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Review Article

A perspective on the journey from planning and setup to accreditation of clinical biochemistry lab in tertiary care cancer hospital

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Abstract

This article is a general review of personal experience of my journey from the setup of clinical biochemistry lab and final accreditation by NABL national accreditation board for testing laboratories.) This general review can useful for post graduates in clinical biochemistry and young clinical biochemists for guidelines to start up a new clinical biochemistry lab. Planning and setup diagnostic clinical biochemistry lab needs requirements like Resource requirement, Equipment procurement and Scope of tests. Quality management system contains Internal quality control, External quality assurance scheme (EQAS). Continous improvement plan need for Technology update and Scope expansion. Accreditation process starts from accreditation body and standards and implementation of standards. Planning and startup of clinical biochemistry lab needs proper resource and equipment requirement along with support from technical staff for preparing documents and implementation. Finally, for accreditation process requires timelines and encouragement from management authorities.

Keywords: Clinical biochemistry lab, Quality management system, Accreditation process, Quality indicators, Internal quality control (IQC), External quality assurance scheme (EQAS).

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1. Introduction

This article is a general review of personal experience of my journey from the setup of clinical biochemistry lab and final accreditation by NABL. This general review can useful for post graduates in clinical biochemistry and young clinical biochemists for guidelines for star up new clinical biochemistry lab. Planning to establish clinical biochemistry lab needs resource, quality management and Continous improvement plan for updates. Clinical biochemistry lab needs trained technical staff and quality control policy for implementation. Finally, accreditation process requires technical records like standard operating procedures, quality management documents management reviews and internal audits.[1-5]

2. Discussion

2.1. Planning and setup

Planning and setup diagnostic clinical biochemistry lab needs following requirements

2.1.1. Resource requirement

Initially started with personnel recruitment of clinical biochemist and two lab technicians, later procurement of sample collection and process requirements like vacutainers, pipettes and centrifuge done by hospital authorities. Sample collection come under pre-analytical or pre-examination part of laboratory testing. This pre-examination part is very important step in the entire process of laboratory testing. Pre-examination process requires labelling vacutainer, proper collection of samples, transport of sample and finally

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receiving of sample in appropriate conditions is important for of seventy percent of errors in total testing process.[6-12]

2.1.2. Equipment procurement

Equipment are planned for common biochemical tests and tumor markers tests. Analyzers are fully automated chemistry and immune assay analyzers installed on reagent rental basis even less workload. Procurement of analyzers are based on broad scope, cost effective and quality assurance. Fully automated analyzers require reasonable workload for cost effective and to maintain quality control procedures. Analyzers on reagent rental basis are more suitable for hospital based laboratories because of proper maintenance and up gradation to new technology whenever requirement comes.

2.1.3. Scope of tests

Scope of tests covered for requirement of oncology hospital like common biochemical tests (Liver function tests, Renal function tests, Electrolytes, Lactate dehydrogenase, Glucose, Calcium, Phosphorus)tumor markers (AFP, CA125, HCG.CEA, CA19.9, PSA), hormones (FSH, LH, Estrogen, Testosterone), and nutrition profiles like vitamin B12, vitamin D and Serum Electrophoresis for multiple myeloma diagnostic work up.

2.1.4. Biomedical waste management

Biomedical waste segregated into three labelled bins red, blue and yellow. Used syringes, gloves and vacutainers are kept in red bin. Anatomical waste, used masks, swabs are kept in yellow bin and vails, ampoules, lab slides are kept in blue bin. White plastic container with hypochlorite used for dispose used needles

2.1.5. Staff management

Technical staff rotated thorough duty roster for twenty-four hours lab services. Staff follows safety guideline by wearing personnel protection equipment. Eye wash and shower provided and first aid kit available for needle stick injury.

2.2. Quality management system

Quality management system implementation done through the following process

2.1.1. Internal quality control (IQC)

Internal controls procured from third party agency and running two levels daily for both chemistry and immunoassay parameters. Summary of the monthly reports reviewed for statistical values like standard deviation (SD), coefficient variance (CV) for checking precision and filed regularly on monthly basis.

Measures taken to manage out-of-control situation

1. Inform the Scientific Assistant /Consultant biochemist of the Department Check the reconstitution date of QC
2. Check the temperature of the refrigerator.
3. Check the reagent (expiry date, opening date etc.)
4. Check the instrument. (Check priming, dispensing etc.)
5. Rerun the controls.
6. If problem persists run the fresh controls.
7. Else calibrate the parameters
8. If problem still persists call the engineer and also refer manufacturerstroubleshooting guide.

2.1.2. External quality assurance scheme (EQAS)

EQAS or proficiency testing (PT) participation is doing with providers like CMC Vellore for common chemistry tests and BIORAD immunoassay EQAS for tumor markers. Summary of monthly reports reviewed for standard deviation intervals (SDI) for accuracy and filed regularly on monthly basis.

