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Original Research Article

Analysis of Quality Indicators in Molecular Laboratory of a Tertiary Care Hospital in India

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Abstract

Introduction: Quality indicators are important parameters to enhance the quality of the clinical laboratory services. Due to the extensive testing processes, errors cannot be completely avoided in a clinical laboratory. To minimize errors, however, adequate training, QC checks, and regular procedure evaluations are beneficial.

Objective: The objective of the study was to establish and evaluate quality indicators on an ongoing basis as an effort to increase quality.

Methods: This retrospective study, different quality indicators in a molecular laboratory in northern Gujarat were assessed over the course of a year (September 2020–August 2021). Data of total 8176 samples were summarized. Each Quality indicator was examined at the end of the month after being divided into the pre, analytical, and post-analytical stages, respectively.

Result: As summarization of total 8176 samples, we found a cumulative error rate for all quality indicators of 346 (4.23%). Preanalytical errors were the most common 180 (2.20%), followed by analytical errors 114 (1.39%), and post analytical errors 52 (0.63%).

Conclusion: There is no question that by continuously striving to develop the outcome of these quality indicators through the adoption of corrective measures over time, the quality of laboratory services and patient care would be improved.

Keywords: Quality indicator, COVID-19 testing, Analysis, Molecular laboratory, RT-PCR.

Introduction

Quality control/quality assurance (QC/QA) is a group of organized procedures, according to the CDC (Centre for Disease Control and Prevention) and CLSI (Clinical Laboratory Standard Institutes).[1,2] Quality indicators encompass a variety of parameters that determine the class of a laboratory care, such as the correctness, dependability, and timeliness of reported test results.[2]Quality indicators are regarded as helpful aspects to enhance the quality of the clinical laboratory services as

they enable laboratory physicians identify and correct the errors in routine practices. [3,4]According to the definition, Quality indicators covers all important aspects, e.g. safety of patients, reliability, equality, focusing on patients, promptness, and efficacy. According to the evidence based analysis, these parameters are subject to implement on constant basis in laboratory settings for a long.[4]

Due to the quantity of samples, the number of personnel handling them, and the number of procedures involved in the testing process, it is difficult to avoid mistakes in a large clinical laboratory. However, with the aid of appropriate guidance, quality control (QC) inspections, and regular procedure review, errors can be reduced.[5] This demonstrates the value of running tests as quickly as feasible (post-analytical phase) using precise and accurate procedures on the appropriate samples (analytical phase). The pre analytical phase includes the steps taken prior to sample testing. Analyzing samples and interpreting results are part of the analytical phase. The objective of the post-analytical step is to deliver precise and consistent lab reports to clients. [3]

A public health emergency of unparalleled proportions has been released by the COVID-19 pandemic by the SARS-CoV-2 virus. Different guidelines for testing in clinical laboratories have established strict control and management systems made up of various Quality Indicators (QIs) to check laboratory procedures. The use of these systems, which have all been shown to support highly effective Quality Assurance (QA) practices, includes audits by trained evaluators as well as accreditation by competent bodies such as National Accreditation Board for Testing and Calibration Laboratories (NABL).[5]

To ensure that results are analogous around the globe, clinical laboratories must follow the international guidelines. To provide high-quality testing facilities, it is essential that laboratories should be established quickly but systematically.[6]

Aims & Objective: This study is aimed to check performance of laboratory services and implement measures to improve in order to raise the standard of laboratory care in terms of Quality assurance.

Material and Methods:

Study design & Location: It was retrospective observational study which was conducted in the Molecular Laboratory, Department of Microbiology, Nootan Medical College, Mehsana, Gujarat.

Sample Size & Duration: All the samples nasopharyngeal and oropharyngeal swabs) those received for SARS-CoV-2 testing over a period of 1 year (September 2020–August 2021) was analyzed.

Ethical clearance: This study focused on analysis of laboratory results and ethical permission was received from institutional ethics committee.

Data Collection: All the recorded data related to quality indicators of SARS-CoV-2 testing by RT-PCR method was taken for analysis. Quality indicators were chosen for situations where errors are common and improvement is attainable. It was feasible to track and measure the crucial phase in the whole testing procedure over an extended period of time by Quality indicators.

