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Spectrum of Laboratory Errors Encountered in the Total Testing Process of a Tertiary Care Teaching Hospital Laboratory

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ABSTRACT

Background: Monitoring laboratory performance continuously is critical for recognizing errors and promoting further improvements in laboratory. This study aimed to review the laboratory errors in the preanalytical, analytical and post analytical phases of testing in a clinical laboratory. **Materials and Methods:** A retrospective and descriptive study was carried out at our clinical chemistry, hematology, immunoassay and coagulation laboratories in CHK - Central laboratory Dr. Ruth K.M Pfau Civil Hospital, Karachi, over a period of 1-year period, from November 2022 to November 2023 and the findings of pre-analytical, analytical and post-analytical errors were analyzed of 413631 samples. **Results:** Errors were detected in 281467 samples out of 413631 samples with total error rate of 68%. Results of the study showed that Preanalytical errors were most common with a frequency of 97.25%, followed by post analytical errors 2.5% and analytical errors 0.25% respectively. **Conclusions:** The study concludes that pre-analytical, analytical, and post analytical errors arising in laboratory not only lead to wrong diagnosis and treatment of patient they also effect the cost, inventory and human resource as well. The results of our study suggest that more efforts are to be made for training of phlebotomy, sample collection and transport of specimens.

INTRODUCTION

Errors encountered during the analysis of patient samples not only hinder the routine activities of a lab, but also create a huge burden of cost with wastage of resources from sample collection tubes to reagents, QC material, calibrators, and most importantly human resources. Statistics provided by The Institute of Medicine (IOM) showed that medical errors contribute to more than 1 million injuries and approximately 44,000–98,000 deaths in hospitals annually [(1)]. The International Organization for Standardization (ISO), has recognized a reasonable definition for laboratory errors as; "a defect occurring at any point from ordering tests to reporting results and appropriately interpreting and reacting on these" [(2)]. Laboratories are so habitual in keeping their routine quality control in check that we tend to forget that most of the errors have already occurred before the sample even reaches out to laboratories. Literature suggests that pre-analytical and post-analytical errors account for 93% of the total errors encountered in the laboratory [(3)]. This study aims to identify the common errors encountered in a tertiary care hospital laboratory of a third-world country, their frequency, and which area of our total testing process we need to work on more for the betterment of our patient services.

MATERIAL AND METHODS

In this study, described the frequency of pre-analytical, analytical, and post-analytical errors observed in our clinical chemistry, hematology, immunoassay, and coagulation laboratories in CHK- Central laboratory of Dr. Ruth K.M Pfau Civil Hospital Karachi for 1 year. The total numbers of samples received were 413631 which had 4762987 tests booked on them. Out of these tests the department of clinical chemistry 3721640, immunoassay 84627, hematology 528477 and coagulation 428243. Our clinical laboratory serves a 1900-bedded tertiary care hospital. Data were collected for all clinical chemistry,

immunoassay, hematology, and coagulation samples during routine hours. Our well-equipped laboratory is staffed by individuals that have undergone mandatory training courses in laboratory techniques. Since our laboratory has undergone accreditation by Pakistan National Accreditation Council (PNAC) for ISO15189 and is licensed by the Sindh Health care commission, our laboratory technical staff is regularly undergoing training sessions. Standard operating procedures (SOPs) for phlebotomy techniques, patient preparation, sample handling, instrument handling, and maintenance, and other aspects of sample processing have been documented and displayed. Sample analysis is performed using two fully automated auto-analyzers – Cobas C501 (Roche-Hitachi) for clinical chemistry, e601 for immunoassay, Sysmex XN-1000 and XP-100 for hematology and Sysmex CS-1600 for coagulation. Although calibration is performed on each lot change and whenever required, the calibration trace is monitored daily. Internal QC is performed 3 times a day. All ancillary equipment such as pipettes, centrifuges, and refrigerators are calibrated by an authorized central agency (PCSIR and Qarshi industries) at regular intervals. Pre-analytical errors are documented in the laboratory after scrutiny of the samples. Pre-analytical errors that we encountered included visible hemolysis after centrifugation, inappropriate volume (deficit in the volume required to perform the analysis), incorrect or missing patient identification, inappropriate container, and lipemic samples. Problems encountered during the analytical phase of sample processing such as non-conformity with QC, and random and systemic errors, are also recorded. Post-analytical errors such as transcription errors and variations in turn-around time (TAT) are documented. All such events were documented in the comments section of the patient's reports.

