“Preventing Adverse Drug Events and Harm”

Frank Federico, RPh, IHI Executive Director
Steve Meisel, Pharm.D., IHI Faculty

January 17, 2012
12:00 - 1:30pm ET
Beth O’Donnell, MPH

Beth O’Donnell, MPH, Institute for Healthcare Improvement (IHI), is responsible for managing and coordinating strategic partnerships. Ms. O’Donnell received her undergraduate degree at St. Lawrence University and her graduate degree from The Dartmouth Institute for Health Policy and Clinical Practice. She joined IHI in August.
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What is an Expedition?

ex·pe·di·tion (noun)
1. an excursion, journey, or voyage made for some specific purpose
2. the group of persons engaged in such an activity
3. promptness or speed in accomplishing something
Where are you joining from?
Frank Federico, RPh

**Frank Federico, RPh**, Executive Director, Strategic Partners, Institute for Healthcare Improvement (IHI), works in the areas of patient safety, application of reliability principles in health care, preventing surgical complications, and improving perinatal care. He is faculty for the IHI Patient Safety Executive Training Program and co-chaired a number of Patient Safety Collaboratives. Prior to joining IHI, Mr. Federico was the Program Director of the Office Practice Evaluation Program and a Loss Prevention/Patient Safety Specialist at Risk Management Foundation of the Harvard Affiliated Institutions, and Director of Pharmacy at Children's Hospital, Boston. He has authored numerous patient safety articles, co-authored a book chapter in *Achieving Safe and Reliable Healthcare: Strategies and Solutions*, and is an Executive Producer of "First, Do No Harm, Part 2: Taking the Lead." Mr. Federico serves as Vice Chair of the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP). He coaches teams and lectures extensively, nationally and internationally, on patient safety.
Steven Meisel, Pharm.D., Director of Patient Safety for Fairview Health Services, an integrated health system based in Minneapolis, Minnesota. In this role he is responsible for all aspects of patient safety improvement, as well as related measurement, reporting, educational and cultural initiatives. Dr. Meisel has served as faculty for the Institute for Healthcare Improvement safety since 1997. Dr. Meisel is the recipient of numerous awards, including the 2005 University Health-System Consortium Excellence in Quality and Safety Award. He is the author of several publications.
Judy Smetzer, RN, BSN is Vice President at the Institute for Safe Medication Practices (ISMP). Fourteen years ago, she completed a 1-year fellowship with ISMP, which provided training in adverse drug event management and prevention. Currently, Smetzer is one of the authors and editors of four ISMP newsletters—one for hospitals, one for nurses, one for community pharmacies, and one for consumers. These publications reach more than 1.5 million readers. The American Public Health Association honored Smetzer with the 2002 Avedis Donabedian Award for her work in the area of medication safety.
Overall Objectives

Participants will be able to:

• Identify opportunities to decrease Adverse Drug Events (ADEs)
• Describe three process changes needed to reduce ADEs
• Discuss what measures are needed to determine the impact of interventions
Session Agenda

• Harm vs. Error
• Scope and significance of Preventable Adverse Drug Events (PADEs)
• Focus on high alert medications
• Causes and contributing factors to ADEs
• Measures
• Q&A
Harm (ADE) vs. Error

Steven Meisel, Pharm.D.
Director of Patient Safety
Fairview Health Services
Minneapolis, Minnesota
WHAT IS MEDICATION SAFETY?
What is medication safety?

• Absence of errors
• Absence of adverse events as measured by_____?
• Absence of preventable adverse events
• Absence of reportable events
• Adherence to guidelines/standards
• Adherence to NPSG
• Positive cultural surveys
• Good responses to self-assessment surveys (ISMP, Leapfrog)?
What is safety?

• Safety is a condition defined by the perception of the customer (patient).

• Safety is not synonymous with the absence of risk or adverse events. Instead it is marked by the knowledge and comfort that all efforts are being made to prevent everything we know how to prevent and that we are striving to make things even better.  
  — Aviation, automobile, nuclear power

• Error reduction, adherence to guidelines, etc. are tactics, not strategies
Harm vs. Error

Preventable Adverse Events

Potential Adverse Events

Adverse Drug Events

Medication Errors
Strong Organizational Leadership & Culture

Deploy Known Best Practices & Design New Best Practices

Build Adaptability, Resilience, & Teamwork

Patient Safety

Measurement

Resources

Training
Total reports are down 35.9% from 2007 to 2011 but up 7.4% from 2010 to 2011.

