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### IDENTIFICATION OF THE PRE-ANALYTICAL ERRORS AMONG GOVERNMENT HOSPITALS AT MAKKAH, SAUDI ARABIA

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#### ABSTRACT

Despite the remarkable advances in all analytical phases of clinical laboratory testing procedure, there is still a long way to achieve 100% accuracy. The rates of analytical errors have been significantly reduced among laboratories during the last few decades, while pre-analytical phase reported more than 90% of errors. This is a retrospective study was performed to investigate the major causes of pre-analytical errors that caused sample rejection at clinical molecular department in the regional laboratory and found that samples with leakage was the most common cause accounting 28% of total rejections. This study was reported a number of different reasons for sample rejection including; mismatching patient's information on the tube and request, incomplete patient's data and missing sample. 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 such laboratory errors.

#### KEYWORDS

Physician's satisfaction, Laboratory services, TAT, Laboratory management and Results accuracy.

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#### INTRODUCTON

Despite the remarkable advances in pre-analytical, analytical, and post-analytical processes of clinical laboratory testing procedure, there is still a long way to achieve 100% accuracy and precision. A significant decrease in the rates of analytical errors in clinical laboratories has been seen during the last few decades, while pre-analytical (all steps in the process prior to the analytic phase of testing, starting with the physician's order) and post-analytical (all steps in the process between completion of the analytic phase of testing and

results receipt by the requesting physician) phases of the process outside the walls of the laboratory account for more than 90% of errors<sup>1-3</sup>. The reduction in the analytical error rate has been reported to 10-folds as a result of improvements in the standardization and reliability of analytical techniques, reagents, and instrumentation<sup>4,5</sup>.

Indeed, measuring and managing pre-analytical critical errors within clinical laboratories is required to reduce errors through the investigation of any possible defect within this phase that may have a negative impact on the patient safety, health service, health workers effort and cost. Moreover, it's crucial to identify whether the pre-analytical error depends on a laboratory professional (e.g. calibration) or a non-laboratory personnel (e.g. error in patient identification and/or blood collection). This identification will improve the performance of the clinical laboratories as well as analytical quality by reduction of the turnaround time (TAT), accurate patient identification, effective patient diagnosis, treatment of diseases, clinical monitoring, and disease prevention<sup>6</sup>. In addition, clear and effective procedures for patient/sample identification and communication of critical results are required in the checklist of many international accreditation programs such as the Joint Commission International (JCI) and the College of American Pathologists (CAP)<sup>7</sup>.

A number of different studies have investigated various pre-analytical errors including; wrong or missing patient identification, inappropriate container, inappropriate sample volume, haemolyzed sample after centrifugation, and lipemic samples<sup>1-4</sup>. In 2009, Rin revealed that the individual or system design defects are the main reason for the pre-analytical phase errors<sup>8</sup>. Another study, found that incorrect collection tubes being used by nurses (mainly) or physician and empty tubes were most common source of pre-analytical errors<sup>8</sup>. Within the same study, they reported that the pre-analytical errors were the most common cause of sample rejection and accounted for 62% of the total errors while analytical and post-analytical errors accounted for 15% and 23% respectively<sup>8</sup>.

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 15% and analytical 7.9%<sup>3</sup>. Sample rejections may also generate as a result of contamination or sample leakage<sup>1</sup>. However, recent research results revealed a significant reduction in the critical errors compared with previously published data, and these may occur as a result of increasing attention focused on patient safety and rapidly expanding the awareness and understanding of medical errors<sup>1,9</sup>.

The aim of this paper is to investigate the main causes of pre-analytical errors that caused sample rejection of patient's samples sent from different laboratories of government hospitals in Makkah city to the clinical molecular department in the regional laboratory in Makkah.

## METHODS

A retrospective analysis was used in this study and the data was obtained from the clinical medical molecular department at the regional laboratory at Makkah city that highlighted pre-analytical errors reported among five government hospitals namely; Ajjad, Al-Noor, King Abdullah Medical City (KAMC), Hera'a General Hospital and King Faisal Hospital. The data showing pre-analytical errors and causes for sample rejection that were received from different hospital laboratories, was recorded during the period of four months between November 2014 to February 2015.

A total of 1,414 samples from five government hospitals were received by regional laboratory at Makkah. Out of these, 179 samples were collected from Ajjad hospital, 313 from Al-noor hospital, 204 from King Abdullah Medical City (KAMC), 391 from Hera'a General Hospital and 327 was collected from King Faisal Hospital during the period of the study.

