Pre-analytical Stage of Blood Sample Collection: A Challenge to the Clinical Laboratories

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Background: Clinical Laboratory Total Testing process is highly complex. Most errors in the venous blood testing process are pre-analytical. Improvement in the pre-analytical stage would yield a better laboratory result.

Objective: To evaluate the standards of pre-analytical procedures and identify sources of error in the venous blood sample collection and implement necessary measures to improve the quality of the sample and reduce the sampling errors.

Design: A Prospective Study.

Setting: Biochemistry Section, Bahrain Defence Force (BDF) Military Hospital.

Method: The study was performed on samples received from medical wards for biochemistry analysis from March 2013 to May 2014. The study consisted of three phases, which included sampling error data collected for six months, finding types, sources of errors and solutions and data collected again for six months after implementing the necessary measures.

Result: Pre-implementation and post-implementation patient sample error data were statistically analyzed; P-value <0.05 was considered statistically significant. Overall, there was 56% decrease in the blood specimen errors within six months of implementation in medical wards (95% CI; P<0.05).

Conclusion: In this study, there was a significant decrease in the sampling errors and thereby improvement in the overall quality of patient samples by implementing the recommended measures.

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Clinical Laboratory total testing process is highly complex. It is divided into three stages: pre-analytical, which is before the sample reaches the laboratory, analytical, which is inside the

laboratory while processing the specimen, and post analytical, which is after processing the sample.

Laboratory results play a key role in patient care. Despite progress in laboratory medicine, pre-analytical phase is considered the most vulnerable part of the total testing process. It has been observed in all studies conducted in other countries that over two-thirds of the laboratory errors arise during the pre-analytical phase[1-5]. Therefore, it is considered to be a serious challenge to laboratory professionals. Improving the quality of the total testing process will reduce the operating costs of any organization and improve the quality of the laboratory result.

As many manual tasks are involved in the pre-analytical stage, errors are not easily avoided compared to analytical errors, which have been eliminated considerably with the invention of advanced automated analyzer systems. The Clinical and Laboratory Standards Institute (CLSI) published guidelines for the collection of blood specimens by venipuncture[6-10].

With the development of automated analytical systems, accuracy, precision, sensitivity and specificity are improved to a greater extent; manual tasks such as pipetting, manual reagent preparation etc., have been eliminated. Therefore, the analytical errors were significantly reduced and improved the turnaround time[7]. The sample collection in the laboratory area is monitored and staffs are updated, but little is known about the blood collection in the hospital wards[8].

However minor the pre-analytical error is, it could lead to very serious medical complications when a physician receives and acts on test results of a wrong patient. Therefore, careful attention to the entire sampling process will significantly improve the error rate[9].

The aim of this study is to monitor pre-analytical procedures and identify errors and its sources.

METHOD

A prospective study was performed in three phases and limited to biochemistry samples received from medical wards.

Phase I: Blood sample errors data collected in laboratory receiving area. The blood sample error data was collected from March 2013 to August 2013. The ward numbers were kept anonymous. A form was designed and tabulated with commonly known sampling errors such as sample source, hemolysis, insufficient, mislabeled, unlabeled, clotted, and not received sample, etc.

Data collected showed that most of the sample errors were hemolytic in nature and were from Accident/Emergency Department (A/E), Intensive Care Units (ICU) and medical wards. The other types of errors were mislabeling and wrong samples.

Phase II: Evaluating the nature and sources of errors in the wards and suggesting solutions. The laboratory quality team conducted an onsite visit to assess how well the nurses follow the standardized procedures for blood sample collection, the quality of samples and the causes of sample errors. A/E and ICUs were excluded in this study because the timings of blood collections vary depending on the emergency situation.

No clear guidelines for blood sample collection were found in the ward, improper mixing of collected blood sample, incorrect sample volume in the collection tubes (blood-additive ratio), bedside labeling was not done in some wards (labeling is done in the nursing stations), unaware of usage of multisampling adapter in many wards[6]. Samples were collected with routine syringes and transferred into the tubes by opening vacutainer caps (Vacuum is lost, which causes improper volume of blood), the importance of 'Order of Draw' was not known to many staff[11].

Based on these observations, the following necessary actions and educational procedures were executed: (1) orientation and training for ward staff in blood collection protocols, (2) workshops on pre-analytical phase of blood collection, (3) preparing guidelines for blood collection in the wards, (4) 'Order of Draw' charts to be displayed in the wards, (5) multi-sample adapters should be using accordingly, (6) causes of hemolysis conveyed to the staff, (7) the importance of vacuum in the vacutainer tubes and correct blood to additive ratio (especially in cases of coagulation profiles), (8) deputing a phlebotomist for certain period if needed.

Phase III: Educational training and workshops for ward staff and deputing a phlebotomist in the medical wards on a trial basis. After implementation of the above recommended measures, the errors data was collected for another six months period from December 2013 to May 2014.

The number of sample errors from the medical wards before and after implementation of the precautionary measures was collected from the laboratory receiving area. Total number of patient samples received from the medical wards for biochemical investigations during the same period is taken from the IT department.

Statistical Package for the Social Sciences (SPSS) version 16.0 was used to analyze the data. Confidence intervals (CIs), Z-test and P-values were calculated.

