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# Steps, Implementation and Importance of Quality Management in Diagnostic Laboratories with Special Emphasis on Coronavirus Disease-2019

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## Abstract

A well-established and functional quality management system is an integral part of any diagnostic laboratory. It assures the reliability and standards of the laboratory function. A pandemic situation such as that caused by the influenza H1N1 2009 virus or the recent severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) increases the demands on the public health system, and the need to build, upgrade and expand the number of diagnostic laboratories. The Coronavirus disease-19 (COVID-19) pandemic caused by the SARS-CoV-2 unleashed a public health emergency of an unprecedented scale. The need has been highlighted for the accreditation of tests relating to COVID-19 by the National Accreditation Board for Testing and Calibration Laboratories (NABL) or any agencies approved by the World Health Organization (WHO) or Indian Council of Medical Research. The implementation of quality system in diagnostic laboratories would ensure accurate, reliable and efficient test results at par with the international standards. The functional aspects of a laboratory such as a well-defined organogram, standard operating procedures, good laboratory practices, quality controls, human resources, equipment management, reagents, inventory of records, proper communication need to be addressed to assure quality. Biosafety considerations should include the guidelines laid out by the WHO, the Institutional Biosafety Committee and the Department of Biotechnology, Government of India for carrying out diagnostic work in the laboratory. Currently, there are 1922 laboratories, operational for COVID-19 diagnosis in India. Considering the urgency of testing, the NABL has expedited the process of accreditation and issued accreditation to 818 laboratories. The adherence to the practicable aspects of quality described in this article would help in establishing quality in COVID-19 testing laboratories.

**Keywords:** Coronavirus disease-19, diagnostic laboratory, pandemic, quality management

## INTRODUCTION

A pandemic situation caused by viruses such as influenza H1N1 2009 virus or the most recent severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) increases the demands of the public health system, and the need to build, upgrade and expand the number of diagnostic laboratories. The advent of modern-day diagnostic techniques has enabled timely identification and rapid diagnosis of infectious agents in today's times. Virus diagnostic methods have evolved rapidly from conventional to molecular assays with reduced turnaround time, and the results are actionable more quickly to the clinicians. On several occasions the diagnostic results along with clinical correlations decide the further plan of treatment and quarantine. This also necessitates the constant validation

of the tests, in order to maintain the sensitivity and specificity of the assays, as any false positive or false negative test results might have serious consequences.

The quality of the results is as important as the turnaround time and cost, and it can never be compromised. It therefore becomes utmost important that the results are accurate and reliable. Most

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molecular test results are available within a short time. There has been a change in the quality control practice in clinical laboratories with effect from 2016 which requires laboratories to perform routine quality control in accordance with the Clinical Laboratory Improvement Amendments or establish their own individualized quality control plan based on the risk, demonstrating performance.<sup>[1]</sup> It has been reported that major factors associated with poor quality laboratory services include non-adherence to standard operating procedures (SOPs), lack of training, inadequacy of supplies and reagents, lack of regular internal and external quality assessment activity, not verifying results, etc.<sup>[2]</sup> The exact number of private diagnostic laboratories is hard to estimate, and so is the margin of erroneous results being reported. Therefore, quality control plays a major role in disease diagnostics. Maintaining accuracy, reliability and meeting timelines are the major challenges for health laboratories.

The on-going pandemic of the Coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus unleashed a public health emergency of an unprecedented scale.<sup>[3]</sup> In the scenario of such an emergency, all countries across the world are committed to build diagnostic and healthcare capacities for the detection of the causative agent and for the increased inflow of patients under quarantine. In the event of a pandemic, timely diagnosis helps doctors to decide line of treatment and epidemiologists in transmission studies of the disease across the community and eventually preventing it from further spread. Outbreak situations build stress on every important element of the public health and diagnostic laboratory systems such as workforce, availability of resources and equipment. Chances of the occurrence of many undetected errors and problems cannot be overruled. Implementing a quality management system (QMS) does yield a high-quality laboratory that detects errors and prevents them from recurring. In India, the Quality Council of India (QCI) is a non-profit autonomous society which establishes accreditation structure and spreads the Quality movement in the country.<sup>[4]</sup> The National Accreditation Board for Testing and Calibration Laboratories (NABL) is a constituent Board of the QCI. It is an autonomous society, providing accreditation (recognition) of technical competence to a testing, calibration, medical laboratory, proficiency testing (PT) provider and reference material producer for a specific scope following various international standards.<sup>[5]</sup>

