

Role of Quality Management System in Setting up and Sustaining a Molecular Diagnostic Laboratory during COVID-19 Pandemic

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ABSTRACT

Introduction: Coronavirus Disease-2019 (COVID-19), caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) catapulted the need to build, upgrade and expand the number of diagnostic laboratories having molecular capacity. Setting up and sustaining a molecular laboratory especially in the backdrop of a lockdown presented many challenges. The Department of Microbiology, in a tertiary level hospital in Mumbai was one of the first to start the molecular testing laboratory. All other tests performed in the department are accredited as per International Organisation for Standardisation (ISO) 15189:2012 since 2015. However, starting a molecular diagnostic facility for COVID-19 testing presented a unique set of challenges as the organism in question belonged to risk category 2 and had the potential for airborne transmission.

Aim: To determine the challenges faced and activities undertaken especially with regards to the role of Quality Management System (QMS) in setting up and sustaining a molecular diagnostic facility during COVID-19 pandemic.

Materials and Methods: A retrospective analysis was carried out of experiences and data generated from March 2020 to April 2021

at the microbiology department of a tertiary level medical college and hospital in Mumbai, Maharashtra, India. The article included the processes which required and data generated during setting up and sustaining a new molecular testing facility as per the QMS with special reference to the 12 Quality System Essentials (QSE). Quality Indicators (QI) were identified, objectives defined and monitored over the period of the study. It was a descriptive study and statistical analysis was not indicated.

Results: All the objectives of the QI were met with. Only 4% staff needed corrective training. Specimen rejection rate pretest and post-test was 0.26% and 0.56%, respectively. Quality control failure was seen in 0.16% runs and Turnaround Time (TAT) deviated beyond 12 hours in 0.52% samples. The run contamination, equipment problems and laboratory associated infections were 0.08%, 0.56% and 0%, respectively. There were no External Quality Assessment (EQAS) failure and negative feedback. Laboratory contamination rate was 1.02%. Definite improvement was observed over time in all identified parameters.

Conclusion: Implementation of QMS with specific reference to strengthening QSE is a necessary requirement for achieving quality standards.

Keywords: Diagnostic facility, Quality essentials, Quality indicators

INTRODUCTION

Viral diagnosis has progressed from conventional culture and serology based methods to molecular assays providing a shorter TAT. When in March 2020, a devastating pandemic knocked on our doors, laboratories across the country were caught unawares. COVID-19 caused by SARS-CoV-2 catapulted the need to develop, improve and expand the number of molecular diagnostic laboratories having capacity to detect SARS-CoV-2 [1]. Testing is an important component of pandemic control. Timely diagnosis is paramount in deciding the line of treatment and in understanding transmission dynamics across the community and eventually intercepting the further spread of the disease. Any outbreak directly causes a stress on public health systems and diagnostic laboratories and chances of errors cannot be overruled [1,2].

Setting up and sustaining a molecular laboratory especially in the backdrop of a lockdown presented many challenges. Quality of results generated was of utmost importance and all 12 QSE needed to be looked into [3]. A laboratory QMS is an integrated process which directs and controls laboratory functions with the objective of ascertaining accurate, reliable and timely results for clinical as well as public health purposes [4]. The 12 QSE in a QMS needs to be controlled in a style best fitted to the laboratory. The 12 QSE are organisation, personnel, equipment, purchasing and inventory, process control, information management, documents and records, occurrence, assessment, continual improvement, customer service and facilities [4,5].

The Department of Microbiology, in a tertiary care medical college and hospital in Mumbai was one of the first to start the molecular testing laboratory in the midst of the pandemic. All other tests performed in the department are accredited as per ISO 15189:2012 since 2015 including molecular tests, wherein QMS and its adherence were already in practice. However, starting a molecular diagnostic facility for COVID-19 testing presented a unique set of challenges as the organism in question belonged to risk category 2 and had the potential for airborne transmission. The challenges included were related to laboratory design, bio-safety (considering the contagiousness of the disease and the greater transmissibility of the pathogen) and risk assessment, procurement of new equipment, consumables and reagents, good laboratory practices, laboratory maintenance, waste management, hiring/training of laboratory personnel, etc., especially in the background of complete lockdown. World Health Organisation (WHO) interim guidance in March 2020 also stated that the availability of timely and accurate results can be threatened when testing demands outstrip capacity, such as when there is a backlog for testing and it is no longer possible to turn around results within 24 to 48 hours, the demand for laboratory reagents exceeds the capacity for supply, laboratory staff are exhausted and working hours need to be reduced, the number of incoming samples exceeds the capacity for safe pretesting storage, critical staff become infected or are otherwise unable to perform their duties (e.g., being in quarantine) or laboratory instruments can no longer be serviced or properly maintained [6].