*100% review of triggers associated with anticoagulants, narcotics, sedatives, and antidiabetic agents. Other ADEs not included.
Scope and Significance of PADEs

Are PADEs really that bad...?
Scope and Significance of PADEs

• ADEs
  — 65 to 520 per 1,000 admissions\textsuperscript{1-3}
  — 28% to 95% ADEs are preventable\textsuperscript{1-4}

• Prescription errors result in PADEs
  — 3.7 to 84.1 per 1,000 admissions\textsuperscript{1-7}

• Preparation/dispensing errors result in PADEs
  — 1.1 to 1.6 per 1,000 admissions\textsuperscript{1,7}

• Drug administration errors result in PADEs
  — 2.1 to 17.9 per 1,000 admissions\textsuperscript{1,7}

• Total: 135 PADEs per 1,000 admissions\textsuperscript{3}
  — 450,000 patients experience PADE/year\textsuperscript{1-2}

• Outpatient PADEs account for 4% (1.4-15.4%) of all hospital admissions\textsuperscript{8-14}

• $121.5 billion for hospital admissions\textsuperscript{15}
  ➢ 70% of total costs of drug-related problems
Patients at Higher Risk for PADEs

• Older patients
  — 7 times more likely to experience PADE\textsuperscript{16}

• Patients taking multiple medications
  — Patients > 65 years
    ➢ 40% take 5-9 drugs
    ➢ 18% take 10 or more drugs\textsuperscript{16}

• Patients with renal or liver impairment

• Patients with low health literacy

• Pediatric patients

• Pregnant/breast-feeding patients
Medications at Higher Risk for PADEs
High-Alert Medications

<table>
<thead>
<tr>
<th>Classes/Categories of Medications</th>
<th>Specific Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>adrenergic agonists, IV (e.g., epinephrine, phenylephrine, norepinephrine)</td>
<td>colchicine injection***</td>
</tr>
<tr>
<td>adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)</td>
<td>epoprostenol (Flolan), IV</td>
</tr>
<tr>
<td>anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)</td>
<td>insulin, subcutaneous and IV</td>
</tr>
<tr>
<td>antiarrhythmics, IV (e.g., lidocaine, amiodarone)</td>
<td>magnesium sulfate injection</td>
</tr>
<tr>
<td>antithrombotic agents (anticoagulants), including warfarin, low-molecular-weight heparin, IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase, tenecteplase), and glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)</td>
<td>methotrexate, oral, non-oncologic use</td>
</tr>
<tr>
<td>cardioplegic solutions</td>
<td>opium tincture</td>
</tr>
<tr>
<td>chemotherapeutic agents, parenteral and oral</td>
<td>oxytocin, IV</td>
</tr>
<tr>
<td>dextrose, hypertonic, 20% or greater</td>
<td>nitroprusside sodium for injection</td>
</tr>
<tr>
<td>dialysis solutions, peritoneal and hemodialysis</td>
<td>potassium chloride for injection concentrate</td>
</tr>
<tr>
<td>epidural or intrathecal medications</td>
<td>potassium phosphates injection</td>
</tr>
<tr>
<td>hypoglycemics, oral</td>
<td>promethazine, IV</td>
</tr>
<tr>
<td>inotropic medications, IV (e.g., digoxin, milrinone)</td>
<td>sodium chloride for injection, hypertonic (greater than 0.9% concentration)</td>
</tr>
<tr>
<td>liposomal forms of drugs (e.g., liposomal amphotericin B)</td>
<td>sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more</td>
</tr>
<tr>
<td>moderate sedation agents, IV (e.g., midazolam)</td>
<td></td>
</tr>
<tr>
<td>moderate sedation agents, oral, for children (e.g., chloral hydrate)</td>
<td></td>
</tr>
<tr>
<td>narcotics/opiates, IV, transdermal, and oral (including liquid concentrates, immediate and sustained-release formulations)</td>
<td></td>
</tr>
<tr>
<td>neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)</td>
<td></td>
</tr>
<tr>
<td>radiocontrast agents, IV</td>
<td></td>
</tr>
<tr>
<td>total parenteral nutrition solutions</td>
<td></td>
</tr>
</tbody>
</table>

# Drugs Causing Inpatient PADEs

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>428</td>
<td>16.2</td>
</tr>
<tr>
<td>Morphine</td>
<td>123</td>
<td>4.6</td>
</tr>
<tr>
<td>Heparin</td>
<td>83</td>
<td>3.1</td>
</tr>
<tr>
<td>HYDROmorpheine</td>
<td>71</td>
<td>2.7</td>
</tr>
<tr>
<td>Warfarin</td>
<td>61</td>
<td>2.3</td>
</tr>
<tr>
<td>FentaNYL</td>
<td>59</td>
<td>2.2</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>53</td>
<td>2</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>45</td>
<td>1.7</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>44</td>
<td>1.7</td>
</tr>
<tr>
<td>Diltiazem</td>
<td>37</td>
<td>1.4</td>
</tr>
</tbody>
</table>

