TOTAL QUALITY MANAGEMENT IN CLINICAL VIROLOGY LABORATORIES

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Abstract

The diagnostic laboratories in India are progressively promoting higher standards and are moving towards accreditation and international acceptance. Hence, the concept of “Quality” will need to be understood and implemented. Total quality management (TQM) in a laboratory is an integrated program involving all laboratory staff and management. TQM is a framework to operate and it is aiming for integration, consistency, increase in efficiency and a continuous drive for improvement. A well structured clinical virology service will include serology setup, cell culture facility and capacity for molecular diagnosis. The quality of results from the laboratory is significantly influenced by many pre-analytical and post-analytical factors which needed attention. The end goal of the TQM should be to provide the best care possible for the patient.

Key words: Total quality management, Virology laboratory, India, QA

Indian medical laboratories are moving swiftly towards international recognition and higher standards and this progress is ushering in a new wave of concepts and systems to enhance quality and directly improve patient care. The burden of careful construction and proper implementation of a quality system can be a daunting task. The resistance to change can be a difficult hurdle to overcome, but responding to the challenge can yield bountiful rewards in increased testing reliability, records management, safety and efficiency. All these add up to the ultimate goal of all those who till in testing laboratories every day, i.e., the best care possible for each and every patient. This is true for the departments of microbiology offering clinical virology service or independent clinical virology set up in academic or corporate setting.

Quality Concepts

The concept and practice of “Quality” in modern medical laboratory is essential for producing results in a reliable and efficient manner. A common misperception is that quality control (QC) encompasses all that is necessary in consideration of quality. However, we need to define certain terms to emphasize the scope.

QC refers to the measures, which must be included during each assay for example to verify that the test is working as it should. Quality assurance (QA) is the overall program that ensures that the final results reported by the testing laboratory are correct.

QA involves an independent or an external evaluation of the laboratory’s performance (e.g., audit conducted by the organisation’s auditors or an inspection conducted by a national accreditation body). The audit/inspection serves as a challenge to the effectiveness of the QC and QA methods.

Hence, when a testing laboratory such as clinical virology is considering adopting total quality management (TQM) as a framework and a way to operate, it is aiming for integration, consistency, increase in efficiency and a continuous drive for improvement. With TQM, the challenge moves from a simple question such as ‘was the test correctly done?’ to ‘was the right test carried out on the right specimen and was the right result and right interpretation delivered to the right patient at the right time?’ In other words, TQM is a new way of working both in the diagnostic and the cultural terms.

Quality ideas have evolved primarily in Western industrial setting, usually through the interaction between regulatory bodies and commercial interests. Quality has become a specialty area and a business by itself and major organizations typically have a significant number of experts and resources that are solely dedicated to quality within the organization to monitor regulatory changes, assess quality systems in the organization, as well as adjust the practice of quality as required. These ideas are being adopted in the medical sector, where implementation of quality concepts can help assure the best patient care. As diagnostic laboratories in India progressively promote higher standards and move towards accreditation and international acceptance, the concept of “Quality” will need to be understood and implemented by all laboratory staff and management as TQM. Quality assessment performed via external inspection and accreditation is now acquiring importance in India. Quality standards that need to be met to achieve accreditation in India are determined by the most current International Organization...
of Standardization (ISO) and National Accreditation Board for testing and calibration Laboratories (NABL) guidelines. The laboratory accreditation assessments are under the sole purview of the NABL.

TQM is an integrated program for managing quality on a continuous basis with periodic upgradation and this requires all laboratory personnel to take ownership of the idea and its importance of adherence.

The laboratory management should provide adequate resources and training when undertaking TQM. Once the laboratory is working to the new policies and procedures, it is important to review the laboratory’s performance through a series of key performance indicators (KPIs) – checks that are predetermined to test the success of TQM. The output from these checks needs to be discussed as a group involving all personnel from management to technical staff responsible for sample analysis and reporting. Changes resulting from these checks may direct a new policy or procedure; hence, these should be widely communicated and well-documented. Examples of KPIs in a clinical virology laboratory include compliance checks against set standard operating procedures (SOPs) on specimen transport, tissue culture and media, reagents and kits, instruments, adherence to safety policies.

