Improving Patient Safety Using Quality Indicators

A Toolkit for Medical Laboratory Professionals

ASCLS
The American Society for Clinical Laboratory Science

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Welcome to the *Improving Patient Safety Using Quality Indicators – A Toolkit for Medical Laboratory Professionals.* The American Society for Clinical Laboratory Science (ASCLS) is dedicated to making a positive impact in healthcare through leadership that will ensure excellence in the practice of laboratory medicine. This toolkit was developed by ASCLS peers to support laboratory professionals to be advocates for patient safety and improve patient outcomes in healthcare delivery. The toolkit is a practical guide with tools, resources, and examples to facilitate implementation of a patient safety improvement program utilizing patient safety indicators.

Section 1 – Introduction

Did You Know?

- A diagnostic error is "the failure to (a) establish an accurate and timely explanation of patient's health problem(s) or (b) communicate that explanation to the patient." [1]
- It is likely that most of us, as health care consumers, will experience at least one diagnostic error in our lifetime, sometimes with devastating consequences [3]
- Diagnostic errors affect 12 million Americans each year in outpatient settings and may seriously harm one-third or 4 million of these patients [4]
- Conservative estimates suggest that 40,000-80,000 Americans die each year from diagnostic failures in U.S. hospitals alone [5] [Average: Every nine minutes, someone in a U.S. hospital dies due to a diagnostic failure]
- A Johns Hopkins study released in May 2016, calculates that more than 250,000 deaths per year are due to medical error in the U.S. [6]

Patient Safety in Laboratory Medicine Matters

Figure 1: Total Testing Process [7]

All healthcare should be safe, effective, patient-centered, timely, efficient, and equitable. [8]

As one of the leading diagnostic service lines in healthcare, patient safety in laboratory medicine matters.

In all phases of the laboratory total testing process, medical laboratory professionals have the ability and responsibility to improve patient safety and health outcome.

Patient Safety-Centered Laboratory Services

Patient safety-centered laboratory services assure care that avoids harm to patients, enhances safe care outcomes through error prevention, allows continuous process improvement, and assures appropriate levels of care are provided to each patient served. The aim of laboratory medicine and its practitioners as stewards of patient safety is to provide services focused on providing safe care and improving patient health outcomes throughout the total testing process which includes all phases of laboratory testing from the time a laboratory test should be ordered, to when the laboratory test result is reported to the clinician, interpreted, and the result is reported to the patient. [7]

Drivers of Change

The primary drivers of the patient safety movement include reports from the National Academy of Medicine as well as requirements identified by national accrediting and regulatory agencies (e.g., Center for Medicare & Medicaid Services (CMS) CLIA [10], College of American Pathologists (CAP) [11], COLA [12], The Joint Commission [13]). The focus of this change is to monitor performance to improve patient safety and health outcome.

National Academies of Sciences, Engineering and Medicine - In 1999, The National Academy of Medicine (then known as The Institute of Medicine) published a landmark report titled *To Err is Human*. [9] This report described an epidemic of preventable medical errors in healthcare and identified gaps in healthcare delivery as the source of the errors. These gaps were created by faulty systems, processes, and conditions which either lead to or failed to prevent mistakes by healthcare workers. An additional report, *Crossing the Quality Chasm* [8], advised healthcare systems to implement safe practices within their delivery models and recommended six quality aims for healthcare that promote a culture of safety and quality. [8] The six quality aims are:

Figure 2: Six Quality Aims for Healthcare

Safe	Provide service which prevents harm to patients and improves healthcare outcomes (e.g., error prevention, improve diagnostic process, ensure continuous quality improvements, etc.)
Effective	Use evidence-based knowledge to limit and prevent overuse, underuse, and misuse of services
Patient-centered	Respond to and be respectful of patient preferences, needs, and values
Timely	Reduce wait times and delays in providing service for patients, clinicians, and other professionals
Efficient	Avoid and reduce waste and inefficiencies (e.g., time energy, ideas, supplies, equipment, etc.)
Equitable	Deliver care without variation due to gender, ethnicity, geographic location, and socioeconomic status

In 2015, more than a decade after *To Err is Human* [9] was published, *Improving Diagnosis in Healthcare* [3], was published by the National Academy of Medicine. This report was directed to all healthcare providers and services involved in the diagnostic process. Specific to laboratory medicine, this report:

- acknowledges the critical role of pathology and laboratory professionals in the diagnostic process
- documents that patient safety, improvement in the diagnostic process, and reducing diagnostic errors are the responsibility of all healthcare professionals, including **laboratory professionals**

Section 2 - Patient Safety Indicators (definition, selection, evaluation)

What is a Patient Safety Indicator?

