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Identification of the Types and Frequencies of Pre-analytical Errors in the Clinical Biochemistry Laboratory: 1-year Study at Hera'a General Hospital

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Abstract

Despite the remarkable advances and the modern innovations, which have transformed laboratory diagnostics from manual and labor-intensive service to fully automated process, the clinical laboratory still shows a number of pre-analytical errors that might lead to erroneous patient diagnosis and treatment that follows. This is a retrospective study performed to investigate the major causes of pre-analytical errors that led to sample rejection at clinical biochemistry department in the laboratory of Hera'a General Hospital, Makkah, Kingdom of Saudi Arabia. The result of this study revealed that samples with visible haemolysis after centrifugation was the most common cause accounting for 35% of total rejections. Furthermore, this study reported a number of different reasons for sample rejection including; mismatching patient's information on the tube and request, incomplete patient's data and clotted samples. Therefore, this study suggests keeping a record of the errors at all stages of the pre-analytical process and then devising corrective strategies for prevention of such laboratory errors.

Keywords: Pre-analytical; Laboratory errors; Biochemistry laboratory; Rejections; Samples haemolysis

Introduction

Nowadays, there is an increasing attention focused on patient safety and improving the performance of clinical laboratory, since physician's diagnostic and therapeutic decisions are mainly dependent on the accuracy and reliability of laboratory results. During sample processing and testing, errors might be generated from three phases; pre-analytical (steps outside the walls of the laboratory), analytical (specimen testing) or post-analytical phase (final phase of the laboratory process including; production of a final value, result and report). Despite the significant decrease in the rates of analytical errors, the majority of errors are found to be arising mainly from the pre-and post-analytical phases with a total of 93% [1]. In 2007, Carraro and Plebani reported 61.9% of the laboratories errors were pre-analytical, 15% were analytical, and 23.1% were post-analytical [2]. Similarly, Goswami et al. found that the pre-analytical errors were the most commonly encountered, with a frequency of 77.1% followed by post-analytical accounting for 15% and analytical contributing upto 7.9% [3]. These results are in agreement with the finding of Astion and his colleagues, which showed that 71% of the errors were observed within the pre-analytical testing phase, while the analytical and the post-analytical phases showed 18% and 11% respectively [4].

A number of other studies have also reported that the highest error rate was related with the pre-analytical phase and that these are mostly generated from mistakes in sample containers, insufficient volume of the sample, handling, storage, transportation and requesting procedures [5-7]. Another study showed that the majority of rejections were caused by sample hemolysis in the clinical biochemistry laboratory [8].

The Emergency Department (ED), requires urgent and accurate test results, however, workload pressures often lead to pre-analytical errors such as incorrect patient identity (ID) and test tubes as well as inadequate mixing, leading to clotting of patient's specimen [2].

The types of error in the pre-analytical phase seem to be vary in different departments even at the similar clinical laboratories. Pre-analytical laboratory errors pose a serious hazard for patient's health, lead to decreased patient satisfaction and increased healthcare costs [9,10]. Moreover, these laboratory errors often lead to misdiagnosis, delay in reporting, unnecessary sample redraws, improper diagnosis and treatment that follows [11]. In 2011, Plebani and Piva found that 25-30% of laboratory errors have an impact on patient's care [5].

Preventing errors in the pre-analytical steps requires excellent communication, closer relationships among all members of the health care team (laboratory personal,

physicians and nurses) and technological developments including; wristband, bar-codes and pre-analytical workstations. Additionally, automation and computer systems have greatly simplified many aspects of clinical laboratory tasks, significantly improving the rate and minimizing pre-analytic errors, which in turn lead to improved care and well being of the patient.

The aim of this study is to investigate the main causes of pre-analytical errors that led to sample rejection at clinical biochemistry laboratory at Hera'a General Hospital in Makkah city.

Material and Methods

This study is based on a retrospective analysis of the results obtained from clinical biochemistry lab at Hera'a General Hospital at Makkah, Saudi Arabia.

At biochemistry lab, routine and reference testing are provided. Upon sample receiving, the department's supervisor visually detected any defect in the specimen. Laboratory personnel were then asked to register rejections and its causes, in the problem notification log book if any pre-analytical error. The data generated was reviewed on a weekly basis.

Samples were collected in the clinical biochemistry laboratory for the period of January 2014 to December 2014.

Errors that occurred during pre-analytical phase have been identified as incomplete patients data on request form, quantity not sufficient (QNS), clotted sample, visible haemolysis after centrifugation, mismatch, wrong tube and others. The frequency of the main factors affecting the pre-analytical quality of test 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

A total of 102197 samples were received by clinical biochemistry laboratory from the patients admitted in the wards as well as outpatient department (OPD) during the period of this study. Venous blood samples were considered unsuitable according to the following accepted criteria: incomplete patients data on request, quantity not sufficient (QNS), clotted sample, visible haemolysis after centrifugation, mismatch, wrong tube and others.

The overall rejected samples, which were found unsuitable for further processing were 2116 samples. This accounted for 2.07% of all samples collected in the biochemistry laboratory **(Table 1)**.

Table 1 Number of total received, total rejected and percentage of rejected samples with pre-analytical errors during January to December 2014.