Table 1: List of Performance Indicator Monitored during Pre-Analytical, Analytical and Post-Analytical Phase over a one Year Period: September 2020- August 2021

Sr. No.	Different Phase	Quality Indicators	Criteria for failure of Quality Indicators
1	Pre-Analytical	Sample Rejection Rate (SRR)	✓ Inadequate volume ✓ Visibly contaminated samples ✓ Sample leakage ✓ Improperly labeled samples ✓ Delay in transportation ✓ Missing of requisition form/ sample
2		Incomplete test Request form (TRF)	✓ Partially filled information about patient (eg. Name, address, contact number, clinical history)
3	Analytical	Failure of performance with Kit control	✓ No. of tests which shows failure of control ✓ Invalid samples whose IC and other graphs were not raised
4		Equipment down time	✓ Instruments that were not working properly at any point
5		Non-conformities with performance of EQA/ILC	✓ NC with non-satisfactory results of EQA/ ILC
6	Post-Analytical	Duplicate reports generated	✓ Misprinting ✓ Loss of report by patient/ hospital staff
7		Turnaround time (TAT)	✓ Measure time exceeds from sample receive to release of results
8		Stock out	✓ Unavailability of any stock (kits, reagents, consumables etc)
9		Transcription errors in reporting	✓ No. of writing error either manually or digitally done by any staff members

Table 1includes lists of quality indicators for the pre-analytical, analytical, and post-analytical stages of sample processing. Each quality indicator's failure criteria were laid out in tabular form for each indicator.

In pre-analytical phase, samples of COVID-19(nasopharyngeal and oropharyngeal swabs) were collected and packed three layer packaging and transported to the laboratory at 2-8 ºC along with the test request form. In the laboratory, technical staff checks for patient details and completeness of test request form as per acceptance/rejection criteria set by laboratory in charge.

Accidental mistakes, replicate testing, proficiency testing and inter-laboratory comparison (ILC) as well as the appropriate operation of the instruments, were all checked during the analytical phase. ILC were evaluated for concordance or discordance between our laboratory's results and those of the referral laboratory.

The creation of duplicate reports, stock maintenance, TATs, and transcription errors in reports were tracked during the post-analytical phase. As quality indicators of the laboratory services, the pertinent data for this facet was examined, and errors were determined for each QI on a monthly

basis. All parameters (Pre-analytical, analytical post-analytical) were evaluated by dividing the total number of samples by the total number of QIs for each month. The medical and para-medical staff of the Hospital, as well as the technicians, were given proper training time to time for different procedures, e.g. TRF completion, collection of samples, documentation, record-keeping, timely preparation and release of reports.

Calculation:

$$\frac{\text{Total errors of the indicator that occurred in a month}}{\text{Total no of the sample in a month}} \times 100$$

Statistical analysis: In this study, results were displayed in number and percentages during the analysis part.

Result

8176 no. of samples were received in the molecular laboratory during this period. Among which, 70% (5723) received from OPD clinics and 30% (2453) received from indoor clinics were analyzed by RT-PCR method. 4.23% (346) of error rate was observed as for all three phases of the procedures. Additionally, this Result was examined in light of QIs divided into the pre-analytical, analytical, and post-analytical phases. Highest error rate was seen in the pre- analytical phase had 2.20% (180), followed by the analytical phase1.39% (114), and lastly the post-analytical phase, 0.63% (52) (Table 2).

Table 2: Total Error Rate

Duration	Total Samples Received	Total errors in 3 phases		Total Error Rate
September 2020 to August 2021	8176	Pre analytical errors	180 (2.20%)	346 (4.23%)
		Analytical	114 (1.39%)	
		Post analytical errors	52 (0.63%)	

Table 3: Quality Indicators of Pre-Analytical Phase180 (2.20%)

Month	Total No of Samples	Sample Rejection		Incomplete Test Requisition Form (TRF)		Stock out
		Total no of rejected samples	Error (%)	Total no of incomplete TRF	Error (%)	Stock was properly maintained throughout the year so there is no stock out.
SEP 20	381	0	0	26	6.80	
OCT 20	309	0	0	41	14.56	
NOV 20	410	0	0	19	4.80	
DEC20	382	0	0	0	0	
JAN21	166	0	0	0	0	
FEB21	133	0	0	0	0	
MAR21	234	2	0.85	0	0	
APR21	2923	34	1.16	3	0.10	
MAY21	2742	54	1.96	0	0	
JUN21	187	1	0.50	0	0	
JULY21	142	0	0	0	0	
AUG21	167	0	0	0	0	

Table 3 represents the data analysis of the pre- analytical phase. The frequent error observed in this phase was the sample rejection rate 1.11% (91) followed by incomplete TRFs1.08% (89).

