td>1,566</td>
<td>11.0</td>
</tr>
<tr>
<td>Preparation of medicines in all locations/dispensing in a pharmacy</td>
<td>1,403</td>
<td>9.9</td>
</tr>
</tbody>
</table>
7th MEDMARX® Data Report in March 2007


Focusing on:
- Outpatient Surgery
- Preoperative Holding Area
- Operating Room
- Postanesthesia Care Unit

Snapshots of Reported Errors:
- Outpatient Surgery Department: 2,437 Errors (3.3% of errors resulting in harm)
- Preoperative Holding Area: Total 2.8% of errors resulting in harm
- Operating Room: 3,773 Errors (7.3% of errors resulting in harm)
- Post Anesthesia Care Unit: 3,260 Errors (5.8% of errors resulting in harm)
## Types of Errors in Care Unit Areas

### Percentage (%) of errors in each care unit areas

<table>
<thead>
<tr>
<th>Phases of Errors</th>
<th>Outpatient</th>
<th>Pre-Op</th>
<th>OR</th>
<th>PACU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing</td>
<td>29.6</td>
<td>11.9</td>
<td>20.1</td>
<td>28.4</td>
</tr>
<tr>
<td>Transcribing/Documenting</td>
<td>11.4</td>
<td>21.9</td>
<td>10.1</td>
<td>12.2</td>
</tr>
<tr>
<td>Dispensing</td>
<td>8.3</td>
<td>7.2</td>
<td>11.6</td>
<td>7.3</td>
</tr>
<tr>
<td>Administering</td>
<td>49.8</td>
<td>57.5</td>
<td>56.3</td>
<td>50.3</td>
</tr>
<tr>
<td>Monitoring</td>
<td>0.9</td>
<td>1.5</td>
<td>2.0</td>
<td>1.8</td>
</tr>
</tbody>
</table>

### Mislabeled Syringe: Neuromuscular Blocker

“An anesthesia provider was preparing induction medications for an upcoming case. After removing vecuronium from the original container, the provider mislabeled the syringe as succinylcholine. As a result of the error, the patient remained intubated with a respirator for an additional 2 hours”

USP MEDMARX Data Report: A Chartbook of Medication Error Findings From The Perioperative Settings from 1998 - 2005
November 15, 2007 Volume 12 Issue 23:
“Errors with injectable medications:
Unlabeled syringes are surprisingly common!”

November 29, 2007 Volume 12 Issue 24:
“Another heparin error:
Learning from mistakes so we don’t repeat them”

Why does this happen so often?
Why don’t we have a user friendly labeling system?
Difficulties Labeling of Syringes

- Injectable drugs withdrawn from vials into unlabeled syringes
- Often unlabeled syringes administered to patients
- Problematic Areas
  - Ambulatory surgery
  - Operating Room
  - Critical care
  - Emergency Department
Anesthetic Color Codes Labels for Syringes

- **International Color Coding Syringe Labeling System**
  - Color coded by drug category anesthesia labels

- **Would this reduce the risk of the wrong label being applied to a syringe?**
  - Still requires anesthesiologist to ensure that the drug that they draw up into the syringe is the correct one for that colour

DISCOVERY: “a potential safety hazard”

What potential errors occur when utilizing this labeling system?
- wrong labels
- labels cover gradation lines
- labels stick to gloves
- run out of labels on reels
PROBLEMATIC LABELS...

Unattached (Packed) Labels

Manufacturer Hospira: Brand Name Quelicin; Generic Name Succinylcholine

Manufacturer Bedford: Generic Name Atracurium Besylate Injection USP

Further Discovery:
- labels hard to remove
- labels does not get stored with drug in same place
- labels cover syringe gradation marks
Manufacturer Organon:  
Brand Name Zemuron  
Generic Name Rocuronium  
Finding: One removable label for a multi-dose vial
Enhanced Labeling System...in Germany

Removable Labels

- Some injectable medication ampoules have transferable labels on a voluntary basis
- NOT MANDATED

Manufacturer Roche (Germany):
Brand name: Dormicum
Generic name: Midazolam

Manufacturer Ratiopharm:
Generic name: Sufentanil

Further Discovery:
incomplete with regulatory labeling requirements
Current Injectable Medicines Labeling System

Principle to apply in research for High-Alert Injectable Medicines Labeling System:
- Peelable Label
- Point-of-Use Label

Manufacturer Merck:
Brand Name Gardasil
Generic Name Papillomavirus Recombinant Vaccine (HPV)

