

# Medical Laboratory Quality Management: Current Scenario and Challenges in Developing Nation

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## Abstract

Medical laboratory quality management though not newer concept to developing nation like India, presence of serious gap in its implementation and continued monitoring is an undeniable fact. There are multiple limiting factors in effective implementation of laboratory Quality Management System (QMS). The very first issue is the health budget allocation and inappropriate distribution of allocated funds. The Primary Health Centers (PHCs) though are considered as the backbone of health infrastructure of developing nations' funds they receive for maintaining their associated medical laboratory services are disproportionate and highly inadequate. Other major challenges are existing level of training and awareness among the workforce deployed, lack of national and local lab Quality Control (QC) policies etc. This article focuses on few of major constraints which when worked upon swiftly would eventually lead to an equal uplifting of quality standards of medical laboratories catering health services in developing nations.

**Keywords:** Medical lab quality • Quality management • Accreditation • Quality assurance • Primary health care

## Introduction

Quality in health care is defined as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge," according to the Institute of Medicine (IOM)" [1]. "Quality costs but poor quality costs more" this statement if applied to the Health care industry, poor quality costs lives. A simple comparison of the Maternal Mortality Ratio (MMR) and Infant Mortality Ratio (IMR) of developing and developed nations would further validate the above statement [2]. The average MMR and IMR of developing countries are 10 to 15 times higher than developed nations; refer to the data shown in Table 1 [3]. Though the causes for the poor performance of these indicators are multifactorial, the quality of health care service in the developing world plays a very significant role, and so is the quality of medical laboratory services. In general, the quality of medical laboratory services in developing countries majorly depends on three major factors, namely a) Infrastructure, b) Awareness and training on international standards, c) Management of available resources [4].

## Infrastructure

Any attempts to reduce disease burden and decrease premature mortality rates will not succeed unless clinicians have access to the high-quality laboratory services necessary for diagnosis, prognosis, and guidance of therapy [5]. In a highly populated country like India, the primary and secondary health centers caters comprehensive health care

services like general medical services to conducting deliveries of high-risk pregnancies. These centers have a limited scope of laboratory services and many of them offer services not more than Glucose, Creatinine, Bilirubin, Hemoglobin, ESR and Urine routine. Most of these tests are done using primitive techniques in an incompatible location and with inappropriate internal quality control or external quality assurance program [6]. Incorrect results generated from the health centers due to inadequate quality control practices can lead to misdiagnosis of patients especially those with non-communicable diseases. There are several screening programs conducted in developing countries like India at the Primary Health Centre (PHC) level. So it becomes a highest priority to upgrade instrumentation and instigate Quality Management System (QMS) in all laboratories catering services to PHCs [7,8]. A proactive approach of governments of developing nation is an absolute necessity. Government should form multiple expert panels and assign them with the responsibility of assessing the gaps in infrastructure and quality management systems of these laboratories. These expert panels shall assist the government to establish clear policies for: a) assessment of required level of automation based on patient load, b) selection of diagnostic equipment which may be a simple POCT devices or large fully automated analysers, c) initiate QMS, d) identifying training requirements of staff at PHC level, e) methods for continual surveillance of performance etc. [9,10].

## Awareness and training

The higher referral centers like Medical College hospitals and other tertiary care centers though are well equipped with state-of-the-art technology for catering laboratory services, these centers lack awareness of International standards and training on the application of statistical quality control tools. The numbers of medical laboratories attached to these centers and those that have gained accreditation to ISO 15189 or College of American Pathologists (CAP) and Joint Commission International (JCI) are mainly disproportionate ("Accreditation of Medical Laboratories-System, Process, Benefits for Labs," n.d.). The workforce in these Laboratories also needs an intense training program to drive the importance of implementing international standards [11]. A nationwide awareness drive in general about healthcare quality is real need of hour. The curriculum of both medical and allied sciences should be revised to include basic components of healthcare quality management standards which are inclusive of laboratory QC practices and accreditation requirements etc. The existing workforce both in public and private sectors should be offered mandatory short courses on quality standards relevant to their field of service [12]. The local accreditation bodies must also initiate awareness about implementation of international standards with the help of the government. They should come out with mandatory

**Table 1:** MMR and IMR in developed and developing nations.

Country	Maternal Mortality ratio (per 100000 live births) (2015)	Infant mortality rate (per 1000 live births) (2017)
Developed Countries		
USA	14	5.7
UK	9	3.7
Japan	5	1.9
New Zealand	0	4.4
China	27	8
Developing Countries		
India	130	32
Pakistan	178	61.2
Nepal	258	27.8
Bangladesh	176	26.9
Myanmar	178	38.5

accreditation schemes for all the Medical college hospitals and referral centers providing tertiary care and above. Developing nations shall also drive such quality awareness program by incorporating them into national health programs [13-15]. Currently imbalances in human resources in public sector may also be due to skilled personnel leaving services due to internal brain drain and they usually choose to join private organisations [7].

## Resources

Resource allocation and distribution had never been an easier task in developing countries like India. Every public sector quaternary care centers and centers of excellence in lower and middle-income countries face serious funding allocation issues [16,17]. Such crisis of funding poses a direct threat to efficient functioning of hospital laboratories. Most times funds are allocated with highest priority given to only procure reagents and other consumables over QC materials in sufficient quantity [18,19]. This shortage in procurement of quality control materials leads to reduced frequency of QC runs and this could be a potential cause of avoidable laboratory errors. This also implies that awareness about importance of quality control practices is required at all levels of laboratory or hospital administration. Similar management issue is also found in most private hospitals in developing countries. They face an issue of controlling running cost of their laboratories in the process of striving hard to deliver their services at affordable prices equal or lower than their competitors. Laboratories of this sector are most often accredited to international standards like ISO, CAP, and JCI and have a vast scope of services performing even rarest and most advanced tests [8]. Therefore; these Laboratories have to carefully calculate the cost for their testing services which usually incorporates the direct and indirect expenditures. The direct costs includes cost of equipment and their maintenance; reagents; consumables; salaries to technical staff etc., and indirect expenses include running daily internal quality control samples; participation in periodic external quality programs; technical staff training for continual improvement; biomedical waste management contracts; costs incurred to comply with the requirement of international standards that also includes charges paid to local accreditation bodies etc. Considering these expenses, the medical laboratory should be meticulous in allocating its resource to provide uncompromised service at an affordable price [20-23].

## Conclusion

In this era of evidence-based medicine it is an undeniable fact that clinical departments are becoming more and more dependent on medical laboratories for efficient patient management. Developing nations are in a real need to devise and issue their own comprehensive quality standards for efficient operation of medical laboratories in rural and urban health centers. Also, a gap analysis needs to be performed between private and government medical laboratories, and appropriate initiatives should be taken to ensure the lab quality. We also suggest that the government of developing nations should be keen on establishing zone wise or district-wise state-of-the-art laboratories in consistent with international quality standards. These laboratories should serve as a working model in terms of infrastructure, work force, scope of testing and quality management for all other existing and upcoming laboratories for a prescribed geographical area. Like a blessing in disguise because of the existing Covid-19 pandemic many district hospitals in India are now equipped with molecular diagnostic instruments which otherwise would have been a distant dream. Similarly Covid-19 pandemic is also the reason for current awareness of public about the importance of medical laboratories. These can be seen as opportunities to strengthen the quality of medical laboratories.

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