RESULTS

From November 2022 to November 2023, a total of 413631 routine venous blood specimens were received in the departments of Clinical chemistry, immunoassay, hematology, and coagulation. Errors were detected in 281467 samples, with a total error rate of 68%. Pre-analytical, analytical, and post-analytical phases contributed to 97.25%, 0.25%, and 2.5% of errors, respectively. We found the highest prevalence of errors in the pre-analytical phase, a total of 273457 (in the 1-year observational period (Table 1). The pre-analytical phase accounted for 97.25% of total errors. Hemolysis (31%) was the most common error encountered due to incorrect procedures for sample collection; which included inappropriate gauge selection and forceful emptying of syringe in collection tube, with a total of 87117 samples being affected. The quantity of samples not sufficient was the next most common cause for pre-analytical error (26%). The staff when asked for short draw they replied with patients being hesitant to give samples adequately or encountered the issue in pediatric population. The third most common error was Clotted sample (21%). When this problem was chased it was found that due to shortage of Heparin available as an anticoagulant for ABGs, the House officers and PG trainees were in habit of taking out sodium citrate from the Blue collection tubes. Other common errors were due to samples not being received (14%) after getting booked (e.g. misconception of HbA1c and CBC being done from same sample sent) , errors in the booking of patients, age > 13 years booked in pediatric (house officers use their previously registered User ID of one department in the other department), male patients registered in ob./gyn (house officers use their previously registered User ID of one department in the other department) (1.8%) , and potassium contaminated samples (1.7%) (Sample collected in edta tube would be poured into Li heparin tubes), prolonged turnaround time (a group of samples being booked beforehand and collection done later) and others.(1.2% I/V site contamination, diluted samples and clumps in samples 0.4% each, turbid sample and empty tube 0.3% each and lastly tube broken in centrifuge contributed to 0.0007% of total errors.)

In the analytical phase which contributed 0.25% to the total laboratory errors; the greatest number of errors occurred due to calibration drift which accounted for 0.2% of total analytical errors, other errors were Non-conformity with NC 0.02%, random error 0.01%, reagent contamination 0.004%, probe, lamp or system error contributed to 0.004% and lastly blocked tubing caused 0.008% of total analytical errors.

The post-analytical phase contributed 2.49% total error and included prolonged turnaround time 1.49% and exceeding measuring range 1%.

Table 1

Errors in the CHK-central laboratory and their distribution amongst different phases of the total testing process

Type of error	Frequency	%	Clinical chemistry	Immunoassay	Hematology	Coagulation
Hemolyzed sample	87117	31	79414	2736	-	4967
Insufficient sample	72511	26	30111	2400	-	40000
Turbid/Lipemic sample	938	0.3	919	19	-	
Diluted	1100	0.4	850	50	-	200
Clotted	58286	21	5000	-	25000	28286
clumps	1057	0.4	-	-	1057	-
Incorrect identification	5078	1.8	1269	1269	1269	1271
Empty tube/ wrong tube	980	0.3	900	180	-	-
I/V site contamination	3320	1.2	3200	120	-	-
Tube broke in the centrifuge	20	0.007	15	-	-	5
Sample not received	38200	14	22200	1250	13400	1350
K^+EDTA/K^+oxalate contaminated sample	4850	1.7	4600	250	-	-
Non-conformity with QC	52	0.02	10	2	5	35
Random error	40	0.01	12	4	3	21
Calibration drift	620	0.2	210	20	40	350

Reagent contamination	13	0.004	5	0	1	7
Systemic error: probe, lamp,	12	0.004	3	2	2	5
blocked tubing	23	0.008	4	1	7	11
Transcription errors(exceeding measuring range)	3050	1	2100	150	280	520
Prolonged turnaround time	4200	1.49	150	15	3000	1035
Total errors	281467	100	154781	12442	47873	81870
%	68		55	4	17	29

Figure 1

Contribution of different departments in the workload of venous samples.

