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Factors and preventions of pre-analytical errors in biochemistry laboratory related to healthcare

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ABSTRACT

Introduction: Pre-analytical laboratory errors (LE) are much more susceptible to worries and accidents which can significantly influence patient concern and make a key contribution to the overall risk of error in healthcare.

Aim: The study was conducted for a period of six months in a Department of Biochemistry, Himalayan Institute of Medical Sciences, Dehradun specialized in medicine, surgery, gynecology, pediatrics, ophthalmology, orthopedic, neurology, cancer and psychiatry offering treatment for in- and out-door patients. In total randomly 10000 patients were screened who were only for Biochemistry investigations and tabulated for pre-analytical LE. The study was divided into two parts: (i) related to physiological factors and (ii) patient samples.

Results: The percentages of pre-analytical LE in out-patients were more as compaired to in-patients in related to physiological factors. Errors in patients address were the most common pre-analytical LE followed by clinical informations. It was also observed that in out-patients the location was also an important pre-analytical LE. Transcription errors contributed to the preponderance of pre-analytical LE.

In the patient samples most frequently detected pre-analytical LE were order of collection followed by urine not properly collected as per laboratory standards. Improper mixing with anticoagulant was also identified as an LE.

Conclusions: The majorities of pre-analytical LEs are avoidable by providing clear instruction, regular education, and also regularly controlling all parts of the pre-analytical phase.

KEYWORDS : pre-analytical laboratory errors, biochemistry, diagnostics.

Introduction:

The laboratory services play a key role in hospital caring and its results are involved in the decision-making as they are backbone of the modern health care sector for the diagnostics, follow-up, treatment, clinical monitoring and prevention. So the quality, accuracy, speed of reports delivered and precision of the results are essential in clinical care and all the health care team requires excellent communication and cooperation.

In spite of rapid advances in technology like automation and computerization in biochemistry laboratory, it is still liable to various manual and systemic errors known as laboratory errors (LE) which are defined as "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these". There are whole groups of factors that contribute to LE in the biochemistry laboratories.

The frequency of errors varies greatly, depending on the steps of pre and post analytical steps of the cycle that usually are not under the laboratory control. The most important contributors being pre-analytical LE as these involve numerous steps and various professionals and non-professionals. These pre-analytical LE are defined as the errors related to samples before they are been send to phlebotomy section or at the time of collection.

There are numerous errors in pre-analytical LE which are grouped into two factors (i) physiological factors like requisition slips, illegible hand-writing, order entry mistakes, patients misidentifications, doctors name & signatures, provisional diagnosis, test- profile requests, and (ii) patient samples like samples taken from infusion route or erroneous time, date and time of collection, warnings, inappropriate vials or containers, improper mixing, handling and transport[1].

In few decades a significant decrease in the rates of analytical errors in biochemistry laboratory tests are been observed that may be due to simplifications in the technology and improvements in standardization of techniques[2].

The present study was to examine the biggest factors of biochemistry laboratory errors and improve the quality by decreasing the risk of LE.

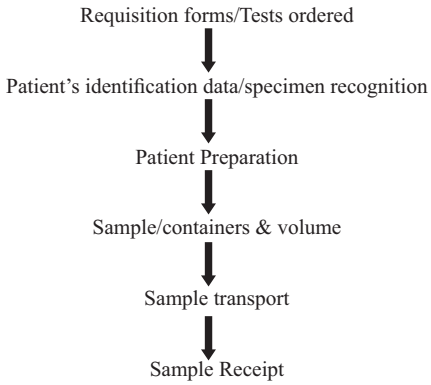
Materials and Methods:

The study was conducted in Department of Biochemistry, Himalayan Institute of Medical Sciences, Dehradun for a period of six months specialized in medicine, surgery, gynecology, pediatrics, ophthalmology, orthopedic, neurology, cancer and psychiatry offering treatment for in- and out-door patients. In total randomly 10000 patients (50% each in and out-door patients) were screened who were only for Biochemistry investigations and tabulated for pre-analytical LE.

The methods were opted with the registration number in the hospital followed by requisition forms from the doctors. The requisition forms were required for patient's identification data which were including name, age, sex, address, hospital patient's number, collection date and time, doctors name with registration number, department & signature, provisional diagnosis, test request and financial payment.

In-patient's phlebotomies were performed by biomedical Scientists –nurses, doctors and health care assistants from different wards of the hospital while out-patient's phlebotomies were collected at collection centre by qualified technicians. Vacuated tubes were used to collect the serum samples for both in- and out-patients. The samples along with detail requisition forms were transported manually by ward staff or relatives of patients to the laboratory. Open collected works approach of specimen collection was used for both inpatients and outpatients by observing manually correct demography of patients, specimen, containers, volume, temperature of transport and time of collection only for Biochemistry investigations. The collection centre was open for 24hrs.

