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Audit of Reporting Errors in Biochemistry Section of NABL Accredited Laboratory in a Tertiary Care Teaching Hospital

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Abstract

Background: In the modern era of tremendous automation in analytical processes, reporting errors have been reduced significantly. Therefore, the focus has been shifted to identifying the extra analytical causes of errors in the laboratory.

Objectives: This study aimed to audit major clinical decisions affecting quality indicators (i.e., reporting errors and error prevention) by adhering to ISO 15189 (2012) and National Accreditation Board for Testing and Calibration Laboratories (NABL) (112) requirements.

Methods: The records of the reporting errors were maintained from the biochemistry section of the central clinical laboratory (CCL) and analyzed based on the aim of this study. Then, the root cause analysis was performed, and the data was collected and audited from November 2015 to July 2020.

Results: The total number of reporting errors between the mentioned periods were 132, with an incidence of 1 error per 384 processed samples on the day of observing the reporting error. In general, 22 (16.67%), 16 (12.12%), and 94 (71.21%) cases were pre-analytical, analytical, and post-analytical errors, respectively. The incidence of the post-analytical error was noted to be more since they were all typographical errors.

Conclusion: Overall, transcriptional or typographical errors were found to be the main causes of reporting errors. In our clinical laboratory, we are attempting to minimize these errors by pre-validating the results by senior technicians and faculty prior to the typing and approval. These avoidable errors can be minimized by the continuous training of laboratory staff. Up-gradation to automated data collection information management systems are of great hope for preventing such errors.

Keywords: Reporting errors, Quality indicators, Typographical errors, Post-analytical errors

Background

Working in the NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited laboratory is an opportunity to witness a changing scenario in healthcare for the laboratory staff. Nowadays, laboratory systems are playing an important role as a pillar in the healthcare system for delivering quality patient care. These new updated accredited laboratory systems have changed the traditional scene of healthcare systems into the more accurate and personalized healthcare delivery of services. To maintain the changed scene, there is a need to critically evaluate and check the system periodically as per standard national and international criteria. The proficiency of laboratory services is the mainstay in clinical medicine regarding providing error-free diagnostic results (1).

The total testing process (TTP) embraces pre-analytical, analytical, and post-analytical phases (2). Automated processing has recently replaced the manual testing of parameters in the field of laboratory medicine.

Among all the laboratory errors, 60% are constituted by preanalytical errors, and majorly-concerning the analytical errors are decreasing drastically (3). Based on the data, the effect on patient care was observed due to only 24%-30% of total laboratory errors while nearly 3%-12% of patients actually or potentially get affected (4-6), and the actual harm rate of 100% can be found in molecular genetics testing, which is highly crucial (7,8).

Quality laboratory reports critically contribute to the patient management decision, which is the primary responsibility of the laboratory. The total quality management starts from proper test ordering to the dispatch of laboratory reports to the correct person (5).

Laboratories should consider the risks associated with each step in the TTP for the services they order and ensure that processes are in place to identify failures and monitor their rate of incidence (10). The efficiency of the laboratory is measured by the quality indicators (QI) of different phases of TTP that are considered as the fundamental measurable tool for the evaluation of

laboratory performance (1). The QI, which constitutes objective measures, denotes the extent up to which a certain system meets the needs and expectations of the customers (11). Any potential QI needs to primarily fulfill the inclusion criteria since it must be an indicator of laboratory functions (12).

A great heterogeneity on laboratory errors was found in studies where the data collection method appeared to have the strongest influence on error prevalence and type (3). Clinical audits and clinician satisfaction surveys can also be useful measures of overall laboratory effectiveness (3,13). The use of laboratory information management systems (LIS) as a recording mechanism for preanalytical errors is recommended as it is the easiest and most standardized mechanism of data capture (10). There are various ways by which the errors can be recorded, including manual recording processes (systems of recording errors manually by means of 'quality query reports', incident reporting, use of LIS (14), data review (9), and etc).

Laboratory quality audit is an essential element of the quality management system of a laboratory and includes the scheduled audits of process effectiveness. ISO 15189: 2012 (15) recommended the incorporation of the audits of preanalytical areas to collect information on the relative rates of errors. The audit forms a crucial part of the quality processes of a laboratory. In addition, it can be used as a retrospective data collection tool and provides a survey of error rates at a particular point in time.

