Anatomy of a Fatal Medication Error

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Objectives
- Discuss the components of a root cause analysis related to a medication error

Disclosures
- I have nothing to disclose
Medication Error

- Any preventable event that may cause or lead to inappropriate medication use or harm to a patient (FDA, 2011)
- Any incorrect or wrongful administration of a medication, such as a mistake in dosage or route of administration, failure to prescribe or administer the correct drug or formulation for a particular disease or condition, use of outdated drugs, failure to observe the correct time for administration of the drug, or lack of awareness of adverse effects of certain drug combinations (Mosby’s Medical Dictionary, 2009)

Medication Error

- Any error occurring in the medication use process (Bates, Boyle, Vander Vliet, Schneider & Leape, 1995)

  “… any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer.” (National Coordinating Council for Medication Error and Prevention, 2011)

Responsibilities

- Physician
- Pharmacist
- Nurse
Medication Administration Process

Medication prescribed → Medication prepared → Medication administered

High Consequence Work

- Observe and interpret pt data before and after administration
- Apply knowledge to patient situations
- Anticipate problems regarding patient’s clinical trajectory
- Consult with other nurses and pharmacists
- Communicate with physicians to advocate for pts to prevent medication errors and adverse drug events
High Complexity Work

- New medications on the market
- Packaging of medications
- Number of medications per patient
- Number of policies and procedures created for administration
- New medical technologies and administration techniques
- Interruptions during preparation and administration
- Travel time

Process Safeguards

- Math/medication tests
- Independent verification
- Smart pump technology
- Bar code administration
- Rights

Rights of Medication Administration

1. Right Patient
2. Right Route
3. Right Dose
4. Right Time
5. Right Medication
6. Right Documentation
7. Right Client Education
8. Right to Refuse
9. Right Assessment
10. Right Evaluation
Medication Error Rates

- A medication error occurs in approximately 1 of every 5 doses given in hospitals or 1 error per patient per day.
- 1.3 million people are injured with approximately 7,000 deaths occur each year in the US.
- Drug-related morbidity and mortality is estimated to cost $177 billion in the US.
- Most common types of errors:
  - Wrong dose - 40.9% (36.4% overdose)
  - Wrong drug - 19%
  - Wrong route - 9.5%


Types of Errors

<table>
<thead>
<tr>
<th></th>
<th>Physician</th>
<th>Transcription and Verification</th>
<th>Pharmacy Dispensing</th>
<th>Nurse Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventable AEDE</td>
<td>80 (20)</td>
<td>20 (5)</td>
<td>10 (2)</td>
<td>50 (12)</td>
</tr>
<tr>
<td>Potential AEDE, reported</td>
<td>20 (5)</td>
<td>20 (5)</td>
<td>10 (2)</td>
<td>50 (12)</td>
</tr>
<tr>
<td>Potential AEDE, intercepted</td>
<td>60 (15)</td>
<td>15 (3)</td>
<td>15 (3)</td>
<td>50 (12)</td>
</tr>
<tr>
<td>Totals</td>
<td>160 (40)</td>
<td>45 (11)</td>
<td>30 (7)</td>
<td>150 (37)</td>
</tr>
</tbody>
</table>

% by stage:
- 50
- 10
- 10
- 10

*Percentages may not add to 100% due to rounding.

Causes of Medication Errors

- Incomplete patient information
- Unavailable drug information
- Miscommunication of drug orders
- Lack of appropriate labeling
- Environmental factors
- Wrong interpretation of doctor’s prescription
- Illegible prescription
- Misinterpreted prescription
- Inaccurate calculation of doses
- Interruptions
- Distractions
- Lack of concentration
- No one available for independent verification
- Staff shortage
- Similar drug names
- Failure to follow label instruction

A Patient Story

Event/Error Recognition

- The nurse who administered the medication recognized that she may have made an error and immediately brought it to the attention of the nurse manager and the attending physician.
- Normal Dilantin level: 10-20 ug/ml
- Patients Dilantin level: > 400 ug/ml
Root Cause Analysis

- Process used to identify factors that underlie variations in performance - a systematic approach to get to the true root causes of process problems
- To do this well be:
  - Focused and open-minded
  - Patient and quick
  - Relentless
  - Looking for fixes - not Band-aids

Root Cause Analysis

1. What happened?
2. What normally happens?
3. What do policies and procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

Fishbone diagram
Pyxis

- Unit pyxis screen read: 50mg/ml/10ml
- Misinterpreted by both nurses as 50mg/10ml
- Pharmacy screen read: 50mg/ml 10ml

10 x dose of medication delivered
April 10, 2008 issue
CEREBYX (fosphenytoin) has been associated with medication errors dating back to the drug’s approval in 1996
Recommendation: Children’s Hospitals should not stock 10ml vials
Identified Immediate Actions

