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A study of preanalytical errors in a hospital based clinical biochemistry laboratory and recommendation of required corrective measures

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Abstract

Background & Objective: The errors associated with the total testing process in laboratory, affecting clinical decision making, may occur at the pre-analytical, analytical and post-analytical phase. This study is aimed at finding out the types and frequencies of errors recorded and recommending the corrective measures in pre analytical phase, which accounts for preventable errors significantly.

Materials & Methods: This was a retrospective analysis of errors observed and recorded over 3 months period in clinical biochemistry laboratory at SMIMER hospital, Surat. Data analysis was done on an average of 12680 samples collected and tested. Samples included blood, urine and other fluids. Pre-analytical errors were identified and recorded subsequent to visual inspection of the samples and corresponding request forms by laboratory staff.

Results: Pre-analytical errors were classified as A) inappropriate form (28.24%), B) inappropriate sample (3.52%), C) inappropriate transport (22.16%) and D) inappropriate centrifugation (7.29%). For category A, high error rate for date and time of sample collection (99.97%), provisional diagnosis (99.92%) and physician's detail (100%) were observed. For category B, error rate for insufficient sample volume was 26.38%. For category C, error rate for date and time of sample receipt was 100%. Pre-analytical error rate was highest for samples received from outpatient department (18.37%) and for urine sample (18.61%) comparatively.

Conclusion: Pre-examination errors were high at this study location. Measures aimed at reducing the same and exposure to accreditation are recommended for improved laboratory quality output.

Keywords: Errors in Laboratory Medicine; Clinical Biochemistry Laboratory; Pre-analytical phase; Corrective measures.

Introduction

Laboratory errors may be defined as 'any defect from ordering tests to reporting results and appropriately interpreting and reacting on these.[1] In 1999, the institute of Medicine published the report which suggested that up to 98000 patients die each year in the United States, as a result of preventable medical errors.[2] Laboratory services have a great influence on clinical decision making: 60–70% of the most important decisions on admission, discharge and medication are based on laboratory test results. With this high degree of influence, the quality of laboratory testing and reporting is of utmost importance.[3]

However, the real number of mistakes made in laboratory testing is not fully recognized, because no widespread process is in place to either determine how often mistakes occur or to systematically eliminate sources of errors. Moreover, total testing process is complex, consisting of a series of inter related processes, each involving a series of process steps, every one of which can result in an error.[4]

The total testing process (TTP) is the total process from the ordering of a test to the interpretation of a test result. The TTP starts and ends with the patient, and can sub divided into three distinctive phases: the pre-analytical step, the analytical step and the post-analytical step.[5]

The ISO 15189:2008 standard for laboratory accreditation defines the pre-analytical phase as 'steps starting in chronological order, from the clinician's request and including the examination requisition, preparation of patients, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins. Examination errors include equipment failure, sample mix-ups, interference whereas post-examination errors include systemic review, formatting and interpretation, authorization for release, reporting and transmission of the result and storage of sample of the examination.[6]

The errors associated with the total testing process (TTP) may occur at the pre-examination (46-68%), examination (7-13%) and post-examination phase (19-47%). The pre- and post- examination phases account for upwards of 95% of total errors.[1]

Pre-analytical variables to consider include the following: patient identification, turnaround time, laboratory logs, transcription errors, patient preparation, specimen collection, transport and separation followed by distribution into aliquots. Quality is the conformance to the requirements of users or customers and the satisfaction of their needs and expectation. Total Quality Management (TQM) is a management philosophy and approach that focuses on processes and

their improvement as the means to satisfy customer needs and requirements.[7]