Patient safety quality indicators are healthcare's equivalent to key performance indicators (KPI) used in the business world. A KPI is something that can be measured and is used to demonstrate to everyone that the company is achieving its key business objectives. [14]

In healthcare, one of the key "business" objectives is to keep patients safe from adverse events. We call healthcare KPIs "patient safety quality indicators" (PSQI) or "patient safety indicators" (PSI) or just quality indicators. According to the Agency for Healthcare Research and Quality (AHRQ), these indicators are measurements that screen for adverse events that patients might experience because of their interaction with the healthcare system. As AHRQ states "These events are likely amenable to prevention of adverse events by changes at the system or provider level." [15]

PSIs should be evidence-based and focus on what matters most, considering personnel and other resources. [15] There is a common saying in the world of quality improvement - "What gets measured gets done." Another way to think about this is, in order to improve a process or an outcome, one needs to measure that process or its outcome. In healthcare and in laboratories, it is essential to measure any process, procedure, or practice that may adversely impact patient outcomes or has the potential to improve healthcare outcomes using well-planned, inclusive patient safety indicators.

What is the Importance of Selecting an Appropriate Patient Safety Indicator?

Selection of appropriate PSIs are a means of evaluating and improving the effectiveness of a process or procedure. Identification of areas of improvement have the ability to not only decrease errors and improve processes but also can lead to performance comparisons with other laboratories. PSIs that are designed to allow peer-to-peer comparison (benchmarking) lead to evidence-based improvement, sharing of best-practices, and achievement of desired state-of-the-art services.

The individual PSI selected must specifically address dimensions of clinical performance and areas for improvement. Data needs to be collected over time to identify, correct, and continuously monitor areas that may adversely impact patient safety, diagnosis, and health outcome. Implementation of continuous corrective interventions using standardized processes will improve performance as well as patient safety.

When possible, the use of nationally defined or literature based PSIs supports needed harmonization to collect data that are comparable and allow direct inter-laboratory comparison. These harmonization efforts include a common definition of the data elements of a PSI (e.g., numerator, denominator, rate expression calculation). [16] As an example, if one laboratory expresses data as # events per patient days, and another tracks the same event as a percentage of daily laboratory tests, those two cannot be directly compared and therefore do not contribute to comparative evaluation. The ability to compare performance to other laboratories allows:

- quantification of performance quality
- establishment of improvement priorities based on best-practice standards
- determination of improvements that are meaningful to patient safety and health outcomes
- effectiveness assessment of interventions
- establishment of standardized reporting systems

Questions to consider in assessing the appropriateness of a patient safety indicator include:

- Does the indicator evaluate and identify areas that pose the greatest risk of harm to patients or have potential to improve service outcomes?
- Does the indicator monitor and evaluate performance of a critical but specific phase of testing (pre-analytical, analytical, post-analytical)?
- Do additional indicators need to be added to assure complete assessment?
- Does the indicator assess one of the six quality aims of healthcare? (e.g., safe, effective, patient-centered, timely, efficient, equitable)
- Is the performance indicator aligned with the organization's or laboratory's patient safety initiatives?

Each step of the laboratory Total Testing Process that relates to the patient safety indicator selected needs to be carefully examined from a systems perspective for potential errors (defects in the process). This can be completed by performing an initial (trial) assessment of the defined patient safety indicator. The assessment should include determining where in the process or procedure an improvement is needed or needs to be sustained. Additional questions may then be asked to assess if the defined indicator will lead to achieving the initial desired outcome. Examples are:

- Have all departments that have responsibilities in the process (e.g., laboratory, nursing, information technology, outreach clients, physicians) been identified?
  - Do they need to be included in the team responsible for achieving the indicator goal?
- Have any critical total testing process steps that can impact the indicator outcome been overlooked?
- Will the data required be consistently available as defined by the indicator?
- Does the data gathered allow identification of systems or processes that need to be improved to achieve the desired outcome?
- Will the data analysis required provide meaningful statistics and allow identification of possible interventions to achieve the improvement desired?
- Are the target and threshold limits set appropriate to achieve the desired outcome?
- Are revisions to the PSI definition required?
- Are any notifications necessary before the quality indicator process begins?

