PRE-ANALYTICAL ERRORS IN A PERIPHERAL HOSPITAL LABORATORY

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ABSTRACT

Objective: To analyse pre-analytical errors which account for the major contribution towards laboratory errors.

Study Design: Cross-sectional descriptive study.

Place and Duration of Study: Combined Military Hospital Kohat, Pakistan from 1st January to 30th June 2012.

Material and Methods: For six months laboratory staff was asked to register rejections and causes for rejection of all samples; including in-patient samples from wards as well as out-patient samples collected in the laboratory. In addition all samples where disparity was noted by the clinicians in the laboratory results were also included for analysis. Suspected samples were reanalyzed, tests were also repeated on fresh samples of the patients and a critical appraisal was made.

Results: Among a total of 328418 analyses, clinicians/laboratory staff notified 350 questionable findings, 270 of which were confirmed errors. Out of total 270 errors, 77% were pre-analytical, 8% were analytical, 15% were post analytical errors. Out of total pre-analytical errors 8% were incorrect samples, 21% were misidentifications, 51% were faulty sampling techniques and 20% were incomplete/illegible laboratory request forms.

Conclusion: The pre-analytical phase in the total testing process currently appears to be more vulnerable to errors than the other phases. Consequently, the pre-analytical phase should be the main target for further quality improvement. Therefore identifying the critical steps in the pre-analytical phase is a prerequisite for continuous quality improvement, further error reduction and thus for improving patient safety.

Keywords: Errors, Laboratory medicine, Pre-analytical.

INTRODUCTION

In the present day the clinical decision-making and patient management is mainly dependent on the laboratory reporting[1]. Around 60 – 70% of the most important decisions on admission, discharge, and medication are based on laboratory test results[2]. Therefore credibility of laboratory results is extremely important and laboratory medicine needs to set very high quality standards.

In recent decades, standardization, automation and technological advances have significantly improved the analytical reliability of laboratory results and decreased the error rates[3]. However a growing body of evidence now strongly recommends that quality in clinical laboratories cannot be assured by merely focusing on purely analytical aspects. Currently pre- and post-analytical steps are more error prone than intra- analytical process[4]. The pre- and post-analytical phases of the process account for 93% of error[5]. Research has demonstrated that most laboratory errors occur in the pre- analytical phase of testing[6]. Particularly the procedures performed neither in the clinical laboratory nor under the direct control of the laboratory personnel require special attention. This phase starts with test request, patient and specimen identification, blood drawing, sample collection and handling, and ends with the transportation of specimens to the laboratory. The laboratory has to bear the burden of the inconsistencies or incorrect reporting that can ensue because of the pre-analytical errors occurring in this phase.

The goal of the present study was to detect and prevent pre-analytical errors by working in collaboration with the clinicians and ward staff.

MATERIAL AND METHODS

This descriptive study was carried out at pathology department, Combined Military

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Hospital Kohat. CMH Kohat is a four hundred bedded hospital having department of general medicine, renal dialysis, general surgery, orthopaedic surgery, gynaecology and obstetrics, paediatrics, ophthalmology, ENT, dermatology, rehabilitation medicine and psychiatry. The pathology department of the hospital has fully functioning and well equipped sections of haematology, clinical biochemistry, microbiology, immunology, clinical pathology, blood banking and transfusion. The equipment includes chemistry analyzers – Selectra E (fully automated), Microlab 200 (semi automated), Metrolab, K-lyte electrolyte analyzer, haematology analyzers (Sysmex-KX21, Medonic M-series, Abacus junior), ELISA reader, Fiocchetti blood bank, Rotanta 460 RF cryofuge, Helmer platelet incubator & agitator and other ancillaries for sample processing. Inpatient phlebotomies were performed by clinical department staff, whereas blood specimens from outpatients were collected at laboratory reception by laboratory staff. The samples were delivered to the laboratory by the paramedical staff from the wards and the laboratory staff from the reception for the outpatients.

The study was carried out over a period of six months from 1st January to 30th June 2012. A total of 328418 different laboratory tests were performed out of these the clinicians and laboratory staff notified 350 questionable laboratory results. Upon receiving the samples, the laboratory staff categorized all samples according to the criteria set for samples with pre analytical issues, and entries were made in the problem notification register. The "operational definition" for pre analytical errors was identified as: inappropriate volume, wrong or missing patient identification, inappropriate container, visible haemolysis after centrifugation, diluted and lipemic samples. The pre-analytical variables were evaluated including all criteria mentioned above for sample rejection as well as incomplete/ incorrect patient details and illegible handwriting. In addition samples of all tests in which disparity was noted by the clinicians in the laboratory results were also included for the analysis. The suspected samples were reanalyzed; same tests were also repeated on the fresh samples collected from the same patients.

Table-1: Frequency of different pre-analytical errors in a peripheral hospital laboratory (n=207).