Accreditation is the procedure by which an authoritative body (National Accreditation Board for testing and calibration Laboratories-NABL) gives formal recognition that a body (laboratory) or person (signatory) is competent to carry out specific tasks (scope). It includes accredits to Criteria- ISO/IEC 15189 (includes all those requirements of ISO 9001 relevant to the scope of laboratory.) It assures the client that the procedure and test results are technically valid. It recognizes the technical competence of laboratory staff, endorses that the laboratory operates the management system effectively. Adherence to the quality standards—and participation in accreditation programs that certify the adherence can improve operational efficiency and customer service and reduce rates of laboratory errors.[8] Accreditation is also likely to have spill over effects on the performance of other areas in the health care system. Laboratory-driven improvements can help improve health care management more broadly.[9]

There is abundant scientific literature dealing with increased laboratory quality (mainly analytical), the literature on errors in laboratory medicine is scarce. One reason for this, in addition to the insufficient attention paid to the problems, is the practical difficulty in reporting and measuring the number of errors. So the very aim of this study is to pro-actively look out for the pre analytical errors, recommend the required corrective measures along with its implementation. This study may open up the new dimensions in providing quality laboratory services which will ultimately be beneficial to the patient's health care.

Materials and Methods

The present cross-sectional study involved screening of clinical biochemistry laboratory for the pre analytical errors. The study was conducted from february-2015 to april-2015 at Surat Municipal Institute of Medical Education and Research (SMIMER), Surat, Gujarat, India. The ethical clearance was obtained from the Institutional Ethics Committee (IEC), SMIMER.

SMIMER Hospital Surat has bed capacity of about 750 which is equipped with clinical biochemistry laboratory. The main analyzers operated here are ERBA XL-640 & 300 for routine clinical chemistry. Other equipment in the laboratory include ABL 800 and COMBISYS-II for Arterial Blood Gas and electrolyte analysis, LANDWIND E 60A-ELECTROLITE analyzer[Na/K/Cl], Cobas e-411 for vitamins, Thyroid function tests & fertility profiles and Bio-Rad D10- for Glycated hemoglobin analysis. The Lab provides routine and special tests and it is a part of Christian Medical College (CMC) Vellore External Quality Assurance Scheme (EQAS) for chemistry, immunology, special hormones and HbA1c.

An average of 12680 samples were received and observed over the study period of 3 months. Blood samples were collected by 2 ml & 5 ml syringe and needle in the plain vaccutainers for routine biochemistry tests, in fluoride for estimation of blood sugar and EDTA for HbA1c test, whereas urine, CSF and other fluid were collected in sterilized containers. The ABG samples were being collected in heparinized syringe.

In this study, we monitored the frequency and type of pre-analytical errors by screening all samples received from OPD, IPD and ICU. The OPD samples were collected by on duty laboratory technician, IPD and ICU patients' samples received from the wards were collected by nursing staff before the analytical phase was undertaken. Samples were sorted out at the collection center room no-50. Dedicated technician separate all (Biochemistry, Microbiology, Pathology) laboratories sample and then attendant of each lab will carry the samples to respective laboratory.

The screening for the laboratory errors was based on preparing a predefined classification of the errors which include all possible pre-analytical errors classified in to different categories; sub & sub-sub categories as mentioned in Table 1. The data pertaining to these criteria was developed, recorded and maintained. The error rate was calculated as a % of error observed in total no of samples against total no of samples observed in the lab for the stipulated time.

Table 1: Classification of pre-analytical laboratory errors

No	Type of error	Error	
		Present	Absent
[A]	**Inappropriate Form**		
1	Incomplete Form		
(a)	*Patient information*		
i]	Name		
ii]	Age		
iii]	Gender		
iv]	Registration number		
v]	Ward particulars		
vi]	Date & Time of collection		
(b)	*Physician Information*		
i]	Name		
ii]	Signature		
iii]	Provisional Diagnosis		
2	Blood stain form		
3	Illegible handwriting		
4	Sample without request		
5	Request without sample		
6	Sample & Form Mismatch		
[B]	**Inappropriate Sample**		
1	Improper patient preparation		
2	Insufficient volume		
3	Improperly labeled		
4	Wrong container		
5	Empty container		
6	Hemolysed sample		

7	Lipemic sample		
8	Clotted sample		
9	Broken tube		
[C]	**Inappropriate Transport**		
1	Date & Time of receipt		
2	Faulty transport medium & method		
3	Sample spillage		
4	Incorrect sorting		
5	Forgotten sample		
[D]	**Inappropriate centrifugation**		
1	Inappropriate time		
2	Inappropriate speed		
3	Broken tube		

Results

A prospective study was carried out at Clinical Biochemistry laboratory SMIMER Hospital, Surat, where total 12860 samples were observed for duration of 3 month and the error rates for pre-analytical phase were evaluated as follows.

