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Original Research Article

Estimation of Pre-Analytical Errors in Biochemical Analysis of Blood Specimen at Tertiary Care Center

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Abstract

Background & Objectives: In health care laboratories most errors occur in the pre-analytical phase which account for 70% of the total errors. This study was conducted to estimate the frequency and type of pre-analytical errors and to determine the frequency of blood specimen rejection and its reasons.

Material and Methods: Current study was a prospective observational study. Total of 15,24,751 samples were collected. Out of these 1,80,952 samples were collected from OPD and 13,43,799 samples were collected from indoor patients. Following categories of pre-analytical data were collected for study period: 1. Quantity insufficient 2. Lipemic specimens 3.NDF: No data found 4. Fibrin clot 5. Hemolysed specimen 6. Autolysed specimen and others.

Results: Out of 15,24,751 samples collected pre-analytical errors were observed in 29,033 samples, which is approximately 1.91%. A major cause of rejection was quantity insufficient.

Conclusion: 1.In our study rejection rate of specimen due to pre-analytical error is around 2%. 2. Major causes of rejection in our laboratory in decreasing order are: a) Quantity Insufficient b) Fibrin Clot c) No Data Found d) Hemolysis and others. 3. Rejection rate of IPD specimen is 1.91% and that of OPD specimen is 1.83%. 4. It is seen that the rejection rate is greater in months of November, December, April, May and June which can be probably due to joining of new junior resident doctors and interns. Corrective actions based on the outcome of Pre Analytical Quality Indicators will be beneficial for patient care service.

Keywords: Pre-Analytical Errors, Biochemical Analysis, Autolysed Specimen, Hemolysis, Quality.

Introduction

The domain of medical laboratories is the performance of diagnostic analysis. As such, the adequate sample, its transport and storage were always part of the diagnostic procedure. [1] Total testing process (or total testing cycle) is based on the original brain-to-brain loop concept described by Lundberg. He outlined a series of activities, starting with the clinical question in the clinician's mind, leading to test selection, sample collection, transport to the laboratory, analysis, reporting back to clinician, and final interpretation and decision making by the clinicians. [2] Laboratory testing consist of three phases: pre-analytical, analytical, post-analytical. [3] Pre-analytical phase as a whole is concerned with ensuring that the right patient gets the right test at the right time. [4] Analytical phase is concerned with getting the right result and post-analytical works to ensure the right interpretation of the result, so that the right decision is made, and that the right action is taken with the overall objectives of obtaining the best outcome for patients. [4]

70% of total errors within the entire diagnostic process occur in pre-analytical phase.[(3)] Pre-analytical phase which can lead to errors are- patient identification and preparation, selecting the site and site preparation for phlebotomy technique, order of draw, proper tube mixing, correct specimen volume, specimen handling and processing and specimen transport. [5] This study was conducted with the aim

to enumerate the different errors and its frequency taking place in the pre-analytical phase, so that corrective measures can be taken to remove them.

Material and Methods

Current study was a prospective observational study, carried out in tertiary care teaching hospital. Duration of the study was one year, from 1/11/2017 to 31/10/2018. All samples received during this period in Biochemistry Central Clinical Laboratory (CCL) on daily basis for routine test analysis were included. Total of 15,24,751 samples were collected, out of these 1, 80,952 samples were collected from OPD and 13,43,799 samples were collected from indoor patients. Venous blood sample was included in the study. On daily basis number of specimen processed and those rejected were collected from HIMS (Health Management Information System). Following categories of pre-analytical data were available for study period: 1. Quantity Insufficient 2. Lipemic specimens 3. NDF: No data found 4. Fibrin clot 5. Hemolysed specimen 6.Autolysed specimen 7.Wrong information 8.Other reasons for rejection include: Wrong container, blank tube without blood sample, contaminated specimen, specimen getting absorbed by the cotton used to cover the tube.