Steps in Selecting, Defining, and Evaluating a Patient Safety Indicator (PSI)

Select a specific patient safety or health outcome improvement area to be measured

- Patient safety and outcome improvement emphasis includes:
  - Assessing the total testing process (pre-analytical, analytical, post-analytical)
  - Assessing diagnostic and service processes based on the six quality aims for healthcare (safe, effective, patient-centered, timely, efficient, equitable)
- Some common sources to consider for identifying areas to improve patient safety include patient safety alerts (national and institutional); review of the published clinical laboratory science literature; the facility's patient safety officer and risk management department; complaints received from providers, nurses, patients; incident reports; and reports of service failures from laboratory personnel.
- Areas to be measured should not just include areas within the direct control of the laboratory. The areas should also include processes for which control and responsibility are shared with other departments (e.g., point-of-care testing, specimen collection by non-laboratory professionals) within the organization or with external customers (e.g., patients, outreach clients and ordering clinicians).
- **Refer to APPENDIX 1: Total Testing Process - Examples of Patient Safety Indicators**

Define the PSI and requirements to measure performance

Using standardized PSI development forms assist with defining the indicator and allow for standardization when developing multiple indicators. (Refer to Section 3: Tools & Resources-Customizable Templates)

Suggested components in defining the indicator: [18]

- Indicator name and the purpose of the indicator (what improvement is desired)
- Scope of the indicator
  - Phase of the total testing process the indicator is assessing (pre-analytic, analytic, post-analytic)
  - Scope of testing included in indicator (e.g., hematology, chemistry, point-of-care, specimen collection)
  - Department(s) that have responsibilities in the process (e.g., laboratory, nursing, information technology, outreach clients, physicians)
- Data elements to be collected or excluded for consistent data collection and rate calculation (e.g., unique identifier, sex, age, date, time, patient population, test result or specific limit criteria for test results to be reported)
- Method of expressing the PSI and its formula for calculation (e.g., occurrence frequency per day or per admission or per month or per tests reported) including the numerator and denominator definition
  - Numerator = the number of times the parameter of the measure occurs (e.g., number of hemolyzed specimens, number of patients, number of result errors, number of transfusion reactions, number of incorrect tests ordered)
  - Denominator = the total number (whole/entire) of the population being evaluated to obtain the statistical value desired for the rate expression (e.g., per total tests, day, admission, accession)
  - Rate Expression Example: Percent of hemolyzed blood specimens received in the laboratory per total specimens received
    - Numerator: number of hemolyzed specimens received during the study timeframe

    - Denominator: total number of specimens received during the study timeframe
- Data collection method (e.g., data sampling frequency, data source(s), method to record data, timeframe for collection)
- Utilization of a commonly used quality improvement process, Plan-Study-Do-Act (PDSA) cycle [17] or other similar quality process, is helpful in organizing and documenting actions required with making changes to the PSI and testing impact of improvement changes. (Refer to Section 3 – Tools for PDSA cycle resources)
- Complete a preliminary data collection (pilot study) using the defined indicator is recommended to assess the definition of the PSI and to ensure required data can be obtained. If needed, adjustments to the definition may be made to provide meaningful data for the criteria being measured.

Define the PSI analysis and interpretation responsibilities

- Determine the target for the PSI (desired level of performance; value or outcome to be achieved) [18]
    - Target may be from an external source (document the resource or reference utilized)
    - Target may be established internally (e.g., organization or department goals, customer expectations)
- Determine the indicator threshold (predefined decision point set to trigger further evaluation and action when it is exceeded) [18]
    - Revise threshold when needed to ensure continuous improvement
- Define who is responsible for collecting data, analyzing data, selecting data display format, and preparing the report; define timeframes that assignments must be completed by
- Define who is responsible for report interpretation, determination of improvement actions to be taken, change impact assessment, specific follow up required, and completion dates
    - Continue utilizing the PDSA cycle quality improvement process until desired outcome is achieved and maintained
    - Emphasize the importance of developing and implementing additional change actions with each data cycle to continuously improve the process
- Provide communication of outcomes and actions to all professionals and departments involved in the quality process, including appropriate education and competency assessments when required

Evaluate the PSI effectiveness and sustain improvement

- Establish a timeline for PSI review to evaluate the effectiveness of the PSI (at a minimum of annually) [19]
- During the review, determine if
    - Target is still appropriate or needs to be adjusted to demonstrate continuous improvement
    - Target is being continuously met and if the indicator should be continued, discontinued, or discontinued but requires a future scheduled study to validate sustainment
    - Target is not attained and progress to achievement is not evident (requires complete evaluation and revision of PSI if indicated)
- Determine if indicator changes are required to ensure continued effectiveness

Refer to Figure 3 (next page): Patient Safety Indicator- Selection, Definition, and Assessment Flow

Figure 3: Patient Safety Indicator – Selection, Definition, and Evaluation Flow

- *Identify patient safety or health outcome area for improvement*
- *Include areas in the Total Testing Process – Preanalytical, Analytical, Postanalytical (including interdepartmental areas not within laboratory's direct control)*
- *Focus improvement efforts on the six quality aims in healthcare (Safe, Effective, Patient-Centered, Timely, Efficient, Equitable)*