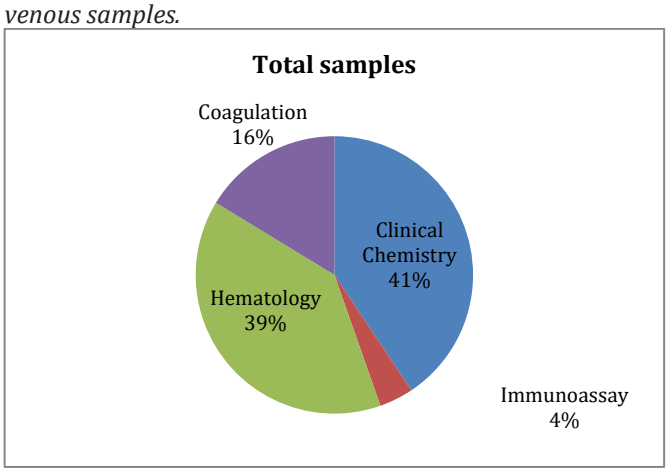


Figure 2

Types of errors and their contribution in the examination phase.

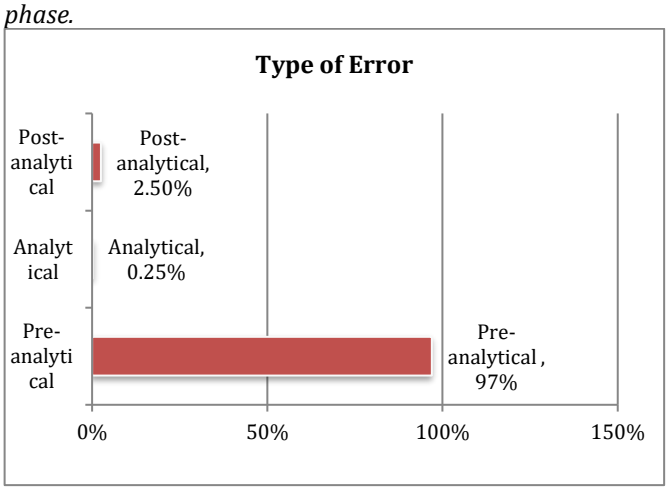
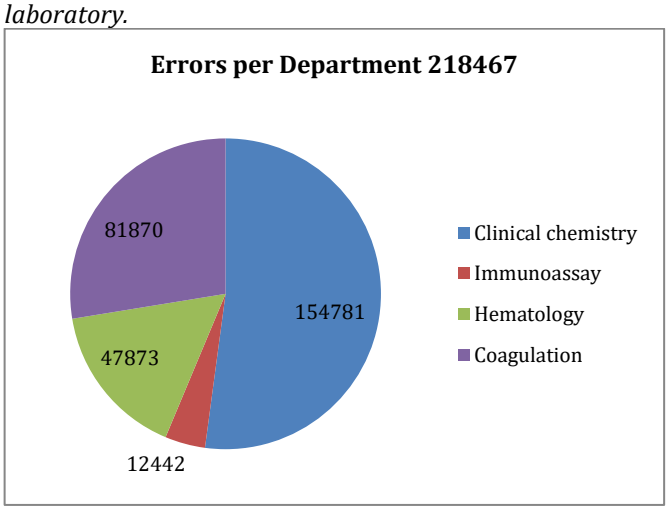


Figure 3

Contribution of departments in total errors of the laboratory.