Table 2: Pre-analytical error rate for different categories

Category of error	Error particulars	Total sample observed	Observed sample with error	Error rate (%)
A	Inappropriate Form	177520	50142	28.24
B	Inappropriate Sample	114120	4026	3.52
C	Inappropriate Transport	63400	14052	22.16
D	Inappropriate Centrifugation	38040	2774	7.29

Table 3: **Pre-analytical errors rate for category A (Inappropriate Forms)**

Category	Error particulars	Total observed sample	Observed sample with error	Error rate (%)
A1ai	Patient Name	12680	8	0.06
A1aii	Patient Age	12680	915	7.21
A1aiii	Patient Gender	12680	3974	31.34
A1aiv	Registration number	12680	2642	20.83
A1av	Ward particulars	12680	2466	19.44
A1avi	Date & Time of collection	12680	12651	99.77
A1bi	Physician name	12680	12680	100
A1bii	Physician Signature	12680	264	2.08
A1biii	Provisional Diagnosis	12680	12671	99.92
A2	Blood stain form	12680	448	3.53
A3	Illegible Handwriting	12680	1385	10.92
A4	Sample without request	12680	9	0.07
A5	Request without sample	12680	20	0.15
A6	Sample & Form mismatch	12680	9	0.07

Table 4: Per-analytical error rate for category B (Inappropriate Sample)

Category	Error particulars	Total observed sample	Observed sample with error	Error rate (%)
B1	Improper patient preparation	12680	22	0.17
B2	Insufficient volume	12680	3345	26.38
B3	Improperly labelled	12680	47	0.37
B4	Wrong container	12680	18	0.14
B5	Empty container	12680	5	0.03
B6	Haemolysed sample	12680	400	3.15
B7	Lipemic sample	12680	182	1.43
B8	Clotted sample	12680	7	0.05
B9	Broken tube	12680	0	0

Table 5: Pre-analytical error rate for category C (Inappropriate Transport)

Category	Error particulars	Total observed sample	Observed sample with error	Error rate (%)
C1	Date & Time of receipt	12680	12680	100
C2	Faulty transport medium & method	12680	1359	10.71
C3	Sample spillage	12680	13	0.10
C4	Incorrect sorting	12680	0	0
C5	Forgotten Sample	12680	0	0

Table 6: Pre-analytical error rate for category D (Inappropriate centrifugation)

Category	Error particulars	Total observed sample	Observed sample with error	Error rate (%)
D1	Inappropriate centrifugation time	12680	1341	10.57
D2	Inappropriate centrifugation speed	12680	1433	11.30
D3	Tube broken	12680	0	0

Table 7: **Pre-analytical error rate according to the ward from which samples received**

Ward particulars	Observed sample	Observed error	Error rate %
OPD	175150	32183	18.37
IPD	201872	36041	17.85
ICU	16058	2770	17.24

Table 8: Pre-analytical error rate according to the type of specimen received

Specimen	Observed sample	Observed error	Error rate %
Blood	386105	69784	18.07
Urine	1612	300	18.61
Fluid	5363	910	16.96

Discussion

Laboratory results play a key role in patient care. It is estimated that around two thirds of important clinical decisions about admission, discharge and medication are based on laboratory test results. Consequently, laboratory testing is also an important source of medical errors that can affect patient safety.[10]

