Error Management in Clinical Laboratory

Dr. Anita Chalak (Kale)
Professor and Head
Department of Biochemistry
Seth GSMC & KEM Hospital, Mumbai

Contents

- Laboratory operations and errors in the pre-analytic, analytic and post analytic phases.
- Monitoring laboratory errors in each stage of the total testing process and its importance.
- Role of a laboratory manager to control laboratory errors in order to improve laboratory performance.

Definition

- Laboratory errors may be defined as “a defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting on these”
- This definition was accepted and incorporated into the draft of the ISO Technical Report 22367 ‘‘Medical laboratories”

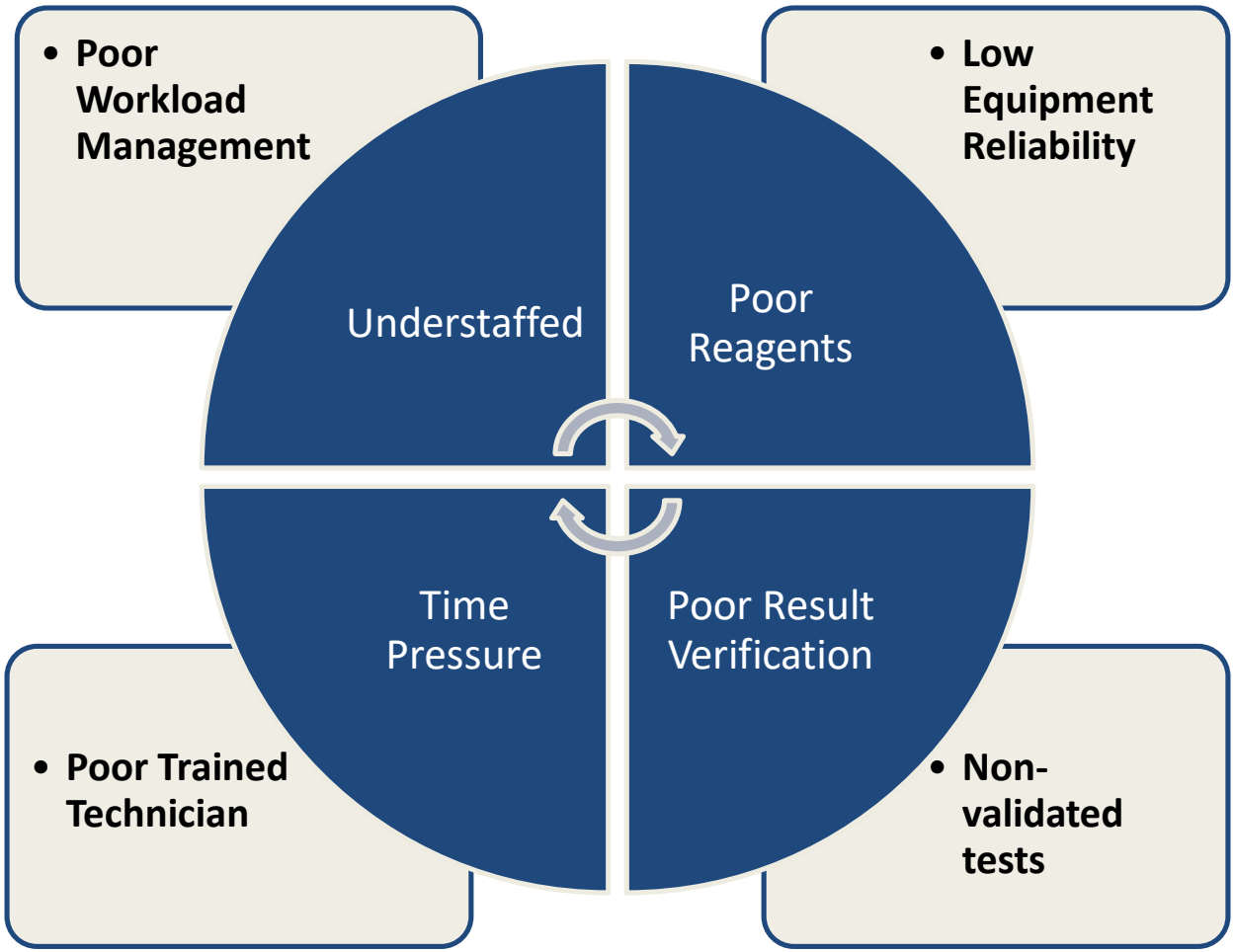
Importance of Error Management

- Consequences of lab errors have implications on finances, service quality and additional training inputs to lab staff.

- In short, lab errors cut the profitability margin of the laboratory and therefore minimizing lab errors is a major task in lab management.

