Goals and Responsibilities of a Medication Safety Officer

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Disclosure

Bob Feroli declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.
Objectives

• List goals and responsibilities of a medication safety officer (MSO)
• List typical functions of a MSO
• Relate MSO functions to a High Reliability Organization
• Describe an approach to investigating a medication error
Not-for-profit Academic Hospital
Part of a Six Hospital Health System

1,007 Staffed Beds
42,300 Inpatient Admissions / year
93,700 ED visits / year
2,400 Births / year
Medication
Use
System
Goal of a Medication Safety Officer

Seek a Medication Use System that is:
- **Safe** – Eliminate preventable harm caused by using or failure to use medications
- **Appropriate** – Pharmacotherapy is evidenced based when feasible
- **Efficient** – Eliminate waste in the medication-use process
Goal of the MSO

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- Safe – Eliminate preventable harm caused by using or failure to use medications
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Safety Sweet Spot

Safe

Appropriate

Efficient
Goal of a Medication Safety Officer

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**Safe** – Eliminate preventable harm cause by using or failure to use medications

**Appropriate** – Pharmacotherapy is evidenced based when feasible

**Efficient** – Eliminate waste in the medication-use process

**Safety Sweet Spot** – *Maintain sensitivity to operations (HRO)*

**Share Lessons Learned** (locally, regionally, nationally, internationally)

**Learn From Others**
Goal of the MSO

Goal of a Medication Safety Officer

Seek a Medication Use System that is:

Safe
Appropriate
Efficient
Safety Sweet Spot
Share Lessons Learned
Learn From Others

Russell L. Ackoff  (1919-2009)
Pioneer of Systems Thinking

“No problem stays solved in a dynamic environment.”
Medication Use System

- Get Information about patient
- Develop & communicate therapeutic plan
- Order medication
- Prepare / Label medication / Deliver
- Administer medication
- Monitor effect

- Infrastructure
  - Support from Leadership / Culture
  - Human Resources
  - Information / Technology
  - Formulary Management
  - Inventory Control; Drug Shortages; Storage
  - Policies

The Medication Use System Is Co-Owned by us all
Medication Safety Committee

- Transdisciplinary ("system-centric")
  - Pharmacists
  - Nurses
  - Prescribers (e.g., Physicians, Nurse Practitioners, Physician Assistants)
  - Risk Managers
  - Information Systems Specialists
  - Regulatory Affairs (e.g., TJC, CMS) Specialists
  - Mix of Sharp and Blunt End Personnel
  - Voice of the Patient

Jean Piaget
Swiss Psychologist
"transdisciplinary" 1970
Medication Safety Committee

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• Part of Medical Staff Committee Structure (described in bylaws)
  – Protect data
  – Keep senior leaders in the loop
Typical Agenda

- Product defect reports
- Error Review Focusing on System Fixes
- FDA alerts
- ISMP newsletter review / External Error Reports
- National Alert Network reports (new heparin labeling)
- Formulary safety check up
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What is your institution’s error rate?

What Is an Error?
Hofer TP & Kerr EA
Eff Clin Pract 2000;6:261-269
Medication Errors

IOM 2006
1 error / inpatient / day reach the patient
NCCMERP (June 24, 2008)
“Use of medication error rates to compare health care organizations is of no value”

Because of differences in:
Culture
Error Definitions
Patient Populations
Error Detection Methods

1,000 bed hospital

Medication errors reported (2-4/day)
IOM 2006 (1 error / pt / day)
Direct observation, chart review, interviews, etc.