System Needs and Focus

A well-structured clinical virology service will include a full-fledged serology setup, cell culture facility, and the capacity for molecular diagnosis. The quality of results from the laboratory depends on the QC of the testing laboratory. The outcome is significantly influenced by many pre analytical and post analytical factors. A good system of QA addresses these concerns, with the objectives such as improvement in diagnostic quality, production of reliable and reproducible results, establishment of inter-laboratory testing comparability, promotion of credibility of the laboratory among patients, doctors, other institutions, collaborators, accrediting/ regulatory bodies, motivation of staff for further improvement and preclusion of poor results which could cause legal complications.

The aim of a good QA program is to address the factors that impact quality, which are the percepts of good laboratory practices (GLP) such as having SOPs. The human resource requirement should have a sound strategy as the quality of the laboratory results is directly related to the motivation, training and dedication of the laboratory staff. A well-structured and highly performing laboratory would have a pyramidal organization of adequate support staff, administrative assistants, trained technical cadre with a BSc. degree in laboratory technology or equivalent; second level supervisory staff with MSc. degree in microbiology with special training and a laboratory supervisor or coordinator at MD or PhD level with special training in virology.

TQM needs to focus on all activities that are occurring in a clinical virology laboratory and make an assessment of how they interrelate and therefore how quality may be enhanced or compromised if one or more procedure is altered or delivered incorrectly.

The following areas are by no means exhaustive but cover some of the core components, which TQM could target:

Written documentation

These include SOPs, policies and procedures, forms and templates. They carry instructions for all activities from sample collection to reporting and include policies from safety to reagent purchase policies. These need to be made available to all and well- controlled with the purpose of the whole laboratory following one consistent process.

Specimen

Selection and collection of the right sample and proper processing is critical to QA. This includes adequate quantity, proper transport, and appropriate pre test processing as per the individual test protocol requirement.

Environmental factors

Virology laboratory space must be separate from other microbiology laboratory space and have dedicated biological safety hoods and equipment. The ambient temperature should be maintained at 22-26°C. Surface of work areas should be made of a material allowing regular decontamination. Molecular diagnosis laboratories have to be conscious of the flow through to avoid ‘amplicon’ contamination. Waste should be properly segregated and disposed by following standard hospital infection control policies. Unsafe working conditions, lack of adequate space, poor ventilation, inadequate utilities and facilities can all negatively influence QA. The use of appropriate bio-safety hoods and personal protective equipment is mandatory. Lack of testing and maintenance of equipment and facilities will place QA in jeopardy.

Analytical factors

High quality supplies of items such as plastic ware, glassware, reagents, immunochrome labeled antibody, culture media and laboratory equipment are all crucial to quality. Supporting technology and software must be reliable and efficient and compliant with regulations. Consistent supplies of all items, as well as technical support of equipment, are essential for upholding good QA. All fine instruments have to be frequently serviced and calibrated by accredited service agencies.

Post-analytical factors

Errors in data and report transcription, interpretation of results, sample tracking, computer data entry, etc. will negatively impact quality. These problems arise due to lack of adequate supervision.
Laboratory audit

An internal exercise that monitors many issues such as specimen integrity and storage, use of appropriate request forms with details, carrying out the appropriate best test with consultation of the requesting doctor, turn-around time from sampling to reporting and efficient deployment of personnel and others. The other items such as safety policies and procedures, corrective action on complaints and use of best reagents etc. are all to be monitored by an auditor (scientific) at regular intervals covering different areas of the laboratory.

TQM should be an inclusive and participative process, which includes behavioural and cultural change of laboratory personnel, to create commitment to quality and to the customer. Thus it integrates organizational management, human resource management and quality management into one overarching philosophy. Implementing TQM is a gradual process integrating the existing traditional approaches with new thinking without any alienation of the personnel involved.