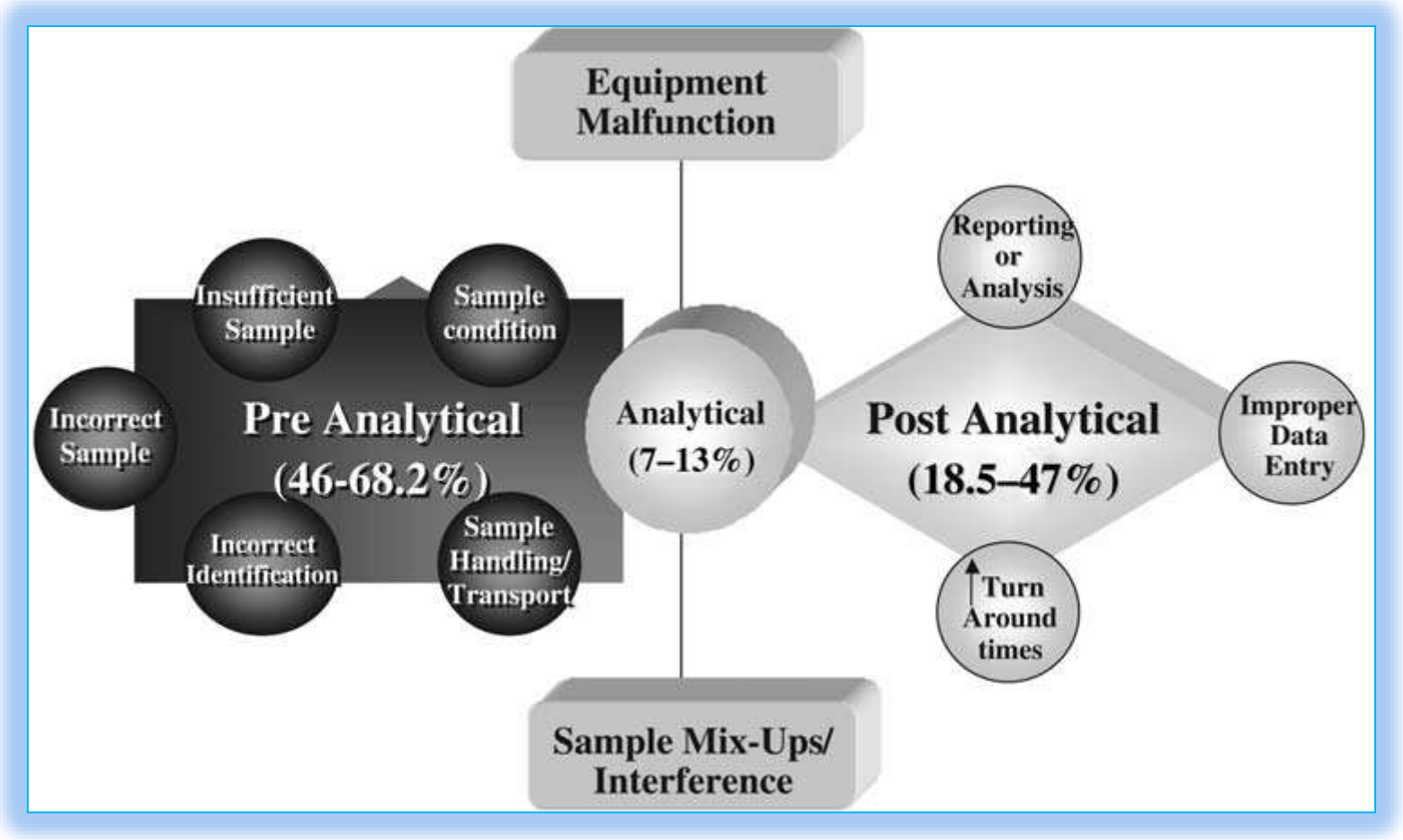
Poor Quality Management

Why do laboratory errors occur?



Blame on Laboratory Manager

Total Testing Process



Pre-analytical Errors and its Management

Pre-analytical Errors

- Majority of laboratory errors (46-68.2 %)
- Most difficult to detect so the focus must be on prevention.

Patient variables: Patient assessment, test order entry, request completion, patient identification, diet, stress, position etc

Specimen variables: Specimen collection, specimen transport or specimen receipt and processing in the laboratory.

Pre-pre-analytical phase

- Procedures performed neither in the clinical laboratory nor under the direct control of laboratory personnel.

- This phase starts with test request, patient and specimen identification, blood drawing (phlebotomy procedure), sample collection and handling and ends with the transportation of specimens to the laboratory.