Moreover, the audits must be extensive in order to accurately reflect the true error rate of the laboratory (10). There are very few studies about auditing and explaining various planning strategies for the prevention of reporting errors. Accordingly, the present study planned to give insight into planning strategies for the continuous improvement of laboratory quality management systems by auditing the reporting errors of the clinical biochemistry section, the central clinical laboratory (CCL) in a tertiary care teaching hospital.

Methods

This hospital-based retrospective observational study was conducted on patients' samples received in the clinical Biochemistry section of the CCL in Bharati Hospital, Pune, Maharashtra, India for 4 years and 10 months. The CCL is an NABL accredited laboratory of Bharati Hospital. All the received blood and fluid samples (e.g., cerebrospinal fluid, pleural, peritoneal, and urine samples) for routine clinical biochemistry and immunoassays were included in this study.

The Bharati Hospital is an 850 bedded and multi-super specialty health center in Pune of Maharashtra, with a centralized sample collection center. Blood samples are collected by phlebotomists, paramedical staff, or resident doctors and trained nursing staff and transported to CCL via an automated pneumatic specimen transporting cute system.

The clinical biochemistry section of CCL is well-equipped with the state of the art 2 Imola fully automatic biochemistry analyzer (Randox), Abbott i1000SR (Abbott) fully automated immunoassay analyzer, 2 Erba Chem-7 semi-auto biochemistry analyzer (Transasia®), Easylyte for electrolyte (Transasia®), Triage SOB (Alere®), and D-10 for HbA1c (Biorad). All samples were analyzed in CCL, and reports were duly dispatched from the laboratory to various wards while the outpatient department (OPD) reports were collected by the patients or their relatives from the OPD collection center.

The reporting error is one of the important QIs for the National Accreditation Board for Hospitals (NABH) and NABL. Given that our laboratory is NABL accredited, this is our routine quality policy to report this QI. In other words, reporting errors and segregating them according to the type of errors (e.g., preanalytical, analytical, post-analytical errors) and performing the root cause analysis and corrective and preventive actions.

The observed reporting errors in the clinical biochemistry section were manually documented and included in the present study. Then, they were grouped as pre-analytical, analytical, and post-analytical errors based on the error in sample collection and transport, processing of the sample, and reporting including the total testing process, respectively. The reporting errors occurring in the clinical biochemistry section were noted as a strategy for continuous quality improvements by the quality management system.

All the reporting errors occurring from November 2015 to July 2020 were recorded, along with the total number of the processed samples in a day. All the quantitative variables were shown by frequencies and percentages, and the difference in the frequencies was compared using the chi-square test.

Results

The present study was conducted between November 2015 and July 2020, which included the auditing of the reporting errors with respect to the type of errors, frequency of errors, and the actual cause behind them. Within this period, the reporting errors were observed on 118 days, and the total number of processed samples on these days were 50721 with an average of 429.84 ± 106.76 samples per day. The incidence of the reporting error per processed sample on days when observing the reporting error in our laboratory was noted to be 0.0026. In other words, there was one reporting error for 384.25 samples.

The reported pre-analytical, analytical, and post-

analytical errors in the present study were 22 (16.67%), 16 (12.12%), and 94 (71.21%), respectively. The comparison among all three types of errors demonstrated a significantly increased frequency of the post-analytical error while the frequencies of preanalytical and analytical errors differed non-significantly (Table 1).

The most prevalent cause in the pre-analytical error included a wrong entry in the software (11), and the other causes were sample discarded before analysis (1), hemolyzed sample (1), a wrong entry on the test requisition form (3), wrong transport of sample (1), wrong sample collection (4), and wrong vacutainer (1). The least commonly found errors were in the analytical phase (12.12%) and the most common cause was wrong test entry in the analyzer (5), followed by machine breakdown (1), processed on the hemolyzed sample (2), sample aspiration error (3), wrong reagent positioning (2), wrong processed sample (1), and wrong processed test (1). All the reported post-analytical errors were due to typographical errors.

The year-wise incidence of the reporting errors from 2015 to 2020 was calculated as per the total reporting errors were documented (n=132) during this period. The annual incidence was the highest (23.48%) in 2018 while it was the lowest (4.55) in 2016. Although the annual incidences of 2015 and 2020 were 15.91 and 15.15, respectively, the data were only for 2 and 7 months, respectively, if considered for the entire year, the incidence would be higher (Table 2).