Mourya DT et al., have highlighted the minimum requirements for the diagnostic laboratories opting testing of material for the diagnosis of COVID-19 and associated biorisk to the individuals and to the community [7]. An analysis of the process involved at the presented institute may help other laboratories in overcoming various obstacles while establishing their molecular laboratories and help them in expediting the process. Therefore, an observational study was conducted to determine the challenges faced and activities undertaken especially with regards to the role of QMS in setting up and sustaining a molecular diagnostic facility during the pandemic.

MATERIALS AND METHODS

Study design and setting: A retrospective analysis was carried out of experiences and data was generated from March 2020 to April 2021 at the microbiology department of a tertiary level medical college and hospital in Mumbai, Maharashtra, India.

Ethical considerations: Exemption from Institutional review board permission was obtained from Institutional Ethics Committee (IEC-III) as it was a quality control and quality assurance study in the institute on available data (IEC/OUT/228/2021).

Procedure

The quality management processes as required and data generated during setting up and sustaining a new molecular testing facility was observed and documented as per the QMS with special reference to the 12 QSE to study the effectiveness of quality processes. Management and technical requirements of all 12 QSE were studied to understand the challenges faced and steps taken to overcome those. QIs were identified for each QSE, objectives were defined for each indicator and the outcomes were monitored over the period of the study.

Organisation: Laboratory management was actively involved especially in getting the laboratory approved as Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) lab for COVID-19 testing by Department of Health Research (DHR)/Indian Council of Medical Research (ICMR), Government of India. Biomedical waste disposal policy was formulated and implemented as per the revised rules [8]. Training was conducted in ethical and legal issues with regard to COVID-19. Needs of users were ascertained. Requirements in terms of resources and QMS were identified, designed, implemented, maintained and improved. Responsibilities, authority and inter-relationships of all personnel were defined. Some pictures regard to lab infrastructure in pandemic time is shown in [Table/Fig-1].



[Table/Fig-1]: Seth GS medical college and KEM hospital, Department of Microbiology, molecular testing laboratory.

Personnel: Existing staff was repurposed. New staff was appointed through institute and Viral Research and Diagnostic Laboratory (VRDL) funds with required educational qualification and experience. Training and competency program was designed and implemented.

Equipment: Process was listed and instruments were identified. Urgent sanction and purchase were carried out. Equipment was installed, calibrated and maintained. Online and offline training was imparted to staff as per availability and lockdown restrictions. Contingency plan was defined.

Purchasing and Inventory: Requirements were identified. Urgent sanction and purchase were carried out through various sources. Supply of kits was made by ICMR and later by Directorate of Medical Education and Research (DMER), Government of Maharashtra, India. Acceptance testing was defined and carried out for all critical supplies.

Process Control

Pre analytical: Vaccine carriers were provided for the transport of specimens. Temperature was monitored. Kits with internal control like RNAse P, Ribonuclease P protein subunit p30 (RPP 30), β -actin, etc., were preferred so as to determine the quality of sample.

Analytical: Quality control and quality assessment policy were defined and implemented.

Post analytical: All results were reviewed, correlated clinically and verified on a real time basis before being released.

Information management: Needs, authorities and responsibilities were defined. ICMR advisory was checked on a regular basis for any updates or modifications including various versions of sample requisition form. Data entry operators were appointed and trained for online data entry.

Documents and records: Required quality system procedures and standard operating procedures were identified and defined. All quality and technical records were identified, updated and maintained.

Occurrence management: All staff were trained in biosafety cabinets before entry into the laboratory, including donning and doffing and biomedical waste management. Systems were put in place to minimise run failure or contamination. Equipment downtime was monitored and contingency policy was defined. Laboratory associated infections were monitored.

Assessment: The laboratory was granted permission to start testing after visit by National Institute of Virology (NIV) representative and satisfactory results in the first 10 samples sent to NIV for confirmation.

Continual improvement: QIs were defined and monitored for all QSE. Trend analysis was carried out for specimen rejection, TAT deviation and EQAS non conformance.