©USP MedMarx Annual Report 2008
Drugs Causing Inpatient PADEs\textsuperscript{4}

1. Cardiovascular drugs (17.9%)
2. Psychoactive and CNS Agents (15.3%)
3. Opioid Analgesics (12.8%)
4. Anticoagulants (9.8%)
5. Anti-infective (9.6%)
6. Insulins (6.7%)
7. Antiasthmatic agents (3.1%)
8. Electrolytes (3.0%)
9. Antineoplastic agents (2.8%)
10. Antiseizure agents (2.1%)
Drugs Causing Adverse Events Leading to Emergency Hospitalizations

1. Hematologic agents (42.3%)
2. Endocrine agents (22.8%)
3. Cardiovascular agents (9.8%)
4. CNS agents (9.8%)
5. Antiinfective agents (3.8%)

- Four most commonly implicated medications
  - Warfarin (33.3%)
  - Insulin (13.9%)
  - Oral antiplatelet agents (13.3%)
  - Oral hypoglycemic agents (10.7%)
- Accounted for two-thirds of hospitalizations
- Most from unintentional overdoses
PADEs During Hospitalization

Most PADEs originate in prescribing, administration, and monitoring phases

<table>
<thead>
<tr>
<th>Study</th>
<th>Node of Origin</th>
<th>PADEs Per 1,000 Adm.</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nebeker et al.³</td>
<td>Prescribing</td>
<td>84.1</td>
<td>Review of EHR</td>
</tr>
<tr>
<td></td>
<td>Dispensing</td>
<td>1.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Administering</td>
<td>17.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>135.4</td>
<td></td>
</tr>
</tbody>
</table>

Most common types of errors associated with PADEs are **wrong dose, wrong drug**

Wrong or inappropriate dose: 22.4%
Use of inappropriate drug/wrong choice of drug: 17%
Inappropriate drug administration, wrong technique: 16.5%
Inadequate/lack of patient monitoring: 12%
Wrong frequency: 8.8%
Known allergy: 6.9%
Causes and Contributing Factors

• System design issues
• Human error
• At-risk behaviors
Human Performance Limits

<table>
<thead>
<tr>
<th>Task Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unfamiliar task performed at speed/no idea of consequences</td>
<td>50%</td>
</tr>
<tr>
<td>Task involving high stress levels</td>
<td>30%</td>
</tr>
<tr>
<td>Complex task requiring high comprehension and skill</td>
<td>15%</td>
</tr>
<tr>
<td>Select ambiguously labeled control/package</td>
<td>5%</td>
</tr>
<tr>
<td>Failure to perform a check correctly</td>
<td>5%</td>
</tr>
<tr>
<td>Error in routine operation when care required</td>
<td>1%</td>
</tr>
<tr>
<td>Well designed, familiar task under ideal conditions</td>
<td>0.04%</td>
</tr>
<tr>
<td>Human performance limit</td>
<td>0.01%</td>
</tr>
<tr>
<td>Team performance limit</td>
<td>0.001%</td>
</tr>
</tbody>
</table>
To Err is Human

• No one is immune
  — Fallible in our choices and slips/lapses
• Human error is not a behavioral choice
• Manage human error
  — Investigate precursors to human error
  — Assess the system design
  — Console individuals
  — Enhance performance shaping factors
  — Genuine fixes are in the system design
To Drift is Human
At-Risk Behaviors

Two primary reasons
• Desire to accomplish more
• Fading perception of risk

Behavioral choice
• Unknowingly create unjustifiable risk
• Convinced in safe place
Examples of At-Risk Behaviors

- Not taking the MAR to the bedside
- Writing incomplete discharge instructions
- Failure to dispense medications in unit doses
- Technology work-arounds/failure to engage technology
- Rushed communication during shift change
- Carrying medications in pockets
- Unnecessary use of verbal orders/stat orders
- Illegible handwriting
- Grab and go
- Not labeling syringes
- Borrowing medications
- Disregard patient concerns
Managing At-Risk Behaviors

• Managing At-Risk Behaviors
  — Uncover the system-based causes
  — Uncover upside-down consequences
    ➢ Remove rewards for at-risk behaviors
    ➢ Remove barriers to safe behaviors
  — Change perceptions of risk
    ➢ Reduce tolerance of risk rather than harp on compliance
  — Change systems that are causing behaviors
  — Coaching (not “counseling”)
    ➢ Discipline unproductive
System Issues
Systems That Underlie the Medication Use Process

- Management of information
  - Patient information
  - Drug information
  - Communication
  - Information on labels, packages, nomenclature
  - Patient education

- Management of the environment
  - Drug storage, stock, standardization, distribution
  - Medication devices
  - Physical environment
  - Risk Management Processes, culture

- Management of human resources
  - Staffing patterns
  - Staff competency verification and education
Patient Information

