

Impact of Haematology Laboratory Accreditation on Patient Care and Health System: Our Experience

Chitturi Ramya*, I.V. Renuka**, P. Premalatha***

*Assistant Professor **Professor ***Professor and Head, Dept of Pathology, NRI Medical College, Chinakakani, Guntur, Andhra Pradesh 522503, India.

Abstract

Introduction: 70% of clinical decision making is predicted upon, or confirmed by, or documented by medical laboratory test results. Accurate laboratory services are required for diagnosis, to identify causative factors, staging, treatment initiation, monitoring drug efficacy and toxic effects in cancer patients. *Purpose:* 1. To provide accurate, early, reliable and universally acceptable results to patients in a Cost-effective way. 2. To improve operational efficiency and safety of laboratory personnel 3. Encourage other laboratories to apply for National Accreditation Board for Testing and Calibration Laboratories (NABL). *Methods:* A quality manager was appointed to supervise the implementation of accreditation. Quality manual was prepared and from it Standard Operating Procedures (SOPs), registers and formats were made according to International Organization for Standardization (ISO) 15189 guidelines. *Results:* Quality of our laboratory services and reports are improved thereby gaining the confidence of clinicians and patients in our institute. Our technicians are more efficient in their work. *Conclusions:* Although accreditation is a time consuming and laborious process, it is a doable process. It provides early warning signs and identifies lacunae in our system. We encourage all the teaching hospitals and laboratories to apply for accreditation.

Keywords: Accreditation; Hematology Laboratory; ISO 15189; NABL.

Introduction

Accurate laboratory services are required for diagnosis, to identify causative factors, staging, treatment initiation, monitoring drug efficacy and toxic effects especially in cancer patients [1]. Reliable and accurate test results are often a prerequisite to the delivery of high quality patient care. Without proper laboratory training, the likelihood of wrong test results increases. False positive and false negative lab results also produce higher costs both for the patient and health care system.

Accreditation is an internationally recognized evaluation process used to assess and improve the quality, efficiency and effectiveness of health care organizations [2]. It promotes development and maintenance of good practices in testing and calibration [3].

Objectives

1. To provide accurate, reliable and universally acceptable results to our patients in a cost-effective way and in improving TAT (Turn Around Time) and STAT (immediate results) standards.
2. To improve operational efficiency and safety of lab personnel by periodic training and strictly implementing health precautions.
3. To encourage/guide other laboratories to go for NABL accreditation and thereby improve their standards of patient care.

Material and Methods

Our hospital decided to apply for accreditation for the hematological laboratory in 2013. Having decided upon going ahead with the accreditation process, the need of the hour was to identify elements that needed to be focused upon and certain prerequisites which should be met and these were fulfilled. Our laboratory is a legally registered laboratory with adequate facilities, technically competent and qualified staff. A

Corresponding Author: I.V.Renuka, Professor, Dept. of Pathology, NRI Medical College, Chinnakakani, Guntur, Andhra Pradesh 522503, India.

E-mail: repriya56@gmail.com

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quality manager was appointed to oversee the implementation of accreditation and quality related activities. Quality manual was prepared and from it SOPs, registers and formats were made. In the pyramid of laboratory documentation the hierarchy of

documents should include test forms/formats, consent form, worksheet, registers, test reports/records, feedback/complaints, etc., at the base followed by standard operating procedures prepared as per guidelines of standard [4].