- Transcription errors are the most common errors in this phase (oral/hand written)

Phlebotomy Procedure and Impact on Testing

- ✓ Identification of the patient is crucial for accurate test results.
- ✓ Inspect all supplies for defects and expiry dates.
- ✓ Select appropriate needle gauge.
- ✓ Tourniquet placement should not exceed 2 minutes, which may result in hemoconcentration and erroneously increased levels of protein-based analytes, packed cell volume and other cellular elements.
- ✓ Introduction of alcohol into specimen may cause hemolysis of specimen.
- ✓ Blood flow should be uninterrupted

- ✓ Immediately mix collection tube containing additives by gentle inversion (end-to-end mixing 5–6 times)
- ✓ Numerous inversions or vigorous shaking can cause hemolysis
- ✓ Label the tubes, record date and time of collection
- ✓ Patient's first and last names
- ✓ Identification number
- ✓ Maintain proper transport conditions to preserve specimen integrity

Ensure that all medical specimens arrive at the testing facility

- At the correct temperature for testing
- Intact in the container (without breakage or leakage)
- Within the time limits for the test
- In compliance with all applicable regulations

Specimen Rejection Criteria

- Unlabeled Specimen
- Insufficient patient information
- Hemolysed / Lipemic / Icteric sample
- Inadequate volume for the amount of preservative
- Inappropriate collection container
- Insufficient Quantity
- Prolonged transport (exposure to heat and cold, vibration, position of specimen tubes and overall time to delivery)
- Ordering wrong test
- Ordering tests on the wrong patient

Just Reject!

Jaundice

Lipemia

Hemolysis

What Else ?

Developing clear written procedures- Validity

Enhancing Health Care Professional Training

The education of health care professionals involved in procedures for the collecting, handling, preparing and transporting biological specimens is crucial to understand the effects of pre-analytic variables on specimen quality.

Automating functions

- Pre-analytical robotic workstations automate some of the steps and reduce the number of manual steps involving more people.

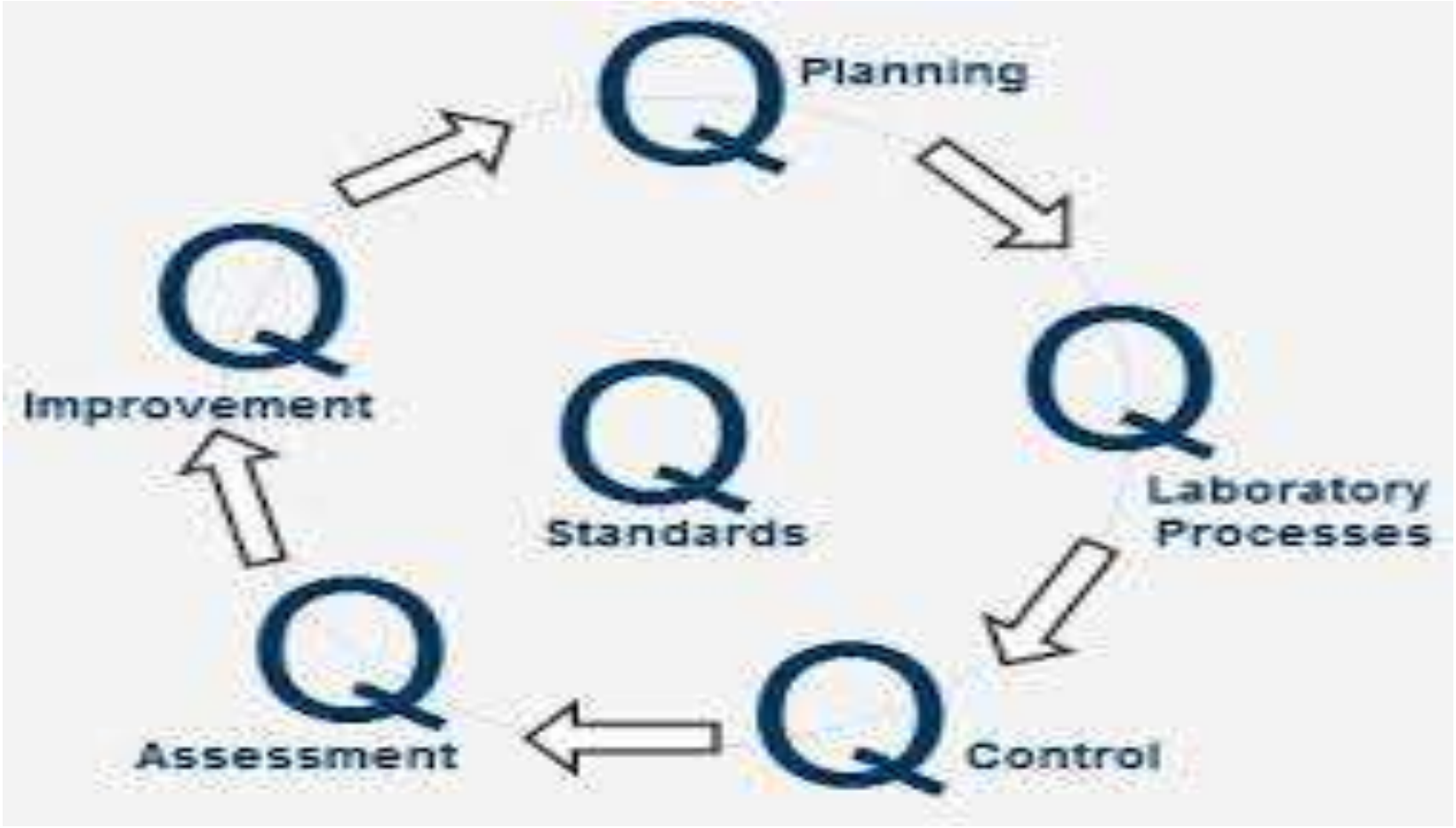
- Computerized order entry.
- Automated phlebotomy tray preparation.

