

# Standardization and Quality Improvement of Laboratory Services in India: Need and Challenges

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## ABSTRACT

Quality is a subjective term – subjective with respect to individual and time. Quality concepts were introduced and implemented by industry during world war II. In health care system, these concepts were introduced later.

Indian health care system is transforming. The publically funded system run by the Government is focusing on coverage but quality of service is doubtful. On the other hand, corporate ‘for profit’ hospitals claim quality but with humongous cost.

Laboratory services are crucial in today’s health care. The laboratory service provisioning in India is very complex with respect to structure, facilities rendered as well as governance. This sector faces many internal and external challenges in affirming quality. Accreditation provides a first step towards quality assurance of laboratory services. This monograph discusses the need and challenges in accreditation of laboratory services in India.

**Keywords:** Accreditation, Diagnostics, Healthcare, Quality Assurance

## QUALITY ASPECTS AND HEALTHCARE

In industrial process, ‘Quality’ can be roughly defined as an attribute, which when met with customer’s needs, should satisfy them. Unfortunately, it is subjective with respect to individuals as well as time. What is “good” for one person may not be the same for another. Moreover, what is “best” today may be “just fair” tomorrow and even “worse” the day after.

For example, X-rays were used to treat cancer patients initially. Due to the terrible side effects, Cobalt machines were developed to treat them with radiotherapy using Gamma rays. For some time, they were called ‘work horse’ and were very popular across the world as it was the best possible method at that time (in 1970-1990). With the advent of Linear Accelerators and Multi Leaf Collimators (MLC), the radiotherapy today is at its best. With sophisticated computerized treatment planning systems, the doctors are able to irradiate the exact part which is affected. Further they are able to deliver different doses to different sections of the same tumour. As of today, the effectiveness and accuracy of radiotherapy is at its peak [1]. The cobalt machine which were so popular three decades ago, are termed as “Toasters” because of the side effects (skin burns) which can be avoided with latest technology [2].

The world witnessed unprecedented technological leap in the last quarter of twentieth century. The diagnostic testing underwent an organic transformation – from subjective manual methods to automated methods to portable non-invasive sensor based methods. Without loss of generality, consider one of the most frequently performed diagnostic test viz., Haemoglobin (Hb) estimation. It was performed using subjective reagent based tests like Sahli’s/acid haematin method that are less accurate. With advent of auto-analyzers, and reagent less methods, the Hb testing became more accurate. The advent of sensor based technology made the testing portable as well as non-invasive without compromising the accuracy.

Quality Control and Quality Assurance concepts and tools were accepted by the industry during and after World War II; more for economic reasons [3]. Healthcare is a unique system where

the clinician acts as consultant as well as provider and the client (patient) has a limited say. With growing law suits and some conscience, the healthcare system felt the need of quality over last few decades. Evidence Based Medicine and Quality Improvement are complementary and together these methods will lead to better and effective healthcare [4].

The healthcare system especially in India is transforming. Before few decades, Government health system was supplemented by a ‘family physician’ led small clinics with advantages like flexibility in billing, easy and quick access, reasonable fee for service etc. With deterioration of Government healthcare system after 1970s along with emergence of private ‘for profit’ healthcare organizations, ‘family physician’ led small clinics are being replaced by corporate hospitals run by group of specialists and administrators [5].

## QUALITY IN LABORATORY SERVICES

Clinicians are relying more and more on diagnostic tests rather than physical examination and signs and symptoms for confirmation of disease [6]. It is not just because of easy availability and improved accuracy of these tests. The disease vectors are changing. For example, high grade fever with shivering was sure shot diagnoses of malaria in the past but now a day shivering is absent in many cases of malaria. When a patient reports high grade fevers it is unclear whether it is due to malaria, flue or thousands of other conditions. Diagnostic tests thus became integral part of health care. The critical role of laboratories beyond individual patient care especially in surveillance and public health is overlooked albeit identified time and again [7,8]. Provisioning of Laboratory services is quite complex in developing economies like India. These services are quite diverse with respect to structure, facilities rendered as well as governance. These aspects along with fee for service and quality assurance dictate patient access to a particular laboratory [9].