- Remove 10ml vials of fosphenytoin from all pediatric locations
- Limit pediatric pyxis stock to 2ml vials
- Limit adult pyxis stock to 10ml vials
- Reprogram pyxis screens with strength only (removing volume size of vial)

Identified Actions

- Review override list for drugs that have nonreversible side effect and require independent verification of dosage prior to administration
- Add drugs given in emergent/urgent situations to pediatric drug calculations form
- Educate nursing staff on proper administration of fosphenytoin
- Built a medication room
Confounding Variables

Inattentional Blindness

- The failure to notice a fully-visible, but unexpected object because attention was engaged on another task, event, or object.
- The person performing a task (you?) fails to see what was plainly visible and later cannot explain the lapse.
- Brain scans about 30-40 pieces of information per second. Attention filter selects a small amount of to process and the rest never reaches our consciousness.
- The brain fills in the gaps - compiling an integrated portrait of reality based on incomplete information.
- More likely to occur if part of your attention is diverted to another task.

50mg/ml/10ml
50mg/10ml
50mg/ml
Lack of Standards

- Processes that don’t have standards cannot be improved
- Individuality in practice
- Differences in practices between institutions
- Differentiating between lack of standards and lack of implementation of standards can be difficult

Systems issues and Workarounds

- Challenge by poorly performing work systems: required equipment is broken, patient medications are in the wrong dose, key information fails to get communicated, and essential supplies are out of stock (Tucker, 2004)
  - Hospital nurses experience an average of one of these “operational failures” per hour. Dealing with them takes valuable time away from patient care—an average of 33 minutes per nurse per 7.5-hour shift
- For every 15 nurses working on a unit, the equivalent of one nurse has been removed from patient care to work full-time obtaining required supplies, information, and equipment.

Workarounds persist exist because:
- Enables patient care to be delivered safely despite obstacles, benefits the current patient
- Enable people to complete tasks without interrupting other harried staff who might otherwise be called upon to help rectify the situation.
- May represent best practices

Negative effects of workarounds:
- Typically work around the immediate issue without engaging in additional steps to prevent recurrence.
- Transfer the problem to another location
- Lack of communication about failures delays or prevents investigations to find and remove underlying causes
- When a workaround is superior to the current standard practice, a lack of discussion about the need for change limits its diffusion.
Staffing and scheduling
- Average daily census calculations
- Scheduled versus unscheduled absences
- Personality conflicts
- Often cited as number one reason why work can't be completed

Experience
- Novice to expert
  - Focused on medical tasks
  - Not secure in practice
  - Don't have the long view
  - Assumptions about expertise
  - Guts

Back to the story
What about the Nurse?

What determines the discipline?
- History
- Nurse
- Organization
- Type of error
- Outcome

Balancing Blame and Accountability
- Finding fault can be a distraction from identifying error prone situations and implementing systems to improve patient safety
- Blame free cultures have their own safety risks
  - Individuals may ignore rules, believing they are not at risk for the mistake the rules are designed to prevent

Wachter and Pronovost 2009
Just Culture

• Values-supportive system of shared accountability
  • Organization is accountable for the systems that are in place and for responding to behaviors in staff in a fair and just manner
  • Staff are accountable for the quality of their choices and for reporting both their errors and system vulnerabilities

Just Culture

• Allocate responsibility for events
  • What is the organization responsible for?
  • What is the individual responsible for?
  • Was it:
    • Human error
    • At-risk behavior
    • Reckless behavior

Nurse’s suicide follows tragedy

• The suicide of [a nurse] who accidentally gave an infant a fatal overdose last year has closed an investigation but opened wounds for her friends and family members.
  • A critically ill infant died in part from complications from an overdose of calcium chloride. After the infant’s death, the hospital put the nurse on administrative leave and soon dismissed her. In the months following, she battled to keep her nursing license in the hopes of continuing the work she loved, despite having made the deadly mistake, friends and family members said.
  • “It broke her heart when she was dismissed ... She cried for two solid weeks. Not just that she lost her job, but that she lost a child.”
  • Her brother said his sister was very close to the seriously ill children she cared for, as well as their families. Many were among the hundreds who attended her memorial service earlier this month, along with many nursing colleagues, he said. “There were many, many people there who appreciated her service in nursing” and lauded her as a “relentless advocate for her patients and the families she cared for.”
Strategies to Prevent Medications Errors

- Structure work environment to reduce probability of error
- Remove dangerous drug concentrations from nursing units
- Be aware of how shift work effects errors
- Evaluate and strengthen the knowledge and performance of nurses and other healthcare providers
- Follow a basic routine when giving meds
- Have cognitive checks

Are patients safe in your care?