

Evaluation of laboratory performance in consideration with quality indicators and rectification measures at clinical biochemistry laboratory

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Abstract

Introduction and Objective: In laboratory, the errors related to the total testing process, affecting clinical decision making, may occur in all the phases. Quality Indicators are fundamental tool to assess the laboratory performance. The aim of this study is to observe the error types and rates for analytical and post analytical phase in order to assess laboratory performance and rectify them. In addition to accreditate laboratory as per international standards, it would also help to improve patient care and safety.

Materials and Methods: For a period of one year, errors were observed, recorded and analyzed at clinical Biochemistry laboratory, SMIMER, Surat by this retrospective study. Data analysis of total 907611 tests carried out on 317212 samples was done. Analytical and post analytical errors were identified; recorded and analysed taking into consideration certain related Quality Indicators.

Results: For analytical phase and post analytical phase error rates recorded were 7.51% and 8.57% of total samples respectively while it was observed to be as high as 46.71% and 53.28% respectively against total errors encountered for the phases. Highest (45.9%) error rate of analytical phase error was due to tests not in conformance with External Quality Assurance - Proficiency Testing scheme in a previously treated cause. 17.52% of post analytical phase error was due to low rate of critical call outs to clinicians. No records were maintained pertaining to (1) delayed delivery of reports due to insufficient reagents, (2) critical values call out time (min) and (3) staff training events. Also the laboratory was not equipped with Laboratory Informatics System.

Conclusion: Quality Indicators based high error rates warrant active intervention and strict supervision of both the phases of TTP under study. Strategic measures should be initiated to minimize the risk of errors. Ultimately it would be useful for betterment of patient care and safety.

Keywords: Total testing process, Errors in analytical and post analytical phase, Quality indicators, Rectification measures, Laboratory medicine.

Introduction

Any error in Total Testing Process (TTP), starting from test ordering to reporting of results is defined as laboratory error. It must be interpreted properly and addressed immediately. It has definitive role in suggesting a clinical decision.¹ Around 60-70% decisions related to hospital admission, treatment initiation and discharge of patients are governed by laboratory results. So it is important to maintain the quality of laboratory testing and reporting.²

TTP is the process which starts and ends with the patient, spanning from test ordering to result interpretation.³ Again, TTP can be sub divided into three different phase viz. pre-analytical, analytical and post-analytical phase. Assessment of critical aspects of the said phases with the help of certain specific measurable determinants has been suggested by number of studies for medical laboratory accreditation adhering to the international standards.⁴

Out of total errors related to TTP, the error rates of 46-68% for pre analytical, 7-13% for analytical and 19-47% for post analytical phase has been observed. Thus whopping 95% of total errors are accounted for by pre and post analytical phase.¹

Errors in analytical phase begin when sample is prepared in the laboratory for testing and ends when the test result is interpreted and verified. Commonly encountered ones are pipetting errors, instrument/equipment

malfunction; mix up of samples, undetected failure in quality control and interferences etc.⁵

The last phase of TTP, the post analytical phase, is related to provide final value of a test or a diagnostic report in context of histopathology reports. Accuracy and timeliness of result reporting and error in efficiency of Laboratory Informatics System (LIS) are errors related to post analytical phase.⁶ As the name suggests, post-analytical factors play its role after generation of report. In general errors observed during this phase are related to data entry, manipulation of test data and dispatch as well as reporting. Handwritten or keyboard entered reports may lead to data entry error. Dispatching report that exceeds Turn Around Time (TAT) and or reporting without notifying the treating doctor includes error related to reporting. Errors related to data communication include faulty relaying or hearing verbal information.⁷

Quality is the conformance to the requirements of users or customers and the satisfaction of their needs and expectation. Total Quality Management (TQM) is an idea and approach that focuses on processes and their improvement as the means to satisfy customer needs.⁸

To assess the quality laboratory services, Quality indicators (QIs) are the tool of prime importance. It includes the assessment of each and every steps of TTP which can be measured. After evaluating such measurable determinants, it

is compared with standard criteria that ultimately would assess the laboratory performance. For that, QI need to satisfy certain criteria as follows. 1) It must indicate laboratory functions and 2) it must serve at least one Institute of Medicine (IOM) healthcare domain.⁹