Customer service: Regular feedback was taken from the clinicians as well as from public health officials. Real time Google sheet was generated for results dispatch to clinician. Reports were emailed to the concerned clinician as and when they were generated. Point-Of-Care (POC) testing {Cartridge Based Nucleic Acid Amplification Test (CBNAAT)} was used for patients needing urgent report.

Facility: Porta cabin was made available in the Out Patient Department (OPD) area for sample collection. Unidirectional work flow was defined. Physical separation of areas was carried out as required. Existing negative pressure laboratory was made available for extraction. Specimen acceptance area was identified and made available on the ground floor. Regular contamination checks were carried out every month. Transport and accommodation arrangements were made for staff during lockdown period.

STATISTICAL ANALYSIS

It was a descriptive study and statistical analysis was not indicated.

RESULTS

The analysis of proposed objectives defined and outcomes achieved of the 12 QSE is shown in [Table/Fig-2]. All the objectives proposed were met with.

QSE	Quality Indicator (QI)	Objective	Outcome	Number/Total	
1	Organisation	Availability of regulatory permissions (ICMR, MPCB)	100%	100%	NA
2	Personnel	Proportion of staff needing corrective training	<10%	4%	1/25
		Staff attrition	<10%	8%	2/25
3	Equipment	Equipment downtime	<24 working hours	<24 working hours	NA
4	Purchasing and Inventory	Stock out periods	0 days	0 days	NA
5	Process control				
	Pre analytical (specimen rejection rate)	Pre test (transport issues, leakage, etc.)	<2%	0.26%	328/123922
		Post test (Invalid samples on RT-PCR)	<2%	0.56%	695/123594
	Analytical	QC failure	<2%	0.16%	4/2514 runs
Post-analytical	Turnaround Time (TAT) deviation beyond 12 hours	<2%	0.52%	642/123594	
6	Information management	Delay in reporting beyond 12 hours	<2 times/month	0	NA
		Delay in ICMR online entry beyond 24 working hours	<2 times/month	0	NA
7	Documents and Records	Number of undocumented procedures	0	0	NA
8	Occurrence management	Run contamination	<2%	0.08%	2/2514 runs
		Equipment problems	<2%	0.56%	14/2514 runs
		Laboratory associated infections	<1%	0	0/25
9	Assessment	EQAS failure (10 samples sent to reference lab each time as per ICMR directives)	<10%	0	0/9 times
10	Continual Improvement	Trends in specimen rejection rate, TAT deviation, EQAS conformity	Improvement	Improvement seen	Fig 1
11	Customer service	Negative feedback	<10%	0	NA
12	Facility	Contamination check (14 sites each month)	<5%	1.02%	2 out of 196

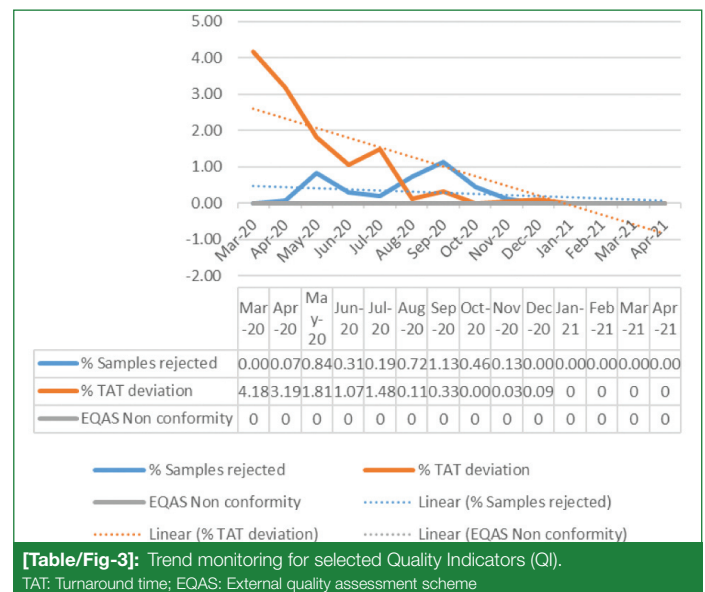
[Table/Fig-2]: Monitoring of Quality Indicators (QI) as per Quality System Essentials (QSE).

