Original Article

Identification of the Types of Pre-analytical Errors in the Clinical Chemistry Laboratory from Jan-2012 to Dec-2012 at Jinnah Hospital, Pathology Department

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ABSTRACT

Objective: To evaluate the leading causes of pre-analytical errors in a clinical chemistry laboratory. **Methods:** A retrospective analysis of the results obtained from the clinical chemistry laboratory for errors in the pre-analytical phase has been carried out to summarize data regarding the frequency of the main factors affecting the pre-analytical quality of results. Laboratory personnel were asked to register rejections, and causes for rejection of ward as well as out-patient samples collected in the laboratory. **Results:** Of the 1,54,554 tubes received during the data collection period, 2505 samples were found unsuitable for further processing. This accounted for 1.52% of all samples collected in the laboratory. Rejections arose as a result of the following reasons: 0.48 % were rejected due to hemolysis; 0.92 % were specimens without proper requisition slips; and 0.14 % had insufficient sample quantity. **Conclusion:** Of all the samples received in the lab, the overall percentage of rejection is 1.62%.

INTRODUCTION

Modern day diagnosis is heavily dependent upon reliable laboratory data. It is therefore pertinent to ensure credibility of the results emanating from the clinical laboratories. Remarkable advances in automation, sample collection, transport, and dispatch of reports have led to a drastic improvement in the performance of these laboratories. But there is long path to tread before we achieve 100% accuracy and precision. Errors arising during sample processing are classified into pre-analytical, analytical, and post-analytical, depending upon their source and time of presentation respectively. The pre-and post-analytical phases of the process account for 93% of errors.[1] The pre-analytical phase comprises all of the processes occurring before the sample is processed in the auto analyzer.[2] These include inappropriate tests that have been ordered, improper sample collection, transport delays, and illegible handwriting on requisition slips.[3,4] Although these areas are beyond the jurisdiction of the clinical laboratory per se, the credibility of the labs is at stake due to these errors.[5,6,7] The labs have to bear the burden of the inconsistencies or incorrect reporting that can ensue because of these pre-analytical errors.[8,9]

The goal of the present paper is to enumerate and analyze the prevalence of different pre-analytical errors that surfaced during sample processing in the clinical biochemistry department during a 1-year period.

Jinnah Hospital is a tertiary care super specialty center in Lahore specializing in cardiology, cardiothoracic surgery, neurology, neurosurgery, gastroenterology, gastro surgery, and psychiatry. Jinnah Hospital is a teaching hospital as well. With 1416 students studying to be doctors at Allama Iqbal Medical College and learning practical procedures at Jinnah Hospital, over 7,000 doctors have graduated from here over the last ten years.

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It is a 1250-bed hospital offering specialized medical and surgical treatment to about an average of patients **700,000** visit the Out-Patient and Emergency Department every year, where 70% of the treatment is given completely free. Every year more than 1,500,000 tests are carried out in Pathology Laboratory

The clinical biochemistry department is equipped with a state-of-the-art autoanalyzer with ISE–Beckman Coulter CX9PRO Clinical System (Hamburg, Germany), electrolyte Plus analyzer–Na/K/Cl,ABG Nova biochemical Analyser, and other ancillaries for sample processing. Inpatient phlebotomies are performed by clinical department staff, whereas blood specimens from outpatients are collected on site at a centralized collection center by laboratory personnel. The samples are delivered to the lab by the paramedical staff from the wards and laboratory support staff from the OPD respectively.