RESULT

The error rate in the medical wards ranged from 7.9 to 30.6 per 1,000 specimen during pre-intervention period. Post-intervention period error rate ranged from 7.1 to 13.1 errors per 1,000 specimens, see table 1 and figure 1. In the medical wards, the decrease in the blood specimen errors ranged from 10.1% to 59.4%. Overall, there was 56% statistically significant decrease in the blood specimen errors within six months.

Table 1: Pre and Post- Intervention Error Rates

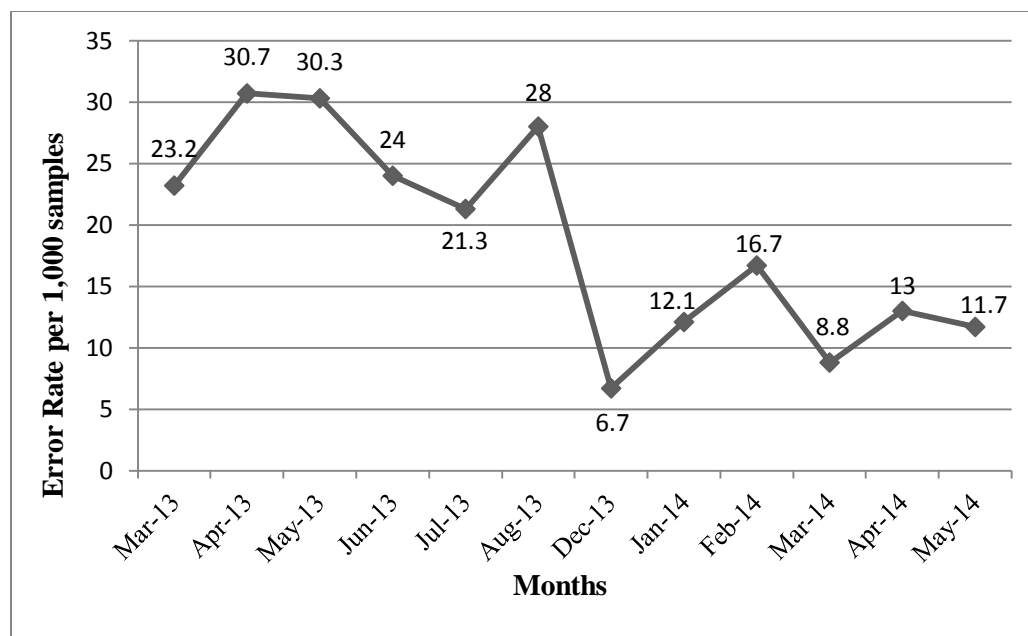| Medical Wards	Pre-Intervention Error Rate (March – August 2013)	Post-Intervention Error Rate (December 2013 – May 2014)
	Rate per 1000 samples	
Ward A	28.1	11.4
Ward B	7.9	7.1
Ward C	30.6	13.1

Figure 1: Specimen Error Rate Pre and Post-Intervention

DISCUSSION

Our study showed that there was a significant decrease of sampling errors (28/1000 to 11/1000) in ward A and (31/1000 to 13/1000) in ward C post-intervention measures. There was only a marginal reduction (7.1/1000) in ward B. The error rate in ward B was low (7.9 per 1,000 samples) even before intervention possibly the ward staff might be more aware of the pre-analytical process.

The average hemolysis error rate in the medical wards post interventional measures was <2%. Although this does not represent the entire hospital pre-analytical error rate, the result is encouraging. Some studies suggest hemolysis rate of <2% as a benchmark.

Chawla et al found that hemolysis of blood samples account for more than half of pre-analytical errors[12]. However, the American Society for Clinical Pathology (ASCP) established 2% or lower benchmark for hemolysis rate among laboratory blood samples[13].

A study in two phases (6 months each) in reducing hemolysis in the Emergency Room (ER) and House wide showed that nursing staff sample error goal was 2% and phlebotomist collection error goal was <1%[14].

Hemolysis could be in vivo which is pathological or in vitro which might be due to improper specimen collection, processing or transport, the expulsion of blood through a small-bore needle with resultant froth formation, or from shaking the blood too vigorously, technically difficult venepuncture may result in haemolyzed samples[15,16].

While visible hemolysis cannot be missed, mild undetectable hemolysis in a blood sample could increase erroneous results[17,18]. Laboratory testing is also an important source of medical errors that can affect patient safety[19,20]. Pre-analytical error prevention requires excellent communication and cooperation among all members of the healthcare team.

Although expensive, modern pre-analytical robotic systems (with clot detection and common interference indices) and a robust Laboratory Information Systems (LIS) could have a positive impact by avoiding many manual steps and thereby decrease the pre-analytical errors. Another advantage of pre-analytical robotic systems is that the specimen routing and tracking will be easily done with barcoded samples. While computerized order entry eliminates manual errors by installing LIS, automated phlebotomy tray eliminates the mislabeling errors[21].

CONCLUSION

Specimen collection error analysis, training, workshops and phlebotomist helped to reduce sampling errors. Education could reduce the pre-analytical errors and improve the result.

Future study would include A/E and ICU. An accurate laboratory result is critical for physician to take immediate decision.

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