Documentation

Proper and complete documentation is a key ingredient of a successful TQM program. In India, the NABL requires the establishment of a quality manual (QM), which describes the QA and TQM of each organization seeking accreditation. This comprehensive document requires an investment in resources to create and a high-degree of dedication for adherence if it is to be successfully implemented. Currently, the NABL utilizes ISO guidance number 15189 (“Medical laboratories-Particular requirements for quality and competence”), as a basis for assessment for accreditation. The NABL guidance number NABL 160 entitled “guide for preparing a quality manual” is a complementary document to ISO15189 and must be used as a reference in QM preparation in India. The focus of this guidance document is the requirement and procedure for medical laboratory TQM and QA, with emphasis on the expectations that will be placed on medical laboratories in the accreditation process.

In addition to the creation and application of quality documents, security and change control must be strictly enforced to assure the integrity of the documentation system and ultimately the TQM system. The process by which these documents are controlled must be determined by consideration of local factors and capabilities and must be described in detail within the document system itself. For example, some institutions may have the ability to implement electronic documentation systems with built-in control features, permitting document change only by specific individuals with clearance who will implement changes through a strictly followed pre-established protocol. In many other cases however, such systems are not practical and a hard-copy system must be devised with original reference documents locked down under restricted access and usable copies clearly marked as such. In all cases, changes to quality documents must be done only by a pre determined procedure as established in the quality system. Such a system normally allows a mechanism by which changes may be suggested and for implementation, needs to be approved by the laboratory management.

The Standard Operating Procedures

An effective SOP is a tool that the laboratory worker utilizes for safe and efficient guidance through a specific procedure. The SOP if properly followed, will link procedures, QC and QA in such a way as to ensure compliance, provide consistency and minimize variables and errors. A poorly written SOP or an SOP that is not complied with, can result in misdiagnosis, QA failures and regulatory repercussions. SOPs should be constructed in a specific and practical manner and should be comprehensive yet concise. Writing a good SOP goes beyond merely listing the steps of the procedure and should be done in a non-constrictive manner to allow for some flexibility where possible. Terminology that confines the user to a specific piece of equipment (in the case where an equivalent item could be substituted in practice) should be avoided. All of the SOPs pertaining to a laboratory or department should be contained in a single location, which is often referred to as the SOP manual (SOPM).

The SOPM should be reviewed periodically and revised as needed. Laboratory staff must be knowledgeable on all aspects of the SOPM especially as it pertains directly to their responsibilities and they may be expected to provide such information in the event of an external audit or assessment for accreditation. The SOPM should be maintained electronically if possible, with restricted access and change control barriers to eliminate the possibility of erroneous changes to the contents. Changes must be made only with proper management approval, rigorously following change control protocols established in advance. While such barriers may seem to hamper the freedom to make necessary updates to the SOPs, such control is required to ensure the credibility of the SOPM. A working “hard-copy” of the SOPM should be made available in a central location, for referral by laboratory staff. When the controlled SOPM is updated, the corresponding laboratory copy should also be updated in the sections that have been changed and laboratory staff must be made aware of the changes.

Personnel Needs

Quality assurance, when properly utilized, requires a substantial resource investment to implement and sustain. Because of this, placing the burden of QA responsibility on a single individual who already has laboratory responsibilities is not the ideal situation. Additionally, conflicts of interest can occur in cases where the person in charge of QA also has laboratory responsibilities that are monitored by the very QA system the individual manages. Due to these reasons, the best situation is the one in which a person or a group are
dedicated solely to the initiation and propagation of QA and can act independently to assess the quality of the laboratories and organization. This will also allow the development of QA expertise and should lead to improved results when dealing with regulatory bodies. Laboratories within health care organizations may wish to consider a common shared position, by appointing a QA person who can inspect or impartially advise all laboratories on quality issues. In cases where the ideal situation is not practical, regulatory and accreditation bodies will still expect to see a dedication of resources and time to QA that includes a clear demarcation of working time towards the effort. Irrespective of where the resource originates, those responsible for running the QA function must also have direct access to the highest levels of management within the organization covered by the QA system. Support by management in this relationship is a critical part of the TQM concept and is fundamental for a successful QA system.

QA experts in the clinical laboratory setting can expect to assess the following quality parameters:

- Specimen selection, collection and handling
- Standard operating procedures
- Personnel
- QC records
- Patient reports
- Referral specimens
- External quality assurance
- Equipment performance
- Commercially/user prepared media
- Specimen/reagent storage
- Safety policies

**QC and QA**

QC is the foundation of a solid QA program. Inadequate QC will render ineffective an otherwise sound QA system. QC is intended to help people do high-quality work by giving them a way to ensure a properly functioning work process.