• Lack of critical patient information
  — Laboratory values, height, weight, diagnoses, allergies, other drug therapy
    ➢ Failure to verify lab values before administering warfarin
    ➢ Too frequent dose adjustments without assessing upward or downward trend in INR
    ➢ Failure to monitor patients receiving opioids
  — Lack of drug information systems that merge with patient information
  — Patient misidentification
## Patient Information

<table>
<thead>
<tr>
<th>Item #</th>
<th>Core Items</th>
<th>% (A+B)</th>
<th>% (C+D)</th>
<th>% (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>Enhanced monitoring if risk factors present when patient on opioids</td>
<td>51</td>
<td>30</td>
<td>19</td>
</tr>
<tr>
<td>5</td>
<td>Inpt/outpt labs automatically display on OES screens</td>
<td>34</td>
<td>33</td>
<td>33</td>
</tr>
<tr>
<td>18</td>
<td>Patient selection criteria for PCA disallows PCA by proxy</td>
<td>22</td>
<td>16</td>
<td>58</td>
</tr>
</tbody>
</table>

2011 ISMP Medication Safety Self Assessment for Hospitals
Patient Information

- Patient weight
  - Mix-ups between pounds and kilograms
  - Estimated or not verified for dosing

Table 4. Types of Errors Involving Wrong Weight (n = 479)

<table>
<thead>
<tr>
<th>CATEGORIES</th>
<th>TOTAL</th>
<th>% OF TOTAL REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confusion between pounds versus kilograms</td>
<td>129</td>
<td>26.9%</td>
</tr>
<tr>
<td>Documented weight was too high</td>
<td>83</td>
<td>17.3%</td>
</tr>
<tr>
<td>Documented weight was too low</td>
<td>48</td>
<td>10%</td>
</tr>
<tr>
<td>No weight was available or used</td>
<td>45</td>
<td>9.4%</td>
</tr>
<tr>
<td>Incorrect estimated weight</td>
<td>17</td>
<td>3.5%</td>
</tr>
<tr>
<td>Mix-up between ideal versus actual weight</td>
<td>11</td>
<td>2.3%</td>
</tr>
<tr>
<td>Calculation error</td>
<td>6</td>
<td>1.3%</td>
</tr>
<tr>
<td>Mix-up between height/temperature versus weight</td>
<td>4</td>
<td>0.8%</td>
</tr>
<tr>
<td>Others</td>
<td>10</td>
<td>2.1%</td>
</tr>
<tr>
<td>Unknown*</td>
<td>126</td>
<td>26.3%</td>
</tr>
</tbody>
</table>

* There was not enough information mentioned in the report to determine what went wrong.
## Patient Information

<table>
<thead>
<tr>
<th>Item #</th>
<th>Core Items</th>
<th>% (A+B)</th>
<th>% (C+D)</th>
<th>% (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>Medication orders cannot be entered into COE system until weight entered</td>
<td>70</td>
<td>17</td>
<td>13</td>
</tr>
<tr>
<td>25</td>
<td>All weights and heights measured and documented in metric units</td>
<td>18</td>
<td>40</td>
<td>42</td>
</tr>
<tr>
<td>26</td>
<td>Scales used to weight patients only measure in or default to metric units</td>
<td>39</td>
<td>36</td>
<td>26</td>
</tr>
</tbody>
</table>

2011 ISMP Medication Safety Self Assessment for Hospitals
Drug Information

• Leape, et al.\textsuperscript{19} found \textbf{35\%} of all ADEs directly related to inadequate drug information, particularly during prescribing and administration
  
  – Lack of accessible or up-to-date references
  – COE systems that don’t merge patient-drug information
  – Duplicate therapy
  – Computer systems that fail to detect unsafe orders
  – Lack of clinical pharmacists in patient care areas
  – Failure to use standardized drug protocols
  – Crush or not crush? IV incompatibilities? Cross allergy?
  – Lack of emergency drug references, titration charts, dosing charts/dosing aids
MEDICATION SAFETY ALERT
From the RIH Medication Safety Team
Dilaudid = A High Potency Opioid

Patients that may be at higher risk for narcotic-related adverse events include:
- Neonates and children
- Opioid naïve patients
- Patients with obstructive sleep apnea
- Patients with hepatic or renal dysfunction
- Elderly patients
- Obese patients
- Use of concurrent CNS depressants
- Post-op period (first 24 hours)

Use caution when determining dose equivalencies between different opioid products.
Patients should be closely monitored at time of peak opioid effect.
In emergency situations, communicate narcotic use/timing of dosing to the responding physician.
Please call Pharmacy Clinical Services (4-4589) or Pharmacy Pain Team (4-3295) with any questions.
## Drug Information

<table>
<thead>
<tr>
<th>Item #</th>
<th>Core Items</th>
<th>% (A+B)</th>
<th>% (C+D)</th>
<th>% (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>Equianalgesic dosing charts for oral/parenteral/transdermal opioids</td>
<td>34</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>35</td>
<td>Protocols, guidelines, dosing scales, checklists for high-alert drugs</td>
<td>3</td>
<td>35</td>
<td>62</td>
</tr>
</tbody>
</table>

