Short communication

Chronicle of getting the diagnostic laboratory NABL accredited in a teaching medical institute: An overview of our experience

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ABSTRACT

Introduction and Aim: Accreditation of medical laboratories by National Accreditation Board for Testing and Calibration Laboratories (NABL) ISO 15189 is needed to improve quality and safety in healthcare. It is a rigorous third-party external evaluation process that encompasses assessment against a given set of standards. The aim is to narrate the process of accreditation of a diagnostic laboratory affiliated to a newly established teaching medical institute and elaborate various facets which were worked upon from initialization till the culmination of the assessment.

Methods: Bulk of data is the author's first-hand experience as all worked hands-on in getting the NABL accreditation from July 2022 to January 2023. For standards and technical information guidelines of NABL & ISO 15189:2012 was referred. Input from peers working in accredited labs was taken. Entire process of preparation and applying for accreditation aspects was compiled and presented.

Results: With interdepartmental coordination and changes in workflow process complemented by document control procedures culminated in the laboratory successfully getting accredited.

Conclusion: The entire process of getting accreditation was challenging but nevertheless gratifying. For medical laboratories affiliated to teaching institutes accreditation needs extra time and effort but is nonetheless achievable.

Keywords: Medical laboratory; accreditation; quality assurance; NABL.

INTRODUCTION

Diagnostic laboratories are the crux of healthcare services. Accreditation of laboratories has many advantages like reports being internationally accepted, increased confidence of clinicians & patients on the results and increased reputation. For the laboratory personnel it not only encourages adoption of quality practices but also stimulates continual improvement and reduces error rates (1,2). National Accreditation Board for Testing and Calibration Laboratories (NABL), New Delhi – a constituent board of Quality Council of India (QCI) is one such society registered under Societies Registration Act, 1860, and an autonomous body under the aegis of Department of Science and Technology, which provides accreditation to medical testing laboratories in India. The laboratory accreditation services are provided in accordance with ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" and ISO 15189 "Medical laboratories- Requirements for Quality and Competence (3,4).

Unlike yester years, practice of getting accredited is no more limited to the silos of diagnostics embodied in corporate sectors. Laboratories affiliated to medical institutes are also working towards getting accredited as a step towards quality assurance and, as the same is being mandated by regulatory bodies over the recent years. Considering the multiple roles and responsibilities of faculties, remote locations, and restricted access to resources the road towards quality assurance comes with challenges. Though many documents are freely accessible in detail on the NABL website, practical experience on the process of how laboratories go through the process of preparing for accreditation is limited in literature (5). Through this article we intend to describe the efforts put in, resources gathered, and overall modifications made in the workflow processes of the laboratory to achieve accreditation in our central diagnostics.

MATERIALS AND METHODS

To comply with the standards of NABL 112, changes in technical aspects, infrastructure, resources, and workflow were pertinent which needed thoughtful planning and implementation (Fig. 1). The various facets worked upon are described in brief as follows from initialization till culmination of the assessment.