“Only for intravenous injection after reconstitution. Fatal when given intrathecally.”
June 2007 Meeting:

- Referred to NPSA Alert #20: Promoting Safer Use of Injectable Medicines
  - Demonstrated impracticality of one of their recommendations:
    “Consider providing pre-printed...stickers that makes the...administering of high-risk product clearer.”
  - Showed preprinted stickers manufactured by various US pharmaceutical firms
  - Presented first design of “peelable” label
Purchasing for safety:
• Labelling & packaging
• MHRA standards
• NPSA guidance
Example taken from Manufacturer Bedford Atracurium Label. Designed the first model concept of preprinted transferable label with Joint Commission requirements and USP <797> regulations.

- **Transferable Label**
- **High-Alert Medication symbol on pre-printed label transferred to syringe**
- **Date Expired, Time Expired and initials of person preparing labeled syringe**
Implementing reconstitution information at MOU on second label behind cover & before “peelable” label to remove for attachment to unlabeled syringe
Innovative Labeling System: Double-Check System

- Provides a possible solution to improve patient safety
  - Risk-reduction strategies

- 7Rs in Administration Safety:
  - Right Medication
  - Right Dose
  - Right Person
  - Right Route
  - Right Dosage Form
  - Right Time
  - Right Documentation
"PEELABLE" LABEL SURVEY

Peelable label on Syringe

Peelable label for IV Bag

"PEELABLE" LABELED SYRINGE

"PEELABLE" LABEL ON IV BAG

FINAL DOCUMENTATION
“POINT OF USE” LABEL
Two different surveys given on Sept 10, 2008 at Patient Safety Seminar:

- “Peelable” labels
- “Point of use” labels

Peelable Labels Surveys:
- 30 clinicians
  - 15 Anaesthetists, 6 Nurses, 6 Pharmacists, 1 Theatre Practitioner, 1 Tech, & 1 Trainee ITU and Anaesthetic

Point of Use Labels Surveys
- 30 clinicians
  - 15 Anaesthetists, 7 Nurses, 6 Pharmacists, 1 Tech & 1 Trainee ITU and Anaesthetic
Questions on Peelable Surveys

1. Which of the following describes your profession?
   - [ ] ANAESTHETIST
   - [ ] THEATRE PRACTITIONER
   - [ ] MD
   - [ ] RN
   - [ ] RPh
   - [ ] Other

2. How concerned are you complying with the labeling requirements from NPSA Alert #20?
   - Not At All Concerned
   - Somewhat Concerned
   - Extremely Concerned

3. Are you interested in having a preprinted drug's name and concentration on a peelable label, with room to document, that can be easily removed from the injectable medicine ampoule/vial and placed on the syringe or IV bag?
   - Not At All Interested
   - Somewhat Interested
   - Extremely Interested

4. Rank your opinions on the following statements in order of importance.
   - 1 = Not important; 2 = somewhat important; 3 = extremely important
   - A Support peelable label on an ampoule/vial containing preprinted drug’s name, concentration and room to document
   - B Eliminates errors associated with unlabeled syringes or IV bags
   - C Use colour coded standardized labels from reel for anaesthetic drug syringes
   - D Fulfils regulatory requirements on labeling IV syringes or IV bags
   - E Colour coded standardization peelable labels from ampoules/vials for anaesthetic drug syringes

5. Did you ever have the following situation:
   - a. Mislabling of syringe? [ ] Yes [ ] No

6. Would you consider purchasing and using injectable vials/ampoules with peelable label in it?
   - [ ] Yes
   - [ ] Not interested
   - [ ] No

7. Please indicate your feedback on having a peelable label on an injectable ampoule/vial containing preprinted drug’s name, concentration to apply to an IV syringe or IV bag.
<table>
<thead>
<tr>
<th>Peelable Labels Surveys Results-Top Two Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anaesthetists (n=15)</strong></td>
</tr>
<tr>
<td>Concern on compliance labeling from alert #20?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Interested preprinted peelable label on vial</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>A: Support peelable preprinted label on vial</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>B: Eliminates errors unlabeled syringes</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>C: Use color coded labels from reels</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>D. Fulfils regulatory requirements labeling</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>E. Color coded peelable labels from vials</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Mislabeling of syringes</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Consider purchasing peelable labels on vials</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Point of Use Labels Surveys Results - Top Two Findings

