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# Six sigma principle as a medical laboratory quality evaluation tool: Experience at a tertiary care hospital

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**ABSTRACT**

Quality in the laboratory has a big impact on the diagnosis of laboratory tests. The identification of reliable QIs to quantify the quality of laboratory services is mandated by ISO15189. The use of QIs is an important laboratory tool to improve the process and guarantee patient safety. Hence we assess the performance of our laboratory through some QIs. The present study was conducted at Medanta-The Medicity Hospital, Gurgaon, Haryana India, from January 2015 till December 2016. The QIs were sample rejection rate (SSR) for pre-analytical, concordant proficiency testing (CPT) and equipment uptime for analytical, turnaround time (TAT), and critical alert callout for post-analytical phase respectively. The trend was observed for all QI for two years. SRR and TAT were evaluated with the sigma scale. A total of 1,414,244 (690,751 in 2015 and 723,493 in 2016) specimens were received for testing. 0.80% of specimens were rejected giving a sigma level of 4.0. There was an improvement in proficiency testing and equipment uptime. A total of 122,712 (8.68%) samples were reported to not meet the TAT with a sigma level of 2.90. For critical value communication improvements were also seen. A general improvement for most of the QIs was observed.

**Keywords:** Quality Indicators, six sigma, sample rejection rate, turnaround time, critical alert.

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**Abbreviation:** QIs: Quality Indicators.

## INTRODUCTION

The laboratory plays a pivotal role in the control and prevention of diseases by providing timely data as required for patient management. Quality in the laboratory has a huge impact on disease diagnosis and prognosis as 80 to 90% of all diagnosis is based upon laboratory testing (O'Kane, 2009). Quality laboratory management system ensures that there is a provision of timely, precise and accurate reports. Continuous monitoring of the total testing process, use of Quality indicators to identify opportunities for improvement of services and measurement of the efficacy of specific interventions are important steps in upgrading the laboratory services (Salinas et al., 2010). QIs are fundamental tools enabling users to quantify the quality of a selected aspect of care by comparing it against a defined criterion. A quality indicator is thus "an objective measure that potentially evaluates all critical care domains as defined by the Institute of Medicine (patient safety, effectiveness, equity, patient-centeredness, timeliness and efficacy) that is based on evidence associated with those domains and can be implemented consistently and comparably across settings and over time (Shahangian and Snyder, 2009)." QI data requires a timely collection to identify, correct and continuously monitor defects and improve performance by identifying and implementing effective intervention strategies. The selection of QIs should be advocated in such a way, to cover the critical activities involved in the pre-, intra- and post-analytical phases of the total testing process which has a significant impact on the laboratory performance

(Howanitz, 2005). The essential steps which affect the quality of test results include proper patient and sample identification, specimen collection and transport, analytical quality, rapid reporting of laboratory results particularly the critical values along with the interpretative services (Phlebani, 2009). QIs are also required to provide information to stakeholders, users, etc, to establish a program of continual improvement for ensuring the quality of health care services and patient safety as per norms of ISO15189 (Jegede et al., 2015). Six sigma is a technique or tool which can be applied to any process to measure the defects and/or error rates and to determine the degree to which any process deviates from its goal. Originally, the concept of Six sigma was coined by Motorola company in 1987 for improving the company-wide quality to improving the quality of products and reduce the cost (Bertolaccini et al., 2015; De Mast and Lokkerbol, 2012). Six sigma refers to a quality level defined as the near-perfect defect rate of 3.4 defects per million opportunities which is the goal for world-class quality (Ahmed, 2019). Sigma metrics are being adopted as a universal measure of quality. In the clinical laboratory, it has been used to evaluate the performance of the total testing processes, provision of services and to establish appropriate benchmarks (Jegede et al., 2015). Thus, the number of errors or defects per million products or tests is a measure of the performance of a laboratory. In the present study, six sigma has been used to assess the performance of some QIs such as sample rejection rate (SRR) and turnaround time (TAT). The main objectives of our study were to identify indicators most crucial for recognising the errors in the laboratory. Also, we assessed the role of formal training of medical, nursing and laboratory personnel regarding patient preparation, sample collection and transport, quality assurance and reporting results which address the errors during the total testing process, thereby evaluating the laboratory quality performance over 24 months i.e January 2015 to December 2016.