The regional laboratory at Makkah city was established in 2012 and receives samples from more than twelve laboratories including both government and private hospitals located in different regions of the Kingdom. The medical molecular biology

department performs a variety of tests including; Corona virus, Dengue virus, Hepatitis B virus (HBV), Hepatitis C virus (HCV) and Human immune deficiency virus (HIV). Upon receiving the samples, the lab specialists visually detect any problems within venous blood samples. When an error is observed, entries are made in the samples rejected log book. Samples are considered unsuitable according to the following accepted criteria: illegible writing, incomplete patient or sample information, wrong labeling, wrong request, wrong collection tube, inappropriate volume, contamination, leaked sample, miss matching, late delivered sample, no samples with patient's request, missing sample code, un-refrigerated sample and not separated samples.

## RESULTS AND DISCUSSION

Data were collected from regional laboratory at Makkah and analyzed by using SPSS version 19. The study results showed that out of the 1,414 blood samples screened over a period of four months; November and December 2014 and January and February 2015, pre-analytical errors were observed in 18 samples (Figure No.1, 2, 3 and 4) (Table No.1), which is approximately 1.3% of the total number of samples received. Samples with leakage and un-separated serum sample were the most common causes and accounted for 28% and 22% of total rejections respectively (Table No.1). There were no rejected samples recorded from Al noor and King Faisal Hospitals between January and February 2015. In addition, only 2% of the total received samples were rejected at December 2014 from these two hospitals, as a result of mismatching patient's information on the tube and request forms and un-separation of serum samples (Figure No.2). Among all the government hospitals, which were included in this study, King Abdullah Medical City

(KAMC) showed the highest percentage of rejected samples between November 2014 to February 2015 (Figure No.1, 2, 3 and 4). However, Ajjad Hospital had no sample rejected among the study period except in January 2015 with 1% of the total samples (Figure No.3).

It is well known that the pre-analytical errors, which include the processes before the sample reaches the laboratory (pre-analytical) were the most common cause of sample rejection compared to the analytical and post-analytical errors<sup>3,9</sup>. Moreover, since the efficiency and accuracy of laboratory results are essential for patient diagnosis and treatment make them mandatory for labs to ensure accountability and accuracy of results to negate incorrect diagnosis as a consequence of faulty reporting. Thus, this study aims to investigate the major pre-analytical errors that caused sample rejection of patient's samples sent from the laboratories of five government hospitals to the clinical molecular department in the regional laboratory in Makkah, Saudi Arabia. Therefore, detecting the pre-analytical personal and/or non-laboratory personnel errors, might inform the development plans for more efficient laboratory services.

A number of studies have been showed different information on the error rate and types<sup>10,11</sup>. Carraro and Plebani observed in their paper that incorrect collection tubes were most common source of pre-analytical errors at the clinical chemistry, which mainly related to lack of staff training engaged in phlebotomy<sup>9</sup>. Here in this study, sample with leakage was the most common cause for rejections. Hemolysis of samples, that occurs when blood is forced through a fine needle, was also noticed in several studies<sup>10-13</sup> and these previous results matching the finding of our study.

**Table No.1: The number of rejected samples among different government hospitals at Makkah in November and December 2014 and January and February 2015**

<b>November 2014</b>		
<b>Name of hospital</b>	<b>No. of rejected samples</b>	<b>Causes</b>
Ajyad	0	---
Al-noor	0	---
KAMC	1	Leaked sample
Hera'a General Hospital	0	---
King Faisal Hospital	0	---
<b>December 2014</b>		
Ajyad	0	---
Al-noor	2	Mismatching patient's information on the tube and request
KAMC	1	Not separated sample
Hera'a General Hospital	0	---
King Faisal Hospital	2	Not separated sample
<b>January 2015</b>		
Ajyad	1	No sample with the request
Al-noor	0	---
KAMC	6	4 samples with incomplete patient's data 2 samples contaminated
Hera'a General Hospital	2	Leaked sample
King Faisal Hospital	0	---
<b>February 2015</b>		
Ajyad	0	---
Al-noor	0	---
KAMC	2	Leaked sample
Hera'a General Hospital	1	Not separated sample
King Faisal Hospital	0	---

