Laboratory Management of a Quality System

Module 5: Laboratory Process Management

ACKNOWLEDGEMENT

- Ministry of Health and Social Welfare – Tanzania
- Muhimbili University of Health and Allied Sciences
- World Bank
- ECSA- HC

Learning Objectives

- Describe the major process control activities in the laboratory
- Describe process control measures for specimen management
- List the components of a method validation
- Implement and manage a comprehensive quality control system in the laboratory

Learning Objectives (Continued)

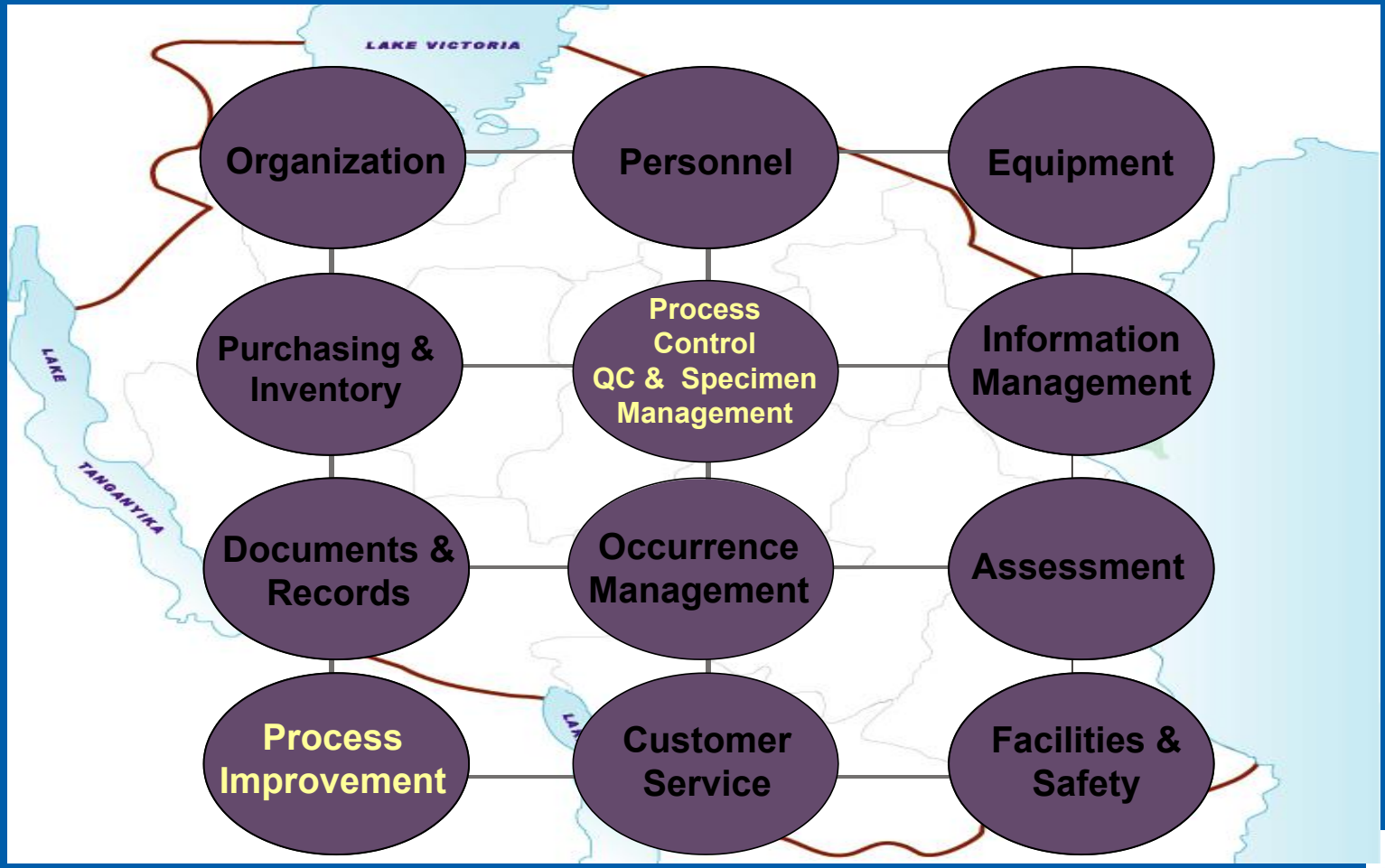
- List the components of a well-written Quality Control (QC) guidelines
- Explain the advantages and disadvantages of the different options for QC rules
- Evaluate and interpret a variety of QC problems
- Design and implement an effective process improvement project

Today's Agenda

The Quality System

- Process Design
- Process Control
  - Specimen Management
  - Method Validation
  - Quality Control
- Process Standardization and Audits
- Process Improvement
- Module Summary

The Quality System



The Laboratory Processes

- Processes within a quality system are well defined and assure work is performed the same way each ti
- Success of a quality system is dependent on processes that:
  - Make errors difficult to commit
  - Make errors visible if committed

Managing Laboratory Processes

- Design the process
- Define process controls
  - Specimen Management
  - Method Validation
  - Quality Control
- Standardize the process
- Audit the process periodically
- Continuously improve the process

Any questions so far?

