

Pre & Post-Analytic Phases— What is Important?

Catherine Otto, Ph.D., MBA, MLS(ASCP)^{CM}
Rutgers University, School of Health Professions,
Division of Clinical Laboratory Sciences
CLEC 2018
February 23, 2018
Houston, TX

Objectives

- Identify common errors that occur in the pre and post-examination phases of laboratory testing.
- Describe two activities to incorporate into didactic, laboratory and clinical courses.
- Create one assignment that addresses pre &/or post examination phases of the laboratory testing process.

Why are we concerned about errors?

- Diagnostic errors estimated to occur:
 - 5% of adults in outpatient setting
 - 10% of patient deaths due to a diagnostic error
 - 6-17% of hospital adverse events due to diagnostic error
- At least one diagnostic error in lifetime

• Source: National Academies of Sciences, Engineering, Medicine *Improving Diagnosis in Health Care 2015*

Potential for Errors in Healthcare

- Multiple, varied interactions with technology
- Many individuals involved in the care; multiple hand-offs for care
- High acuity of illness or injury
- Ambient environment prone to distraction
- Need for rapid decisions; time pressured
- High volume, unpredictable patient flow
- *National Forum for Health Care Quality Management and Reporting*

What is the goal of health care?

Patient Safety

- freedom from accidental injury: avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the process of care"

IOM, To Err is Human, 2000

Health Care Quality

- The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." *IOM, Crossing the Quality Chasm. 2001*

What are the components of healthcare quality?

- **Safe:** "Avoiding harm to patients from the care that is intended to help them"
- **Efficient:** "avoiding waste, including waste of equipment, supplies, ideas and energy"
- **Effective:** "providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit"
- **Patient-centered:** "providing care that is respectful of and responsive to individual preferences, needs, and values and ensuring that patient values guide all clinical decisions"
- **Timely:** "reducing waits and sometimes harmful delays for both those who receive and those who give care"
- **Equitable:** "providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status"

Crossing the Quality Chasm, 2001

Errors in Laboratory Testing Process in Primary Care Setting

- Breakdowns in the following processes:
 - Test ordering, Reporting of results, Patient notification
- Delays in diagnosis
 - Patients do not always receive test result information within 24 hours of physician receipt of test results
- Communication gaps within the Physician Office Practice
 - Lack of defined responsibilities as to who handles test reconciliation and communicating test results with patient
- Errors in judgment & cognition
 - Lead to test ordering errors & errors in test interpretation
- Lack of Patient Centeredness
 - Lack of a systematic & consistent method to inform patients of test results

Source: Smith ML et al. *Arch Pathol Lab Med* 2013; 137: 120-125

Failure to Follow-Up Test Results

- Clinicians fail to follow-up abnormal laboratory test results: 6.8% to 62%
 - Source: Callen JL et al. *J Gen Intern Med* 2011; 27 (10): 1334-48



- Results in missed or delayed diagnosis

Gaps in Laboratory Testing Process in Primary Care

- Test ordering processes
 - Paper copy of test orders
 - Electronic health record
 - Clinical flow sheets & guidelines
- Test tracking processes
 - Lack of tracking system for tests ordered and reconciliation method for orders & test results
- Communicating test results to patients
 - Multiple methods to contact patients
 - 25% of respondents—tell patients: no notification = normal test results



- Source: West DR et al. *J Am Board Fam Med* 2014; 27:

Physicians & Laboratory Testing

- A study of primary care physicians
 - Diagnostic tests ordered for **31.4%** of patient encounters per week
 - Uncertainty about ordering tests **14.7%**
 - Uncertainty about interpreting tests **8.3%**
- Sought assistance/consultation with laboratory professionals **infrequently** **AND** **valued** the consultations when occurred

- Source: Hickner J. et al. *JABFM*, March-April 2014; 27(2): 268-274

Recognition of Laboratory Professionals

- Medical Laboratory Professionals are critical to the diagnostic process!
- “The roles of some healthcare professionals ...have been insufficiently recognized...”
- Patient Safety is the responsibility of **ALL** healthcare professionals



