EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 3
Issue: 6
637-641
Year: 2016

# A RETROSPECTIVE SIX MONTHS STUDY ON PRE-ANALYTICAL ERRORS OCCURRING IN OPD IN A TERTIARY CARE HOSPITAL: "THE FIRST STEP FOR PATIENT SAFETY IN CLINICAL DIAGNOSTICS AND ITS IMPACT."

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**Article Received on 11/04/2016** **Article Revised on 01/05/2016** **Article Accepted on 21/05/2016**

## ABSTRACT
**Objective:** To evaluate the pre-analytical errors occur in Outpatient department (OPD) samples and strategy planning to minimize the leading causes of pre-analytical errors in a Clinical Chemistry Laboratory (CCL) of a busy tertiary care hospital. **Methods:** A retrospective six months analysis of the pre-analytical errors observed in OPD collection center of the clinical chemistry laboratory in a tertiary care hospital has been carried out in two phases, each of three months. In phase one data collected and summarize regarding the frequency of the factors affecting the quality of laboratory testing. Laboratory personnel's were asked to register rejections and causes for rejection of out-patient samples collected at the OPD collection center. In second phase, pre-analytical data is collected after imparting training to the laboratory and paramedical staffs along with resident doctors coming to OPD collection center related to error observed in phase-1. **Results:** During phase-1, 9500 samples observed under biochemistry section of clinical chemistry laboratory and 4367 pre-analytical errors were observed. This accounted for almost 46% frequency error of the total blood samples collected at OPD collection center. In phase-2 with same sample size the frequency (%) of pre-analytical errors was reduced to 16.5%. **Conclusion:** By continuous training and making medical and paramedical staff aware about pre-analytical errors, the errors can be minimized or rather eradicated to ensure better quality of laboratory testing and hence patient safety.

**KEYWORDS:** Clinical Chemistry Laboratory (CCL), Outpatient department (OPD), Patient safety, Pre-analytical errors, Quality.

## INTRODUCTION
Out of many areas of health care dealing with the issue of patient safety, laboratory diagnostics is becoming a key area to be focus. Laboratory diagnostics is the field which provide considerable role about 60 to 70% in clinical decision making by supporting prevention, diagnosis and remedial monitoring of most, if not all, human disorder.[1] Consequently, laboratory diagnostics becomes a significant source of medical errors affecting patient safety.

Laboratory error is define as ''A defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting on these''.[2,3] Testing is a highly complex process, the testing cycle, commonly called the total testing process (TTP), was well described several years ago by Lundberg.[4]

In the routine of any laboratory tests, Lundberg described the series of nine steps those are: ordering, collection, identification, transportation, preparation, analysis, reporting, interpretation and action. Traditionally, laboratory practice can be divided into 3 phases (pre-analytical, analytical and post-analytical) All 3 phases of the total testing process can be targeted individually for improving quality, although it is well published that for the most part errors occur in the pre- and post-analytical phases.[5]

Errors at any of the phases can have a severe impact on the appropriate diagnosis and overall health of the patient. With computerization of laboratory analysis laboratory errors have appreciably decreased, mainly those that occur during the analytical phase. 70% of total errors within the entire investigative process occur in pre-analytical phase.[6] Various researchers have reported it as 77.1%, 81% and 31.6-75%.[7, 8, 9]

In this article we retrospectively analyzed the data for a period of 6 months on pre-analytical errors observed in OPD samples coming to the clinical laboratory of a busy

tertiary care and super - speciality Dhiraj General Hospital located in Gujarat. The data covered errors occurred during pre-analytical phases and discussed strategies to minimize their occurrence.

## MATERIALS AND METHODS

The Dhiraj General Hospital (DGH) is 1276 bedded tertiary care center with super speciality departments that includes Cardiology, Neurosurgery, Nephrology, Neurology and Urology. DGH serves on an average more than 2 lakhs patients for a year not only from Gujarat but also from parts of central and west India. In hospital, CCL receives on an average more than 1.75 lakhs samples from OPD per year and out of which around 60% of samples coming to biochemistry analysis.

A prospective observational study was done on OPD samples for Biochemistry section of CCL of DGH for a period of six months from 1st May, 2014 to 31st October, 2014. Presuming that errors mainly occur in the pre-analytical phase this study was conducted with the following objectives:

1. To observe the different pre-analytical errors those occurred in the biochemistry section of laboratory and calculate their frequency and percentage.
2. To determine in which step the errors occurred the most so that corrective measures can be formulated to avoid such errors and to make aware medical as well as paramedical staffs involved in diagnostics and patient safety.
3. Also to see the consequences and degree of seriousness in many of the pre-analytical error that was observed.

This evaluation was exempted from ethical consideration because it was based on quality assurance.

## COLLECTION OF DATA

Collection of blood samples for biochemical parameters is done by residents, nursing staff and phlebotomists at the OPD collection centre. Samples along with computer generated request which includes patient information and tests request delivered by paramedical staff to the CCL for the sample analysis.