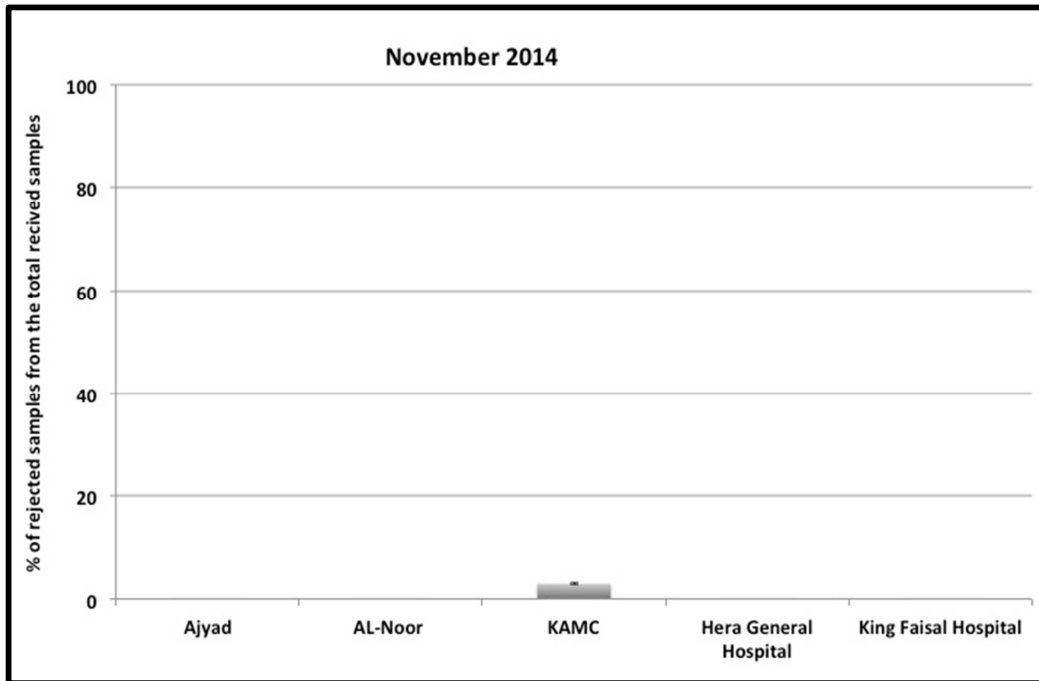


Figure No.1: The percentage of rejected samples among different government hospitals at Makkah in November 2014

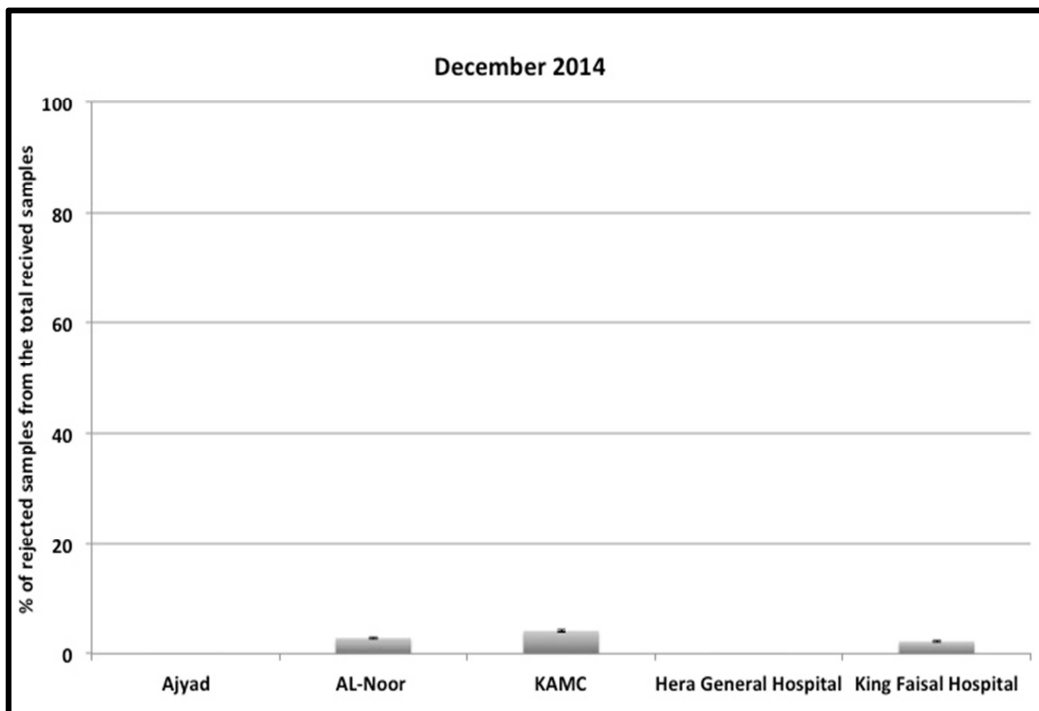


Figure No.2: The percentage of rejected samples among different government hospitals at Makkah in December 2014

