Incorporating Patient Safety in the Clinical Laboratory

Stephanie Blackburn, EdD, MLS(ASCP)CM
LSU Health Shreveport

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- Patient is at a meeting at work where he begins experiencing severe chest pains
- Ambulance arrives in 10 minutes
- Quickly triaged
- Physician orders labs
- Phlebotomist collects blood

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What happens next…

- MLS runs labs and results sent to ED within 30 minutes
- Several results were **critical values**
- **What do we do with a critical value?**

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Calling the critical value…

- MLS calls ED
  …There was no answer
- 5 minutes later, MLS calls again
  …There was no answer
- ED very busy! The lab results were mixed in with other papers on desk in ED

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And the patient waits…

- Nurse checked on patient every 20 minutes, telling him they were waiting for the lab results
- Waiting for labs before providing treatment
- MLS got busy with another trauma and forgot to call again about the critical value

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90 minutes later…

- Patient found unresponsive in his bed after never receiving treatment
- Code blue called and CPR started

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Diagnostic errors – an ongoing concern

- 13.8 billion lab tests reported in 2017
- Most individuals will experience at least one diagnostic error in their lifetime
- Every 9 minutes, someone in a U.S. hospital dies due to a delayed or incorrect diagnosis
- 12 million adults/year in outpatient setting will experience a diagnostic error

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Most people will experience at least one diagnostic error in their life

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Objectives

1. Review current initiatives to ensure patient safety in the clinical laboratory setting.
2. Discuss laboratory-related diagnostic errors.
3. Explain how laboratory professionals can impact patient safety.

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"Do no harm"

- Where humans are involved, there will be mistakes
- Certain level of trial-and-error that is acceptable for patient diagnosis
- Laboratory professionals often feel removed from direct patient care

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Essential Role of the Laboratory

~70% of all health care decisions involve laboratory testing

~10% of all diagnoses are not considered final until laboratory testing is complete

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What is patient safety?

Integral component in health care

- Assessment
- Diagnosis
- Treatment

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What is patient safety?

- Focuses on preventing errors associated with laboratory services
- Striving to improve care for the patient

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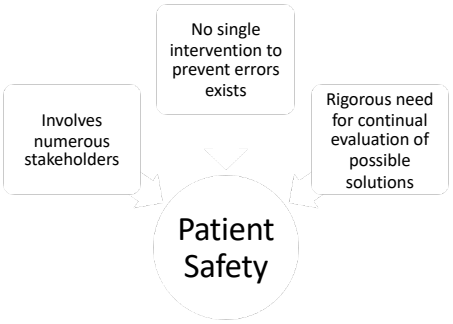

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"Medical Laboratory Professionals are stewards of patient safety and must promote a culture of safety and quality defined by the Institute of Medicine (IOM, now the National Academy of Medicine) as safe, effective, patient-centered, timely, efficient, and equitable practice."

Patient Safety and Clinical Laboratory Science' ASCLS Position Paper.

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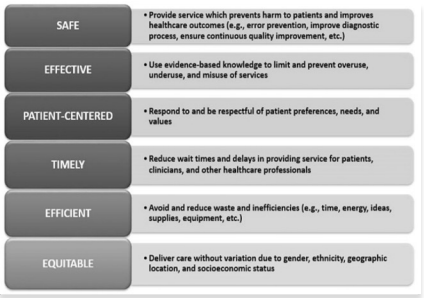

Six Quality Aims for Healthcare

Committee on Quality of Health Care in America. Institute of Medicine. Kohn L, Corrigan J, Donaldson M, eds. To err is human: building a safer health system. Washington DC: National Academy Press; 2000.

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What is the relationship between these aims and the laboratory?

- Focus on all phases of laboratory testing
- Strategic assessment and improvement
- Evaluate each phase based on how it meets each of the six aims
- This in-depth assessment can improve outcomes, quality, and patient safety

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The Laboratory's Role

- Competencies and skills in multidisciplinary teams
  - No longer in "silos"
- Awareness of the impact of laboratory errors on patient care
- Implementation of quality assurance tools

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It is more than just internal laboratory processes

It is the total testing pathway

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Lab plays a role in every aspect of the pathway

Treatment decision

Patient's 1st appointment

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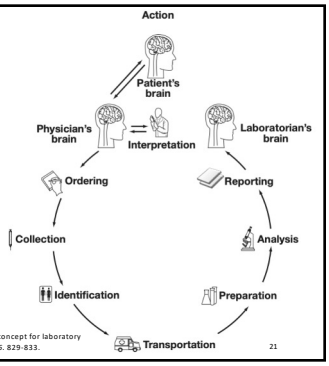
Brain-to-brain loop

Encompasses the steps of the total testing process



From: Plebani, M., Laposata, M., Lundberg, G.D. (2011). The brain-to-brain loop concept for laboratory testing 40 years after its introduction. *American Journal of Clinical Pathology, 136*. 829-833.