Discussion

TTP is a unique framework for identifying and reducing errors, including initial steps such as patient identification and appropriateness in test requesting, and final steps such as communication and interpretation of test results. The errors in healthcare and the laboratory medicine field can be dealt with different personal, legal, and system approaches. There is a need to be dealt with as per approach to reduce the error rates.

In the personal approach, the ECRI Institute PSO listed different people who bear the responsibility for the accuracy of the testing process, including the health care professional who orders the lab test and makes decisions based on the findings and the person who collects the specimen for testing. Further, other individuals were the transporter who delivers the specimen to the lab, the lab technician who processes the test order and records the test results, and the person who makes the test results available to the health care team initially ordering the testing (16).

The system approach mainly focuses on the fact that there are certain system failures which have scopes for improvement. The systems can be improvised by the personal and supervisory attention on all aspects of the major priority areas of laboratory medicine. These dimensions were accuracy of patient/specimen identification, the effectiveness of laboratory data communication, communication of critical test results, sample acceptability and rejection criteria, appropriateness of test request, and avoidance of manual data transcription (5).

The reporting errors in our hospital were manually documented while not in the LIS. Accordingly, it led to missing many errors (i.e., undocumention of errors). In

Table 1. The Number and Frequencies of Pre-analytical, Analytical, and Post-analytical Errors With Root Cause

Type of Error	Root Cause	Number	%
Pre-analytical (n=22)	Urine sample discarded before analysis	1	
	Hemolyzed	1	
	Wrong entry in software	11	
	Wrong entry on TRF	3	16.67
	Wrong sample collection	4	
	Wrong transport of sample	1	
	Wrong vacutainer	1	
Analytical (n=16)	Machine breakdown	1	
	Processed on hemolyzed sample	2	
	Sample aspiration error	3	
	Wrong reagent positioning	1	
	Wrong sample positioning	2	12.12
	Wrong processed sample	1	
	Wrong test entry on the analyzer	5	
	Wrong processed test	1	
Post-analytical (n=94)	Typographical error	94	71.21*

Note. TRF: Test requisition form; *Statistically significant; Pre-analytical vs. analytical (P=0.2933); Post-analytical vs. pre-analytical (P<0.0001); Post-analytical vs. analytical (P<0.0001).

Table 2. Year Wise Incidence of Reporting Errors From 2015 to 2020 With Year Wise Distribution of Pre-analytical, Analytical, and Post-analytical Errors

Year	Type of Error	Number (%)	Year wise Incidence (%)	No. of Tests During the Period
November to December 2015	Pre-analytical	1 (11.11)	15.91	305172
	Analytical	1 (11.11)		
	Post-analytical	7 (77.78)		
2016	Pre-analytical	4 (100)	4.55	392743
	Analytical	0 (0)		
	Post-analytical	0 (0)		
2017	Pre-analytical	4 (28.57)	20.45	395201
	Analytical	2 (14.29)		
	Post-analytical	8 (57.14)		
2018	Pre-analytical	0 (0)	23.48	459592
	Analytical	3 (20)		
	Post-analytical	12 (80)		
2019	Pre-analytical	1 (7.69)	20.45	835925
	Analytical	1 (7.69)		
	Post-analytical	11 (84.62)		
January to July 2020	Pre-analytical	0 (0)	15.15	224898
	Analytical	0 (0)		
	Post-analytical	8 (100)		

our study, the researchers strictly followed the sample rejection criteria, which included the samples with hemolysis, lipemia, wrong patient identification, and the like, leading to fewer number of hemolytic and lipemic sample errors. It was further found that transcriptional reporting errors in the post-analytical phase were frequent in our laboratory set-up. Therefore, there is a need for developing planning and prevention strategies mainly focusing on reducing them in order to effectively complete the TTP loop. Evidence suggests that most reporting errors are documented in the pre- and post-analytical phases, with advances and automation in the analytical step, reducing the errors in the analytical phase. The rate of transcription errors up to 39% was reported in an Australian survey (17).

According to the report from the College of American Pathologists in collaboration with the CDC Outcomes Working Group describing error stratification in the working process for clinical laboratories, the pre-analytical, post-analytical, and analytical phases of testing contribute to 41%, 55%, and only 4%, respectively (18). Moreover, the importance of the post-analytical phase was demonstrated for maintaining and improving turnaround time (TAT) (19). As stated by Blumenthal, "quantitatively largest reductions in laboratory errors are likely to result from interdepartmental cooperation designed to improve the quality of specimen collection and data dissemination" (20).

