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"	Age 1½
CONJECTURE •Probable drug was erythromycin •One prominent side effect: • Ototoxicity (hearing loss)	<ul> <li>AHFS Drug Information 2007</li> <li>"Ototoxicity consisting of bilateral hearing loss, in at least one case irreversible, has been reported rarely with erythromycin lactobionate, stearate, or ethylsuccinate"</li> <li>"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)"</li> </ul>	DEDICATION Life-long disability impetus fuels my passions for helping others to avoid such errors
	American Honoldar Dannie. American Kolonia dona dona dona dona dona dona dona don	

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. PHARMACOPEIA MEDMARX <sup>®</sup> 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						
Stage of Medication Process	Number	Per cent of total				
Administration (which may include preparation)	10,394	73.1				
Prescribing	1,566	11.0				
Preparation of medicines in all locations/dispensing in a pharmacy	1,403	<b>9.9</b>				

National Patient Safety Agency Alert 20: Promoting Safety Practice with Injectable Medicines.

## U.S. Pharmacopeia (USP)

7<sup>th</sup> MEDMARX<sup>®</sup> Data Report in March 2007

 Titled: MEDMARX Data Report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998 - 2005

#### 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)

USP MEDMARX Data Report: A Chartbook of Medication Error Findings From The Perioperative Settings from 1998 - 2005. Pages 1-2

Types of Errors in Care Unit Areas						
Percentage (%) of errors in each care unit areas						
Phases of Errors	Outpatient	Pre-Op	OR	PACU		
Prescribing	29.6	11.9	20.1	28.4		
Transcribing/ Documenting	11.4	21.9	10.1	12.2		
Dispensing	8.3	7.2	11.6	7.3		
Administering	49.8	57.5	56.3	50.3		
Monitoring	0.9	1.5	2.0	1.8		

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

#### **ISMP Medication Safety Alert!**<sup>®</sup>

- November 15, 2007 Volume 12 Issue 23:
- "Errors with injectable medications:
- Unlabeled syringes are surprisingly common!"

November 29, 2007 Volume 12 Issue 24:

Why don't we have a user friendly labeling system?

Why does this

happen so often?

- "Another heparin error:
- Learning from mistakes so we don't repeat them"

## **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"



Anesthesia Patient Safety Foundation Newsletter Winter 2008

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



SUCCINYLCH Special Solution WARN	OLINE CHLORIDE INJECTION, USP QUELICIN*
By	Lasic sploten used)
01-8855-R13-5/03	Special Solution OUELICING Special Solution OUELICING CHLORIDE INJECTION, USP
SUCCINYLCH Special Solution WARN	OLINE CHLORIDE INJECTION, USP QUELICIN® IING: PARALYZING AGENT
By (name of	Ibasic solution used) Use only in State
01-8855-R13-5/03	Special Solution QUELICIN® Special Solution QUELICIN® Chronic Control
SUCCINVLCH Special Solution WAR	OLINE CHLORIDE INJECTION, USP QUELICIN® SURVICE, PARALYZING AGENT
By 01-8855-R13-5/03	Biotection Contract C
SUCCINYLCH Special Solution WARM	IOLINE CHLORIDE INJECTION, USP QUELICIN®
By	Use only in
01-8855-R13-5/03	
SUCCINVLCH Special Solition WARK	TOLINE CHLORIDE INJECTION, USP QUELICIN*
By	259 201 201000 ODETICIA e 259 201 201000 ODETICIA e 200 201 201000 ODETICIA e 200 201000 ODETICIA e

Manufacturer Hospira: Brand Name Quelicin; Generic Name Succinylcholine

#### NDC 55390-102-05 10 X 5 mL Single Dose Vials ATRACURIUM BESYLATE INJECTION USP FOR IV INJECTION 50 mg/5 ml **Rx ONLY** (10 mg/mL) terile, non-pyrogenic

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

## USA – Existing Peel Off Label



Manufacturer Organon: Brand Name Zemuron Generic Name Rocuronium Finding: One removable label for a multi-dose vial



November 2, 2007

Miriam Klein, M.D. Medication Safety Fellow Kingsbrook Jewish Medical Center 585 Schenectady Avenue Brooklyn, NY 11203

Dear Dr. Klein

Thank you for contacting Organon regarding your question about labels on Zemuron® vials. We want to assure you that patient safety has always been our primary concern, and we comply with all vial label requirements as specified in the FDA regulations.