- Barcodes also simplify specimen routing and tracking.

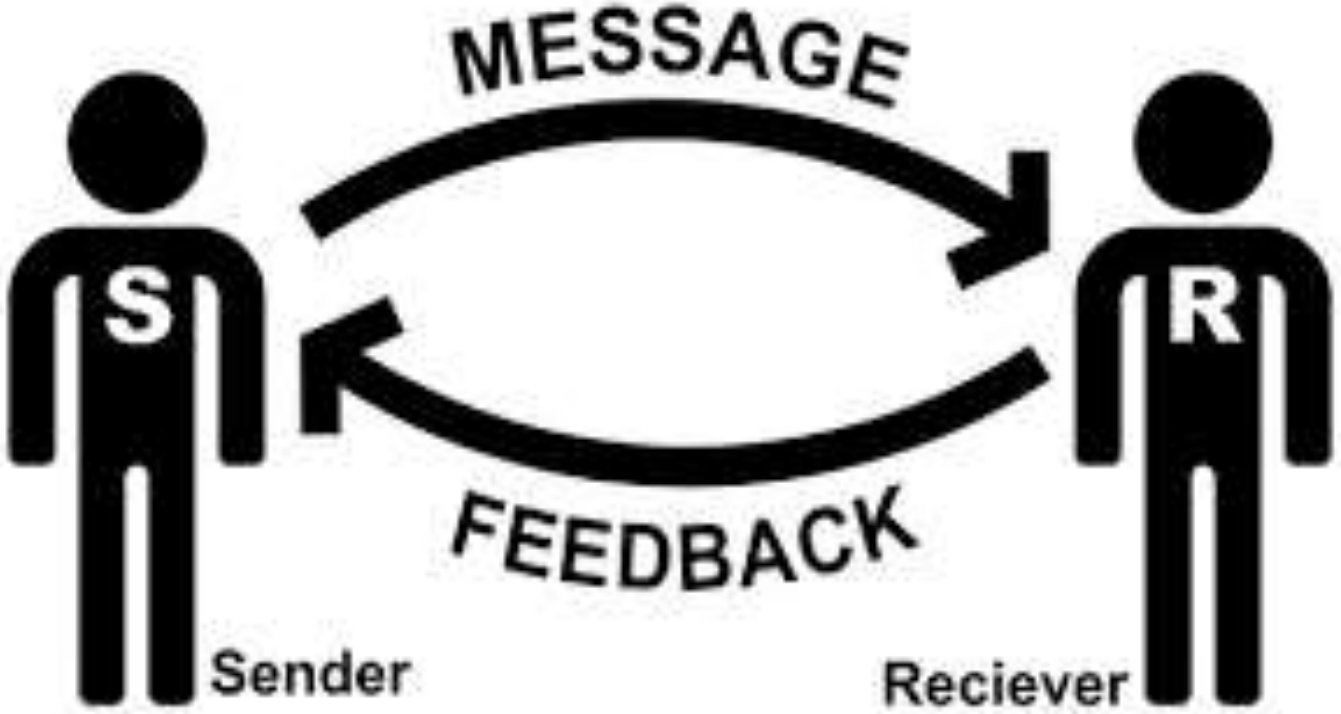
- Recent advances in laboratory technology have made available new and more reliable means for the automated detection of the serum indices including the hemolysis index.

- Visual detection of hemolysis must be abandoned due to low sensitivity and low reproducibility.