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There is a risk of error throughout the process…

The key to patient safety is continually reviewing and monitoring

And taking steps to reduce risk and errors that would negatively impact the patient

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Most errors in this loop do not fall within the analytic phase

Last 30ish years:

- Technological advancement
- Advancement in IT
- Improvements in QC and QA procedures

➢Significant decrease in rate of analytical errors

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Other improvements in the laboratory:

Preanalytics:	• Preanalytic workstations • Less errors involving specimen preparation, centrifugation, aliquoting, pipetting
Postanalytics:	• Interfacing analyzers and LIS • More rapid and effective validation of results • Improved timeliness of result notification

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Where are many errors occurring?

Procedures not performed in the clinical lab or under control of the lab

- Patient/specimen misidentification
- Patient not prepared for specimen collection
- Improper collection
- Incorrect orders
- Delay between collection and receipt in lab
- Misinterpretation of laboratory results
- Delay in critical values reported to physicians

Most of these activities are poorly monitored

Many of the responsibilities fall between the lab and clinical departments

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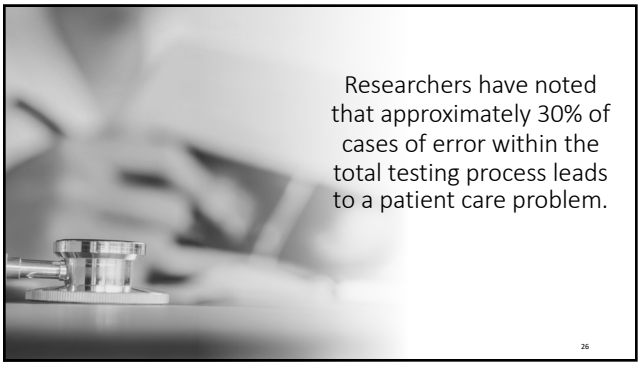

Researchers have noted that approximately 30% of cases of error within the total testing process leads to a patient care problem.

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Errors in the Analytical Phase

- Survey regarding error rates reported by anatomic pathologists and laboratory directors
  - 43.6% serious errors
  - 69.1% minor errors
  - 77.6% near misses

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Errors in the Analytical Phase

- Hemodialysis performed on healthy patient due to erroneously transcribed methanol result
  - 6 mmol/L instead of 0.06 mmol/L
- Incorrectly reported HIV result led to death of three transplant recipients
- Falsely elevated glucometer readings with GPD-PQQ test strips for 82 patients
  - 16 deaths
  - 46 severe hypoglycemia
  - 12 minor hypoglycemia

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Frequency of diagnostic errors compared with lost baggage in airports

Specialty	Frequency (%)
Radiology	4
Pathology	5
Ecography	0.8
Laboratory Medicine	0.3
Luggage lost in airport	0.6

Lippi G, Plebani M. A Six-Sigma approach for comparing diagnostic errors in healthcare-where does laboratory medicine stand? Ann Transl Med. 2018 May;6(10):180. doi: 10.21037/atm.2018.04.02. PMID: 29951502; PMCID: PMC5994534.

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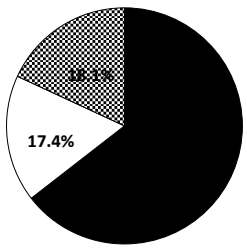
Cross-Sectional Study in 2018

- Examined 21,746 tests in clinical labs
- 304 errors reported



Roy, A. D., & Das, D. (2019). An evaluation of the errors occurring in pathology and microbiology laboratories of a tertiary care teaching hospital and their root cause analyses. *Journal of Health Research and Reviews*, *6*(3), 102.

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Number and Percentage of Errors by Section

Sections	Total number of tests	Number of errors (%)
Hematology	10,424	210 (2)
Cytology	602	10 (1.7)
Histopathology	1202	20 (1.7)
Clinical pathology	4450	18 (0.4)
Bacteriology	1820	21 (1.2)
Serology	2480	24 (1)
Mycology	62	1 (1.6)

Roy, A. D., & Das, D. (2019). An evaluation of the errors occurring in pathology and microbiology laboratories of a tertiary care teaching hospital and their root cause analyses. *Journal of Health Research and Reviews*, *6*(3), 102.