## MATERIALS AND METHODS

### Study design and setting

The present retrospective study was conducted in the Department of Biochemistry at Medanta-The Medicity Hospital Gurgaon, India, a tertiary care super speciality hospital during the 2 year period from 1st January 2015 till 31st December 2016. The hospital was established in 2009 and houses 1,250 beds and over 350 critical care beds, with 45 operation theatres. The laboratory has its defined policies and procedures regarding sample preparation (patient preparation, phlebotomy techniques, sample handling and transport), equipment procurement and maintenance, testing performed, validation and quality assurance program followed. Furthermore, the laboratory staffs undergo regular training pertaining to these policies and procedures, their implementation and documentation. To ensure the continuity of quality of care and continuous quality improvement, the department continuously reviews its performance in all the processes during pre-analytic, analytic and post-analytic phases of the total testing process through monitoring of indicators developed by the laboratory. All blood specimens received for clinical chemistry were included in the present study. All tests were analysed on fully automated analysers of Vitros integrated systems and Abbott diagnostics.

### Quality indicators

The indicators were developed to improve the quality and reliability of test results, health providers and patient safety. The eight QIs monitored were grouped according to the phase of the total laboratory testing process which is in accordance with clinical laboratory improvement amendments (CLIA) guidelines (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA) which states that a laboratory's quality improvement programme must monitor all the steps of the total testing process. QIs were reviewed regularly by the laboratory management and steps were taken to improve the quality management process. For purpose of our study, the various QIs were defined and/or measured. Specimen rejection rate (SRR): This indicator was used to analyse performance in the pre-analytical phase and is defined as the percentage of specimen rejected and not tested due to some reasons. For example blood clot, haemolysis, insufficient sample, diluted sample, wrong barcode, wrong vacutainer, wrong additive, etc. The performance in the analytical phase was monitored in terms of proficiency testing (PT) performance which included a percentage of partial concordant PT results, equipment uptime which indicated the number of hours in a month that the equipment was functional. For post-analytical phase indicators including critical value reporting which included a percentage of critical values reported to physician and turnaround time (TAT) compliance which included a percentage of tests that met a particular reporting deadline.

### Data collection, validation and analysis

Raw data were collected for each indicator by the laboratory quality manager and cross-checked and approved by the laboratory supervisor. Data was entered manually into an excel file and reviewed by the laboratory staff before analysis. SRR and TAT were normalized to parts per million defects with the formula DPMO = DPO × 1,000,000 (Defects per million opportunities) and converted to a sigma scale using the Yield to Sigma conversion table. Sigma score calculators are also available at http://www.westgard.com/six-sigma-calculator-2.htm. Concordant PT, equipment uptime and critical value communicated to the physician were tested by student's T-test and a probability of 0.05 was considered statistically significant (Figure 1).

## RESULTS

A total of 1,414,244 (690,751 in 2015 and 723,493 in 2016 respectively) specimens were received for testing over the study period. The overall specimen rejection rate(SRR) was 0.80% (11,280/1,414,244) which improved over the study period. On analysing with the six sigma scale, the sample rejection rate (SRR) was 7976 defects per million with a sigma level of 4.0 (Table 1 and Figure 2). SRR was mostly due to diluted sample collection (38.9%) in 2015 and haemolysed sample (35.1%) as shown in Table 2 and Figure 3. Table 3 and Figure 4 shows the proficient testing for biochemistry tests over the study period. In 2015 the concordant PT

was 97.7% which improved to 99% in 2016; however, there was no statistically significant difference ($p > 0.05$). There was an improvement in equipment uptime from 91.1% in 2015 to 96.8% in 2016 which was not statistically significant ($p > 0.05$). On evaluating the post-analytical QIs as shown in Table 4 and Figure 5, critical alert value reporting showed a statistically significant improvement from 95.8 to 98.9% with $p < 0.05$. The TAT default rate was 86769 defects per million with a sigma level of 2.90.