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Process Design

- Design good processes to meet customer needs
- Eliminate steps that do no add value to the custome
- Arrange equipment and supplies close to staff to eliminate time in motion

Process Design (Continued)

- Plan workflow and physical space to enhance efficiency
- Minimize number of workstations
- Mistake-proof processes to minimize human error
- Automate tasks where possible

Process Design Goals

- Make errors difficult to commit
- Make errors visible if committed

Mistake Proofing Phlebotomy

- Double check patient identifiers with order form
- Do NOT pre-label specimen container
- Do NOT give an unlabeled specimen container to another individual to be labeled
- Never leave the patient's bedside without first checking to make sure all specimen containers are labeled
- Each specimen label must legibly display:
  - Initials of person who collected the specimen
  - The date and time it was collected
  - Patient Name and number

Exercise

- Design a phlebotomy process that will insure quality for the customer and client.

- Work in groups for 20 minutes followed by 10 minutes for discussion.

What questions do you have about process design?

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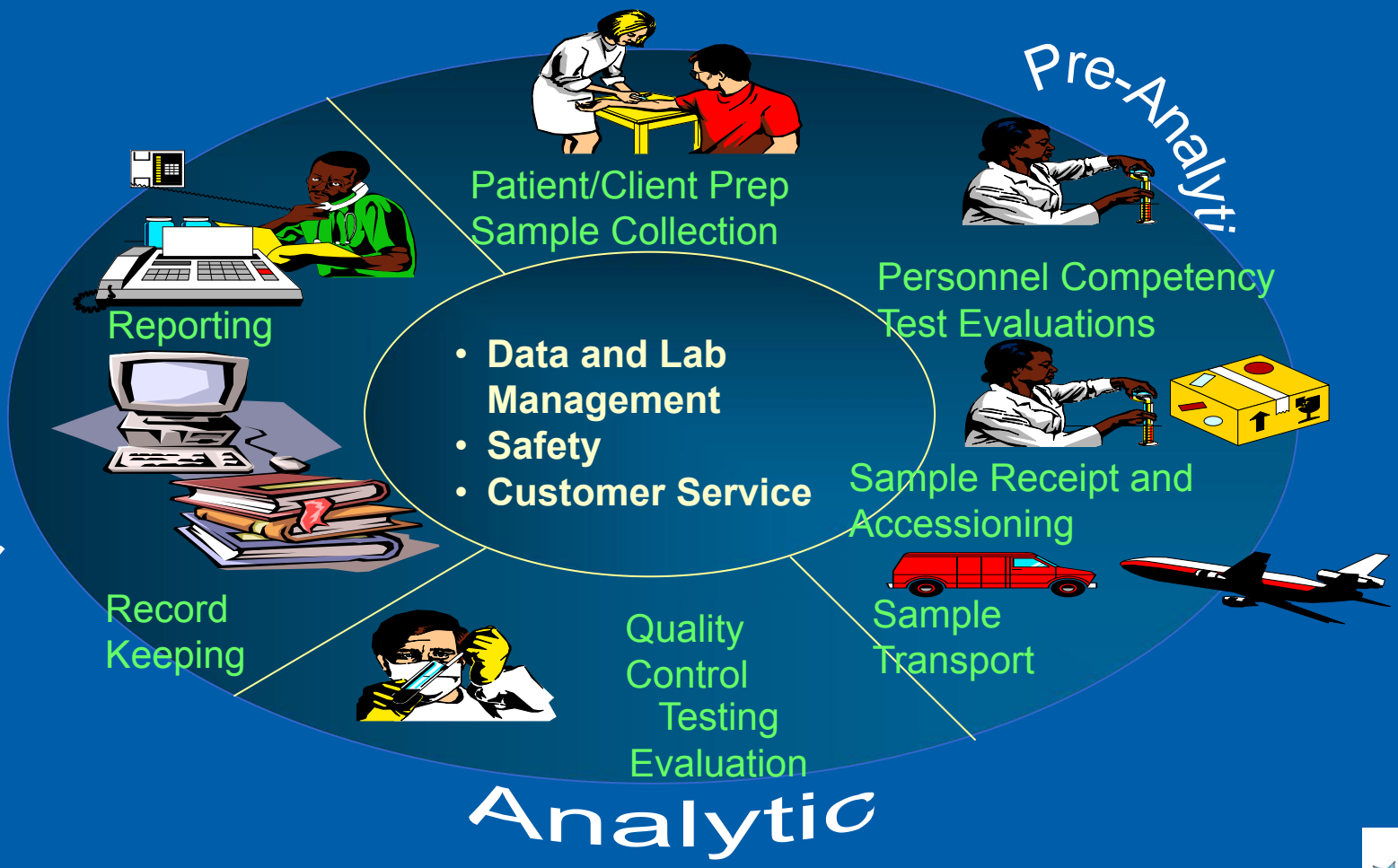
Process Control

