Error disclosure in clinical laboratory

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Visible service defects ➔

INVISIBLE DEFECTS ➔

- Re-examination
- Excessive use of reagents & other material
- Overtime work
- Loss of customer goodwill
Estimated Deaths Due to Medical Error

120,000 deaths from medical error

**Accidental Deaths in the U.S.**

An estimated one million people are injured by errors during hospital treatment each year and 120,000 people die as a result of those injuries, according to a study led by Lucian Leape of the Harvard School of Public Health. Here's how that number compares with other causes of accidental death in the United States*.

*SOURCE for accidental deaths shown in blue: National Safety Council. Data are for 1996.

KEVIN BURKETT / Inquirer Staff Artist

- 43,649 motor vehicle deaths
- 14,986 deaths from falls
- 3,959 drowning deaths
- 329 commercial aviation deaths

Source – The Philadelphia Inquirer
Errors…

Health care processes are increasingly being implicated in causing harm to patients.

Hippocrates

– the “Father of Medicine” (4th century BC)

coined the maxim “First do no harm”

*To Err is Human: Building a Safer Health System* - IOM Report, 2000
Ethical Complexities in Error Disclosure

• Should I disclose:
  – Errors with minor/transient harm
  – Fatal errors
  – Harmful errors in patients who are hopelessly ill
  – Other doctors’ errors
Patients’ Preferences for Error Disclosure

• Information patients want disclosed
  – Explicit statement that error occurred
  – What happened, implications for their health
  – Why it happened
  – How will recurrences be prevented

• Importance of an apology
Total no. of venous samples (2008 – 2009) … 67,438

Errors detected in … 954

Pre-analytical error … 77.1%
Analytical error … 7.9%
Post-analytical error … 15.0%

Goswamia B, Singha B,*, Chawla R
Pre-analytical errors

Inappropriate sample
- Unlabelled specimen
- Grossly hemolysed
- Inappropriately labeled specimen
- No test requested

Inappropriate form
- Incomplete form
- Blood stained form
- Unlabelled form

Inappropriate volume
- Broken sample
- Spilled sample
- Insufficient volume

Inappropriate tube
- No request form received
<table>
<thead>
<tr>
<th>Issue</th>
<th>Frequency</th>
<th>%</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-conformity with QC</td>
<td>6</td>
<td>0.6</td>
<td>Old QC, improper storage</td>
</tr>
<tr>
<td>Random error</td>
<td>15</td>
<td>1.6</td>
<td>Unknown cause</td>
</tr>
<tr>
<td>Calibration drift</td>
<td>10</td>
<td>1.0</td>
<td>Reagent instability, reagent changeover, expiry of calibration data with time</td>
</tr>
<tr>
<td>Reagent contamination</td>
<td>8</td>
<td>0.4</td>
<td>Reagent mix up, improper storage</td>
</tr>
<tr>
<td>Systemic error: probe, lamp,</td>
<td>36</td>
<td>3.8</td>
<td>Inherent technical problem/blocked tubing routine wear and tear</td>
</tr>
</tbody>
</table>
Favourite Quotes

• Don’t fix the blame, fix the problem
• If you mess up, ‘fess up
• Use PPE to stay cool – free
• SAFE - Staying Accident-Free Everywhere
• You get the level of safety that you are prepared to walk fast
Barriers that hinder Error Disclosure by Healthcare Workers

- Fear of harming the patient or patient’s family
- Fear of litigation - could precipitate a lawsuit
- Fear of financial or emotional damage (loss of reputation)
- Awkwardness (shame) of the disclosure
- Lack of confidence: poor communication skills
Create a culture of error reduction

• Focus on how best to usher in a *culture of safety* by changing mindsets, understanding error mechanism, and devoting resources towards improvements in this area

• **Benefits:**

  Creates a medical system in which all the *stake holders* – patients, medical professionals and insurers *have increased trust in one another* making confrontations including costly malpractice claims less likely to occur
Definitions

• **Error**
  – Failure of a planned action to be completed as intended (i.e., *error of execution*) or the use of a wrong plan to achieve an aim (i.e. *error of planning*)

• **Adverse Event (AE)**
  – An injury caused by medical management rather than the underlying condition of the patient

• **Preventable Adverse Event**
  – An adverse event attributable to an error

Source – IOM, 2000
Medical Errors

Potential AEs

Adverse Events (complications)

Non-preventable AEs

Preventable AEs

Near Misses

Relationship of Errors and Adverse Events
Why report near misses?