ASCLS Position Paper on Patient Safety

1. Medical Laboratory Professionals are **stewards of patient safety** and must promote a culture of safety defined by the IOM as safe, effective, patient-centered, timely, efficient, and equitable practice.
2. Medical Laboratory Professionals must **incorporate each of these IOM competencies into daily practice**, i.e. provide patient-centered care, employ evidence-based laboratory practice, apply quality improvement principles, use informatics, and work on interprofessional healthcare teams. Medical Laboratory Professionals:
 - Recognize that the **patient** is the focus of our practice;
 - Acknowledge that **evidence-based laboratory practice** is critical to providing effective healthcare;
 - **Apply quality improvement principles** to healthcare processes to reduce opportunities for errors that could harm patients and to improve patient outcomes;
 - **Use informatics** as an essential component of their practice, due to advanced technology of laboratory testing systems and integrated systems to manage and communicate information for laboratory testing systems;
 - **Bring laboratory testing expertise to interprofessional healthcare teams** as they develop and provide standards of care.

ASCLS Code of Ethics— Pledge to the Profession

- As a Medical Laboratory Professional, I pledge to uphold my duty to Patients, the Profession and Society by:
- Placing patients' welfare above my own needs and desires.
- **Ensuring that each patient receives care that is safe, effective, efficient, timely, equitable and patient-centered.**
- Maintaining the dignity and respect for my profession.
- Promoting the advancement of my profession.
- Ensuring collegial relationships within the clinical laboratory and with other patient care providers.
- Improving access to laboratory services.
- Promoting equitable distribution of healthcare resources.
- Complying with laws and regulations and protecting patients from others' incompetent or illegal practice
- Changing conditions where necessary to advance the best interests of patients.

What does NAACLS say? Medical Laboratory Scientist Profession

- "...**collaborate** in the diagnosis and treatment of patients. ...interpretation and evaluation of clinical procedures and results; ...continuous assessment of laboratory services."
- "Medical Laboratory Scientists practice **independently and collaboratively**, ... They have the requisite knowledge and skills to **educate** laboratory professionals, other **health care professionals**, and other in laboratory practice as well as the **public**."

Source: NAACLS Unique Standards, p. 9. www.naacls.org

What does NAACLS say?

- Provide examples of how each course addresses pre-analytical, analytical & post-analytical components for each:
 - Problem-solving
 - Trouble shooting techniques
 - **Interpretation & evaluation** of clinical procedures & results
 - Quality assurance / **Quality improvement**
 - **Continuous assessment** of laboratory services for all major areas practiced in the contemporary clinical laboratory

Source: NAACLS Standards Compliance Guide, p. 26. www.naacls.org

How do we deliver quality healthcare?

- **Work in interprofessional teams**
 - Move from disciplinary silos to collaborative outcomes that are continuous and reliable
- **Practice evidence-based laboratory medicine**
 - Integrate best research with clinical expertise and patient values for optimum care
- **Use information technology**
 - Use electronic data to measure outcomes and support decisions.
- **Focus on quality improvement**
 - Design and test interventions to change processes and systems of care with the objective of improving quality
- **Deliver patient-centered care**
 - Identify, respect, and care about patients' unique knowledge, differences, values, preferences, and expressed needs

A Bridge to Quality, 2002

Diagnostic Process

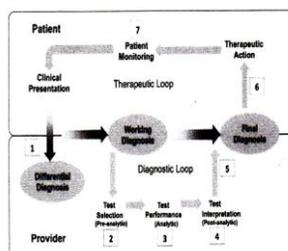
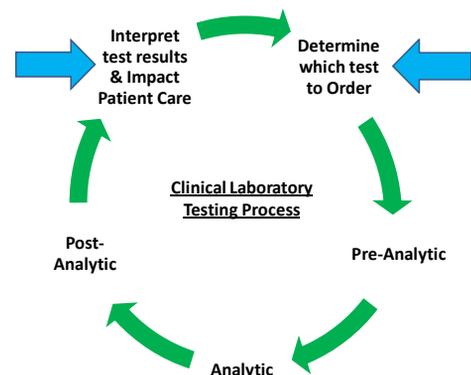
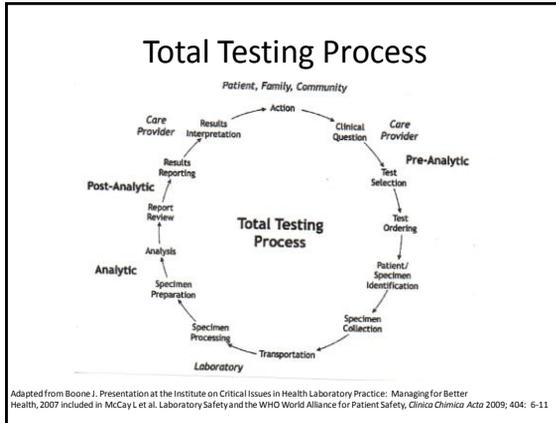


Fig. The conceptual diagram illustrating the diagnostic and therapeutic loops in the diagnostic process.

