Reporting Laboratory Errors Without Fear

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What is the number of deaths from Medical Errors in the US each year?
Objectives

- Identify components of an effective Error Management Program
- Improve event investigation and action processes
- Identify ways to foster an error reporting culture without fear
- Explore strategies to coach employees with high error rates
Medical Event Reporting System (MERS)

• How does a MERS fit into the process control for an organization?

• What culture change will be required to adapt a MERS for use in a medical environment?

• How do you get past the fear factor?
Case Study 1: Community Hospital

One day old full term male

- Increasing respiratory rate
- Given antibiotics
- Air transport to community children’s hospital
Case Study 1: Community Children’s Hospital

- Confluent ecchymoses
- Suspected meningitis
  - LP resulted in bleed and LE paralysis
- Subsequent ICH detected
Case Study 1: Community Children’s Lab Results

- PT > 100 sec
- PTT > 100 sec
  - Correction > 100 sec
- Fibrinogen = none detected
- D-Dimer = 2 ug/ml
- Platelet Count 170 K/mcl
Case Study 1:
Reference Lab Results

- PT > 150 sec
- PTT > 150 sec
  - Correction > 100 sec
- Fibrinogen = 165 mg/dl
- D-Dimer = 1 ug/ml
- Platelet count 155 K/mcl
Case Study 1: Heparin Assay

• 4.75 U/ml

• Therapeutic Range .2 -.4 U/ml
Case Study 1: Root Cause

- Heparin 10,000 U/ml used to flush catheter after antibiotic infusion
Case Study 1: Corrective Action

- Hospital temporarily closed for investigation
- Nurse fired and lost license
- Problem solved?
Backbone of a Quality Assurance Program

• MERS
  Medical Event Reporting System
  – Accessible
  – Easy to Use
  – Prompts for Information
  – Responsibility to Report Identified
  – Non-punitive
Medical Event Reporting System (MERS)

- Accidents
- Near Misses
- Dangerous Situations
- Variances and Deviations
Elements of a Good MERS

• ALL errors and variances are reported
  • Non-reprisal system
  • Identify trends and root causes
  • Fix system failures
What is an “ERROR”?

- Can be attributed to an individual’s mistake
- *Unintentional* deviation from a standard practice or procedure

➤ Some systems can be error-prone by design
What is an “ACCIDENT”?

- Unexpected occurrence during the process
- Not directly attributable to deviation from standard procedure

➤ May or may not involve the individual performing the process
What is an “INCIDENT”?

- An occurrence that is external to the immediate process
- Has some impact (major or minor) on that process
- Usually not within the direct control of the affected area

⇒ For example, post donation information
Error Documentation

- Internal report form
  - paper, electronic form
  - user training required
- Efficient mechanism for reporting
  - E-mail, phone (hot-line), LAN
- Unique control number assigned to each error report to allow tracking
Error Detection

- Record Review
- QC Test Results
- Employees
- Internal Audits
- Inspections (External Audits)
- Customers
  - Complaint System
Error Investigation

- Focus on the “root cause” of the error
- Utilize the person(s) involved in the error as well as process experts
- Get all the facts
- Verify, if necessary, with other personnel or through record review
Error Evaluation

- Assess the impact of the error on patient, services, and organization
- Identify the scope of the error -- which results/processes were really affected
- Is this an isolated incident or a systemic problem?
- Is FDA notification required?
Error Prevention

- QA Unit follow up on corrective actions
- Get feedback from process users
- Establish system checks to monitor the performance of the process with the corrective action in place
- Look for similar vulnerabilities in other processes
How Do We Implement an MERS In a Medical Setting?