- Goal
  - To assure work processes are performed the same way each time
- Definition
  - A set of control measures for the 3 phases of testing to assure quality of the entire laboratory process

The Quality Assurance Cycle



Process Control Activities

- Pre-analytic:
  - Specimen collection and transport guidelines; criteria for acceptability of specimens
- Analytic:
  - Method evaluation and validation
  - Calibration, calibration verification, periodic linearity checks

Process Control Activities (Continued)

- Analytic (continued):
  - Use of calibrator and control materials at defined frequencies for the method
  - Quality control program with defined rules; performing and documenting corrective action
  - Statistical evaluation of QC data; shifts and trends identified
  - Repeat of questionable results

Process Control Activities (Continued)

- Post-analytic
  - Result review criteria and/or delta checks (limits set for significant change in results)
- All Phases:
  - Well written policies and procedures under document control
  - Clear documentation of all steps

Major Process Control Activities

- Specimen Management
- Process/Method Validation
- Quality Control
  - Statistical Quality Control
  - Reagent lot validation

What questions do you have on process controls so far?

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Specimen Management

- Standardized patient identification procedures
- Standardized specimen labeling procedure
- Written specimen collection procedures with collection containers and handling procedures
- Defined quality indicators for specimen collection and transport process
- Written and enforced specimen rejection policies
- Written procedures for situations

What questions do you have on specimen management?

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Process/Method Validation

- Process validation includes method evaluation and validation of pre-analytic and post-analytic processes
- Prior to reporting test results, each method must have performance characteristics validated to assure the quality of the expected results

Process/Method Validation (Continued)

- What is done?
  - Precision Analysis
  - Carryover Study
  - Correlation Study
  - Accuracy Assessment
  - Linearity (Reportable range verification)
  - Normal/Reference Range

Process/Method Validation (Continued)

- How is it done?
  - Laboratory can perform process validation but it is very time-consuming and requires special technical expertise
  - Vendor may perform and document the performance aspects of the instrument during the evaluation
  - Laboratory leaders must review and approve the method validation regardless of how it is done

What questions do you have on process validation?

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Quality Control

- A set of procedures for continuously assessing the quality of laboratory results
- Using quality control sample

Stable Control Materials

- Commercial controls (assayed or unassayed)
- Patient or employee controls (controls internally obtained)
- Statistical measurement using patient data

Types of Quality Control

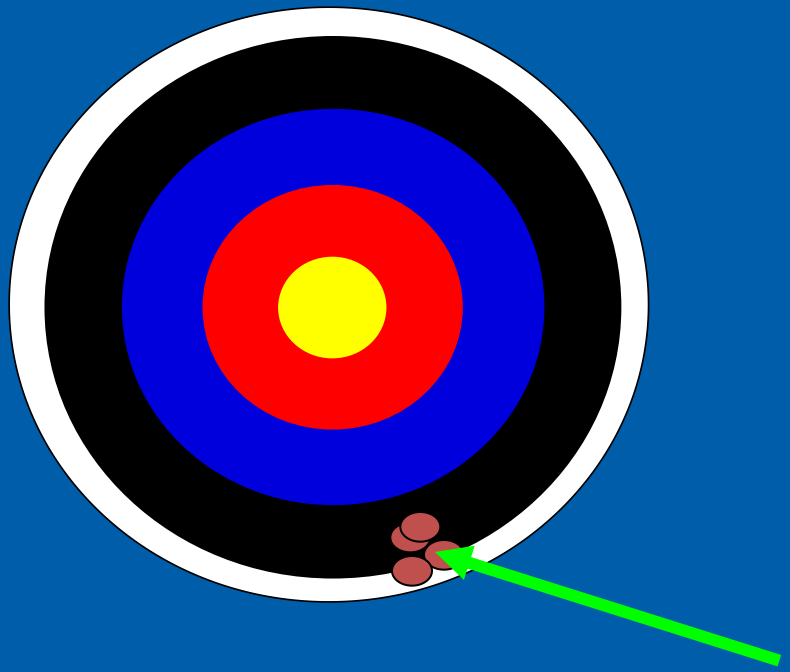
- Qualitative – run at least one positive and negative control each day
- Quantitative – run at least 2 controls (normal and abnormal) once per shift