REVIEW OF THE LITERATURE ON LABORATORY ERRORS

Sector of the laboratory	**Lapworth and Teal.[12]**	**Goldschmidt and Lent. [11]**	**M.Pleban.[15]**	**Plebani and Carro.[16]**	**Stahl M et al.[14]**	**Jahangir Kokab and Tariq**	**Ranjan and Binita.[17]**	**Romero and Cobos.[18]**
Sector of the laboratory	**Clinical chemistry**	**Whole laboratory**	**Primary care.**	**Stat laboratory**	**Whole laboratory**	**Clinical chemistry**	**Clinical chemistry**	**Primary care.**
Data collection period	1 year	6 year	6 month	6 month	3 year	1 year	1 year	3 month
No of Patients	997000	ND	160714	ND	ND	154554	96328	52,669
No of errors	120	123	180	189	4135	2505	736	3885
Frequency				0.47 % of patients	0.61% of patients	1. 6% of patients	1.5 %.of patients	7.4% of patientss
Pre-analytical phase	31.6%	53%	55%	55.65	68.2%	0.05%		0.11%of patients

MATERIALS AND METHODS

A total of 1,54554 samples from the outpatient department and in-house patients were received by our clinical chemistry laboratory during the period from January 2012 to December 2012. Out of these, 97,185 samples were collected from the patients admitted in the wards and 57,369 samples were collected in the outpatient department. The samples are collected using evacuated tubes (vacutainers evacuated tubes from BD (Franklin Lakes, NJ). The lab provides routine and reference testing in biochemistry. Upon receiving the samples, the lab supervisor visually detects any problems. When an error occurs, entries are made in the problem notification log book. The data generated is reviewed on a weekly basis. The data collection procedure involved review of blood samples received from the inpatient as well as outpatient departments. Venous blood samples are considered unsuitable according to the following accepted criteria: inappropriate volume, wrong or missing patient identification, inappropriate container, visible hemolysis after centrifugation, and lipemic samples. The pre-analytical variables evaluated included all the criteria mentioned above for sample rejection as well as incomplete/incorrect patient details and illegible handwriting.

RESULTS

We will first discuss the findings of the routine samples obtained from the inpatients in our hospital. Out of the 97,185 blood collection tubes screened over a period of 1 year, pre-analytical errors were observed in 1626 samples, which is approximately 1.6 % of the total number of samples received. The distribution of the different types of errors was then calculated (Table

1). The majority of the rejected samples were hemolyzed. Hemolysis was responsible for rejection of 692 samples, which accounts for 0.71% of the total number of samples received during this period. The amount of blood was insufficient for complete analysis in 0.15 % (i.e., 144out of the 97,185samples).

A total of 687 samples were accompanied by inappropriate slips (i.e., wrong requisition slip, without requisition slip, central registration number ward not mentioned). This comprised approximately 0.70 % of all the samples received by the laboratory. Out of these 203 samples, laboratory personnel managed to ascertain correct patient data in 153 cases, and hence reporting was completed successfully for these patients. Fifty samples could not be processed even after elaborate and painstaking efforts by the laboratory staff. Gross lipemia led to rejection of 103samples (0.10 %).

Similarly, we evaluated the slips obtained from the outpatient department. A total of 57,369 samples were received for processing from our OPD. Out of these, the number of pre-analytical errors documented was 879. This constitutes an error rate of 1.5 %. The distribution of the various pre-analytical variables is depicted in (Table 2). The most frequent error encountered during processing was sample with insufficient information (wrong vial/wrong slip). This constitutes an error rate of 1.28% this led to rejection of 738 samples out 57369 samples. The insufficient volume with an incidence of 0.13 %. Hemolysis, which constituted the most frequent pre-analytical error observed during sample processing of admitted patients, contributed to the rejection of 0.09 % of the samples in OPD as compared to 0.71% in the previous case.

Table-1

Frequency of the Different Preanalytical Errors Observed in a Total of 97,185 Routine Inpatient Samples

Sr. No.	Preanalytical Variable	Frequency
01	Insufficient volume	144(0.15%)
02	Hemolysis	692 (0.71%)
03	Sample with insufficient information (wrong vial/wrong slip)	687 (0.70%)
04	Lipemic samples	103(0.10 %)

Table-2

Preanalytical Errors Observed in a Total of 57,369 Outpatient Samples

Sr. No.	Preanalytical Variable	Frequency
01	Insufficient volume	75(0.13 %)
02	Hemolysis	55(0.09 %)
03	Sample with insufficient information (wrong vial/wrong slip)	738(1.28 %)
04	Lipemic samples	11(0.019%)