- *Define the patient safety indicator (scope, data elements, data collection method, rate calculation)*
- *Utilize a "Plan, Do, Study, Act (PDSA)" type process to organize/ document actions*
- *Complete preliminary (pilot study) to validate the indicator definition and the ability to collect meaningful data*
- *Revise definition and process if needed*

- *Set target and threshold limits using reference literature, individual laboratory or facility goals, or peer studies/best practice resources*
- *Determine process for data collection, analysis, and reporting*
- *Identify who will be responsible for collection, analysis, reporting, and interpreting*
- *Define suggested outcome actions for interpretations and reviews to support continuous improvement*

- *Complete study as defined and for timeframe required*
- *Complete report and submit to individual or group responsible for interpretation*

- *Identify and implement change actions needed to further improve process*
- *Trial change actions initially on a small scale to evaluate impact before full implementation*
- *Determine how to measure effectiveness of changes that are implemented*

- *Continue using PDSA quality improvement process until desired outcome is achieved and is maintained*
- *Revise threshold and target limits to assure continuous improvement*
- *If target is not achieved after several process changes and data reporting cycles, complete total review (indicator selection, definition, and target)*
- *Communicate outcomes and actions to all professionals and departments involved in process, including appropriate education and competency assessments when required*

- *Establish timeline for indicator review to evaluate continued effectiveness of the quality measure (at a minimum of annually)*
- *Define outcome actions of review*
  - *Assess if target is still being met and is valid or requires adjustment to support continuous improvement*
  - *Determine if indicator should be continued or discontinued*
- *Determine if indicator revisions are required to ensure effectiveness*

- **Refer to APPENDIX 2: Case Study - Patient Safety Indicator Example**
- **Tools to assist in selecting and defining patient safety indicators are found in Section 3 – Tools and Resources**

Section 3 – Tools and Resources

Toolbox

Tools and resources are provided in this section to assist in implementing various performance improvement actions. Tools include resources collected from other distinguished organizations or sources and may be in the form of example protocol, procedure, spreadsheets, forms, and links to websites that offer downloadable forms and resources.

It is not necessary to use all the tools provided to be successful. Select and download the tools that will assist you with your patient safety improvement initiatives. Tools can be adapted to the needs of the laboratory or patient safety process.

Institute for Healthcare Improvement (IHI) Quality Improvement Resources

(Forms, Templates, Toolkit, "How To" Videos)

Resource	Description	URL
IHI Quality Improvement Essentials Toolkit	Includes tools and templates that can be used for quality improvement projects and manage improvement.	All resources are available at: http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx Note: IHI registration is free and required to download resources
IHI downloadable tools and templates: • Cause and Effect Diagram: can be used to analyze failure root causes and possible improvement actions; common name: fishbone diagram • Driver Diagram: can be used to display relationship between goal/aim of project and areas/drivers related to achieving the goal/aim • Failure Modes and Effects Analysis (FMEA) Tool: can be used to analyze and identify risks and impacts on outcomes • Flowchart (Process Map): can be used to visually display and analyze all steps in a process • Histogram: can be used to visually represent variation in data in chart format • Pareto Chart: can be used to display and arrange factors (largest to smallest) that impact improvement to an aim/goal • PDSA (Plan-Do-Study-Act) Worksheet: can be used to document a test of change and the impact to achieving the aim/goal • Project Planning Form: can be used to keep the project organized and be able to visualize the whole project and timeframes • Run Chart and Control Chart: can be used to determine if changes made are improving the outcome and to assess variations in process • Scatter Diagram: can be used to display the relationship between two variables		
IHI Quality Improvement "How to" Videos – videos that can be used to learn how to use the tools listed above		http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx

American Society for Quality – Quality Tools A to Z

Resources	URL
Tools to help identify causes, understand processes, collect, and analyze data, keep projects on track, and make informed decisions for improvement activities. Examples of downloadable tools include: • Box and Whisker Plot • Check Sheet • FMEA • Gantt Chart • Pareto Chart • Cause & Effect Diagram • Control Chart • Flow Chart • Histogram • Scatter Diagram	https://asq.org/quality-resources/quality-tools

Other Organizations' Tools

Resource/Organization/Description	URL
Improving Diagnosis in Medicine Change Package (Society to Improve Diagnosis in Medicine) – can be used to help identify and reduce patient safety incidents during the diagnostic process	https://www.improvediagnosis.org/improving-diagnosis-in-medicine-change-package/
Patient Safety Resource Center (American Society for Clinical Laboratory Science) – resource center with educational materials, references, and patient and provider educational brochures	https://ascls.org/patient-safety-resources/

