Development of Non-Conforming Event Risk Management Program for Laboratory Errors

Margaret Grabowski, MLT and Andrea Park, MLT, CSSGB, CQIA (ASQ)

Past

Present

Future

LABORATORY ERRORS
PATIENT SAFETY
RISK MANAGEMENT
RETURN OF INVESTMENT

HISTORY: DEVELOPMENT OF NON-CONFORMING EVENT RISK MANAGEMENT PROGRAM FROM LABORATORY ERRORS
### HISTORY: WHAT WE HAVE DISCOVERED

**"To Err is Human: Building a Safer Health System"**

#### EVERY YEAR IN THE USA:
- 43,458 Deaths due to Motor Vehicles
- 42,297 Deaths due to Breast Cancer
- 16,516 Deaths due to AIDS

<table>
<thead>
<tr>
<th>Year</th>
<th>Motor Vehicles</th>
<th>Breast Cancer</th>
<th>AIDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>43,458</td>
<td>42,297</td>
<td>16,516</td>
</tr>
<tr>
<td>2002</td>
<td>43,500</td>
<td>42,357</td>
<td>16,528</td>
</tr>
<tr>
<td>2003</td>
<td>43,550</td>
<td>42,417</td>
<td>16,540</td>
</tr>
<tr>
<td>2004</td>
<td>43,600</td>
<td>42,477</td>
<td>16,552</td>
</tr>
<tr>
<td>2005</td>
<td>43,650</td>
<td>42,537</td>
<td>16,564</td>
</tr>
</tbody>
</table>

#### MEDICAL ERRORS IS THE 8TH LEADING CAUSE OF DEATH IN USA

**LABORATORY ERRORS:**
- Frequency of occurrence
- Relative frequency of lab errors – 0.47% – 1/200 tests
- Pre-analytical errors – 68.2%
- Analytical errors – 13.3%
- Post analytical errors – 18.5%

#### LOS 2005

**$17 - $29 billion**

- **LOST DUE TO MEDICAL ERROR**
- **COST OF HEALTHCARE**
- **$264 MILLION – $3.828 BILLION**

- **COST OF LABORATORY ERRORS**

#### PAST

**To Err is Human**

<table>
<thead>
<tr>
<th>Year</th>
<th>Medical Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
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<td>2012</td>
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<tr>
<td>2013</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td></td>
</tr>
</tbody>
</table>

#### HOSPITALS: WHAT WE HAVE DISCOVERED

**"To Err is Human: Building a Safer Health System"**

- Congressional hearings and task force on patient safety
- $50 millions annually appropriated to the Agency for Healthcare Research and Quality to support a variety of efforts targeted at reducing medical errors
- Patient Safety and Quality Improvement Act of 2005 (Act)
- Canadian Patient Safety Institute
- Institute for Healthcare Improvement (IHI) (Accreditation)
- Accreditation Canada (Accreditation) enhanced accreditation program focused on patient safety and quality improvement
HISTORY: WHAT WE HAVE DISCOVERED
"To Err is Human" – Report Message

RISK MANAGEMENT

- Preventing Error
- Recognizing Error
- Mitigating from Error

STRATEGIES

1999
$14.5 BILLION
Healthcare lost due to Medical error

PREVENTING
RECOGNIZING
MITIGATING

PAST

REALITY CHECK

In 1999,
$14.5 BILLION
Healthcare lost due to Medical error

HISTORY: WHAT WE HAVE DISCOVERED
"Crossing the Quality Chasm; A New Health System for XXI Century" – Recommendations

PAST

NATIONAL CENTER FOR PATIENT SAFETY

PATIENT CENTERED CARE (PCC)