2011 ISMP Medication Safety Self Assessment for Hospitals
## Drug Information

<table>
<thead>
<tr>
<th>Medication Order</th>
<th>Patient Information</th>
<th>Unsafe Order NOT Detected</th>
<th>Able to Override</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Varivax 0.5 mL</td>
<td>Pregnant female</td>
<td>81%</td>
<td>89%</td>
</tr>
<tr>
<td>2. methotrexate 7.5 mg PO daily</td>
<td>Rheumatoid arthritis</td>
<td>71%</td>
<td>87%</td>
</tr>
<tr>
<td>3. Lantus 25 units IV now</td>
<td>Diabetes</td>
<td>70%</td>
<td>61%</td>
</tr>
<tr>
<td>4. carbamazepine 400 mg PO BID</td>
<td>4-year-old child</td>
<td>68%</td>
<td>89%</td>
</tr>
<tr>
<td>5. vincristine 2 mg intrathecally</td>
<td>Acute leukemia</td>
<td>65%</td>
<td>60%</td>
</tr>
<tr>
<td>6. Fluzone 0.5 mL IM</td>
<td>Allergy to eggs</td>
<td>57%</td>
<td>84%</td>
</tr>
</tbody>
</table>

Pharmacy computer system field test 2005 (n = 183)
## Item #

<table>
<thead>
<tr>
<th>Item #</th>
<th>Core Items</th>
<th>% (A+B)</th>
<th>% (C+D)</th>
<th>% (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>41</td>
<td>IT systems (OES, smart pumps, ADCs) tested for dose alerts</td>
<td>26</td>
<td>38</td>
<td>36</td>
</tr>
<tr>
<td>42</td>
<td>OES perform dose range checks and warn about overdoses</td>
<td>27</td>
<td>36</td>
<td>37</td>
</tr>
<tr>
<td>43</td>
<td>OES requires explanation for overriding maximum dose alert</td>
<td>32</td>
<td>28</td>
<td>40</td>
</tr>
</tbody>
</table>

2011 ISMP Medication Safety Self Assessment for Hospitals
Barriers to ineffective communication

- Handwritten orders
- Verbal orders
- Dangerous abbreviations/dose designations
- Ambiguous or incomplete orders
- Complex dose regimens
- Fax-related, transmission problems
- Presentation on MARs
- Hold orders
- Communication/consideration of prior therapy
- Culture (intimidation)
Communication
Dangerous Abbreviations

Nurse’s history:

Humalog 4u/2u/6u
Lantus 14u QHS

Becomes the doctor’s order:

Accu-Chek QID
Humalog 44 u  8u 12u/64 7.5q
Lantus 14 u QHS 5q
Communication
Dangerous Abbreviations

\[\text{5 P.M. 40mg. Q.5 Am.}\]

\[\text{Can'ts 6 onts} \text{ Q.45} \text{ at night}\]

\[\text{Can'ts 8 onts} \text{ 8 & 9 nightly & Supper}\]
Communication
Different Formulations

• Mix-ups between controlled-release tablets (eg., OxyContin) and immediate-release tablets (eg., oxycodone)
  — “OXYcodone 10 mg q2h prn pain” became “OxyContin 10 mg, 1 tablet every 2 hours as needed for pain”
• ER, CR, SR, XR, XL, CD, LA, IR
• CC, PM, DS, ES, HP, AF

Communication
Hold Orders

• Insulin
  – Patient on continuous enteral feedings and subcutaneous NPH insulin
  – Feedings held for a CT scan but insulin not held
  – Blood glucose only 26 mg/dL when tested

• Warfarin
  – Hold order for warfarin for patient undergoing GI work-up for bleeding
  – Pharmacy discontinued warfarin order
  – After endoscopy, order for warfarin not resumed since not on 24-hour medication summary
  – Patient suffered stroke 6 days later
INSULIN ASPART (NOVOLOG) *HIGH* 100 UNIT/M (None)
(NOVOLOG INSULIN)
DOSE: SEE SLIDING SCALE SUBQ AS NEEDED/PRN
COMMENTS: DOSE PER SLIDING SCALE BELOW AND DOCUMENT ON DIABETES RECORD FORM. *HIGH DOSE*
BS < 60 OR SYMPTOMATIC REFER TO ROUTINE HYPOGLYCEMIA ORDERS, OBTAIN STAT LAB GLUCOSE AND NOTIFY MD. 151-200 = 6 UNITS,
201-250 = 8 UNITS, 251-300 = 10 UNITS,
301-350 = 12 UNITS, 351-400 = 14 UNITS,
401-500 = 16 UNITS, >500 GIVE PRESENT REGIMEN DOSE FOR BS 401-500, OBTAIN STAT LAB BLOOD SUGAR AND CALL MD WITH RESULTS.
(SUBSTITUTE FOR HUMALOG)
*CAUTION: MAY LOOK/SOUND ALIKE OTHER DRUGS!*
Drug Labeling, Packaging, and Nomenclature