DISCUSSION

Advances in science and technology have led to many path-breaking innovations that have transformed laboratory diagnostics from manual, cumbersome testing methods to fully automated science, ensuring accuracy and speed.[1, 2] However, the laboratory cannot function in isolation. It is dependent upon other departments; mainly the clinical division for properly filled requisition slips and samples for analysis.[1, 2]Mounting evidence indicates that reliability cannot be achieved in a clinical laboratory through the mere promotion of accuracy in the analytical phase of the testing process. [3]

It is evident that the majority of all errors in the total testing processing are of pre-analytical origin, i.e. they occur before the sample arrives in the laboratory and the phase after the sample is analyzed (post-analytical) are equally important.[4] The pre-analytical phase is riddled with many shortcomings ranging from lax attitude about filling the requisition slips to the staff's lack of education about ideal phlebotomy procedures. The health care system must be more diligent in applying scientific knowledge to reduce the errors in this phase. This is imperative to curtail the dent on laboratory services that arise due to human errors.

There has been varied information on the error rate within the whole lab testing procedure (0.1% to 9.3%). Plebani and Carraro observed in their paper that the great majority of errors result from problems in the pre-analytical or post-analytical phases.[5]

Pre-analytical errors are largely attributable to human mistakes and the majority of these errors are preventable.[15]This is understandable, since the pre-analytical phase involves much more human handling, compared to the analytical and post-analytical phases. [6]

Hemolysis accounted for the majority of rejections in our study. The introduction of vacuum tubes along

with the closed system of blood collection has made blood collection efficient and easy. But lack of staff training engaged in phlebotomy is an impediment for expediting sample collection and transport. Hemolysis of samples occurs when blood is forced through a fine needle, shaking the tubes vigorously, and centrifuging the sample specimens before clotting is complete.[7] Red top vacutainers without any anticoagulant should not be shaken after the sample has been collected, and vacutainers for plasma should be gently inverted a few times so the anticoagulant mixes with the blood.

Freezing and thawing of blood specimens may cause massive hemolysis. In a study by Jay and colleagues, the majority of hemolyzed samples (>95%) could be attributed to in vitro processes resulting from incorrect sampling procedure or transportation.[8] Hemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of potassium and intracellular enzymes such as SGOT and LDH. It also leads to a prolongated turn around time (TAT) due to the need for fresh samples for processing the request.[9] The frequency of hemolysis was more in the samples that were collected from the admitted patients as compared to the patients attending the OPDs (0.71% as compared to 0.09 %). One plausible explanation for this phenomenon could be the systematic blood collection technique followed by the laboratory staff in the OPD.[10] As a part of our endeavor to achieve accreditation for our laboratory services; we carry out regular in-house training sessions for our technicians to familiarize them with the standard protocols for sample processing. For this purpose, we have developed standard operating procedures (SOPs) for the different steps involved in ideal laboratory operations and ethics. Such training has facilitated in the adoption of ideal phlebotomy practices by our laboratory personnel. The samples are thereby transported to our laboratory from the collection center by our staff following the basic precautions that must be adhered to during transportation. There is an urgent need to instill awareness about the intricacies of a seemingly "easy and basic" activity that forms the mainstay of laboratory services - phlebotomy among the staff engaged in sample collection in our hospitals to reduce inadvertent hemolysis.[11]

Another factor leading to rejection of blood samples in Our study was insufficient blood volume. Every analytical process requires a fixed volume of serum/plasma for analysis. The main reasons behind this anomaly are ignorance of the phlebotomists, difficult sampling as in pediatric patients, patients with chronic, debilitating diseases, and patients on chemotherapy whose thin veins are difficult to localize. Insufficient sample volume constituted the most frequent cause of test rejection in the samples collected in the OPD (1.28%). [12]