There is a widespread need to emphasize, for laboratory testing, the need to follow a standard procedure. By providing laboratory reports devoid of errors, clinicians will get supported in terms of reaching to a conclusive diagnosis and accordingly start and monitor the treatment. A consensus has been made to develop a model of QIs by The Technical Committee of International Organisation for Standardisation (ISO/TC 212) and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). It will encourage patient centred approach and emphasize the needs mentioned above.¹⁰

Though, out of all phases, error in pre analytical phase contributes to the highest error rates amongst all three phases of TTP, in a government hospital based laboratory set up it was felt to observe the error rates for phases other than pre analytical phase i.e. analytical and post analytical phase too with the help of various quality indicators. The reason for such study being (1) insufficient attention paid to the problems (2) practical difficulty in reporting and determining the frequency of errors in these phases. This approach would enable us to identify the various lacunae and improve laboratory performance by implementing applicable corrective measures, a prerequisite for accreditation of laboratory as per international standards. Ultimately it is going to contribute to provide quality laboratory services beneficial to the patient's health care.

Materials and Methods

The present retrospective study involved a study of errors, observed during analytical and post analytical phases

at clinical Biochemistry laboratory, during the period from April-2017 to March-2018 at Surat Municipal Institute of Medical Education and Research (SMIMER), Surat, Gujarat, India. The ethical clearance was obtained from the Institutional Ethics Committee (IEC), SMIMER.

SMIMER Hospital has bed capacity of about 750 which is equipped with clinical Biochemistry laboratory. The main analyzers operated here are ERBA XL-300 & 640 for routine clinical chemistry. Other equipment in the laboratory include ABL 800, COMBISYS-II and COMBILINE for analysis of blood gases and electrolyte analysis whereas LANDWIND E 60A-ELECTROLYTE analyzer (direct ISE) for electrolyte analysis. The laboratory is also having Cobas e-411 for hormonal assays like thyroid function tests, fertility profiles and vitamins while Bio-Rad D10 analyzer is available for analysis of Glycated hemoglobin (HbA_{1c}). The Lab caters routine and emergency tests and it is a part of Christian Medical College (CMC) Vellore External Quality Assurance Scheme (EQAS) for chemistry, immunology, special hormones and HbA_{1c}.

The data of total 9,07,611 tests performed on 3,17,212 samples was collected and analyzed for QIs during study period of one year. We monitored the frequency and type of errors in analytical and post analytical phase by screening all the samples processed in clinical Biochemistry laboratory.

The screening for the laboratory errors was carried out with the help of specific QIs as per table 1 and 2.⁶ The data pertaining to these criteria was developed, recorded and maintained. The error rate was calculated as a % of error observed in total no of samples/tests against total no of samples/tests observed in the laboratory during study period.

Table 1: Various analytical phase errors under study

| Quality Indicators | No of errors | % |
|---------------------------|---|---|
| Analytical performance | 1. No. of parameters not in conformance with EQUAS-PT per year/total no. of tests performed per year | |
| | 2. No. of tests not in conformance with EQUAS-PT per year/total number of tests carried out in EQA schemes per year | |
| | 3. No. of tests not in conformance in EQUAS-PT per year in previously treated cause/total number of tests not in conformance | |
| | 4. No. of IQC results that exceed warning or rejection criteria per year/Total no. of IQC results | |
| Efficient instrumentation | 5. Instrumentation failures leading to delayed reports delivery (No.) per year/total no. of reports | |
| | 6. No. of samples reanalyzed due to flags or alarms, per year/total no. of reports | |
| | 7. Insufficient reagents leading to delayed reports delivery (No.) per year/total no. of reports | |
| Transcription of data | 8. Faulty transcription &/ data entry in computer or ledger leading to false results (No.) /total no. of results requiring data entry in computer or ledger | |

Table 2: Post-analytical phase errors under study

| Quality Indicators | | No of errors | Percentage |
|------------------------------|--|--------------|------------|
| Reporting of results in time | 1. No. of delivery of reports not within the specified time/total no. of reports | | |
| Reporting accuracy | 2. No. episodes of recollection due to sample rejection or incorrect results/total no. of patients | | |
| | 3. No. of reports corrected /total no. of reports | | |
| Reporting of results in time | 4. No. of verified critical values or STAT samples informed within an hour/total no. of critical values to communicate | | |
| | 5. Minutes taken to inform verified critical values | | |
| Supportive processes | 6. No. of episodes of LIS non functioning per year | | |
| LIS Efficiency | 7. No. of training events organized for all staff, per year | | |
| Employee competence | | | |

Results

A retrospective study was carried out at clinical Biochemistry laboratory SMIMER Hospital, Surat, where the data of total 9,07,611 tests performed on 3,17,212

samples was collected and analyzed for quality indicators during study period of one year and the error rates for both phases under study evaluated as follows.

