Jail Time for a Medication Error-
Lessons Learned from a Medication Error

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Meet Eric Cropp

• Introductory statement
• Why I wanted to be a pharmacist?
• Academic background
  University of Toledo, BS Pharm 1993
• Professional interest
  – Chemotherapy /Pediatrics
  – Hospital environment
  – Former President North Ohio
    Academy of Pharmacy, 2001 - 2002
What happened

• Pharmacy technician accidentally compounded an etoposide base solution with hypertonic saline (23.4%) instead of 0.9%
• Error missed during pharmacist checking process
• Child suffered severe hypernatremia, CNS dysfunction, death
System analysis

- Error happened on a Sunday morning; weekend staffing, missing one pharmacist
- Routine maintenance had been done on the computer system during the night; system not available until mid-morning
- Labels normally print at 1 am and some base solutions made by start of shift at 6 am
- Label batch not printed until 10 am; includes labels for morning, afternoon and evening.
- Orders and solutions backed up
- I felt rushed
System analysis

• Physical space limitations in IV area where checking is done
• Led to crowding of IV bags, syringes to be checked, vials, other materials (“Vials all over the place.”)
• Baskets hold materials but some items don’t fit or even pop out of the top
• Nurse calls requests chemo order for noon. In truth, not due until 5 pm
System analysis

• I again feel overwhelmed and rushed
• No breaks, no lunch; calls friend to bring food and drink. Other staff refuse to work at that pace and leave for breaks. I elect to “step up to the plate and keep working”
• Day pharmacy technician makes IV base solutions
System analysis

• Hospital policy for base solutions was to use 0.9% saline from IV bag as base solution for chemotherapy. But…
  – Automated compounding often used (included 23.4% saline and water to titrate to 0.9% given the volume of chemo to be included.
  – Sometimes they did self-mixing
  – Sometimes they make solutions by using premixed 0.9% as per procedure
System analysis

- I checked technician’s work
- Bag of 0.9% saline by the finished product (etoposide 150 mL bag)
- Assumed the technician had pulled the base solution from the empty 250 mL bag of 0.9% NS nearby, as per policy
- Did not see empty vials of 23.4% NaCl
  – Hospital says more than one vial was there
System analysis

• I believed NaCl 23.4% vial I see had been used for a prior solution hand-mixed by the tech. Tech actually used three vials of 23.4% NaCl as base solution

• There was testimony that the technician said “something is weird about this” (referring to solution I was checking)
  – I asked the tech if 0.9% NS was used and she said yes
  – I thought to myself, the solution didn’t look or smell weird and volume looked right so I accept this base.
  – Confirmation bias – you see what you expect to see; miss disconfirming evidence
System changes

• Check system reinforced with two pharmacists checking
• Policy to use 0.9% reinforced
• Hypertonic NaCl now kept under lock
Reaction

• I am dismissed from hospital job
• Board of Pharmacy action
• Criminal charges
Board of Pharmacy

• Board order available on internet
• Found no system issues at hospital
• Found that misbranding of drug had occurred
• I said to have made dispensing errors at community pharmacy post-hospital incident which were training errors on the computer.
• Demeanor and present mental state
• Guilty of professional misconduct; Pharmacy license permanently revoked
What Eric wants others to know

• Slow down, fight for breaks, lunch
• Be careful what you initial
• Make sure staff are comfortable with checking pediatric doses
• Checks should be more organized
• Document compounding instructions
• Document what was done
Does the criminal system have a role?

• Even in accountability framework, accountability should be at professional level
  – With tort system for true negligence
• Criminal system is not appropriate for professional mistakes
  – Certainly not for at-risk behaviors and systems errors
  – Rare exceptions: willful and egregious negligence
• Natural for some patients/families to seek retribution
# The Three Behaviors

<table>
<thead>
<tr>
<th>Human Error</th>
<th>At-Risk Behavior</th>
<th>Reckless Behavior</th>
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<tbody>
<tr>
<td><em>Inadvertent action: slip, lapse, mistake</em></td>
<td><em>A choice: risk not recognized or believed justified</em></td>
<td><em>Conscious disregard of unreasonable risk</em></td>
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**Manage through changes in:**
- Processes
- Procedures
- Training
- Design
- Environment

**Manage through:**
- Removing incentives for At-Risk Behaviors
- System changes
- Creating incentives for healthy behaviors
- Increasing situational awareness

**Manage through:**
- Remedial action
- Disciplinary action

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**Console**

**Coach**

**Punish**
Gaps in pharmacy IV compounding

- Absence of specific practice guidelines related to product preparation checks
- Variability in practices across the country
- Ambiguity in ability to validate additives
- Need for expanded technology solutions
- Lack of awareness of associated risks by pharmacists as well as senior leadership/RM

