



## Evaluation of the Quality Indicators in Laboratories at National AIDS Research Institute, Pune, India

Sangeeta Kulkarni<sup>1</sup>, Sachin Kale<sup>2</sup>, Urmila Ghodke<sup>3</sup>, Arun Risbud<sup>4</sup>, Smita Kulkarni<sup>4</sup>

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### Author's Affiliation:

<sup>1</sup>Quality Manager; <sup>2</sup>Research Assistant; <sup>3</sup>Supervisor; <sup>4</sup>Laboratory Director, Quality Management Cell, National AIDS Research Institute, Pune, India

### Correspondence:

Dr Smita Kulkarni,  
skulkarni@icmr.org.in,  
skulkarni.nari@gov.in

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## ABSTRACT

**Introduction:** Quality indicators in a clinical laboratory are considered as useful tools for continual improvement of the laboratory services.

**Aim:** The aim of this study was to assess timely performance of the NARI service laboratories in three phases of testing - pre-analytical, analytical and post-analytical, in an effort to improve their performance.

**Methodology:** The study included an assessment of different quality indicators from six laboratories - Clinical Biochemistry, Hematology, Serology, Microbiology, Virology and Immunology at the NARI central laboratory which provide service for the patient care.

**Results:** Data obtained from a total of 39139 clinical samples collected over a period of two years was used in the study. The overall error rate was found to be 2.72%. The commonly observed indicators were revision of the laboratory requisition form (0.49%) and sample rejection (0.31%) during the pre-analytical phase, equipment breakdown (0.12%) and failure of the controls (0.03%) during the analytical phase, turnaround time (1.55%) and revision of the report form (0.15%) during the post-analytical phase.

**Conclusions:** Quality indicators are important tools in improving the quality system in a clinical laboratory and patient care.

**Key words:** Quality indicators, pre-analytical, analytical, post-analytical, quality control

## INTRODUCTION

Clinical laboratories play vital role in prevention and control of infectious diseases by providing timely test results which help in the patient management and disease surveillance<sup>1</sup>. In an era of medical diagnostics, around 80% of decisions depend on the medical laboratory services and thus the quality of laboratory tests has a huge impact on the diagnosis and treatment planning<sup>2</sup>. This highlights the significance of carrying out tests on correct samples (pre-analytical phase) using accurate and precise techniques (analytical phase) at the earliest (post-analytical phase).

The pre-analytical phase comprises the procedures before processing the sample. Studies indicate that approximately 40% to 70% of errors occur in the pre-analytical phase, most of which arise from

problems in patient preparation, sample collection, transportation and storage. Errors in this phase generally occur due to high patient turn over, negligence, lack of understanding about good laboratory practices and ineffective training<sup>3,4,5,6,7</sup>.

The analytical phase involves actual performance of assays on the samples and interpretation of investigations. Establishing and verifying test method performance to assess accuracy, precision, sensitivity, specificity, and linearity is utmost important in reducing the errors occurring during this phase. Even though automation, standardization and technological advances have significantly improved the analytical reliability of the laboratory tests, analytical errors still continue to occur<sup>6,7</sup>.

The post-analytical phase deals with providing accurate and reliable test reports to the clinicians and

subsequently to the patients. The procedures performed in this phase include verifying laboratory results, entering data into the laboratory information system, communicating results to the clinicians using different methods like by generating reports and verbal communications, especially in case of the "alert" or panic values<sup>5,6,7</sup>.

With the advent of technology, the automated tools, databases and computers have significantly improved the rate of the analytical errors, however errors pertaining to the pre- and post-analytical phases are still a source of concern indicating the need of adapting defined Quality indicators (QI) to assess and monitor continuous improvement in these phases<sup>8</sup>. It is essential that each laboratory establishes its own quality management system (QMS) to control and monitor the quality in the overall testing process. This promotes and encourages investigations when errors occur, their route cause analysis leading to the identification of strategies and procedures for improvement.

The International Organization for Standardization-Medical Laboratories (ISO 15189:2012) specify continuous monitoring of testing process, improvement using QI and measurement of the efficacy of specific interventions as the key measures for improving the laboratory services<sup>9</sup>. In India, the policy of continual improvement for medical laboratories has been laid by the Bureau of Indian standards<sup>10</sup>.

