

TYPES OF PRE-ANALYTICAL ERRORS IN CLINICAL HEMATOLOGY LABORATORY

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ABSTRACT:Background:Since, clinical laboratory results play an important role in patient's diagnosis, investigation and treatment. Thus, errors with laboratory tests might lead to inappropriate medical decision-making. Such errors can be pre-analytical, analytical, and/or post-analytical errors. However, the vast majority of errors arise during manually intensive pre-analytical phase and more than 90% of errors occurred at the process outside the walls of the laboratory. This study aimed to assess the number of the frequency of pre-analytical errors occurring in a hematology laboratory at Hera'a General Hospital. **Method:**this study was a retrospective one and carried out in hematology lab at Hera'a General Hospital from January 2016 to December 2016. All samples received during this period in hematology lab were included. **Results:** total samples received in hematology lab were 110240 during the study period, out of which 2256 were rejected. The most frequent pre-analytical error was the clotted blood samples with 79%. The second most common cause was the haemolysed samples (9%), followed by insufficient blood volume (8%). This study also showed that the lowest cause for rejection was reported with the incomplete request. Moreover, the highest specimen rejection percentage was observed in intensive care unit. **Discussion:**the accurate laboratory results are vital for patient health. Thus, quality improvement in patients safety and healthcare would be improved with daily registration of pre-analytical errors occurring in the lab, proper sampling procedure training and education to all staff, coordination between lab and the hospital ward staff and computerization of the laboratory.

KEYWORDS:Pre-analytical, Laboratory errors, Hematology Laboratory, Rejections.

INTRODUCTION:

The clinical laboratory results play an important role in patient's diagnosis, investigation, treatment and management¹. Data has been revealed that more than 70% of physician's decisions are based on the laboratory test results². Thus, errors at the clinical laboratory tests might lead to inappropriate medical decision-making³. Such errors can be generated as a result of poor standardization, mishandled procedures and lack of good practice guidelines during sample processing including pre-analytical, analytical, and post-

analytical phase. The pre-analytical stage includes all steps in the process prior to the analytic phase of testing, starting with the physician's order, while the post-analytical includes all steps in the process between completion of the analytic phase of testing and results receipt by the requesting physician⁴. There are several studies that have suggested that the vast majority of errors arise during the manually intensive pre-analytical phase³⁻⁵. In addition, more than 90% of errors occurred at the process outside the walls of the laboratory^{4, 6, 7}.

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The significant reduction in the analytical error rate has been reported with 10-fold as a result of improvements in the standardization and reliability of analytical techniques, reagents, and instrumentation⁸. Although, the remarkable advances and the automated haematological analysers in hematology laboratories still there are incorrect test results as well as many variables, which can influence the accuracy and precision of the lab results⁹. In 2013, Upreti and colleagues have reported that incorrect filling of forms (wrong names or IDs) as the most common cause of sample rejection at hematology labs¹⁰. Another study showed statistically significant differences for hemoglobin measurements after a mean time of 2.30 +/- 0.12 tourniquet holding⁵.

The types of error in the pre-analytical phase seem to be varying in different department even at the similar clinical laboratories. Pre-analytical laboratory errors directly lead to serious hazard for patient's health, decreased patient satisfaction and increased healthcare costs^{11,12}. In general, to reduce laboratory errors, measuring and managing of the pre-analytical critical errors within clinical laboratories are required through the investigation of any possible defect within this phase which might have a negative impact on the patient care and diagnosis⁹. Thus the aim of this study was to assess the number of the frequency of pre-analytical errors occurring in a hematology laboratory at Hera'a General Hospital in Makkah.