DISCUSSION

With the strike of covid19 on our healthcare services the laboratory services got their well-deserved recognition as the backbone of the modern healthcare system. Effective laboratory service comprises of a blend of precision, accuracy, and shorter turnaround time with the staff being healthy both mentally and physically while delivering their best efforts to the patient services. Even though we have seen rapid development in laboratory science, it still remains vulnerable to various types of errors. Various types of errors that we, as clinical laboratorians, encounter in the total testing process are classified as pre-analytical, analytical, and post-analytical. These names have been assigned based on when the error actually occurred during the examination process. The contribution of these errors to the total testing process was studied by Plebani and Carraro and established as pre-analytical 68.2%, analytical 13.3%, and post-analytical 18.5% [4]. GIUSEPPE LIPPI et al found that among pre-analytic variables, inappropriate procedures for the collection of venous blood specimens account for 60% of the errors, highlighting the need for more rigid and effective supervision of this pivotal and irreplaceable parts of the diagnostic process [5]. Similar results were derived from a study conducted in Iran Najat D who found the pre-analytical errors to contribute 39% to total errors [6]. A study conducted in Sheikh Zayad hospital Pakistan demonstrated the following results pre-analytical errors (80.95%), analytical (0.80%), and post-analytical (18.25%) (7). Over time the gathered evidence suggests that a large percentage of laboratory errors occur in the pre-and post-analytical steps [8-11]. An observation study that was conducted by the EFLM working group for the pre-analytical phase (WG-PRE) found that errors in phlebotomy had a median error rate of 26.9% [12]. The findings of our study are following this well-established data. A major chunk of error is contributed due to noncompliance with phlebotomy rules and lack of knowledge of a task as simple as the selection of the bore of needles. Considering the setup of our hospital we have found that all wards have their people for blood collection; ranging from phlebotomists to nursing staff, untrained doctors, and paramedics who fail to acknowledge the importance of appropriate sample collection and transport. There is a lack of training for the phlebotomy staff of wards. Multiple training sessions have been conducted by our laboratory as well as other agencies that support our laboratory. However, attendance and interest to take home knowledge regarding phlebotomy are lacking in the nursing and paramedical staff. WHO recommends using 21-23 gauges for routine adult blood sample collection according to the site of sample collection, 22-23 gauges for pediatric, elderly adults or people with smaller and narrower veins, and 23 gauges for neonatal blood