Table 4: Quality Indicator of Analytical Phase114 (1.39%)

Month	Total no of samples	Failure of performance with kit control		Equipment breakdown time		Non-conformities with performance of EQA/ILC	
		Total no of invalid samples	Error (%)	Breakdown occurred	Error (%)	Samples sent in the month	Error (%)
Sep-20	381	2	0.50	2	0.52	-	0
Oct-20	309	13	4.20	0	0	Results were satisfactory	0
Nov-20	410	6	1.46	1	0.24	-	0
Dec-20	382	3	0.78	0	0	-	0
Jan-21	166	0	0	0	0	-	0
Feb-21	133	0	0	0	0	-	0
Mar-21	234	0	0	0	0	Results were satisfactory	0
Apr-21	2923	41	1.40	0	0	-	0
May-21	2742	25	0.91	1	0.03	-	0
Jun-21	187	11	5.80	1	0.53	-	0
July-21	142	7	4.92	1	0.70	-	0
Aug-21	167	0	0	0	0	-	0

Table 4 describes quality indicators during the analytical phase. Common indicators during this phase was Invalid samples 108 (1.32%) followed by equipment break down 6 (0.07%). EQAS/ILC was done biannually in the month of October and March; the result was satisfactory with the referral lab and there were no Non-Conformities observed.

The data analysis of post-analytical quality indicators are presented in Table 5.

Table 5: Quality Indicator of Post Analytical Phase52 (0.63%)

Month	Total no of samples	Duplicate reports generation		Delay reports (TAT)		Transcription errors	
		Total no	Error (%)	Total no	Error (%)	Total no	Error (%)
Sep-20	381	0	0	0	0	0	0
Oct-20	309	2	0.60	14	4.50	0	0
Nov-20	410	0	0	6	1.46	0	0
Dec-20	382	1	0.26	0	0	2	0.50
Jan-21	166	0	0	0	0	0	0
Feb-21	133	0	0	0	0	0	0
Mar-21	234	1	0.42	0	0	0	0
Apr-21	2923	3	0.10	1	0.03	8	0.27
May-21	2742	5	0.18	1	0.03	3	0.10

Jun-21	187	3	1.60	0	0	1	0.50
July-21	142	0	0	0	0	0	0
Aug-21	167	1	0.59	0	0	0	0

Delay in reports –TAT 0.26% (16) was frequent error which was observed. Release of duplicate reports 0.19%(22) and transcription errors 0.17% (14). The reasons behind not maintaining TAT were mainly; invalid results and repeat testing of samples. In addition to all these QIs; no shortage of stock (Kits/Reagents, consumables etc.) was seen and it was properly maintained throughout the year.

Discussion

Millions of individuals throughout the world have faced new issues as a result of the Covid-19 pandemic. Many of the laboratories at regional level were not prepared to deal with diagnostic management of this pandemic which was the main challenges faced by clinical microbiologists.

During such situations every molecular or clinical laboratory faced some immense challenges such as increased sample load, proper processing of the samples, timely delivering the reports to the patient and facing low on manpower etc. Continuous assessment of the quality indicators can keep the laboratory vigilant about the important issues that could affect quality of work. Preparedness of dealing with these kinds of problems had helped laboratory to maintain optimum performance in emergency situations in India.

For many years, research and manufacturing industries have been engaged in improvement in quality management to lower common errors occurring in the laboratory diagnosis. The application of these efforts in healthcare and laboratory services has helped us to standardized techniques through which we may spot and address mistakes as well as deficiencies in our work. One of the five competencies listed by the Institute of Medicine as crucial for all healthcare personnel is the capacity to implement quality improvement (QI) principles to assess system performance. [7]

In this study, a method is described that makes it easier to recognize, record, and classify the errors related to diagnostic procedures in laboratories. In the reference studies the word "quality failure" is used instead of common terms for errors in Laboratory settings. Also, the definition of this word includes failing to meet quality requirements during the whole process of testing, from choosing the appropriate test to the interpretation of the reports by clinicians which might have an adverse impact on patient care. [8]

We evaluated the performance of the molecular laboratory in north Gujarat, India over the course of a year based on the selected quality indicators in the three testing phases (pre-analytical, analytical, and post-analytical). During this study period we have collected the data of 8176 samples so overall rate of errors was 4.04% and among this highest error were occurred in pre analytical phase seen in 180 (2.20%)samples followed by analytical phase seen in 105 (1.21%)samples and post analytical phase seen in 61 (0.63%) samples. Similarly in the study of AK Savitha et al [9] they also reported 1.23% overall error rate which is lower from our observation. Although problems occurred in all phases of testing, rate of errors was higher during pre-analytical part which was similar in the study of H F Wolfgang et al. [10]

In pre analytical phase total errors were in 180 (2.20%) samples, among which sample rejection rate was highest in 91 (1.11%) samples followed by error rate of incomplete test request form (TRF) which was seen in 89 (1.08 %) samples. In our study Sample rejection mostly occurred from March to June and the main reason for

sample rejection was poor quality of the sample and the mislabelling of the samples. To overcome this problem, we organized regular training of technical and administrative staff for SOPs (Standard operating procedures) of collection and transportation of the samples.

