ORIGINAL ARTICLE

Enhancing Clinical Chemistry Laboratory Performance: Analyzing the Impact of Intermittent Training and Feedback on Quality Indicators in Tertiary Care Settings.

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ABSTRACT:

Objectives: The objective of the study is to evaluate and improve the quality indicators with respect to the manual errors in total testing process in a clinical chemistry laboratory investigation by giving suitable intervention to the laboratory technical staff.

Materials and Methods: The Quality indicators of pre-analytical, analytical and post-analytical phases were documented for a period of 4 months and sensitization given for lab personnel for a period of 1 month regarding the laboratory errors that frequently occurred during the study period. Their knowledge was assessed by conducting pre-test and post-test, by means of multiple choice questions. After sensitization the Quality indicators of pre-analytical, analytical and post-analytical phases were documented for a further period of 4 months. Laboratory errors of the three phases were compared before and after sensitization and were expressed as percentage.

Statistical analysis: Descriptive statistics were used to assess the categorical data using SPSS statistical software version 19.0 and the values are represented as frequency (n) and percentage distribution of relative frequency (%).

Result: The Laboratory errors during the total testing process were compared and evaluated before and after sensitization. In our study errors were more in the pre - analytical phase. However there was a significant decrease in errors in all the three phases following sensitization.

Conclusion: It is observed that sensitization of lab personnel will produce sustainable reduction in errors that occurred during total testing process. Hands on practical training of lab personnel, continuous monitoring and interfacing are crucial to minimize the laboratory errors.

Keywords: Total Testing Process, Quality Indicators, Pre-analytical Phase, Analytical Phase and Post-analytical Phase.

INTRODUCTION

Central Clinical Laboratory plays a crucial role in providing accurate and timely diagnostic information that directly impacts patient care. By delivering timely reports, appropriate treatment, reduced hospital, continuous monitoring and enhanced outcome of the patient can be ensured as modern day medicine practice is more evidence based[1]. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the Institute of Medicine (IOM) both play a role in quality indicators (QIs) and healthcare quality. IFCC world group Laboratory Errors and Patient Safety" (WG-LEPS) proposed the Model of Quality Indicators (MQI) to assess and monitor critical events in laboratory medicine that covers all stages of the Total Testing Process (TTP) so as to take right decisions and choices. This TTP include three phases such as pre - analytical phase, analytical phase and post-analytical phase[2–4]. As stated by Lundberg et al, the generation of laboratory test result involves nine steps that includes ordering, collection, identification, transportation, separation, preparation, analysis and reporting actions[5]. Any error that occur from any of these steps are termed as Laboratory errors that impact on diagnosis and patient management as the clinician depends predominantly on the laboratory tests results[6]. The laboratory errors can be minimized by implementation of error detecting systems specifically developed to specialize all three phases of the total testing process, i.e., pre-analytical, analytical and post-analytical phases [2,7]. The pre analytical phase includes test request, patient identification, sample collection, handling and transportation which are usually performed within the clinical laboratory under the supervision of laboratory personnel. The key Quality Indicators (QI) in pre – analytical phase of the total testing process includes, Clotted samples, Test transcription error, Specimen transport, and Hemolyzed samples [8,9]. In the analytical phase, biochemical investigations were carried out using automation especially in the clinical biochemistry laboratory for validation of the test results. The laboratory automation implemented with quality control (QC) practices such as external and internal quality control schemes and calibration helps in minimizing laboratory errors [9–11]. The post–analytical

phase involves reporting of results to clinicians, communication of critical values and Turn Around Time (TAT) where the common QI includes typographical error, report delivery, and test reporting error [12,13]. Any error in these phases results in wrong interpretation of results and diagnosis, poor quality of management, extra burden on cost, wrong diagnosis or treatment, bad public reputation of the laboratory and the hospital. It is observed that with the advancement of automation and QC protocols especially in clinical chemistry laboratory, human errors can be a major cause of preventable mishaps in clinical investigations to ensure quality in clinical laboratory [14–16]. In this study we have made an attempt to minimize the clinical chemistry laboratory errors by assessing the quality indicators and knowledge of the laboratory staffs followed by training and feedback on quality indicators.