It has been increasingly challenging to contain the spread of emerging or re-emerging infectious agents in India with a population of 133.92 crores especially in today's era of fast international and intranational travel. As per the Ministry of Health and Family Welfare website, the active cases of COVID-19 in India are 838,729, with 6,227,295 discharged and 109,856 deaths (as on 13<sup>th</sup> October 2020).<sup>[6]</sup> The ever-increasing number of patients required thorough preparedness for setting up of dedicated healthcare facilities while protecting healthcare workers and the community. Thus, the guidelines for building such facilities amalgamated patient

care with appropriate biosafety protocols.<sup>[7]</sup> The Indian Council of Medical Research (ICMR) built or upgraded a network of capable diagnostic laboratories through its Virus Research and Diagnostic Laboratories (VRDL) to provide diagnostic services for the ever-increasing surge of samples.<sup>[8]</sup> Currently, there are 1922 Government and private laboratories which are operational for the diagnosis of COVID-19 in India and this number is increasing.<sup>[9]</sup> The various requirements for the diagnostic laboratories involved in the testing of SARS-CoV-2 from infrastructure and biosafety point of view in India have been reviewed and highlighted previously.<sup>[10]</sup> The Clinical and Laboratory Standards Institute (CLSI) has also made documents for the laboratory community's use during the current pandemic freely accessible on their website.<sup>[11]</sup> The Department of Biotechnology of the Government of India has also laid out interim guidelines on laboratory biosafety to handle COVID-19 specimens.<sup>[12]</sup> The non-propagative diagnostic laboratory work such as nucleic acid amplification tests (NAAT) and sequencing should be conducted at biosafety level (BSL) 2 laboratories and propagative work such as virus culture, isolation or neutralisation assays at a containment laboratory with inward directional airflow (BSL-3 laboratories) laboratories.<sup>[13]</sup> Approvals from the institutional biosafety committees should be taken before starting the diagnostic work.

In order to maintain comparability of results across the world, it is necessary that the participating laboratories adhere to the international standards. It is necessary that diagnostic laboratories are set up in urgent yet systematic fashion to ensure quality testing facilities. Adherence to the practicable aspects of quality is an utmost necessity, which would ensure reliability of the test results and would enable public health professionals to take necessary actions.

The need has been highlighted for the accreditation of tests relating to COVID-19 by the National Accreditation Board for Testing and Calibration Laboratories (NABL) or any agencies approved by the World Health Organization (WHO) or Indian Council of Medical Research.<sup>[14]</sup> Following this, the ICMR released a protocol for the approval of new COVID-19 testing facilities, where it was mandatory for the applicant laboratories to have accreditation from NABL for carrying out real-time polymerase chain reaction (PCR) assays for negative stranded genome viruses. In response to the COVID-19 pandemic, the NABL has expedited the process of accreditation in pandemic situation and has issued accreditation to 818 Government and private laboratories.<sup>[15]</sup> In view of this, the present article summarises certain pivotal aspects, which would be helpful for setting up and operations of a diagnostic laboratory with special emphasis on COVID-19 laboratory.

## AN OVERVIEW OF THE LABORATORY QUALITY MANAGEMENT SYSTEM

A laboratory QMS is a coordinated approach to directing and controlling laboratory functions with the aim of ensuring

accurate, reliable and timely results for clinical and public health purposes.<sup>[16]</sup> All the aspects of functioning of the laboratory which includes organisational structure, the SOPs followed for the testing, good laboratory practices, qualified and competent staff, good quality equipment, standard reagents, quality control procedures, inventory of records, proper communication, need to be addressed to assure quality.

Several procedures and processes exist in the laboratory and each of these must be carried out correctly in order to assure the accuracy and reliability of testing. An error in any part of the system could lead to spurious and erroneous results. The aims of laboratory quality management are to ensure that results are accurate, consistent, traceable; personnel are trained, competent and safe; processes and procedures are documented; records are retained; clients are satisfied; and the system continually improves.

## ELEMENTS OF QUALITY MANAGEMENT SYSTEM

These CLSI consensus-based medical laboratory standards are addressed to continually improve the testing quality, safety and efficacy promoting medical care excellence.<sup>[11]</sup> In the QMS model, there are 12 quality system essentials which need to be managed in a manner that best suits the laboratory and addressed with equal importance to assure accuracy and reliability throughout the path of workflow.<sup>[17]</sup> The 12 elements have been highlighted in Table 1.

## ACCREDITATION AND CERTIFICATION

Accreditation is recognition of the laboratory's Quality and competence. It is achieved when the laboratory has a QMS in place that complies with the requirements of the quality standard. To accredit a laboratory, an independent notified accreditation body assesses the laboratory to investigate if the QMS indeed functions as it is supposed to and if it complies with the quality standard. Accreditation is an important step in the continual improvement of the QMS. The laboratories perform assessment to understand whether their performance is comparable to a benchmark, which allows revision of their policies or procedures for continuous improvement. Assessments are performed in a variety of ways which include assessments for the purpose of accreditation, certification or licensure. Accreditation provides a higher level of assurance by the third party to those using the laboratory that the testing is reliable and accurate because it includes an evaluation of competency.