The method opted was:



Results: In total randomly 10000 patients (50% each in and out-door patients) were screened who were only for Biochemistry investigations and tabulated for pre-analytical LE. Each patient was tabulated on different parameters separately which were lacking with related to two factors (i) related to physiological factors-laboratory request forms and (ii) patient samples as shown in Table 1.

Out of 10000 patients the percentage of pre-analytical LE in out-patients (2.89%) was more as compare to in-patients (1.68%) in relation to request forms. Patient address was the most common pre-analytical LE followed by clinical information in both in and out-patients. It was also observed that in out-patients an error related to location (0.49%) was an important pre-analytical LE. Transcription errors contributed to the preponderance of pre-analytical LE.

In the patient samples most frequently detected pre-analytical LE was order of collection (0.30%) followed by urine not being properly collected (0.25%) in out-patients. Improper mixing with anticoagulant was also identified as an error accounting for 0.02%.

Discussion: Use of Biochemistry laboratory test results in diagnostic assessment creation has become an integral part of health care center. More than 60-70% of the most vital decisions on admission, discharge and medication are based on these test results. With this high degree of influence, the trustworthiness of Biochemistry laboratory testing and reporting is of extreme importance. Even though automation, standardization and technological advances have significantly improved the analytical reliability of tests, pre-analytical LE still occur in the process sample collection, analysis and reporting which have a serious impact on diagnosis and treatment of patients [3,4].

The pre-analytical LE consists of the techniques occurring before the sample process for phlebotomy/test. They are beyond the control of Biochemistry laboratory per se, the integrity of the results were at risk due to these pre-analytical LE as reported by other studies [5, 6]. In our study related to physiological factors-laboratory request forms it was observed that almost (65-75%) did not hold necessary information. The numbers of pre-analytical LE in out-patients were double as in-patients which may be due to the lack of knowledge and more patients' input. It was also noted that in some cases of out-patients, patients' relatives had also filled the required forms by just taking help of doctor on phone before bring the patient to hospital which had increased the pre-analytical LE as they may not be familiar to the medical & clinical significance of the required information. For example due to lack of knowledge progesterone test was marked instead of testosterone test. Similar studies were also done by others and reported that 53% forms did not contain satisfactory information[7,8].

It was observed in our study that many times the doctors give oral orders to the nurses/junior staff for investigations which were not correctly/completely followed or understood while preparing written orders for investigation for example a verbal request was done for fasting blood glucose but test was done for random blood glucose or instead of lipid profile- liver function profile was ordered. The relative percentage of error in this phase was suggested to be as high as 84.5% by other studies at different centers[9].

The errors related to the data about patient's age and sex were very high which were necessary to avoid properly interpreting as the normal ranges are different for every age groups between both the sexes. The date of specimen collection was filled in mostly all the requisition forms but very few forms contain the time of specimen collection. Sending in blood sample too early after the administration of a drug can lead falsely high or low values in monitoring. Interpretations of tests like fasting or postprandial glucose test or cortisol were totally reliant on the time of day when the blood was sampled[10].

The patient's addresses and location were neglected (80-85%) which play an important role because if any abnormal reports were observed they had to be brought urgently to the notice of doctors or patients attenders or if the sample is compromised samples i.e fasting samples or early morning samples needed, they had to be informed to correct locations. The address will also help to for speedy sample critical reports to the patients to initiate beneficial interventions at the earliest or for information. Some of the forms (10-15%) were also lacking in signifying whether the sample were from outpatients/inpatients thus preventing the appropriate medical intervention.

A similar study reported that the information regarding the details of treating physician was missing in 61.2% the details of diagnosis was not indicated in 19.1% whereas in 80.9% where the diagnosis was mentioned, 37.3% were in the abbreviated forms. In total of 151 Critical results encountered in their study 19.9% were not communicated to physicians [11,12].

Clinical information was not written or in abbreviated in 75-80% in laboratory request forms. The percentage in out-patients was more than in-patients. These pre-analytical LE were the most common errors as they involve processing the doctors' probable diagnosis correlation with laboratory results. If any critical alerts are observed corrective actions can be initiated which may leads to achieve precious time and intensive activity. When compared to other study from Nigeria our study shows better results in filling clinical informations [13].

Some times urgent/stat tests were also required by the doctor for critical cases/emergencies but the laboratory request forms were not containing any information which were leading to delay collection of specimens, and hence delayed test reports. Similar studies were reported that indicating the urgency/stat will prevent the LE [14,15,16].