Change or Improve the Current Culture
Problems With the Current Culture

• Need to assign blame
  – Incident reports
  – Morbidity and Mortality Conference
  – Execute individuals or services
Problems With the Current Culture

- Lack of Standardization
  - Specialties, Attendings
  - Patient Care Units
  - Reluctance to Comply
Freedom of Practice vs. Standardization?
Problems With the Current Culture

• Inconsistent Training and Competency
  – “See one, Do one, Teach one”
  – Training modules are rare
  – Written and practical competency exams are now common in most facilities
  ➤ Small procedures may be the starting point
Impediments to Change

• Tradition
• “Herding Cats”
  – What makes us good is what makes us bad
• Not understanding the need for common goals
  – Million points of veto
Drivers of Change

• Government (Federal)
  – Medicare: Hospital Compare
    • offers data on quality measures in treatments
  – www.hospitalcompare.hhs.gov
Drivers of Change

• Government (Federal)
  – Senate Health, Education, Labor & Pensions Committee (Legislation S. 544)
    – Create patient safety organizations to collect and analyze patient safety data
    – Congress to create system for voluntary, confidential reporting of medical errors without fear of reprisal
Drivers of Change

• Government (State)
  – >20 states have mandatory reporting requirements
  – vary from state to state
    • serious injuries only
    • aggregate data
    • public vs. non-public reporting
Drivers of Change

• Accreditation Organizations
  – JCAHO: National Patient Safety Goals
    • Goal (Patient Identification)
    • Goal (Communication)
  – CAP Checklist
    • Does the laboratory have a procedure for reporting device-related adverse patient events, as required by the FDA?
Drivers of Change

• CAPS- Consumers Advancing Patient Safety

• Get consumers involved
Healthcare Concerns with MERS

- Survey of hospital executives
  - 2/3 believe MERS will discourage reporting of patient safety incidents internally
  - 3/4 believe MERS will encourage lawsuits
  - Confidential reporting systems = greater compliance
Healthcare MERS “Shoulds”

- States that do require reporting should:
  - analyze data to ID trends, best practices
  - refrain from looking at case-by-case
  - clarify definitions of reportable events
  - provide access to anonymous abstracts of reported incidents

» AHA News, March 15, 2005
Implementation of a “Doctor’s Scorecard”

• Utilize claims data to measure individual performance against well-established and generally accepted QA standards based on medical evidence.
  – Wall Street Journal, March 25, 2004
MERS Key Components

- Organizational Culture Acceptance
- Personnel Training
- Detection AND Reporting of Events
- Investigation of Events
- Corrective Action
- Follow-up and Evaluation
- Analysis of Events
- Preventive Action
- Documentation
Action Definitions

- **Corrective Action**: eliminate cause of existing nonconformity to prevent recurrence (reactive)
- **Preventive Action**: eliminate cause of potential nonconformity to prevent recurrence (anticipatory)
- **Remedial Action**: alleviate the symptom of exiting non-conformity (may not prevent recurrence)
Determining a Course of Action…. 
Case Study 1: Community Hospital

- Alternative System Fixes
  - Remove high concentration heparin from the hospital
  - Mix heparin for DVT treatment in the pharmacy
  - Only allow 10 U/ml heparin on the floor
  - Institute a bar-coding system that requires positive ID of drug and patient
Case Study 2: Transfusion Reaction Due to Antibody Screen Error

- Automated antibody screen result negative
- RBCs crossmatched using immediate spin technique
- All units compatible
Case Study 2: Transfusion Reaction Due to Antibody Screen Error

- One hour into transfusion
  - Patient exhibited chills, shaking, headache
- Transfusion Reaction Work-up
  - Extremely weak positive DAT
  - Technique dependent - Some techs may have reported negative DAT
Case Study 2: Root Cause Investigation

- Retested both pre- and post-transfusion specimens using manual technique
  - Both antibody screens were positive
- Retested both pre- and post-transfusion specimens using automated instrument
  - Both antibody screens were negative
Case Study 2:
Root Cause Investigation

Defective reagent used with automated device
Case Study 2:
Action Taken

• Short term - all manual screens
• Notified manufacturer of problem
  – National recall of reagent kit lot
  – Revised production process and materials
• Blood Bank performed duplicate manual testing with all automated screens until new reagents proven effective
Case Study 3: Calculi Loss

- Increased loss of irreplaceable stones
- Initial response: denial, no responsibility
- FMEA ID’d 2 significant error points:
  - 1. Collapsible bin in lab not fully opened
  - 2. Static Electricity build up
    - caused small stones to “fly” off counter onto variegated linoleum
Case Study 3: Action Taken

• Solutions:
  – Anti-static mats
  – Ordered new linoleum from Europe to get proper color/texture