CONSUMERS

CULTURE OF SAFETY

PROFESSIONALS

REALITY CHECK

From 1999 to 2001,
$43.5 BILLION
Healthcare lost due to Medical error

15 YEARS LATER: WHERE DID WE FAIL

LABORATORY ERRORS REVIEW

<table>
<thead>
<tr>
<th>Carro and Plebani</th>
<th>Julie A. Hammerling</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>2010/2011</td>
</tr>
<tr>
<td>Preanalytical Errors</td>
<td>68.2% - 68.3%</td>
</tr>
<tr>
<td>Analytical Errors</td>
<td>13.3% - 7%</td>
</tr>
<tr>
<td>Postanalytical Errors</td>
<td>18.5% - 4.1%</td>
</tr>
</tbody>
</table>

REALITY CHECK

From 1999 to 2015
$232 BILLION
Healthcare lost due to Medical error
15 YEARS LATER: WHAT DID WE LEARN

WE CANNOT SOLVE OUR PROBLEMS WITH THE SAME THINKING WE USED WHEN WE CREATED THEM

- Albert Einstein

15 YEARS LATER: WHERE WE ARE TODAY

LAB TESTS INFLUENCE ABOUT 70% OF MEDICAL DECISIONS

The public assumes lab results are correct and improper oversight and lab failures put patients at risk of harm

$232 BILLION

Healthcare lost due to Medical error

PROVINCE OF ONTARIO LABS ACCREDITED AGAINST
ISO15189: Medical Laboratories Requirement For Quality and Competence

- American Association for Laboratory Accreditation (A2LA)
- College of American Pathologists (CAP)
- The Joint Commission
- Commission on Office Laboratory Accreditation (COLA)

15 YEARS LATER: WHERE WE ARE TODAY

Lab Accreditation and Certification
15 YEARS LATER: WHERE WE ARE TODAY

Patient Safety

React to Proactive
Measure of Improvement

Laboratories have developed:
- Systems of Monitoring
- Incident Reporting
- Non-Conforming Event Programs

What Is Risk Management And Why Is Applying Risk Management Strategies To Laboratory Errors Important?

Action and/or inaction

Action of tomorrow – Prevention

Development of an NCE Risk Management Program

- Conduct survey across your laboratory’s physician population to determine the weight of the NCE according to the severity:
  - Low, Medium, High
  - Sample size calculations (i.e., Roseth™)
  - Calculated probability of NCE to occur

Use of risk quantification in preventive action
LEVEL OF IMPACT TOWARDS PATIENT CARE

<table>
<thead>
<tr>
<th>NCE IMPACT</th>
<th>NCE OCCURRENCE CATEGORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>Missing/lost/misplaced sample</td>
</tr>
<tr>
<td></td>
<td>Mislabeled specimen/patient misidentification</td>
</tr>
<tr>
<td></td>
<td>Incorrect storage/transport</td>
</tr>
<tr>
<td></td>
<td>Equipment/reagent failure impacting report of incorrect or delayed results</td>
</tr>
<tr>
<td></td>
<td>Delayed reporting of abnormal/critical results</td>
</tr>
<tr>
<td>MEDIUM</td>
<td>Expired sample container, media kit, collection devices</td>
</tr>
<tr>
<td></td>
<td>Specimen preparation error</td>
</tr>
<tr>
<td></td>
<td>Misdirected reports to wrong physician office</td>
</tr>
<tr>
<td></td>
<td>Equipment/material recall</td>
</tr>
<tr>
<td></td>
<td>Result of testing verified prior to QC run completion</td>
</tr>
<tr>
<td>LOW</td>
<td>Data entry errors other than patient misidentification/results</td>
</tr>
<tr>
<td></td>
<td>Delay of normal results report</td>
</tr>
</tbody>
</table>

Probability of potentially serious NCEs according to examination phase (pre analytical/analytical/post analytical)

What is Probability?
"Likelihood" of potentially serious NCE to occur
(1 frequent/Occasional/Rare/Isolated)

How is Probability determined?
- Review of laboratory historical data

% Probability of Occurrence of Potentially Serious NCEs by NCE Occurrence Category/Month (Example)
15 YEARS LATER: WHERE WE ARE TODAY
Development of an NCE Risk Management Program

Divide # of NCEs per potentially serious event occurrence category by the total number of NCEs generated and multiply by 100 to determine the % probability of serious occurrence (Frequent/Occasional/Rare/Isolated).