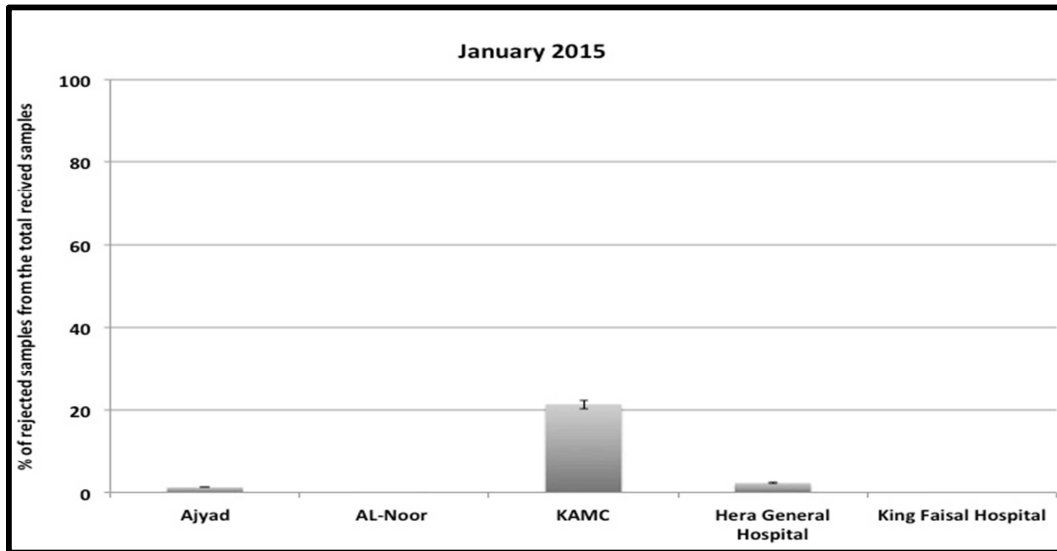


Figure No.3: The percentage of rejected samples among different government hospitals at Makkah in January 2015

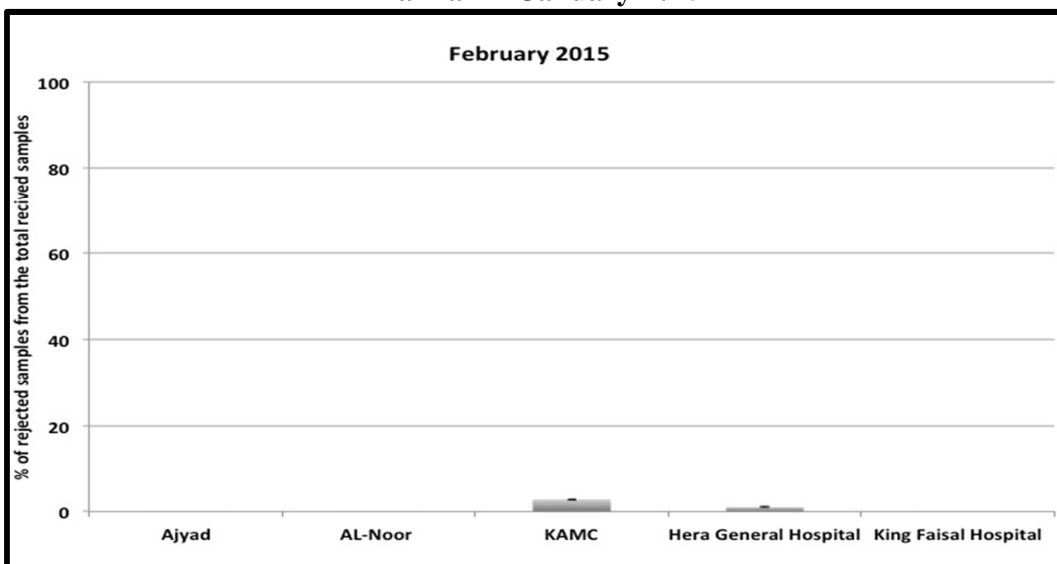


Figure No.4: The percentage of rejected samples among different government hospitals at Makkah in February 2015

### CONCLUSION

To conclude, this study would like to states that among all the government hospitals included in this study the pre-analytical errors ware generated as a result of few causes including; samples leakage, un-separated serum sample, mismatching patient's information on the tube and request, incomplete

patient's data and missing sample. 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 hospital according to the common causes for rejections for their prevention, which can gradually free a laboratory from such errors.

## CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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