Research Article

Evaluation of quality indicators in microbiology and infectious disease serology laboratory: A study from a tertiary cancer care centre in Gujarat, India

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Abstract

Introduction: Quality indicators (QIs) are important for the monitoring and evaluation of laboratory performance at pre-analytical, analytical, and post-analytical phases. Errors in the laboratory arise more frequently before and after the analysis of samples. The total testing process (TTP) therefore needs to be evaluated for good laboratory performance. A good quality indicator should give information about the performance of a process, thereby governing the quality of services.

Objective: To analyse TTP and QIs for a period of six years of screening of laboratory performance.

Methods: This retrospective analysis was conducted for the period 2017 to 2022. QIs at pre-analytical (12), analytical (04) and post-analytical (03) phases were defined and analysed on a monthly basis. The laboratory followed the guidelines of the International Organization for Standardization (ISO) 15189:2012 to identify errors in all sections.

Results: A total of 259,694 samples were received during the study period. A total of 628,817 tests were performed. The overall error rate was 1.25/1000 tests. Error in the pre-analytic phase was 0.96/1000 tests, the commonest being haemolysed samples. Error in the analytical phase was 0.33/1000 tests. The error of postanalytical phase was 0.48/1000tests with turn round time (TAT) outliers being the commonest.

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Conclusion: Amongst all phases of QIs, errors were minimum in the analytical phase. Continuous monitoring and analysis of QIs helps in identification of common errors in the laboratory. Corrective measures will help to improve quality of the laboratory services, and hence the patient outcome. Regular training, evaluation of technical staff, regular preventive maintenance and calibration of all analytical instruments helps in reducing the errors.

Keywords: *Quality Indicators, Microbiology, laboratory errors*

Introduction

The diagnostic laboratory has a major role in any hospital. A laboratory report consists of the analysis of the received sample and is used to guide clinicians for optimal patient outcome. Since many decisions are based on laboratory results, it is important to maintain quality in all phases of testing from collection of samples to the final report.[1,2] The ISO defines quality as the "totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs." In a diagnostic laboratory, 'quality' is the level of equivalence between expectation and conformance in all parts of testing.

ISO 15185-2012 and the National Accreditation Board for Testing and Calibration Laboratories (NABL) provide the detailed documents required for the Quality Management System (QMS) of a medical laboratory. QMS describes the methodology to meet the parameters defining quality. These parameters, which are known as quality indicators (QIs), are established to determine how well a clinical laboratory meets the needs and operational and performance expectations regarding quality. A good indicator should give information about the performance of a process, govern quality of services, highlight areas of concern that need further investigation, and track changes over time.[4]

There are three main parts of total testing processes (TTPs) in a diagnostic laboratory, namely pre-analytical, analytical, and post-analytical.

- The pre-analytical phase includes sample acceptance and handling .
- The analytical phase comprises of testing in diagnostic laboratories, i.e. the diagnostic processes, and products that are required for the final report.
- The post-analytical phase includes appraisal of final laboratory test results, proclamation of these results on time to concerned patients/clinicians, and modification and/or annulment of results or expert opinion by subject experts if required, to assist in clinical decision-making for better outcome of the patient.[5]

All clinical laboratories should develop a set of quality indicators for all phases of GCRI testing, i.e. pre-analytical, analytical, and post-analytical.

In a large hospital, laboratory errors are inevitable due to the large number of samples, the number of technicians processing these samples and also the complex procedural steps involved in the testing protocol. However, proper induction and on-going training, implementation of quality checks and periodic review of testing process can reduce laboratory errors.[6,7]

The Gujarat Cancer & Research Institute (GCRI) hospital serves more than 30,000 new patients every year. The hospital comprises specialist and super-specialty departments and one thousand beds offering a wide range of services, including diagnostic support for a variety of cancer-related conditions.

The microbiology and infectious diseases serology laboratory of GCRI has had NABL accreditation in all its sections since 2012. The microbiology laboratory is well equipped with bio-safety level 2 (BSL-2) facilities to manage a variety of clinical samples and for the safety of staff.