Additional Internet Resources

Resource	URL
Agency for Healthcare Research and Quality (AHRQ): Improving Diagnostic Safety & Quality	https://www.ahrq.gov/topics/diagnostic-safety-and-quality.html
Agency for Healthcare Research and Quality (AHRQ); Patient Safety and Quality Improvement	https://www.ahrq.gov/patient-safety/index.html
American Society for Clinical Laboratory Science (ASCLS); Patient Safety Resources & Information	https://ascls.org/patient-safety-resources/
American Society for Quality	https://asq.org/
College of American Pathologists – Q probes/ laboratory benchmarking	https://www.cap.org/laboratory-improvement/quality-management-programs
Lab Guidelines and Standards; "How Does a Laboratory Measure Process Improvement?"	https://academic.oup.com/labmed/article-abstract/42/5/314/2505024
Society to Improve Diagnosis in Medicine (SIDM); ACT for Better Diagnosis Resources for Clinical Teams	https://www.improvediagnosis.org/awareness/ https://www.improvediagnosis.org/clinicians/
Joint Commission (TJC); National Patient Safety Goals	https://www.jointcommission.org/standards/national-patient-safety-goals/

Customizable Templates (Forms & Spreadsheets)

Find these templates at https://ascls.org/improving-patient-safety-using-quality-indicators/

Template	File Type
Patient Safety Indicator – Bar Chart	Excel
Patient Safety Indicator – Example Procedure & Indicators	Word
Patient Safety Indicator – Scatter Diagram	Excel
Patient Safety Indicator & PDSA Plan	Power Point
Patient Safety Indicator Form (Basic) & Example	Word
Patient Safety Indicator Form (Complex) & Example	Excel
Patient Safety Indicator Reporting Form & Graph	Excel
Patient Safety Indicator Tracking & Graph	Excel
Patient Safety Indicators – Review & Outcome Report	Word
PDSA Performance Improvement Form	Excel
PDSA Performance Improvement Project Plan Worksheet	Word
Performance Improvement Specific Aim Statement	Word
Performance Indicator Project Plan Worksheet	Word
Performance Indicator Tracking – Example Dashboard	Excel
Policy Examples – Patient Safety Identified in Quality Plan	Word

APPENDIX 1: Total Testing Process – Examples of Patient Safety Indicators

NOTE: This list is not meant to be interpreted as all inclusive.

Pre-analytic:

– Blood specimen collection associated patient adverse events

- hematoma
- multiple failed phlebotomy attempts (>2 by one employee or >3 total by multiple employees)
- fainting
- lapse in infection prevention/hand hygiene
- skin reaction to tape/bandage/latex
- sharps left in patient bed
- unacceptable service wait time for patient
- patient complaint (e.g., pain, customer service handling)

– Patient or Specimen Identification

- wrong patient drawn
- failure to use two patient identifiers
- patient without required identification at time of collection
- specimen mislabeled
- specimen unlabeled

– Order Entry

- incorrect order information entered (e.g., misspelled patient name, sex, DOB, fasting status, ordering clinician)
- test ordered on the wrong patient
- test not ordered (e.g., data entry error, order overlooked, no order available)
- failure to order appropriate test for clinical needs
- unintelligible clinician order
- incorrect or inappropriate test ordered
- inappropriate test frequency (e.g., too many, too few)
- incorrect date/time for test (e.g., fasting, therapeutic drug monitoring, serial timed tests)
- wrong blood product ordered
- duplicate test order

– Specimen Collection, Handling, Transport

- specimen integrity like hemolyzed, lipemic, clotted, and contaminated or diluted (e.g., incorrect order of draw, drawn above IV line)
- insufficient specimen volume or unacceptable sample-anticoagulant volume ratio
- incorrect specimen collection container (e.g., EDTA, sodium citrate, heparin, no additive)
- incorrect specimen collected (e.g., blood, saliva, urine)
- incorrect collection time
- lost or unavailable sample
- specimen special handling not followed (e.g., time to centrifugation, temperature)
- specimen transport (e.g., not transported, delay in transport, incorrect temperature, specimen container damaged or leakage)
- incorrect patient preparation (e.g., non-fasting, incorrect diet, time medication taken)
- delayed test turn-around-time due to specimen rejection requiring specimen redraw

Analytic:

– Test Result Error

- incorrect result (e.g., incorrect specimen, data entry error, technical problem, dilution error, procedure not followed)
- questionable result not identified and verified before reporting
- failure to recognize specimen type or integrity problem that affects result
- failure to recognize specimen handling or transport problem that affects result
- failure to recognize and resolve quality problem before test result reporting (quality control, calibration, instrument flags, etc.)
- delayed test turn-around-time due to analytical process problem (e.g., instrument malfunction, misplaced testing specimen, communication breakdown)

Post-analytic:

– Transfusion Services

- wrong blood product dispensed/ administered
- wrong patient received product
- transfusion adverse event