Table 3: Error frequencies (%) in the two phases of TTP

| Phases of TTP | Percentage of errors | | |
|---------------------------------|---|--|---|
| | Total sample (N _S) = 317212 | Total tests performed (N _T) = 907611 | Total No. of errors (N _E) = 51049 |
| Analytical phase (n=23849) | 7.51 | 2.62 | 46.71 |
| Post-analytical phase (n=27200) | 8.57 | 2.99 | 53.28 |
| Total | 16.08 | 5.61 | - |

Table 4: Error frequencies (%) in analytical phase of TTP

| Quality Indicators | | No of errors | Percentage |
|---------------------------|--|--------------|------------|
| Analytical performance | 1. No. of parameters not in conformance with EQUAS-PT per year/total no. of tests performed per year (9,07,611) | 37 | 0.004 |
| | 2. No. of tests not in conformance with EQUAS-PT per year/total number of tests carried out in EQA schemes per year (324) | 37 | 11.4 |
| | 3. No. of tests not in conformance in EQUAS-PT per year in previously treated cause/total number of tests not in conformance with EQUAS-PT (37) | 17 | 45.9 |
| | 4. No. of IQC results that exceed warning or rejection criteria per year/Total no. of IQC results (38930) | 4699 | 12.07 |
| Efficient instrumentation | 5. Instrumentation failures leading to number of delayed reports delivery per year/total no. of reports (3,17,212) | 122 | 0.038 |
| | 6. No. of samples reanalyzed due to flags or alarms, per year/total no. of reports (3,17,212) | 5129 | 1.61 |
| | 7. Insufficient reagents leading to number of delayed reports delivery per year/total no. of reports (3,17,212) | No record | NA |
| Transcription of data | 8. Faulty transcription &/ data entry in computer or ledger leading to false results (No.) /total no. of results requiring data entry in computer or ledger (9,07,611) | 13845 | 1.52 |

Table 5: Error frequencies (%) in post-analytical phase of TTP

| Quality indicators | | No of errors | Percentage |
|-------------------------------------|---|--------------|------------|
| Reporting of results in time | 1. No. of delivery of reports not within the specified time/total no. of reports (9,07,611) | 7297 | 0.80 |
| Reporting accuracy | 2. No. episodes of recollection due to sample rejection or incorrect results/total no. of patients (3,17,212) | 5129 | 0.28 |
| | 3. No. of reports corrected /total no. of reports (3,17,212) | 13875 | 4.36 |
| Reporting of results in time | 4. No. of verified critical values or STAT samples informed to clinicians within an hour/total no. of critical values to communicate (5129) | 899 | 17.52 |
| | 5. Minutes taken to inform verified critical values | No record | NA |
| Supportive processes LIS Efficiency | 6. No. of episodes of LIS non functioning per year | No record | NA |
| Employee competence | 7. No. of training events organized for all staff, per year | No record | NA |

Table 6: Comparison of efficiency of our laboratory against IFCC working group project proposed quality specifications

| | Performance level | | | | Our report | Remarks |
|--|-------------------|-----------|---------|--------------|------------|---------------|
| | Optimum | Desirable | Minimum | Unacceptable | | |
| No. of delivery of reports not within the specified time /total no. of reports | < 0.4 | 0.4-0.5 | 0.6-0.7 | > 0.7 | 0.8 | Un acceptable |
| No. of verified critical values or STAT samples informed to clinicians within an hour/total no. of critical values to communicate /total no. of critical values to communicate | > 96 | 77-96 | 58-76 | < 58 | 17.52 | Un acceptable |
| Minutes taken to inform verified critical values | < 50 | 50-100 | 101-160 | >160 | No record | NA |

Discussion

It is estimated that around two thirds of decisions related to hospital admission, treatment initiation and discharge of patients are governed by laboratory results. Hence, laboratory testing, playing a key role in patient care, is also an important source of medical errors that can affect patient safety.¹¹