• Results:
  – No recurrence of calculi loss!
Case Study 4: Cytology Lab

• Error: 2 different patient’s cervical brushes were combined into same vial

• Corrective Action: Employee was placed on probation
  – Employee had been error free and high performer for >2 years
Case Study 4: Root Cause Analysis

- Disciplined Employee requested a team to look at process so that she wouldn’t make error again.
Case Study 4: Root Cause Analysis

• Team Investigation:
  – Supplies had changed nearly 2 yrs prior
    – caps no longer attached to brush
  – Change in supply material design increased potential for error
  – Team was surprised more errors hadn’t been made prior to one in question

• Corrective Action: Supplies were changed to better design
• Two traumas received in ED
  – A – head CT revealed ICH
  – B – broken arm

• A to OR
• B to patient care unit

• Addressographs switched
• Request for blood from OR
  – Used addressograph for release form

• Checked blood against addressograph in OR
  – Transfused A pos red cells
• Collected additional labs in OR
  – CBC to hematology
• Critical value called to patient care unit
  – Nurse indicated the value was impossible
  – Patient was sitting up in bed watching TV and eating dinner
• Hematology called blood bank and asked if they were dispensing lots of blood on a patient
  – Blood bank said they had a bad patient in OR

• Patient in OR was O pos
• Patient on PCU was A pos
• Patient expired
  – Sentinel event
  – FDA report
  – CMS investigated
• New policy for identifying patients in OR
  – Move band to another extremity
  – Tegaderm label on forehead, shoulder, etc.

• No samples accepted for crossmatch with addressograph labels
Labeling Nightmares - 1

- Mandatory training module (with quiz) for all employees involved in patient transfusion (RNs, anesthesia, house staff)
  - Included new policies and processes
  - Symptoms of transfusion reactions
  - Emphasized that misidentification of sample or patient was primary cause of hemolytic transfusion reactions
• Two brothers in hospital at same time for transplant
  – One was the patient
  – One was the donor

• Both had same last name
• Both first names started with the same letter
• One week after transplant Blood Bank received new sample for crossmatch
• Labeled with the wristband sticker from the donor
• Donor had been discharged from hospital 5 days earlier
• Pre-made labels from donor wristband
  – Labels still at nursing station
  – PCU collected sample from patient was labeled at the nursing station

• “Didn’t need to check armband because we know our patients”
• Sample came to the laboratory for type and screen.

• Blood type changed.

• Patient still in hospital but on different patient care unit.
Labeling Nightmare -3 continued:

• Tube had been pre-labeled, not used.

• Wrong blood in tube.

• Education regarding pre-labeled tubes.
Reduce Fears by……

• Hardwiring Error Reporting

• Including Employees in finding solutions

• Emphasizing quality patient care

• Rewarding for improvement
Employees with High Error Rates

• Same type of error?
• SOP clear?
• Training adequate?
High Employee Error Rates Continued

• What was happening at time of event?

• Staffing adequate?

• What external forces are impacting performance?
Involving Employee in Analysis of Error

• Include Employee in discussion of incident

• Have Employee evaluate why the error occurred

• Have employee participate in improvement team or RCA
Coaching Employees with High Error Rates

- Crucial Conversation regarding issues
- Praise what they do well
- Discuss performance issues ongoing
- Team them up with employees with low error rates
When Errors result in disciplinary action

- Blatant disregard for SOP or process
- Consistent Poor Judgment with Adequate Training
- Repeat of same Error over and over
Summary

- Goal of MERS:
  - ID problems so operations and quality can be improved
- Cultural buy-in
- Non-punitive or just culture
- Define MERS and train
- Classify, trend and analyze reported events
- Implement corrective and preventative actions
MERS Rewards

- High Quality Patient Care
- Improved Processes
- Improved Employee Satisfaction
- Must do’s re: employees with high error rates:

  - Crucial conversations with employees
  - Actively involve employees
  - Mentor employees
  - Evaluate right fit for department/lab?
Rewards of Coaching:

- Retain Employee
- Cultural Buy-in
- Improve Quality
If you always do ....
....what you’ve always done

You will always get ....
.... what you’ve already got!