Purpose for Quality Control

- Why do it?
  - Quality control is used to monitor the precision and the accuracy of the assay in order to provide reliable results
  - Quality control statistics (i.e. Mean and SD) indicate whether observed results are within the expected limits of the analytical process

Precision

- Reproducibility or closeness of results to each other

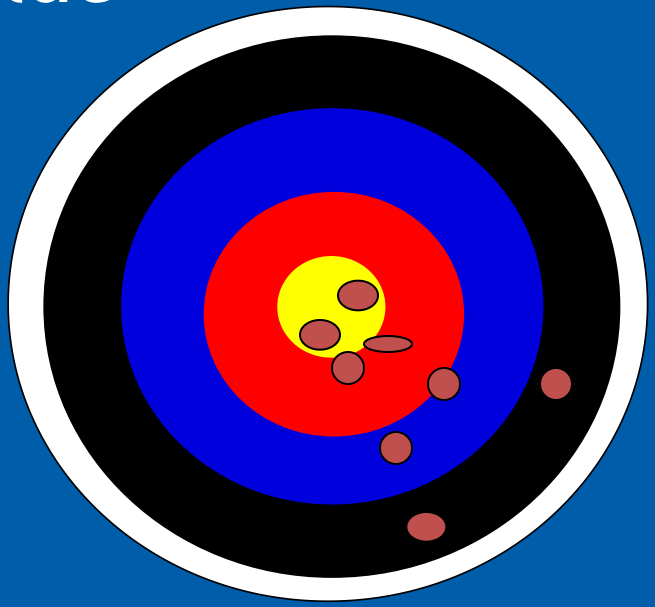


Imprecision: Random Error

- An unexpected and unpredictable error
- For example, one control out of two control results exceeds 3 standard deviations from the mean

Accuracy

- The closeness of the measured result to the true value



Inaccuracy: Systematic Error

- Repeated error that occurs in a predictable manner
- For example when two consecutive control values exceed the same mean +2s limit or the same mean -2s control limit
- This rule is sensitive to shifts in the mean in which a sustained change either higher or lower would cause a new mean to be calculated if allowed to continue without resolving the problem

Knowledge Check

- A repeated error that occurs in a predictable way is an example of:

A. Accuracy
B. Inaccuracy
C. Imprecision
D. Precision

Knowledge Check

- The closeness of a measured result to a true value is referred to as:

A. Accuracy
B. Standard Deviation
C. Imprecision
D. Precision

Knowledge Check

- An unexpected and unpredictable error is an example of:

A. Accuracy
B. Inaccuracy
C. Random error
D. Standard deviation

Knowledge Check

- Reproducibility or closeness of results to each other is referred to as:

A. Accuracy
B. Inaccuracy
C. Imprecision
D. Precision

Knowledge Check

- What is the difference between a random
  error and a systematic error?

Knowledge Check

- What is the difference between a random
  error and a systematic error?
  - A random error is unexpected and unpredictable
  - A systematic error repeats in a predictable way.

What questions do you have on Quality Control so far?

QC Program Management

- Written quality control guidelines and procedures
- Statistical evaluations to set quality control limits
- Determination of QC rules to be used
- Defined system for running, documenting, and charting QC data

QC Program Management (Continued)

- Defined procedures for handling out-of-control situations
- Procedures for troubleshooting of QC failures
- Supervisory review of QC data and corrective actions

QC Program Management (Continued)

- Written QC Guideline
- Quality Control limits
- QC Rules
- QC Documentation
- Out-Of-Control Procedures
- QC Supervision

Written QC Guideline

Guidelines and procedures must be written to include:

- Goals of the program
- Type of quality control materials to be used
- Internal or electronic QC allowed
- Frequency of QC testing

Written QC Guideline (Continued)

- Quality control rules for different assays
- QC statistics and control limits
- Tech review and acceptance of patient test results
- Corrective action to be taken for out-of-control situations
- Supervisor review of QC results

Quality Control Limits

- Statistical evaluation process to set limits using mean and standard deviation
- Manufacturers/supplier QC limits are determined from large groups of laboratories in order to provide information about the comparative performance between laboratories and between methods
- These are cumulative control tolerance limits

Calculate Quality Control Limits

- Given the mean and standard deviation (s) for a control material, control limits are calculated as the mean +/- a certain multiple of the standard deviation, such as 2s or 3s.
- For example: cholesterol Control 1 mean = 200 mg/dL, s = 4 mg/dL, 200 – (2x4) and 200 + (2x4); the 2s control limits would be 192 and 208 mg/dL.
- The 3s control limits would be 188 and 212 mg/dL as determined by 200 – (3x4) and 200 + (3x4).

