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Biochemistry Section

An Insight View on Pre and Post-Analytical Errors in Clinical Chemistry Laboratory of A Tertiary Care Super Specialty Teaching Hospital

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ABSTRACT

Introduction: In today's modern world of technology with automation in laboratory testing took place to ensure a more efficient and safer service within a short interval of time helped clinicians in diagnostic and therapeutic decisions taking. Despite plentiful literature on improving the quality of services in laboratories and improvement done at various stages, errors still persists.

Aim: To evaluate the leading causes of pre-analytical and post-analytical errors in a clinical chemistry laboratory of a tertiary care super specialty teaching hospital.

Materials and Methods: An analysis of errors obtained in clinical chemistry laboratory in the pre-analytical and post-analytical phase has been carried out over a period of 6 months for OPD and IPD samples. All pre and post-analytical errors that took place during the study were observed and were recorded during the study period.

Results: In the present study, the pre-analytical errors were found to be more common in both OPD and IPD cases (85.51%) than the post-analytical errors (14.49%). Both pre and post-analytical errors were more common in OPD cases (53.85%) than IPD (43.72%) cases.

Conclusion: By investigating the percentage of errors that occurred during study period of 6 months, it was found that pre-analytical errors were more common than post-analytical errors and were seen more frequently in OPD cases compared to IPD. Amongst the pre-analytical errors, quantity insufficient and incomplete TRF were the major errors observed whereas in the post-analytical category, reports that were transcribed wrongly and failure to report clinicians which leads to increased turn around time (TAT) and causes patients inconvenience. Thus, identification of such valuable errors and to minimize them is a fundamental step in assessing and improving laboratory services otherwise it may hinder the quality of laboratory results.

Keywords: Indoor patient department (IPD), Outdoor Patient Department (OPD), Test requisition form (TRF), Turn Around Time (TAT)

INTRODUCTION

In today's modern world of technology with automation in laboratory testing, diagnosis is largely dependent upon integrity of laboratory data. Although remarkable advances in sample collection, transportation, automation and dispatch of reports have greatly reduced errors and have led to far-reaching perfection in the routine of laboratories [1] yet compliance is still low [2,3]. Laboratory error is define as "A defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting on these" [2,3].

Conventionally, the routine of laboratory practice can be broadly divided into 3 phases of total testing process (pre-analytical, analytical and post-analytical phases), which can be individually monitored for the quality check, as it is very well published in most of the articles that majority of errors took place during pre-analytical and post-analytical phases [4].

The pre-analytical and post-analytical phases of the process account for 0.1 - 9.3% of errors influencing outcome and cost of results [5].

It has been found that for laboratory professionals pre-analytical phase is of great challenge [6]. A study by Plebani M and Carraro P showed about 49-73% error in pre-analytical phase and post-analytical phase error to be 38-66% [7]. Similarly, Goswami et al., found pre-analytical around 77.1% and post-analytical errors at 15.0% [8].

As per the recent articles published, it has been observed that due to increasing attention towards health care, there has been significant decrease in the laboratory errors [9,10].

AIM

The aim of this paper is to investigate the main causes of

pre and post-analytical errors that caused sample rejection and increased turn-around time (TAT) of patient's samples sent from OPD and IPD to the CCL, in the tertiary care super specialty teaching hospital.

MATERIALS AND METHODS

This hospital based prospective observational study was conducted in Dhiraj General Hospital, Piparia, Vadodara, Gujarat, India, for the duration of six months on patients sample from two different Department's OPD and IPD. All the blood specimens received for routine clinical biochemistry and immunoassays were accepted and samples other than biochemistry like pathology, histopathology, cytology, microbiology (serology) and others were excluded from the study. Fluid samples like CSF, pleural, peritoneal and urine samples were also excluded.

The Dhiraj General Hospital (DGH) is a 1276 bedded hospital in Gujarat. It is multi-superspecialty hospital which receives more than 2 lakh patients in a year. CCL is the part of DGH receives on an average 1.75 lakh samples from OPD and around 2.2 lakh samples from IPD and around 60% of samples are received in the biochemistry section for analysis.

DGH has a centralized sample collection center for OPD. Blood collection is done by phlebotomists, paramedical staffs or by resident doctors and transported to CCL in a sample transport box. Whereas, the blood samples from wards are performed by trained nursing staffs, resident doctors or intern doctors on duty. Samples collected from IPD are delivered to CCL by the paramedical staff or by patient's relative in case of emergency.

The clinical biochemistry section of CCL is well equipped with state of the art EM-200 fully automatic biochemistry analyzer (Transasia®), Erba Chem-5 Plus semi-auto biochemistry analyzer (Transasia®), Easylyte for electrolyte (Transasia®), AIA 360 immunoassay (Alere®), Triage SOB (Alere®) and Mispa-I 2 (make Agapee®). All samples analysed in CCL and reports were duly dispatched from the laboratory to various wards, while the OPD reports were collected by the patients or their relatives from the OPD collection centre.