The post-analytical error was the most frequent type of error (71.21%) in the present study, which is consistent with the finding of Plebani (21). Kulkarni et al (22) found TAT (1.55%) as the most common cause, followed by the revision of reports in the post-analytical phase. In contrast to our results, Bonini et al (3) showed pre-analytical errors to be the most common. There are few other studies, with contradictory results having more prevalent pre-analytical errors than post-analytical ones (1,4,6,23).

As provided in Table 2, the year-wise distribution of each type of error was evaluated in the current study. The annual incidence was the highest (23.48%) in 2018 whereas the lowest (4.55) in 2016. The cause behind the highest incidence might be the vigorous training of the staff and the induction training conducted for the newly joined staff after obtaining the NABL accreditation due to which the training made the staff more aware of the error detection, resulting in higher reporting of errors compared to previous years.

Along with the NABL accredited laboratory, Bharati Hospital is NABH accredited. There are systems in place to detect the reporting errors after dispatch (i.e., errors in the post-analytical phase by raising the incidence of the same). This helps to detect the missed post-analytical phase errors before dispatch, highlighting the need for collaborative efforts from all departments.

As stated by Leape et al (24), the role of the clinical audit is detecting the type of error, and laboratories need to monitor adverse incidents, to learn how to minimize risks by studying them, and to establish procedures to prevent them. Although pre- and post-analytical

clerical errors would be eliminated in a fully automated laboratory, any human involvement necessitates strategic measures to eliminate the risk of manual transcription errors. Laboratories should review all error-prone steps in the transcription process to ensure accuracy in order to achieve the desired error reduction (25). Accordingly, standard operating procedures were prepared to mitigate transcription errors at our setting.

According to previous evidence, implementing LIS-ready platforms in the laboratory eliminates data entry transcription errors by automatically releasing results directly to the LIS (26). Using these LIS platforms, important indicators showing improvements in error rates are test and data transcription errors, unsuitable samples due to transportation and storage problems in addition to patient and sample misidentification errors (17). Platforms enabling rule-based auto-verify functionality can be configured to automatically send specific results to the LIS and reduce sample TAT. Additionally, delivering rapid order-to-report TAT enables faster clinical actions positively impacting patient safety by reducing TAT and transcription errors. Continued advances in laboratory automation and platforms with patient safety as a core design element increasingly contribute to delivering on the shared goal of delivering high values, patient-centred care (26).

Conclusion

The continuously evolving field of laboratory medicine is also prone to laboratory errors which can be mitigated by a systematic and highly critical approach. There is a need for better teamwork, collaborative efforts from all departments, along with the active and critical participation of the clinicians who are across the side. With the output of the present study at our current laboratory set up, it was possible to get an insight into various possible causes of reporting errors, and planning for strategies, and policy decision-making was incorporated accordingly. It ultimately had an effect on the patient care at our hospital. Considering the results of this study, it is suggested to make use of LIS-based platforms for all sections of a laboratory, have mitigating effects on transcriptional post-analytical errors.

Authors' Contributions

All the authors declared that they have contributed to their intellectual inputs for conception and design, administrative support, provision of study materials, collection and assembly of data, data analysis and interpretation, manuscript writing, and final approval of the manuscript.

Conflict of Interest Disclosures

All the authors declare that there is no conflict of interests.

Ethical Issues

The present study was approved by the institutional ethics committee letter No. BV(DTU)MC/IEC/67.