Example:
10 NCEs related to incorrect storage/transport divided by total NCEs month (e.g., 100) x 100 = 10%
According to Pre-analytical NCE Probability of Occurrence Table (on previous slide) the number of incorrectly stored/transported samples would be occasional probability (8.5 – 10.5%).

<table>
<thead>
<tr>
<th>Probability</th>
<th>NCE Occurrence MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>FREQUENT</td>
<td>&gt;10.5%</td>
</tr>
<tr>
<td>OCCASIONAL</td>
<td>8.5 – 10.5%</td>
</tr>
<tr>
<td>RARE</td>
<td>6 – 8.4%</td>
</tr>
<tr>
<td>ISOLATED</td>
<td>&lt;6%</td>
</tr>
</tbody>
</table>

PRESENT

Example:
10 NCEs related to incorrect storage/transport divided by total NCEs month (e.g., 100) x 100 = 10%
According to Pre-analytical NCE Probability of Occurrence Table (on previous slide) the number of incorrectly stored/transported samples would be occasional probability (8.5 – 10.5%).

15 YEARS LATER: WHERE WE ARE TODAY
Development of an NCE Risk Management Program

CALCULATING LEVEL OF RISK (SAFETY ASSESSMENT CODE)

- Determine level of impact on patient care (Risk Level) according to potentially serious event occurrence category
- Correlate % probability of NCE potentially serious event occurrence by level of severity (weight) to determine Safety Assessment Code

Incorrect storage/transport = Pre-Analytical Error

Safety Assessment Codes (SAC)

<table>
<thead>
<tr>
<th>Probability Of Occurrence = Occasional</th>
<th>Safety Assessment Code</th>
<th>Weight of NCE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>Frequent</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Occasional</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Rare</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Isolated</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

PRESENT

Safety Assessment Code = 3
Probability Of Occurrence = Occasional
Severity (Weight) = High

PREVENTION AND RISK MITIGATION OF POTENTIALLY SERIOUS NON-CONFORMING EVENTS

Next Steps…

Trending and Continuous Process Improvement

Example: All NCEs relating to storage/transport in the month of analysis = SAC level 2

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Risk type</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low Impact to Patient Care</td>
<td>Monitoring for effectiveness of corrective action</td>
</tr>
<tr>
<td>2</td>
<td>Medium Impact to Patient Care</td>
<td>1. Correct/Preventive Action (CAPA) and follow-up on NCE to be performed as per discrepancy occurrence management program 2. Improvement Plan to be developed on NCE occurrence category trend and implementation</td>
</tr>
<tr>
<td>3</td>
<td>High Impact to Patient Care</td>
<td>1. Correct/Preventive Action (CAPA) and follow-up on NCE to be performed as per discrepancy occurrence management program 2. Improvement Plan to be developed on NCE occurrence category trend and implemented ASAP</td>
</tr>
</tbody>
</table>
## Development of an NCE Risk Management Program

### Continuous Process Improvement

- Patient Centered
- Total Employee Involvement
- Process Oriented
- Strategic and Systematic
- Leadership Commitment

### Invention of Magnifying Glass

- 423 BC

### Invention of Microscope

- XVII Century

### iPhone with Human Tissue

- 2015

### Monthly NCE Log

<table>
<thead>
<tr>
<th>NCE Log</th>
<th>Examination Occurrence Category</th>
<th>Month</th>
<th>NCE/Type</th>
<th>Total NCE</th>
<th>Probability (as per phase)</th>
<th>Severity</th>
<th>SAC Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing/lost samples</td>
<td>13%</td>
<td>Frequent</td>
<td>High</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mislabeled samples</td>
<td>4%</td>
<td>Isolated</td>
<td>High</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Improvement Plan: Description and Action Steps:**

<table>
<thead>
<tr>
<th>Responsible Individual</th>
<th>Anticipated Completion of Action Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4/16</td>
</tr>
</tbody>
</table>
15 YEARS IN THE FUTURE
Where do we go from here?