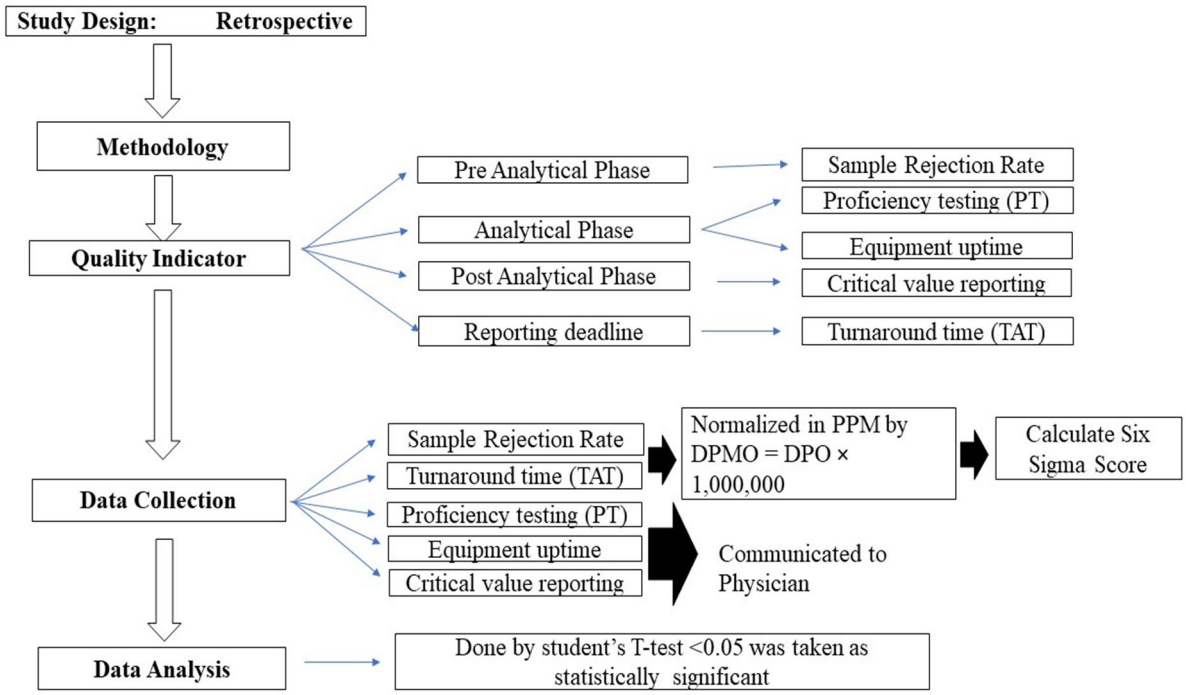


**Figure 1.** Flow chart of work.

**Table 1.** SRR expressed in sigma scale.

| Year | No. of samples | Variance (%) | DPM | Sigma value |
|---|---|---|---|---|
| 2015 | 690,751 | 6564 (0.95%) | 9503 | 3.9 |
| 2016 | 723,493 | 4716 (0.65%) | 6518 | 4.0 |
| Total samples | 1414,244 | 11,280 (0.80%) | 7976 | 4.0 |