- Organizations
  - Unlabeled medications or syringes
  - Doses dispensed in bulk supplies without patient-specific labels
  - Mislabeled medications
  - Label similarity

- Manufacturer
  - Product misidentification due to
    - Look-alike drug labels
    - Look-alike packages
    - Look-alike/sound-alike drug names
  - Confusing or ambiguous labels
## Labeling, Packaging, and Nomenclature

<table>
<thead>
<tr>
<th>Item #</th>
<th>Core Items</th>
<th>% (A+B)</th>
<th>% (C+D)</th>
<th>% (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>91</td>
<td>Medications and solutions on and off the sterile field are labeled</td>
<td>1</td>
<td>25</td>
<td>73</td>
</tr>
<tr>
<td>93</td>
<td>Anesthesia syringes are labeled with the drug name, strength/concentration, and date/time of expiration</td>
<td>5</td>
<td>33</td>
<td>61</td>
</tr>
</tbody>
</table>

2011 ISMP Medication Safety
Self Assessment for Hospitals
### Labeling, Packaging, and Nomenclature

**Confused Name Pairs**

<table>
<thead>
<tr>
<th>Drug #1</th>
<th>Drug #2</th>
<th>Total Reports</th>
<th>Wrong Drug Errors, % (N = 8400)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>HYDROmorphine</td>
<td>295</td>
<td>3.5</td>
</tr>
<tr>
<td>HYDROcodone with acetaminophen</td>
<td>OXYcodone with acetaminophen</td>
<td>199</td>
<td>2.4</td>
</tr>
<tr>
<td>OXYcodone</td>
<td>OxyContin</td>
<td>188</td>
<td>2.2</td>
</tr>
<tr>
<td>Alprazolam</td>
<td>Lorazepam</td>
<td>173</td>
<td>2.1</td>
</tr>
<tr>
<td>Acetaminophen with codeine</td>
<td>OXYcodone with acetaminophen</td>
<td>146</td>
<td>1.7</td>
</tr>
<tr>
<td>OXYcodone</td>
<td>OXYcodone with acetaminophen</td>
<td>108</td>
<td>1.3</td>
</tr>
<tr>
<td>MS Contin</td>
<td>OxyContin</td>
<td>79</td>
<td>0.9</td>
</tr>
<tr>
<td>NovoLog Mix 70/30</td>
<td>Novolin 70/30</td>
<td>75</td>
<td>0.9</td>
</tr>
<tr>
<td>Morphine</td>
<td>Meperidine</td>
<td>70</td>
<td>0.8</td>
</tr>
</tbody>
</table>

Labeling, Packaging, and Nomenclature
Morphine or HYDROMorphone

• Of all wrong drug error reports that include morphine and/or HYDROMorphone
  —36% involve a mix-up between two drugs
    ➢ 62% show morphine as the prescribed medication and HYDROMorphone given in error
    ➢ 71% of reports indicate that the errors occurred when these medications were obtained from unit stock

morpheine

HYDROmorPHONE
Labeling, Packaging, and Nomenclature
Look-Alike Drug Names

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose/Rate</th>
<th>Sig/SCH</th>
<th>Route</th>
<th>Last</th>
<th>Doc</th>
<th>Next Admin</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSULIN HUMAN NPH/REG MIX 10</td>
<td>15 UNITS</td>
<td>0800</td>
<td>SC</td>
<td>L</td>
<td>10/03</td>
<td>0835</td>
</tr>
<tr>
<td>INSULIN HUMAN NPH/REG MIX 10</td>
<td>11 UNITS</td>
<td>1700</td>
<td>SC</td>
<td>L</td>
<td>10/03</td>
<td>1919</td>
</tr>
<tr>
<td>INSULIN HUMAN NPH/REG MIX 10</td>
<td>13 UNITS</td>
<td>0800</td>
<td>SC</td>
<td>L</td>
<td>10/03</td>
<td>1919</td>
</tr>
<tr>
<td>INSULIN HUMAN REGULAR 100 UN</td>
<td>SLIDING SC</td>
<td>QIDAC</td>
<td>SC</td>
<td>L</td>
<td>10/03</td>
<td>0749</td>
</tr>
<tr>
<td>INSULIN HUMAN REGULAR 100 UN</td>
<td>2 UNITS</td>
<td>1 DOSE</td>
<td>SC</td>
<td>L</td>
<td>10/01</td>
<td>1115</td>
</tr>
<tr>
<td>INSULIN HUMAN REGULAR 100 UN</td>
<td>6 UNITS</td>
<td>1 DOSE</td>
<td>SC</td>
<td>L</td>
<td>10/01</td>
<td>1115</td>
</tr>
<tr>
<td>INSULIN LISPRO 100 UN/ML ML</td>
<td>SLIDING SC</td>
<td>QIDAC</td>
<td>SC</td>
<td>L</td>
<td>10/03</td>
<td>1712</td>
</tr>
<tr>
<td>INSULIN LISPRO 100 UN/ML ML</td>
<td>SLIDING SC</td>
<td>TIDAC</td>
<td>SC</td>
<td>L</td>
<td>10/03</td>
<td>1730</td>
</tr>
<tr>
<td>INSULIN LISPRO 100 UN/ML ML</td>
<td>2 UN</td>
<td>NOW</td>
<td>SC</td>
<td>L</td>
<td>10/03</td>
<td>1730</td>
</tr>
</tbody>
</table>
Which Insulin Did You Want?