Ethical Consideration: Ethical approval was obtained from institutional ethical committee and guidelines were followed

STATISTICAL ANALYSIS

In this study, we calculated frequency percentage and proportion percentage to evaluate the errors that was observed in OPD and IPD samples.

$$\text{Frequency percentage (\%)} = \frac{\text{Error observed (No.)}}{\text{Total sample size}} \times 100$$

$$\text{Proportion percentage (\%)} = \frac{\text{Error observed (No.)}}{\text{Total error observed}} \times 100$$

RESULTS

In this 6 months study, CCL received around 15,320 samples from 1st May, 2014 to 31st July, 2014 from OPD from which 9500 samples and 18,210 samples from 1st March, 2015 to 31st May, 2015 from various indoor departments during working hours from which 9500 samples fulfilled the inclusion and exclusion criteria. In both OPD and IPD samples for pre-analytical and post-analytical errors observed were recorded in error recording log book and data collected were noticed by visiting OPD sample collection centre and sample receiving area of CCL.

All the pre-analytical errors were considered for OPD and IPD samples are tabulated as shown in [Table/Fig-1-4].

DISCUSSION

The Institute of Medicine reported *To Err Is Human: Building a Safer Health System* and other have reported [11-15] increased concern over the negative impact of medical errors on public health care and patient safety. Although the TTP starts and ends with the patient, the increase in Turnaround time (TAT) happens if any error occurs in any phase that is pre-analytical, analytical or post-analytical. In our study we focused mainly on pre- and post-analytical errors.

In this study we observed, pre-analytical errors accounted for 85.51 % and post-analytical errors accounted for 14.49 % out of total errors in both OPD and IPD samples [Table/Fig-1]. Similarly, various studies [1,4,7,8,10] shows pre-analytical errors are responsible for the quality of lab testing. Total frequency (%) of both errors in OPD and IPD samples in this study was accounted to be 53.85 % and 43.72 %, it was found that OPD has higher percent of errors as compared to indoor samples [Table/Fig-2]. Increased errors were observed in OPD samples may be due to increase in patient turnover.

In this study commonly observed pre-analytical error for OPD and IPD samples, frequency of insufficient sample quantity (19.33%, 11.77%) and illegible hand writing (13.49%, 7.02%) is found to be high as compare to others [Table/Fig-3]. Few studies [16,17] proposed that consequences of errors could be life threatening to patients who included insufficient sample quantity and illegible hand writing also.

As per the study done by Lippi et al., [18] various causes

Errors	Total Errors observed (OPD & IPD)	Proportion (%)
Pre-analytical	7344	85.51
Post-analytical	1244	14.49

[Table/Fig-1]: Proportion (%) of total pre- and post-analytical errors observed in both OPD and IPD samples.

Cases	Pre-analytical Errors	Post-analytical Errors	Total	Frequency (%)
OPD	3948	792	4740	53.85
IPD	3396	452	3848	43.72

[Table/Fig-2]: Frequency (%) of total Pre-and Post-analytical errors observed in both OPD and IPD samples.

Errors Observed	OPD (No.)	Frequency (%)	Proportion (%)	IPD (No.)	Frequency (%)	Proportion (%)
Order of blood draw	198	2.08	5.02	NA	NA	NA
Blood vaccutte inversion	158	1.66	4.00	NA	NA	NA
Samples not clotted	71	0.75	1.80	4	0.04	0.12
Quantity not sufficient	1836	19.33	46.50	1118	11.77	32.92
Illegible handwriting	1282	13.49	32.47	667	7.02	19.64
Labeling error	107	1.13	2.71	48	0.51	1.41
Misidentification of patients	8	0.08	0.20	5	0.05	0.15
Misidentification of samples	22	0.23	0.56	NA	NA	NA
Prolonged tourniquet time	8	0.08	0.20	NA	NA	NA
Sample collected without tourniquet	13	0.14	0.33	NA	NA	NA
Transportation error	87	0.92	2.20	86	0.91	2.53
Container inappropriate	12	0.13	0.30	6	0.06	0.18
Wrong/Loose capping on tubes	16	0.17	0.41	14	0.14	0.42
Tests not mentioned	59	0.62	1.49	NA	NA	NA
Sample lost	9	0.09	0.23	5	0.05	0.15
Software problem	30	0.32	0.76	49	0.52	1.44
Repetition of samples	32	0.34	0.81	97	1.02	2.86
Incomplete Test Requisition Form (TRF)	NA	NA	NA	1193	12.56	35.13
Improper mixing of sample	NA	NA	NA	68	0.72	2.00
Loose capping of samples	NA	NA	NA	9	0.09	0.27
Sample collected without proper safety	NA	NA	NA	36	0.38	1.06
Total	3948	41.56	100.00	3396	35.75	100.00

[Table/Fig-3]: Total pre-analytical errors, frequency (%) and proportion (%) were observed for OPD and IPD samples.
*Note: NA-Not Applicable

for insufficient quantity of sample were either weak patients or patients whose veins were thin to localize. Also small children and uncooperative patients did not allow sample collection easily. Additionally in our study one of the causes observed for insufficient quantity of sample was that there is one common collection centre in OPD where samples have to be collected for pathology, biochemistry and microbiology. Moreover, if the number of investigations is more many times it occurs that sample quantity is found less for analysis. Proper training to phlebotomists can minimize such type of error.