The International Standardization Organization (ISO) certification is widely used by laboratories by which an independent body gives written assurance that a product, process or service conforms to specific requirements.<sup>[17]</sup> Accreditation is an additional level in quality than certification in which formal recognition is given by an authoritative body, that a body or person is competent to carry out specific tasks. Representatives from an accreditation body visit the laboratory and evidence the laboratory's compliance with standards, policies, procedures, requirements and regulations and ensure

**Table 1: Elements of the laboratory quality management system**

Elements	Requirements for diagnostic and COVID-19 laboratories
Organisation	Structure of the laboratory and management of responsibilities that are integral in achieving and maintaining quality
Personnel	Recruiting and retaining qualified, well-trained and competent laboratory staff to perform and manage the activities of the laboratory
Equipment	Right selection, correct installation, proper maintenance and calibration of equipment and maintaining records
Purchasing and inventory	Management of critical supplies and services and maintaining inventory
Process control	Control of the processes that are directly or indirectly related to the laboratory workflow to maintain smooth functioning and accuracy in results
Information management	Guidance for the management of the information generated to ensure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the health-care providers
Documents and records	Guidance for generation, maintenance and retention of the documents such as policies, processes and procedure and records generated during the workflow
Occurrence (Nonconformity) management	Detection and documentation of the non-conformances (an error or an event), their root cause analysis and correction of the problems represented by them
Assessment	External or internal assessment of the laboratory performance compared to the standards or benchmarks laid by other laboratories to verify how well the laboratory processes meet the requirements
Continual improvement	Identification of methods or means for a strategic and systematic continuous improvement
Customer service	Designing the work in such a way so as to meet the expectation of the customers. Methods for seeking customer's feedbacks to understand their expectations
Facilities	Maintenance and safety programs needed to support the laboratory. Establishment and maintenance of a facility with adequate space, proper environmental conditions, safety and comfort for all staff in compliance with requirements to maintain the quality of testing, including safety programs, containment measures, ergonomics security

COVID-19: Coronavirus disease-19

that the laboratory staff performs functions and duties correctly and competently.

The ISO/IEC 17025 standard applies to accreditation of the testing or calibration laboratories whereas the ISO 15189 standard is applicable for clinical laboratories. The choice between certification and accreditation depends on the requirements from potential customers, regulatory boards or the expected growth and development of the laboratory.<sup>[17,18]</sup>



The accreditation benefits an organisation in various ways. It facilitates the implementation and maintenance of an effective quality system for the organisation. The laboratory generating the results becomes confident about the integrity and reliability of the results. It gives assurance of good laboratory practices to the customers and thereby building confidence in them to avail the services. The test results are reliable so the decision-makers can rely on it. It provides national/international recognition of technical competence to the laboratory and thus provides global equivalence. As all the regulatory specifications for all the processes involved in testing are met, right from the purchase of materials and reagents, it automatically reduces the operating costs of the laboratories by getting results right the first time and every time.

### IMPLEMENTATION OF THE LABORATORY QUALITY MANAGEMENT SYSTEM

A raging pandemic situation demands fast-track diagnosis and accurate reporting of results. However, it is advisable to implement the practical recommendations of a QMS to enhance the functioning of the laboratory for generation of reliable results. Following are the important aspects involved in the entire process. Figure 1 shows a summary of the testing procedure and the corresponding quality management aspects at each step.

#### Laboratory facility and safety measures

As per the WHO guidelines, there are three key elements in the establishment of a virology laboratory, namely (a) physical

infrastructure, (b) human resources and (c) equipment and supplies.<sup>[19]</sup> The location of a diagnostic virology laboratory should be physically separated from the rest of the building and should have restricted staff access. This ensures restricted entry of visitors thereby preventing contamination and maintaining biosafety standards. The infrastructure should be built keeping in mind the BSL of the suspected organisms being handled. Designated independent areas should be identified for processes such as sample receipt, sample handling, clean work, reagent preparation, infectious work, nucleic acid extraction, performance of tests and storage. Such delineation of laboratory activities also prevents potential cross-contamination of samples. Thus, there should be a segregation of ‘clean’ and ‘dirty’ areas for preparation of reagents, PCR mix; and for RNA extraction, RNA addition and real-time reverse transcription-PCR (RT-PCR), respectively. This would ensure a unidirectional work-flow and would prevent the chances of contamination. The work space must be such that there are no compromises on the quality of work and the safety of the laboratory staff, health care of personnel and the community. Appropriate personal protective equipment (PPE) must be used for the safety of the laboratory staff. As per the recommendations of the WHO, suspected cases which meet the case definition of COVID-19 should be screened for the virus with NAAT, such as real time RT-PCR.<sup>[20]</sup> This entails expeditious specimen collection, transportation and testing. The recommended work flow and the appropriate Quality measures that must be followed are summarised in Figure 1. Proper adherence to these steps would