References

1. Patel S, Nanda R, Sahoo S, Mohapatra E. Congruity in quality indicators and laboratory performance. Indian J Clin Biochem. 2018;33(3):341-7. doi: 10.1007/s12291-017-0687-9.
2. Chawla R, Goswami B, Singh B, Chawla A, Gupta VK, Mallika V. Evaluating laboratory performance with quality indicators. Lab Med. 2010;41(5):297-300. doi: 10.1309/lms2cbxba6y0owmg.
3. Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. Clin Chem. 2002;48(5):691-8.
4. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. Clin Chem. 2007;53(7):1338-42. doi: 10.1373/clinchem.2007.088344.
5. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem. 2010;47(Pt 2):101-10. doi: 10.1258/acb.2009.009222.
6. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem. 1997;43(8 Pt 1):1348-51.
7. Hofgärtner WT, Tait JF. Frequency of problems during clinical molecular-genetic testing. Am J Clin Pathol. 1999;112(1):14-21. doi: 10.1093/ajcp/112.1.14.
8. Lippi G, Fostini R, Guidi GC. Quality improvement in laboratory medicine: extra-analytical issues. Clin Lab Med. 2008;28(2):285-94. doi: 10.1016/j.cll.2007.12.007.
9. Giménez-Marín A, Rivas-Ruiz F, Pérez-Hidalgo Mdel M, Molina-Mendoza P. Pre-analytical errors management in the clinical laboratory: a five-year study. Biochem Med (Zagreb). 2014;24(2):248-57. doi: 10.11613/bm.2014.027.
10. West J, Atherton J, Costelloe SJ, Pourmahram G, Stretton A, Cornes M. Preanalytical errors in medical laboratories: a review of the available methodologies of data collection and analysis. Ann Clin Biochem. 2017;54(1):14-9. doi: 10.1177/0004563216669384.
11. Barth JH. Clinical quality indicators in laboratory medicine. Ann Clin Biochem. 2012;49(Pt 1):9-16. doi: 10.1258/acb.2011.011126.
12. Kohn LT, Corrigan JM, Donaldson MS, editors. To Err is Human: Building a Safer Health System. Washington, DC: National Academies Press; 2000.
13. Plebani M. Appropriateness in programs for continuous quality improvement in clinical laboratories. Clin Chim Acta. 2003;333(2):131-9. doi: 10.1016/s0009-8981(03)00177-3.
14. O'Kane MJ, Lynch PL, McGowan N. The development of a system for the reporting, classification and grading of quality failures in the clinical biochemistry laboratory. Ann Clin Biochem. 2008;45(Pt 2):129-34. doi: 10.1258/acb.2007.007097.
15. ISO 15189:2012. Medical laboratories – requirements for quality and competence, 2012.
16. A study from ECRI Patient Safety Organization, test related-safety-events-finds-most-occur-outside-the-laboratory. Accessed on 15.09.2020. Available at https://www.mloonline.com/home/article/13006435/ecri-institute-pso-study-on-lab.
17. Khoury M, Burnett L, Mackay MA. Error rates in Australian chemical pathology laboratories. Med J Aust. 1996;165(3):128-30.
18. Boone DJ, Steindel SD, Herron R, Howanitz PJ, Bachner P, Meier F, et al. Transfusion medicine monitoring practices. Arch Pathol Lab Med. 1995;119(11):999-1006.

19. Negri M, Carraro P, Caenaro G, Cappelletti P, Giavarina D, Mezzena G, et al. External quality assessment of stat test intralaboratory turnaround times. Clin Chem Lab Med. 1998;36(11):867-70. doi: 10.1515/cclm.1998.152.

20. Blumenthal D. The errors of our ways. Clin Chem. 1997;43(8 Pt 1):1305.

21. Plebani M, O'Kane M, Vermeersch P, Cadamuro J, Oosterhuis W, Sciacovelli L. The use of extra-analytical phase quality indicators by clinical laboratories: the results of an international survey. Clin Chem Lab Med. 2016;54(11):e315-e7. doi: 10.1515/cclm-2016-0770.

22. Kulkarni S, Kale S, Ghodke U, Risbud A, Kulkarni S. Evaluation of the quality indicators in laboratories at National AIDS Research Institute, Pune, India. Natl J Community Med. 2017;8(2):47-51.

23. Toshniwal P, Toshniwal S, Shah RM. An insight view on pre and post-analytical errors in clinical chemistry laboratory of a tertiary care super specialty teaching hospital. Natl J Lab Med. 2016;5(4):10-4. doi: 10.7860/njlm/2016/22587:2173.

24. Leape LL, Woods DD, Hatlie MJ, Kizer KW, Schroeder SA, Lundberg GD. Promoting patient safety by preventing medical error. JAMA. 1998;280(16):1444-7. doi: 10.1001/jama.280.16.1444.

25. Manual of "Laboratory Investigation of Discordant Proficiency Testing Findings." Centre for Proficiency Testing, IQMH. Available from: https://iqmh.org/Portals/1/Docs/Resources/News/Archive/2016/Elevate%202016-12.pdf. Assessed 16 September 2020.

26. Tieman BF. The role of lab automation in reducing diagnostic errors. Lab Management, Lab Safety, Medical Laboratory Observer; September 21, 2017.