Errors that lack an adverse outcome are called near misses or precursor events. They have the same root causes as sentinel events. Most plane crashes are preceded by near misses that have been ignored. Thus, we should report near misses.
Relationship of Medical Errors to Adverse Events
Active vs. latent error

• **Active errors**
  – occur at the level of the frontline operator
  – their effects are felt almost immediately

• **Latent errors**
  – removed from the direct control of the operator
  – poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations
Active vs. latent error

• **Active errors**
  – the pilot crashed the plane

• **Latent errors**
  – a previously undiscovered design malfunction caused the plane to roll unexpectedly in a way the pilot could not control and the plane crashed
The Reason Model and Accident Causal Chain

Organizational Influences
Unsafe Supervision
Preconditions for Unsafe Acts
Unsafe Acts
Latent Failures
Latent Failures
Latent Failures
Active Failures
Mishap

Failed or Absent Defenses

Source: Adapted from Reason, 1990
Retrospective Analysis

Institution
Systems
Procedures
Organization

Sharp End

Blunt End
The Just Culture

• Creates a structure to address errors in a setting that is safe and open
• Lets us learn from our errors and “near misses” in a blame free environment
• Helps us hold each other accountable
• Makes the system safer
• Manages behavioral choices
3 Types of Errors

- **Human error** - Inadvertent action; inadvertently doing other than what should have been done; slip, lapse, mistake
- **At risk behavior** - Behavioral choice that increases risk where risk is not recognized or is mistakenly believed to be justified
- **Reckless behavior** - Behavior - to consciously disregard a substantial and unjustifiable risk
<table>
<thead>
<tr>
<th>Error Type</th>
<th>Example</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadvertent error</td>
<td>• A aliquotting errors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Calculation errors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Labeling errors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data entry errors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Specimen routing errors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Most examples of shortcutting, for example:</td>
<td>Coach and then</td>
</tr>
<tr>
<td></td>
<td>• Reviewing microscope slide for less time than stated in procedure</td>
<td>monitor</td>
</tr>
<tr>
<td></td>
<td>• Batch labeling of specimens at nurse station, rather than labeling</td>
<td></td>
</tr>
<tr>
<td></td>
<td>at bedside</td>
<td></td>
</tr>
<tr>
<td>At-risk behavior</td>
<td>• Pouring specimen down sink and falsifying results</td>
<td>Punish</td>
</tr>
<tr>
<td></td>
<td>• Performing lab services (phlebotomy, processing, testing, reporting)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>while under the influence of drugs or alcohol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Any at-risk behavior that has been repeatedly coached</td>
<td></td>
</tr>
</tbody>
</table>
While preparing lab reports, a laboratory observed the computer print-out of a patient’s report as urea 20 mg/dl and creatinine 8 mg/dl. This anomaly was investigated
In a hospital the cardiologists have been complaining that K+ results for their patients are always high for samples sent to the lab after 11:00 am on Saturdays. The main lab is closed on Saturdays by 1 pm and thereafter only the emergency section functions.
Scenario 1: Insulin Overdose

You have admitted a diabetic patient to the hospital for a COPD exacerbation. You handwrite an order for the patient to receive “10 U” of insulin. The “U” in your order looks like a zero. The following morning the patient is given 100 units of insulin, ten times the patient’s normal dose, and is later found unresponsive with a blood sugar level of 35. The patient is resuscitated and transferred to the intensive care unit. You expect the patient to make a full recovery.
How likely would you be to disclose this error?

1. I would definitely not disclose this error
2. I would disclose this error only if asked
3. I would probably disclose this error
4. I would definitely disclose this error
What would you most likely say about what happened?

1. Your blood sugar level went too low
2. Your blood sugar went too low because you received more insulin than needed
3. Your blood sugar went too low because an error happened and you received too much insulin
How much detail would you most likely give about the error?

1. I would not volunteer any specific information about the details of the error unless asked

2. You received more insulin than needed

3. You received 100 units rather than your usual 10 units
What most closely resemble what you would say about the cause of the error?

1. I would not volunteer a cause unless asked
2. This occurred because of a miscommunication about your insulin order
3. I wrote your order for “10 U” of insulin and the “U” looked like “O”. Therefore you received 100 units than 10. This was also missed by our nurse and pharmacist.
What would you most likely say about an apology?

1. I would not volunteer that I was sorry or apologise
2. I am sorry about what happened
3. I am sorry that you were harmed by this error
Examples of Disclosure of a Laboratory Error

- The error was a data entry on a troponin, which caused an incorrect diagnosis of myocardial infarction.