<table>
<thead>
<tr>
<th>Category</th>
<th>Anaesthetists (n=15)</th>
<th>Nurses (n=7)</th>
<th>Pharmacists (n=6)</th>
<th>Others (n=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerned protocols or procedures not followed</td>
<td>53.3% Somewhat concerned 40% Extremely concerned</td>
<td>85.7% Extremely conc. 14.3% Somewhat conc.</td>
<td>100% Extremely concerned</td>
<td>50% Extremely conc. 50% Somewhat conc.</td>
</tr>
<tr>
<td>Interested point of use label on injectable vial</td>
<td>53.3% Somewhat interested 40% Extremely interested</td>
<td>85.7% Extremely inter. 14.3% Somewhat inter.</td>
<td>66.7% Extremely int. 33.3 Somewhat impt.</td>
<td>100% Extremely interested</td>
</tr>
<tr>
<td>A: Reconstitution info on point of use label</td>
<td>40% Extremely important 33.3% Somewhat important</td>
<td>57.1% Extremely impt 42.9% Somewhat impt.</td>
<td>83.3% Extremely impt 16.7% Somewhat impt.</td>
<td>50% Extremely impt. 50% Somewhat impt.</td>
</tr>
<tr>
<td>B: Administration info on the point of use label</td>
<td>46.7% Extremely important 40% Somewhat important</td>
<td>71.4% Extremely impt. 14.3% Somewhat impt.</td>
<td>66.7% Extremely impt 33.3% Somewhat impt.</td>
<td>50% Somewhat impt. 50% Not important</td>
</tr>
<tr>
<td>C: Infusion rates on the point of use label</td>
<td>53.3% Somewhat important 26.7% Extremely important</td>
<td>42.9% Extremely impt. 42.9% Somewhat impt.</td>
<td>50% Extremely impt. 33.3% Somewhat impt.</td>
<td>50% Extremely impt. 50% Somewhat impt.</td>
</tr>
<tr>
<td>D. Incompatibility drug info on point of use label</td>
<td>33.3% Extremely important 33.3% Not important</td>
<td>42.9% Extremely impt. 28.6% Extremely impt.</td>
<td>66.7% Somewhat impt 33.3% Not important</td>
<td>50% Not important 50% NO ANSWER</td>
</tr>
<tr>
<td>E. Support feasibility of point of use label</td>
<td>53.3% Extremely important 20% Somewhat important</td>
<td>42.9% Extremely impt. 28.6% Not important</td>
<td>50% Extremely impt. 50% Somewhat impt.</td>
<td>100% NO ANSWER</td>
</tr>
<tr>
<td>Consider purchasing vials with point of use label</td>
<td>73.3% Yes to purchase 20% Not interested purch. 6.7% NO ANSWER</td>
<td>100% Yes to purchase</td>
<td>100% Yes to purchase</td>
<td>100% Yes to purchase</td>
</tr>
</tbody>
</table>
Simulation Models: Peel Off Labels from Vials/Color-Matched Labels

Using Improved Visual Techniques to Reduce Drug Administration Errors in the Operating Room

Fady Wassef, M.D., Elizabeth H Sinz, M.D., Jansie Prozesky, M.D., Donald Martin, M.D. and Anne-Marie Dyer. Penn State Milton S. Hershey Medical Center, Hershey, PA, United States.

Introduction

Medication administration errors are a significant cause of adverse events resulting from patient harm. Recent series report approximately 1 drug administration error every 153 administrations.[1] Recovery from an error may itself cause harm. This study investigated the frequency of near misses and omissions among anesthesia (27% - 33%) and surgical anesthesia (93% - 97%) nurses, with similar errors reported in the emergency and the operating room. These errors due to color blindness are especially common in the operating room.

Methods

Eighty anesthesiologists, residents, and nurses drew up and labeled medications using 3 different labeling techniques. The newly designed labeling system included:

1. Black and white labels and vials
2. Color labels and vials
3. Color-matched labels and vials

Each subject performed 3 trials using a different drug vial and labeling technique, in predetermined order.

Results

The frequency of near misses and omissions was significantly lower for peel-off compared to black and white labels, and peel-off compared to colored labels in this simulation model (p-values ranging between 0.02 to <0.0001). The rate ratio of omissions using peel-off labels, as may be expected, was almost half that of using standard black and white labels, reaching the same proportion while using color-matched labels.