Reported 4
“Actual” 1,000

0.4%
Investigating an Error Report

• Assume all error reports are incomplete and inaccurate
  – Be preoccupied with failure (HRO)

• Gather data promptly – the trail gets cold fast

• Clearly define what happened (focus on the system, not on who did it)
Investigating an Error Report

- Provide Second Victim support – Commitment to Resilience (HRO)
- Collect data across silos - Sensitivity to Operations (HRO)
- Understand the “world view” of those involved with the error at the time the error was made - Sensitivity to Operations (HRO)
- Analyze Event – Reluctance to Oversimplify (HRO)
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| Human Factors Engineering | SEIPS (Systems Engineering Initiative for Patient Safety)  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>People</td>
<td>number, skill, orientation, staffing patterns</td>
</tr>
<tr>
<td>Policy</td>
<td>appropriate given current “sharp end” realities</td>
</tr>
<tr>
<td>Technology</td>
<td>interface, usability, intuitiveness, availability</td>
</tr>
<tr>
<td>Task</td>
<td>reasonable given human limitations?</td>
</tr>
<tr>
<td>Environment</td>
<td>temperature, lighting, noise</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Human Factors Engineering</th>
<th>Pt Data</th>
<th>Tx Plan / Order</th>
<th>Prepare / Label</th>
<th>Deliver</th>
<th>Give</th>
<th>Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>People</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Technology</td>
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Investigating an Error Report

System Changes
make them as strong
as feasible

RCA²
Improving Root Cause Analyses and Actions to Prevent Harm

National Patient Safety Foundation
268 Summer Street | Boston, MA 02210 | 617.391.9900 | www.npsf.org
Investigating an Error Report

System Changes make them as strong as feasible

<table>
<thead>
<tr>
<th>Action Category</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stronger Actions</strong></td>
<td></td>
</tr>
<tr>
<td>Architectural/physical plant changes</td>
<td>Replace resolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.</td>
</tr>
<tr>
<td>New devices with usability testing</td>
<td>Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.</td>
</tr>
<tr>
<td>Engineering control (forcing function)</td>
<td>Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fitting that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDS).</td>
</tr>
<tr>
<td>Simplify process</td>
<td>Remove unnecessary steps in a process.</td>
</tr>
<tr>
<td>Standardize on equipment or process</td>
<td>Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.</td>
</tr>
<tr>
<td>Tangible involvement by leadership</td>
<td>Participate in unit patient safety evaluations and interact with staff; support the RCA² process; purchase needed equipment; ensure staffing and workload are balanced.</td>
</tr>
<tr>
<td><strong>Intermediate Actions</strong></td>
<td></td>
</tr>
<tr>
<td>Redundancy</td>
<td>Use two RNs to independently calculate high-risk medication dosages.</td>
</tr>
<tr>
<td>Increase in staffing/decrease in workload</td>
<td>Make float staff available to assist when workloads peak during the day.</td>
</tr>
<tr>
<td>Software enhancements, modifications</td>
<td>Use computer alerts for drug-drug interactions.</td>
</tr>
<tr>
<td>Eliminate/reduce distractions</td>
<td>Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.</td>
</tr>
<tr>
<td>Education using simulation-based training, with periodic refresher sessions and observations</td>
<td>Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.</td>
</tr>
<tr>
<td>Checklist/cognitive aids</td>
<td>Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.</td>
</tr>
<tr>
<td>Eliminate look- and sound-alikes</td>
<td>Do not store look-alikes next to one another in the unit medication room.</td>
</tr>
<tr>
<td>Standardized communication tools</td>
<td>Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.</td>
</tr>
<tr>
<td>Enhanced documentation, communication</td>
<td>Highlight medication name and dose on IV bags.</td>
</tr>
<tr>
<td><strong>Weaker Actions</strong></td>
<td></td>
</tr>
<tr>
<td>Double checks</td>
<td>One person calculates dosage, another person reviews their calculation.</td>
</tr>
<tr>
<td>Warnings</td>
<td>Add audible alarms or caution labels.</td>
</tr>
<tr>
<td>New procedure/ memorandum/policy</td>
<td>Remember to check IV sites every 2 hours.</td>
</tr>
<tr>
<td>Training</td>
<td>Demonstrate the hard-to-use defibrillator with hidden door during an in-service training.</td>
</tr>
</tbody>
</table>

RCA² Improving Root Cause Analyses and Actions to Prevent Harm

Figure 3. Action Hierarchy

Action Hierarchy levels and categories are based on Root Cause Analysis Tools, VA National Center for Patient Safety, http://www.patientsafety.va.gov/docs/joe/ica_tools_2_15.pdf. Examples are provided here.