- Choosing words too carefully
- Reasonable disclosure
- Disclosing too much
Examples of Disclosure of a Laboratory Error

Choosing words too carefully:

“I am calling to correct a troponin result. The troponin result on patient *** which was reported as 57 ng/mL on 3rd Dec has been changed to 0.02 ng/mL.”
Examples of Disclosure of a Laboratory Error

Reasonable disclosure:

“The troponin result on patient *** which was reported as 57 ng/mL, has been changed to 0.02 ng/mL. This was due to a manual, data-entry error. In the lab, there was a specimen for troponin from another patient received at the same time. That patient had a troponin of 57 ng/mL, and we incorrectly entered that patient’s results into this patient’s record. We are sorry that we made this error. We are doing a further analysis on this error to look for ways to prevent its recurrence.”
Examples of Disclosure of a Laboratory Error

**Disclosing too much:** This was due to a manual, data-entry error by a technologist Joey. In the lab, there was a specimen for troponin from another patient received at the same time. That patient had a troponin of 57 ng/mL, and Joey got all confused as usual and incorrectly entered the patient’s results into *** record. We are sorry that Joey made this error. Joey has been having some personal problems. He has been making lots of these errors, and everybody has been talking about it. But management around here is too timid to do anything, and they are never around anyway, as they are usually taking some kind of fancy retreat or driving around in their boats. Nobody listens to us, and that is why these things happen. It is a good thing we didn’t kill the patient. This place stinks. If I had more money, I would retire. We are doing a further analysis, even though we all know what is going on. Please feel free to call the laboratory supervisor in a few days if you have additional questions.
Error Reporting

- Voluntary reporting allows scope to review and critically analyse the event.
- Many centers encourage voluntary reporting in clinical laboratory by eliminating some of the known disincentives and offering confidentiality, anonymity and protection from personal liability.
- Non-punitive reporting is the most important requirement in a successful reporting system.
National Patient Safety & Quality Care Council/Committee

- Evolves policies and guidelines for standards
- Ensure strict quality control
- Recommend and implement action
- Promotes continuous research and education
- Interface between Government and healthcare provider

Medical Advisory Committee

Hospital Board/Regional Authority

Records and analyzes the error
Recommends actions

Laboratory Advisory Committee

Division Head/Lab Manager

Quality Care Council/Quality Care Committee
Physician
Departmental/Divisional Quality Care Committee
Lab Staff

Volunteer Error Incident Report

- APPROPRIATE ACTION RECOMMENDED

ERROR
How Should Error Disclosure Occur?

- Most health care systems have well-established incident reporting systems.
- The technical and support staff are well trained in issuing incident reports that involve interdepartmental problems.
- Reporting an error as an incident does not always lead to disclosure to the patient.
- Pathologists/Laboratory medical directors report an error directly to the patient’s physician first to ensure that the patient receives proper care.
- But, at the same time, they may also discuss the case with risk management staff. Disclosure to the patient usually happens through the clinician with advice of risk management.
A very good error-reporting system in place

- Any member of the staff is encouraged to bring errors and near misses to the attention of an administrator, who then initiates a review
- Findings are discussed in weekly meetings, and all staff involved are notified of changes in the process, if any
- The focus is on process and systems
Error disclosure – Successful initiatives

- Non-punitive
- Confidential
- Independent
- Analyzed by experts
- Timely
- Systems oriented
- Responsive
Emotional impact on healthcare workers

Error coping mechanism: Denial, Discounting & Distancing

Denial: negation of the concept of error

Discounting: defenses which externalise the blame

Distancing: …

First victim: Patient

Second victim: Healthcare workers

… faced with trauma, dilemma and emotions

Seek adequate support from the institutions to deal with the situation
Quality Care Council

Objective:
- Quality & patient safety improvement
- Evaluate trends & recommend corrective actions
- Implement voluntary reporting system

Canadian Patient Safety Institute (CPSI) 2003:
- Independent, non-profit body
- Promotes patient safety among health care partners, and general public
- Interface between health care organizations and Govt.
National Quality Forum

The NQF endorses a set of safe practices that are considered fundamental to quality care.

Elements of an effective Disclosure Support System

- Education to care providers and other healthcare workers
- 24-hour availability of coaching /mentoring
- Emotional support available to healthcare workers, patients, families of patients
- Institutional support of disclosure to care provider
- The disclosures cannot be used as evidence of guilt regarding the event described in the disclosure
• University of Michigan

• In five years since implementing full disclosure program:
  – Annual litigation costs:
    • $3 million $1 million
  – Average time to resolution of claims:
    • 20.7 months 9.5 months
  – Number of claims and lawsuits
    • 262 114
Conclusions

• Human beings will always make errors
• Errors are common in medicine
• Naming and blaming have no remedial value
• We need to design health care systems that put safety first (First, do no harm)
• We know a lot about how to do that
• It’s a long, never ending job
Core Beliefs of Just Culture

• We all make mistakes
• We tend to drift from what we are taught
• Our sense of risk diminishes over time when no adverse outcomes occur
• We are accountable for actions regardless of the outcome
• We must use our values to evaluate behaviors and systems
“The paradox of modern quality improvement is that only by admitting and forgiving error can its rate be reduced”
THIS PROBABLY ISN'T GOING TO MEAN MUCH TO YOU... BUT WE TOOK YOUR BRAIN OUT AND MISPLACED IT!
Thank you
To Err is Human