Conclusion

In this simulation model, the transfer of peel-off labels from medication vials directly onto syringes within the simulated environment is shown to significantly decrease both the error rate and the time required to transfer medications into syringes. The use of peel-off labels directly onto syringes labeled with the same name deserves serious consideration to enhance patient safety.
COMPOUNDED IV BAGS & IV SYRINGES…
New Research: Labels for Compounded IV Bags and IV Syringes

- Safety concerns and issues relating to labeling
  - Encounter errors with mislabeling IV meds
- Impact on identifying right drug
- Incompatibility notification
- Avoid giving wrong route administration
  - Epidural IV bag may be assumed that the infusion should be administered intravenously
- Unlabeled IV bags/additives or IV syringes
- Not always can administer premixed IV bags or IV prefilled syringes
Appendix D
Institute for Safe Medication Practices
IV Piggyback Medication Label Format
Pharmacy generated label for dispensing to inpatient clinical units
Minimum content

John Jones  Room 2647
Second identifier
amphotericin B  ___ mg
(FUNGIZONE)
hydrocortisone  ___ mg
(SOLU-CORTEF)
In DSW  IVPB
Total Volume  ___ mL

1. Patient name - 48 character field - bolded 12 point font
2. Location 12 character field - 12 point font
3. Second identifier 10 character field (Date of birth, financial #, Encounter #, Medical Record #) - 10 point font
4. Generic name - 40 character field - bolded 12 point font
5. BRAND name - 18 character field - 12 point font
6. Patient dose - 20 character field - bolded 12 point font
7. Route - 12 character field - 12 point font
8. Diluent - 30 characters - 10 point font
9. Total volume - 30 characters - 10 point font
10. Bar code - placed vertically or horizontally to allow for the best readability on a flat surface
11. Initials as needed - these maybe handwritten or if computer generated 10 point font
12. Expiration Date as needed in a MM/DD/YYYY format - 10 point font
13. Other information as required by State or Federal Law
14. Pharmacy information if required should be at the bottom of the label
15. Comments - 10 point font

Exp: 12-31-2006  Initials: ___/Initials___
Draft Models IV Compound Bag Label

1. Batch record of compounding drug
2. Preprinted label to put on IV bag
3. Two-sided label attached via hook strip to opening of IV bag
4. Symbol for high-risk injectable medications to put on IV bag
5. Preprinted drug’s name line marker for IV line
6. Peelable label of documentation after finish infusion
Draft Models IV Compound Bag Label
Line marker has preprinted drug’s name available from peelable label. It is put on IV line at the moment of labeling IV bag with peelable label containing preprinted drug’s name.
ISMP Recommendations

Appendix C
Institute for Safe Medication Practices
Small Volume Injection Medication Label Format
Pharmacy generated label for dispensing to inpatient clinical units
Minimum content

Mary Jones
Room 3727
MR# 2345678
ondansetron (ZOFRAN) 4 mg IV Push
Dose = 4 mg = 2 mL
(2 mg per mL)

Exp: 12-31-006 RPI: ______

1. Patient name 48 character field – bolded 12 point font
2. Location 12 character field – 12 point font
3. Second identifier 10 character field (Date of birth, financial #, Encounter #, Medical Record #) – 10 point font
4. Generic name – 40 character field – bolded 12 point font
5. BRAND name – 18 character field – 12 point font
6. Patient dose – 20 character field – bolded 12 point font
7. Route – 12 character field – 12 point font (this may wrap to the next line as needed)
8. Patient specific dose with the corresponding number of mL – 30 characters – 10 point font
9. Concentration of the solution per mL – 30 characters – 10 point font
10. Bar code – placed vertically or horizontally to allow for the best readability on a flat surface
11. Pharmacist initials (handwritten), if needed, indicating that the product has been checked
12. Expiration Date as needed in a MM/DD/YYYY format – 10 point font
13. Other information as required by State or Federal Law
14. Pharmacy Information if required should be at the bottom of the label
15. Comments – 10 point font

Injectable Label Design Research: Compound Label for Syringe (Draft Model)
MEETINGS/DISCUSSIONS WITH: FDA...USP...ISMP...

• “Present evidence-based medicine research”
• “Revolutionary”

REQUEST RECOMMENDATIONS/MANDATES

ADOPT for BEST PRACTICES

“...maximize the safe use of medication...”
“...error-prevention strategies...”

“need for distinctive packaging, labeling....products associated with actual or potential medication errors...

“...using tactile cues in container design...”

“...easily accessible product information as close to the point of use as possible...”

www. nccmerp.org/council/council.  Access on 6/7/09
Thank You

QUESTIONS?

Email Contacts: MKlein@kingsbrook.org
mkpharmacy@yahoo.com