* Standard deviation may be abbreviated SD

QC Rules

- Each analytic run is either accepted or rejected based on the control rules chosen to monitor quality control values
- Control rules should be carefully selected to maximize error detection and minimize false rejection
- Control rules will vary from method to method and will be based on the quality (allowable error) required by the test

QC Rules (Continued)

- Options for QC rules:
  - Simplest – if one control value is more than 3 SD from the mean value the run is rejected
  - Complex – Multi-rule procedures developed by James Westgard
- What rules are you currently using for your chemistry assays?

Rejection Rules

- Multi-rule System
  - Mean +/- 2s (95% limits) are commonly used quality control ranges to set limits for acceptance and rejection of analytical runs.
  - Use of automation suggests the need for more rules to check for systematic errors like shifts or trends.
  - A high level of false rejection occurs when rules are so stringent that analytical runs are rejected when they shouldn't be.
  - Rules should be set to minimize false

Warning Rules

- Multi-rule System
  - A warning rule may be set up to allow acceptance of results in one run but extra precaution to check for shifts and trends in this and the next consecutive runs.
  - When one control exceeds 2s but not 3s (either high or low) and no shifts or trends occur, the Westgard Multi-rule system calls this a warning.

QC Documentation

- Running and Documenting QC
  - Quality control results obtained for each quantitative or qualitative test should be recorded and documented by plotting the values onto the control charts
  - Documentation of the quality control results will provide evidence of routine monitoring of the system
  - Quality control measurements from out-of-control runs must be documented
  - Corrective actions to bring the test system

Out-of-Control Situations

- Procedures for out-of-control situations
  - The patient run with out-of-control quality control values must be rejected
  - Rerun the control using a new control vial
  - Identify the problem using instrument or method troubleshooting process
  - Resolve the problem and implement appropriate corrective action
  - Rerun QC and if control is within limits, rerun and report patient samples from rejected r

Quality Control Supervisor

- A well-documented and managed QC program is the laboratory supervisor responsibility!

What questions do you have on quality control management policies and rules?

Reagent Lot Validation

- Qualitative Tests
  - New lots must be checked by running one known positive and one known negative patient before using the lot to assure there is not a problem with the new lot.
  - New lots of reagents must give the same results as obtained with the old lot.
  - QC material may be used as an alternative.

Reagent Lot Validation (Continued)

- Quantitative Tests
  - Changes in lot numbers of reagents may cause the need to recalibrate the system and then rerun the controls to verify proper calibration.
  - The assayed control mean and standard deviation often takes into consideration changes in reagent lot numbers since the values are calculated as lot-to-date.

What questions do you have on Quality Control case studies?

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Process Standardization

- Standard Work
  - Processes must be standardized to create standard work – one way of doing things!
- Process standardization is achieved through well-written standard operating guidelines and procedures
- Hold staff accountable for following SOPs

Process Audits

- Process control can be assessed through internal assessment/audit of the various processes for example:
  - Audits of calibration records
  - Audits of preventative maintenance records
  - Audits of daily QC records
  - Audits of procedure manuals for out-of-date documents
  - Audits of logs and records for complete information

What questions do you have on process standardization and audits?

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Process Improvement

- Identify opportunities for improvement based on occurrence reports, internal and external audits, complaints, customer feedback, and employee input
- Select problems to work on that have significant impact on patient care, finance, or customer satisfaction
- Define the process that you will use
  (Ex. PI team, FOCUS(find, organize, clarify, understand, select)-PDCA (plan, do, check, act)
- Prioritize the problems you wish to solve

Activity: Process Improvement

- Define the problem “What happened?”
- Assemble the right team to solve the problem
  - Those close to the issue
- Assess the current state
  - Team flowcharts how the process currently works
- Gather data on what happened
- Perform root cause analysis to identify root cause of the problem

Activity: Process Improvement

(Continued)

- Brainstorm solutions
- Develop the implementation plan
- Communicate the process changes to all staff
- Evaluate results by collecting data
  - Were the objectives achieved?
- Create a standard process that can be performed in one standard way
- Do quality checks periodically on the