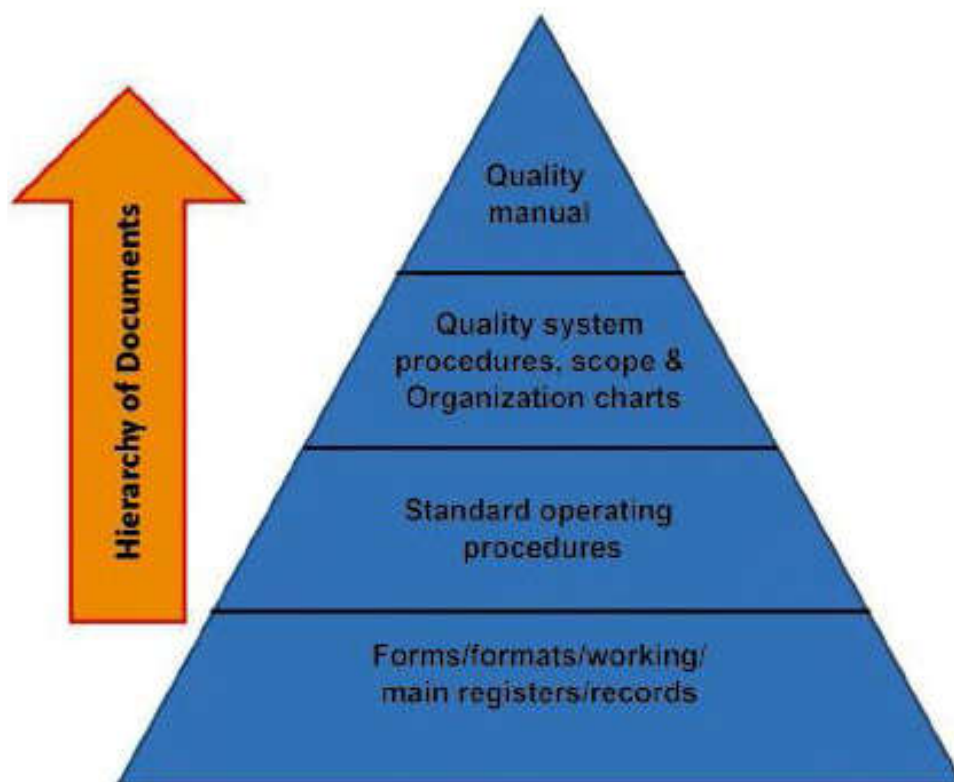


Fig. 1: Pyramid of laboratory documentation

Thirteen hematological parameters like Hemoglobin (Hb), Red Blood Cell Count (RBC Count), Packed Cell Volume (PCV), Total WBC Count (Total White Blood Cell Count), Differential Count, Platelet Count, Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Mean Platelet Volume (MPV), Red Cell Distribution Width (RDW), Reticulocyte count and Peripheral smear examination were included in our Scope. Internal audit and management review was done before applying for accreditation. Internal quality control was done by running controls daily and Levy-Jennings (LJ) charts were prepared. External quality control was done by participating in an External Quality Assurance Services (EQAS) conducted by BIO-RAD monthly and All India Institute of Medical Sciences (AIIMS) quarterly. We also participated in the interlaboratory comparison (ILC) programmes by sending samples to PATHCARE laboratory.

Results

1. Our patients were provided with right test performed by right method on the right specimen after right preparation and right result issued, based on right reference data, at right time and at right price.
2. Gaining confidence of clinicians and patients in our laboratory Services by universal standards of our results.
3. The efficiency and performance of the staff has improved due to periodic training and competence assessment. Staff are more confident and focused on work.
4. Productivity has increased due to decreased error and wastage of resources.
5. Cost effectiveness has improved for the laboratory by proper utilization of chemicals.

6. There was a decrease in TAT and STAT through automated results.

Discussion

The concept of laboratory accreditation was developed to provide third party certification that a laboratory is perform specific test or type of tests [5]. Although accreditation has the potential to improve the quality of health care, very few laboratories are accredited to date. Most of the small and medium sized laboratories are under resourced and are marked by poor performance due to lack of pathologists and maintenance by technical staff. This resulted in distrust among clinicians and underestimation of laboratory services. Now the scenario is gradually changing. Simultaneous improvements in the quality of laboratory testing along with expansion of diagnostic services ensures clinician's and patient's confidence in our test results thereby reducing chances of sending samples to multiple laboratories. We take pride in quoting that our medical institute is the first to be accredited in our state by NABL. Some of the important aspects which were incorporated during our accreditation process and helped in improvement of our laboratory services were regarding employees, aspects of Pre-examination, examination and Post-examination processes.

Employees Training and Safety

Most of the tests in many laboratories are subjected to inaccuracy due to incompetent technicians. Employee training and competence assessment by tests were viewed seriously and done periodically, so that our technicians became more confident and efficient in their work. We ensured safety of all our employees by vaccinations and following biosafety precautions during handling and transportation of samples, Spillage and cleaning, Sample storage and disposal, and waste segregation.

During Pre-examination processes importance was stressed upon in providing information leaflets to patients, proper sample collection, handling and transport.

In the Examination Process

SOPs: Many tests in most of the laboratories are subjected to inaccuracy associated with lack of operator competence or failure to adhere to SOPs. SOPs are the documented processes to ensure tests are done consistently every time. They were made available to

all the technicians so that change of staff during rotations did not affect the result and each and every technician was competent to handle all instruments. All the SOPs were made according to NABL guidelines under the following heads.

- a. Purpose
- b. Principle and method
- c. Performance specifications
- d. Type of sample
- e. Patient preparation
- f. Type of container and additives
- g. Required equipment and reagent
- h. Environmental and safety controls
- i. Calibration procedures
- j. Procedural steps
- k. Quality control procedures
- l. Interferences
- m. Principle of procedure for calculating results
- n. Biological reference intervals
- o. Reportable interval of examination results
- p. Instructions for determining quantitative results when a result is not within the measurement interval
- q. Alert/ Critical values
- r. Laboratory clinical interpretation
- s. Potential sources of variation
- t. References

Calibration: Manual errors like incorrect labeling and mix up of samples during pre-examination phase were greatly reduced by automation. However automated assays are subject to instrument errors due to miscalibration or instrument malfunction [1]. Every year calibration of our instruments was done by SIMCO calibration laboratory, so that instrument error was reduced to minimal. Calibration was done for micropipettes, centrifuge, digital thermo hygrometer, hot air oven, incubator and digital thermometer.