- IOM releases report *To Err is Human* (2000)
  - Estimates 44,000 to 98,000 unnecessary deaths each year due to medical error
  - Estimated 1,000,000 excess injuries due to medical error
  - Numbers based on the MPS and extrapolated to the general population
Pre-analytical errors

- Requisition incorrect
- Patient injured during phlebotomy
- Patient unhappy with phlebotomy customer service
- Primary specimen or aliquot mislabeled or unlabeled
- No specimen collected
- Incorrect tube used or "order-of-draw" problem
- Specimen suboptimal or ruined
- Specimen lost or delayed in transport
- Specimen delayed or lost in the laboratory
- Failure to order, add, or modify a test
- Data entry error or other information systems problem
"Death by Decimal"

Oprah Winfrey's "Outrageous Medical Mistakes" uses the phrase "death by decimal," which kills seven to ten thousand people a year.

– E.g. a patient gets 10 milligrams instead of 1.0 milligram.
What would work better?

- The problem is not bad people
- The problem is that the system needs to be made safer.
One technique uses “CUS” words

- I am Concerned
- I am Uncomfortable
- This is a Safety issue
# Pre-analytical errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Patients’ samples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inappropriate sample</strong></td>
<td></td>
</tr>
<tr>
<td>Unlabelled specimen</td>
<td>98</td>
</tr>
<tr>
<td>Groosly haemolyzed</td>
<td>3</td>
</tr>
<tr>
<td>Inappropriately labelled specimen</td>
<td>15</td>
</tr>
<tr>
<td>No test requested</td>
<td>1</td>
</tr>
<tr>
<td><strong>Inappropriate form</strong></td>
<td></td>
</tr>
<tr>
<td>Incomplete form</td>
<td>32</td>
</tr>
<tr>
<td>Blood stained form</td>
<td>1</td>
</tr>
<tr>
<td>Unlabelled form</td>
<td>14</td>
</tr>
<tr>
<td><strong>Inappropriate volume</strong></td>
<td></td>
</tr>
<tr>
<td>Broken sample</td>
<td>15</td>
</tr>
<tr>
<td>Spilled sample</td>
<td>5</td>
</tr>
<tr>
<td>Insufficient volume</td>
<td>1</td>
</tr>
<tr>
<td><strong>Inappropriate tube</strong></td>
<td></td>
</tr>
<tr>
<td>No request form received</td>
<td>21</td>
</tr>
<tr>
<td><strong>No request form received</strong></td>
<td>1</td>
</tr>
<tr>
<td>Type of error</td>
<td>Sample freq</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Hemolysed Sample</td>
<td>508</td>
</tr>
<tr>
<td>Insufficient Sample</td>
<td>72</td>
</tr>
<tr>
<td>Illegible handwriting</td>
<td>69</td>
</tr>
<tr>
<td>Incorrect identification</td>
<td>44</td>
</tr>
<tr>
<td>Order slip without sample</td>
<td>16</td>
</tr>
<tr>
<td>Empty Tube</td>
<td>10</td>
</tr>
<tr>
<td>Lipemic Sample</td>
<td>7</td>
</tr>
<tr>
<td>Tube broken in centrifuge</td>
<td>6</td>
</tr>
<tr>
<td>Physician’s request order missed</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total Pre-Analytic</strong></td>
<td><strong>736</strong></td>
</tr>
<tr>
<td><strong>Total Analytic and post Analytic</strong></td>
<td><strong>218</strong></td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>954</strong></td>
</tr>
</tbody>
</table>
Active and Latent Errors

Most immediate and proximate error appears to be human error, while the background and provoking errors are system errors, well beyond the individual’s control.

Healthcare errors be viewed in a systemic perspective to bring about effective changes in delivering safe healthcare.
Quality in Australian Health Care Study

- Reviewed 14,179 admissions in 1995
- 16.6% of admissions had an Adverse Event
  - Permanent disability 13.7%
  - Death 4.9%
- 51% of events preventable

Source – Wilson, 1995
Institutional Disclosure Support System

- Emotional support for patients, families, healthcare workers
- Disclosure education/skill building
- Provide disclosure coaching 24/7/365
"Listen up, my fine people, and I'll sing you a song 'bout a brave neurosurgeon who done something wrong."
Conclusions

• Human beings will always make errors
• Errors are common in medicine, killing tens of thousands
• We begin to know something about the epidemiology of error, but we need to know much more
• Naming, blaming and shaming have no remedial value
Human Error

- We are fallible
- We must expect error
- We must examine our systems in terms of choices employees make that can increase risk. (forced functions)
- Systems are designed to get the results they yield

Response to HE Console Learn
At Risk Behavior

- **Highway Driving**
  - Do you always drive the Speed Limit?
  - Do you always stay a few car lengths away?

- **Hand Washing**
  - Do people always perform hand hygiene in between patients?