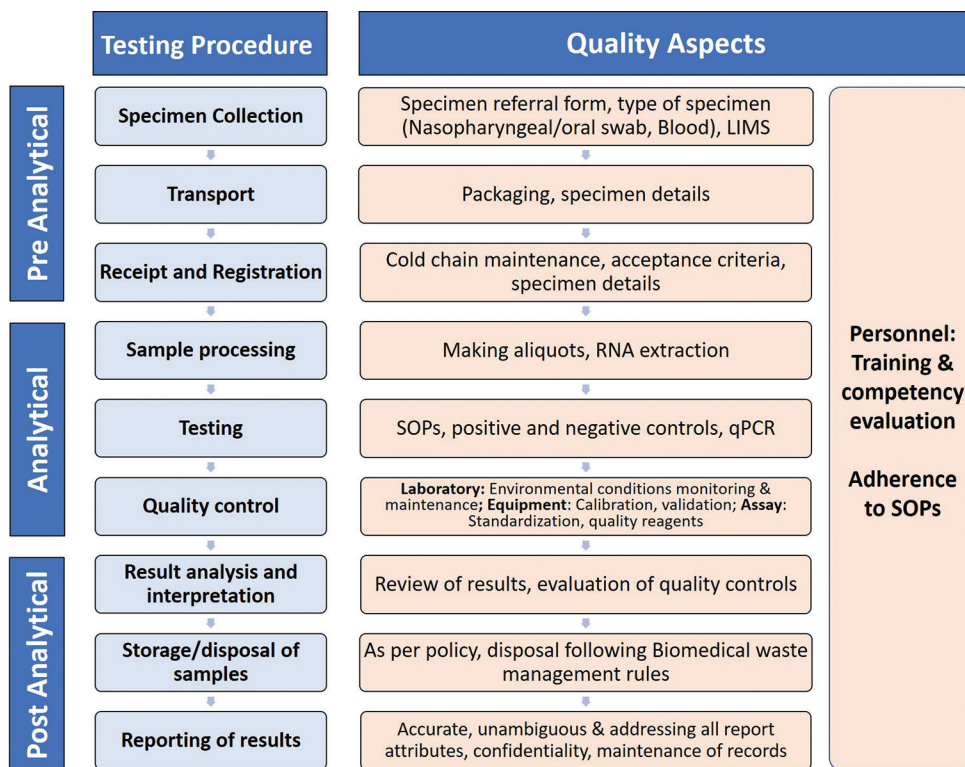


Figure 1: The key steps in testing procedure and appropriate quality aspects to be followed at each level

enable efficient and accurate reporting of results, thereby leading to appropriate clinical management and outbreak control. In addition to following the recommended biosafety measures, safety programmes for other emergencies such as fire, earthquake, power outage, spills and medical emergencies should also be in place.

### Collection and transport of specimens

Specimen collection is very crucial in microbiological testing as the value of the test is compromised or negated using specimens that have not been properly collected, labelled, handled or stored. Such results affect patient care and outcomes and laboratory efficiency. It is mandatory to collect the samples following pre-collection guidelines and proper documentation of the sample as the samples are precious.<sup>[20]</sup> Good clinical sampling is the key to getting proper results. An SOP which contains information on how to prepare the patient before specimen collection, the exact methodology of collection, labelling the specimen as well as its handling, transportation and storage should be followed. The sample container must possess a label with a unique ID of that sample, to maintain confidentiality. Since all samples for COVID-19 diagnosis are referred samples, the ICMR has developed a specific specimen referral form, which covers all the vital information about the patient such as name, age, location, patient history, symptoms, underlying conditions, if any and hospital details. The transport of the collected specimens requires adherence to the protocols for transportation of dangerous goods regulations as recommended by the competent authorities such as the International Air Transport Association<sup>[21]</sup> and the local Government. The WHO has also released a document for guidance on regulations for the transport of infectious substances (2019–2020).<sup>[22]</sup> For receipt of the samples, the specimen rejection criteria should be prepared by the individual laboratories. Records of specimens which were rejected prior to analysis due to unforeseen factors such as improper maintenance of cold chain or insufficient sample volume, leakage and absence of labels on vials should be maintained. Getting the right diagnosis is contingent on laboratory results that are accurate and clinically relevant. On receipt of the samples, it should be ensured that the samples are stored in ultra-freezer immediately. The container should be surface sterilised and only then it should be opened inside a biosafety cabinet for further processing.

### Equipment management

Equipment management is one of the essential elements of a QMS. Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable and timely testing. Proper selection and installation of the equipment is important. Since the test of choice for COVID-19 diagnosis is the real-time RT-PCR<sup>[23]</sup> the equipment such as the real-time PCR machine, plate spin, centrifuge, deep freezers, ultra-freezers and class II A2 biosafety cabinets are required.<sup>[10]</sup> It is mandatory to calibrate and evaluate performance of all the equipment. Daily monitoring of the temperature of the deep/ultra-freezers, as well as the 4°C cabinets where the reagents and samples

are stored is also very important. There should also be a monitoring schedule of the environmental conditions of the laboratory i.e., the ambient temperature which should be defined. This temperature may be in the range of 20°C–25°C. The micropipette sets to be used should also be dedicated for one activity and must be calibrated regularly. Autoclaves must be regularly monitored and validated to avoid accidental breach of biosafety. Maintenance of the equipment following a preventive maintenance schedule should be carried out routinely. Troubleshooting procedure for each equipment should be in place. It is important to ensure that all persons using the equipment have been appropriately trained and understand how to operate the equipment properly and perform all necessary routine maintenance procedures as well.