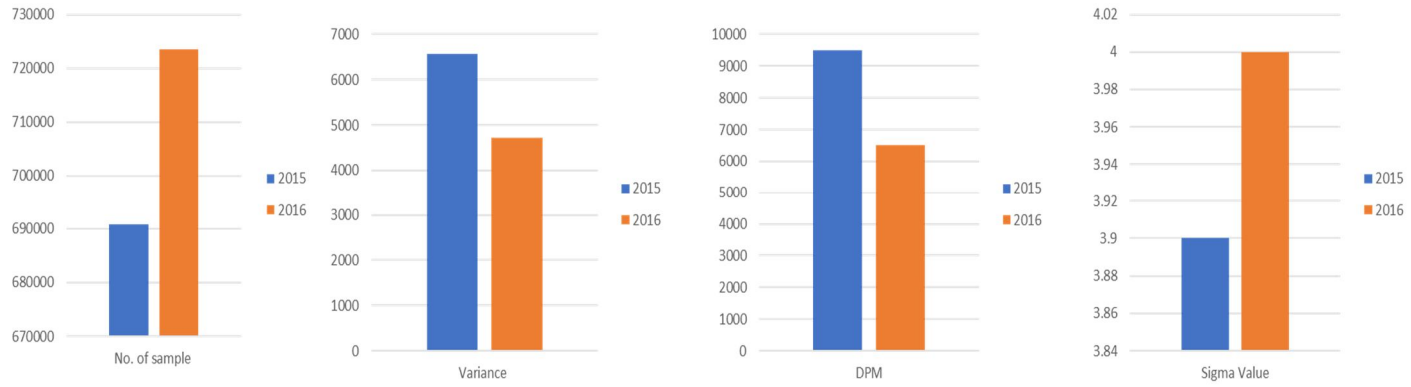


**Figure 2.** Difference pre-analytical quality indicator between 2015 and 2016 years.

**Table 2.** Sample rejection % causes.

| Specific issue | No. of defects (%) | | Total no. of defects (%) |
|---|---|---|---|
| | 2015 | 2016 | |
| Clotted specimen | 204 (3.1) | 144 (3.1) | 348 (31.1) |
| Haemolysed | 1908 (29.1) | 1656 (35.1) | 3564 (31.6) |
| Insufficient | 1716 (26.1) | 1332 (28.2) | 3048 (27) |
| Wrong tube/Label | 180 (2.74) | 120 (2.54) | 300 (2.66) |
| Diluted Sample | 2556 (38.9) | 1464 (31.1) | 4020 (35.6) |
| Total | 6564 | 4716 | 11,280 |

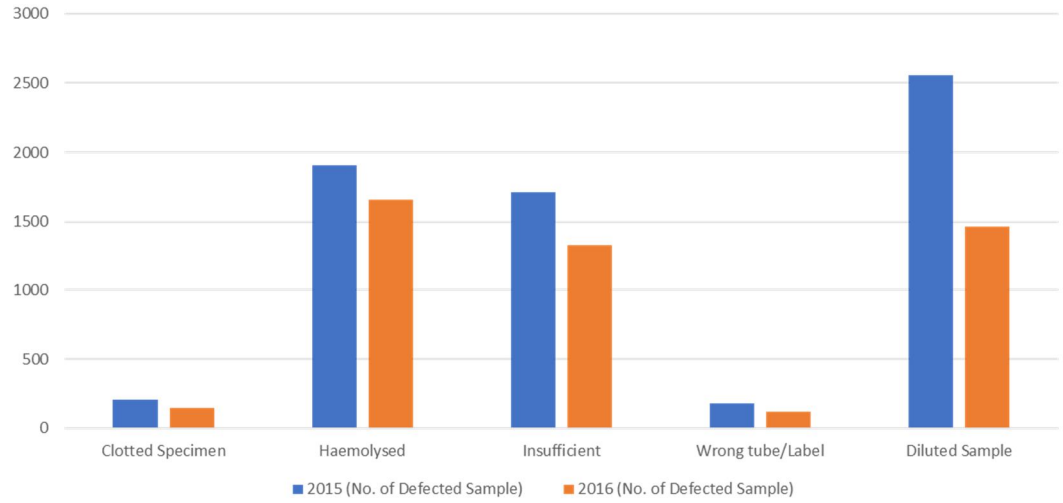


**Figure 3.** Sample rejection causes (Specific Issue between 2015 and 2016).

**Table 3.** Quality Indicator in the analytical phase.

| | 2015 | 2016 |
|---|---|---|
| Concordant PT | 97.7% | 99% |
| Equipment Uptime | 91.1% | 96.8% |

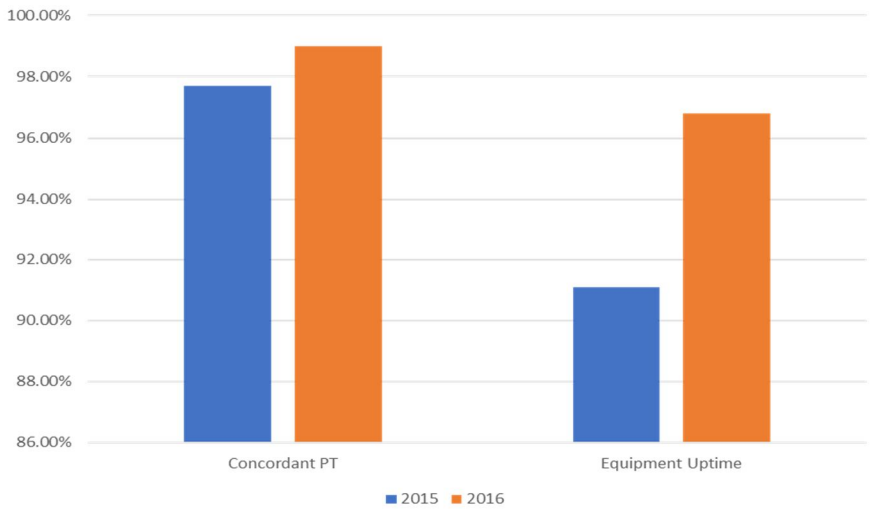


**Figure 4.** Quality indicators in the analytical phase.

**Table 4.** Quality Indicator in the post-analytical phase.

| Year | No. of samples | Critical value reporting | No. of samples not meeting TAT (Variance (%)) | DPM | Sigma value |
|---|---|---|---|---|---|
| 2015 | 690,751 | 97.8% | 80,554 (11.6) | 116618 | 2.70 |
| 2016 | 723,493 | 98.9% | 42,158 (5.83) | 58270 | 3.10 |
| Total | 1414,244 | | 122,712 (8.68) | 86769 | 2.90 |