Monitoring quality indicators. Benchmarking



Communication among health care professionals

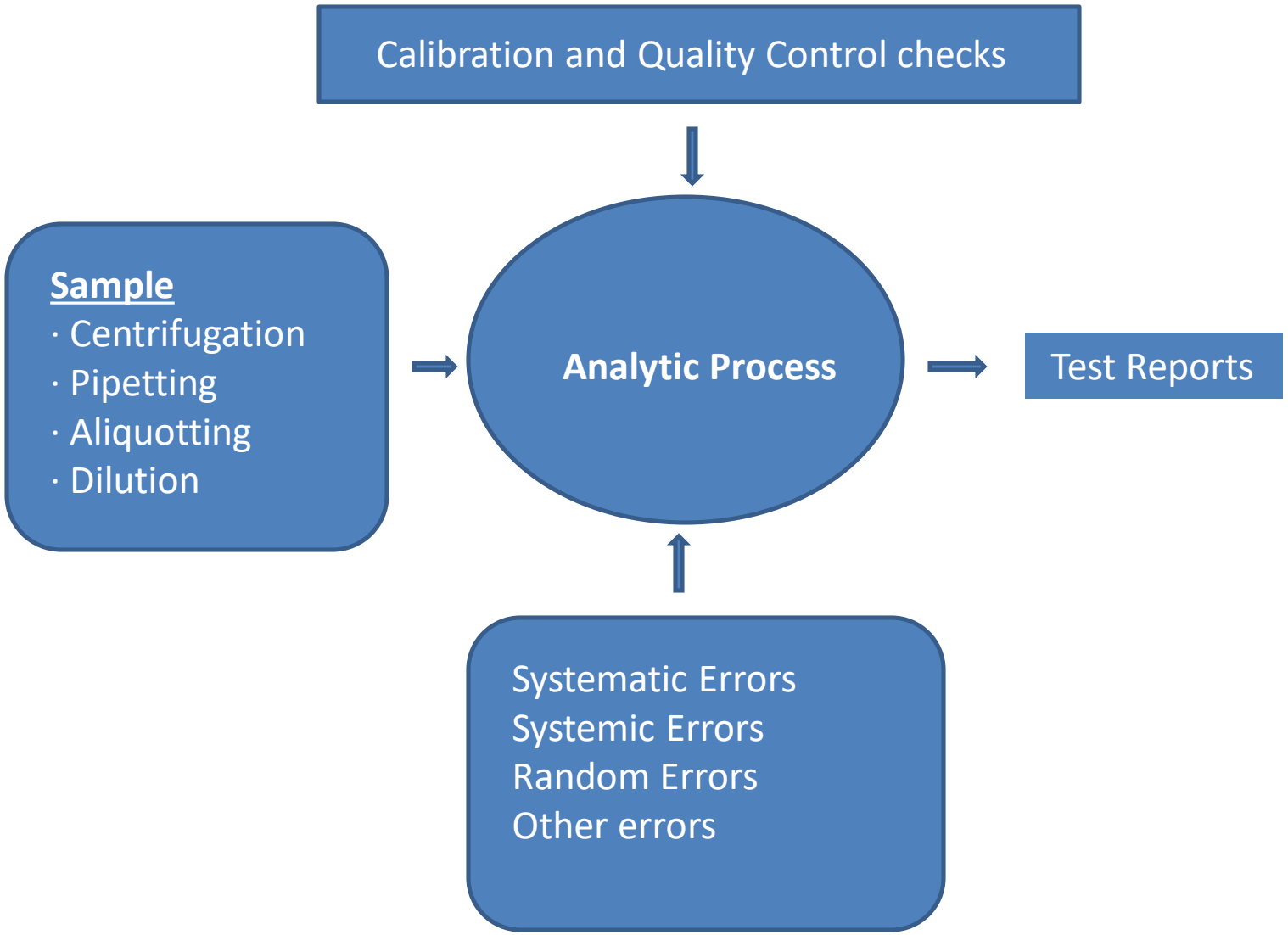


Fosters interdepartmental cooperation

Excellent communication and cooperation among all members of the health care team, from the phlebotomist who collects the specimen, to the courier who picks up the samples for transport to the testing laboratory, to the personnel receiving the specimen.

Analytical Errors and its Management

Analytic Process: A Conceptual view



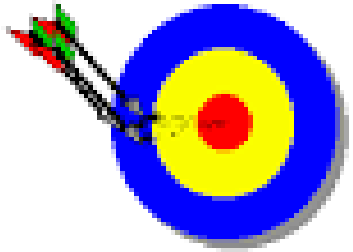
Analytical Errors

- Begins when the patients' specimen is prepared in the laboratory for testing.
- Ends when the test result is interpreted and verified by the technologist in the laboratory.