The label-on-label affixed to the Zemuron® vial is not a USP requirement or regulation. Organon initiated the label-on-label as a value-added service for the convenience of our customers and the safety of patients. The label can be affixed to the syringe for identification purposes when the medication is drawn into the syringe.

Historically, our experience has shown that, in general, the entire contents of the vial are drawn into the syringe, used throughout the surgery, and then any remaining drug discarded at the end of the procedure. In the event that multiple doses are required, our customers may use commercially available labels. Your comment has been forwarded to our Marketing Department to be considered for possible future improvements.

Thank you again for giving us the opportunity to address your inquiry. If we can be of further assistance, please feel free to contact us again.

Sincerely,

Stapuv Sudesh Kapur Complaint Coordinator Quality Affairs

> Organon USA Inc. 56 Livingston Avenue Roseland, NJ 07068

www.organon-usa.com

T 1 973 325 4500 F 1 973 325 4589

The label-on-label affixed to the Zemuron® vial is not a USP requirement or regulation. Organon initiated the label-on-label as a value-added service for the convenience of our customers and the safety of patients. The label can be affixed to the syringe for identification purposes when the medication is drawn into the syringe.

## Enhanced Labeling System...in Germany

#### **Removable Labels**



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

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

#### Transferable Label

Further Discovery: -incomplete with regulatory labeling requirements

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Manufacturer Ratiopharm: Generic name: Sufentanil

#### **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."

#### National Patient Safety Agency (NPSA) 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



Professor David Cousins, BPharm, MSc, PhD, MCCP, MRPharms Head of Safe Medicine Practice

NHS National Patient Safety Agency **Patient Safety Division** 

2008

#### 2008

#### 2.2 b Labelling methods



### Test Model: Neuromuscular Blocker Label



## 2<sup>nd</sup> Test Model: Moment of Use (MOU)



 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



















Deutscher
 Arzte-Verlo
 Sendavedag und
 Dreck Drevestionation





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#### "POINT OF USE" LABEL



## **Derby Hospitals NHS Foundation Trust**

- 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. Mislabeling of syringe?
- 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.