- **Food in clinical areas**
  - Do you always avoid having coffee at the Main Nursing Desk?

Response to ARB

Coach

Learn
Reckless Behavior

- Behavioral Choice to consciously disregard a substantial and unjustifiable risk.
- Having knowledge that harm is practically sure to occur.
  - Performing a procedure without scrubbing in and draping per standards
  - Treating and caring for patients while intoxicated or impaired by drugs.

Response to RB

Punish
May I have some clarity?

• A signal to others on the team to pause before proceeding is for a team member to declare, “May I have some clarity?”
• This lets other members know that a team member wants to raise safety concerns.
Requirements for success

- Leadership mandate and champions at highest levels.
- Laboratory Directs’ leadership
- Information management support
- Practice driven, not cost driven
- A sense of urgency and a desire for change
Disclosure Performance Gap
Increasingly Evident

• Harmful errors often not disclosed
• When disclosure does take place, often falls short of meeting patient expectations
• Little prospective evidence exists regarding what disclosure strategies are effective
• Impact of disclosure on outcomes unclear
In a Just Culture you will

• Look for the risks around you to protect yourself, coworkers and patients
• Reports errors and safety hazards
• Make suggestions to your supervisor to make the system safer
• Make safe choices by following procedures and processes
How to think of error?

• A systems failure
  – This is the starting point for redesigning the system and reducing error
What would work better?

• Preventing errors and improving safety for patients requires *a systems approach*
  – to modify the conditions that contribute to errors
  – which recognizes people working in health care are among the most educated and dedicated workforce in any industry
IOM Recommendations

- Establish national focus
- Identify and learn from medical errors through mandatory reporting
- Raise standards and expectations
- Implement safe practices
10 Steps for FMEA

1. Review the process
2. Brainstorm potential failure modes
3. List potential effects of each failure mode
4. Assign a severity rating
5. Assign an occurrence rating
6. Assign a detection rating
7. Calculate the risk priority number for each effect
8. Prioritize these failure modes based on the RPN and severity
9. Take action to reduce or eliminate the high-risk failure modes
10. Recalculate the RPN
Role of professionals

- Become active leaders in encouraging and demanding improvements in patient safety.
- Setting standards, convening and communicating with members about safety
- Incorporating attention to patient safety into training programs
- Collaborating across disciplines
- Contribute to creating a culture of safety. As patient advocates, health care professionals owe their patients nothing less.
Patients’ Attitudes about Errors

- Patients conceive of errors broadly
- Desire full disclosure of harmful errors
  - Worry that health care workers might hide errors
## General Attitudes About Disclosure

<table>
<thead>
<tr>
<th>Statement</th>
<th>Medicine</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% agree, US</td>
<td>% agree, Canada</td>
</tr>
<tr>
<td>“NEAR MISSES should be disclosed to patients.”</td>
<td>32%</td>
<td>42%</td>
</tr>
<tr>
<td>“MINOR errors should be disclosed to patients.”</td>
<td>77%</td>
<td>79%</td>
</tr>
<tr>
<td>“SERIOUS errors should be disclosed to patients.”</td>
<td>98% (49% SA)</td>
<td>98% (59% SA)</td>
</tr>
</tbody>
</table>
Active vs. latent error

- **Latent error**
  - greatest threat to safety in a complex system
  - often unrecognized
  - have the capacity to result in multiple types of active errors.
  - *Challenger* accident traced contributing events back nine years
  - Three Mile Island accident, latent errors were traced back two years
Why is medicine so susceptible?

- Lack of awareness to the problem
- "Culture of Silence"
  - Blame and shame mentality
- System constraints
  - Staffing problems
  - Fatigue
  - Knowledge requirements
  - Communication and continuity of care
Six Sigma Process Performance

SD (σ)

- Tolerance

Target

+ Tolerance

Probability

-6 -5 -4 -3 -2 -1 0 1 2 3 4 5 6

.95 .67 .999997
An 81-year-old female maintained on warfarin for a history of chronic atrial fibrillation and mitral valve replacement developed asymptomatic runs of ventricular tachycardia while hospitalized. The unit nurse contacted the physician, who was engaged in a sterile procedure in the cardiac catheterization laboratory (cath lab) and gave a verbal order, which was relayed to the unit nurse via the procedure area nurse. Someone in the verbal order process said "40 of K." The unit nurse (whose past clinical experience was in neonatal intensive care) wrote the order as "Give 40 mg Vit K IV now."
Case Exercise #2

The hospital pharmacist contacted the physician concerning the high dose and the route and discovered that the intended order was "40 mEq of KCl po." The pharmacist wrote the clarification order. However, the unit nurse had already obtained vitamin K on override from the Pyxis MedStation® (an automated medication dispensing system) and administered the dose intravenously (IV). The nurse attempted to contact the physician but was told he was busy with procedures. A routine order to increase warfarin from 2.5 mg to 5 mg (based on an earlier INR) was written later in the day and interpreted by the evening shift nurse as the physician’s response to the medication event. The physician was not actually informed that the vitamin K had been administered until the next day. Heparin was initiated and warfarin was re-titrated to a therapeutic level. The patient’s INR was sub-therapeutic for 3 days, but no untoward clinical consequences occurred.
Case Exercise #2