However, incomplete TRF received in the lab was mostly seen in the month of September, October and November as lab personals were not aware about filling of TRF. After training the nursing and laboratory personnel on the need of giving the laboratory with comprehensive information, a notable improvement in the completeness of TRFs obtained was seen. On contrast study of Rachna Agarwal et al. [11] reported higher errors in incomplete TRF that was 4.05% (103), followed by sample rejection errors 3.56% (91).

In analytical phase, Out of total samples, 108 (1.32%) samples were retested because of invalid results. Common errors might be related to pipetting, calibration or poor quality of the samples. All the invalid samples were subjected to repeat PCR plating to reach out the turnaround time of our laboratory to confirm the results. There were 78 samples in which the results were confirmed by PCR plating and remaining 21 samples were not confirmed by PCR plating. Therefore, those samples further subjected for repeat RNA extraction followed by PCR plating. There were 9 samples which were mistakenly reported as invalid samples due to misinterpretation of result. None of these samples required repeat sample collection as the procedure for sample collection and transportation of our laboratory was satisfactory. In addition, routine inspections were carried out, and a checklist was created to verify that kit stock and reagents were stored and maintained properly. Instruments were routinely inspected, and the lab personnel were more strictly made aware of the use of the same. Similar results were found in D. Sudha Madhuri's study, [12] which had a higher than average repeat testing error rate of 4.37%.

Equipment breakdown occurred 6 times (0.07%) during our study period mainly in -80º Deep freeze because of improper temperature maintenance. Similarly in the study of Sangeeta Kulkarni, [3] Error rate in analytical phase was 0.16%. during this phase, more frequent error was equipment breakdown (0.13%) and failure of Kit QC (0.03%). Likewise participation in EQAS/ILC was done twice during our study period and results were 100% concordant with our referral laboratory but in the study of D. Sudha Madhuri, [12] It showed 0.20% non-conformities.

In post analytical phase total error rate was seen in 61 samples (0.63%), among which the highest error was seen in 22 samples (0.26%)of Turnaround time (TAT) due to delay in dispatching reports followed by generation of duplicate reports issued to 16 patients (0.19%) and transcription errors were seen in 14 samples (0.17%). Among all these errors of QIs, the indicator of Stock maintenance was properly maintained throughout.

Due to unforeseen and unavoidable issues, 22 reports were having long TAT. TAT is a parameter which is used to deliver the laboratory results in defined time period. The best TAT cannot be determined by using any rules. However, our lab has defined TAT of 24 hrs. Longer TAT may be caused by delays in the analytical step, repeated testing, and erroneous results. The satisfaction of doctors and patients may increase with prompt reporting.

We have generated 16 duplicate reports that were either lost by the patient attendants or our hospital staff. Nonetheless, it is our responsibility to guarantee that every report is delivered to the clinicians or patients, so that patients are not inconvenienced and that treatment can begin as soon as possible [4]. Lastly transcription errors were seen in 14 reports (0.17%) and it was observed in the month of April, May and June, which

occurred because of misprinting of results, patients details etc. However it gradually decreased after timely monitoring by senior staff.

Limitations of the study-Assessment of quality indicators can help to identify loopholes in delivery of the laboratory services to clinicians and patients. This assessment should always be compared with regional data. In this study, there was limited scientific literature available for comparison from same geographic location. So for better outcome, this kind of analysis of QIs is readily available to the regional laboratories. Also clinicians feedback and patients satisfaction can be included to enhance the analytical value of quality indicators.

Conclusion

Laboratories have a Major responsibility in healthcare services as accurate laboratory reports on timely basis are essential in initiation of treatment protocol. Quality indicators and its analysis can be vital in establishment of effective quality assurance system in laboratory services. Assessment of performance for Quality indicators in laboratory whether in percentage or sigma scale [13] on regular intervals has proven its role in upgrading accuracy, precision and clinician satisfaction. [14,15]

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