#### Peelable Labels Surveys Results-Top Two Findings

	Anaesthetists	Nurses	Pharmacists	Others
	(n=15)	(n=6)	(n=6)	(n=3)
Concern on compliance	53.3 % Somewhat Concern	83.3% Extremely Con.	83.3% Extremely Con.	66.7% Somewhat Con.
labeling from alert #20?	33.3% Extremely Concerned	16.7% Somewhat Con	16.7% Not Concerned	33.3% Extremely Conc.
Interested preprinted peelable label on vial	60% Extremely Interested	100% Extremely	83.3% Extremely Inter.	66.7% Extremely Inter.
	20% Somewhat Interested	Interested	16.7% Somewhat Inter	33.3% Somewhat Inter.
A: Support peelable preprinted label on vial	46.7% Extremely important	50% Extremely impt	83.3% Extremely impt	33.3% Extremely impt
	40% Somewhat important	50% Somewhat impt	16.7% Somewhat impt	33.3% Not important
B: Eliminates errors	53.3% Extremely important	83.3% Extremely impt	100% Extremely impt	66.7% NO ANSWERS
unlabeled syringes	33.3% NO ANSWERS	16.7% Somewhat impt		33.3% Somewhat impt
C: Use color coded labels from reels	40% Extremely important	50% Somewhat impt	50% Somewhat impt	66.7% Extremely impt
	33.3% Somewhat important	33.3% Not important	33.3% Not important	33.3% NO ANSWERS
D. Fulfils regulatory requirements labeling	33.3% Extremely important	50% Extremely impt	66.7% Extremely impt	66.7% NO ANSWERS
	33.3% Somewhat important	33.3% NO ANSWERS	16.7% Not important	33.3% Not important
E. Color coded peelable labels from vials	60% Extremely important	33.3% Extremely impt	66.7% Somewhat impt	66.7% NO ANSWERS
	13.3% Not important	33.3% NO ANSWERS	16.7% Extremely impt	33.3% Somewhat impt
Mislabeling of syringes	60% Yes to mislabeling 33.3% No to mislabeling	50% Yes to mislabel 50% No to mislabel	<b>33.3% Yes</b> to mislabel 50% No to mislabel	<b>33.3% Yes</b> to mislabel 66.7% No to mislabel
Consider purchasing peelable labels on vials	66.7% Yes to purchase 20% Not interested to purch.	100% Yes to purchase	100% Yes to purchase	100% Yes to perchase

#### Point of Use Labels Surveys Results-Top Two Findings

	Anaesthetists	Nurses	Pharmacists	Others
	(n=15)	(n=7)	(n=6)	(n=2)
Concerned protocols or procedures not followed	<ul><li>53.3% Somewhat concerned</li><li>40% Extremely concerned</li></ul>	85.7% Extremely conc. 14.3% Somewhat conc.	100% Extremely concerned	50% Extremely conc. 50% Somewhat conc.
Interested point of use label on injectable vial	<ul><li>53.3% Somewhat interested</li><li>40% Extremely interested</li></ul>	85.7% Extremely inter. 14.3% Somewhat inter.	66.7% Extremely int. 33.3 Somewhat impt.	100% Extremely interested
A: Reconstitution info on point of use label	40%Extremely important33.3%Somewhat important	57.1% Extremely impt 42.9% Somewhat impt.	83.3% Extremely impt 16.7% Somewhat impt	50% Extremely impt. 50% Somewhat impt.
B: Administration info on the point of use label	46.7% Extremely important 40% Somewhat important	71.4% Extremely impt. 14.3% Somewhat impt.	66.7% Extremely impt 33.3% Somewhat impt	50% Somewhat impt. 50% Not important
C: Infusion rates on the point of use label	53.3% Somewhat important 26.7% Extremely important	42.9% Extremely impt. 42.9% Somewhat impt.	50% Extremely impt 33.3% Somewhat impt	50% Extremely impt. 50% Somewhat impt.
D. Incompatibility drug info on point of use label	33.3% Extremely important 33.3% Not important	42.9% Somewhat impt. 28.6% Extremely impt.	66.7% Somewhat impt 33.3% Not important	50% Not important 50% NO ANSWER
E. Support feasibility of point of use label	53.3% Extremely important 20% Somewhat important	42.9% Extremely impt. 28.6% Not important	50% Extremely impt. 50% Somewhat impt.	100% NO ANSWER
Consider purchasing vials with point of use label	<ul><li>73.3% Yes to purchase</li><li>20% Not interested purch.</li><li>6.7% NO ANSWER</li></ul>	100% Yes to purchase	100% Yes to purchase	100% Yes to purchase

#### 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. Department of Anesthesiology, Penn State Hershey, PA, United States.