Updating the knowledge on laboratory services, adequate training of the staff and sensitization about the importance of the quality indicators in all the three phases will help in minimizing errors. Only few studies on the quality indicators have been reported from India. Hence in the present study, we assessed the quality indicators covering three critical phases associated with the testing (pre-analytical, analytical and post-analytical) in the six service laboratories (Clinical Biochemistry, Hematology, Serology, Microbiology, Virology and Immunology) at the National AIDS Research Institute (NARI), Pune, India.

## METHODOLOGY

**Study site:** The data collection was carried out by the Quality Management (QM) cell at NARI, Pune, India over a period of two years (January 2013 to December 2014) as a strategy for continuous quality improvement. The QM cell monitors processes related to sample collection, handling and transportation, performance of the tests and participation in the quality assurance program. In addition to this, it monitors regularity of the technical training of the laboratory staff pertaining to the institutional policies and procedures, their implementa-

tion and documentation. To ensure implementation of these policies and continuity of the quality improvement, the QM cell continuously reviews performance of the six laboratories during the pre-analytical, analytical and post-analytical phases.

**Sample collection and transportation to the Central laboratory:** For obtaining the data, the clinical samples in the present study were collected from NARI clinics which are situated in different locations of the Pune city, at a distance of approximately 5-18 km from the NARI central laboratory. These clinics provide voluntary counseling, care and support to the patients enrolled in various institutional projects and clinical trials. The specimens were collected in suitable containers at these clinics and transported to the NARI central laboratory at appropriate temperature along with the laboratory requisition forms (LRFs) through sample transport vehicle. Regulations for transporting biohazardous samples were strictly followed while transporting the samples. The samples and LRFs were received at the NARI central laboratory, Bhosari and distributed to the respective laboratories. The data obtained in this study were from the specimens collected under various institutional projects approved by institutional ethics committee.

**Pre-analytical procedures followed in the laboratories:** The indicators during the pre-analytical phase included the LRF and the quality of the sample. The completeness of the LRFs was checked and verified for essential entries by the concerned laboratory staff. The quality of the samples (haemolysed/clotted/lipaemic/quantity not sufficient) was checked in the respective laboratories in and the sample was categorized as "accepted or rejected". In case of rejection of any sample, the respective clinic was informed and a rejection note was sent to the respective clinic.

**Facilities available in the laboratory:** The six laboratories in the NARI central laboratory where the processing and testing of specimens is carried out are well equipped with equipments like Olympus AU 400 biochemistry autoanalyzer (Olympus, Germany) and Roche AVL 9180 electrolyte analyzer (Roche, USA), Coulter ACT 5 hematology analyzer (Coulter, USA), ELISA Washer and ELISA reader (BioRad, USA), Abbott real time PCR (Abbott, USA), FACs count and FACs Calibur (Becton Dickinson, USA) and other required ancillaries.

The assays performed in these laboratories include HIV-1 plasma viral estimation, CD4 and CD8 estimation, Enzyme Linked Immunosorbent assays (ELISAs), Western blots, Complete blood count (CBC), Peripheral blood smear (PBS), Clinical Biochemistry, Urine pregnancy test (UPT), Dip stick tests, etc. The laboratory staffs carrying out these tests are well trained in respective tests and under-

go external as well as internal competency assessment regularly.

**Analytical and post-analytical procedures followed in the laboratories:** After reaching to the NARI central laboratory, the samples and LRFs are distributed to the respective laboratories, where entries are made in the sample receiving register and verified following institutional policies. The samples are further processed according to the standard operating procedures for each assay with quality control procedures and wherever applicable, Levy-Jennings chart are plotted for quality control checks. All protocols, kits, reagents and the assay procedures are reviewed by the Supervisor/Lab-in-Charges. The results are entered in the electronic software and verified by the Supervisor. After verification and obtaining signature of the authorized signatory, the reports are sent to the respective clinics by transport vehicle.

The indicators during the analytical phase included routine equipment maintenance, equipment down time, processing of the specimens as per the standard operating procedures, inter-laboratory

comparison, reagent stability, parallel testing, validation of method, validation of instrument, inter instrument comparison, quality control (QC) assessment, internal quality controls and external quality assessment (EQA). The post-analytical indicators considered for analysis include quality control of the report, maintenance of the turnaround time (TAT, time between receiving and reporting of the sample) specific for each test, generation of the revised reports in the six designated laboratories.