Similarly, illegible hand writing is the second highest error observed in our study in OPD and IPD which includes short forms of test names, spelling mistakes, laboratory identification number, overwriting of test name and patients name. All such errors can be easily reduced by using electronic test request or by using barcode system for sample analysis.

In our study this error was observed to be second most common in case of OPD and IPD. Even bar coding connected to patient sample for test could be the ideal method to minimize such errors.

Moreover, incomplete test requisition forms (TRF) which is having frequency of 12.56 % among the errors observed for IPD. Which includes incomplete history, sample analysis priority or not, ward not mentioned, clinician's signature, etc. along with wrong test mentioned it becomes difficult to whom to contact for repeat sample or while reporting results. This adds an extra cost of burden to the institute if sample has to be repeated, patients inconvenience, a delay in the test results and diagnostic treatment. At times during any emergency analysis repeat sample due to such carelessness may cause hindrance in the reporting and required vital treatment which in turn deprives the patient from critical care that may prove life threatening. Many times delay in the reporting was due to new staff unaware of the duty assigned to them.

Increased turnaround time (TAT) was one of the major quality indicator found during the study. Similar type of study on pre- and post-analytical phases was done by Robert Hawkins [19]. Meanwhile if sample is hemolysed or insufficient in quantity (if further test required), we have to wait for repeat sample and its analysis till the patient again comes for collecting his report.

Post-analytical errors observed in this study were common in both OPD and IPD samples [Table/Fig-4]. Frequency of

delay in reporting is more for both OPD and IPD in this study, reason behind it could be that staff on duty did not attach the reports in the proper file due to increased work flow or may be patient is shifted to other wards for other diagnosis. Such type of negligence eventually delayed the treatment process. In present study, transcription error observed was 0.71% and 0.47% respectively in OPD and IPD samples. The reason behind such error was mostly manual entry of some tests which are not done on fully automatic instruments and are not attached to laboratory information system so there is no online reporting system for this test. Such errors can easily be minimized with careful alertness.

Errors Observed	OPD (No.)	Frequency (%)	Proportion (%)	IPD (No.)	Frequency (%)	Proportion (%)
Transcription error	67	0.71	8.46	45	0.47	9.96
Failure of reporting	81	0.85	10.23	52	0.55	11.50
Delay in reporting	566	5.96	71.46	302	3.18	66.81
IT software problem	24	0.25	3.03	17	0.18	3.76
Physician not notified of problem	54	0.57	6.82	36	0.38	7.96
Total	792	8.34	100.00	452	4.76	100.00

[Table/Fig-4]: Post-analytical errors observed during study in OPD and IPD samples.

Sr. No.	Year	Author	Sample Size	Duration of Study	Sector of Laboratory	Error (%)
1	1996	Plebani and Carraro [7]	40490	3 months	Stat laboratory	Pre- 68.2 Post-18.5
2	2006	Carraro and Plebani [10]	51746	3 months	Stat laboratory	Pre- 61.9 Post- 23.1
3	2009	Chawla R et al., [1]	67,438	1 year	Clinical chemistry	Pre- 77.1 Post- 14.9
4	2015	Toshniwal P et al., [17]	9500	6 months	Clinical chemistry	Pre- 77.30 Post- 13.10

[Table/Fig-5]: Frequency (%) of pre and post-analytical errors shown by various authors.

Over all it is observed that in our study pre and post-analytical errors mostly occurred at OPD department [Table/Fig-2] which might be due to centralized collection centre and report distribution as well as daily patient turnover to OPD is more. Similarly, on comparison with other articles [Table/Fig-5] the frequency (%) as observed was similar in range 60-80% for pre-analytical errors and 10-20% for post-analytical errors.

Thus, from the aim of investigating the pre and post-analytical errors we come to the conclusion that mostly all the errors taking place is due to the negligence of human knowledge which can easily be minimized by proper training.

LIMITATIONS

The study was only limited to clinical biochemistry section of CCL; it did not include samples from pathology, microbiology and other sections. Also the study was limited to pre-analytical and post-analytical errors only the analytical errors were not taken in account.

CONCLUSION

This study has been carried out to evaluate the errors that take place while performing test on the patient's sample. All the errors (pre-analytical, analytical or post-analytical) occurring at the different stages of TTP results in increase turnaround time, patient inconvenience , extra work load on staff, extra cost to repeat testing and as a whole significantly affect the patient well being.

From this study laboratory staff and doctors both will get benefit along with patients as former one will not waste time for recollection and repeat analysis and the latter will get accurate reports on time so they can start their treatment towards patients well being.

Though, it is impossible to completely eliminate errors, it is possible to reduce them. Correcting such problems is mainly dependent on increased co-operation between higher management authority, laboratory personnel, paramedical staffs and clinicians and implementing new strategies as well as continuous training programme will surely reduce the errors occurring in such phases.

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