The Pre-analytical phase occurs outside the laboratory, consisting of the selection of appropriate tests on the basis of the clinical question, ordering, collection and handling, transportation and preparation samples to make them suitable for analysis.[3]

To reduce the number of errors in the pre-analytical phase and achieve the standards of high quality, special attention must be devoted to this phase. It is a natural responsibility of the healthcare provider to ensure the accuracy and authenticity of the details of the patient identification and hence this must be done with utmost vigilance making it as less error prone as possible. Further, it is also the direct responsibility of the health functionaries to give the complete information about the presumptive or confirmed diagnosis, in a clear and legible handwriting, avoiding the abbreviations as far as possible. This would justify the relevance of the requested tests and also give a clinical impression to the staff as well as ensure promptness of action.[11]

Pre-analytical error rates in the clinical biochemistry laboratory at the SMIMER Hospital, Surat were classified under the main categories: A) Inappropriate form, B) Inappropriate Sample, C) Inappropriate Transport and D) Inappropriate centrifugation. These were further sub divided in to applicable sub & sub-sub categories.

As per Table 2, the error rate for category [A] was highest 28.24%, followed by 22.16% for category [C], 7.29% for category [D] and 3.52% for category [B].

As per Table 3, category [A] was classified in to six sub categories A_1 to A_6 out of which A_1 was further sub classified in two categories, (a) Patient information and (b) Physician information. The error rate for sub category A1a (Patient information) was found 29.77%. Amongst error defined in patient information, the highest error rate was observed for (A1avi) Date & Time of collection (99.77%). Date & Time are important for the sample handling and processing. Delayed in sample receipt after collection, leads to false low value for certain test like blood glucose (5-7% fall

in an hour). With respect to gender, two persons with similar name can have different gender so one can easily avoid the mix up of sample as well as report released for the sample. In the classification, the error rate for category (A1b), Physician Information, was found to be 67.33%. Further in the sub classification of A1b, the error rate for (A1bi) Physician name and (A1biii) provisional diagnosis were 100% and 99.92%. Provisional diagnosis helps to correlate the clinical condition of patient with results. Further for inappropriate form category, the higher error rate was found for category (A3) Illegible hand writing (10.92%) and (A2) Blood stain form (3.53%). Blood stained forms contaminated by patients' blood carries the risk of infection transmission like HIV & hepatitis. Instances were noted where instead of dedicated person; patients' relatives were given the sample for transport to the lab which also resulted in delay in the sample receipt. To prevent this error it is recommended that sample should be transported by dedicated person from the particular ward.

In a study by Lowell L. Dilworth, Donovan A, McGrowder and Rory K Thompson et al, 30% of errors were associated with the "Inappropriate request Form". In line with laboratory protocol for unlabelled forms, samples that come to the laboratory with errors in forms should normally be discarded. Requesting physician and attending staff responsible for completing request forms should ensure that all relevant data, including appropriate signatures with name are included in order to avoid delays which can prove critical to patient care.[7]

The causes of patient misidentification, a common charting error, involves a physician ordering laboratory tests on the wrong patient, either because the patient gives someone else's identity or because the physician makes mistake while completing the order. Patients with identical names present a unique challenge to acute healthcare settings, a situation particularly relevant in communities where most individual's names are not unique.[12]

Mistakes might also occur as a result of language or communication barriers: names of patients coming from different geographical location might be unfamiliar to the local healthcare personnel and potentially misspelled or misinterpreted, especially when handwritten.[13] To prevent such errors, clinicians must rely on standardized patient wristbands for identification purposes where in identification bands are often affixed to a patient's wrist, bedside or chart.[14] Since most identification errors arise during order entry or patient admission, handwritten entries and small font size should be avoided. Moreover, patient data should be carefully checked for potential duplication (patient name and codes). If feasible, computerized physician order entry should be preferred and system of alerts should be made available to warn about potential duplication of data (patients name and /or codes). Barcode data entry can be used for recording patient's data on admission, for safe collection and labelling of the specimens and for entering results in the LIS.[15]