It is almost impossible to over emphasize the importance of accuracy of laboratory results in healthcare.

## Complications

Without loss of generality, consider the importance of accurate blood glucose level for a diabetic patient. An overestimation will burden the patient with over-medication which may result in hypoglycaemia or coma whereas an underestimation may result in eye and kidney damage or atherosclerosis in the long run.

## Cost Implications

The cost implications of a wrong clinical decision are humongous. For example, if a patient is diagnosed as malignant when he is not, the surgery, radiotherapy and chemotherapy costs are unnecessarily borne by him. On the contrary, if he is diagnosed as non-malignant when he is, the advancement of disease and further complications will require more sophisticated treatment that means more costs.

## Generalizability

When a patient is referred to higher centre or he wants to continue the treatment at different center, the test results of previous health facility are generally discarded. The poor patient is burdened with unnecessary repeat tests for the "quality" reasons. The acceptance of previous test results can be enhanced by assuring reliability and validity of the diagnostic tests performed at any particular centre.

Quality Assurance (QA) is the total process whereby the quality of laboratory reports can be guaranteed. Accreditation (laboratory) is formal recognition of technical competence for specific tests/ measurements, based on third party assessment and following international standards. The new era physicians and managers perceive many advantages of QA and Accreditation. Accreditation involves internal and external validation through rigorous management and technical competencies in continuum. This not only ensures quality but also provide opportunity to identify and resolve issues hampering quality. It is a common banter that "Accreditation is easy to obtain but difficult to retain". Accreditation is thus a long term commitment for maintaining the standards through team efforts [6,7].

## Physician's Perspective

Physicians want quick and accurate test results in time to decide the line of treatment as soon as possible. Early start of the appropriate treatment saves hospital days, time to cure and also improves physician's personal reputation. With the growing lawsuits, the physicians always want to complement their clinical judgement with laboratory test results.

## Manager's Perspective

In today's world of competition, "I need to attract patients to my hospital". Comprehensive care under one roof, Total Quality Management, ISO certification and other accreditation are keywords for advertising my hospital.

In general, Government as well as private healthcare professionals in India endorsed accreditation albeit for different reasons. The private hospital owners expressed concerns over regulatory mechanism and financing for the same [10].

It is important to note that the considerable growth in number of tests and general productivity actually decreased the per unit test cost over time [11]. Further, it is also evident that most errors occur in the pre and post analytical stages making the total testing process error prone [12]. Thus QA of laboratory services should focus on overall process control than focusing merely on analytical stages.

## Accreditation of Laboratories in India

With globalization and medical tourism, many institutions started realizing the quality issues and are trying to introduce "Quality" concepts in all parts of healthcare. The situation is still not very encouraging as only 864 labs across India have documented proof of the reliability and validity of the diagnostic tests performed [13]. Further most of these accredited labs are in metro/big cities with

very poor representation in small town/villages [13]. Gadre A et al., elaborated the horrifying perils of private "for profit" healthcare sector that is completely unregulated [14]. Specific to laboratory services, 'sink tests', cut practice are abundant in metro cities as well as smaller towns. The duo strongly endorsed to regulate the healthcare sector. Albeit this may require a diligent strategy, accreditation may serve as a first basic step towards some regularization.

Beyond accuracy of test results, safety in laboratories is an important issue overlooked by many laboratories in India. It is indicative that accredited laboratories have better safety parameters [15].

## Challenges in Accreditation of Laboratories

Through an extensive review, Jain R and Rao B immaculately listed the challenges in Medical Laboratory Diagnostic Services from management perspective. They classified the challenges into external and internal challenges and covered almost all the domains briefly [16]. We will try to highlight important issues and possible solutions beyond mere accreditation.

## Philosophy behind Accreditation

As someone rightly pointed out- "The dignity is not in possessing but in deserving". QA and accreditation should not be considered merely for advertising gimmick. The basic objective of providing reasonably accurate results to clients should not take a back seat in enthusiasm to achieve the accreditation through complex administrative process along with immaculate record keeping. Pranesh GT and Faith N assessed standardization of HbA1C in National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited laboratories across India and found poor standardization. They also noted gross differences in test nomenclature, methodology and analytical performance [17].