Quality indicator, comprised of certain measurable determinants, is a tool that enables us to quantify laboratory's performance by comparison against standard criterion. The idea of QI formation has emerged over past few years for ensuring high standards of quality rendered by any service provider. Its implementation in a continuous and comparable form across various set ups and over the time is necessary.⁷

The whole logic behind implementation of the QIs is 1) to check and monitor the TTP and proficiency of the laboratory there by formulate steps to implement a quality system 2) to provide the quality reports which help to win clinician's and general population's trust for the reports. Also in order to accreditate any laboratory, it must have the

baseline efficiency to follow the already set protocols/procedures by staff associated directly or indirectly with laboratory.⁴

For evaluation of our laboratory, the set of QIs related to certain critical processes, were followed from a study carried out by Plebani et al.⁴ As per the feasibility, we adopted 15 QIs to evaluate both phases analytical and post-analytical, from the list proposed by IFCC working group project related to laboratory errors and patient safety.

The study regarding errors in laboratory testing process for pre analytical phase has already been conducted at our laboratory. This study was an attempt to evaluate the error frequencies even for the remaining two phases of TTP viz. analytical and post analytical.

As per table 3, total error rate observed was about 16.08% of all samples included in the study whereas the same observed for all tests performed was 5.61%. Amongst various studies, pre analytical error rates are reported to be up to 70%¹²⁻¹⁵ while it varies between 7-13% and 19-47% respectively for analytical and post analytical phase.¹⁶

Present study, contrary to studies discussed above, found the error rates in analytical phase as high as 46.71% against the total number of errors encountered whereas 7.56% against the total samples analysed.

As per table 4, again in analytical phase, amongst various determinants laid down, the highest error rate of 45.9% was observed for tests not in conformance in EQUAS-PT per year in a previously treated cause of all tests performed. This was particularly observed in various parameters from highest frequency to lowest frequency as follows:

(1) Total creatine phosphokinase (Total CPK) (2) serum alanine transaminase (ALT) (3) serum uric acid (4) serum phosphorus (5) serum total T₃ (6) serum potassium (7) serum aspartate transaminase (AST) (8) serum alkaline phosphatase (9) serum creatinine

These parameters required frequent calibrations, reagent change or change in reagent lot. One of the reasons which need to be regulated properly is the selection of the kits provided to the hospital based laboratories. The kits which we receive in our laboratory are at times of very low quality due to the procurement by government tendering system. The kits are procured primarily based on prices rather than quality. Also the department of interest is not consulted for thorough evaluation of quoted kits by tender system.

Furthermore, whenever the department of interest is consulted for evaluation of the said kits, at times, the quality of reagents supplied during that period would drastically differ from the kits provided during actual routine run. Further probing into the matter showed that the specifications of kits submitted by the department of interest were not revised periodically which again was responsible for further decline in quality of the kits being procured and used on a day to day basis. These very reasons also accounted for non compliance of results in EQUAS-PT schemes.

The ratio of Internal Quality Control (IQC) results that exceed warning or rejection criteria per year to total no. of IQC results was also observed to be high as 12.07%. In addition to poor quality of reagents, poor quality of Quality Control (QC) material was held accountable for such high error rates. We feel that reduction of IQC and EQUAS-PT related high error rates warrants procurement of reagents, calibrators and QC material that are complying to international standards and shall possess applicable traceability. Proactive steps should be taken to identify the inferior quality kits supplied by the tenderer and if needed it should be blacklisted. Also the specifications of the kits should be revised periodically to get the quality kits available in the market, manufactured following standard norms.

There was no account or record of reports delayed delivery due to reagent insufficient. Lapses like these might result in missing of the actual error for the particular phase concerned. In order to fine tune the quality of laboratory reporting, we feel that above records or logs need to be maintained and critically evaluated periodically.