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Distribution of Errors

Section	# Errors	Preanalytical Errors (%)	Analytical Errors (%)	Postanalytical Errors (%)
Hematology	210	142 (46.7)	35 (11.5)	33 (10.9)
Cytology	10	2 (0.7)	2 (0.7)	6 (2)
Histopathology	20	10 (3.3)	6 (2)	4 (1.3)
Clinical Pathology	18	12 (3.9)	2 (0.7)	4 (1.3)
Bacteriology	21	14 (4.6)	4 (1.3)	3 (1)
Serology	24	16 (5.3)	4 (1.3)	4 (1.3)
Mycology	1	0	0	1 (0.33)
Total	304	196 (64.5)	53 (17.4)	55 (18.1)

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Types and percentage of different errors

Preanalytical Error (*n* = 196)	*n* (%)
Inappropriate test request	10 (5.1)
Order entry error	24 (12.2)
Misidentification of patient	8 (4.2)
Container inappropriate	22 (11.2)
Sample collection and transport	27 (13.8)
Inadequate sample/anticoagulant volume ratio	21 (10.7)
Insufficient sample volume	18 (9.2)
Sorting and routing errors	20 (10.2)
Labeling errors	24 (12.2)
Sample misplaced	22 (11.2)

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Types and percentage of different errors

Analytical Error (*n* = 53)	*n* (%)
Sample mix-ups/interference	12 (22.6)
Undetected failure in QC	25 (47.2)
Procedure not followed	10 (18.9)
Equipment malfunction	6 (3.1)

Postanalytical Error (*n* = 55)	*n* (%)
Failure in reporting	13 (23.6)
Erroneous validation of analytical data	12 (21.8)
Improper data entry	20 (36.4)
Wrong reporting	5 (9.1)
Pending reports	5 (9.1)

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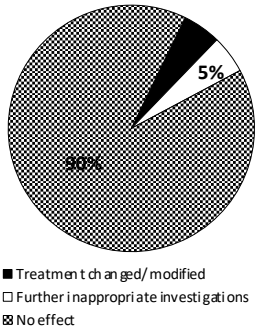
Impact of Errors on Patients



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Root Cause Analysis of Errors

Cause of errors	*n* (%)
Miscommunication between nursing staff and clinician	18 (5.9)
Untrained nursing staff	38 (12.5)
Untrained technical staff	30 (9.9)
Failure of quality indicators	77 (25.3)
Procedure not followed	30 (9.9)
Improper handover of duty between shifts	18 (5.9)
Transcriptional error	75 (24.7)
Lack of skills and knowledge among doctors particularly in cytology, histopathology, and bacteriology	18 (5.9)

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Laboratory professionals are in a position to see the total testing process in its entirety. We recognize potential errors and vulnerabilities within the process.

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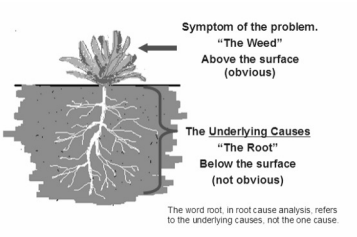
Root Cause Analysis (RCA)

Problem solving technique to identify the root cause of adverse event



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Process of Root Cause Analysis

Meet with interdisciplinary team

- Write out detailed event description, including timeline
- What was the intended process flow?
- Were there any steps that did not occur as intended?
- Human factors, equipment performance, environmental factors, external factors?
- Staff properly qualified and currently competent?
- Staffing appropriate levels? Performance met expectations?
- Appropriate communication occurred?

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Goal of Root Cause Analysis

Establish and implement a Plan of Action/Risk Reduction Strategy

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RCA: Use the "WHY" technique

Event: The turn-around-time for a test was too long.

1. WHY was the TAT too long?	The controls were expired, and testing had to be delayed
2. WHY were there no non-expired controls?	The order did not get shipped in time
3. WHY didn't the order get shipped in time?	The order was not placed on time
4. WHY was the order not placed on time?	The person who normally does the ordering was out sick and there was no one designated as the backup

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Two units of RBCs were taken to the Dialysis unit for transfusion of two different patients. The first unit was hung by one clinical person and started just as another clinical person noticed that the unit that he/she picked up for transfusing another patient had the wrong identifying information. The blood was stopped immediately on the first patient

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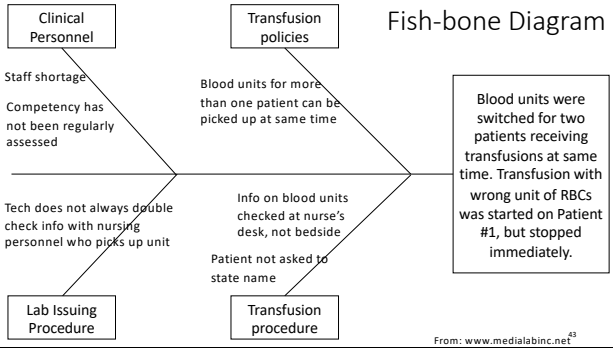
Fish-bone Diagram