III. THE RCA² EVENT REVIEW PROCESS • 17
Investigating an Error Report

- **Strong Actions**
  - Forcing function (engineering control)
  - Remove unnecessary steps in a process
  - Standardize on equipment or process

- **Intermediate Actions**
  - Checklists / cognitive aids
  - Eliminate / Reduce distractions
  - Simulation Training

- **Weaker Actions**
  - Double checks
  - Training
  - Warnings

From NPSF RCA²
Medication Errors

Errors Perceived

Errors Reported

Errors Investigated
Medication Errors

Errors Perceived

Errors Reported

Errors Investigated

System Δ

Where does safety live?
Medication Errors

Errors Perceived

Errors Reported

Errors Investigated

System

Safety
Medication Errors

Errors Perceived

Errors Reported

Errors Investigated

System Δ

Introduction
Description of process & criteria for a system change

Table 1: System changes categorized by process step

<table>
<thead>
<tr>
<th>Process Step</th>
<th># of System Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Data</td>
<td>0</td>
</tr>
<tr>
<td>Therapeutic Plan</td>
<td>2</td>
</tr>
<tr>
<td>Prescribing</td>
<td>16</td>
</tr>
<tr>
<td>Transcribing/Order Processing</td>
<td>0</td>
</tr>
<tr>
<td>Preparing/Dispensing</td>
<td>18</td>
</tr>
<tr>
<td>Administration</td>
<td>2</td>
</tr>
<tr>
<td>Monitoring</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
</tr>
</tbody>
</table>

Table 2. Systems Changes Type and Strength

<table>
<thead>
<tr>
<th>Systems Change Type</th>
<th>Relative Strength of Change</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process simplified</td>
<td>High</td>
<td>5</td>
</tr>
<tr>
<td>Software modification</td>
<td>High</td>
<td>15</td>
</tr>
<tr>
<td>Eliminate LASA</td>
<td>Medium</td>
<td>7</td>
</tr>
<tr>
<td>Reduce distractions</td>
<td>Medium</td>
<td>5</td>
</tr>
<tr>
<td>Information JIT</td>
<td>Low</td>
<td>6</td>
</tr>
</tbody>
</table>

Appendix
Table with description of incidents & system changes

Confidential, for peer review only.

Error: hydrALAZINE was ordered, dispensed and administered instead of hydrOXYzine

Fix: Order menu changed to: “hydrALAZINE (Vasodilator)” & “hydrOXYzine (Antihistamine)”
Typical Agenda

- Product defect reports
- Error Review Focusing on System Fixes
- FDA alerts
- ISMP newsletter review / External Error Reports
- National Alert Network reports (e.g., Safe handling of concentrated electrolyte products)
- Formulary safety check up
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Formulary Safety Check Up

• Dose Range in CPOE

• Drug Name / Amount / Concentration Display is Consistent
  – CPOE, Pharmacy System, ADC, Infusion Pump, eMAR, Drug Label, Storage Label

• Interactions
  – Drug, Food, Pregnancy, Disease, Lab, Policy (aka Formulary Restriction)

• Look-Alike Sound-Alike (LASA) assessment

• Special Labeling
  – Hazardous, EPA Waste, Chemotherapy, Vesicant, Refrigerate, Do Not Refrigerate,
  – Do Not Crush, Paralytic Agent, Shake Well, Protect From Light

• Preparation Considerations
  – Stability, Dilution/Preparation Instructions, Standard Concentrations

• Administration Considerations
  – Medication Administration Policy(s)
• Medication Use policy review / development / update

• TJC Sentinel Event Review
  – e.g., Developing a reporting culture; Manage risks of DOAC (e.g., dabigatran, rivaroxaban)

• Drug shortage safety issues e.g., using large volume concentrated KCl, making your own NS infusion, changing concentration of epinephrine

• Yearly
  – Review of Medication Safety Committee Charter (create grid showing each responsibility and indicate months when each was addressed)
  – Review of High Alert Medication policies and procedures
  – Look-Alike Sound-Alike storage procedures review
Typical Agenda (cont.)