Process Improvement Project

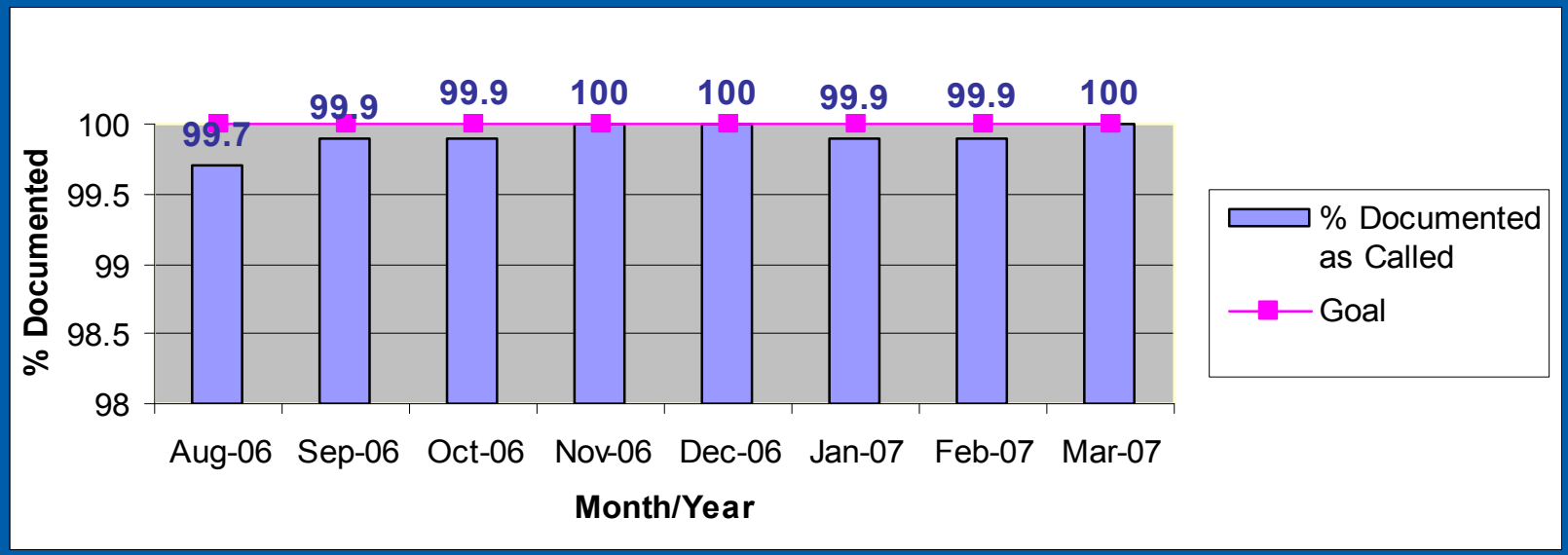
- F- Finding a process to improve
  - Panic Results Reporting

PLAN -Set Project Goals/Objectives

- 100% of results audited will reflect that documentation of notification was performed for all results
- At least 90% of results audited will reflect that lab to clinician/nursing notification occurred within 30 minutes of result availability
- At least 90% of results audited will reflect that clinician notification (if applicable) occurred within 60 minutes of result availability