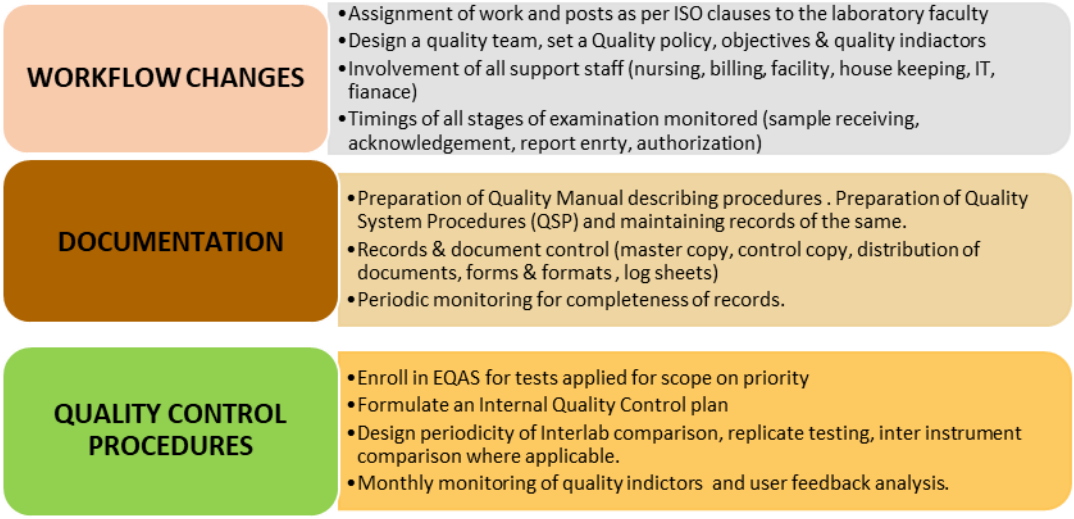

Fig. 1: Modifications in functioning of the lab to meet NABL requirements

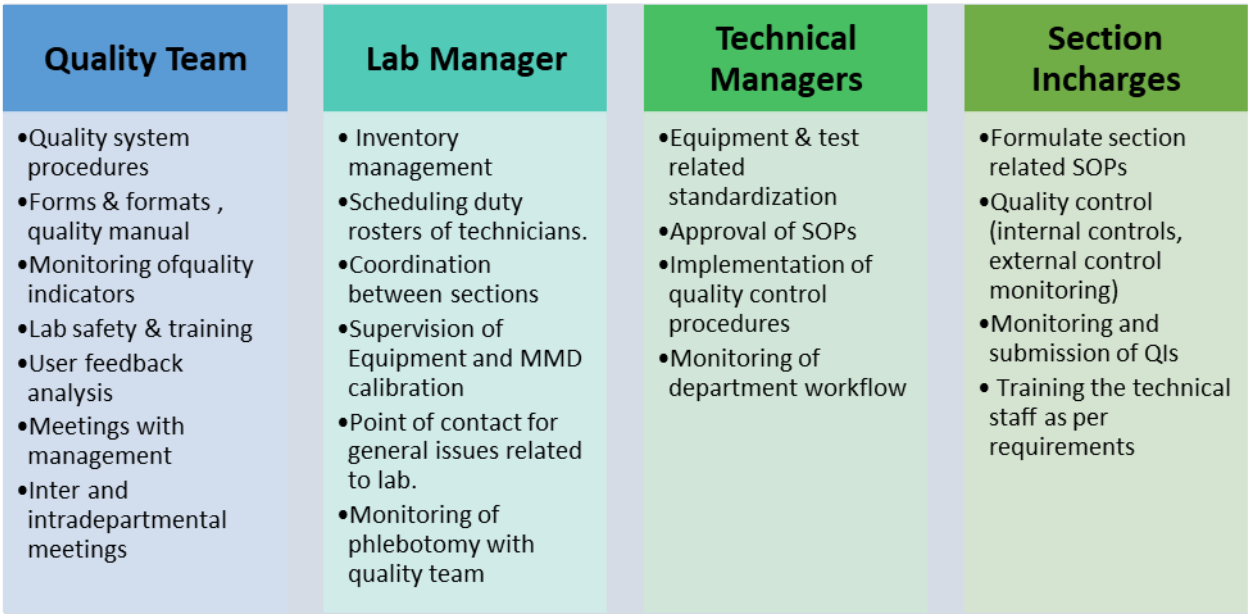

Fig. 2: Roles and responsibilities of key personnel involved in NABL team

Initial preparations

A meeting was scheduled by the management in which the NABL core team was formed, and faculty assigned for all posts from lab director, quality manager, technical managers to section in charges for Pathology, Microbiology and Biochemistry (Fig. 2). Deputy posts were allotted as back up where applicable. Timelines were laid out for applying for assessment. A few basic standard references and self-help publications were downloaded from the NABL website - https://nabl-india.org/ (NABL 112, 131, 121,161 etc.,) and input collected from our peers who had recently applied or were affiliated to NABL accredited laboratories**.** A directory of services (DOS) was formulated that included the tests with all relevant details for the benefit of users. A primary sample collection manual was designed with input from all sections consisting detailed procedures and protocols for sending samples to laboratory. The same was also uploaded on the intranet portal for access to the nursing staff & clinicians in wards.