The following factors should be taken into account for equipment management;

- Installation: equipment should be suitably located in the laboratory to allow accessibility, smooth workflow and sequential utilisation
- Validation: validate the performance of new equipment prior to use
- Calibration: calibrate equipment at regular intervals
- Regular maintenance: there should be an SOP for maintenance and repair of equipment. Internal preventative maintenance as well as vendor provided maintenance/repair for laboratory equipment is important. Proper decontamination of equipment and the laboratory must be done before starting any repair work
- Equipment inventory: An equipment inventory system assists in the control of equipment. Records should be maintained for each item of equipment contributing to the performance of examinations.

### Quality control during performance of laboratory assays

In order to ensure reliability of the results, it is important to standardise all the laboratory protocols for the performance of the real time PCR assay. The laboratory assay protocols are standardised and the methods are validated for their accuracy, precision, inter- and intra-laboratory comparison, robustness, etc., The following are key aspects of assay standardisation.

#### *Reagents and material*

Certified standard quality reagents should be used. The quality of newly purchased reagents should be validated before use. Reagents, chemicals and consumables should be stored under appropriate environmental conditions with appropriate labels. The consumables to be used in the assays must be sourced only from standard and established manufacturers to ensure quality in the assay. To ensure an uninterrupted supply of quality reagents, the ICMR has identified regional laboratories across the country as a depot facility to cater to the requirements of COVID-19 public sector testing laboratories across the nation.<sup>[24]</sup>

#### *Laboratory assay*

This should be done through validation of the laboratory assays as per the validation SOP. Good laboratory practices should be followed right from the sample receipt and sample processing

steps to the result reporting and waste disposal steps. On receipt of the samples, the following steps should also be performed while maintaining a cold chain. While sample processing, and preparation of aliquots, it should be ensured that there is no cross-contamination. Only one sample should be handled at a time, with change of the micropipette tips in between. Filtered tips should be used. Internal and external quality controls should be incorporated in every assay, wherever applicable. For example, for testing of respiratory swab specimens for COVID-19 diagnosis the test for RNase P gene control is incorporated in the assay.<sup>[25]</sup> Biomedical waste generated in the laboratory could be a potential source of infection to the community. It should be segregated at source, autoclaved and then handed over to the authorised agencies for their proper disposal. All the laboratory surfaces must be cleaned with appropriate disinfectants i.e., with freshly prepared 1% sodium hypochlorite or 70% ethanol on metal surfaces where the use of hypochlorite is not possible.<sup>[26]</sup> Fumigation of the laboratory should be done in case of accidental spillage of potentially infectious material.

### External Quality assurance and proficiency testing program

External quality assurance (EQA) programs are a tool which allows the evaluation of the analytical performance for every variable involved (staff, equipment, reagents and method) in comparison with the expected results. Samples prepared by the EQA provider are sent to the laboratories for their analysis. These samples of unknown nature are handled by the laboratory from their reception until the report emission as usual samples. EQA provider receives the analytical results maintaining the confidentiality from all of the laboratories and a confidential report with the identified deviation regarding to an assigned value is prepared.

The ICMR-National Institute of Virology (NIV), Pune, functions as the resource centre for the VRDL network and the apex laboratory to optimise the conventional and real-time PCR assays targeting different genomic regions of SARS-CoV-2. All the laboratories are supplied with the primers, probes, PCR reagents, positive and negative controls and SOPs for the real-time PCR assay either by ICMR-NIV, Pune, or by the reagent depot. The laboratories then perform the pilot test with the positive and negative controls supplied by ICMR-NIV along with the RT-PCR kit. The test results for the negative and positive controls, snapshots of the Ct values and the amplification curves are sent to ICMR-NIV for analysis. Once approved by ICMR-NIV, the laboratories start testing clinical specimens referred to them. The laboratories send a set of five negative and five positive samples to ICMR-NIV for concordance of results, as a part of Quality control. The National Institute for Biological Standards and Control, UK, has made available international standards for the molecular diagnosis of COVID-19.<sup>[27]</sup>

According to ISO/IEC 17043:2010, PT is the evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons. A PT program is important for several reasons. It enables laboratories

to demonstrate competency for a particular measurement discipline which can be used to validate a measurement method, technical training of personnel, traceability of standards; and estimates of measurement uncertainty.

### Human resources

The key element of a QMS is the human resources. Recruitment of appropriate number of staff with a proper job description is the first important requirement followed by providing orientation training to new employees and conducting competency assessments of all personnel and maintaining records. It is important to ensure that the laboratory staff is experienced and appropriately trained for handling the suspected samples for the disease as per the designated BSL of the infectious agent. Updated trainings for new techniques, methods or updates for existing methods can be introduced using continuing education courses. A programme for continuous technical training and updating of skills should be developed to achieve this. The roles and responsibilities of each person must be defined in order to ensure smooth functioning of work. Implementing this, many problems can be prevented. The institutional organogram should reflect the roles such as top management, laboratory director, quality manager, biosafety officer and laboratory staff. There could be further divisions of authority, as per requirement. Implementing a QMS is a continuous process with many activities in many different areas of laboratory practice. Coordinating this process is a big task that cannot be done by one person alone. More people, joined together in a team, are needed to coordinate, plan, manage and execute the implementation of quality management.