2.1.3. Total quality management (TQM)

Total quality management consists from pre-examination process, examination process and post examination process

2.1.3.1. Preexamination process

Pre -analytical quality needs proper selection of sample collection tubes, labeling of sample, technique of phlebotomy, transport of sample and centrifugation with prescribed time and speed. Quality indicators like percentage of inadequate sample volume, mislabeled percentage, hemolyzed sample percentage monitoring required for pre-examination process improvement.

Examination process: Analytical process quality monitoring with internal quality control statistics like coefficient variation (cv) for precision, inter lab comparison or proficiency testing for accuracy of analytical process. Before the processing of the samples the equipment's are checked for its performance byperforming maintenance as per the equipment requirements followed by the quality control. QC is checked as per the QC policy and then barcoded samples are loaded and processed. In case barcodes are not read by the equipment, then the samples are programmed manually and then processed.[13]

As and when the results are generated they are either interfaced or manually entered on the DIS system for the release of the report finalized by the consultant. All the samples sealed or recapped are stored at 2-8°C for 24 hrs.[14]

The test procedures and reference materials used for the examination are traceable to the international standards and are performed according to the instructions given on the examination procedure manual which could be the pack inserts supplied along with the kits, calibrators and controls or the standard manual procedures which are adopted by the department maintained in the typed form.

Calibration: Calibration is done

1. If there is a new lot of reagent,
2. If control values are not according to the QC policy
3. Following preventive maintenance, breakdown and repairs (when parts are replaced dueto certain service or maintenance which could have affected the calibration) or when calibration expires.

Post examination process: Post analytical process quality requires proper interface of test report values, interpretation of report, monitoring of percentage of amended reports.

2.1.3.2. General quality management areas

In addition to the three main phases, ISO 15189:2022 highlights other areas that impact

Overall laboratory quality:

Some of the Key Areas Include:

1. Document Control.
   a. Maintaining up-to-date and accessible procedures, policies, and records.
2. Risk Management.
   a. Identifying and mitigating risks to quality and patient safety.
3. Non-Conformance Management.
   a. Investigating and addressing errors, deviations, and complaints.
4. Continual Improvement.
   a. Regularly reviewing processes and implementing improvements.
5. Feedback.
   a. Collecting and acting on feedback from clinicians and patients.
6. Internal Audits.
   a. Conducting regular audits to ensure compliance with ISO 15189.
7. Management Review.
   a. Periodic review of the QMS by laboratory management to ensure its effectiveness.
8. Inter-phase Considerations.
   a. Some areas overlap between phases and require special attention:
9. Communication.
   a. Effective communication between laboratory staff, clinicians, and patients.
10. Turnaround Time (TAT).
    a. Monitoring TAT across all phases to ensure timely results.
11. Sample Traceability.
    a. Ensuring samples are traceable throughout the entire process.

2.2. Continous improvement plan

Planning also done for continual improvement for technology update and expanding the test menu as for the requirement of the clinical doctors.

2.2.1. Technology update

Electrophoresis and latest turbidometry method analyzer installed on reagent rental basis for diagnosis and monitoring multiple myeloma patients. Therapeutic drug monitoring also initiated for methotrexate, cyclosporin drugs which are used in the treatment of oncology patients. Chemistry and immunoassay analyzers are interfaced with laboratory information system for reducing transcriptional errors.

2.2.2. Scope expansion

Scope of tests are increasing as required by the clinical doctors which are useful for oncology practice like hormones (Prolactin, Estradiol, Testosterone PTH, FSH, LH) are doing along with initially planned scope.

2.3. Accreditation process

2.3.1. Accreditation body and standards

Lab accreditation process initiated as per the standards ISO15189:2022 under the national accreditation board for testing laboratories (NABL). Laboratory staff are trained for implementation of the standards and guidelines given by the NABL based on the ISO15189:2022 standards.

2.3.2. Implementation of standards

Required standards are fulfilled by preparing and implementation of following documents and polices.

2.3.2.1. Prepared the SOPs, quality system documents and formats

Three level documents must prepare from first line management system document as per ISO 15189:2022 guidelines. Second level quality system procedures and third line are formats for document control.

2.3.2.2. Staff trainings and competency assessment records

Regular staff trainings for enhance competence and assessment done with MCQ examinations and testing with duplicate samples and known value samples. Trainings must include both quality related documents and technical guidelines

2.3.2.3. Method verification records

Method verifications through inter instrument comparison done by linear regression r value, analytical sensitivity, linearity by standard operating procedures

2.3.2.4. Quality indicators

Quality indicators monitoring monthly for various indicators like rate of sample rejections and internal quality control

failures, percentage of amended reports which include total testing process. Quality indicators are review monthly basis for improvement of total testing process. Pre-Analytical Phase.

The pre-analytical phase includes all processes that occur before the actual testing of the sample. This phase is critical because errors here can significantly affect the accuracy and reliability of test results.