Workflow related changes

To conform to NABL standards, workflow processes required constant monitoring including documentation of timings of all steps from patient sample collection in OPD/wards through acknowledgement, report entry and authorization. Sample transportation was being overlooked by the lab manager at all stages for safety and adequacy. Laboratory Information System (LIS) was customized to make all entry points of timings from sample collection to report verification. The LIS was validated and verified. Billing staff was trained regarding access to and basic knowledge about the laboratory's DOS.

Training

Training sessions were organized periodically for housekeeping staff, technicians, and faculty by the quality team for fire safety, biomedical waste management, communication skills, spill management and emergency codes. Individual sections of the lab had also scheduled brief teaching sessions to orient about their tests and protocols. Common areas like

monitoring of quality indicators, waste disposal, lab safety, report generation time, were being monitored by the quality team. Induction training records for newly joined technicians were documented with annual competency assessment for others.

Documentation

As the backbone of NABL is documentation, this was duly taken care of. Forms and formats (temperature monitoring logs, equipment maintenance logs, troubleshooting logs, corrective action & preventive action (CAPA) logs, amended report formats) were formulated and distributed to sections to fill details. Quality System Procedures (QSPs) were designed as per the lab needs by the quality team. Any meeting/ training was documented by a circular, geotagged photographs, record of attendance, pre and posttests when applicable. A thorough vendor evaluation and inventory management system was put in place in collaboration with the store manager. Feedback from users (clinicians and patients) and resolution of complaints was being done on a regular basis.

Infrastructure and equipment

A dedicated small room was assigned as a quality manager room (QM Room) for accreditation related work. Additional storage space was provided for files, forms, records, and equipment documents. Casing of wires, adequate power supply, signages, eye wash, safety alarms, restricted access and sprinklers were provided. As back up equipment is mandatory in NABL this aspect was investigated. Basic documents related to equipment (IQ, OQ, PQ, linearity check, carry over, precision check, calibration certificates, annual and preventive maintenance, labeling) were compiled. It was ensured that all tests applied for scope had internal quality control procedures and were also enrolled for External Quality Assurance programmes/Interlab comparison/split testing as applicable and results assessed.

Table 1: Overview of the NABL accreditation process

STEP 1 Login, registration of Lab & Submission of documents in NABL Portal	
Login to NABL portal	Unique use ID will be assigned to each laboratory Lab Director being the first choice for contact
Submission (online uploading) of basic documents & details of the laboratory	Quality Manual Scope of tests applied (principle, method, reference range, CV%) Legal entity of Lab, details of lab location. Authorized signatories with specimen signatures and details Details of Technicians Equipment details (installation date, unique ID, calibrated on and due date, company name & location)
Organogram	Flowchart on how the lab is linked to the parent organization Lab organogram
Quality Manual	Customized as per laboratory protocols with content as per NABL
STEP 2 Acknowledgement of application Reply from NABL regarding QM adequacy report Submission of corrections if any	
STEP 3 Submission of fees (online/DD) Option of pre assessment can be opted for Final Assessment date options (3 choices can be given by the Lab)	
STEP 4 Approval of proposed dates of audit by lab, Approval of proposed Lead Assessor & Technical assessors. Lab can approve/decline the assessors/ dates with justification	
STEP 4 Final 2-day NABL assessment Opening and closing meeting & submission of recommendation by assessor team Assessment can be completely onsite or hybrid (both onsite & offsite)	
STEP 5 Closure of NCs raised during audit followed by approval by assessors Issue of NABL certificate by NABL Secretariat Logo to be used for test reports under scope only. (NABL 133)	

Readiness for final audit

The quality team had conducted regular meetings with all sections to investigate the readiness of documentation. Monthly monitoring of Quality indicators (QIs) was being done and consolidated. Internal audit was conducted across all sections as per NABL 131. This was followed by a management

review meeting and closing of the non-conformities (NCs) raised during the audit. All records and files were neatly compiled in respective sections including the QM room for ease of access to show the assessors and avoid confusion on the day of the audit. An overview of the process of applying till accreditation by NABL is depicted in Table 1.