- Improper processing of specimen prior to analysis or substances interfering with assay performance can affect test results in the analytical phase.

- Establishing and verifying test method performance specifications as to test accuracy, precision, sensitivity, specificity and linearity are other areas where errors can occur in the analytical phase of laboratory testing.

Types of Errors



Analytical errors:

1. **Systematic Errors:** Caused by a defect in the analytical method or by an improperly functioning instrument. It produces a biased value raising concerns on accuracy of test results.

   Underestimates or overestimates the true value.

Sources of systematic error include:

- Interferences
- lot-to-lot variations
- matrix effects
- carry-overs

Types of Errors

2. **Systemic Errors:** Systemic errors are caused by inherent technical problems and/or by the wear and tear of the equipments and instruments.

- Probe malfunctioning
- Aging of lamp (light source for spectrophometric measurement) can cause faulty reading.
- Blocked or a kinked tube can affect the delivery of proper amount of sample and or reagents leading to measurement error.

Types of Errors

3. **Random Errors:** Random errors are unavoidable since they arise from the limitations of physical measurements.

   Random errors can be caused by timing, temperature or pipetting variations. They occur randomly and are independent of the operator performing the measurement.

- Incorrectly calibrated pipettes
- Improperly used pipettes
- Defective negative pressure leading to wrong sample volume aspirated in pipettes.
- Incorrectly calibrated automated volume dispensers
- Measuring reading early/late than prescribed time limits
- Improperly functioning temperature system

Types of Errors

4. Other types of errors: Factors outside of analytic variability can have a profound impact on a laboratory's ability to produce an accurate result.

- For example, the blood glucose level in a tube of blood can decrease over time.

- Refrigeration/ Fluoride bulbs

Analytic Error Management

- Internal quality controls (IQC) and external quality assessment (EQA).
- **The role of EQA and proficiency testing (PT):**

✓ to provide reliable information allowing laboratories to assess and monitor the quality status of internal procedures and processes.

✓ the suitability of the diagnostic systems.

✓ the accountability and competence of the staff.

✓ the measurement of uncertainty in laboratory results.

Calibration

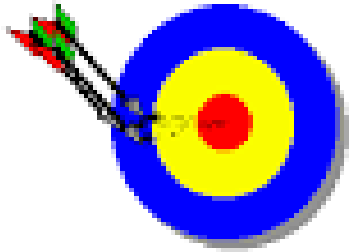
- **Calibration** is the act of checking or adjusting (by comparison with an acceptable value) the accuracy of a measuring instrument.

- Accuracy of any instrument is established through regular calibration of the instrument.
- Accuracy is the degree of conformity of a measured or calculated quantity to a Reference Value.

Calibration

- It requires testing of sample against one or more materials (calibrators) that behave similarly to the specimen and for which the true result is known.
- Calibration drift is a systematic change in measurement that occurs over a time period of unadjusted, continuous operation of a test instrument.
- The multipoint calibrator is usually much better compared to a single or two point calibration.

Quality Control



- Quality Control is a measure of precision or how well the instrument system reproduces more or less same results over time.
- Any process with a low analytic variation would produce more reliable test results than a process with high analytic variation.

- Precision refers to the closeness of agreement between independent test results obtained under varying operating conditions.

Quality Control

- QC checks are usually run at the beginning of each shift, after an instrument is serviced, when the reagent lots are changed, after calibration and when patient results seem inappropriate.

- The materials used for quality control should have the same matrix (characteristics) as patient specimens; viscosity, turbidity, composition, colour, minimal vial to vial variability etc.
- Acceptability of quality control result is established by estimating the variability or standard deviation of the process.

Quality Control

- The standard deviation (known as Sigma) quantifies the degree of dispersion of data around the mean value.
- Acceptable SDI values are between ±2 SD.

- Three Sigma quality level for an analyte means 66807 errors out of a total of 1,000,000 tests results which means only 93.32% results of this analyte are reliable.
- Four Sigma quality level would produce 99.38% reliable results.
- Six Sigma quality level would mean only 3 errors out of every 1,000,000 test results.

Minimizing Laboratory Errors

Advances in analytical techniques	Benchmarking for minimal acceptable quality
laboratory instrumentation	Standard Methods
Information technologies	Sample introduction and transport
Automation and organization	Interfering substances are to be looked
Regular Calibrations/Controls/Standards	Linearity- Proper Dilution
Check for critical values	Reagent checks
Sample processing before analysis(labeling, Centrifugation, aliquoting)	Sample integrity (includes volume checks, Clot detection)
System check	Incubation
Mixing of sample and reagent	Report preparation
Calculations and Readout result for reporting	Verification of the reports

Post-analytical Errors and its Management

Post Analytical Activities

Phase	Activity
Post analytic	Report validation
	Communicating the results to physician or patient
Post post analytic	physician receives the report
	Interpretation by physician & follow up

Post-analytical Error

- Test reporting variables
  - Recording
  - Reporting
  - Interpreting

- Inappropriate use of laboratory test results, critical result reporting and transmission of correct results are areas of potential error in the post-analytical phase of the total laboratory testing process.