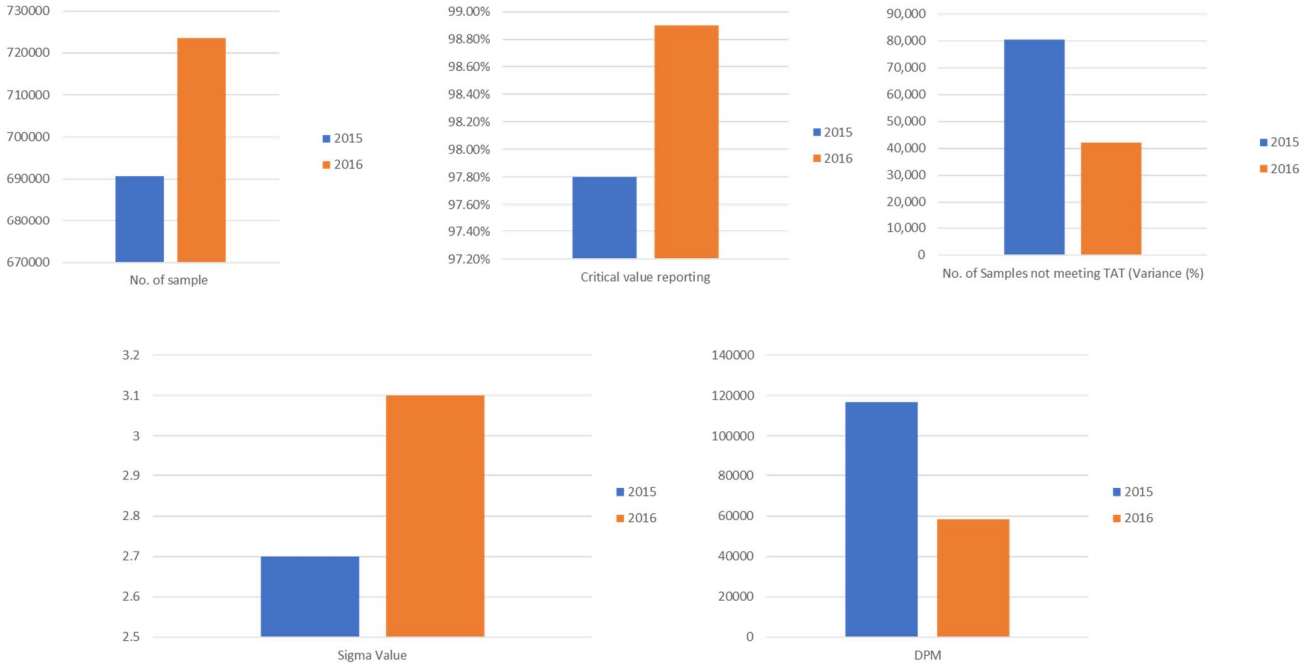


**Figure 5.** Quality indicators in the post-analytical phase.

## DISCUSSION

Laboratory processes are essentially divided into 3 phases which include the Pre-analytical, Analytical and Post-analytical. An error occurring at any one stage can invalidate the quality of analysis and cause the laboratory to fall short of its quality goals.

Quality controls are available for monitoring the analytical errors however there is still a need to improve the pre-analytical process which contributes to 60% of the total laboratory errors (Kulkarni et al. 2018). A wide variation in the total number of laboratory errors from 0.1 to 9.3% has been observed (Kulkarni et al. 2018). A six sigma value of ≤ 3 is considered as poor performance with 66,807 defects per million opportunities and a sigma value of 4 implies 6210 defects per million opportunities. A preanalytical quality indicator with a sigma value of ≥ 4 is considered to be a well-controlled process. The pre-analytical quality indicator with a sigma value below the set sigma benchmark is considered as poor performance and needs corrective and preventive action (Kulkarni et al. 2018).