### Records and inventory

The inflow of a massive number of samples requires the maintenance of suitable records and inventory to avoid sample mix-up. To circumvent such issues arising during sample receipt and coding, computerised laboratory information management system (LIMS) should be used. Such a software assigns a unique identifier to samples to maintain confidentiality of the patient or study participant. It would also eliminate the possibility of sample mix-up, and makes information easier to find. This ensures smooth flow from receipt, to result to records. Rules and procedures for the same should be followed with designated staff handling the labelling, storage of aliquots and maintenance of records. The policy for retention of specimens should be a part of the inventory management. It is mandatory to maintain records in a uniform pattern. Uniformity is to be ensured by the laboratory's top management. The records should be retained for a designated period of time, pre-determined by the laboratory. All related documents and samples should have restricted access to ensure privacy and control. Various types of records are required to be maintained in the diagnostic laboratory, which include, specimen referral/request forms, test results and reports, test procedures, laboratory work-books or sheets, accession records, quality control records, complaints and action taken, records of internal and external audits, external quality assessment records/inter-laboratory comparisons, equipment



records, including maintenance and calibration records, lot documentation, certification of supplies, package inserts, incident/accident records and action taken, staff training and competency records.

Specific measures should be taken to maintain inventory of reagents, kits and consumables. The laboratory should monitor the condition, quantities and supplies of reagents. The responsibility to assess requirement, procurement, receiving, inspection, storage of the material and to maintain logs should be assigned to designated individuals in a computerised format, with suitable backup.

### Contingency planning

Contingency planning refers to the preparation for a future event or circumstance regarded as likely to occur, or as influencing present action. It includes provision of back-up of manpower, equipment, consumables, reagents, test kits, PPE, etc.,. During pandemic situation, normal operating conditions get disrupted. In these events; shift duties for staff, alternate use of equipment, use of alternative facilities (if available), introduction of backup systems (e.g., power supplies), use of alternative means of decontaminating materials in the event of the failure of critical systems, could be implemented through contingency planning. Redundancy of equipment and facility i.e., the availability of alternate equipment or facility must be ensured in case of any eventuality. Sufficient financial resources should also be allocated for such events.

### Reporting

After the test results are reconfirmed and verified by the authorised signatory, immediate reporting should be done to ensure rapid communication of results. Results should be clearly reported in a proper format without any errors. Proper records of the outgoing reports should be maintained in the laboratory. The results should be sent in a timely manner to the State and Central Government authorities, local government authorities and to the concerned hospitals so that preventive actions and treatment decisions could be implemented quickly. Sensitive reports should not be disseminated directly to the patients or to the public. To ensure hassle-free reporting, a reporting algorithm should be followed, as this also helps in implementing prevention and control measures.

The results are crucial as the treatment and health outcomes depend on the accuracy of the testing and reporting. If inaccurate results are provided, the consequences can be very significant which include unnecessary treatment, complications, failure to provide the proper treatment, delay in correct diagnosis and additional and unnecessary diagnostic testing. Maintaining the confidentiality of the report is utmost important.

### Continual improvement

The implementation and adherence to quality system in the laboratory would lead to established processes and reliable results. However, looking forward, the laboratory should always adopt the policy of continual improvement. This would lead to better performance and increasing capacities of the laboratory in terms of not only the quantity of tests, but also

the quality of every test. The recommended methods to ensure continual improvement, like internal and external audits, and management review could be implemented whenever possible. If not practical to implement these during a pandemic, it is still possible to practice the simple Deming Plan-Do-Check-Act cycle.<sup>[17]</sup> Briefly, the cycle involves the following; Step 1: Plan - identify the problems and the potential sources of error. Decide on the steps to be used to gather information and develop a plan for improvement. Step 2: Do- implement whatever plans have been developed put the plan into action. Step 3: Check - It is a monitoring process. Review the effectiveness of the action taken, using focused review and audit processes. Step 4: Act - Take any corrective action that is required, and then recheck to be sure that the solution has worked. This cycle is a continuous process, so the laboratory will begin again with a planning process to continue the improvements.

## USE OF THE WORLD HEALTH ORGANIZATION-LABORATORY QUALITY STEPWISE IMPLEMENTATION TOOL FOR ESTABLISHING QUALITY MANAGEMENT IN LABORATORIES

The laboratory quality stepwise implementation toolkit by the WHO is available in the form of an interactive webpage that provides a stepwise plan to guide medical laboratories towards implementing a QMS in compliance with ISO 15189.<sup>[28]</sup> This is a handy tool for laboratories fulfil the requirements of the standard to enable achievement of accreditation. It was developed by the Royal Tropical Institute (KIT) for the WHO, and is described here in brief. This tool is a stepwise plan for implementing a QMS. Each step of this plan is called an activity. To implement the QMS in a logical way, the activities are divided over four phases of implementation, where each phase has a specific focus. The tool is constructed such that, even when a laboratory does not reach full implementation of the QMS, it has already improved its quality service. The four phases for implementation of the quality management includes:

- Phase 1: Ensuring that the primary process of the laboratory operates correctly and safely
- Phase 2: Controlling and assuring quality and creating traceability
- Phase 3: Ensuring proper management, leadership and organisation
- Phase 4: Create continuous improvement and prepare for accreditation.

