PERFORMANCE IMPROVEMENT
The Cornerstone Of
Quality in the Clinical Laboratory

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In the program today, we will:

- Outline the basic concepts and definitions of Performance Improvement.
- Review the evolution of Performance Improvement (PI).
- Discuss the models/strategies used in nurturing quality in the clinical laboratory.
- Examine tools/applications associated with the plan-do-check-act (PDCA) cycle.
- Explain the role of accrediting agencies in the PI process.
Program Objectives

Upon completion of the program, the participant will be able to:

- Explain the theory, strategies, and tools associated with PI.
- Describe the role of accrediting agencies in promoting PI as a model to ensure quality health care and patient safety.
Performance Improvement –
The Cornerstone of Quality in the Clinical Laboratory

- Lean Thinking
- Performance Improvement
- Continuous Quality Improvement (CQI)
- Six Sigma
- Robust Performance Improvement (RPI)
- ISO 9000
- Total Quality Management (TQM)
Definitions

**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.

**Quality Improvement (QI) or Continuous Quality Improvement (CQI):** a management technique to assess and improve internal operations. QI focuses on organizational systems rather than individual performance and seeks to improve quality rather than correcting errors when safety thresholds are crossed. The process involves setting goals, implementing systematic changes, measuring outcomes, and making subsequent appropriate improvements.

**Performance Improvement:** an approach to the continuous study and improvement of the processes of providing health care services to meet the needs of patients and others.
What Does It All Mean?

- Lean
- ISO 9000
- Six Sigma
- CQI
- RPI
- TQM
- ISO 9000
What Is Driving Performance Improvement?

- Consumers are more aware of quality and performance issues in health care and they are demanding higher quality and accountability while containing costs.

- Accrediting bodies such as The Joint Commission and the National Committee for Quality Assurance, as well as state agencies, are requiring demonstrated PI activities.

- Those with purchasing power, such as Health Maintenance Organizations and insurance companies, want to work with health care organizations committed to improved outcomes.

- Cost and reimbursement issues in healthcare are forcing health care providers to look for more cost-effective ways to provide care while maintaining quality.

- Media coverage of quality issues such as the Institute of Medicine report on medical errors brings to light the critical importance of PI.
HIV and hepatitis C testing problems are "far more widespread than previously indicated," and equipment failures at the "poorly run" laboratory could have led to thousands of incorrect test results, according to a report recently released by state health officials, the AP/Asbury Park Press reports (AP/Asbury Park Press, 4/3). Last month, Maryland officials said that approximately 460 patients might have received incorrect test results after hospital laboratory personnel overrode controls in the testing equipment that indicated the results might be in error. State officials discovered the problem in January after a former hospital employee filed a complaint. State inspectors, who conducted interviews with hospital personnel and reviewed medical records, discovered that as a result of the laboratory staff's failure to follow standards set by the manufacturers of the tests, 10% to 15% of the HIV tests performed during the 14-month period ending in August 2003 might have produced inaccurate results. However, hospital officials reported in an official statement that they believe the analyzer itself -- not improper employee methodology -- could have caused inaccurate test results (Kaiser Daily HIV/AIDS Report, 3/22).
Government Mandates
A New Paradigm

POST ANALYTICAL

Specimen Reporting

PRE ANALYTICAL

Specimen Handling/Processing

ANALYTICAL

Quality Control (QC) Testing
FOCUS (on) PDCA Strategies

Continuous Quality Improvement

Find a Process Improvement Opportunity
Organize a Team Who Understands the Process
Clarify the Current Knowledge of the Process
Uncover the Root Cause of Variation/Poor Outcome
Start the "Plan-Do-Check-Act" (PDCA) Cycle

PLAN: Identify and Analyze the Problem
DO: Develop and Implement Solutions
CHECK: Evaluate The Results
ACT: Standardize The Solution
Understanding the Need to **FOCUS**

The **FOCUS** approach provides a structure and framework for PI. **FOCUS** is based on the **PLAN-DO-CHECK-ACT** cycle that is a fundamental element of quality management. **FOCUS** is a consistent, five-step business-wide approach to PI:

- **F**ind an improvement opportunity.
- **O**rganize a team who understands the process.
- **C**larify current knowledge of the process.
- **U**nderstand the causes of variation in the process.
- **S**elect the improvement that needs to take place.
Find a Process to Improve

Sources:
- *The Quarterly Review*
- *Standards of Care*
- Customer satisfaction surveys
- Incident reports
- Employee suggestions
- Action/Recommendations section of committee minutes

Criteria:
- High volume
- High cost
- Problem prone
- High Risk
Organize a Team

Defined Roles for Team Members:

- Team Leader
- Facilitator
- Recorder
- Time Keeper
- Members
Clarify Current Knowledge of the Process

Discussion:
- How does the process work?
- Who are the customers?
- What are the customers’ needs?
- What is the actual flow of the process?
- Is there needless complexity/redundancy in the process?

Tools:
- Flow charts
- Outlines
Understand the Reason for Variation

Questions:
- What are the major causes of variation or poor quality?
- Can you measure key elements of the process?
- What, when, where, how, and by whom will the data be collected?
- What causes of variation can be changed to improve the process?

Tools:
- Cause and effect diagrams
- Pareto analysis
- Brainstorming
- Multivoting
Common Variations

**Common Cause Variation:**

Variation in a process that is due to the process itself and is produced by interactions of variables in that process. Common cause variation is inherent in all processes; it can be removed only by making fundamental changes to a process (JCAHO, 2002).

For example, slight variations in O.R. start times, either starting several minutes ahead or behind of the scheduled start time, are examples of common cause variation.

**Special Cause Variation:**

The variation in performance and data that results from variables that are not a part of the original process or system. Special cause variation is intermittent, unpredictable, and unstable (JCAHO, 2002).

For example, a delay in the O.R. start time that is outside of the normal or expected variation, such as a two-hour delay from the scheduled start time on the day of a major snowstorm.
Select the Improvement

Questions:
- Does the solution really deal with the root cause of the problem?
- What are the potential negative consequences of each solution?
- Which consequences will be easiest to implement and maintain?

Tools:
- Failure Mode and Effect Analysis (FMEA)
- Root cause analysis (RCA)
- Matrix prioritization
Finding a process to improve, should be a:
Performance Improvement Strategy

Plan → Do → Check → Act → Plan
Breaking Down Plan-Do-Check-Act

- **Plan.** Recognize an opportunity and plan a change.
- **Do.** Test the change. Carry out a small-scale study.
- **Check.** Review the change, analyze the results, and identify what you’ve learned.
- **Act.** Implement the process. Sustain the Gains
Plan
Recognize an Opportunity and Plan a Change

Activities:
- Cite opportunities for improvement from data sources.
- Prioritize improvement activities.
- Develop an action plan for the selected activity.
  - Initiating a new process
  - Improving an existing process
- Identify:
  - Customer needs
  - Participants
  - Time frames
  - Outcome measurements
  - Success criteria

Tools:
- Brainstorming/affinity diagram
- Cause and effect diagram
- Check sheet
- Decision matrix/prioritization matrix
- Failure modes and effects analysis (FMEA)
- Flow chart/value stream map
- Gap analysis
- Charts
  - Histogram
  - Pareto chart
  - Scatter plot/XY graph
  - Statistical process control/control chart
  - Stratification
  - Survey
Proposed Laboratory Indicators
Pre Analytical—Analytical—Post Analytical

**Pre Analytical**
- Patient is identified.
- Sample requisitions/orders (electronic and/or manual) are complete and accurate.
- Samples are properly collected and labeled.
- Chain of custody is documented.
- Samples are properly stored and transported.

**Analytical**
- Performance of and corrective action for QC are monitored. (Was the QC performed accurately and on schedule? Were appropriate investigations and actions taken when QC results were out of range?)
- Proficiency testing performance and corrective action are monitored.