MATERIALS AND METHODS

The study was conducted in clinical biochemistry laboratory in a tertiary care center at Puducherry. This study is an interventional study that was conducted from August 2020 to April 2021 to assess errors in Total testing process within the clinical biochemistry laboratory of host Hospital and it was carried out before obtaining ISO 15189 accreditation. This study was approved by the Institute's Ethics committee vide no. IRC/05/2020/60/IHEC/153 and the study was conducted in accordance with the Helsinki ethical code of conduct. The blood samples collected from Out Patient Department (OPD) and In Patient Department (IPD) patients visiting to hospital for clinical chemistry investigation were assessed for laboratory errors. The study was divided into two phases as pre-sensitization and sensitization with each phase consists of 4 months duration and the Quality indicators were analyzed before and after each phases. Heer, during the pre-sensitization phase the QIs were assessed and the laboratory staffs were sensitized for the rectification of errors. In the post sensitization phase the test requests were again analyzed for the laboratory errors and the results were compared.

DATA COLLECTION METHODS AND PROCESS:

Process inspection sheets were formulated to help in the evaluation of pre–analytical, analytical and post–analytical errors for clinical chemistry investigations among the laboratory staffs. Data was collected in the clinical chemistry section during routine hours each day in the study period. Requests which were ordered for clinical biochemistry tests taking into account quality indicator data were included in the study. Investigation requests for Hematology, Pathology, Histopathology, Cytology and microbiology were not included in this study. All the technical staffs were requested to attend a pre-test with 10 validated Multiple Choice Questions (MCQs) to assess their knowledge and skills before the start of the study. Time given for each question was 45 seconds in which the questionnaires were formulated on all the three phases of the testing process. We had conducted several training classes once in 15 days, on

various crucial topics such as Clot samples, Test Transcription error, Specimen Transport, Specimen Collection, Hemolyzed Samples, Container Monitoring, Delayed Centrifugation Performance, Specimen separation, Documentation of Redo's, Turn Around Time, Report Delivery, Critical Value Reporting and Test Reporting Error. After the training classes, the knowledge and skills were assessed by validated post intervention questionnaire on these topics. Skills were assessed by direct observation of the method of cleaning of the phlebotomy site by using 70% of isopropanol in circular motion from inwards to outwards. The quality indicators before and after intervention were compared and analyzed statistically using SPSS statistical package, version 19. The quality indicators used in the pre-analytical phase are misidentification of patient, test transcription error, specimen transport, specimen collection, Hemolyzed sample. The QI used in post-analytical phase are clerical error, container monitoring, delayed centrifugation performance, specimen separation and documentation of redo's. The QI used in post-analytical phase are turnaround time, incidence of typographical errors, report delivery, critical value reporting and test reporting error.

STATISTICAL ANALYSIS:

In this study, we calculated frequency and proportion (%) using the following formula to evaluate the errors of quality indicators that were observed in Clinical Biochemistry Laboratory. A frequency percentage (%) is measured by percentage of relative frequency which is the ratio of total number of errors (QIs) that have occurred to the total number of data value (cases) [17].

RESULTS:

In this study, the Quality Indicators of Pre–analytical, analytical and post–analytical phases were recorded in the error recording book from the data collected from OPD and IPD sample collection of the clinical biochemistry laboratory. All the errors were compared, evaluated and tabulated as shown in (Table 1) before and after sensitization. It has been found that in all the three phases, the pre-analytical, analytical and post-analytical errors had lower levels of laboratory indicators after sensitization phase than the presensitization phase (Figure1). In the preanalytical phase, the most common errors were clotted samples (0.27%) and haemolysed samples (0.39%). In the Analytical phase, the most common errors were from documentation of redo's (0.50%) and clerical error (0.11%). In the post analytical phase, Test reporting (0.47%) and TAT (0.47%) were the commonest error (Table 1).