## RESULTS

During the period of two years (Jan 2013 -Dec 2014), data from a total of 39139 samples received in the six laboratories of the NARI was analysed. The overall error rate was 2.72%. The error rate was further analysed considering QIs categorized into the three phases: pre-analytical, analytical and post-analytical (Table 1). The error rate during the post-analytical phase was highest (1.75%) followed by error rates during the pre-analytical (0.80%) and analytical (0.16%) phases.

**Table 1: Quality indicators in Pre-Analytical, Analytical and Post Analytical phase of testing (n=39139)**

Quality Indicator	Phase of testing	Frequency of data collection	Number of errors (%)
Revised Laboratory requisition form (Sign not done, discrepancy in time of collection and sending the sample, Improper ID, Gender /Age corrections, Test not marked, correction in year)	Pre-analytical	Monthly	195 (0.49)
Sample rejection (Insufficient quantity, Haemolysed, Lipaemic, Blood clot)	Pre-analytical	Monthly	122 (0.31)
Internal QC failure	Analytical	Monthly	13 (0.03)
Equipment breakdown	Analytical	Monthly	49 (0.12)
Missed test	Analytical	Monthly	01 (0.002)
Revised report (Transcriptional error)	Post-Analytical	Monthly	62 (0.15)
Missed data on report	Post-Analytical	Monthly	16 (0.04)
Turnaround time (TAT)	Post-Analytical	Monthly	609 (1.55)

**Table 1a: Frequency of Pre-Analytical Errors**

Types of Pre-Analytical Errors	Frequency (%)
Discrepancy in time	25 (0.06)
Improper ID	122 (0.31)
Gender/age corrections	21(0.05)
Test not marked	27(0.06)
Insufficient quantity	29(0.07)
Haemolysed	38(0.09)
Lipaemic	38(0.09)
Blood Clot	5(0.01)

The data was further analysed considering various QI under each of the three phases. Table 1 and 1a the pre-analytical quality indicators. The most common indicator observed in the pre-analytical phase was revision of the LRF (0.49%) followed by rejection of samples (0.31%) due to the quality of sample. It was noted that the LRF were revised mainly due to discrepancy in the time of sample collection and transportation, incorrect sample

identification, correction in the gender/age and not selecting an appropriate test. Lipaemic sample (0.10%) was the common cause for sample rejection, followed by rejection due to insufficient quantity, haemolysis and clotting.

Table 1 describes important quality indicators during the analytical phase. Common indicator during this phase was equipment break down (0.12%) followed by failure of internal QC (0.03%). No sample remained untested during the analytical phase.

The post-analytical indicators measuring the quality of laboratory are shown in Table 1. In this phase, turnaround time (1.55%) was the common indicator followed by revision of the report (0.15%). The reasons for not maintaining the TAT were mainly unavailability of the kits; break down of the equipment or transcriptional error in reports.

