ARUP® LABORATORIES

NATIONAL REFERENCE LABORATORY

ARUP LABORATORIES

Reporting Laboratory Errors Without Fear

February 10, 2014

Errors in Medicine

- 98,000
- 210-440,000
- 44,000

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)

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

Labeling Nightmares - 1

- Two traumas received in ED
  - A – head CT revealed ICH
  - B – broken arm
- A to OR
- B to patient care unit
- Addressographs switched

Labeling Nightmares - 1

- Request for blood from OR
  - Used addressograph for release form
- Checked blood against addressograph in OR
  - Transfused A pos red cells

Labeling Nightmares - 1

- 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

Labeling Nightmares - 1

- 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

Labeling Nightmares - 1

- Patient expired
  - Sentinel event
  - FDA report
  - CMS investigated

Labeling Nightmares - 1

- 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

Labeling Nightmares - 2

- 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

Labeling Nightmares - 2

- 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

Labeling Nightmares - 2

- 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”

Labeling Nightmares - 3

- 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

Summary Continued

- 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!

ARUP® LABORATORIES

NATIONAL REFERENCE LABORATORY