#### Introduction

Medication administration errors are a significant source of motibity and motality in the OR as elsewhere in the hospital. Recent series report approximately 1 drugs (1) Approximately 13 of the errors during anesthesia (21% - 33%) were syringe labeling errors, occurring along with a similar percentage (20% - 40%) of syringe swaps, or incorrect use of a correctly labeled errors led to major motibity and 0.3% led to cetah. (3)

Many improvements in labeling and the administration proceed, including colorid labels, machine-read bar high colorid labels, machine-read bar high colorid labels, machine-read high colorid labels, machine colorid high colorid labels, machine colorid high colorid labels, and the OR who "cross check" each other. Some pharmaceutical manufactures, transferred directly from a will be syringe. However, to our howlidge, enther reduced arror rate onr increased efficiency. Thas ever however, to our howligated the effect of "pael off labels, as compared to conventional black-and-white and colored labels, on in

yringe labeling errors and time required to omplete the labeling process.

Internet and the

FREQUENCY AND RELATIVE RATES OF ERRORS, NEAR-MISSES, AND OMISSIONS						ONS
	Number per (Average betwee	r 234 attemp en two obse	ts rvers)	Rate Ratio o	f Errors, Near Mi	sses, Omissions
LABELS	Black and White	Color	Peel- off	B/W vs Color	Peel-off vs B/W	Peel-off vs Color
ERRORS	6	3.5	0.5	1.88	0.06	0.11
Confidence interval				0.25	0.02	0.07
				0.62-5.71	0.01-0.63	0.01-1.18
NEAR MISSES	29.5	23	11.5	1.34	0.38	0.51
Confidence interval				0.17	0.001	0.02
				0.87-2.07	0.22-0.65	0.30-0.88
OMISSIONS	129.5	112	68	1.18	0.51	0.60
Confidence interval				0.10	<0.0001	<0.001
				0.97-1.43	0.40-0.64	0.47-0.75

#### Methods

Eighteen anesthesiologists, residents, and nurses drew up and labeled medications using 3 different labeling modalities. The randomly-ordered modalities were:

- 1- Black and white labels and vial.
- 2- Color labels that match the color of the vial. 3- Peel off labels from the vial itself.

3- Peer off labels from the viai itself. Trials consisted of a series of pre-recorded instructions that prompted the subject to label and load a given amount of a simulated IV medication with decreasing time between commands to create time pressure. Two independent observers graded performance counting errors (wrong drug

or label), omissions (skipped a command), and near-misses (nearly committed an error but corrected it before the end of the trial). All of the medications used were simulated saline vals using similarly named

medications, that all start with the letter P

The rate ratios of both near misses and omissions were significantly lower for paelof compared to black and while labels, and here peel-off compared to colored labels in this near the second second labels in this of 20 to -0.000 /). The rate ratio of omissions using peel-off labels, as may be expected, was almost half of that using standard labels, reflecting the simpler process and fewer decision points using peel-off labels. The rate ratio of errors was significantly lower for peel-off compared to black and white labels (p-value = 0.02), and lower but not statistically significant for peel-off compared to colored labels (p = 0.07). The rate ratio of errors, near misses, and omissions did not differ significantly between the two other modalities (standard black and white and colored labels).

#### Conclusion

Results

In this simulation model, the transfer of peel oft labels from medication viais directly onto syringes into which that medication is drawn appears to have the potential to decrease both the error rate and the time required to transfer medications into syringes for use during anesthesia or in critical care settings. Therefore, this simple and relatively inexpensive technique deserves serious consideration as one of the ways to improve OR efficiency and, at the same time, enhance patient safety.

Reterences 1- Fasting S, Grisvold. Can J Anesth 2000; 47:1060 2- Currie: Anaesth Intensive Care 1993; 21:598-601



"...transfer of peel off labels from medication vials directly onto syringes into which that medication is drawn appears to have the potential to decrease both the error rate and the time required to transfer medications into syringes...deserves serious consideration...enhance patient safety"

#### Enhancing Visual Recognition: Effect of Labeling Techniques on Drug Administration Error Rate

Geneva Berwith, B.S., Elizabeth Sinz, M.D., Gary Chase, Ph.D., Donald Martin, M.D. Department of Anesthesiology, Penn State University College of Medicine