DISCUSSION:

Laboratory services play an important role in patient care and it sets a high standard in regulation of quality care. In this study, we assessed errors of quality indicators of the total testing process (pre-

analytical, analytical and post-analytical phase) in clinical biochemistry laboratory. We observed the quality indicators for

Table–1: Comparison of Quality indicators before and after Sensitization of laboratory Health professionals:

Laboratory errors	Before sensitization (Total. no. of cases: 16508)		After sensitization (Total no. of cases: 24507)	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
Pre – analytical phase				
Clot samples	45	0.27%	31	0.12%
Test transcription error	13	0.07%	10	0.04%
Specimen transport	10	0.06%	7	0.02%
Specimen collection	12	0.07%	6	0.02%
Hemolyzed sample	65	0.39%	49	0.19%
Analytical phase				
Clerical error	19	0.11%	11	0.04%
Container monitoring	16	0.09%	15	0.06%
Delayed centrifugation performance	9	0.05%	6	0.02%
Specimen separation	42	0.25%	25	0.10%
Documentation of redo's	83	0.50%	50	0.20%
Post – analytical phase				
Turn Around Time	79	0.47%	64	0.26%
Incidence of typographical error	16	0.09%	7	0.02%
Report delivery	18	0.10%	11	0.004%
Critical value reporting	30	0.18%	13	0.05%
Test reporting	83	0.50%	50	0.20%

Note: [Table 1] represents the laboratory errors in various phases of sample processing in clinical chemistry laboratory. It has been found that, there are a good number of improvements achieved after the laboratory staffs were sensitized of the laboratory errors in pre-analytical, analytical and post analytical phases. The frequency percentage (%) is the percentage of relative frequency which is the ratio of total number of errors (QIs) that have occurred to the total number of data value (cases) analyzed in the clinical chemistry laboratory during the study period.