– Test Reporting Error

- incorrect result reported
- test results not communicated to clinician
- critical values not reported as defined by protocol
- delayed test turn-around-time (e.g., LIS/ HIS problem, pre-analytic error, analytic error)
- corrected result report not issued or not received by clinician

– Effective Utilization of Test Results

- incorrect interpretation of test results
- failure to order required follow-up test(s)
- continuing to re-order the same laboratory test without clinical need

– Outcome of Laboratory Testing

- inappropriate follow up action taken or lack of documentation on reported critical value
- failure to follow best practice protocol (e.g., coagulation monitoring, therapeutic drug monitoring, approved clinical pathway)
- failure of clinician to notify patient of abnormal test result(s) and required next steps

Additional Resources:

- College of American Pathologists Q-Probes, Laboratory Benchmarking; https://www.cap.org/laboratory-improvement/quality-management-programs
- Plebani M, Sciacovelli L, Marinova M, Marcuccitti J, Chiozza ML. Quality indicators in laboratory medicine: a fundamental tool for quality and patient safety. *Clin Biochem*. 2013 Sep;46(13-14):1170-4. doi: 10.1016/j.clinbiochem.2012.11.028. Epub 2012 Dec 5. PMID: 23219744.
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APPENDIX 2: Case Study - Patient Safety Indicator Example

Case Study: Emergency Department (ED) Delayed Testing Results Due to Specimen Rejection

Background/Facility Information	– 150-bed rural hospital – ED utilizes contracted physicians for coverage – ED Blood Specimen Collection: performed by ED staff (patient care techs and nurses) – Laboratory Department: performs high complexity testing with an extensive test menu; 24/7 coverage
Performance Problem Identification	Suspected Problem Reported and Source: – Laboratory received formal complaint from one of the newer contracted physicians – Complaint: unacceptable laboratory testing turnaround time is causing delayed diagnosis, delayed treatment, and is negatively impacting the flow of patient admissions – Two specific patients' names were documented Actions Taken in Response to Complaint: – Immediate review of the documented patients' records was completed – Delayed testing results were confirmed; records documented that both patients had rejected specimens that required specimens to be redrawn – A brief review of all patients seen in the ED in the last 10 days was completed to determine if the two patients were isolated cases. Review results: • 100 patients received ED services that required laboratory testing • 15 of the 100 patients had documented rejected specimens (15% of the patients were impacted) • 400 total specimens were received from the 100 patients; 45 specimens of the 400 were documented as specimen rejected and required redraws (11.3% rejection rate) • Reasons for rejection included: specimen integrity (hemolysis) (35), specimen labeling error (7), specimen not received (3) • Laboratory leaders met with ED physicians and nursing staff. o It was determined that an 11.3% rejection rate was negatively impacting patient outcomes o It was decided to implement a Patient Safety initiative to "decrease the ED specimen rejection rate to <2%"

Performance Problem Identification	o Laboratory designated as the lead department for the initiative and would include appropriate representation of ED physicians, nurses, and patient care techs o Laboratory proceeded to develop the "Patient Safety Indicator" to be used in the initiative
Patient Safety Indicator - Title & Form	Delayed Test Results Due to Specimen Rejectiont: – ***Refer to "Patient Safety Indicator example form"***
Indicator Metrics & Generalized Plan/Do/Study/ Act (PDSA) Information	– 10-Day Snapshot Rejection Rate: 11.3% – 2-Month Baseline Assessment: • November 2020 Rejection Rate: 10.5% • December 2020 Rejection Rate: 10.9% • Improvement Actions: No change actions were implemented during baseline assessment o Processes were evaluated (specimen collection and transport) o Areas for improvement were identified (e.g., education on specimen collection, handling, transportation would be completed for four new employees, education would be provided for all staff to decrease the # of line draws that were being performed – January 2021 Rejection Rate: 7.0% • Specimen rejection occurrences were reviewed, and improvement actions identified and implemented o Two new ED staff members since December 2020; specimen collection and handling errors again noted o It was noted that non-laboratory staff was responsible for new ED staff orientation and training o Specimen collection and handling training and competency process reviewed and updated o It was decided that laboratory staff would begin performing new ED staff specimen collection, handling, and transport orientation and training beginning February 2021 o Monthly competency assessments by observation were implemented

Indicator Metrics & Generalized Plan/Do/Study/ Act (PDSA) Information	– February 2021 Rejection Rate: 6.5% • Specimen rejection occurrences and competency assessment outcomes were reviewed, and improvement actions identified and implemented o Specimen handling and transport errors by multiple staff noted o Education on specimen handling and transport was provided for all specimen collection staff – March 2021 Rejection Rate: 4.0% – ***Refer to "Patient Safety Indicator Tracking & Graph Example"*** (Note: Process, staff performance and specimen rejection reviews continue, improvement actions are implemented, and the indicator requirements continue until target is reached and maintained)