The present study was conducted to evaluate performance and trends of QIs over a 6-year timeline and initiate corrective actions to further improve the quality of the clinical microbiology and infectious disease serology laboratory.

Methods

A retrospective study was conducted in the microbiology and infectious diseases serology department of GCRI over a six-year period from 2017 to 2022. The study was approved by the Institute's scientific as well as ethics committees. ISO 15189-2012 guidelines were used by the laboratory .

The bacteriology section has a fluorescence microscope, automated blood culture system (BACTEC FX 40) and fully automated identification and antibiotic susceptibility testing systems (VITEK-2 COMPACT) for bacterial and fungal identification and susceptibility testing. The infectious disease serology section is equipped with a fully automated ELISA (Euphoria 4.1) and ELFA (MINI-VIDAS) system for detection of viral infections. The serology section has a fully automated turbidometry system (Turbodyn CV). All the analytical instruments are validated before their use and regularly calibrated and maintained as per recommendations and all related documents are filed.

The laboratory staff were trained in the use of the analytical instruments, standard laboratory techniques, safe laboratory practices and on ISO 15189:2012 and NABL 112 quality systems.

Sample collection: Samples were collected from different areas of the hospital and properly labeled with a unique patient identification number with barcode and with test details requested by physicians. All data including patient demographic details, details of referring physician, the type of sample, the date and time of sample collection were recorded in the laboratory software (LIS).

Processing of samples: Samples were checked by the receiving laboratory technician (LT) for pre-analytical errors. A repeat sample was requested if the sample was rejected. The LT documented, monitored, and analysed sample rejection patterns on a regular basis to discover common pre-analytical errors. Root cause analysis was performed by laboratory personnel on common errors.

All accepted samples were labelled with a laboratory number and processed by the LT. Laboratory based medical officers (MOs) verified and signed the reports into the GCRI Infodiagnostica software (LIS). The MOs quickly communicated critical findings to the relevant clinical team. Interim reports were then issued to the physician and patient.

The microbiology and infectious diseases serology department of GCRI participated in state and national proficiency assessments including Quality Assurance Forum - Ahmedabad (QAF) and Indian Association of Medical Microbiologists External Quality Assurance Services (IAMM EQAS). We managed QA samples the same way we managed regular samples. For tests for which proficiency testing programmes were not accessible, we conducted split-specimen studies to confirm the reliability of the results. To reduce the likelihood of mistakes, each stage of the examination procedure was recorded. To guarantee that staff members have up-to-date knowledge of the methods and technologies used in the laboratory, staff training in the form of continuous medical education (CME) was carried out annually.

The laboratory report included the turnaround time (TAT), which is the time taken from collection of samples to report dispatch. TAT varies from test to tests as given below:

- Rapid serological test and special microscopy, 3 hours.
- Culture and sensitivity (except blood and sterile body fluid), 3 days.
- Culture and sensitivity (only for blood and sterile body fluid), 6 days.
- ELISA test, 8-24 hours.

To assess the frequency of post-analytical error, laboratory technicians also recorded the date of amended or modified reports.

Various types of errors that can happen in a diagnostic facility were identified. They were divided into three categories: pre-analytical, analytical, and post-analytical as shown in Table 1.

Table 1: Quality Indicator in all the three phases

Pre-analytical(n=12)	Analytical(n=4)	Post-analytical (n=3)
Haemolysed blood sample	Re-dos staining (Gram stain & ZN stain)	TAT outlier of serology
Insufficient sample quantity	Kit control failure of ELISA	TAT outlier of bacteriology & mycology
Wrong patient/sample ID number	IQC failure of ELISA (LJ chart outlier)	Amended reports
Soiled container/request form	EQAS/PT Outlier	
Lipaemic blood sample		
Incomplete test request form		
Wrong sample collection		
Sample collected in unsterile container		
Salivary sample		
Improper urine sample : received >2 hours of collection /sample not refrigerated		
Improper tissue sample: received in formalin		
Transportation error: long duration between collection and receiving of sample.		