Some of the Key Areas include

1. Patient Identification and Preparation
   a. Correct patient identification.
   b. Proper patient preparation (e.g., fasting requirements).
2. Sample Collection.
   a. Use of appropriate collection techniques and containers.
   b. Proper labeling of samples.
3. Sample Transport:
   a. Timely and safe transport of samples to the laboratory.
   b. Maintenance of appropriate conditions (e.g., temperature) during transport.
4. Sample Reception and Handling
   a. Verification of sample integrity upon receipt.
   b. Proper documentation and logging of samples.
5. Sample rejection criteria.
   a. Clear criteria for rejecting unsuitable samples (e.g., hemolysis, insufficient volume).
   b. Request Form Accuracy.
   c. Completeness and accuracy of test requisition forms.

2.3.2.4.1. Analytical phase

The analytical phase involves the actual testing of samples. This phase requires strict control to ensure accurate and reliable results.

Some of the key areas include

1. Method Validation and Verification.
   a. Validation of new methods and verification of established methods.
   b. Ensuring methods are fit for their intended use.
2. Calibration and Maintenance
   a. Regular calibration of equipment.

Routine maintenance and troubleshooting of instruments.

1. Internal Quality Control (IQC).
   a. Use of control materials to monitor the precision and accuracy of test results.
   b. Establishing and adhering to control limits.
2. External Quality Assessment (EQA).
   a. Participation in proficiency testing programs.
   b. Comparison of results with other laboratories.
3. Competence of Personnel.
   a. Training and competency assessment of laboratory staff.

Ensuring staff are qualified to perform tests.

1. Reagent and Supply Management.
   a. Proper storage and handling of reagents.
   b. Monitoring reagent expiration dates and performance. Post-Analytical Phase

The post-analytical phase includes processes that occur after the test is completed, such as result reporting and interpretation. Errors in this phase can lead to misdiagnosis or inappropriate treatment.

Some of the Key Areas Include:

1. Result Reporting.
   a. Timely and accurate reporting of results.
   b. Use of appropriate reference intervals and units.
2. Critical Result Notification.
   a. Prompt communication of critical or abnormal results to clinicians.
   b. Documentation of notifications.
3. Result Interpretation.
   a. Providing interpretive comments or recommendations, if applicable.
   b. Ensuring results are clinically relevant and actionable.
4. Data Management.
   a. Secure storage and retrieval of test results.
   b. Protection of patient confidentiality.
5. Turnaround Time (TAT).
   a. Monitoring and meeting established TAT goals.
   b. Investigating and addressing delays.
6. Post-Analytical Review.
   a. Reviewing results for consistency and accuracy.

2.4. Internal control records (IQC)

Internal control records archived monthly with levy Jenning charts and statistical monthly data of standard deviation (SD) and coefficient variation (CV). Internal QC failures must take corrective actions and root cause analysis with preventive actions must document. Levy jennig charts are printed monthly and review for any trends and shifts for corrective actions. Multi control rule are applied in monitoring the daily QC results.[15-16]

1. If both the controls are within +/- 2SD control values are accepted.
2. If any of the controls exceed +/- 2SD control values are rejected
3. If the values of both the controls fall on one side of the mean for 5 consecutive days or if the values of one of the control fall on the same side of the mean for 10 consecutive days the control values are rejected.

4. If one of the control value is > 2SD and the other control < 2SD the control values are rejected.

2.5. Proficiency testing records (PT)

Proficiency reports or EQAS reports review monthly and any outliers must take corrective actions and root cause analysis with preventive action must document. Proficiency testing result notification received through mail and results are interpreted by standard deviation interval of plus or minus two.

2.6. Lot to lot verification records

New lot of reagents must verify with old lot reagent values and percentage of variation and the percentage of variation must be \ within the range of measurement uncertainty of that parameter. Records of lot-to-lot verifications archived for review.

2.7. Measurement of uncertainty (MU) and CV for all scope parameters

All scope parameters CV calculated from monthly quality control statistics. Measurement of uncertainty (MU) calculated by the CV multiple with 1.96.Scope prepared by format given by national accreditation board for testing laboratories with measurement of uncertinity

2.8. Internal audit records and corrective and preventive actions taken for non-conformities.

Internal audits conducted by our internal auditors for non-conformities of all testing process from standard operating procedures, analytical process and final reporting.

2.9. Management review meeting records

Mangement review meeting planned yearly for requirements like equipment and improvement of quality system and other necessities like manpower.

2.10. Final assessment non-conformities, corrective, and preventive actions records.

Final assessment non-conformities given by external auditors are addressed with proper corrective actions and documented. The proofs of corrective actions are attached with records and send them to the auditors for acceptance.

3. Conclusion

Planning and start-up of clinical biochemistry lab needs proper resource and equipment requirement along with support from technical staff for preparing documents and implementation. Quality management is the key process for laboratory accreditation. The training of latest guidelines of accreditation body and equipment updating and maintenance also important part of the lab management. Finally, for accreditation process requires timelines and encouragement from management authorities.

4. Source of Funding

None.

5. Conflict of Interest

None.

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