In the present study, six sigma values for SRR were 3.9 in 2015 which improved to 4.0 in 2016. This showed SRR to be a well-controlled process in our laboratory. The overall SRR was 0.80%. Our findings were lower than similar laboratory studies by Agarwal et al. (2012) and Jacobsz et al. (2011) but higher than other studies. Furthermore, we observed a diluted sample to account for 39% of the SRR in 2015 and haemolysed sample to account for 35% of the SRR in 2016.

Our findings differed from others who found the clotted sample and insufficient sample volume as important factors for SRR (Jacobsz et al., 2011; Guimarães et al., 2012). This may be due to the fact that in our set up most of the patients were chronically ill and were staying for a longer duration. Hence repeated blood sampling leads to a collapse of veins making it difficult to withdraw the sample leading to haemolysis and insufficient sample volume. A diluted sample may be due to the withdrawal of the sample from the side of the IV line due to the unavailability of veins. Over 50% of the blood samples in this study were collected by the nursing staff in the admitted patients. This might have been an important factor for the development of these types of errors in the pre-analytical phase. To address these errors, we held

sensitisation sessions on phlebotomy techniques. Fewer errors were however observed for the outdoor patients. This could have been because their samples were collected from the phlebotomy staff which are under the direct supervision of the laboratory. Similar findings were observed in other studies (Lippi et al., 2008; Mbah, 2014). The proficiency testing score also improved from 97.7% in 2015 to 99% in 2016. Improvement may have been due to the proper training and sensitisation of the laboratory staff with proper supervision by the consultants. Furthermore, proper calibration of the analysers as per schedule along with their periodic maintenance may have also contributed to improvement in equipment uptime and henceforth proficiency test results. Post analytical phase was another domain where we observed improvement. In this phase, we evaluated critical value reporting and the number of samples not meeting the required TAT. On evaluating the urgent sample and critical value reporting we observed a poor awareness amongst the nursing and laboratory staff. The laboratory staff was found to be reluctant in communicating reports and the nursing staff were not aware of their responsibility in this regard. Most of the complaints revolved around accessing the physician telephonically to inform the reports. Similar findings were also reported by Aggarwal et al. (2012). Critical value is defined as a value that may lead to a life-threatening situation if treatment is not promptly given. Ineffectiveness of critical values notification or the failure to provide notification within the target time might prove to be life-threatening in certain cases (Dighe et al., 2008). Literature reports critical value frequency to be 1 in 2000 (Howanitz et al., 2002) to 14 in 1000 (Chawla et al., 2000). In our study, we were able to communicate 97.8% critical value in 2015 which further improved to 98.9 % in 2016. This problem was resolved by sensitising the staff and also by including data entry operators who would send the critical result message by SMS to the concerned physician alongside the telephonic call. In our hospital, the average TAT set for clinical biochemistry is 6 hours for routine inpatients and 24 hours for outpatients. These goals were similar to those of Goswami et al. (2010). We reported an average performance for TAT as 8.68% of our total samples failed to meet the required TAT. The six sigma value for TAT was 2.70 in 2015 which improved to 3.10 in 2016. The improvement in TAT was due to an increase in equipment uptime. However, our overall six sigma values for TAT is <3.0 which is below the acceptable standard of Six sigma. The most probable cause of increased TAT which we could analyze was in the analytical phase due to increased sample load beyond the working capacity of the analysers, leading to equipment breakdown. LIS failure was also observed which lead to a delay in the transfer of reports. These problems can be overcome by managing the analytical phase of our laboratory by complete automation, using analyzers with higher throughputs, use of plasma or whole blood samples, primary tube sampling, ensuring minimal instrument downtime with adequate facilities for backup, adopting efficient quality control procedures, automatic dilutions of results exceeding linearity, auto-verification along with timely validation of reports, etc. A proper division of labour among the technicians can also be ensured so that sample processing and reporting occur smoothly.

## Conclusion

The present study shows a steady improvement in the performance of most of the QI analyzed. These indicators provide a means for evaluating the performance of an individual laboratory or with other laboratories. The study highlights the need to continuously evaluate QIs and calls for improved effort on the frequent training on best practices in phlebotomy for technicians, interns and doctors to reduce the number of pre-analytical errors along with complete automation of the analytical phase to improve the sample TAT.

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