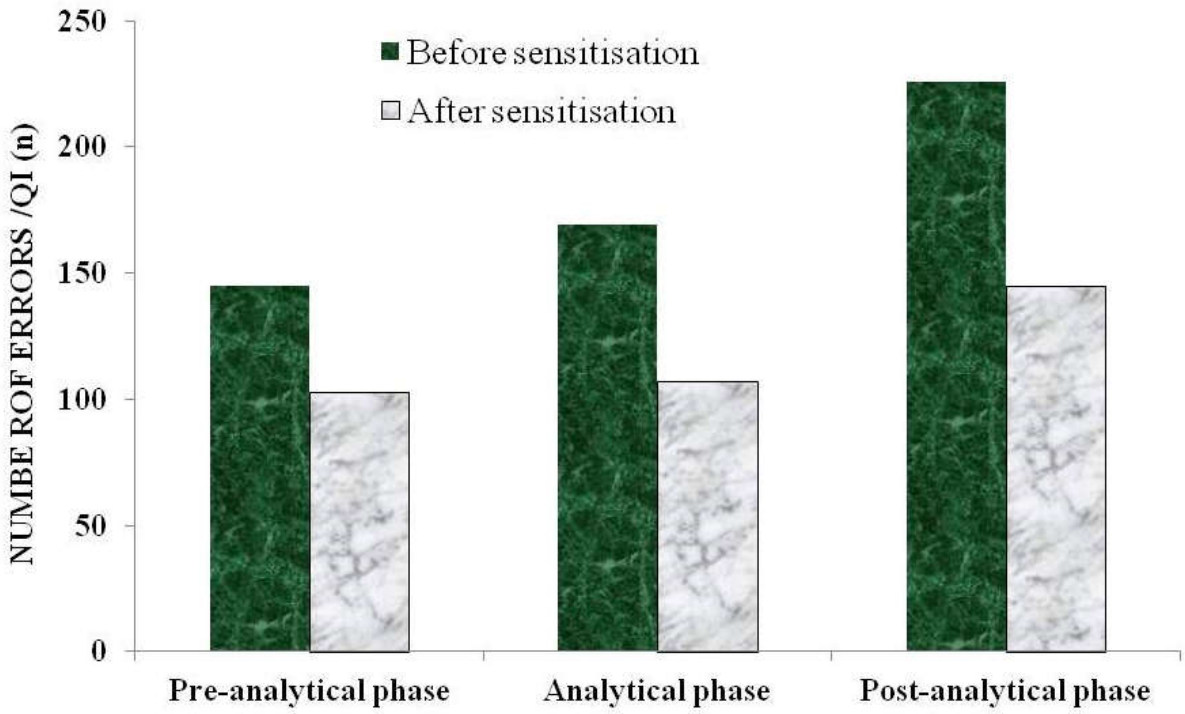

Figure 1: Comparison of frequency of quality indicators among pre-analytical, analytical and post-analytical phases.

post–analytical errors such as TAT, incidence of typographical error, report delivery, critical value reporting and test reporting errors. We concentrated on the errors frequently occurring in various phases of the total testing process during our study period at the clinical chemistrylaboratory. Pre – analytical and Post–analytical phase were accounted for over 83% of total errors that is in line with the previous studies from various parts of the country [8,18–22]. In our study most significant improvement was observed after sensitization of lab personnel in all the phases. Total frequency (%) of errors in both OPD and IPD samples during this study accounted to be 53.85 % and 43.72 % respectively. It has been found that OPD has higher percentage of errors as compared to inpatient samples which could also be due to increase in patient turnover as observed in other similar studies [23–25]. In this study, some of the commonly observed pre-analytical error in all the samples were sample insufficiency and illegible hand writing which is also in line with similar studies on laboratory errors [23,25] which were reported to a life threatening to the patients [20,26]. As per the study done by Favalora et al, It is documented that the treatment is usually delayed owing to the necessity for repeat sample, extra time taken for its analysis and the time taken by the patient to come again for collecting the report [27]. In this study we have also observed that the increase in TAT in most of the cases were due to non attachment of reports with proper file by the

technical staff due to increased work load especially during out of routine duties and also due to shift of patients to other wards. Such sort of negligence besides lack of adequate skills eventually delayed the treatment process which is also being reported from low resource settings of developing and underdeveloped countries [9,12,13,28,29]. In present study the reason behind transcription error was mostly due to manual entry of data into laboratory information system as there is automatic feeding system attached to the instruments to the server which can easily be minimized by being careful and alert [30,31]. Over all it was observed that in our study pre and post- analytical errors has occurred more frequently in OPD department which is in line with the other findings from various articles [18,32,33]. Availability of adequately trained and skilled laboratory personals was in high demand in across all the parts of the world with no exceptions to the developed countries [34]. In developing countries, with the low human resources, face short of well qualified and trained laboratory technologists as they migrate to the developed countries in search of better economy. However in the peripheral parts of the country with low availability of stable skilled technical staffs, the private tertiary care centers hire relatively low skilled staffs although they could invest higher end instruments imported from the leading manufacturers of diagnostics instruments [35]. After analyzing the different phases of the quality indicators, it has been observed that most of the laboratory errors happen due to the human negligence that needs to be addressed with adequate intermittent training followed by instant feedback of the quality indicators to the laboratory personal. As a result, it is essential to continuously resolve errors in order to enhance laboratory performance and, in turn, the efficaciousness of the clinical decision-making process.

CONCLUSION: In our study there was a definite decrease in the percentage of errors in quality Indicators following sensitization of lab personal. From this we conclude that errors may occur at any phase of the total testing process. Constant monitoring and periodic intervention will definitely help in maintaining high quality of results and lab standard.

LIMITATION OF THE STUDY:

The major limitation of this study is that the study is a single centered study conducted over a short period.

ETHICS STATEMENT:

All the procedures undertaken in this study were as per the ethical standards of the institutional ethical committee and with the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.

FUNDING: None

CONFLICT OF INTEREST:

The author declare no conflict of interest

ACKNOWLEDGEMENT: The authors acknowledge the host institute for giving space and facility for the conduct of the study.

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