This study was divided into two phase, 3 months for each phase. In both the phases, all the pre-analytical errors and their types were recorded by visual inspection of OPD samples, from test request and by visiting OPD collection center for the observation of error at the time of sample collection.

For phase-2 data collection done, after imparting training to the resident doctors, phlebotomists and paramedical staffs coming to OPD collection center related to error observed in phase-1. Training was conducted by putting instructions at the collection center and charts were framed on the wall of OPD collection center, so that the paramedical staffs and resident doctors can easily read and understand all the do's and don'ts during blood collection. They were also made aware about what type of serious issues can occur due to such pre-analytical errors.

Total number of samples received in 6 months for biochemistry was 28,234, of which we considered 9500 samples for each phase of study after inclusion and exclusion criteria. Pre- analytical errors observed during the study are mentioned below.

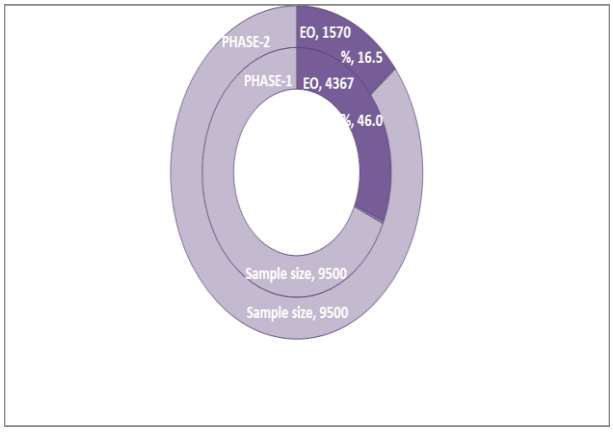
| |
|---|
| Order of blood draw |
| Blood vaccutte inversion |
| Samples not clotted |
| Insufficient quantity of sample |
| Illegible handwriting |
| Incorrect labeling |
| Misidentification of patients |
| Misidentification of samples |
| Prolonged tourniquet time |
| Sample collected without tourniquet |
| Transportation error |
| Wrong tube collected |
| Wrong capping on tubes |
| Tests not mentioned |
| Misplace of samples |
| Software problem |
| Repetition of samples |

## RESULTS AND DISCUSSION

The first step for patient safety is to develop knowledge and understanding of errors in health care by developing a standard agenda, to note down the problems, evaluate methods for identifying and preventing errors and communication of activities to improve patient safety.

In this study out of the 9500 blood collection tubes screened over a period of 3 months for each phase, pre-analytical errors were observed in 4367 samples for phase-1, which is approximately 46% and for phase-2 after training were 1570, which is approximately 16.5% for the respective phase ("Fig.1"). The distribution of the different types of errors[10, 11] was then calculated (Table-1), for the both phase.

We found that maximum frequency (%) is of insufficient sample quantity (20.9) followed by illegible writing (14.76) for the phase-1, which is reduce to almost half and one third in phase-2 respectively.




**"Fig.1": Showing phases of study with number of pre-analytical errors observed with respect to same sample size. EO- error observed**

The comparison of proportion of each individual error between the two phases has been done using chi squared test and the differences was sought for (Table-1).

**Table-1: Frequency (%) and comparison of proportion of Pre-analytical errors for both phases using Chi square test**

| Sr. No. | Errors observed | Frequency (%) | | Chi square value | P value |
|---|---|---|---|---|---|
| | | Phase 1 | Phase 2 | | |
| 1. | Order of blood draw | 2.36 | 0.82 | 71.014 | <0.0001 |
| 2. | Blood vaccutte inversion | 1.98 | 0.67 | 61.34 | <0.0001 |
| 3. | Samples not clotted | 0.88 | 0.23 | 35.19 | <0.0001 |
| 4. | Insufficient quantity of sample | 20.97 | 8.64 | 571.55 | <0.0001 |
| 5. | Illegible handwriting | 14.76 | 4.17 | 620 | <0.0001 |
| 6. | Incorrect labelling | 1.29 | 0.51 | 31.53 | <0.0001 |
| 7. | Misidentification of patients | 0.11 | 0.04 | 2.24 | 0.134 |
| 8. | Misidentification of samples | 0.29 | 0.14 | 4.3 | 0.03 |
| 9. | Prolonged tourniquet time | 0.12 | 0.06 | 1.29 | 0.255 |
| 10. | Sample collected without tourniquet | 0.19 | 0.09 | 2.72 | 0.0991 |
| 11. | Transportation error | 1.12 | 0.34 | 38.81 | <0.0001 |
| 12. | Wrong tube collected | 0.16 | 0.08 | 1.91 | 0.1667 |
| 13. | Wrong capping on tubes | 0.19 | 0.06 | 5.43 | 0.0198 |
| 14. | Tests not mentioned | 0.66 | 0.19 | 23.696 | <0.0001 |
| 15. | Misplace of samples | 0.12 | 0.07 | 0.78 | 0.3772 |
| 16. | Software problem | 0.40 | 0.23 | 3.84 | <0.05 |
| 17. | Repetition of samples | 0.38 | 0.17 | 6.89 | 0.0087 |
| 18. | Total | 45.97 | 16.53 | 1914 | <0.0001 |