As per Table 4, Category (B) Inappropriate Sample was further sub classified in categories B1 to B9. The error rate for the category [B] recorded was 3.52% out of which the highest error rate was observed for (B2) insufficient volume. Every analytical process requires a fixed volume of serum/ plasma for analysis. The main reasons observed for this anomaly were ignorance of the phlebotomists, difficult sampling as in paediatric patients, patient with chronic, debilitating disease, and patients on chemotherapy whose thin veins were difficult to localize.[16] To prevent this error the technical staff should be educated to uniformly fill sufficient volume of approximately 3-5 ml in the tubes and in case of paediatrics patients, the use of tuberculin-syringe must be advocated.

The error rate for sub category (B6) Haemolysed sample was 3.15%. Instances such as forcing blood through a fine needle, vigorous shaking of sample tubes, forceful transfer of blood samples from syringe to container and centrifugation of the samples before clotting is complete, were observed. For this we recommend that red top vaccutainers without any anticoagulant should not be shaken after the sample has been collected, vaccutainers for plasma should be gently inverted a few times so the anticoagulant mixes with the blood. We also recommended collecting the blood with evacuated system which could nullify the collection associated haemolysis, and educate the technical staff about proper method of blood collection.

The error rate for sub category (B7) lipemic sample was 1.44%. Lipemic samples can arise due to collection after heavy meals or the presence of some metabolic disorder (hyperlipoproteinemias). Lipemia interferes with optical reading by the instrument and can affect interpretation of electrolyte values. This can be avoided by adequately educating patients for fasting before collecting sample. If a patient has a metabolic disorder, the same must be mentioned in the requisition slip.[17]

The error rate for sub category (B3) inappropriately labelled was 0.37%. Phlebotomists and nurses should be educated regarding the proper policy and procedure for blood collection. Whoever draws the direction blood, he/she must label the tube at the patient's bedside without taking the tube away from the patient's bedside.[18] Error rate for category (B4) wrong container & (B8) clotted sample were respectively 0.14 & 0.06%. Generally for routine chemistry serum sample required but for Blood Gas analysis the sample is collected in syringe flushed with anticoagulant heparin. Because of the faulty transport method, ABG samples were not received in time so clotted samples were received only to get rejected.

In the study carried out by the Chemical Pathology laboratory at the University Hospital of the West Indies, sample denoted as "Inappropriate Sample" accounted almost 60% of all pre-analytical errors over three year

study time frame. In our study "Inappropriate Sample" error accounted for 3.52% of all pre-analytical errors over the study period. Due to the paucity of manpower, the disproportionate ratio of patient to phlebotomists made sample collection difficult, leading to inadequate collection.[1]

As per Table 5, the error rate for category [C] inappropriate transport was 22.16%. Inappropriate transport error was further sub classified in five categories C1 to C5. In this category the highest error rate was noted for sub category (C1) date and time of receipt (100%). To reduce such errors, we recommend that primary samples received shall be recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt of sample in the laboratory and identity of the receiving officer shall also be recorded. The error rate for (C2) faulty transport medium and method was 10.27%. In biochemistry laboratory, ABG samples were received by faulty transport method. At times it was observed that patient's relatives brought the ABG sample instead of ward boy or dedicated person. On several occasions, when ABG samples brought by patients' relative were not along with ice pack, as they would deliver ABG sample and ice pack by holding them in separate hand. Also on some occasions, venous blood was taken instead of arterial and without mentioning time of collection. Error rate for category (C3) sample spillage was 0.10%. The spillage could be due to loosening of the tube stopper during transport, resulting in loss of sample or inadequate sample volume.