The error rates for analytical phase observed in a study by Hawkins et al was 7% to 13% whereas it was around 8% in a study carried out by Goswami et al. These errors included sample mix ups, undetected failure in QC, equipment malfunction and interferences.^{7,9}

As per table 3, our study showed that the error rate for post analytical phase was the most common, 53.28% of total number of errors. As per table 5, these were ascribed to the determinant categorised as the ratio of no. of verified critical values or STAT samples informed to clinicians within an hour to total no. of critical values to communicate. In our study it was observed that out of 100, only around 18 critical or STAT values were communicated within an hour to clinicians (18%). In a study carried out by Patel S et al, the laboratory executed the call outs related to critical value or STAT samples very efficiently (97.31%).⁶

At our laboratory first and foremost, there is no provision of display of parameters along with its critical value. There has been no consensus between clinicians and laboratory departments to develop a critical value for the parameter. Such a poor critical call out rates could be ascribed due to these reasons. We feel that there has to be a consensus between clinicians and laboratory departments to assign a critical value for a particular parameter. Also the technical staff involved in laboratory affairs must be sensitized about the importance of critical call outs to various departments and implement the same consistently to improve patient care.

As per table 5, again it was observed that the ratio of corrected reports to total number of reports was as high as 4.37%. Such a high percentage needs to be evaluated for manipulation practices. Such practices support the fact that the laboratory needs a separate faculty in charge who monitors such malpractice and by doing so he/she might prevent the inadequacy of quality of laboratory reports. There is also need of starting laboratory interface system in order to get an accountability of such type of serious errors.

In post analytical phase there was no record pertaining to minutes taken to inform verified critical values the. Clinically for certain conditions, the lower the time to communicate critical value higher the benefit to the patient awaiting the treatment based on laboratory results. We feel that the maintenance of the record of time to communicate verified critical values must be documented as a part of routine practice by all laboratory staff to ensure timeliness of results reporting.

Indicators of support processes like laboratory informatics system (LIS) after analytical phase is highly valuable and critical to decrease the errors related to transcription of data. Our hospital based laboratory with daily load of around 600 to 700 samples per day does not have the facility of LIS. Being the most common error of our study (53.28%), the post analytical phase cannot afford to miss out on critical determinants like LIS efficiency. Hence we strongly favour to acquire a fully functional LIS system in order to prevent such vital post analytical errors which we could not include in our study.

Total number of training events organised for all staff during the year was nil. If the laboratory staffs do not undergo different training events related to total quality management (TQM) then one cannot expect that particular laboratory to dispatch quality reports. At least two to three training events related to TQM should be organised to sensitise all working staff of laboratory regarding the importance of committing as less errors as possible. This would help the laboratory to deliver quality reports and ultimately improve patient care.

As per table 6, while evaluating performance level for post analytical indicators proposed by IFCC working group project, it was observed that there was unacceptable performance for following indicators.

1. No. of verified critical values or STAT samples informed to clinicians within an hour (17.52%, <58 unacceptable).
2. No. of delivery of reports not within the specified time (0.8%, > 0.7 unacceptable).

In a study carried out by Suprava Patel et al., it was observed that there was optimum performance level for critical value call outs (97.30%) but had an unacceptable performance level for number of reports delivered outside specific time (12%, >0.7 unacceptable).⁶

In a nut shell, high error rates due to various reasons calls for the need to formulate frequent training and strategic guidelines and intense supervision of all related processes, may it be within laboratory or out of laboratory, to reduce the risk of errors in TTP and improve patient safety.

The present study has shown the various factors in different phases of TTP, playing their role which might well affect the final outcome of the laboratory results. By pointing out the various errors related to these phases of total testing process and recommending required corrective measures one can improve the outcome of the laboratory results and their by patient care.

Conclusion

In present study analytical and post analytical error rates were analysed for the samples received at clinical biochemistry laboratory, SMIMER, Surat for the period of 1 year. Total quality management includes all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians. Pre analytical phase accounts for high error rates amongst all three phases of TTP. With the help of QIs, we found that our clinical Biochemistry laboratory accounts for significant error rates for analytical and post analytical phase too. We opine to procure reagents which are manufactured by companies following international norms, simultaneously considering the budget escalation, to reduce the non-conformities related to IQC and EQAS-PT schemes. Also QC material and calibrators which are procured must have traceability. The laboratory departments and clinicians should reach to consensus related to define critical values of various parameters. All records pertaining to delayed report delivery, critical call outs to clinicians and technical staff training should be maintained. Finally, the laboratory needs

to be equipped with fully functional LIS system to counter post analytical errors. To conclude, there is a definite need for an integrated approach toward laboratory diagnosis and function along with the clinicians to provide effective patient care services at SMIMER, Surat.

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