We tried to highlight the consequences of pre-analytical errors along with degree of seriousness[12] on patient's safety (Table-2). From the table, one can notice that the simplest error of misidentification of patient and test tube labeling can lead to life threatening situations of patient. Misidentification usually occurs when two patients come with a same name and in that also test tube labeling errors occurred. Suppose when one has cardiac profile test and other have HbA1c test request, then there will be wrong test analysis done for a patient whose medical condition is not matching with the test request received at laboratory, which becomes a life threatening error.

**Table-2: Pre-analytical errors, its consequences and degree of seriousness on patient safety**

| Sr. No. | Pre-analytical errors | Consequences | Degree of seriousness |
|---|---|---|---|
| 1 | Patient identification | Wrong sample and wrong test | Mild to life threatening |
| 2 | Order of blood draw | Blood was not drawn in proper order | Mild to moderate |
| 3 | Blood vaccutte inversion | Not mixing properly the anticoagulants | Mild to moderate |
| 4 | Test tube labeling | Wrong patient's blood in the test tube, wrong test | Mild to life threatening |
| 5 | Wrong capping on tubes | Chances of mixing additive where not required or vise a versa | None to moderate |
| 6 | Wrong tube collected | Chances of mixing additive where not required or vise a versa | Moderate to severe |
| 7 | Samples not clotted | Improper sample (blood, serum or plasma) for analysis | None to mild |
| 8 | Insufficient quantity of sample | Analysis cant done with less sample quantity | Mild to severe |
| 9 | Illegible handwriting | Wrong patient identification or wrong test or analysis cant done | Mild to severe |
| 10 | Tests not mentioned | Analysis can't be done | None to moderate |
| 11 | Transportation error | Improper sample quality (temperature not maintained, spillage of sample, sample lost) for analysis | Moderate to severe |
| 12 | Misplace of samples | Analysis can't be done | Mild to severe |

Mistakes in patient identification often occur during manual tasks which can be avoided using electronic technologies like barcodes, radiofrequency identification and wristbands.[13,14]

Test tube labeling should always be done immediately prior to sample collection while, labeling them after sample collection can increase the risk of the sample collection from the wrong patient. It is reported that mislabeling is responsible for 50% of all identification errors.[15]

Errors like insufficient quantity of sample and illegible handwriting whose frequency was found maximum in phase-1 is categorized as mild to severe. The reason for such error could be ignorance of the phlebotomists, difficult sampling as in pediatric patients, patients with chronic and debilitating diseases and patients on chemotherapy whose thin veins are difficult to locate. Difficult sampling and patient non-compliance further aggravates such problem. To overcome insufficient quantity of sample proper training on sample collection with efficiency shall be given to phlebotomists so as to handle mentioned situations.

Pre-analytical error leads to increased turn-around time for laboratory diagnostics, inconvenience to patients for repeat collection of blood sample and increases cost to hospital. Hence quality check at each and every step of pre-analytical phase in laboratory testing and proper training would definitely minimize not only the errors but also reduces the turn-around time in making clinical decisions as well as cost to hospital.

## CONCLUSION

The role of total quality management is to keep check on various steps from the beginning with test request, sample collection and to the final interpretation of test results by the clinicians so as to reduce or eliminate the errors that affects patient's safety.

The practice of ideal phlebotomy with good training and education is a pre-requisite for the efficacy of laboratory functioning. To reduce the pre-analytical errors is obviously in our own hands and so the improvement in the quality of laboratory diagnostics.

A practice of keeping all the records of errors at all stages of analysis and then making quality strategies for their prevention can gradually make error free laboratory from such pre-analytical errors.

Though it is impossible to completely eliminate the pre-analytical errors, but it is possible to reduce them. We conclude that continuous training and educating of phlebotomists and resident doctors, using of bar coding for samples, proper use of standard protocols and transportation procedures can help to reduce laboratory errors to a maximum.

## ACKNOWLEDGMENT

I acknowledge my sincere thanks to President M K Shah, Chancellor G D Mehta, Vice Chancellor Dr. V P Singh, Dean Dr G V Shah, Hospital Superintendent Dr. Ajay George, who facilitates me to conduct my study, CCL in-charge Dr. Jasmin Jasani for giving me permission in monitoring and data collection for the study, all the medical and paramedical staffs of hospital for supporting me during my study period and Dr. Shashwat Nagar Assistant Professor from Community Medicine, SBKS MIRC for statistical analysis.

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