Thammasitboon S. et al. System-Related Factors Contributing to Diagnostic Errors. *Curr Probl Pediatr Adolesc Health Care* 2013, 43: 242-247





Pre-Analytic Errors

Clinical Question

- Clinical question is inaccurate
- Influenced by
 - Communication by patient
 - Communication by provider
 - Expectations of patient
 - Expectations of provider
 - Clinician experiences
 - Environment in which practicing

Test Selection

- Wrong test is selected
 - Test names are similar
 - Too many choices
 - Obsolete test is listed on the test menu
 - Write in option
- More tests than needed are ordered
 - panels
- No test is ordered

Pre-analytic Errors—Ordering Process

- Wrong test is selected
 - Test names are similar
 - Obsolete test is listed on the test menu
- Wrong name or other identifiers on test requisition
- Wrong physician listed
- Wrong or no diagnosis code listed
- Lack of information—OTC medications & other medications, last dose taken

Pre-Analytic Errors—Specimen Collection

- Patient identifiers
 - Wrong patient—lack of 2 identifiers
- Labeling
 - Unlabelled, mislabeled
- Inaccurate specimen collected
 - Wrong anticoagulant; plasma instead of serum; serum instead of plasma
- Collection procedure failure
 - Multiple attempts—failed attempt
 - Tourniquet—left on too long
 - Needle size—too small
 - IV infusion—specimen collected above an IV, or port not flushed
- Specimen integrity
 - Clotted
 - Hemolyzed
 - Insufficient quantity
 - Quantity too large
 - Lipemic
 - Interferences—contrast media, OTC medications
- temperature (↑, ↓)
- Timing for collection
 - Blood cultures
 - TDM
 - Fasting/Not fasting
- Specimen lost or not received in the laboratory

Post-Analytic Errors

Result Reported

- Sent to the wrong clinician
- Sent after patient discharged from hospital
- Multiple attempts to contact clinician with test results
- Communication not relayed to appropriate care provider
- Communication not relayed to patient

Clinical Answer

- No change in diagnosis
- Inaccurate diagnosis
 - False positive
 - False negative
- Delayed diagnosis

Post-Analytic Errors

Action Taken

- No action, when action required
- Action, when no action required
- Next test improperly ordered
- Next test properly ordered, however delayed
- Inappropriate treatment selected

Effect on Patient Care

- Diagnosis
 - Misdiagnosis
 - Delay in diagnosis
- Treatment
 - No treatment
 - Inappropriate treatment
 - Delay in treatment
- Quality of Life
 - Decrease QOL

1st: Use Patient Centered Language

- Change our language from specimens to **patients**—we are advocates for patients
- Begins 1st day of program—
- Code of Ethics: <http://www.ascls.org/about-us/code-of-ethics>
- Patient Safety Position Paper: <http://www.ascls.org/position-papers/185-patient-safety-clinical-laboratory-science>
- ASCLS A Life Saved: <http://www.ascls.org/promote-the-profession/108-a-life-saved>
- Josie King Foundation: www.josieking.org
<http://www.ihl.org/education/IHIOpenSchool/resources/Pages/Activities/WhatHappenedtoJosieKing.aspx>

2nd: Communication Skills

- Changing how we communicate → dramatic changes → improve patient safety
- TeamSTEPS
 - “Team Strategies and Tools to Enhance Performance and Patient Safety”
- Change in culture
- Use common methods to communicate

TeamSTEPS Model



Instructor Manual Print Components, March 2014, Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/education/curriculum-tools/teamsteps/instructor/printver/index.html>

TeamSTEPS Tools & Strategies

- Huddle
 - Beginning of shift
 - Share information
- CUS
 - I am Concerned
 - I am Uncomfortable
 - This is a Safety Issue

TeamSTEPS Tools & Strategies

- SBAR
 - Situation: What is going on with the patient?
 - Background: What is the clinical background or context?
 - Assessment: What do I think the problem is?
 - Recommendation: What would I recommend?
- Call-Out
 - Leader communicates to all