Results

In this study 15,24,751 samples were analyzed for a period of 1 year. Out of 13,43,799 in-patient samples collected, pre-analytical errors were observed in 25,708 samples; which was approximately 1.91% of the total blood samples received. Similarly, for the samples collected from the OPD, out of 1,80,952 samples, 3325 samples were rejected which accounted for rejection rate of 1.83% of total samples received. The different types of errors were also screened and their distribution was calculated. The primary cause of overall rejection rate in our laboratory is due to quantity insufficient i.e.36%. Rejection rate is 36.19% in IPD and 35.15% in OPD samples. Next cause of rejection was NDF (no data found). This accounts for rejection of 35.5% specimen from OPD and 21.24% from IPD samples with overall laboratory rejection rate of 22.87%. Third most common cause of rejection is hemolysis with rejection rate of 19.6% i.e. 5680 samples were hemolysed. Rejection rate in OPD samples was 5.17% and in IPD samples was 21.42% of the total sample rejected. Another cause of rejection of samples was due to fibrin clot with overall rejection rate of 10.58%. Rate of rejection due to other reasons is 6.64% and 7% in OPD and IPD samples respectively. Autolysed specimen whose rejection rate is higher in IPD samples (1.95%) than OPD samples (0.06%) and the main cause of it is delayed processing. Wrong information rejection rate is much greater in OPD (4.75%) than IPD (1.04%). Lipemic specimen rejection rate was higher OPD (2.43%) than in IPD samples (0.58%). (Table 1)

Month-wise sample rejection rate was studied. It is seen that the rejection rate was greater in months of November (2.55%), December (2.11%), April (2.54%), May (2.03%) and June (2.28%). (Table 2)

Table 1: No. of specimen rejected among OPD and IPD

Parameter	No. of specimen rejected					
	OPD	%	IPD	%	OPD+IPD	%
Hemolysis	172	5.17	5508	21.42	5680	19.6
Lipemic	81	2.43	149	0.58	230	0.8
Insufficient	1169	35.15	9305	36.19	10474	36
Autolysed	2	0.06	503	1.95	505	1.73
Fibrin clot	341	10.25	2733	10.6	3074	10.58
No data found	1181	35.5	5461	21.24	6642	22.87
Wrong information	158	4.75	269	1.04	427	1.47
Others	221	6.64	1780	7	2001	6.89
Total	3325		25708		29033	

Table 2: Rejection rate distribution among different months

Month	Total specimen received	Total specimen rejected	Rejection rate	Month	Total specimen received	Total specimen rejected	Rejection rate
NOV	126682	3235	2.55	**MAY**	136831	2789	2.03
DEC	126842	2683	2.11	**JUNE**	123356	2820	2.28
JAN	130994	2205	1.68	**JULY**	129187	2209	1.7
FEB	128007	1731	1.35	**AUG**	128592	2010	1.56
MAR	137674	1965	1.42	**SEPT**	117408	2063	1.75
APRIL	120889	3078	2.54	**OCT**	118289	2245	1.89
				Total	1524751	29033	1.9

Discussion

Advances in science and technology have led to many innovations that have transformed laboratory diagnostics from manual testing to the highly sophisticated methods, ensuring accuracy and speed. [1] However, the laboratory is dependent upon other departments, mainly the clinical division for proper online orders and samples for analysis. Evidence indicates that reliability cannot be achieved in laboratory through mere promotion of accuracy in the analytical phase of total testing process. [5] The phases before the sample reaches the laboratory (pre-analytical) and the phase after the sample is analyzed (post-analytical) are equally important.

Currently, the pre-analytical errors accounts up to 70% of all errors made in laboratory diagnostics. Majority of these errors arise from problems in patient preparation, sample collection, transportation, storage, and preparation for analysis.

In our research, we have studied the pre-analytical errors in two different categories of samples, samples from indoor patients, and sample collected from OPD. Pre-analytical errors were more common in IPD sample collection, where usually nurses and paramedical staff collected samples, many of whom were not aware of the importance of collection of samples by correct techniques. Rotational duties, excessive workload and variety of workload were the main reasons behind no data found (NDF), wrong information or wrong bulb for sample collection.

The primary cause of overall rejection rate in our laboratory is due to quantity insufficient i.e., 36%. Rejection rate is 36.19% in IPD and 35.15% in OPD. The main reason for this can be as follows: 1. Nurses and paramedical staff collect samples, many of whom did not recognize/ were not aware of the importance of collection of samples by correct techniques. [1] 2. Rotational duties changing the technicians. [1] 3. Excessive workload and variety of workload. [1] 4. Difficult sampling as in [5] a) Pediatric patients b) Patients with chronic debilitating diseases c) Patients on chemotherapy whose thin veins are difficult to localize 5. Tube broken/Spillage [6] 6. No time for clot retraction [6] 7. Repeated sampling from patients who are admitted to ward for longer period of time for treatment of chronic diseases or repeated sampling in less volume of time.

Next cause of rejection was NDF i.e. no online request placed for that sample. This accounts for rejection of 35.5% specimen from OPD and 21.24% from IPD with laboratory rejection rate of 22.87%. The rejection rate was greater among the OPD patients than that of IPD.