Introduction: The frequency of drug administration errors during anesthesia is well established. Recent series report approximately 1 drug administration error every 133 anesthetics.[1] however it is difficult to evaluate factors contributing to drug administration errors



Most studies of drug administration errors during anesthesia rely on concurrent or retrospective self-reporting, although this methodology is suboptimal.[2] Therefore we developed a simulation model to isolate medication identification and syring labeling errors. Under gradually increasing time pressure, speed and accuracy of drug preparation are measured.



under the second second

Methods: In response to verbal commands medical student volunteers identified vials labeled with of 8 similar drug names, and drew a volume of the simulated medication into subject performed 3 trials using different drug labeling techniques, in predetermined order. Labels were:

1) black and white,
 2) color matched (colored with the same color
 on the vial and syringe for the same drug)
 3) color mismatched (colored with different
 colors on the vial and syringe for the same drug)

Abse: Bisk and What Calor Material Calor Menaded Trais consisted of 39 prirecorded instructions giving the drug name and volume to use to label the giving the drug name and wings and solution to draw into the synthebases galaxies of the synthemetable.

The following water recorded for each trial? -The actual errors in vial selection or label selection for the syringe -The *near misses* where the volunteer touched the error and corrected him/herself -The omissions for insufficient time Compared using Wilcoxon signed-ranks tests. Results: Of the 780 attempts in each trial for Discussion: Color-matched labels significantly all participants, the 7 near misses with color matched labels was significantly lower than reduced the number of near misses in thi simulated environment, tending to confirm the the 85 near misses with black and white labels (Z=-3.594, p<0.001) or the 140 near advantage of using color-matched vial and syringe labels in the OR compared to the current misses with color mismatched labels (Z= use of color-mismatched labels. The similarity in 3.815, p<0.001). The number of errors and the frequency of actual errors between this omissions were not significantly different model and clinical practice supports the among the three label types. The frequency of total actual errors in this study (9:1000) vance of this model to clinical practice. [1] was similar to that found in clinical practice

Left: Simulated color matched labeling.

ith svringe labels mismate



Webster CS: The frequency and nature of drug administration error during ansatzbasis. Anasthesis & Internet Care, 2001, 22: p. 494-500. [2] Fasting S: Adverse drug errors in anesthesis, and the impact of coloured synteps labels: Car J Anasth 2000.47: p. 1005-1007 (Jubic1)

Permission granted by Dr. Donald Martin, Penn State Milton S. Hershey Medical Center

# 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

### **ISMP Recommendations**

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 Second identifier	Room 2647
amphotericin B (FUNGIZONE)	mg
hydrocortisone (SOLU-CORTE	F)mg
In D5W	IVPB
Total Volume	mL
Exp: 12-31-2006	Initials:Initials

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 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

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### **Draft Models IV Compound Bag Label**



G

File Edit

Done

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**















refusion	restants 5000 may in 100 ml (50 neglina) Patients trans. <u>Plat</u> Work: <u>Plat</u> <u>Poper IIIs</u> administered by <u>Art</u> checked by <u>Cattor</u>



## Addenbrookes' Hospital (UK)

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.

al cobur		
	Ura materi	Viennensyste ty is 318ed Channe 79 Bete/Texe Bytest 
		only is is
it i i i i i i i i i i i i i i i i i i	ancom	Cln 1g ucose 5 g ucose 5 g indue tortel nidue tortel nidue totel nidue totel n
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	111	

### **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 MR# 2345678		Roo	om 3727	
ondansetron	(ZOFRAN)	4 mg	IV Push	
Dose = 4 mg = 2 mL				
(2 mg per mL)				
Exp: 12-31-	2006 R	Ph:		

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 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/desired, 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

Comments – 10 point font

www.ismp.org/Tools/guidelines/labelsFormat/injectablesyringesFinal.pdf. Accessed on 2/18/09.

#### 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