S.no	Pre-analytical variable	n (%)
1.	Incorrect samples	17 (8%)
2.	Misidentification of patient	43(21%)
3.	Illegible/incomplete laboratory request forms	41 (20%)
4.	Faulty sampling technique	106 (51%)

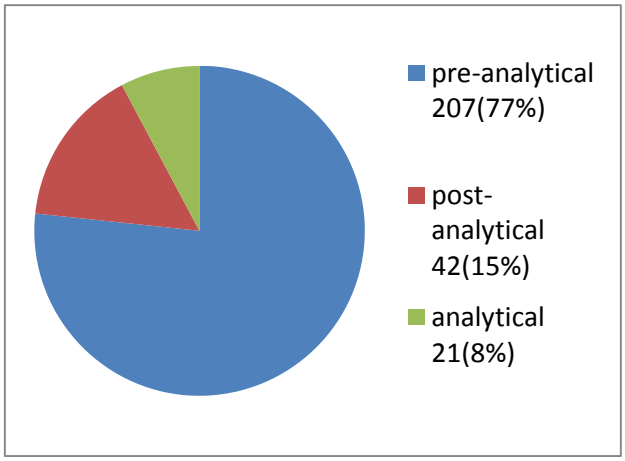

Figure-1: Types of laboratory errors in a peripheral hospital laboratory (n =270).

Critical appraisal was made to know the source of error. The data was analyzed using SPSS version 11. Frequency and percentage were used to describe the data.

RESULTS

During the study period of six months total number of different tests performed in laboratory was 328418. The clinicians and laboratory staff notified 350 questionable findings which were carefully investigated and 270 were confirmed to be errors. When we analyzed these 270 errors 77% were pre-analytical, 8% were analytical and 15% were post-analytical errors as shown in figure-1.

According to our study objective main focus was on the analysis of pre-analytical errors. The distribution of the different types of pre-analytical errors was then calculated as shown in table-1.

The majority of the pre-analytical errors were caused by faulty sampling techniques. Improper sampling techniques resulted in 106 errors which were 51% of total pre-analytical errors. Taking samples from the cannula sites and drip arm was the commonest mistake. Out of total 106 errors caused due to faulty sampling technique 36 (34%) were due to diluted samples taken from drip arm, 20 (19%) were due to improper mixing of the samples with the preservative, 26 (25%) were due to insufficient sample volume, 15 (14%) were due to haemolyzed samples and 9 (8%) were due to improper patient preparation prior to collecting samples.

DISCUSSION

In the past most studies on laboratory errors were limited only to what happened in the clinical laboratory. This lead to the advances in the field of laboratory medicine in the form of standardization, automation, quality assurance programs and technological advances resulting in significant improvement of the analytical reliability of the laboratory results and decrease in the error rates[3]. All recently available studies demonstrate that a large percentage of laboratory errors occur in the pre- and post-analytical phases, with fewer mistakes occurring during the analytical step[7]. This is exactly in concordance with our study findings of 77% pre-analytical, 15% post-analytical and 8% analytical errors.

The modern approach of patient-centered care demands investigation and rectification of any possible defect that occur in the total testing process bearing negative impact on the patient. This requires complete control of the testing process whether or not coming directly under the domain of a clinical laboratory. This can only be achieved by liaising with and involving other professionals in the quality loop.

Faulty sampling techniques resulted in majority of the pre-analytical errors (51%) in our study. These faulty techniques include samples taken from drip arm or canula site. This leads to lowering of various blood parameters like haemoglobin concentration or false rise in certain parameters like blood glucose level due to sample mixing with 5% dextrose infusion. The samples if not properly mixed with the preservative, can cause erroneous results. Like small clots in samples for coagulation profile can result in false prolongation of prothrombin time. Insufficient blood volume is also a source of erroneous results. Every analytical process requires a fixed volume of serum/ plasma for analysis. The main reasons behind this anomaly are ignorance of the phlebotomists or difficult sampling. Haemolysis of the samples is another reason for erroneous results. Haemolysis occurs when blood is forced through a fine needle, shaking the tubes vigorously and centrifuging the sample before clotting is complete[8]. Improper patient preparation prior to a specific test results in errors. It occurs due to ignorance, non-compliance or miscomprehension of the preparation rules by the patient or ward staff collecting samples. Hence many patients give samples in non- fasting states, incomplete volume collection for twenty four hours urinary parameters, improper culture samples etc. It is the responsibility of the clinicians and the phlebotomists to ensure that proper patient preparation is instituted before sample collection.

Accurate patient identification is one of the first steps in ensuring correct laboratory results. Misidentification of the patient and specimens can have serious consequences[9]. In our study 21% of the pre-analytical errors were due to misidentification of patients, 20% were due to illegible/ incomplete laboratory request forms and 8% were due to incorrect samples. In an Australian survey on transcription and analytical errors the transcription error rate was up to 39% with the most frequent types of errors associated with misidentification of the requested tests, the requesting doctors and the patient[10].

This data are comparable to those provided by other investigators, which confirm that problems directly related to specimen collection are the main cause of pre-analytical errors[11]. It is clear from the above discussion that incorrect phlebotomy practices are the main reason behind pre-analytical errors. The reason for incorrect phlebotomy practice includes lack of awareness or possibly a heavy workload. We must initiate steps for the inculcation of ideal phlebotomy practices among health care workers[12,13]. These mistakes stress the importance of inter-departmental cooperation in improving the quality of specimen collection and handling[14].

CONCLUSION

The pre-analytical phase in the total testing process currently appears to be more vulnerable to errors than the other phases. Consequently, the pre-analytical phase should be the main target for further quality improvement. Therefore identifying the critical steps in the pre-analytical phase is a prerequisite for continuous quality improvement, further error reduction and thus for improving patient safety.

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