Patient Safety Indicator Example Form

Patient Safety Indicator	
Use this form to document an approved quality indicator. Complete all parts necessary prior to indicator implementation.	
Part 1: Indicator Selection, Purpose, Scope	
Indicator Unique Identifier:	ED001
Descriptive Name:	Delayed Test Results Due to Specimen Rejection
Effective Dates:	Start Date: 11/1/20 End Date: 5/31/21 or ☐ Ongoing
Purpose/Desired Improvement:	Decrease number of rejected blood specimens to <2% to improve result turn-around-times
Literature Reference (if applicable):	NA
Published Standards/Benchmarks:	NA
Indicator Scope:	
Laboratory Phase(s) Involved:	☒ Pre-analytical ☐ Analytical ☐ Post-analytical ☐ Other: _____
Quality Aim:	☐ Safe ☐ Effective ☐ Patient-Centered ☒ Timely ☐ Efficient ☐ Equitable
Departments Involved:	☐ Laboratory Only ☒ Laboratory and non-laboratory
Laboratory Department(s) (list):	All departments utilizing blood specimens for testing
Non-Laboratory Dept(s) (list):	Emergency Department
Team Members (list all):	Laboratory: M Smith, S Jones, M Techi, J Johnson, J Path MD ED: S Carter, D Cutter, P Carrol, S Trauma MD
Study Type:	☒ Trial ☒ Initial /Baseline ☒ Continuous ☐ Maintain Gain ☐ Pro-active Risk Assessment Other: _____

Part 2: Data Collection, Responsibility

Person(s) Responsible for Collection:	M Smith (primary), M Techi (secondary)
Data Time Frame:	☐ Retrospective Start: ___/___/_____ End: ___/___/_____ ☒ Concurrent Start: 11/1/20 End: 5/31/21 Frequency of Collection: ☐ Daily ☐ Weekly ☒ Monthly ☐ Other If other (specify): _____
Data Collection Method:	☒ Manual ☐ Electronic Manual or Electronic Collection Instructions: LIS: total specimen count and redraw documentation Manual: Specimen rejection log in specimen processing
Method to Record Data:	☒ Manual Tally ☒ Electronic (e.g., LIS, HIS, EHR) Manual Specifics: Manual specimen rejection log in specimen processing Electronic Specifics: LIS (specimen count report) LIS (specimen redraw report)
Data Elements to Collect (list all):	name, accession #, phlebotomist, date/time of service, specimen rejected, specimen rejection reason, time redraw specimen collection
Data Calculations (if applicable)	NA
Data Sources (list all):	Specimen rejection log, LIS (specimen count and redraw report)
Numerator Description:	Total # of rejected blood specimens requiring redraw in one calendar month
Numerator Instructions:	Compare manual specimen rejection log to LIS redraw report to verify total # rejected; do not include non-blood specimens
Denominator Description:	Total # of received blood specimens in one calendar month
Denominator Instructions:	Do not include non-blood specimens
Data Expression & Calculation: Expression Description (e.g., frequency, rate, raw number, range, mean, median, Sigma value)	Rejection Rate
Expression Calculation:	(total # rejected specimens/total # specimens received) x 100 = Rejection Rate %
Instructions (if required)	Report to one decimal (e.g., 5.0%); include total days in a calendar month

Part 3: Reporting & Interpretation	
Person(s) Responsible for Reporting:	M Smith (primary), M Techi (secondary)
Person(s) Responsible for Interpretation:	M Smith, J Path MD (primary) All team to review and approve interpretation
Frequency of Reporting:	☐ Daily ☐ Weekly ☒ Monthly ☐ Quarterly ☐ Other _____
Deadline for Submitting Report:	15th of the month
Report Content Specifics:	Monthly reports will include actions and responsibilities for change as needed
Indicator Target (expected value) & Source:	<2% Internally set
Indicator Threshold Requiring Action:	2-3%
Data Display Method:	☐ Bar Chart ☒ Line Chart ☐ Histogram ☐ Pie Chart ☐ Parento Chart ☐ Run Chart ☐ Other _____

Approval Signatures:	Date:
Joe Path, MD	10/15/2020
Sally Trauma, MD	10/17/2020
Mary Smith, Laboratory Director	10/14/2020