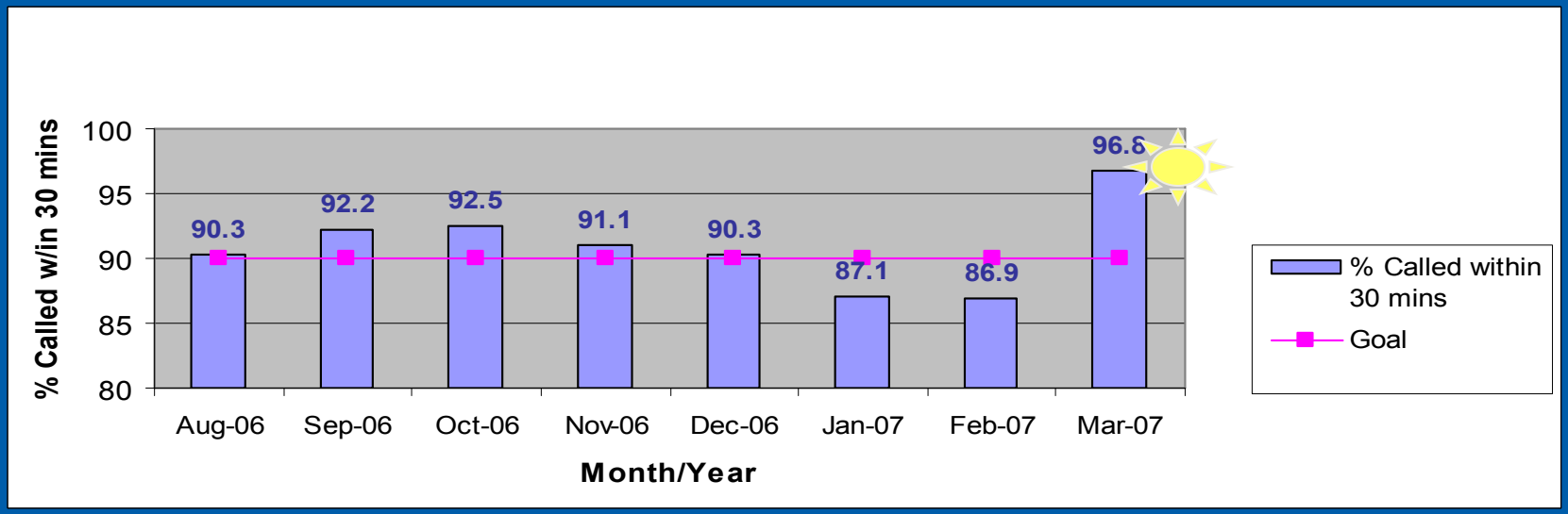
DO- Gather Data

- Panic Values – Documentation of Notification



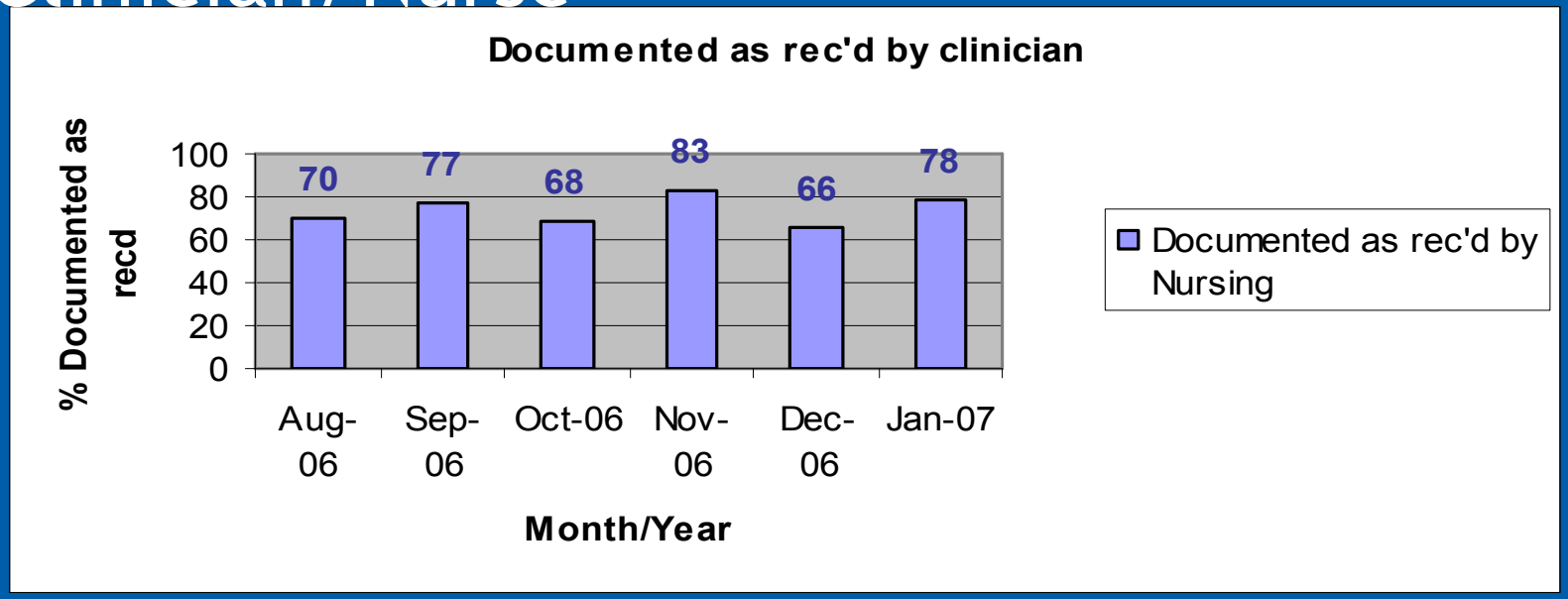
DO- Gather Data (Continued)