MATERIAL AND METHODS:

This study was a retrospective one and it was carried out in hematology lab at Hera'a General Hospital at Makkah, Saudi Arabia. Duration of study was one year, from January 2016 to December 2016. All samples received during this period in hematology lab were included. In patient department (IPD) samples were collected in wards, Emergency (ER), Intensive Care Unit (ICU), Male Medicine ward (MMW), Female Medicine ward (FMW), Male surgery ward (MSW), Female surgery ward (FSW), Pediatric

ward (PW), Pediatric Intensive Care Unit (PICU), Nursery Intensive Care Unit (NICU), Obstetric gynecology (OB) and Labor ward (LW) and transported to IPD sample collection Centre by attendants of the respective wards. While, outpatient department (OPD) samples were collected then centralized for different sections of central laboratory, like hematology lab for analysis. Upon sample receiving, the department's supervisor visually detects any problems such as inadequate amount of sample. Laboratory personnel were asked to register rejections, and causes for rejection in the problem notification log book if there is any pre-analytical error occurs. The data generated was reviewed on a weekly basis.

Errors of the pre-analytical phase have been identified as incomplete patients data on request, quantity not sufficient (QNS), clotted, visible hemolysis after centrifugation, mismatch, wrong tube and other including lost and leakage sample. The frequency of the main factors affecting the pre-analytical quality of results was calculated. Data was analyzed statistically using SPSS version 19.

Study's proposal was approved by the Research Ethical Committee of the Health affairs and Committee of the Hera'a General Hospital in Makkah

RESULTS:

Total samples received in hematology lab were 110240 from the patients admitted in the wards as well as outpatient department during the study period, out of which 2256 were rejected. This accounted for 2.05% of all samples collected in the hematology laboratory (Table 1). Blood samples were considered unsuitable for haematological investigations for the following reasons; incomplete patients data on request, quantity not sufficient (QNS), clotted, visible haemolysis, mismatch, wrong tube and other.

The most frequent pre-analytical error encountered was that the clotted blood samples from admitted patients and outpatient department with 79%. The second most common cause was the haemolysed samples (9%), followed by insufficient blood volume (8%). Other causes have been given in the table (Table 2). On the other hand, the lowest cause for rejection was

reported with the incomplete request with 0.1% (Table 2).

The Intensive Care Unit (ICU) and Labor ward (LW) were reported with the highest percentage of rejected samples with 32% and 16% respectively (Table 3). However, rejected samples from outpatient department showed the lower percentage (0.5) during January to December 2014 (Table 3).

Table 1: Number of total received, total rejected and percentage of samples with pre-analytical errors in the hematology laboratory during January to December 2016.

Month	Total received	Total Rejected	% of rejected
January	9269	160	1.73
February	9085	188	2.07
March	10306	226	2.19
April	9042	205	2.27
May	9070	187	2.06
June	8951	186	2.08
July	8195	203	2.48
August	8672	192	2.21
September	8502	142	1.67
October	9342	161	1.72
November	9732	202	2.08
December	10074	204	2.03
	110240	2256	2.05

Table 2: Distribution of pre-analytical errors frequencies in the hematology laboratory during January to December 2014.

Month	Incomplete request	QNS	Clotted	Hemolysed	Missmatch	Wrong tube	other
January	0	9	138	6	2	1	4
February	0	11	162	11	2	1	1
March	0	18	168	32	2	3	3
April	0	23	163	13	3	1	2
May	0	9	159	9	0	1	9
June	0	15	139	24	2	0	6
July	1	23	156	16	2	0	5
August	1	23	146	18	0	1	3
September	0	11	113	12	0	1	6
October	0	9	135	17	0	0	0
November	1	13	149	30	0	1	8
December	0	17	159	23	0	1	4
Total	3	181	1787	211	13	11	51
	0.13	8.02	79.21	9.35	0.58	0.49	2.26

Table 3: Number of rejected samples from different wards and outpatient department (OPD) in the hematology laboratory during January to December 2014. Emergency (ER), Intensive Care Unit (ICU), Male Medicine ward (MMW), Female Medicine ward (FMW), Male surgery ward (MSW), Female surgery ward (FSW), Pediatric ward (PW), Pediatric Intensive Care Unit (PICU), Nursery Intensive Care Unit (NICU), Obstetric gynecology (OB) and Labor ward (LW).