## RESPONSE OF NATIONAL ACCREDITATION BOARD FOR TESTING AND CALIBRATION LABORATORIES TO CORONAVIRUS DISEASE-19 PANDEMIC

In response to the COVID-19 pandemic, the NABL has taken the initiative for accreditation of COVID-19 laboratories and also to facilitate quick response to the pandemic.<sup>[29]</sup> During the lockdown period, the NABL conducted remote assessment of



the laboratories for molecular diagnosis of COVID-19. Scope extension for COVID-19 molecular diagnosis was given to the laboratories already having NABL accreditation. The audit process was conducted online and based on the documentary evidences. As laboratories have started operations, conduct of assessments with local assessors has been started in some areas. However, assessments in respect to COVID-19 are being conducted remotely in respective areas, not compromising on the integrity of the accreditation process. Extension of accreditation is given to the laboratories which had applied 6 months in advance (before expiry) as per procedure for maintaining continuity of accreditation. The NABL also issued accreditation for various types of standards to the laboratories for certification of PPE, medical devices, disinfectants, etc.<sup>[5]</sup> As of 13<sup>th</sup> October 2020, a total of 818 laboratories have been accredited for RT PCR RNA by the NABL as per ISO 15189 standard, which is a very significant contribution by the NABL for the QMS of COVID-19 laboratories in India.<sup>[15]</sup>

## CONCLUSIONS

The implementation of QMS improves overall quality of laboratory procedures. It significantly reduces laboratory errors and progressively improves quality, efficiency and outcomes, thus enabling delivery of timely and accurate services for patients. Implementation of the QMS in a systematic stepwise manner addressing all quality essentials definitely leads to achievement of quality standards in the laboratory. However, extensive follow-up, monitoring and continued documentation are necessary to ensure the long-term success of implementing QMS programs.

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## Conflicts of interest

There are no conflicts of interest.