## Cost and Regulator

The accreditation process involves test runs, immaculate record keeping as well as external validity process. This demand for additional manpower inflates cost of the test. It is difficult for even bigger laboratories to manage the cost incurred unless there is sufficient volume for a particular test. In fact, few tests are outsourced at the accredited lab of an institution where one of the authors works due to insufficient volume.

Small laboratories face greater difficulty and many may not be able to manage funds for additional manpower without increasing cost of the tests. A typical dilemma is that they may lose regular clients due to increased cost. A consortium of small laboratories in an area could be formed to decrease cost of accreditation provided the laboratories believe in symbiosis and do not try shunting of patients.

The role of regulator is very crucial. The regulator must be supportive and encouraging. Rather than just listing out the deficits, possible solutions should be provided.

## The Work Environment and Retention of Staff

The work environment gets very little attention by managers. This particular job is repetitive and laborious in nature. The technicians are bound to get exhausted quickly in such situations. The opportunities to get promotions are limited. As a result, the attrition rate is reported very high and that mars the quality drastically [16]. Improving work conditions, reorienting the work schedules, minimizing the knowledge gap and skill gap for technicians by proper training and using ergonomics (humanization of work) are necessary to improve and maintain quality. These things are prerequisite before one tries to improve the reliability and validity.

## The Infrastructure

Improving quality (reliability and validity of a test in this case) is an artful combination of individual skills (man) and the technology

(machine). Following important issues may be considered before a QA programme is initiated.

1. What machines are used?: Are they manual, semi automatic or fully automatic.
2. What are the error margins stated by manufacturer? Doctors who use the results of the diagnostic tests should be aware of these error margins.
3. Are these error margins acceptable? (clinically): A manufacturer may state error margins as 50% but they may not be acceptable clinically. The machine using old technology may have unacceptable error margins (which were best possible ones at that time) in today's context.
4. Is there any Annual Maintenance Contract? Who provides it? What is the cost? This will ensure the machines to be in good working condition.
5. What logbooks say? (are the logbooks maintained?) Logbooks usually provide good information about status of the machine, the frequent problems with the machine and help to decide whether to buy the same brand or not when it is time to replace the machine.

### Whether Accreditation Works?

Accreditation not only improves quality of the laboratory services but also contribute in improving the health care system in the long run [18]. In general, accreditation improves process that in turn improves the system [19]. Considering the challenges in developing economies, innovative approaches to accreditation are identified [20].

Accreditation is just a formal recognition of quality. Lack of quality of lab services inversely affects the healthcare outcome. Most importantly, it mars the trust between the laboratories and clinicians. As lab services account for a considerable out of pocket healthcare expenditure in developing economies [21], the quality of lab services is very important. Holistic healthcare depends largely on continuum of care and not merely treatment of the present conditions/symptoms. With increasing prevalence of Non-Communicable Diseases (NCDs) in India, quality of lab services is crucial.

Besides the strategies suggested above, NABL and Quality Council of India (QCI) can play a catalytic role in improving quality of lab services in India.

Aware and Empower: These two organizations should take additional responsibility of empowering organizations about the process and provide supportive supervision. Government of India must fund all such initiatives so that the labs can provide quality services at affordable cost.

Gradation of Labs: Without compromising quality issues, grading of labs like hotels is possible. This hopefully will encourage labs in smaller towns to get some accreditation after maintaining basic quality checks.

Incentives vs punitive action: Individual labs or consortium of labs should be provided partial cost of accreditation by the Government without discriminating between public sector and private sector labs. They should be provided sufficient window period to acquire some basic gradation.

Technology Shift: Old reagent based manual (and subjective) methods should be steadily replaced by point of care non-invasive methods after immaculate validation of the new technology.

## CONCLUSION

QA and accreditation of laboratories is essential component of health care system. The developing economies are steadily gearing towards quality in health care. Accreditation improves quality in the long run but there are some challenges faced especially in developing economies. Improving quality through accreditation in a phased manner with supportive regulator can transform the efficiency of health care in developing world.

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