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Original Article

Evaluation of Key Performance Indicators in the Pre-analytical Phase of Testing in a Clinical Chemistry Laboratory of a Reference Institute

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ABSTRACT

Objectives: To check the performance in the pre-analytical phase of testing in the clinical chemistry laboratory of a reference institute using five key performance indicators and to compare these indicators between the morning and night shifts to ascertain the most probable source of pre-analytical errors.

Study Design: Comparative cross-sectional study

Place and Duration of Study: Department of Chemical Pathology & Endocrinology, Armed Forces Institute of Pathology (AFIP), Rawalpindi Pakistan, from Apr to Sep 2021.

Methodology: Defined key performance indicators (KPIs) were observed for a period of six months. The frequency and percentage of each KPI were calculated. Defects per Million were calculated for deriving Six Sigma (σ) values. KPIs were also compared between the morning and night shifts.

Results: A total of 272,731 samples were observed in which 2306(0.84%) were found haemolysed (σ=3.5), 604 samples (0.22%) were not received in the Department due to various pre-analytic reasons (σ=4.0), 260 samples (0.09 %) were found having insufficient sample volume for analysis (σ=4.5), 181(0.06%) samples were found having improper/ wrong labelling or bar code errors (σ=4.5) and 161(0.05%) samples were delivered in wrong tubes (σ=4.5). KPI-1, KPI-2, and KPI-3 were found to be significantly higher during the night shift than the morning shift.

Conclusion: Haemolysed samples and lost-not-received samples were the main causes of pre-analytical errors Key performance indicators aided as an instrument to screen and improve process execution in the laboratory.

Keywords: Key performance indicators, Pre-analytical error, Six sigma.

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INTRODUCTION

Laboratory errors are any errors occurring during the total testing process (TTP), which starts from test ordering to final result reporting. They must be addressed immediately and interpreted carefully due to their undeniable role in clinical decision-making.[1]

The complete testing procedure is comprised of three stages, namely pre-testing or pre-analytical stage, testing or analytical stage and post-testing or post-analytical stage.[2] Various studies have highlighted the importance of assessing the critical steps of each stage with the assistance of specific, quantifiable factors for medical laboratory accreditation that sticks to worldwide guidelines.[3] A pre-analytical error rate of 46 – 68 %, analytical of 7-13 % and post-analytical phase error of 19 – 47 % has been reported.[4,5] Together, pre and post-analytical errors constitute 95% of total errors. The pre-analytical phase is the most vulnerable phase as far as laboratory errors are concerned because most of the steps involved in this phase are performed outside of the laboratory premises and are not supervised by the laboratory personnel.[6] The analytical errors can be held in check by quality control procedures requiring stringent quality checks. Inaccuracy, delay in data entry/result reporting, keyboard-entered reports, reports exceeding turn-around time (TAT), and errors in Laboratory Information Management System (LIMS) efficiency are errors of the post-analytical phase.[7] Faulty relaying, illegible handwriting or hearing wrong verbal information constitute the errors related to data communication.[8]

Defining some indicators as a measure to monitor the laboratory trend and performance is of vital importance. Quality improvement, as defined by The College of American Pathologists (CAP), is the performance adjustment and continuous assessment by the use of statistically and scientifically approved procedures. Laboratory outcomes can be enhanced by reducing errors by the constant scrutiny of performance indicators and subsequent remedial measures.[9,10] The aim of the current study was to assess the defined key performance indicators (KPIs) in

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our setup using Six Sigma metrics and to compare these indicators between the morning and night shifts to ascertain the most probable source of pre-analytical errors.

METHODOLOGY

The comparative cross-sectional study was conducted at the Department of Chemical Pathology & Endocrinology from April to September 2021 after getting ethical approval (FC-CHP-25/READ-IRB/21/655) from the Institutional Review Board of AFIP, Rawalpindi.

Inclusion Criteria: Five key performance indicators in the pre-testing phase were used in the study. Samples lost but not received (KPI-1); haemolysed sample (KPI-2); samples with insufficient sample volume (KPI-3); samples collected in the inappropriate tubes (KPI- 4); improperly labelled or un-labelled sample (KPI-5).

Exclusion Criteria: Nil

Our clinical chemistry laboratory is equipped with a fully automated clinical chemistry analyser, ADVIA 1800 for routine chemistry tests, ADVIA Centaur XP for the Endocrinology section and Sebia Octa for glycosylated haemoglobin. Specimens were received from four different receptions and parcels from all over the country. Screening for pre-analytical errors in the laboratory request forms and in the specimens is carried out upon receiving them in the laboratory. Errors were recorded in the Excel sheet for pre-analytical errors.

The frequency and percentage of each KPI were recorded. Defects per million (DPM) were calculated using the formula, DPM=(Number of errorsx 10,00,000)/Total number of specimens. Sigma values were derived from DPM based on the table available at https://www.westgard.com/sixsigtable.htm as shown in Table-I. A Six Sigma assay is one for which 99.99966% of results are error-free, corresponding to 3.4 defects per million opportunities, in this case, assay results.[11,12]

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Quantitative variables were expressed as Mean±SD and qualitative variables were expressed as frequency and percentages. Independent sample t-test was applied to explore the inferential statistics. The *p*-value lower than or up to 0.05 was considered as significant.