Month	OPD	ER	ICU	MMW	FMW/Man	FMW EX	MSW	FSW	PW	PICU	NICU	OB MAN	OB EX	LW
January	1	19	54	2	18	3	3	3	1	13	3	3	2	35
February	3	41	48	11	16	2	1	2	1	12	2	0	3	46
March	5	22	85	10	15	6	4	4	2	15	6	0	10	37
April	0	34	66	6	15	10	5	3	4	2	18	6	10	21
May	0	34	61	4	11	6	2	4	4	7	14	6	8	26
June	0	22	76	6	10	6	2	1	1	0	12	8	8	34
July	0	33	71	5	13	4	5	5	2	0	10	5	5	45
August	1	38	54	8	10	3	9	3	1	5	18	2	7	33
September	1	21	39	14	11	2	3	2	2	1	8	4	5	28
October	0	36	51	5	16	0	3	2	1	5	5	8	0	29
November	1	47	58	6	10	7	1	12	4	0	10	4	16	25
December	1	35	70	11	9	10	2	7	4	2	10	5	6	32
Total	13	382	733	88	154	59	40	48	27	62	116	51	80	391
Percentage	0.58	16.93	32.49	3.90	6.83	2.62	1.77	2.13	1.20	2.75	5.14	2.26	3.55	17.33

DISCUSSION:

Although, the remarkable advances and the full automated in haematological analysers in hematology labs still there are incorrect test results and many variables, which can influence the accuracy and precision of the hematology lab results⁹. A number of research studies have reported different pre-analytical errors at hematology labs. Upreti and colleagues have reported that incorrect filling of forms (wrong names or IDs) as the most common cause of sample rejection at hematology labs¹⁰.

For various national and international accreditations, the clinical laboratory is required to reduce errors in all phases of laboratory functioning¹⁰. Thus, detection and prevention of pre-analytic errors including; problems in specimen collection,

transportation, preparation, pipetting, and sorting are crucial steps to improve patient care, safety and the performance of clinical laboratory over time⁹. Data from this study has found that the rejected samples were approximately 2% of the total in hematology lab. The result of this study also showed that sample's clotting was the most frequent cause for sample rejection at hematology lab. Improper mixing of samples following sample collection is the most common reason for clotting, which may have been the case in this study. A recent study (2015) has been showed that the most common rejection cause was the presence of clots followed by insufficient volume¹³.

Another factor leading to rejection of blood samples in this study was haemolysed samples and insufficient blood volume with 9% and 8% respectively. Similarly, in 2010, sample's haemolysis has been accounted for the majority of rejections at clinical biochemistry lab⁶.

A number of different reasons could be behind this anomaly including; ignorance of the phlebotomists, difficult sampling as in newborn and pediatric patients, patients with chronic, debilitating diseases, and patients on chemotherapy whose thin veins are difficult to localize. Haemolysed samples has been reported in more than 3.2% of routine samples at hematology lab.¹⁴ however, haemolyzed samples are more difficult to be detected in hematology labs than biochemistry labs, as samples are usually not centrifuged in the former.

The highest specimen rejection percentage was observed in intensive care unit, labor ward and emergency department with 32%, 17% and 16% respectively. Unlike to our result Dikmen *et al*, reported that a higher proportion of specimens rejection was reported at the adult emergency department followed by the intensive care unit¹³. Another study found that the proportion of the rejected samples at emergency department was two-fold more than inpatients departments¹⁵. The reasons behind these variation might be as a results of different strategies at different hospitals in their; communication, sample collection and sample transportation.

CONCLUSION:

Since the accurate laboratory results are important for patient diagnosis and treatment, it is mandatory for labs to ensure accountability and accuracy of results to prevent any incorrect diagnosis as a consequence of faulty reporting. Thus, quality improvement in patients safety and healthcare would be improved with daily registration of pre-analytical errors occurring in the lab, proper sampling procedure training and education to all staff, coordination between lab and the hospital ward staff and computerization of the laboratory.

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