Patient Safety Indicator Tracking & Graph Example

ABC Laboratory
Anytown, USA

Delayed Test Results Due to Specimen Rejection

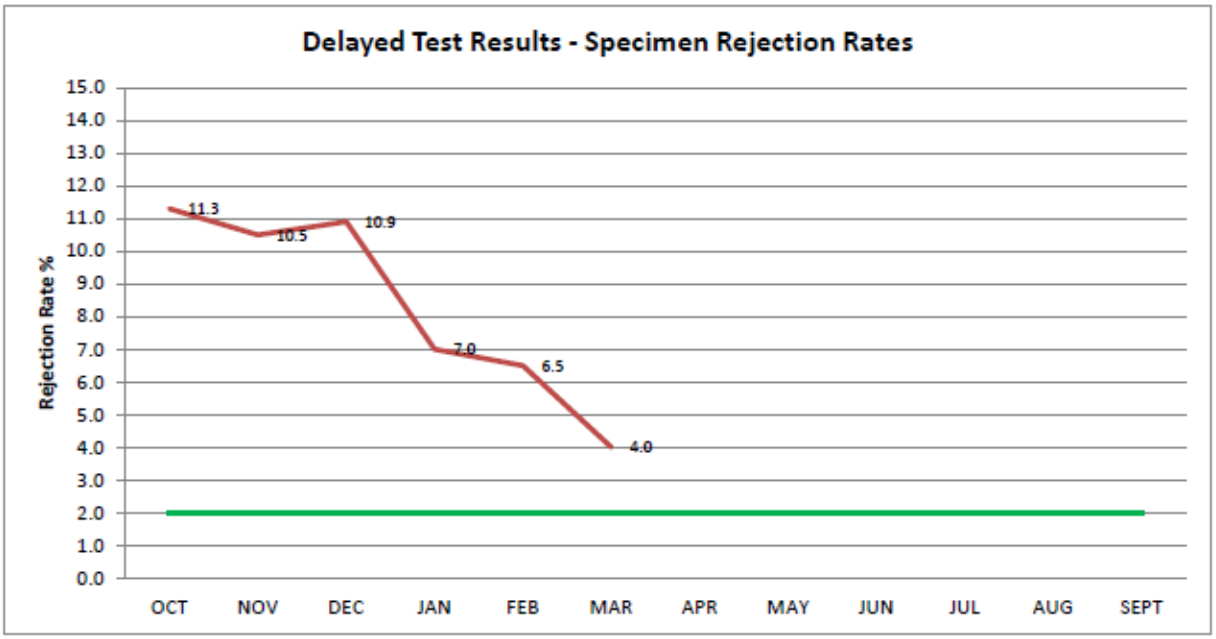
Reason for Indicator: Turn-around-time complaints received and validated; identified increase specimen rejection impacting on timely reporting

Indicator Expression: Specimen Rejection Rates

Responsible Department(s): Laboratory and Emergency Department

	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT
Result	11.3	10.5	10.9	7.0	6.5	4.0						
Target	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Outcome (Acceptable (A)/ Unacceptable(U)	U	U	U	U	U	U						
Threshold: 2-3% all results >3% require change actions be evaluated and implemented												

Month	SUMMARY: CORRECTIVE ACTION / FOLLOW UP / OUTCOME or N/A Acceptable
Oct	10-Day Snapshot data
Nov	1-Month Baseline: No change actions
Dec	2-Month Baseline: No change actions; specimen collection, handling and transport processes evaluated; education for 4 new employees, all staff education on line draws to decrease # of line draws
Jan	December education completed prior to 1/1/21; Actions: 1)specimen collection, handling, transporting training & competency assessed and revised 2) Laboratory staff to assume responsibilities for orientation, training and competency assessments Feb 2021; monthly competency assessments by observation started
Feb	Competency assessments identified specimen handling errors by multiple staff; Action: education on correct specimen handling provided for all specimen collection staff
Mar	Patient Care Tech float staff from inpatient floors identified; Action: Implement orientation, training and competency for all staff that can float to ED for coverage during staff shortage
Apr	
May	
Jun	
Jul	
Aug	
Sept	



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11 – College of American Pathologists; https://www.cap.org

12 – COLA Inc.; https://www.cola.org

13 – The Joint Commission; https://www.jointcommission.org

14 - https://www.klipfolio.com/resources/articles/what-is-a-key-performance-indicator

15 - https://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V30/2006-Feb-PatientSafetyIndicators.pdf

16 - Mario Plebani, Maria Laura Chiozza, Laura Sciacovelli. *Towards harmonization of quality indicators in laboratory medicine*. Clin Chem Lab Med. 2013; 51(1):187-195. DOI 10.1515/cclm-2012-0582

17 – Institute for Healthcare Improvement (IHI). *Quality Improvement Essentials Toolkit; PDSA Worksheet tool*. http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx

18 - Clinical Laboratory and Standards Institute (CLSI) – *QMS 12-ED2: 2019 Developing and Using Quality Indicators for Laboratory Improvement, Second Edition*

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