sample collection. 23 gauge to be used with a winged butterfly set [13]. The smaller the bore of the needle, the greater are the chances of hemolysis. Since all our requests are generated electronically we cannot counter-check the identification of samples coming from wards. However, identification is confirmed at our specimen collection unit by 2 identifiers as recommended by CLSI [14]. We know that hemolyzed lipemic and icteric samples result in interference with the analytical measurement of various parameters such as glucose, creatinine, and cholesterol. Along with that the presence of hemolysis or lipemia often results in the generation of a request for a fresh sample to be drawn. However, we do not reject or exclude such samples as it is not possible to keep in mind the precious samples of neonates, pediatric population, and samples from the department of accident and emergency, workload, and waste of resources. Thus, all such reports were released with a note cautioning the interpretation of the test results due to accompanying hemolysis/ icterus/ lipemia and asked for a repeat sample. Internationally too there is wide debate on how to deal with such samples [15]. We also report critical alerts on results exceeding the designed critical values. Our sample repetition rate was 27%, however, a study conducted by Toll A Liu Gulati G et al found that repeated testing for critical values did not offer an advantage or provide additional benefit in hematology and coagulation settings [16]. Hemolyzed samples were the most commonly encountered problem in our laboratory (31%). Of the total samples received in our laboratory in 1 year, 31% were found to be hemolyzed, compared to 53.2% reported by Goswami B. et al [17], 9% by Najat D [6] 9.7% by Nusrat A [18] in a study conducted in tertiary care hospital of Lahore, Pakistan. The next most frequent cause of the error was insufficient sample volume, with a frequency of 26%, Goswami B. et al reported their insufficient sample frequency to be 7.5% whereas Najat D. found it to be 9% and 8.8% by Nusrat A. The third most common error identified was clotted sample with a frequency of 20% where as Najat D. reported it to be 27% [6]. Other types of pre-analytical mistakes reported by our laboratory staff were sample not received 14%, incorrect identification of samples 1.8%, potassium contaminated samples contributed to 1.7%, lipemic samples (0.3%), empty vacutainers (0.3%) and tubes breaking during centrifugation (0.007%). Of the total number of samples received during the year, the observed frequency of incorrect patient identification was 1.8% which had a major contribution from the department of pediatrics for registering children greater than 13 years of age and Ob/gyn registering male patients. Rico et al. reported an error in patient identification contributed 0.08% of their total errors [19]. Automation, training of laboratory personnel and adoption of QC programs has led to an impressive decline in the occurrence of analytical errors [20-22]. We observed a frequency of 0.25% for analytical errors in our clinical laboratory. Goswami B et al noted in their study for it to be 7.9% [17]. These errors were comprised of systemic errors such as malfunctioning of probes, photometric lamps, blockage of tubing, non-conformity with internal QC, random errors due to pipetting difficulties or the analyzer, or related to problems such as calibration drift, and contamination of reagents. Calibration drift was the most frequent analytical error amounting to 0.2%. Next was Non-conformance to NC (0.02%), random errors 0.01%, blocked tubing 0.008, reagent contamination, and systemic errors amounted to 0.004% of the total errors respectively. Sample processing was delayed until the problem was identified and rectified by the service engineer. Random errors due to fibrin clots and other unidentified causes contributed significantly to analytical errors (0.01%). Repeat calibration needed to be performed six hundred and twenty times (0.2%), over and above the routine calibrations that are performed. Calibration of a parameter is considered to be within limits if the optical density (OD) of the reagent and the factor generated following the calibration procedure falls within the range specified by the manufacturer. This can be attributed to inappropriate storage of QC by the laboratory staff, improper handling, or use of expired or contaminated QC materials. Inaccurate results due to reagent contamination were the least frequent error encountered in our laboratory (0.004%). Most of this reagent contamination occurred in coagulation and ISE of clinical chemistry. We have been enrolled in a Proficiency testing program to achieve maximum analytical precision and accuracy and monitor our performance; in Randox International Quality Assurance Scheme (RIQAS) for clinical chemistry, hematology, immunoassay, and coagulation. Results are analyzed as soon as the results are received and any observed shortcomings are addressed on a priority basis and nonconformity generated. This instills a sense of confidence in our staff. In the post-analytical phase, the frequency of errors was 2.49%. Of these, prolonged turnaround time is 1.49%. Rico´s et al. reported that 11% of the samples analyzed could not be delivered within the specified time limit [19]. When it comes to clinicians they are interested in overall service quality encompassing total testing error, cost, availability, timeliness, and relevance [23]. Reduction of TAT should improve the quality of service. Timeliness is most important to the clinician and it is the most judged parameter of a lab report. Timeliness is defined as who may be prepared to sacrifice analytical quality for faster TAT [23,24], but laboratorians prefer to maintain analytical quality as well as reduce TAT. In our setup, the most delay in turnaround time was caused by the samples coming in late after being booked majorly contributed by the wards.

CONCLUSIONS

With the acknowledgment of the role of clinical laboratories in diagnostic medicine has come the cost of greater vigilance and interrogation of laboratory efforts for maintaining and enhancing the quality of services. Errors arising in a laboratory not only lead to wrong diagnoses and treatment of patients but affect the cost, inventory, and human resources as well. If the result of your lab-generated result does not fulfill the expectation of the clinician, they will consider it the error of the laboratory being oblivious to the fact that pre and post-analytical aspects of the total testing process contribute more to the errors. Considering that we cannot eliminate errors; however, it is still in our control to reduce them. The results of our study and the already gathered data suggest that more efforts are to be made for training in

phlebotomy, sample collection, and transport of specimens. Better recording of errors and streamlining the process of non-conformance monitoring.

We would like to further explore the reasons for these errors by proposing to perform evaluation of knowledge of medical students, house officers, postgraduates, consultants, faculty, nursing staff, paramedics, all laboratory staff of their knowledge regarding total testing process with special attention to pre-analytical aspect for non-laboratory staff. We can further conclude that reforms should be made on government level since we are government body that our staff should be sent for external training local /international annually as part of their Annual appraisal /confidential report requirement for greater exposure to healthcare and laboratory setup worldwide. Along with that we need continuing medical education programs in our setup as mandatory requirement.

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