- Turn around time (TAT) for Notification of Panic Values – Lab to Clinician



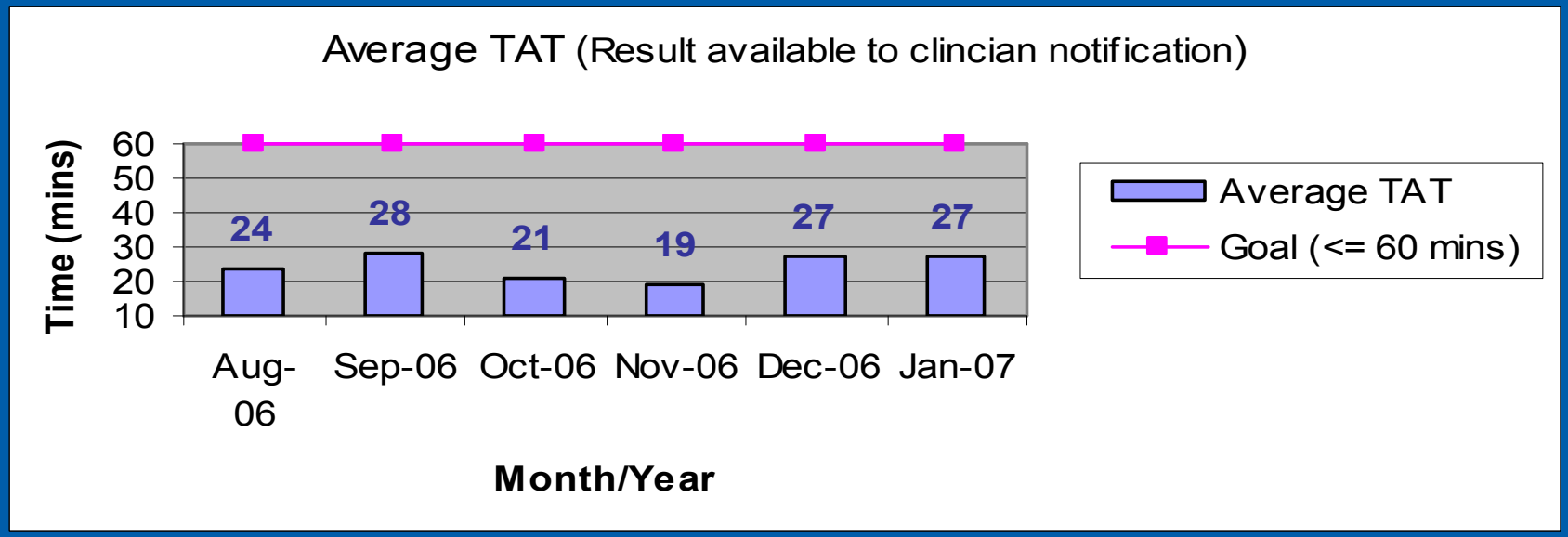
DO- Gather Data (Continued)

- Clinician Review – Documentation of receipt by Clinician/Nurse

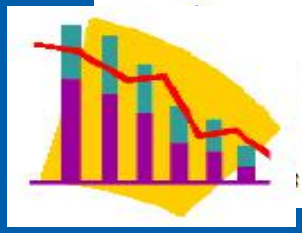


DO-Gather Data (Continued)

- TAT for receipt by clinician of panic values (Based on Clinician Audit)



CHECK -Assess Data



- Lab
  - Downward trend:
    - Documentation: Jan and Feb 2007
    - TAT for Notification: Jan and Feb 2007
- Clinical Area
  - Not all Panic values called by lab to clinicians were documented as received
  - Read back was not always documented

ACT- Develop Action Plan – Generate Ideas

- Reviewed variances and limitations. Looked at time of day, department workflow, instrumentation, interfaces, location of patient etc.
- No documentation of notification
  - Tech sent result without calling
  - Panic value called but not documented in Computer

ACT- Develop Action Plan – Generate Ideas (Continued)

- Timeliness of Notification
  - Long delay to report Panic Values/tech unable to reach clinician
  - Multiple results on instrument interface; no autoverification of normal results on hematology analyzer
  - Results left on interface of instruments with autoverification

ACT – Implement

- Patient Safety Review Checklist
- Interface screen snapshots
- Document delays in reporting results
- Reminders posted on computers and instruments
  - Check interfaces frequently

Check

- A review of the data collected for March 2007 showed an improvement!
  - [100%] Critical Values were documented as called
  - [96.8%] Critical Values audited were called within 30 minutes. The highest % ever attained.

Assess

- Continue to review
  - Monthly audits
  - Variances
  - Make midcourse corrections as needed!

For the safety of our patients!

Case Study

- In reviewing Your quality monitors you note that there were three occurrences of corrected rapid HIV test results your threshold is 0. Therefore the laboratory has an unacceptably high number of corrected rapid HIV reports.
- Describe the PI process you would use to solve this problem

Module Summary

- Described the major process control activities in the laboratory
- Described process control measures for specimen management
- Listed the components of a method validation
- Implemented and managed a comprehensive quality control system in the laboratory

What questions do you have on process improvement?

Module Summary (Continued)

- Listed the components of a well-written QC guideline
- Explained the advantages and disadvantages of the different options for QC rules
- Evaluated and interpreted a variety of QC problems
- Designed and implemented an effective process improvement project

What questions do you have on Laboratory Process Management?

Thank you