- New Version Released in Sept 2015
- Most likely other standards including labs will adopt changes

KEY CHANGES
Clause 6.1.1 and 6.1.2 Applying Risk Based Thinking
Clause 5.1.1 Leadership commitment to embrace Quality

15 YEARS IN THE FUTURE
Where do we go from here?

WHAT IS RISK BASED THINKING?

- The context is everything
- Types of risk based thinking

Organizational Risk  Strategic Risk  Compliance Risk  Operational Risk

15 YEARS IN THE FUTURE
Where do we go from here?

HOW TO APPLY RISK BASED THINKING?

- Start small
- Include risk concepts in your laboratory’s management review
- Involve your employees
16 YEARS IN THE FUTURE
Where do we go from here?

TOP MANAGEMENT COMMITMENT TO EMBRACE QUALITY

- Accountability
- Quality objectives are compatible with organizational strategy
- Ensuring resources needed for Quality Management System are available
- Promoting continual improvement

RETURN ON INVESTMENT (ROI)

Recapture of Lost Resources

1 = 15 + 77 + Pituitary computed tomography scan + Inappropriate treatment
RETURN ON INVESTMENT (ROI)
Recapture of Lost Resources

<table>
<thead>
<tr>
<th>Resource Required</th>
<th>Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlebotomist</td>
<td>1.29</td>
</tr>
<tr>
<td>Materials</td>
<td>1.29</td>
</tr>
<tr>
<td>Accessioning Technician</td>
<td>0.04</td>
</tr>
<tr>
<td>Laboratory Technologist (MLT)</td>
<td>0.72</td>
</tr>
<tr>
<td>Analyzer</td>
<td>0.72</td>
</tr>
<tr>
<td>Error Investigation</td>
<td>18.66</td>
</tr>
<tr>
<td>Error Reporting</td>
<td>3.11</td>
</tr>
<tr>
<td>Supervisor Investigation and Report</td>
<td>3.9/5 min; 70.14/90 min</td>
</tr>
<tr>
<td>Error-related activities Total</td>
<td>37.71 average (29.92/5 min; 96.16/90 min)</td>
</tr>
</tbody>
</table>

2011 Sunnybrook Hospital – Total Cost of Laboratory Error = 5 Months of FTE

SCIENTIFIC LITERATURE REPORTS
2005 - Loss of specimen (due to misidentification) - $712 per specimen; $280,000 per million samples tested

RETURN ON INVESTMENT (ROI)
Recapture of Lost Resources

<table>
<thead>
<tr>
<th>Error</th>
<th>Error Related Activities (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-examination patient demographic error</td>
<td>20</td>
</tr>
<tr>
<td>Pre-examination labeling error</td>
<td>40</td>
</tr>
<tr>
<td>Examination mechanical</td>
<td>400</td>
</tr>
<tr>
<td>Examination mechanical indexing required</td>
<td>900 – 1000</td>
</tr>
<tr>
<td>Patient recall for test and retest</td>
<td>200</td>
</tr>
</tbody>
</table>

COST OF ERROR
Recapture of Lost Resources

Patient
- Prolonged treatment
- Physical/emotional distress
- Extended hospital length of stay (LOS): *
- Financial loss: days of work, transport, child care, purchase of incorrect medication

Personnel/Organization
- Loss of time
- Inappropriate allocation of resources
- Decrease of morale
- Decrease of productivity
- Loss of revenue due to withdrawal of the client

* LOS average 4.5 days - cost $10,400/stay
POSITIVE OUTCOME OF ROI ENSURED BY RISK BASED THINKING

- Risk Management of laboratory occurrences
- Increased Patient Safety – impact on clinical outcome by providing quality results
- Efficiency – allocation and relocation of resources
- Customer retention
- Increased personnel satisfaction
- Increased productivity
- Compliance with regulations

$232 BILLION

DEVELOPMENT OF NON-CONFORMING EVENT RISK MANAGEMENT PROGRAM

$232 BILLION

ACKNOWLEDGMENTS

This presentation was inspired by the patients past, present and future!

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