MPCB: Maharashtra state pollution control board; RT-PCR: Reverse transcriptase polymerase chain reaction; QC: Quality control; ICMR: Indian council of medical research; EQAS: External quality assessment

All the required permissions from ICMR and Maharashtra state Pollution Control Board (MPCB) were available. Only 4% staff needed corrective training and attrition rate of staff was 8%. The downtime of equipment was never more than 24 hours and there were no stock out periods. In the process control, specimen rejection rate pretest (transport issues, leakage, etc.) was 0.26% and post-test (invalid samples on RT-PCR) was 0.56%. Quality control failure was documented in 0.16% runs and in 0.52% samples TAT was deviated beyond 12 hours. There was no delay in reporting and online portal entry. All procedures were documented before being put in practice. The run contamination, equipment problems and

laboratory associated infections were 0.08%, 0.56% and 0% respectively. There were no EQAS failure and negative feedback. Laboratory contamination rate was 1.02%.

Trends in specimen rejection rate, TAT deviation, EQAS non conformity are depicted in [Table/Fig-3]. Definite improvement was observed in trend over time in all identified parameters with zero specimen rejection, TAT deviation and EQAS non conformance from January 2021 onwards.



[Table/Fig-3]: Trend monitoring for selected Quality Indicators (QI).

TAT: Turnaround time; EQAS: External quality assessment scheme

DISCUSSION

Quality requirements are particularly high in molecular testing, especially for COVID-19 as the implications of the test result go far beyond an individual patient. QMS should be applied in such a manner that international standards are met with and the accuracy, reliability and timeliness of results are guaranteed [9]. Gachuki T et al., have shown that implementation of QSE and monitoring of QIs definitely has a positive outcome on the quality of the testing [10]. The presented department is accredited as per ISO 15189:2012 for all tests conducted in the laboratory and the objective was to maintain and ameliorate QIs for Real time RT-PCR for COVID-19 diagnosis comparable to other accredited tests. ISO is the first QMS for medical laboratories [11]. Similarly, the Clinical and Laboratory Standards Institute (CLSI) has developed 12 QSE based on ISO standards. These 12 essentials serve as a starting point in establishing a quality system that covers pre-testing, testing, and post testing operations [12].

The allegiance at all levels, especially from high level leadership and other stakeholders significantly contributed in upgrading and sustaining continuous laboratory quality and harmony. The commitment of the institute in providing required equipment and manpower augmented the testing services. The DHR/ICMR took a far-sighted decision of enhancing the country's capacity for early identification and diagnosis of all viral infections of public health importance by sanctioning/ establishing VRDL [13].

Our department was recognised as a medical college level VRDL and that helped in initiating testing and establishment of laboratory. Also, the commitment of Ministry of Health and Family Welfare, Government of India (through ICMR/DHR) and state government through Directorate of Medical Education and Research (DMER) towards timely supply of consumables and kits went a long way in providing continuous uninterrupted services.

Human resources are most important in any organisation. In order to minimise the chance for errors and to guarantee quality of testing and results, all laboratorians should be equally well versed and knowledgeable about all facets of the QMS in their laboratory operation [14]. Having a training and competency programme in

place and fostering ownership definitely led to a low attrition rate and need for retraining [Table/Fig-2]. Also, providing lodging and boarding to the staff during the initial lockdown phase increased the staff allegiance to the institute. Diverting staff to cover for absences cross training of other laboratory technicians and residents between various activities, programming a break into the duty plan and deferring or ceasing of non-essential activities were just a few activities which were carried out for optimum utilisation. However, the appointment was on a contract basis and attrition still remains a challenge.

Another important resource is the various equipment and consumables required for the molecular testing. To ensure the availability of quality equipment and consumables a multifaceted approach was utilised. The urgent purchase through Institute and VRDL funds or direct supply of an additional RT-PCR machine by ICMR definitely helped. Repurposing of automated extraction and amplification equipment provided for HIV 1 viral load testing assisted in augmenting the daily capacity. However, what was most important was having a contingency plan; manual extraction in case the automated fails, or having a backup equipment on a loan basis or a memorandum of understanding with other molecular testing laboratories. The maintenance contract of all the equipment ensured that the downtime never interfered with the continuous service. The availability of consumables was a significant issue especially during national lockdown. Literally the policy of “beg, borrow and steal” had to be followed for avoiding stock out. Being located in a metropolis was an asset as far as supplies were concerned. An RT-PCR kit failed acceptance testing and was returned. The same kit was then rejected by DMER. Having acceptance testing in place circumvented the need for recall of erroneous results.