- The most common mistakes accounting of total laboratory errors are: wrong validation, results that are delayed, not reported or reported to the wrong providers and incorrect results reported because of post-analytical data entry errors and transcription errors.

- Incorrect interpretation of results.

- Another well-recognized source of post-analytical problems is inter laboratory variability and inaccuracy of reference intervals.

Post-post-analytical phase

- Performed outside laboratory control, a clinician receives, reads and interprets results and makes a decision on the basis of information from laboratory and other sources.

Post-analytic Error Management

- Three level report validation:

1. Technician
2. Technologist (Supervisor)
3. Expert (Biochemist/Pathologist)

- Automation of the validation process, besides minimizing transcription errors, would also allow senior level pathologists to focus on difficult cases and interact with clinicians.

- The term “auto-validation” is used to define a “post-analytical computer-based intelligent system designed to simplify test interpretation”

- These systems may allow laboratory specialists to perform rapid assessment and reporting of analytical data.

Communicating the Results

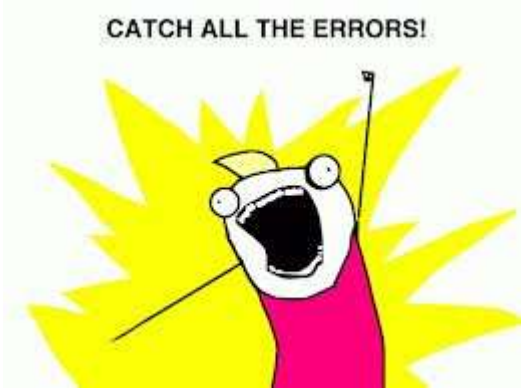
- Timely and accurate critical value reporting for quality of care and medical error prevention
- Miscommunication should be avoided
- Transcription error: Automated data entry, Carefully checked and approved by the laboratory manager
- Validation of laboratory results.
- Alert critical values- Separate record

- The success of any efforts made to reduce errors must be monitored in order to assess the efficacy of the measures taken.

- Quality indicators must be used for assessment.

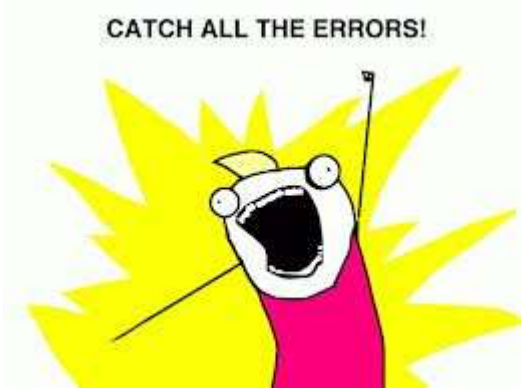
- In the testing process areas involving non-laboratory personnel, interdepartmental communication and cooperation are crucial to avoid errors.

Role of a Lab Manager



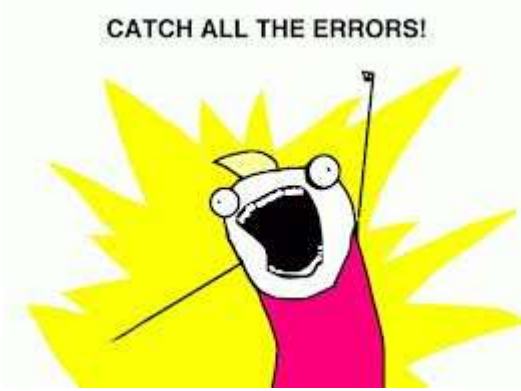
- Laboratory personnel must ask for new samples when hemolysis/lipemia/icterus is detected.
- If a new sample cannot be obtained, it is the responsibility of the laboratory specialist to communicate the problem to the clinician.
- Analyze EQA/PT samples and reports.
- Perform calibration and quality control runs as per protocol and thereby ensure that the lab results are reliable.
- Documentation of quality control and validation of laboratory results.

Role of a Lab Manager



- Detect trends or bias that may not be apparent in single results.
- Investigate root causes producing unacceptable performances.
- Apply and monitor opportune actions for removing the underlying cause(s).
- Prompt and predictable reporting of test results.
- Determine whether the problem affected clinical decision making.