Inpatient sampling with a frequency of 0.15 % for inadequate volume only. The difference is striking. This may be attributed to a number of factors. We have a centralized collection center where samples for clinical biochemistry, hematology, microbiology, and gastroenterology are collected simultaneously.[13] Due to the paucity of man power; the ratio of patients to phlebotomists is disproportionate, making sample collection difficult. This may hamper proper sample collection, leading to inadequate collection. The collection is carried out during fixed hours. Hence, this patient load combined with shortage of time may adversely affect proper sample collection in the OPD setting. Difficult sampling and patient non-compliance further aggravates this problem. Nevertheless, it is mandatory for the laboratory staff to practice a certain basic level of workmanship and skillful phlebotomy techniques to reduce such errors to a minimum.[14]

A total of 0.70 % samples in the wards were accompanied by inappropriate requisition slips. The same figure for OPD samples was1.28 %. It has been observed that the clinicians often send incomplete slips with the samples. This could be due to excessive patient load or lack of awareness regarding patient information. Modern day diagnostics is not merely sample processing and preparation of reports. The laboratories are actively involved in disseminating information about critical results to clinicians so corrective measures can be initiated at the earliest. Incomplete/wrong patient information makes the practice redundant. Our laboratory staff could arrange the correct information about some of the patients admitted in the wards through their painstaking efforts. This leads to loss of precious time and is a labor-intensive activity. The same protocol could not be followed for the OPD patients as it was virtually impossible to ascertain the patient/test information from either the clinicians or the patients. We followed a different protocol for these patients. The requisition slips, with an appropriate note citing reasons for

sample rejection, were dispatched to the OPD for the clinicians' knowledge. Those tests were repeated with fresh samples and new requisition slips as and when the patients revisited the hospital for checkup. This is definitely inconvenient for patients, who have to undergo the same process of registration and consequent sampling. Such errors can be completely wiped out by persistence by the laboratories for complete information and sincere efforts by the clinicians to provide the same. This will facilitate speedy sample processing and report dispatch to the patients to initiate therapeutic interventions at the earliest.[15, 16]

Lipemia accounted for rejection of 0.10 % and 0.019 % of the samples in the inpatient and outpatient departments respectively. Lipemic samples can arise due to collection after heavy meals or the presence of some metabolic disorder (hyperlipoproteinemias). This can be avoided by sample collection, preferably after an overnight fast. If the patient has a metabolic disorder, the same must be mentioned in the requisition slip. Lipemia interferes with optical reading by the instrument and can affect interpretation of electrolyte values. A higher incidence of lipemia in OPD patients may be due to non-dissemination of information regarding prior preparation to the patients by the clinicians as well as non-compliance and/or miscomprehension of preparation rules by the patients. Hence, many patients give samples in non-fasting states leading to erroneous reporting. It is the responsibility of the clinicians and the phlebotomists to ensure that proper patient preparation is instituted before sample collection.[17]

These data are comparable to those provided by other investigators, which confirm that problems directly related to specimen collection are the main cause of pre-analytic errors, especially hemolyzed, clotted, insufficient, and incorrect samples.[16, 17]

With the exclusive use of vacutainers, the frequency of errors found in our study is 1.62 %. It is clear from the above discussion that incorrect phlebotomy practices are the main reason behind pre-analytical errors. The reason for incorrect phlebotomy practice includes lack of awareness or possibly a heavy workload. This is the reason phlebotomy has been considered a separate area of improvement for medical technicians in developed Countries. Those of us in developing nations must adopt a similar approach toward phlebotomy and initiate steps for the inculcation of ideal phlebotomy practices among health care workers.[17, 18]

CONCLUSIONS

The concept of total quality management encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians to reduce or eliminate the errors that may arise during the various steps. The promotion of ideal phlebotomy practices and sample transport procedures is a pre-requisite for the efficacy of Laboratory functioning. The dependence on accurate laboratory results for diagnostics makes it mandatory for labs to ensure accountability and accuracy of results to negate incorrect diagnosis as a consequence of faulty reporting. A practice of keeping a record of the errors at all stages of analysis and then devising corrective strategies for their prevention can gradually free a laboratory from such errors.