• What are the systems/processes involved in this incident?
• What were the failure points?
Analysis

• Verbal orders
  – Third party “messengers”
  – Use of abbreviations
• Failure to question unusual orders
• Lack of control over medication availability
Six Sigma Paradigm: DMAIC
Scenario 2: Hyperkalemia

You start an outpatient with hypertension on a new medicine with a common side effect of increasing the potassium level. The patient’s baseline potassium level is normal (4.0). You order a repeat potassium blood test to be drawn the next week, but forget to check the lab results. Two weeks after the patient begins this new medicine they start feeling palpitations and go to the emergency room. In the ER the patient experiences an episode of ventricular tachycardia requiring cardioversion. The patient’s potassium level at the time of this event is 7.5. The patient is hospitalized for four days, and makes a full recovery. The patient returns to your office for a follow-up visit. On reviewing the patient’s chart you see the overlooked labs, which showed the patient’s potassium had risen substantially from 4.0 to 5.6. Had you seen this elevated potassium earlier, you would have stopped the new medicine and treated the hyperkalemia, likely avoiding the life-threatening arrhythmia.
A Comparison of Risks

Risk (per flight) of dying in a commercial airline accident: 1 in 2 million*

Risk (per hospital admission) of dying from a medical error: >1 in 1,000
Deaths due to Medical Error

- 44,000 to 98,000 unnecessary deaths each year
  - More Americans are killed in US hospitals every 6 months than died in the entire Vietnam War
  - Death rate equivalent to three “jumbo” jet crashed every two days
Harvard Medical Practice Study

• >30,000 randomly selected discharges
• 51 randomly selected hospitals in New York State in 1984
  – Adverse events, manifest by prolonged hospitalization or disability at the time of discharge or both = 3.7%
  – Preventable adverse events = 58%
  – Negligence = 27.6%
Harvard Medical Practice Study

- 13.6% resulted in death
- 2.6% caused permanently disabling injuries

- Type of adverse event
  - drug complications = 19%
  - wound infections = 14%
  - technical complications = 13%
Proximity

• It is intuitive to focus on the location where the failure occurred

• “Sharp end” vs. “Blunt end”
  – The “sharp end” is the point at which the failure occurs
  – The “blunt end” is the set of systems and organizational structure that supports the activities at the “sharp end”
Retrospective Analysis

- Sharp End
- Blunt End

- Institution
- Systems
- Procedures
- Organization

Time
Human Error

• Extensively studied in other industries
• Cognitive psychologists divide errors into:
  – Errors occurring in “automatic mode”
    • Slips
      – Occur during fatigue, interruptions, anxiety
  – Errors occurring in “problem solving mode”
    • Mistakes
      – Occur due to incomplete knowledge and the tendency to apply rules to simplify problem solving
Active vs. latent error

- **Latent error**
  - "normalization of deviance"
    - small changes in behavior became the norm
    - additional deviations became acceptable
    - the potential for errors is created
      - signals are overlooked or misinterpreted
      - signals accumulate without being noticed
How likely would you be to disclose this error to the patient?

<table>
<thead>
<tr>
<th>Response</th>
<th>US Medicine</th>
<th>Canadian Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>I would definitely not disclose this error</td>
<td>0.5%</td>
<td>0.6%</td>
</tr>
<tr>
<td>I would disclose this error only if asked by the patient</td>
<td>3.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>I would probably disclose this error</td>
<td>31.8%</td>
<td>22.8%</td>
</tr>
<tr>
<td>I would definitely disclose this error</td>
<td>64.8%</td>
<td>75.3%</td>
</tr>
</tbody>
</table>
What would you most likely say about what happened?

<table>
<thead>
<tr>
<th>Dialogue</th>
<th>US Medicine</th>
<th>Canadian Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your blood sugar went too low and you passed out.</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Your blood sugar went too low because you received more insulin than you needed.</td>
<td>28%</td>
<td>21%</td>
</tr>
<tr>
<td>Your blood sugar went too low because an error happened and you received too much insulin.</td>
<td>71%</td>
<td>78%</td>
</tr>
</tbody>
</table>
How much detail would you most likely give the patient about the error?

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>I would not volunteer any specific information about the details of the error unless asked by the patient.</td>
<td>11%</td>
<td>8%</td>
</tr>
<tr>
<td>You received more insulin than you needed.</td>
<td>36%</td>
<td>31%</td>
</tr>
<tr>
<td>You received 100 units rather than your usual 10 units of insulin.</td>
<td>54%</td>
<td>62%</td>
</tr>
</tbody>
</table>
What most closely resembles what you would say about the cause of the error?