Role of a Lab Manager



- Achieving accuracy and precision requires strict adherence to established protocols, rigorous use of controls, careful selection of reagents and the quality of specimens submitted for analysis.
- Insist on her/his lab staff to record all errors and their causes as and when they occur.
- An analysis of documented lab errors and taking corrective actions to avoid such errors in future would go a long way to minimize sample rejections and thereby provide reliable test results within the shortest possible time.

Quality Standards

- Regulation of quality in the health care sector is based on accreditation, certification, quality monitoring, patient's rights, standard operation processes, and standards of health care quality.


LEGAL IMPLICATIONS OF
LAB
ERRORS

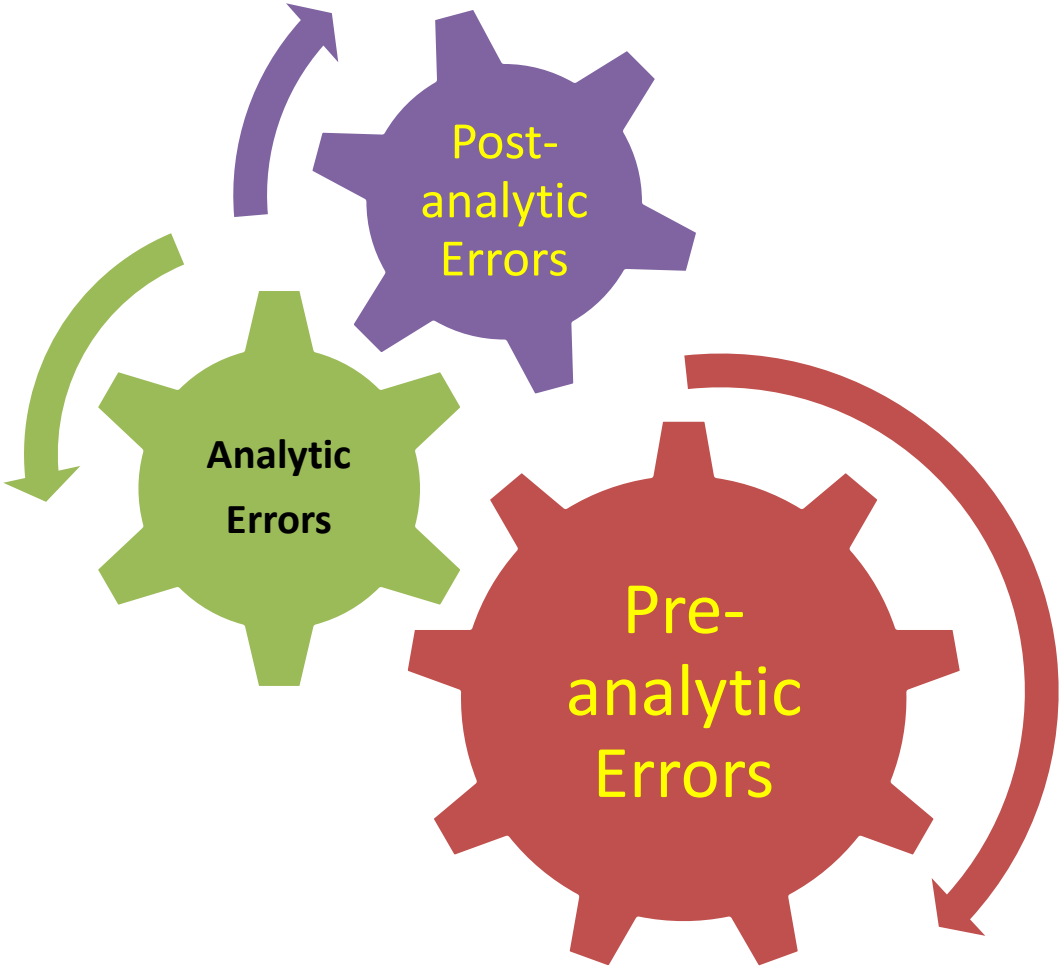
Summary

- Development and widespread implementation of a Total Quality Management (TQM) system is the most effective strategy to minimize uncertainty in laboratory diagnostics. Pragmatically, this can be achieved using 3 complementary actions:

1. Preventing adverse events (error prevention)
2. Making them visible (error detection)
3. Mitigating their adverse consequences when they occur (error management)

- Therefore the entire health care system must be involved in improving the total testing process.
- More rigorous methodology for error detection and classification and the adoption of proper technologies for error reduction.
- Clinical audits should be used as a tool to detect errors caused by organizational problems outside the laboratory.

Take Home Message



Total Quality Management

Roles and Responsibilities

Quality Control/Calibration

Communication

Benchmarking

Training

SOPs

Thank You