Errors in each phase were noted in the relevant non-conformances register (NC). The frequency of these errors was calculated monthly and necessary corrective and preventive actions to minimise the errors was taken. The root cause analysis of these errors was then carried out to identify the factors that can cause them and prevent them from happening in the future. A half yearly internal audit was regularly conducted to monitor the laboratory performance as per NABL guidelines. Formulae used to calculate the errors are shown in Table 2.

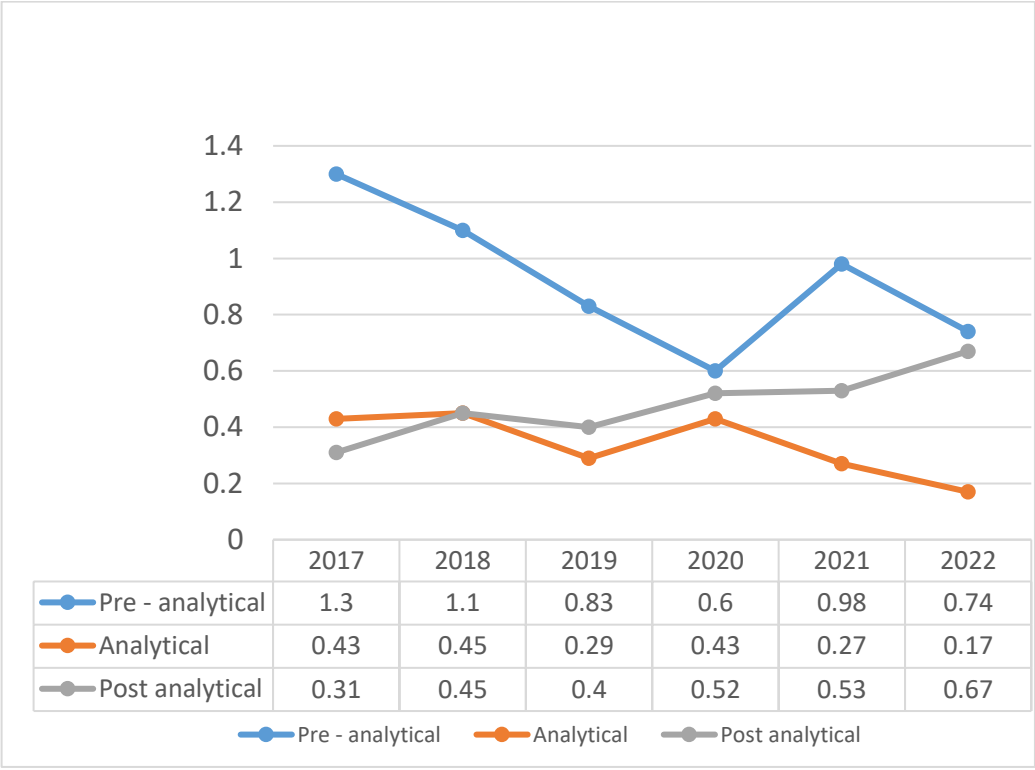
Table 2: Formulasto calculate errors

1. Rate of reporting errors	$\frac{\text{Number of reporting errors x1000}}{\text{Number of tests performed}}$
2. Rate of re-dos	$\frac{\text{Number of re-dosx1000}}{\text{Number of tests performed}}$

Results

Over a period of 6 years (2017-2022), 259,694 samples were received, and 6,928,817 tests were carried out in the microbiology and infectious disease serology laboratory. QIs were divided into three categories: pre-analytical (12), analytical (4) and post-analytical (3) phases.

Figure 1 shows the overall error rate for all the three phases of testing process (pre-analytical, analytical and post-analytical).



	2017	2018	2019	2020	2021	2022
Pre - analytical	1.3	1.1	0.83	0.6	0.98	0.74
Analytical	0.43	0.45	0.29	0.43	0.27	0.17
Post analytical	0.31	0.45	0.4	0.52	0.53	0.67

Figure 1: Year-wise total errors per 1000 tests (n= 62,8817)

Table 3 displays the year-wise error rate of different pre-analytical quality indicators. The overall pre-analytical error rate was 0.96/1000.