RESULTS

With good interdepartmental coordination, communication, and collaboration along with changes in workflow process, infrastructure and equipment, resources, periodic training complemented by document control procedures resulted in the laboratory successfully getting through the assessment. The entire process from inception till getting accredited by NABL took a little over nine months.

DISCUSSION

In the current era of evidence-based medicine, ensuring quality and efficiency of diagnostic laboratories is a pressing priority as lab results determine clinical decisions and directly affect patient outcomes. Accredited laboratories have a system of standard procedures that helps them to improve quality and patient safety. In India, NABL is an autonomous body that provides accreditation to CAB (Conformity Assessment Bodies) including medical testing laboratories (6).

Documentation is the foundation of the NABL accreditation process. The rule of thumb is to start preparing all the levels of documents which will later be compiled, and documents controlled by the quality team. Drafting of the quality manual, primary sample collection manual and QSPs require good interdepartmental communication and repeated checking of drafts before the final version. Low tier documents like formats & logs can be drafted initially followed by the higher ones like quality manual and QSPs.

Technicians play an integral part in the lab workflow process. Training them in various aspects of documentation and testing standards in respective sections is pertinent as they are primary sample handlers. Daily filling and maintaining log sheets, records, registers, checklists, stringent compliance to workstation practices though difficult initially and time consuming soon became a daily practice. This is in concurrence to the observed attitude of laboratory personnel globally (7). Participation in EQAS and running daily internal controls though involved extra cost and time, yielded direct improvements in the quality of testing, and increased the confidence of users on our results. As authorized signatories were also teachers, it was challenging to balance between academic and lab work. The quality team scheduled periodic and frequent meetings with all to keep track of progress and discuss the problem areas to be addressed (8). Making everyone a part of the team was essential and it involved communication, collaboration, and cooperation. A good administrative guidance with timely support was mandatory which made the entire process of accreditation smooth in our case.

Though NABL does not specify the minimum floor area allotted for different sections, infrastructure had to comply with standards like segregation of clean and unclean areas, sterile and unsterile sample storage etc., Sample collection areas - though the face of a laboratory is often sidelined as it does not fall under the direct supervision of any diagnostic sections of pathology, microbiology or biochemistry unless allotted (4). Having a functioning quality team in our lab helped in monitoring of common areas like phlebotomy by conducting periodic technical and communication skill training including assessments. One of the most important quality indicators of laboratory services is customer satisfaction that needs constant monitoring and addressal (9). This was implemented through collecting hard copy of feedback forms from patients and Google forms from clinicians quarterly. Matters needing action were taken up by a quality team and documented, conveyed to concerned sub sections when involved and resolved accordingly. This brought about significant positive changes in patient satisfaction and largely streamlined sample collection (10,11).

The final process of accreditation inspection is scheduled for two days during which a lead assessor and technical assessors (the number depending on the scope) visit the lab in person or sometimes have online assessments. An opening meeting on day one is followed by a detailed audit of the clauses and day two ends with a closing meeting during which the result of assessment is announced. The key to getting through smoothly in the audit is to provide genuine data, accepting shortcomings if any, and being open to suggestions given by assessors. It is also pertinent to note that once accreditation is granted quality practices must not slump back to primitive levels but be a day-to-day process to avoid overburden and confusion when subsequent audits are scheduled as maintaining accreditation and ensuring quality is an ongoing process.

CONCLUSION

The entire process of accreditation, though challenging, was rewarding as it increased competency of the team and the reputation of the laboratory. This also helped bring about a better control of laboratory operations and gave us an insight into various facets of quality assurance with focus on continual improvement. As our medical laboratory was affiliated to a teaching institute accreditation mandated extra time and effort by the faculty and technical team but was nonetheless achievable with good interdepartmental collaboration and planning.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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