Over the past few decades, various studies have observed that more errors are reported in the pre and post examination phases compared to the examination phase of the testing cycle [15]. A review by Hammerling JA has reported that in a laboratory, the types of errors are- pre analytical 46-68.2%, analytical 7-13% and post analytical 18.5-47% [16]. In a systematic review and meta-analysis in 2020, Asmelash D et al., have reported a pooled prevalence of pre analytical and post analytical errors in Africa as 17.5% (95% CI: 11.55, 23.45) and 10.99% (95% CI: 5.30, 16.67) respectively [17]. Minimising errors has the potential to result in significant cost savings [18]. A significant effort was made to identify and minimise possible causes of errors at all phases of testing. Being an accredited laboratory, QIs were identified and stringent objectives were defined particularly it being a new test. Concentrated efforts could accomplish those objectives [Table/Fig-2].

A well-functioning routine Health Information System (HIS) is required to provide the information needed for governance and management of health systems and services especially during a pandemic [19]. The unavailability of laboratory information management system provided a challenge. However, pre planning and use of online portal provided by ICMR, real time accessible google sheets with results and emailing the reports to clinicians assisted in providing the information required on a real time basis [20].

In quality management, if an activity is not documented, it is not considered as being done. The quality policy was already in place, the process and procedures were defined and records maintained. Defining the technical procedures was especially crucial as the laboratory was working round the clock with multiple changes of both extraction and amplification kits with different technicians working in various shifts. This contributed immensely in reducing the laboratory errors.

Non conformities include any aspect of laboratory functioning be it pre analytical, analytical, or post analytical; that does not abide by its own policies and procedures or the requirements of its customers [4]. Events can also be classified according to the potential for patient harm [4]. Occurrence management in the laboratory was

broadly classified into three categories; equipment related issues, non compliance to procedures and laboratory associated infections. It was heartening to note that in the 14 months of the laboratory working round the clock not a single laboratory associated infection was reported. Also, the run contamination was seen in only 2 (0.08%) RT-PCR runs.

To achieve accuracy and reproducibility of laboratory-based testing, both internal and external quality control measures are essential [21]. ICMR initiated Inter Laboratory Quality Control (ILQC) for molecular based testing laboratories for COVID-19 and 100% concordance was seen in the results [22].

The old adage that what gets measured, gets done is true. QIs refers to collection and analysis of data at each step of the testing cascade that can serve as indicator for correct performance of the whole testing process [4]. The intense preparation by the laboratory staff was instrumental in achieving the outcomes. With a QMS implemented, the laboratory continuously monitored daily operations and easily identified areas that required more attention for continuous and systematic improvement. The regular monitoring of QIs allowed for rapid identification of systematic and random errors and rapid resolution of problems. An analysis over time of selected QIs showed an improvement [Table/Fig-3].

Customer orientation has gained increasing attention in healthcare. A customer satisfaction survey is one way to raise areas and topics for quality improvement [23]. Regular feedback taken from both clinicians and public health officials helped to innovate and improve the service delivery. For situations where urgent report was required, CBNAAT testing was initiated. The 12 TAT even with increased workload was appreciated and acknowledged.

Changes to the work processes and laboratory design allowed systematic and structured flow patterns. The essential parts of PCR contamination control include space and time separation of pre and post PCR activities, use of physical aids, use of Ultraviolet (UV) light, use of aliquoted PCR reagents, incorporation of numerous positive and negative or blank controls (H₂O substituted for template), and use of one or more contamination control methods that use chemical and biochemical reactions [3]. The fundamental principle for all these measures is the certitude that amplicon contamination can neither be seen nor felt nor foreseen. All these practices were put in use. Monthly contamination checks were carried out from 14 sites and when contamination was observed in two sites, root cause analysis followed by corrective and preventive action was carried out. Having systems in place, went a long way in mitigating the risks.

Cost considerations must be weighed against the benefits of quality improvement. Some improvements will result in large cost savings over time [8]. Zeh CE et al., have demonstrated that implementation of QMS minimises wastage of reagents leading to increased cost savings to the laboratory [24]. Although such an analysis was not performed at our laboratory, the results in terms of minimising wastage and failure and timely dispatch of reports contributed in the timely management during COVID-19 pandemic.

Limitation(s)

As it was a new test which was introduced, there was no baseline data and objectives were laboratory defined.

CONCLUSION(S)

Implementation of QMS with specific reference to strengthening QSE is a necessary requirement for achieving quality standards. Even for a newly initiated test, incorporating and monitoring QIs right from the beginning can minimise both systematic and random errors leading to uninterrupted quality services.

Data availability statement: Data sharing is not applicable to this article as no new data were created or analysed in this study.

Disclaimer: The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of any affiliated agency of the authors.

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