From: www.medialabinc.net

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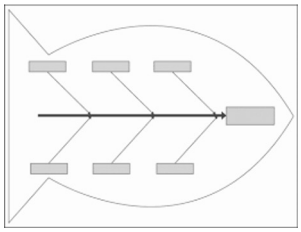
Benefits of a Fishbone Diagram

- Helps determine root cause using structured approach
- Encourages group participation
- Utilizes knowledge from different disciplines
- Indicates possible variations in process
- Indicates areas where more data should be collected



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We need to provide laboratory services that are patient safety-centered

- Information from the lab significantly affects diagnosis and management of patient care
- Enhance safe care outcomes:
  - Error prevention
  - Continual process improvement
- Group effort between laboratory professionals and practitioners
  - Provide service to improve patient's lives during total testing process

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National Academy of Medicine's Patient Safety Competencies

Patient-centered	• Provide care and service that are patient-centered
Evidence-based	• Employ EBP to provide effective healthcare
Quality Improvement	• Apply QI principles to all facets of healthcare
Informatics	• Use informatics to manage and communicate lab information
Interprofessional teams	• Inclusion of laboratory professional to interdisciplinary teams

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Interdisciplinary Teams are Key

- As a laboratory professional, volunteer to serve on interdisciplinary teams in the hospital
- Develop partnerships
  - Trust
  - Open lines of communication
- Mutual accountability and ethical responsibility

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Interdisciplinary Teams

- We need to view laboratory services as more than just generating results
- We contribute to patient outcomes
- 55% missed/delayed diagnoses due to failure to order appropriate tests
- Healthcare providers do not have the same understanding about lab tests
- COLLABORATION IS ESSENTIAL

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Interdisciplinary Teams

- Data demonstrates the importance of laboratory testing and results in clinical decision-making
- Educate and provide guidance for ordering tests
- Provide feedback regarding improper test utilization patterns
- Provide consultation services
- Improve test reporting

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Event Management Systems

- Lab needs a ”reporting culture”
- Captures laboratory errors, errors outside of the lab, and near misses
- Near misses provide excellent quality improvement opportunity

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Patient Safety Advocacy

It is MY ethical duty and responsibility, as a laboratory professional, to protect the safety of our patients

- The PATIENT is our focus
- Help patients and families understand laboratory testing
- Collaborate with other healthcare professionals
- Create a blame-free environment in the lab
- Encourage the study of errors and near-misses
- Improve lines of communication
- Be a lifelong learner

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What can we do, as laboratory professionals?

- Interdisciplinary cooperation
- Patient safety should be core value in lab’s mission
- Help build and support a lab culture focused on patient safety
- Maintain accountability
- Establish zero tolerance for reckless behavior
- Incorporate IOM’s aims in daily practice

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Reliability of laboratory results is an essential part of providing quality healthcare and reducing risk of harm to patients.

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“Laboratory diagnostics is an essential science, which provides a fundamental, virtually inalienable, contribution to the clinical decision making, despite only modestly eroding the available healthcare resources. Unlike other diagnostic areas in medicine, error reduction strategies have now become routine part of comprehensive quality management programs in clinical laboratories and have probably allowed to make laboratory medicine the safest diagnostic discipline in healthcare.”

Lippi G, Plebani M. A Six-Sigma approach for comparing diagnostic errors in healthcare-where does laboratory medicine stand? Ann Transl Med. 2018 May;6(10):180. doi: 10.21037/atm.2018.04.02. PMID: 29951502; PMCID: PMC5994534.

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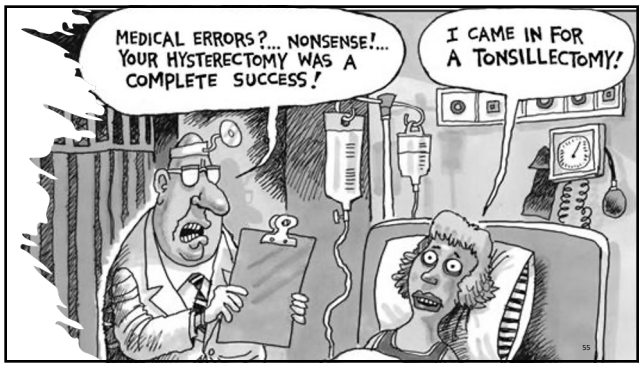

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