## REFERENCES

1. Pulido JX. Respiratory infection diagnostics and the role of quality control testing. *Medical Laboratory Observer*; 2018. Available from: <https://www.mlo-online.com/diagnostics/microbiology/article/13017203/respiratory-infection-diagnostics-and-the-role-of-quality-control-testing>. [Last accessed on 2020 Oct 13].
2. Biadgo B, Zakir A, Malede T, Getachew E, Girma M. Assessment of quality of medical laboratory services provision and associated factors in public health facilities at Gondar Town, Amhara Regional State, Northwest Ethiopia. *Clin Lab* 2019;65: [doi: 10.7754/Clin.Lab.2018.181037].
3. Coronavirus Disease; 2019. Available from: <https://covid19.who.int/>. [Last accessed on 2020 Oct 13].
4. Quality Council of India: Creating an Ecosystem for Quality. Available from: <https://www.qcin.org/>. [Last accessed on 2020 Oct 13].
5. Welcome to the NABL India. Available from: <https://nabl-india.org/>. [Last accessed on 2020 Oct 13].
6. MoHFW. Ministry of Health and Family Welfare, MoHFW, Home. Available from: <https://www.mohfw.gov.in/>. [Last accessed on 2020 Oct 13].
7. Agarwal A, Nagi N, Chatterjee P, Sarkar S, Mourya D, Sahay RR, *et al.* Guidance for building a dedicated health facility to contain the spread of the 2019 novel coronavirus outbreak. *J Dent Educ* 2012;76:1532-9.
8. Gupta N, Potdar V, Praharaj I, Giri S, Sapkal G, Yadav P, *et al.* Laboratory preparedness for SARS-CoV-2 testing in India: Harnessing a network of Virus Research & Diagnostic Laboratories. *Indian J Med Res* 2020;151:216-25.
9. Indian Council of Medical Research. Total Operational (Initiated Independent Testing) Laboratories Reporting to ICMR. Indian Council of Medical Research; 2020. Available from: [https://www.icmr.gov.in/pdf/covid/labs/archive/COVID\\_Testing\\_Labs\\_11102020.pdf](https://www.icmr.gov.in/pdf/covid/labs/archive/COVID_Testing_Labs_11102020.pdf). [Last accessed on 2020 Oct 13].
10. Mourya DT, Sapkal G, Yadav PD, Belani SK, Shete A, Gupta N. Biorisk assessment for infrastructure & biosafety requirements for the laboratories providing coronavirus SARS-CoV-2/(COVID-19) diagnosis. *Indian J Med Res* 2020;151:172-6.
11. Clinical & Laboratory Standards Institute. CLSI Documents Helpful for COVID-19 Testing. Available from: <https://clsi.org/standards-development/helpful-documents-for-covid-19-testing/>. [Last accessed on 2020 Oct 13].
12. Department of Biotechnology. Regulations and Guidelines for Recombinant DNA Research and Biocontainment – Interim Guidelines on Laboratory Biosafety to Handle COVID-19 Specimen for R&D Purpose. Available from: [http://dbtindia.gov.in/sites/default/files/OM\\_Interim\\_Guidance\\_COVID.pdf](http://dbtindia.gov.in/sites/default/files/OM_Interim_Guidance_COVID.pdf). [Last accessed on 2020 Oct 13].
13. World Health Organization. Laboratory Biosafety Guidance Related to the Novel Coronavirus (2019-nCoV). World Health Organization; 2020. p. 1-12. Available from: [https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version1-1-1.pdf?sfvrsn=912a9847\\_2](https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version1-1-1.pdf?sfvrsn=912a9847_2). [Last accessed on 2020 Oct 13].
14. Supreme Court Orders Free Coronavirus Tests. *The Telegraph, India*. Available from: <https://www.telegraphindia.com/india/supreme-court-orders-free-coronavirus-tests/cid/1763298>. [Last accessed on 2020 Oct 13].
15. National Accreditation Board for Calibration and Testing Laboratories. List of NABL Accredited Laboratories for RT PCR RNA (updated as on 13-10-2020). Available from: <https://nabl-india.org/wp-content/uploads/2020/10/RT-PCR-RNA.pdf>. [Last accessed on 2020 Oct 13].
16. Clinical and Laboratory Standards Institute. QMS01: QMS – A Model for Laboratory Services-CLSI. Available from: <https://clsi.org/standards/products/quality-management-systems/documents/qms01/>. [Last accessed on 2020 Oct 13].
17. WHO. Laboratory Quality Management System: Handbook. Available from: <https://www.who.int/ihr/publications/lqms/en/>. [Last accessed on 2020 Oct 13].
18. Valdivieso-Gómez V, Aguilar-Quesada R. Quality management systems for laboratories and external quality assurance programs. In: Zaman GS, editor. *Quality Control in Laboratory*. IntechOpen; 2018.
19. Asia WHORO for SE. Guidelines on Establishment of Virology Laboratory in Developing Countries; 2009. Available from: <https://apps.who.int/iris/handle/10665/205181>. [Last accessed on 2020 Oct 13].
20. World Health Organization. Laboratory Testing for Coronavirus Disease 2019 (COVID-19) in Suspected Human Cases. Interim Guidance. World Health Organization; 2020. p. 1-7. Available from: <https://apps.who.int/iris/handle/10665/331501>. [Last accessed on 2020 Oct 13].
21. IATA – Novel Coronavirus (COVID-19) Guidance for Operators – Rev 2020:1. Available from: <https://www.iata.org/contentassets/5b7bfb49568442049a384623cefb3cea/covid-19-guidance.pdf>. [Last accessed on 2020 Oct 13].
22. WHO. Guidance on Regulations for the Transport of Infectious Substances 2019–2020. Available from: <https://www.who.int/ihr/>

- publications/WHO-WHE-CPI-2019.20/en/. [Last accessed on 2020 Oct 13].
23. Corman VM, Landt O, Kaiser M, Molenkamp R, Meijer A, Chu DK, *et al.* Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. *Euro Surveill* 2020;25:1-8.
  24. Indian Council of Medical Research. ICMR Depot. Available from: <https://www.icmr.gov.in/cdepot.html>. [Last accessed on 2020 Oct 13].
  25. CDC. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel; 2020. p. 1-42. Available from: <https://www.fda.gov/media/134922/download>. [Last accessed on 2020 Oct 13].
  26. Ministry of Health and Family Welfare. COVID-19: Guidelines on Disinfection of Common Public Places Including Offices. Available from: <https://www.mohfw.gov.in/pdf/Guidelinesondisinfectionofcommonpublicplacesincludingoffices.pdf>. [Last accessed on 2020 Oct 13].
  27. National Institute for Biological Standards and Control (NIBSC) U. NIBSC-COVID-19-Related Research Reagents. Available from: [https://www.nibsc.org/science\\_and\\_research/idd/cfar/covid-19\\_reagents.aspx](https://www.nibsc.org/science_and_research/idd/cfar/covid-19_reagents.aspx). [Last accessed on 2020 Oct 13].
  28. WHO. Laboratory Quality Management System (LQMS) Training Toolkit. Available from: [https://www.who.int/ihr/training/laboratory\\_quality/introduction/en/](https://www.who.int/ihr/training/laboratory_quality/introduction/en/). [Last accessed on 2020 Oct 13].
  29. National Accreditation Board for Testing and Calibration Laboratories. Rapid Response to COVID-19 dtd: dtd: 16.05.20. Available from: <https://nabl-india.org/wp-content/uploads/2020/06/covid-writeup-dtd-16.05.20-1.pdf>. [Last accessed on 2020 Oct 13].