Humalog 70/30 20 units 7 AM
14 units 1 PM - Begin this

Humalog R 100 units 6 AM
80 units 6 PM
Standing scale with Humalog Regular
Labeling, Packaging, and Nomenclature

Lilly Insulin Color Differentiation
Labeling, Packaging, and Nomenclature

Changes in Heparin Label
Drug Storage and Stock
### Standardization and Distribution

<table>
<thead>
<tr>
<th>Item #</th>
<th>Core Items</th>
<th>% (A+B)</th>
<th>% (C+D)</th>
<th>% (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>97</td>
<td>Concentrations for infusions of high-alert drugs used for pediatric patients are standardized to a single concentration (90%)</td>
<td>6</td>
<td>16</td>
<td>62</td>
</tr>
<tr>
<td>96</td>
<td>Concentrations for infusions of high-alert drugs used for adult patients are standardized to a single concentration (90%)</td>
<td>2</td>
<td>9</td>
<td>89</td>
</tr>
<tr>
<td>98</td>
<td>When more than one standard concentration needed for high-alert medication infusions, use consistent terminology and visual cues to identify/distinguish concentrations</td>
<td>15</td>
<td>25</td>
<td>60</td>
</tr>
</tbody>
</table>

2011 ISMP Medication Safety Self Assessment for Hospitals
Medication Devices

• Infusion pumps
  — Failure to limit the variety of pumps/differentiate pumps
  — Programming errors
  — Failure to engage pump library
• Tubing
  — Misconnections (e.g., Enteral-IV, IV-Intrathecal)
• Syringes
  — IV syringes used to give oral medications
## Medication Devices

<table>
<thead>
<tr>
<th>Item #</th>
<th>Core Items</th>
<th>% (A+B)</th>
<th>% (C+D)</th>
<th>% (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>144</td>
<td>PCA and syringe <strong>smart pumps</strong> with full functionality used in all areas</td>
<td>20</td>
<td>23</td>
<td>46</td>
</tr>
<tr>
<td>270</td>
<td>Pen devices dispensed for individual patients, never used as unit stock for multiple patients</td>
<td>10</td>
<td>1</td>
<td>89</td>
</tr>
</tbody>
</table>

2011 ISMP Medication Safety Self Assessment for Hospitals
Environmental Factors
Patient Education

• Failure to adequately educate patients
  ─ Lack of pharmacist involvement in direct patient education
  ─ Failure to provide patients with understandable written instructions
  ─ Lack of involving patients in check systems
  ─ Not listening to patients when therapy is questioned
  ─ Making assumptions that patients understand the obvious
System Design Strategies

• Knowledge and Skill
  — Knowledge: what I know
  — Skill: the ability to apply the knowledge

Baseline Strategy
System Design Strategies

• Performance Shaping Factors (external)
  – Task/information complexity
  – Design labels
  – Differentiate items (conspicuity)
  – Reminders
  – Warning labels
  – Procedures and job aids
  – Work environment
  – Workflow and workload
  – Time urgency
  – Supervision and culture

Indirectly Manage Human Error And Drifting
System Design Strategies

• Performance Shaping Factors (internal)
  – Training
  – Experience
  – Familiarity with task
  – Mental and physical health/fitness for duty
  – Stress, tension, fatigue
  – Motivation
  – Task tension and engagement

  Indirectly Manage Human Error And Drifting
System Design Strategies

• Simplify and Standardize
  — Reduces risk and variation in work
  — Examples:
    ➢ Use commercially prepared products
    ➢ Use evidence-based standard order sets
    ➢ Standardize concentrations, container sizes, drugs
    ➢ Dispense unit doses
    ➢ Utilize dosing charts
System Design Strategies

• Limit Access, Externalize/Centralize
  —Reduces opportunities for errors
  —Examples:
    » Sequester neuromuscular blocking agents
    » Prepare all chemotherapy in a central location
    » Require special training for access to prescribing, preparation, dispensing, administration of high-alert medications
    » Restrict concentrated oral liquid opioids
    » Carefully select drugs, concentrations, quantities in floor stock/ADCs