Table3: Pre-analytical quality indicator: a summary.

Year		2017	2018	2019	2020	2021	2022	Total	Error rate/per 1000 tests
Variables	Total Samples	40521	42334	49655	32417	46576	48191	259694	
	Total Tests	10673	110014	117095	76185	110387	108398	628817	
Haemolysed blood sample		32	30	27	22	47	13	171	0.27
Insufficient sample quantity		2	0	2	1	2	1	8	0.01
Wrong patient/sample ID number		4	10	2	0	0	0	16	0.03
Soiled container/request form		12	14	5	1	2	1	35	0.05
Lipaemic blood sample		1	0	3	4	3	5	16	0.02
Incomplete test request form		7	13	5	1	6	4	36	0.05
Wrong sample collection		7	16	4	2	3	11	43	0.07
Sample collected in unsterile container		8	3	15	3	17	12	58	0.09
Salivary sample		54	32	35	12	27	33	193	0.03
Improper urine sample : received after > 2 hours of collection or sample not refrigerated		2	3	0	0	2	0	7	0.01
Improper tissue sample: received in formalin		0	0	0	0	0	1	1	0.001
Transportation error: long duration between collection and receiving of sample.		11	11	0	0	0	0	22	0.03
Total errors		140	132	98	46	109	81	606	0.96

Year-wise analytical error rate is given in Table 4. Over a period of six years, the overall error rate was 0.33/1000.

Table4: Analytical quality indicator: a summary.

Year		2017	2018	2019	2020	2021	2022	Total	Error rate/ 1000 tests
Variables	Total samples	40521	42334	49655	32417	46576	48191	259694	
	Total Tests	106738	110014	117095	76185	110387	108398	628817	
Re-dos (Gram/ZN stains)		21	31	24	18	11	10	115	0.18
Kit control failure of ELISA		22	10	0	13	9	7	61	0.09
IQC failure of ELISA (detected on regular monitoring of Levy Jennings (LJ) chart for each ELISA test parameter)		0	4	3	0	4	0	11	0.01
EQAS/PT Outlier		3	5	7	2	6	2	25	0.03
Total errors		46	50	34	33	30	19	212	0.33

Table 5 shows the prevalence of errors in post-analytical quality indicators. It includes TAT outliers and amended reports. In the last six years, the error rate ranged from 0.31 to 0.67 with an average of 0.48/1000.

Table5: Post-analytical quality indicator : a summary.

Year		2017	2018	2019	2020	2021	2022	Total	Error rate/ 1000 tests
Variables	Total samples	40521	42334	49655	32417	46576	48191	259694	
	Total tests	106738	110014	117095	76185	110387	108398	628817	
TAT outlier of serology		14	15	22	18	35	53	157	0.24
TAT outlier of bacteriology &mycology		20	35	25	22	23	20	145	0.23
Amended reports		0	0	0	0	1	0	1	0.001
Total errors		34	50	47	40	59	73	303	0.48

Discussion

Monitoring and analysing QIs of pre-analytical, analytical, and post-analytical phases have a significant positive impact on performance of a diagnostic laboratory. More than 80% of clinical diagnosis and treatment of the patients is based on diagnostic test results. As modern technology for treatment relies heavily on laboratory results, improving the quality of testing is essential.

Being a regional cancer centre, our hospital has a department of multidisciplinary laboratory medicine. It performs routine as well as advanced diagnostic tests. Quality becomes essential to offer advanced therapies to immunocompromised patients.

Laboratory performance was therefore assessed in the present study by evaluating QIs and analysing the error rate over the six-year period of the study. Error rate was analysed using defined QIs (as mentioned in the QMS of the laboratory) in all three phases of testing.

Figure1 shows year-wise total errors in all three phases of testing. There was an increase in errors from 2021-2022, most probably due to the Covid-19 pandemic.