These tests were repeated with fresh samples and new online request when the patients re-visited the hospital for checkup. This was definitely inconvenient for patients, who had to undergo the same process of registration and consequent sampling. Reasons behind greater rejection rate in OPD are: a. It is due to excessive patient load during OPD hours b. Paucity of manpower c. Lack of awareness regarding patient information and online order placement.

Third most common cause of rejection was hemolysis with rejection rate of 19.6% i.e. 5680 samples were hemolysed out of 29033 rejected samples. Rejection rate in OPD was 5.17% and in IPD was 21.42% of the total sample rejected.

So, in the current study the rejection rate of IPD was higher than of OPD due to hemolysis. The possible reasons for higher rejection rate among the IPD specimens are [7] 1. An improper choice in the venepuncture site such as drawing from a distal site to the antecubital region of the arm rather than drawing from an antecubital site. 2. The use of intravenous catheters and the vacuum sampling technique have often been demonstrated to provoke hemolysis. 3. Prolonged tourniquet time causes the interstitial fluid to leak into the tissue and cause haemolysis. 4. Cleansing the venepuncture site with alcohol and not allowing the site to dry may cause haemolysis. 5. The use of a small-bore needle resulting in a large vacuum force applied to the blood may cause shear stress on the red blood cells causing them to rupture. The use of a very large bore needle may result in a much faster and more forceful flow of blood through the needle resulting in haemolysis. 6. Under filling of tubes and excessive shaking of specimens. 7. When centrifugation lasts too long or is done repeatedly. 8. Pneumatic tube system (PTS)-transported samples tend to be more strongly affected by hemolysis compared to hand-carried ones.

Another cause of rejection of sample in our laboratory was due to fibrin clot with rejection rate of 10.25% and 10.6% in OPD and IPD respectively. The rejection rate is higher among IPD specimen than OPD specimen. Common reasons for Fibrin Clot specimen are:

a. short lag period between the blood collection process and centrifugation step. The mean time between blood collection and centrifugation is usually 10 minutes. To prevent the formation of fibrin, use of rapid serum tubes (RST), which accelerates coagulation, reduces sample processing time and increases serum quality, suitable especially for emergency departments and ICUs. b. Another Major cause of fibrin clotted samples is probably due to poor mixing after blood collection and leaving the tubes horizontally instead of keeping them vertical. All diagnostic blood specimens collected in vacuum tubes are recommended to be inverted gently several times by all vacuum tubes

manufacturers' datasheets and Clinical Laboratory Standards Institute (CLSI) documents to maximize the contact between blood and additives following blood collection. [8] c. Overfilling of tubes d. If the patient is on dialysis or on anticoagulant therapy. [6]

Next cause of rejection rate was other reasons 1. Wrong container, 2. Blank tube without blood sample, 3. Contaminated specimen, 4. Specimen getting absorbed by the cotton used to cover the tube. Its rejection rate was almost similar in OPD and IPD with rejection rate of 6.64% and 7% respectively.

After this comes autolysed specimen whose rejection rate was higher in IPD than OPD. The main cause of it is delayed processing i.e. forgotten sample that stayed for overnight at collection site sample especially during summer season. Wrong information rejection rate was much greater in OPD than IPD. Reasons for higher rejection rate in OPD are: a. It is due to excessive patient load during OPD hours, b. Paucity of manpower, c. Lack of awareness regarding patient information.

Lipemic specimen rejection rate was higher in OPD than IPD is due to inadequate preparation of patient.

Conclusion

1. Pre-analytical error is major cause of rejection of specimens in all laboratories. In our study rejection rate of specimen due to pre-analytical errors was 2% of the all collected samples. 2. Major causes of rejection in our laboratory in decreasing order were: a) quantity insufficient b) fibrin clot c) no data found d) hemolysis e) other reasons f) wrong numbering g) autolysed specimen h) lipemic specimen 3. Rejection rate of IPD specimen is 1.91% which is slightly greater than that of OPD with a rejection rate of 1.83%. 4. Higher rejection rate in IPD can be probably due to nurses and paramedical staff collect samples, many of whom are not aware of the importance of collection of samples by correct techniques. 5. It is seen that the rejection rate is greater in months of November, December, April, May and June which can be probably due to joining of new interns and junior resident doctors. Corrective actions based on the outcome of 'Pre Analytical Quality Indicators' will be beneficial for patient care service.

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