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>I would not volunteer a cause of the error unless the patient asked me.</td>
<td>11%</td>
<td>8%</td>
</tr>
<tr>
<td>This occurred because of a miscommunication about your insulin order.</td>
<td>55%</td>
<td>42%</td>
</tr>
<tr>
<td>My handwriting is sometimes difficult to read. I wrote your order for “10 U” of insulin and the “U” looked like a “0.” Therefore, you received 100 units of insulin instead of 10. This also slipped by our nurse and pharmacist.</td>
<td>34%</td>
<td>51%</td>
</tr>
</tbody>
</table>
What would you most likely say regarding an apology?

<table>
<thead>
<tr>
<th>Dialogue</th>
<th>US Medicine</th>
<th>Canadian Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>I would not volunteer that I was sorry or apologize.</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>I am sorry about what happened.</td>
<td>54%</td>
<td>48%</td>
</tr>
<tr>
<td>I am so sorry that you were harmed by this error.</td>
<td>43%</td>
<td>49%</td>
</tr>
</tbody>
</table>
What would you most likely say about what happened?

<table>
<thead>
<tr>
<th>Dialogue</th>
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<th>Canadian Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your potassium level got too high, which led to a dangerous heart rhythm.</td>
<td>6%</td>
<td>1%</td>
</tr>
<tr>
<td>The new medicine we started caused your potassium level to become too high, which led to a dangerous heart rhythm.</td>
<td>55%</td>
<td>57%</td>
</tr>
<tr>
<td>You had a dangerous heart rhythm because an error happened and we did not notice that the new medicine had caused your potassium to become too high.</td>
<td>40%</td>
<td>41%</td>
</tr>
</tbody>
</table>
Duties of Organization and Employees

- The Duty to Avoid Causing Unjustifiable Risk or Harm
- The Duty to Produce an Outcome
- The Duty to Follow a Procedural Rule
Duty to Produce an Outcome
(system largely controlled by the employee)

• Be to work on time
• Bring badge; Wear badge
• Don’t steal
• Don’t sexually harass
• Don’t use profanity at work
• Don’t look in medical records that aren’t your business
Duty to follow Procedural Rules
(system largely controlled by employer)

- Two patient identifiers
- Hand hygiene
- Pump repair
- Dietary protocols
- Patient restraint
- Medication administration
- Accounting controls
- Controlled substance discrepancies
The Duty to Avoid Causing Unjustifiable Risk or Harm
(placing organizational value or interest in harm’s way)

• Do the right thing for the patient
• Do the right thing for coworkers
• Do the right thing for the family and visitors
• Do the right thing for the organization
Case #1

- Jenna RN works on a very busy Medical Surgical Unit. Jenna is a seasoned nurse with 10 years experience. She has worked for Metropolis Medical Center for 5 years.
- She currently has 4 patients and expecting an admission within 15 minutes. She is in with Mrs. Jones performing a difficult wound care and dressing change.
- The Student nurse comes in and reminds her that Mr. Johnson’s medications are 25 minutes late.
- Jenna is feeling pressured and knows she will have a Medication Error but also will be another 15 minutes with Mrs. Jones.
- Jenna gives the student her PYXIS password and ask if the Student will get Mr. Johnson’s medication and work with her instructor to administer the medication.
- While in the Medication Room the Pharmacy Technician witnesses the Student access PYXIS.
Other Facts

- Hospital established a policy forbidding the sharing of personal passwords to all clinical computer systems 6 years before.
- Jenna was educated on policy at orientation and it is part of the hospital's annual HIPAA training.
- There are four other RN’s working with Jenna and 3 Care Tech’s.
- Jenna has never been disciplined for anything before. She admitted to giving other passwords to people when she was in a bind, but never considered it a big deal.
- The day after Jenna shared her password there was a discrepancy in the controlled substances.
Duty to Follow Procedure

Was the duty to follow the procedure known to the employee?  YES

Was it possible to follow the rule?  YES

Did she knowingly violate the rule?  YES

Did the social benefit exceed the risk?  NO

Social Benefit – Would the greater good be served?

Coach Employee and conduct further at-risk behavior investigation

Did the employee have a good faith but mistaken belief that the violation was insignificant or justified?  YES
Case #2

- Ken works as the unit coordinator in a busy CCU/Telemetry unit. His desk is surrounded by computers and monitors.
- Under the desk is a tangle of wires connecting the equipment to the power source.
- Three days before during some rounds by administration Ken was asked about having his coffee at the desk. Ken apologized and removed it because he was reminded by the VP that the policy was no food or beverage at the desk.
- On this day Ken brought his coffee to the desk because upon arrival the phones were ringing and no one was answering.
- While Ken was entering in orders, a Physician drops 5 records on the desk – they slid and knocked over Ken’s coffee.
- The coffee runs all over the desk into medical records and down through the hole with the power cords. All the computers and monitors pop then go off.
Other Facts

• Electrical Safety is a mandatory annual educational program and condition of employment.