QC practices are somewhat analogous to safety practices, often only recognized to be important if something bad happens and seeming to be a misuse of time and effort when things are going right. The key to success of these systems is advance planning, anticipation of what might go wrong, warnings when things are going wrong and a planned course of action to respond to a problem and minimize the damage. It is helpful to use a safety analogy and think of the QC violation as a fire and of the QC procedure as a smoke detector. People may agree that a smoke detector is necessary. In spite of that, some may think it is a misuse of time and resources to have an evacuation plan, fire drills, training with fire extinguishers, records of smoke detector activity and periodic testing and calibration of the detector (all representative of the QA system). But then when a real fire breaks out, these systems and plans are instantly essential and hopefully it is not too late at that point to respond to the emergency.

QC/QA training needs to be part of basic laboratory training in order for TQM to be effective, prevent unfortunate events, detect problems and respond quickly as and when they occur. QC procedures need to be designed to detect errors in a manner that does not generate a lot of false alarms and periodic review is essential. A good example of monitoring is the use of Shewhart’s chart in any quantitative assays. Fig. 1 shows a typical example. The use of Westgard rules is a useful approach of QC violation.

**Figure 1:** Shewhart’s chart plotted with the standard 4 (excepted copies 3.55 log) copy numbers of the artus HIV-1 real time qualitative per assay
Virology laboratories widely use commercial tests for serological assays. Traditional in-house preparatory steps carry out almost all cell culture based work and only certain confirmatory steps may use commercial reagents. Molecular diagnosis today is achieved by a combination of in-house assays and commercial kits. In serological assays using commercial kits in addition to using the controls and calibrators that are provided by the manufacturer for validation is a good policy to use pre tested samples as external quality controls. In cell culture laboratories the cell culture susceptibility has to be checked with standard virus strains known to produce typical changes in the culture i.e., cytopathic effect or interference or haemadsorption as the case may be. All assays using cell cultures have to use adequate controls as indicated in their respective protocols. As for molecular diagnosis, apart from the rigor of GLP to be undertaken, the use of appropriate reagents, plastic ware, standards and read out systems are mandatory.

Plan of Action

What is the best strategy for taking action and developing a system that will assist a laboratory in achieving accreditation in India? The optimum plan of action will vary with each laboratory and will require a good understanding of the requirements for accreditation and the current status of the laboratory. In a resource-limited environment, extra care must be taken to avoid over-emphasizing certain development areas too soon or too rapidly. For example, creation and harmonization of laboratory SOPs is a good step, but will not be sufficient for accreditation without the supporting quality system and all the facets included. The following steps may provide some guidance in developing a successful plan of action:

- Assess need/want pros/cons for accreditation and TQM system
- Assess current situation and estimate challenge to design/implement
- Project requirements/ability/commitment to sustain post-accreditation
- Determine path forward and key players; interact with the larger organization QA authority, if one exists
- Begin education and documentation system build (QM, SOP, etc.)
- Identify management interaction, responsibly matrix, reporting structure; mesh with document change control (QM direct line to top management)
- Identify and implement laboratory changes needed to comply with regulations and QA system
- As soon as systems are in place and utilized, internal audit process should initiate and run – this can then be extended to application for an accreditation inspection as and when the laboratory feels ready.

Keeping Eyes on the Horizon

All of the development and implementation stages involved in TQM need to be carried out with the end goal in mind, which should be to provide the best care possible for the patient. It is easy to get distracted or bogged down as the new systems are taken on and expectations must be carefully managed and balanced with practical concerns. An educational/training program, intended to instruct and sell the program, should accompany the implementation of the quality system; in fact, the NABL will expect to see evidence of such a program at assessment time. Getting all hands on board (achieving team play) and maintaining a vision of the horizon (providing understanding and motivation) are essential in the race towards quality and accreditation.

Finally, once the accreditation is granted, it is equally important to keep the momentum going to maintain accreditation through continuous improvement. To support this momentum, adequate resourcing, training and a keen interest in advances in laboratory standards are paramount.

References


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