It was also observer that patient's samples need special precaution like in cases of positive HIV, Hepatitis B, tuberculosis or any infections, no information was written on the forms (75%) which were also pre-analytical LE. These informations will help to consider the laboratory person for adequate universal safety measures and protection as reported by other study[17].

As regards to inappropriate container only 0.01-0.02% pre-analytical LE was detected in our study but the nature of sample like CSF samples or any other body fluids were high. This information play an important role in analyzing the samples as the methods for both were different.

When quality related to samples collected was considered, only 0.2% of total samples were insufficient in volume but errors related to mixing of samples with anticoagulants had played an important role in pre-analytical LE. Red top vacutainers without any anticoagulant should not be shaken after the sample specimens before clotting was completed and vacutainers for plasma should be gently inverted a few times so that anticoagulants mixes with the blood. Incidences of Hemolysis were almost same (0.01%) in the samples that were collected from in- and out-patients which were similar with other study[18].

It was also observer that the order of collection of samples was not followed which had been one of the major pre-analytical LE in our study, for example the sequence as suggested by National Committee for Clinical Laboratory Standards (NCCLS) is blood culture tubes should be collected first, followed by non-additive tubes, coagulation (buffered sodium citrate anticoagulant) tubes and finally additive tubes in the following order: tubes containing a clot activator, sodium heparin anticoagulant tubes, EDTA anticoagulant tubes, acid citrate dextrose containing tubes and oxalate/fluoride tubes. Disorder blood sample collection can make up a major source of pre-analytical LE as the device for puncturing the tube stopper can become contaminated with stabilizer from the preceding tube as reported by other study[19].

In particular, errors due to the use of incorrect containers or procedures for example from infusion route or excessive aspiration force stress had played an important role in pre-analytical LE errors. Sample taken from close to site of an intravenous infusion may lower the test results for example using of normal saline as an infusing fluid would lead to a lowering of all test results but with sodium and chloride results which are likely to be raised[20].

Improper urine collection had high pre-analytical LE in our study. Out-patients had more percentage than in-patients as urine samples were collected by patients themselves and were not acidified or sent without volume indications which show lower prevalence. Inadequate preservation and/or refrigeration, loss of voided specimens and inclusion of two morning specimens, container types (sterile, with/without preservatives) and collection of the midstream urine sample were the errors[21].

As with any type of laboratory specimen, there are certain criteria that need to be met for proper collection and transportation especially for urine specimens. This will ensure correct stability of the specimen and

more accurate test results. In our study errors related to transport and storage of samples were almost same prevalence (0.01%) from in- and out-patients and were not very high because the laboratory is in the same building of hospital. These data were very less as comparable to other study done in US [22].

Conclusion: Based on our study, major pre-analytical LE are of great apprehension and needs corrective advancement via proper instructive programs to related personnel. These are poorly uneven and needs proper guidelines in nationally and internationally laboratory process.

This study showed that pre-analytical LEs related to physiological factors and patients samples are common in assessed sections. Improper patient identification, absence of doctor name, missing date & time of specimen collection, lack of sender address and clinical data were observed in the forms. Insufficient sample, volume, mixing with anticoagulant was also common LE in the study.

If these errors are unnoticed, that may lead to negative patient outcome. However, a better specimen quality and patient satisfaction are achieved with the high quality personal-based education regarding pre-pre–analytical LE.

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Conflicts of interest: There are no conflicts of interest

Table1:

		Inpatients(5000)		Outpatients(5000)	
A: Related to Physiological factors:					
S.no	Parameters	Number	% from total	Number	% from total
1	Hospital number	528	0.11	1265	0.25
2	Patients name/ illegible handwriting	3	0.01	9	0.01
3	Patients age	1006	0.20	1589	0.32
4	Patients sex	624	0.12	987	0.19
5	Patients address	2120	0.42	3114	0.62
6	Date/Time of specimen collected	1541	0.30	2541	0.51
7	Doctors name with signature or seal	56	0.01	169	0.03
8	Wards or OPD or location	1006	0.20	2471	0.49
9	Clinical informations	1569	0.31	2358	0.47
Total			1.68		2.89
B: Related to Patients sample:					
10	Inappropriate container/wrong slip/form missing	50	0.01	76	0.02
11	Insufficient Volume/ Proper mixing ratio with anticoagulants	60	0.01	95	0.02
12	Urine: not properly collected	542	0.10	1245	0.25
13	Specimen collected from infusion route	59	0.01	2	0.00
14	Hemolysis/clotting/lipamic	56	0.01	68	0.01
15	Transport time delay/Storage/temperature alteration/ payment	65	0.01	659	0.13
Total			0.15		0.43

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