Helps Reduce Human Error
System Design Strategies

- Maximize Access to Information, Automation with Decision Support

  — Examples
  - Clinical pharmacists
  - Dosing charts
  - Smart pumps
  - Barcode scanning
  - CPOE
  - EHR
  - Data monitoring software

Directly Manage Human Error
System Design Strategies

• Barriers, Forcing Functions, Fail-Safes
  – Prevents the error from occurring
  – Prevents hazard from touching target

Examples:
• Personal protective equipment
• Needleless system
• Different medical gas connectors
• Oral syringes
• Safe defaults, required fields
• Free-flow protection with infusion pumps

Directly Manage Human Error And Drifting
System Design Strategies

- Redundancy
  - Multiple pathways so if first fails, second successful
  - No single failure can cause accident
  - Examples:
    - Back-up supplies and power
    - Independent double-checks
    - Time-out process
    - Marking surgical site
    - Patient identification
    - Listing brand and generic names
    - Read-back
    - Automated redundancies
System Design Strategies

• Recovery
  – Allows the error to occur
  – Relies on ability to detect initiating event and correct before the critical undesired outcome
  – Examples:
    • Downstream checks and tests (e.g., order review)
    • Making the error visible through feedback (e.g., review screen on pump)
    • Patient monitoring (e.g., labs, capnography, timed assessments)
    • Surgical sponge count (can also be redundancy)
    • Capture of prescribing, dispensing, administration errors
Rank Order of Error-Reduction Strategies

- Forcing functions
- Barriers and fail-safes
- Automation and computerization
- Redundancies
- Standardization and protocols
- Performance shaping factors (e.g., checklists, reminders)
- Rules and policies
- Education
- Information
- Make no mistake

Improve system reliability
Improve human reliability


References


Measures
# The Three Faces of Performance Measurement

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Improvement</th>
<th>Accountability</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>Improvement of care</td>
<td>Comparison, choice, reassurance, spur for change</td>
<td>New knowledge</td>
</tr>
<tr>
<td><strong>Methods:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Observability</td>
<td>Test observable</td>
<td>No test, evaluate current performance</td>
<td>Test blinded or controlled</td>
</tr>
<tr>
<td>Bias</td>
<td>Accept consistent bias</td>
<td>Measure and adjust to reduce bias</td>
<td>Design to eliminate bias</td>
</tr>
<tr>
<td>Sample Size</td>
<td>“Just enough” data, small sequential samples</td>
<td>Obtain 100% of available, relevant data</td>
<td>“Just in case” data</td>
</tr>
<tr>
<td>Flexibility of Hypothesis</td>
<td>Hypothesis flexible, changes as learning takes place</td>
<td>No hypothesis</td>
<td>Fixed hypothesis</td>
</tr>
<tr>
<td>Testing Strategy</td>
<td>Sequential tests</td>
<td>No tests</td>
<td>One large test</td>
</tr>
<tr>
<td>Determining if a Change is an Improvement</td>
<td>Run charts or Shewhart control charts</td>
<td>No change focus</td>
<td>Hypothesis, statistical tests (t-test, F-test, chi square), p-values</td>
</tr>
<tr>
<td>Confidentiality of the Data</td>
<td>Data used only by those involved with improvement</td>
<td>Data available for public consumption and review</td>
<td>Research subjects’ identities protected</td>
</tr>
</tbody>
</table>
Use multiple measures

• **Outcome Measures** (voice of the customer or patient): How is the system performing? What is the result?

• **Process Measures** (voice of the workings of the system): Are the parts/steps in the system performing as planned?

• **Balancing Measures** (looking at a system from different directions/dimensions): Are changes designed to improve one part of the system causing new problems in other parts of the system?
Our Measures

- **Outcomes**: Are we reducing harm?
- **Process**: Are we reliably using the processes we implemented, unless contraindicated?
- **Balancing**: Have we impacted some other part of the system? (selection will be in the context of your work and organization)
Some Measurement Guidelines

• The key measure should clarify the aim and make it tangible.
• Don’t track too many process measures (vs. outcome measures).
• Use sampling to make measurement efficient and representative.
• Integrate measurement into people’s daily routine.
• Plot data on the measures over time.
Homework for Next Call

• Review your approach to medication safety.
• How are you measuring safety?
• How do you identify where the opportunities for improvement?
• How do you decide what to work on to improve medication safety?
Next Call

Session 2- Improving Narcotics and Opiate Management

Date: Tuesday, January 31st
12:00-1:00pm ET
Listserv

- ade_expedition@ls.ihi.org
- Send and receive questions and comments to/from faculty and participants
- To be added to the listserv please email bodonnell@ihi.org