**Post Analytical**
- Test reports (electronic and/or manual) are complete and accurate.
- Interpretive information (such as reference intervals) is consistent with standards of practice and provides sufficient information to interpret examination results.
- Calculated results are periodically verified for accuracy.
- Documentation of reviews and approvals is evident.
Do

Implement Solution

Activities:
- Implement the action plan.
  - Pilot project first
  - Broaden only after success
- Collect performance data.

Tools:
- Checklist
- Prioritization matrix
- FMEA
- Flow chart
- Charts
  - Pareto
  - Run/control
  - Scatter
  - Surveys
Check
Test the Solution

Activities:
- Analyze collected data.
- Compare performance data to established success targets and original performance data to determine if improvement was achieved.
- Identify any unexpected peripheral benefits.
- Identify unanticipated problems in other areas.

Tools:
- Checklist
- Prioritization matrix
- FMEA
- Flow chart/value stream map
- Charts
  - Histogram
  - Pareto
  - Run/control
  - Scatter
  - Surveys
Act
Integrate and Sustain Improvements

Activities:
- Determine if customer needs were met.
- Take action based on the results.

Success:
- Revise the processes for further improvements (optional).
- Assess again to determine if improvement is maintained.
- If a pilot project, standardize to the bigger group.

Lack of success:
- Revise the action plan and repeat studies.

Tools:
- Checklist
- Charts
  - Histogram
  - Run/control
  - Scatter
  - Surveys
Tools to help with the “Do” portion of the PDCA strategy include:
Tools of the Trade
## Prioritization Matrix

### XY Decision Matrix Example—Selecting a Continual Improvement Initiative

| Desired Criteria/Expectations: Criteria Weight (Low – 1, Medium – 2, High – 9) | Improve Patient Safety Score | Improve Patient Safety Weighted Score | Meet Regulatory Requirements Score | Meet Regulatory Requirements Weighted Score | Meet Accreditation Requirements Score | Meet Accreditation Requirements Weighted Score | Improve Quality or Service Score | Improve Quality or Service Weighted Score | Improve Customer Satisfaction Score | Improve Customer Satisfaction Weighted Score | Improve Financial Performance and/or Affordability Score | TOTAL Weighted Score |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | |
| **Potential Opportunity for Improvement** | **Comments** | **Score** | **Weighted Score** | **Score** | **Weighted Score** | **Score** | **Weighted Score** | **Score** | **Weighted Score** | **Score** | **Weighted Score** | **Score** | **Weighted Score** |
| Reduce STAT emergency department turnaround times | Patient care is delayed, patient beds full 65% of the time | 3 | 81 | 3 | 27 | 2 | 9 | 3 | 27 | 3 | 9 | 2 | 3 | 156 |
| Reduce days in accounts receivable | New budget requires 10% overall reduction | 1 | 9 | 1 | 9 | 1 | 3 | 1 | 3 | 1 | 1 | 3 | 9 | 34 |
| Reduce patient wait time in outpatient draw facility | High patient dissatisfaction reported | 1 | 9 | 1 | 9 | 1 | 3 | 1 | 3 | 1 | 1 | 3 | 9 | 60 |
| Reduce needlestick accidents | Increasing number of employee needlesticks in past 12 months | 3 | 81 | 3 | 81 | 3 | 27 | 3 | 27 | 1 | 1 | 1 | 1 | 218 |
# Work Plan: Mislabeled or Unlabeled Specimens

**DEFINITION**
Rate of mislabeled or unlabeled samples

## DATA COLLECTION METHODOLOGY
An incident report is completed for each mislabeled/unlabeled event. The number of reports will be counted and broken down by patient area. Criteria for a mislabeled/unlabeled event are as follows:
- Sample received in laboratory with no sample label adhered to the sample.
- Sample received in laboratory with a discrepancy between the sample label adhered to the sample and the patient identification on the sample requisition.
- Sample labeled but label incomplete (ie, missing two patient identifiers).

## DATA PRESENTATION: QUALITY INDICATOR GRAPHIC
(Bar graph showing number of mislabeled/unlabeled samples per patient care area.)