- Medication Use policy review / development / update
- TJC Sentinel Event Review
  - e.g., Developing a reporting culture; Manage risks of DOAC (e.g., dabigatran, rivaroxaban)
- Repackaging of large volume concentrated KCl (e.g., using large volume concentrated KCl, making your own NS infusion, changing concentration of epinephrine)
- Yearly
  - Review of Medication Safety Committee Charter (create grid showing each responsibility and indicate months when each was addressed)
  - Review of High Alert Medication policies and procedures
  - Look-Alike Sound-Alike storage procedures review

- Repackage in 20ml vials
- Cut hanging strap
- Attached warning label
- Segregate storage
- Educate pharmacy staff
Typical Agenda (cont.)

- Medication Use policy review / development / update
- TJC Sentinel Event Review
  - e.g., Developing a reporting culture; Manage risks of DOAC (e.g., dabigatran, rivaroxaban)
- Drug shortage safety issues e.g., using large volume concentrated KCl, making your own NS infusion, changing concentration of epinephrine
- Yearly
  - Review of Medication Safety Committee Charter (create grid showing each responsibility and indicate months when each was addressed)
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Be “at the table”

- Other important “medication” safety meetings
  - Board of Trustees Quality Improvement Council
  - Risk Management Committee
    - RCA meetings involving a medication
    - Device Safety Subcommittee
  - Patient Safety Committee
  - Committee that reviews all events
  - Steering Committees and Work Groups
    - e.g., EPIC, Infusion pump replacement
Other Responsibilities

• Promoting a just culture
• Helping to Maintaining Constant *Regulatory Affairs* Readiness
• Teaching
• Research
# Important Topics for the MSO

<table>
<thead>
<tr>
<th>Topic</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Alert Fatigue</td>
<td>Idealized design</td>
<td>Respect</td>
</tr>
<tr>
<td>Color: coding / differentiating / matching</td>
<td>Inattentional blindness</td>
<td>Root Cause Analysis (RCA)</td>
</tr>
<tr>
<td>Communication</td>
<td>Just culture</td>
<td>Safety strategic planning</td>
</tr>
<tr>
<td>Error (definition, reporting, investigation, analysis, disclosure, intervention)</td>
<td>Labeling</td>
<td>Second victim</td>
</tr>
<tr>
<td>1st &amp; 2nd order problem solving</td>
<td>Lean methodologies</td>
<td>Situational awareness</td>
</tr>
<tr>
<td>Failure Mode and Effects Analysis (FMEA) Common Cause Analysis</td>
<td>Measuring safety</td>
<td>System thinking</td>
</tr>
<tr>
<td>High Reliability Organization attributes</td>
<td>National Patient Safety Goals Standards of Joint Commission and CMS</td>
<td>Swiss cheese error model</td>
</tr>
<tr>
<td>Hindsight bias &amp; fundamental attribution error</td>
<td>Normalization of deviance</td>
<td>Transitions in care / Med. Reconciliation</td>
</tr>
<tr>
<td>Human error mechanisms / cognitive science</td>
<td>Patient as a safety partner</td>
<td>Technology used in healthcare</td>
</tr>
<tr>
<td>Human factors engineering / usability studies</td>
<td>Quality vs. Safety vs. Risk Management</td>
<td>Teamwork</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trigger events (e.g., IHI trigger tool)</td>
</tr>
</tbody>
</table>
References for the MSO


ISMP Call to Action: The case for Medication Safety Officers; A white Paper. July 2018
Thank You

for helping to make

our Patients Safer