Use Patient Safety Language Every Day

- Lecture/Laboratory/Clinical:
- List 6 quality components on Board in Lecture & Lab—Ask questions about each during the session
- Huddle at the beginning of Laboratory
- Use Call Out—if there is an unsafe situation
- Use SBAR for case analysis in lecture/laboratory/clinical

Lecture—preanalytic

- Requirements for pre-analytic phase for each test/disease process
- Hematology—CBC
 - When should a CBC be ordered
 - What other tests should be performed at the same time
 - When would performing testing on the specimen be inappropriate
- Hematology—suspected infection—use signs and symptoms
- Hematology—suspected bleeding—use signs and symptoms
- Hematology—suspected anemia—use signs and symptoms
- Hematology—suspected leukemia—use signs and symptoms
- For what conditions is a CBC used to follow treatment
- When is it inappropriate to order a CBC
 - Frequency in hospitalized patients

Lecture—postanalytic

- Requirements for post-analytic phase for each test/disease process
- Hematology—CBC
 - TAT estimate for routine, ASAP, emergent/STAT
 - Based upon test results of CBC what is the next test that needs to be performed
- Hematology—suspected infection—use signs and symptoms
- Hematology—suspected bleeding—use signs and symptoms
- Hematology—suspected anemia—use signs and symptoms
- Hematology—suspected leukemia—use signs and symptoms
- For what conditions is a CBC used to follow treatment
- What happens if testing is not performed in an appropriate timeframe/follow-up
 - Frequency in hospitalized patients

Hematology Example

- A 19 year old woman presents to the ED with fever of 103 F, fatigue, stiff neck for the past 24 hours.
- Identify the appropriate procedures to be performed? What do you expect the results to indicate?
- When would these tests be collected?
- What timeframe should these tests be analyzed and reported?
- Which tests should be performed to follow the progress of this patient?

Lecture—preanalytic

- Requirements for pre-analytic phase for each/test disease process
- Chemistry—electrolytes, liver enzymes, renal function, glucose
 - When should each be ordered
 - What other tests should be performed at the same time
- Chemistry—suspected dehydration—use signs and symptoms
- Chemistry—suspected hypo or hyperglycemia—use signs and symptoms
- Chemistry—suspected liver disease—use signs and symptoms
- For what conditions are electrolytes, liver enzymes, renal function, glucose used to follow treatment
- When is it inappropriate to order electrolytes, liver enzymes, renal function, glucose
 - Frequency in hospitalized patients

Lecture—post analytic

- Requirements for post-analytic phase for each test/disease process
- For what conditions is _____ used to follow treatment
- Chemistry—electrolytes, liver enzymes, renal function, glucose
 - TAT estimate for routine, ASAP, emergent/STAT
 - Based upon test results of _____, what is the next test that needs to be performed
- What happens if testing is not performed in an appropriate timeframe/follow-up
 - Frequency in hospitalized patients

Assignment:

Communicating with Providers & Patients

- Using discussion board in Learning Management System
- Create questions that would be asked by clinicians, nursing or other health care practitioners
- Create questions that would be asked by patients about their laboratory tests (collection & results)
- Specific to discipline & topic
- As part of didactic/lecture component of course

Example for Hematology: Communicating with Providers & Patients

- Hello,
I have recently begun to practice at your facility. Some of your laboratory reports are different than what I'm used to seeing. Can you please explain why WBCs are reported both as % and as absolute numbers. What does the absolute number represent, and how should I use that information?
Thanks,
I.M. Newhere, M.D.
- Hello,
My doctor sent me to the lab for something called a CBC. They sent me a copy of the results, and there are a lot of numbers and letters here that I don't understand. What is this test for?
Mrs. Confused Patient

Example for Laboratory Management: Communicating with Providers

As the Supervisor of the Coagulation Laboratory, you routinely monitor the number of specimens collected for PT/INR that are rejected because the sodium citrate tube is not properly filled. You notice that there is an increase in rejected specimens from the Coagulation Clinic. The Coagulation Clinic is a special outpatient clinic that is supervised by a nurse, who is also responsible for communicating the test results to patients regarding adjustments in their medication.

Describe what information you will communicate and how you will communicate this information with the nursing staff responsible for collecting specimens from this group of patients.