## ACTION THRESHOLD/TARGET
Zero mislabeled or unlabeled samples received in a one-month timeframe.

## INTERPRETATION
Each patient care area had greater than a zero mislabeled/unlabeled sample rate except for the outpatient service area, which was in compliance.

*(NOTE: This information is provided as a hypothetical result to clarify the use and completion of a quality indicator worksheet.)*

## LIMITATIONS ON INTERPRETATION
Documentation is a manual process, requiring a technologist to complete the report for each event. Events not documented will not be accounted for.

## ACTION PLAN FOR VARIOUS OUTCOMES AND INTERPRETATIONS
Workgroup assembled to identify the barriers to successful sample labeling.
Clinical laboratory establishes a zero tolerance policy for mislabeled/unlabeled samples, which includes the rejection of a sample that is not labeled appropriately.
Incidents of mislabeled/unlabeled samples will be communicated to the nurse manager of the patient care area.
Monthly reporting of mislabeled/unlabeled sample rates will be published and distributed to nurse managers, director of nursing, and hospital administrators.
Cause and Effect (Fishbone) Diagram
## Affinity Diagram

<table>
<thead>
<tr>
<th>People</th>
<th>Process</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>No one to transport specimen</td>
<td>Test QC failed</td>
<td>Instrument malfunction</td>
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<tr>
<td>Not enough trained staff</td>
<td>Lack of reagents</td>
<td>Information system not available</td>
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<td>Unacceptable specimen</td>
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<td>Insufficient specimen</td>
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<tr>
<td>Unable to locate specimen</td>
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<td>Pneumatic tube failure</td>
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</tbody>
</table>
Flow Chart

Key for flow chart symbols

- **Start/end**
- **Action/task**
- **Decision**
- **Process sequence**

Blood Sample Collection Process as a Flow Chart

1. Order for collection received by the laboratory
2. Sample collection document generated
3. Special collection precautions needed?
   - No: Hands are washed, Patient is identified, Patient is seated
   - Yes: Special collection precautions taken
4. Capillary puncture performed or Venipuncture performed
5. Blood sample is labeled
6. Proceed to next patient?
   - Yes
   - No: Sample(s) transported to laboratory
Run Chart

Defectives/Sample

1  2  3  4  5  6  7  8  9  10
Control Chart (Levey-Jennings)
Pillars That Support Quality in Health Care

- Culture
- Using Data
- Planning
- Communicating
- Changing Performance
- Staffing

Care, Treatment, and Services
(Addressed in other parts of the manual.)

Leadership
Leadership Standards:

- **LD.03.01.01** Leaders create and maintain a culture of safety and quality throughout the laboratory.

- **LD.03.02.01** The laboratory uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

- **LD.03.03.01** Leaders use laboratory-wide planning to establish structures and processes that focus on safety and quality.
Leadership Standards:

- **LD.03.04.01** The laboratory communicates information related to safety to those who need it.
- **LD.03.05.01** Leaders implement changes in existing processes to improve the performance of the laboratory.
- **LD.03.06.01** Those who work in the laboratory are focused on improving safety and quality.
The Joint Commission Laboratory Standards (cont’d)

Performance Improvement:

- PI.01.01.01 The laboratory collects data to monitor its performance.

- PI.02.01.01 The laboratory compiles and analyzes data.

- PI.03.01.01 The laboratory improves performance.
National Patient Safety Goals:

- NPSG.01.01.01 Use at least two patient identifiers when providing laboratory services.

- NPSG.02.03.01 Report critical results of tests and diagnostic procedures on a timely basis.

- NPSG.07.01.01 Reduce the risk of health-care associated infections. Comply with either CDC or WHO hand hygiene guidelines.
Quality Assessment Standards for Nonwaived Tests:

- **Standard QSA.01.01.01** The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.

- **Standard QSA.01.02.01** The laboratory maintains records of its participation in a proficiency testing program.