Month	Total samples received	Total samples rejected	% age of rejected samples
January	7137	199	2.79
February	8654	251	2.9
March	8439	207	2.45
April	6318	168	2.66
May	5950	153	2.57
June	5807	134	2.31
July	5713	193	3.38
August	9357	124	1.33
September	9351	130	1.39
October	10792	156	1.45
November	9751	209	2.14
December	14928	192	1.29
Total	102197	2116	2.07

The most frequent pre-analytical error encountered was that of sample hemolysis with an incidence of 35% **(Table 2)**. Clotted samples from admitted patients and OPD constituted the second most frequent reason for sample rejection during pre-analytical phase reaching to 19.5% **(Table 2)**. Mismatch of patient's information on test request with that on sample tube and incomplete patient's information accounted for 5.5% and 6.6% of the total rejected samples respectively **(Table 2)**.

The highest percentage of rejected samples was reported from the Emergency Department (ED), which presented with 24% followed by Intensive Care Unit (ICU) with 14.18% **(Table 3)**. On the other hand, rejected samples from outpatient

department showed much lower percentage (1.8%) during January to December 2014 **(Table 3)**.

Table 2 Distribution of pre-analytical errors frequencies during January to December 2014.

Month	Incomplete request	QNS	Clotted	Haemolysis	Missmatch	Wrong tube	Other	Total
January	13	29	42	73	10	25	7	199
February	25	44	39	86	16	31	10	251
March	18	34	29	77	14	27	8	207
April	6	29	34	68	10	13	8	168
May	4	23	33	61	9	14	9	153
June	3	25	29	57	8	9	3	134
July	15	29	42	65	19	18	5	193
August	2	39	13	54	1	13	2	124
September	3	22	35	43	9	17	1	130
October	5	37	31	55	10	17	1	156
November	29	33	43	48	8	35	13	209
December	17	29	44	51	4	27	20	192
Total	140	373	414	738	118	246	87	2116
Percentage	6.62	17.63	19.57	34.88	5.58	11.63	4.11	

Table 3 Number of rejected samples from different wards and outpatient department (OPD) in the clinical biochemistry 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), Neonatal 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	5	38	31	19	19	17	26	5	8	19	6	0	0	6	199
February	7	48	39	24	21	25	29	6	10	22	11	0	0	9	251
March	5	49	32	27	10	14	28	5	7	16	7	1	0	6	207
April	3	44	19	28	6	7	31	5	9	7	2	3	0	4	168
May	3	39	23	19	5	6	29	7	8	7	3	2	0	2	153
June	2	38	20	15	4	8	29	5	3	5	1	3	0	1	134
July	7	45	27	21	9	15	33	7	5	7	3	9	2	3	193
August	0	24	26	13	10	10	9	6	4	6	2	1	7	6	124
September	1	31	18	7	8	11	17	5	5	8	2	10	1	6	130
October	1	38	22	6	5	12	16	4	5	24	2	10	1	10	156
November	3	56	21	20	10	15	5	2	8	37	3	10	2	16	209
December	1	52	22	19	11	15	5	1	3	31	5	8	13	14	192
Total	38	502	300	218	120	155	258	58	75	189	47	57	16	83	2116
Percentage	1.8	23.72	14.18	10.3	5.67	7.33	12.19	2.74	3.54	8.93	2.22	2.69	0.76	3.92	

Discussion

Despite significant advances, which have transformed laboratory diagnostics from manual and labor-intensive process to an automated one, clinical laboratory still shows a number of pre-analytical errors that ultimately leads to inappropriate patients diagnosis and treatment.

Prevention of pre-analytical errors including; problems in specimen preparation, centrifugation, aliquot preparation, pipetting, and sorting is required to improve patient safety and the performance of clinical laboratory.

In this study, the pre-analytical errors was observed with 2.07% of all samples collected in the biochemistry laboratory at Hera'a General Hospital from January to December 2014. However, Chawla and colleagues reported a lower percentage (1.52%) of rejection from the clinical chemistry laboratory for errors in the pre-analytical phase during a period of one year [8].

The result of this study showed that the most frequent pre-analytical error was the visible haemolysis after sample centrifugation. Haemolysis of samples, that occurs when blood is forced through a fine needle, was also noticed in several studies [12-14] and these previous results matched the findings of our study. In 2010, a study has emphasized that sample's haemolysis accounted for the majority of rejections at clinical biochemistry lab [8]. Moreover, this observation is similar to 3-5% pre-analytical errors observed by Hawkins in his review [6].

This study also detected an overall specimen rejection rate of 23.72% from emergency department (ED), which might be related to workload and pressured environment in the ED. On the other hand, the lowest percentage of rejected samples was reported from the OPD with 1.8%.

Conclusion

This study reveals that the pre-analytical errors were generated as a result of few causes including; quantity not sufficient (QNS), clotting, visible haemolysis after centrifugation, mismatch and wrong tube. Therefore, this study suggests keeping a record of the errors at all stages of the pre-analytical process and then devising corrective strategies among different department according to the common causes for rejections, for their prevention, which can gradually free a laboratory from such errors. In addition to documentation of rejected samples, the periodic training of healthcare personnel is an essential step in decreasing sample rejection ratios, improving quality of the total testing process in the clinical laboratory and promoting patient-centered health care service.

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