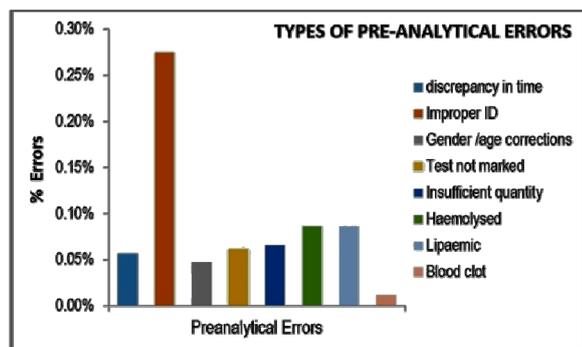


Fig 1: Frequency of Pre-Analytical Errors

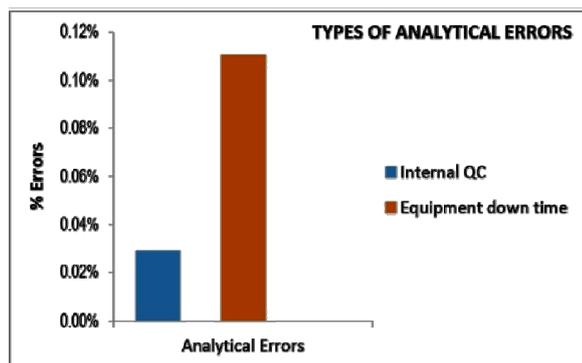


Fig 2: Frequency of Analytical Errors

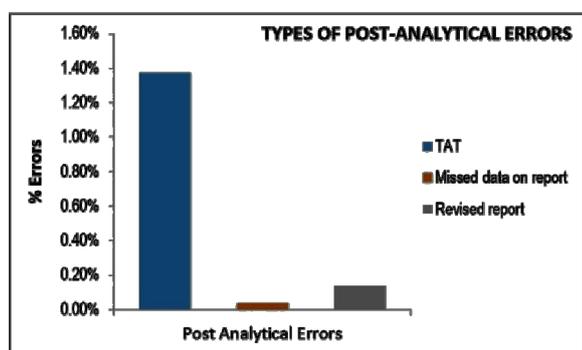


Fig 3: Frequency of Post-Analytical Errors

## DISCUSSION

In today's world of medical diagnostics, ensuring high standards of quality rendered by any service provider is a top priority because it has great impact on the outcomes delivered by the health systems. The concept of QI as a part of the QMS has emerged over the past few years for the fulfillment of quality work as it indicates the performance of the health system which leads to improved care. Based on the identified quality indicators in the three phase of testing (pre-analytical, analytical and post-analytical), we assessed performance of six service laboratories located at NARI, Pune, India over a period of 2 years.

The errors observed in pre-analytical phase were found to be 0.80%. Of these, the revision of the LRF (0.49%) was the common quality indicator followed by rejection of samples (0.31%) due to the quality of sample. In our study, the sample rejection was comparatively lower (0.28%) as compared to that reported in other studies conducted in India<sup>11,12,13 14,15,16</sup> and other parts of the world<sup>3,4,5,17,18,19,20</sup>. This can be due to appropriate sensitization of the concerned staff regarding patient preparation, filling of LRFs and appropriate labeling of samples as well as continuous monitoring in our institute.

We assessed the frequency of rejection due to insufficient quantity and quality (haemolysis, lipaemic, blood clotting) due to wrong phlebotomy technique, incorrect transportation or centrifugation before the sample is clotted. A lipaemic sample was the common quality indicator observed during the evaluation of pre-analytical indicator followed by insufficient quantity. This may be due to collection of blood sample within a short time period after the meal as patients travel to our clinics from distant places or parenteral administration of synthetic lipid emulsions. The analysis of pre-analytical errors in our laboratory revealed low frequency of rejection due to quality of sample, ie lipemic (0.10%), hemolytic (0.07%) and insufficient quantity (0.07%) as compared to other studies (0.2%-1.4%)<sup>2, 7, 11,12, 20</sup>. The error due to insufficient quantity could be due to lack of knowledge on the required sample quantity for a particular project or difficulty while sample collection.

In the analytical phase, the error rate in our study was 0.16%. Of these errors, equipment break down (0.13) was the common quality indicator followed by internal QC (0.03%). As compared to other studies<sup>2, 11, 20</sup> the error rate due to failure of internal QC in our study was found to be low. This could be due to frequent and stringent hands on practical training of the laboratory staff, continuous monitoring as well as timely competency assessment to monitor their performance. Another important reason could be regular monitoring of quality indicators by our QM cell and creating awareness about the same to the concerned individuals. We did not find any sample which remained untested during this phase while other studies have reported missed test ranging from 0.74% to 1.4%<sup>2, 4, 11, 15, 18,19</sup>.

As compared to the pre-analytical and analytical phases, the rates of overall errors observed in the post-analytical phase were comparatively higher (1.75%). The data was analysed for maintaining the TAT of a particular test report as provision of test results in timely manner is important for patient care and clinician's satisfaction. In our study, the TAT was missed for 1.6% samples which were

mainly due to unavailability of the kits (shortage in kit supply from the manufacturer) and break down of the equipments. The request for a revised report was another indicator which was mainly due to transcriptional error (0.15%) while completing the lab requisition form. The delay in pre-analytical and analytical phases also affects the TAT of a particular test; however it was not noticed in our study.

To summarize, the assessment of the quality indicators in our laboratories indicated that the error during the post-analytical phase was higher as compared to the pre-analytical and analytical phases.

## CONCLUSION

Quality indicators play a key role in reducing the risk of errors in clinical diagnostics. Thus, the use of quality indicators to assess and monitor the quality system is an extremely valuable tool for improving the quality of laboratory services and patient care.

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