Observations and analysis presented based on data from the ISMP Medication Error Reporting Program (MERP) and onsite risk assessments across the US
Risk points for the preparation of IV compounds

- Prescribing/Communication
- Technology/Automation
- Product production
- Product checking
- Environment

Observations and analysis presented based on data from the ISMP Medication Error Reporting Program (MERP) and onsite risk assessments across the US
Risk related to prescribing/communication

• Open formulary

• No restrictions on prescribing

• The use of non-standard concentrations
  – “custom formulations”
Risk related to prescribing/communication

- Handwritten orders
  - Legibility
  - Dangerous abbreviations and dose expressions
  - Ambiguous orders
- No preprinted templates/inadequate order sets
- No requirement for dose in $m^2$ or mg/kg and total dose
Risk related to prescribing/communication

- Orders in mg, mcg, and MEq; orders in ratio percent
- Alignment of ingredients on order forms does not follow sequence of the order entry into a database
- Turnaround time expectations
Risk related to technology/automation

• Using manual processes when automation is available

• Lack of/outdated clinical decision support in order verification, drug selection, and production
Risk related to production

• Not using commercially-available products when available
• Maintaining only one strength of a product when multiple strengths are available
• No preparation ticket or directions for compounding; preparation from memory
Risk related to production

• Restricted times for ordering/production
• Using the label to prepare IV compounded solutions (not the original order)
• Lack of standardization of preparation procedures between technicians and pharmacists
Risk related to production

• More than one patient-one product in the hood or isolator
• Flawed labeling procedures
• Low volume (rarely prepared) solutions made in house
• Lack of clinical expertise for specialty products
Risk related to IV checking

• Variable checks
  – Before the product is prepared
  – When diluent is prepared
  – When product is prepared- but before it is placed in the solution
  – After compounding using a syringe pull back
  – After compounding using the vial
  – After compounding writing the volume on the label
Risk related to IV checking

• Lack of technology to test solutions
  – specific gravity, photometric analyzers, weighing of final solutions
Risk related to the environment

• Number of distractions during the order review and preparation of products
• Variable workflow (individual based)
• Variable production speed
Risk related to the environment

• Insufficient space
  – Hood space/Number of hoods for amount of production
  – Inadequate counter preparation space
  – Shared space in hood or isolator
  – Inadequate checking space
Risk identification

• Limited understanding of these errors
  – Only those that are dispensed and later recognized as compounding issues get reported
  – If corrected before the product leaves the pharmacy- not included in usual error-reporting programs
Risk identification

• Missing Link
  – The same system issues that led to the compounding error are likely to repeat themselves; the next time may not be caught
  – These undetected system issues are latent failures that may contribute to the next error event with IV compounding
  – Imperative that these variable processes in IV compounding and checking are discovered and corrected
Limited understanding of these errors

- Only those that are dispensed and later recognized as compounding issues get reported
- If corrected before the product leaves the pharmacy, not included in usual error-reporting programs
- Needs pharmacy cooperation with reporting to risk management
- Needs analysis as near hit
Storytelling

• Exercise

• Powerful communication strategy
  – package experiences in an interesting way
  – people remember information that evokes emotion, captures attention, involves personalization
  – people who remember stories also remember the rationale behind specific error-reduction strategies, thus improving compliance
Define Second Victims and describe what resources are available to pharmacists that may need support dealing with medication errors.

**Second Victim**

- Caregivers and staff
- Negative Feelings
  – Survivor Guilt
- Suicide
- Support
Healing

- It takes one person to forgive, it takes two people to be reunited
TRUST: The 5 Rights of the Second Victim

Charles R. Denham, MD

Historically, we have referred to “The Five Rights” when we consider medication safety. We deliver treatment to the right patient, with the right drug, at the right time, with the right dose, and use the right route.

The purpose of this article is to propose 5 rights of our caregivers—5 human rights that our health care leaders must consider as an integral part of a fair and just culture when patients are harmed during the process of care. They may be remembered by the acronym, TRUST (Treatment that is just, Respect, Understanding and compassion, Supportive Care, and Transparency and the opportunity to contribute to learning). Not only must we bear in mind the sacred trust of our patients but we also must honor the sacred trust of our caregivers who serve in our hospitals and health care organizations.

Unintentional human error and systems failures account for most preventable harm to patients. Intentional negligence and harm because of malice is extremely rare; however, we treat our caregivers who are involved in human error and system failures with blame, shame, and, what may be most harmful, abandonment.
In Honor of Emily

“A Closer Look at a Medication Error”

www.emilyjerryfoundation.org
Final Comments

• Practice Environment
  – Next Eric?

• 2nd Victims

• Patient Safety Advocacy

• Contact
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What is your Pharmacy destiny?