The ISO 15189 standard states that the laboratory must monitor the transport of samples to the laboratory so that they arrive within an appropriate time frame and temperature in a manner that safety of all persons involved in transportation is ensured, and in accordance with all national and international regulations.[19]

Sources of error in the collection and handling of blood gas specimens include the collection device, form and concentration of heparin used for anticoagulation, speed of syringe filling, maintenance of the anaerobic environment, mixing of the sample to ensure dissolution and distribution of the heparin, as well as transport and storage time before analysis. While both dry (lyophilized) and liquid heparin are acceptable anticoagulants, the liquid form is not recommended because excessive amounts can dilute the sample and possibly contaminate the sample if equilibrated with room air. Once drawn, the blood in the syringe must be mixed thoroughly with the heparin to prevent micro clots formation. Adequate mixing is again important to re suspend the settled cells immediately before the sample is analysed. Maintenance of an anaerobic environment is critical to correct results. Any air trapped in the syringe during the draw should be immediately expelled at the completion of the draw. Transport time prior to analysis should be minimal to reduce cell metabolism, which results in oxygen and glucose consumption and carbon dioxide and lactate production. Placing the filled syringe in ice-water slurry immediately after the draw minimizes metabolism. In addition, lower temperatures cause increased oxygen solubility in blood and a self-shift in the oxyhemoglobin curve resulting in more oxygen combining with haemoglobin. The best practice in avoiding many of the pre-analytical errors is to analyse the sample as quickly as possible. The CLSI guideline advocate samples should be kept at room temperature and analysed in less than 30 minutes. Because sample procurement and handling are the source of many possible errors in blood gas analysis, it is necessary that procedures and policies are carefully constructed and its adherence is monitored to ensure quality.[20]

As per Table 6, the error rate for category [D] inappropriate centrifugation was 7.29%. Inappropriate centrifugation was further classified in three category (D1) incorrect time, (D2), incorrect speed and (D3) Broken tube. Amongst three sub categories, the highest error rate was observed for (D2) incorrect speed (11.30%) and the error rate for category (D1) incorrect time was 10.58%. There was no instance of broken tube during centrifugation. It was observed that due to high rush of the samples during peak hours and availability of less tube capacity centrifuge, the process of centrifugation was carried out at around 5000 rpm for short duration.

For the blood (serum) specimen by NCCLS standard H18-A, the speed of centrifugation should be 1000 to 1200 rpm and time 5 to 10 min.[5] we also recommend to use high capacity centrifuge cope up the high sample load.

As per Table 7, when analysed the error rates, it was observed that error rate for samples received from OPD (18.37%) was higher than IPD (17.80%). Further amongst inpatient department marginally high error rate was found for ICU samples (17.5%) compared to general ward samples (17.24%). The reason for comparative higher error rate for outpatient seemed the lack of adequate technical staff to cope up the load. We recommend in order to improve this vital error rate adequate staff should be ensured & revised time to time at blood collection centre.

As per Table 8, when analysed the error rate, it was observed that amongst the various samples received, error rate was highest for urine samples (18.61%) against blood samples (18.07%) & fluids (16.96%). This was unexpected based on the assumptions that the high error rate coincides with high no sample received for particular sample type.

The present study has reflected the various pre-analytical factors playing their role which might well affect the final outcome of the laboratory results. By pointing out the various errors related to pre-analytical phase of total testing process and recommending required corrective measures one can improve the

outcome of the laboratory results and their by patient care.

Conclusion

In present study pre-analytical error rates were analysed for the samples received at clinical biochemistry laboratory, SMIMER, Surat for the period of three month. 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. It is mandatory for labs to ensure accountability and accuracy of results to negate incorrect diagnosis as a consequence of faulty reporting. The practice of keeping a record of the errors at all stages of analysis and then devising corrective strategies for their prevention can gradually make laboratory free from such errors. To conclude, it would be apt to state that, there is a definite need for an approach toward laboratory diagnosis and function in concert with the clinicians to provide effective services to the patients at SMIMER, Surat. Adoption of quality control in all the phase and not merely the analytical process and regular appraisal and audits are necessary to safeguard patient interests and deliver our services to society.

Conflict of interests: None to declare

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