Pre-analytical errors ranged from 0.6/1000 to 1.3/1000. For the analytical phase, they ranged from 0.27/1000 to 0.45/1000. In the post-analytical phase, the error rate ranged between 0.31/1000 to 0.67/1000. In a study by Savitha et al., the overall error rate was 1.23%, which is similar to our rate.[2] In our study, the error rate was highest in the pre-analytical phase similar to the observations of Savitha et al.[2] and Ranjana et al.[1]

Pre-analytical phase

We identified twelve different QIs (Table1). The total error rate in this phase was 0.96/1000 tests.

Amongst different pre-analytical QIs, the highest error rate of 0.27/1000 was seen with haemolysed samples followed by samples received in unsterile containers (0.09/1000). A study

by Ranjana et al.[1] observed a haemolysis rate of 0.7/1000 and studies by Ricos et al[9] and Sudha et al[8] showed 0.2/1000 and 0.27/1000 error rates respectively. It is possible that the low rate in the present study is due to the use of gel containing plain vaccute for collection of blood, which minimizes the rate of haemolysis.

We also calculated other important quality indicators like insufficient sample for testing, wrong patient demographic data, lipaemic blood samples, soiled container/request form, sample collected in unsterile container, salivary sample, and transportation errors which ranged from 0.01-0.09/1000.

Regular training of phlebotomists and laboratory technicians on blood collection techniques in phlebotomy area helped in reducing the rate of pre-analytical errors.

Analytical phase,
Our laboratory identified four major QIs in this phase of testing: Re-dos, kit control failure of ELISA, IQC failure of ELISA (LJ chart outlier), and EQAS/PT Outlier PT programme.

Overall error rate in this testing phase was 0.33/1000 with a range from 0.01-0.18/1000. (Table 4). A study by Priyanka et al.[3] observed a rate of 0.4/1000 in their study, which is almost the same as our results.

Amongst the different QIs, an error rate of 0.18/1000 was observed in re-dos of testing which is lower than those shown by Ranjana et al.(4/1000)[1]and Sudha et al.(4.37/1000)[8]. The low error rate in the present study could be due to the use of automation systems for testing and also trained and competent technical staff.

Other indicators were failure of kit controls as shown on the Levy Jennings (LJ) chart (0.09/1000) which may be due to calibration failure, pipetting error, and/or instability of reagents. These errors were detected on regular monitoring of the LJ chart for each ELISA test parameter. Outlier in PT testing was observed only once (0.03) which may have been due to inappropriate storage of reconstituted QC/PT material in the laboratory before testing. Sudha et al.[8] reported 0.01% in outliers in the PT programme, which is similar to our results.

Induction and continuous training of technical staff, with regular evaluation, adherence to the SOP, regular monitoring of LJ chart, daily checklist for monitoring of storage of kits, preparation of reagents and, most importantly, regular preventive maintenance and calibration of analytical instruments can help to reduce the analytical errors.

Post-Analytical phase
We defined two QIs for the post-analytical phase of testing which included TAT outliers and amended reports. The average rate of errors in this phase was 0.48/1000. The observed range was 0.000 to 0.24/1000. The error rate for TAT outliers in our study was 0.24/1000 which was lower than reported by Ranjana et al. (0.5/1000).[1] Amended reports error rate was 0.001/1000 in the present study whereas Ranjana et al. reported an 0.05% error rate. The lower rate in our study may be due to the use of LIS for reporting and dispatch of reports in the hospital.

Proper training of all technical and reporting doctors on the hospital information system (HIS) is necessary to reduce transcription errors in reporting.

Conclusion

The present study shows that regular monitoring and evaluation of quality indicators in the total testing process is very important to improve laboratory performance and for better services in patient care. To further strengthen and improve quality in laboratory, we recommend that regular training, evaluation of technical staff, and regular preventive maintenance and calibration of all analytical instruments is carried out by all testing laboratories. Ongoing commitment of laboratory staff to the QMS is also needed to ensure continuing improvement of the healthcare services.

Declarations

Conflicts of Interest: None
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Ethics statement: Approved from Institute review board (.(IRC/2320/P-81))
Authors' contributions:
Patel F: Study design, data analysis & writing
Patel H: Data collection & Interpretation
Chaudhari H.: Data collection
Parmar V: Data collection

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