- **Standard QSA.01.03.01** The laboratory has a process for handling and testing proficiency testing samples.

- **Standard QSA.01.04.01** The laboratory performs its proficiency testing independent of other laboratories.
The Joint Commission Laboratory Standards (cont’d)

Quality Assessment Standards for Nonwaived Tests:

- **Standard QSA.01.05.01** The laboratory verifies the accuracy and reliability of results obtained for nonregulated analytes and for those regulated analytes for which compatible proficiency testing samples are not available.

- **Standard QSA.02.06.01** Each laboratory specialty and subspecialty has a quality control policy.
The Joint Commission Sentinel Event Policy

**Definition:**
- A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, *or the risk thereof.* **Serious injury specifically includes loss of limb or function.** The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
  - Such events are called “sentinel” because they signal the need for immediate investigation and response.
  - The terms “sentinel event” and “error” are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events.
The Joint Commission Sentinel Event Policy (cont’d)

Goals:

- To have a positive impact in improving an individual’s care, treatment, or services and preventing sentinel events.

- To focus the attention of a laboratory that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions, and active failures in defense systems, or organizational culture), and on changing the laboratory’s culture, systems, and processes to reduce the probability of such an event in the future.

- To increase the general knowledge about sentinel events, their contributing factors, and strategies for prevention.

- To maintain the confidence of the public and accredited laboratories in the accreditation process.
The Joint Commission Sentinel Event Policy (cont’d)

Activities:
- Identify the cause of the event.
- Develop an action plan.
- Implement the plan.
- Monitoring the effectiveness of improvements.

Tools:
- RCA
- Checklist
- Prioritization matrix
- FMEA
- Flow chart/value stream map
- Charts
  - Histogram
  - Pareto
  - Run/control
  - Scatter
  - Surveys
Essentials of Successful Performance Improvement

**COLLABORATION**
- Laboratory Staff
- Nursing Staff
- Leadership

**COMMUNICATION**
- Internal Customers
- External Customer
- Governing Agencies

**COMMITMENT**
- Leadership
- Workforce
- Stakeholders
## Communication

### Score Card/Dashboard

<table>
<thead>
<tr>
<th>Key Performance Indicators (KPIs)</th>
<th>Accountable</th>
<th>Jan</th>
<th>Feb</th>
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<th>Nov</th>
<th>Dec</th>
<th>Current Year-To-Date Performance</th>
<th>Current Year Goals</th>
<th>Fiscal Year Performance</th>
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<td>Increase Employee Satisfaction</td>
<td>AHLManagers</td>
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<td>Decrease employee turnover by XX%</td>
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<td>Implement action plans responding to employee and physician satisfaction survey results</td>
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<td>Improve quality and patient safety</td>
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<td>Reduce total occurrence of (X) or (some goal)</td>
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<td>Reduce work error occurrences by XX%</td>
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<td>Increase patient safety diary submission occurrences by XX%</td>
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<td>Increase consumer satisfaction average score by XX%</td>
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<td>Achieve total outreach goals/total volume by XX%</td>
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*Note: Colors indicate performance status.*
Communication of Performance Improvement Projects

Laboratory Dashboard - ANNUAL STRATEGIC PLAN METRICS

CLINICAL QUALITY - OVERALL DEPARTMENT

Accessioning Errors
- Parts per Million Errors per Month
- Lower is Better

Proficiency Testing
- % Challenges
- Higher is Better

Patient Satisfaction Outreach Patient Service Centers CY10 Q2
- % Excellent
- % Very Good
- % Good
- % Poor

Documentation Compliance of Critical Values Communicated
- % of Cases
- Goal for Automated Callback system
- Peer Benchmark

Correlation of Pathology Diagnosis of Patients Referred to Hospital for Treatment or 2nd Opinion
- Total # Cases Sent for Review
- If Substantial Agreement
- If Major Disagreement

Physician Client Satisfaction Compared to Other Labs CY4 2009
- Better Than
- Same As
- Not as Good As

25%
References


Questions?

It's QUESTION TIME!!