• Ken had been told multiple times not to have his coffee at the desk. Ken understood the risk of damaging our paper records however never considered electrical damage as a risk.

• On the day of the event Ken had been called in on his day off to cover a sick call. He came to the unit and found the phone ringing on several lines because no one was answering the phone.

• Ken stated he just started to work and forgot he had his coffee on the desk.
Duty to Avoid Causing Unjustifiable Risk or Harm

- Was it the employee purpose to cause harm? NO
- Did the employee knowingly cause harm? NO
- Did the behavior represent a substantial and unjustifiable risk? YES
  - Did the employee choose the behavior? YES
  - Should the employee have known they were taking a S&U risk? NO
- Did the employee consciously disregard this substantial and unjustifiable risk? NO

Coach Employee and conduct further ARB investigation.
Case #3

- Ben has been working as a Registrar for about a year and a half.
- Ben sees a friend's name on the census.
- During a lull in registration, Ben accesses the EMR and checks on his friend's condition.
- 2 days later, his manager receives a report from IS on EMR activity from her department. She cross-checks this information with registration activity. She notes that there is a discrepancy between the two reports.
- The manager calls Ben into her office to inquire about his activity in the EMR.
Other Facts

• Ben has gone through the organizations orientation and HIPAA training.
• Ben explained to his manager that this friend is like his brother so he saw no harm in checking in on him.
**Duty to Produce an Outcome**

**Was the duty to produce an outcome known to the employee?**

- **YES**

**Was it possible to produce the outcome?**

- **YES**

**Did the social benefit exceed the risk?**

- **NO**

**Is the rate of failure to produce the outcome within the expectations of those to whom the duty is owed?**

**Helps employee in producing better outcomes or Consider Punitive Action.**

* *Social Benefit – Would the greater good be served?*

**The outcome in this case is protection of patient privacy – do patients expect privacy?**

**YES**

**NO**

**The outcome in this case is protection of patient privacy – do patients expect privacy?**

**Yes**

**No**

**Assist employee in producing better outcomes or Consider Punitive Action.**
Case #4

• Susan is the Nurse Manager of the Med/Surg Unit.
• Susan has recently participated in a patient safety program that discussed Just Culture and improving staff accountability to P&P’s designed to protect patients.
• She decided to block out time to observe staff on the unit. She doesn’t believe her staff is disregarding policies and wants to reassure herself.
• She observes Kelly a nurse with 15 years experience and 10 years at this hospital hanging IV fluids and medications. She does not see Kelly verifying the Patient ID or double checking against the Medication Administration Record.
• As Kelly walks from the Med room to the patient room she is stopped 3 times with questions from other staff.
Other Facts

- Susan retrieved the Med Administration record and went into the patient room to verify the correct IV’s were hung – they were.
- Susan went back to the Policy on Medication Administration and found that the Standard was to check meds in the med room, leave medications in original packing until at bedside and take the Medication Administration Record to the bedside for a second check. Also using the Med Administration Record as a tool in the Patient ID check.
- Susan now plans a random day and block of time each week for similar observations.
- Susan calls Kelly to the office for a discussion.
Duty to Follow a Procedural Rule

Was the duty to follow the rule known to the employee? 
- YES

Was it possible to follow the rule? 
- YES

Did the employee knowingly violate the rule? 
- YES

Did the social benefit exceed the risk? 
- NO

Coach employee and conduct further at-risk behavior investigation.

Did the employee have a good faith but mistaken belief that the violation was insignificant or justified?

Social Benefit – Would the greater good be served?
First Scenario: A non-cognitive error in phlebotomy

- A phlebotomist draws 3 tubes and one tube is the wrong type. The other 2 tubes are the correct type.
- This is an example of a “system problem” – can you think of a solution to prevent this type of slip or lapse from recurring?
Example of an at-risk behavior

- A medical technologist is in a hurry and doesn’t follow the correct protocol for cleansing the skin before drawing blood from the antecubital fossa.
- What do you think is the proper response by the supervisor – console, coach or punish?
Concepts to Know

Behaviors
- At-Risk Behavior
- Reckless Behavior
- Human Error

Duties
- The Duty to Avoid Causing Unjustifiable Risk or Harm
- The Duty to Produce an Outcome
- The Duty to Follow a Procedural Rule
More definitions

• **Slips**
  – action conducted is not what was intended
    - eg. Physician chooses an appropriate medication, writes
      10 mg when the intention was to write 1 mg

• **Mistakes**
  – the planned action is wrong
  – Eg. selecting the wrong drug because the diagnosis is wrong