Errors in the laboratory can lead to inaccurate reports dispatched to clinicians, affecting health care services greatly. Ensuring the credibility of results is of utmost importance. While many clinicians probably believe that most errors in the laboratory are analytical, there are data showing that the pre-analytical and post-analytical phases are the greatest contributors to laboratory mistakes.

Though it is impossible to completely eliminate errors, it is possible to reduce them. We conclude that training of phlebotomists and technicians, bar coding of samples, implementation of a LIS, adoption of standardized procedures along with participation in external quality assessment programs and accreditation schemes can help to reduce laboratory errors to a minimum.

To attain this goal, we first implemented a continued education program, financed by our Regional Health Service and focused in Primary Care Nurses.

REFERENCES

1. Ranjna Chawla, PhD, Binita Goswami, MD, DNB, Devika Tayal, MD, V Mallika, MD.Identification of the Types of Preanalytical Errors in the Clinical Chemistry Laboratory: 1-Year Study at G.B. Pant Hospital. LAB MED. 2010; 41: 89-92.

2. Plebani M, Carraro P. The detection and prevention of errors in laboratory medicine Ann Clin Biochem. 2010; 47: 101-110.
3. Robert Hawkins Managing the Pre- and Post-analytical Phases of the Total Testing Process. Ann Lab Med. 2012; 32: 5-16.
4. Mai M,H. Mansour, Hassan M. E, Azzazy, Steven C. Correction Factors for Estimating Potassium Concentrations in Samples With In Vitro Hemolysis.Clin Chem. 2010; 46: 306–307.
5. Characterization and mathematical correction of hemolysis interference in selected Hitachi 717 assays. Arch Pathol Lab Med. 2010; 133:960–966.
6. Jones BA, Calam RR, Howanitz PJ Chemistry specimen acceptability: A College of American Pathologists Q-Probes study of 453 laboratories. Arch Pathol Lab Med. 2011; 121:19–26.
7. Romero A, Munoz M, Ramos JR, et al. Identification of preanalytical mistakes in the stat section of the clinical laboratory. Clin Chem Lab Med. 2010; 43:974–975.
8. Jones BA, Meier F, Howanitz PJ .Complete blood count specimen acceptability: A College of American Pathologists Q-Probes study of 703 laboratories. Arch Pathol Lab Med. 2012; 119: 203–208.
9. Fidler JR. Task analysis revisited: Refining the phlebotomy technician scope of practice and assessing longitudinal change in competencies. Eval Health Prof. 2007; 30:150–169.
10. Lippi G, Blanckaert N, Bonini P, et al. Causes, consequences, detection and prevention of identification errors in laboratory diagnostics. Clin Chem Lab Med. 2011; 47:143– 153.
11. Goldschmit HMJ, Lent RW. Gross errors and work flow analysis in the clinical laboratory. Klin Biochem Metab 2010; 3:131-140.
12. Lapworth R, Teal TK. Laboratory blunders revisited. Ann C Biochem 2010; 31:78-84.
13. Plebani M, Carraro P. Mistakes in a stat laboratory: type frequency. Clin Chem 2009; 43: 1348-1351.
14. Stahl M, Lund ED, Brandslund I. Reasons for a laboratory's inability to report results for requested analytical tests. Clin Chem 2012; 44:2195-2197.
15. Nutting PA, Main DS, Fischer PM, Stull TM, Pontious M, Seifert M, et al. Problems in laboratory testing in primary care. JAMA 2006; 275:635-639.
16. M. Pleban The detection and prevention of errors in laboratory medicin Ann Clin Biochem, 2010; 47: 101 - 110.
17. Ranjan and Binita. Do we know what inappropriate laboratory utilization is? A systematic review of laboratory clinical audits. JAMA 2011; 280: 550-558.
18. Romero and Cobos. The need for an outcomes research agenda for clinical laboratory testing. JAMA 2010; 280: 565-566.

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