Laboratory

- Use Huddle at beginning of laboratory session
- Call it a 'Huddle'—discuss patient safety issues—behaviors/actions that either caused an error or a near-miss
- Require pre-analytical & post-analytical questions for every analytical procedure

Activities for Student Laboratory

- Specimen: name, birth date, requisition, physician, ICD-10 code &/or signs & symptoms
- Complete report form as similar to 'real laboratory' experience
- Use LIS if possible
- Require for each laboratory assignment: specimen requirements, description of specimen integrity issues, interpretation of test results, next tests to be performed based upon the information, what does the test result mean & possible diagnosis

Activities for Student Laboratory

- Laboratory Practical—more than analytical component—entire process (each discipline)
- Create situations where there are problems that have to be solved:
 - Specimen integrity issues
 - Requisition not match patient name
 - Test results require phoning clinician
- Meet expected turn-around-times
- Require interpretation of test results, next tests to be ordered
- Require communication with clinician, nursing staff

Activities for Student Laboratory

- Simulate a clinical laboratory:
- Create separate areas in the laboratory
- Teams—clinicians, nurses, CORE laboratory, microbiology, transfusion services
- Set this up so that need to use TeamSteps concepts

Activities for Laboratory Management

- Quality Improvement Principles & Processes
- Set up a QI Committee (group project)
- Give students patient safety events to evaluate
- Assign roles
- Cases available:
- Patient Safety Network WebM&M
– <https://psnet.ahrq.gov.webmm>

Activities for Education Activity

- Develop a Patient Information Product or Clinician Education Program
- Group project—focus on patient-centered care or product/program to educate clinicians
- Product to inform patients about laboratory test results/preparation for specimen collection
- Programs on point of care testing, specimen collection, new laboratory test

ASCLS Patient Safety Tips Flyers— Vitamin D

What is considered a normal Vitamin D level?

There is some debate over this, but general health guidelines include that the measure should be 20-50 ng/mL. The high end of normal is about 40-50 ng/mL. Some tests may be higher than what you know.

If my Vitamin D level is below normal, what will my doctor do?

If a test to have this conversation with your doctor, because every patient is different, but he or she may prescribe Vitamin D supplementation. Follow-up Vitamin D testing may not be indicated as the supplementation is considered safe without monitoring.

If my doctor does not order a Vitamin D test, should I ask to have it done?

Routine screening for Vitamin D is not recommended for the general population who are not at risk of deficiency due to another primary

I've heard there are two "types" of Vitamin D. What is the difference between the two?

One provides a better indication of how much Vitamin D is available for your body to use because it is more stable. This type is called 25-hydroxy Vitamin D.

The other type is called 1,25-dihydroxy Vitamin D, and is not a good indicator of Vitamin D status. But may be ordered if your doctor suspects you have severe kidney disease or low amounts of an enzyme that changes the 25-hydroxy Vitamin D to 1,25-dihydroxy Vitamin D.

Testing for both types of Vitamin D at the same time is not required or appropriate.

If I want more information, what is a reputable resource?

<https://labtestsonline.org>

ASCLS
The American Society for
Clinical Laboratory Science

Activities for Clinical Experiences

- Writing assignments:
- Describe communication within the laboratory & clinicians
- Identify & Report on unusual/problem/safety issues using SBAR
- Identify opportunity for process improvement (pre and post analytic)—identify evidence required, people involved, steps to required for CQI project
- Attend staff huddles, staff meetings, quality improvement committee and report findings
- Spend day(s) or week with supervisor, quality improvement laboratory staff

Summary

- Use patient safety **communication tools** throughout the curriculum
- Ensure **entire** total testing process is included in all aspects of the curriculum—intentional focus upon **pre & post-analytic phases**
- Require & evaluate **patient safety competencies** in order to prepare laboratory professionals for full participation on healthcare team

Resources & Contact Information

- ASCLS
 - Code of Ethics
 - Patient Safety Position Paper
 - Patient Safety Committee—Patient Safety Tips
 - Patient Safety & Healthcare Quality Community
- Labtestingmatters.org
 - Article/blogs on Quality Care/Patient Safety & the Lab
- IHI.org
 - patient safety modules
- AHRQ—Patient Safety Network
- AHRQ—TeamSteps:
<https://www.ahrq.gov/teamsteps/curriculum-materials.html>
- Catherine Otto
- cathyottopatientsafety@gmail.com