IQAS (Internal Quality Assurance Services): We usually run two levels of controls two times a day and document the data in the form of LJ charts. Any outliers in internal controls were corrected and documented.

EQAS: External quality assessment or proficiency testing (PT) assesses accuracy of a test result [6]. In addition to internal audit done by other departments, we participated in EQAS Programme conducted by AIIMS quarterly and BIORAD monthly. The successive

corrective actions after internal audit and EQAS results helped us to continually improve our services.

Validation: Platelet values which are of great value in the evaluation of fevers, especially dengue were validated by using two different machines to minimize intrinsic machine error.

Importance was given to certain aspects in reporting and release of results.

Critical alert value is a result suggesting that the patient is in imminent danger unless appropriate therapy is initiated promptly. Detecting and correcting hidden components of critical alert policy can lead to immediate attention and treatment of critical patients and prevent mortality on one hand and on the other

Critical alert values in hematology laboratory

S. No.	Test	Low	High	Units
1.	Hemoglobin	< 4	> 20	gms/dl
2.	RBC	< 0.5	> 10	Millions/cumm
3.	WBC	< 2000	> 30,000	/ µl
4.	Platelets Adults	< 50,000	> 1,000,000	/ µl
	Children	< 20,000	> 1,000,000	/ µl
5.	Hematocrit	< 20 vol %	> 60 vol %	%

Final Report: Principle of tests and biological reference intervals were generated automatically in the final report, according to age and sex, by making changes in our software as required by NABL.

Laboratory Information System (LIS): LIS is a software system that records, manages and stores data for laboratories. Analysers were directly connected to computers so that Manual errors like spelling mistakes and wrong entry were reduced, easy retrieval of data saving lot of time and reducing the work load of staff, TAT and STAT were also reduced.

Clinician's feedback form

Services provided by the diagnostic centre

I. Hematology laboratory services

S. No.	Hematology lab services	Excellent	Very good	Good	Satisfactory
1.	Public relation officers				
2.	Managerial services				
3.	Lab Reports				
4.	Emergency lab services				
5.	Out sourcing reports				
6.	Turn around time				

II. Administration services

S. No.	Hematology lab services	Excellent	Very good	Good	Satisfactory	Poor
1.	HR department					
2.	Billing					

hand the hospital that implements this system can be prevented from the burden of medico legal cases to an extent [7]. We have defined criteria for critical values of certain parameters like Hb, RBC Count, platelet count, Total WBC Count. Any value outside these were informed orally or in written to the clinicians. In addition to those values, any newly diagnosed case of hematological malignancy, malarial infection and hemolytic anemias were informed to respective clinician over the telephone and documented, so that timely intervention is taken. These parameters may be considered an important laboratory outcome measurement because they reflect clinical effectiveness, patient safety and operational efficiency [8].

Previously TAT of complete blood picture was around 8 hours, but now it was greatly reduced to 4 hours, due to introduction of LIS and automation.

Interim Reports: are the reports issued during night hours, by qualified technicians when the authorized signatory is unavailable, for immediate treatment and convenience of the patients. Final report is issued in the day time by the pathologists.

Clinician Feedback form was taken from various departments to know whether our services have met their needs and requirements.

Other Important areas were

Stock Management of Chemicals: Wastage of reagents was reduced by maintaining stock register which includes lot number, expiry date, date of opening of reagent and date of consuming. We made sure that reagents are used before the date of expiry.

Records and Formats: All the records and files were maintained as per NABL guidelines and ISO 15189: 2012 standards. A total of 52 registers and 60 formats were prepared.

Controls and Sample Storage: Incorrect reagent storage or expiration can also lead to errors. We stored all the reagents at appropriate temperature.

After the final assessment we had few NC'S (*Nonconformances*), which are nonfulfilment of requirements and these were cleared within 3 months to get accreditation. The findings of the internal audit and the successive corrective actions to close the non-conformities helped immensely to continually improve the system [9]. Once accredited, follow up was done within a year by desk top surveillance.

Conclusion

Accreditation of a hematology lab aims not only at documentation and functioning of quality management system, but also examines whether the laboratory has competence and technical resources to carry out the required tests. Although accreditation is a time consuming and laborious process, it is a doable process. Successful accreditation resulted from well directed planning, implementation of requisites needed and active support from the staff and management. We have realized it is not a one time process but is a continual process for laboratory improvement. Accreditation provided early warning signs and lacunae in our system.

Major problems faced during our accreditation were preparation of LJ charts, corrective actions of EQAS results and documentation in the form of registers, formats and SOP'S.

We encourage all the teaching hospitals and laboratories to apply for accreditation and we also intend to apply for accreditation of bone marrow examination, cytology and histopathology in the near future.

Key Messages

NABL Accreditation has a positive impact on quality of health care. Successful accreditation resulted from well directed planning, implementation of requisites needed and active support from the staff and management.

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Nil

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