Table-I: Conversion of Defects per Million to Sigma metric

Defects Per Million	Sigma Metric
698,000	1.0
308,000	2.0
159,000	2.5
66,807	3.0
22,750	3.5
6,210	4.0
1,350	4.5
233	5.0
32	5.5
3.4	6.0

RESULTS

A total of 272,731 samples from the clinical chemistry laboratory were screened for pre-analytical errors over a period of six months, and 3,512(1.2%) samples were rejected due to pre-analytical errors. The frequencies of each KPI were calculated. Haemolysed samples were 2,306(0.84%), and the concerned departments were communicated accordingly, whereas 604 (0.22%) were not received in the department which was either delivered to the wrong department or were not given by the patient due to various reasons such as fear of double prick or lost by sample carrier during transportation. Insufficient sample volume for analysis in 260(0.09%) samples, improper/wrong labelling or bar code errors in 181(0.06%) samples and samples delivered in wrong tubes were found in 161 samples (0.05%). All KPIs show well-controlled performance, as shown in Table-II. Comparison of Errors during Morning and Night Shifts are shown in the Figure.

Table-II: Six Sigma Metrics for Key Performance Indicators Evaluated

Key Performance Indicators	Errors	Frequency(%)	Defects Per Million	σ	Performance
Samples lost-not received (KPI 1)	604	0.22	2,214	4.0	Acceptable
Hemolyzed sample (KPI 2)	2306	0.84	8,455	3.5	Acceptable
Samples with insufficient sample volume (KPI 3)	260	0.09	953	4.5	Acceptable
Samples collected in inappropriate tube (KPI 4)	161	0.05	590	4.5	Acceptable
Improperly labeled or un-labeled sample (KPI 5)	181	0.06	653	4.5	Acceptable

KPI, key performance indicator; DPM, defects per million; Sigma value, σ; Acceptable, sigma value >3

The defined KPIs were also compared between morning and night shifts. Mean values of all KPIs during the night shift were higher as compared to the morning shift. During the night shift, mean KPI 1 (59.1±12.70), KPI 2 (230.0±36.33) and KPI 3(28.0±12.44) were found to be significantly higher as compared to the morning shift, $p < 0.05$ as shown in Table-III.

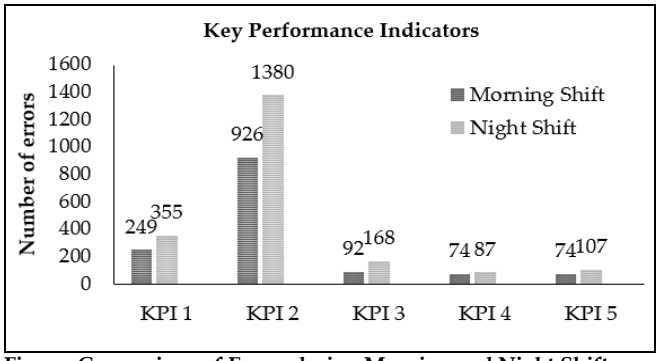

Figure: Comparison of Errors during Morning and Night Shifts

Table-III: Comparison of Key Performance Indicators between Morning and Night Shifts

Key Performance Indicators	Day Shift (Mean±SD)	Night Shift (Mean±SD)	*p*-value
KPI-1	41.5±4.46	59.1±12.70	0.009
KPI-2	154.3±40.56	230.0±36.33	0.007
KPI-3	15.3±3.55	28.0±12.44	0.037
KPI-4	12.3±3.50	14.5±5.39	0.429
KPI-5	12.3±5.60	17.8±7.80	0.191

KPI, key performance indicator; SD, standard deviation

DISCUSSION

Laboratory results provide definite answers to the clinical impression of the clinicians. Specimen handling and processing prior to sample analysis is of huge importance in quality reporting.[13] Rejection of any specimen can lead to repeat sample collection in some cases and inconvenience to patients, including the unnecessary delay in reporting. Hence, monitoring of specimen selection for analysis is an essential quality assurance measure for clinical chemistry laboratories. KPIs aid in objectively quantifying laboratory performance and evaluation.[14,15]

All KPIs in our study had acceptable sigma values. Haemolysis (0.84 %) and sample lost-not received (0.22 %) were observed as the leading causes of pre-analytical errors in our study. One study observed insufficient sample quantity and haemolysis to be the most prevalent causes of specimen rejection.[16] Whereas, Chawla *et al*. observed haemolysed samples as a dominating cause of specimen rejection in their work.[5] Another study found insufficient specimen quantity to be the leading cause of pre-analytical error, followed by haemolysed samples.[17] In contrast to our study, one study observed contamination as a main cause of specimen dismissal in their work.[18]

Studies conducted by Astion *et al*., Wiwanitkit *et al*., and Plebani et al. revealed pre-analytical errors to be the leading cause of errors in total testing processes, as observed at 71%, 84% and 68.2 %, respectively.[19-21]

This shows that there is a high percentage of recoverable sample loss due to various reasons of haemolysis and sample loss- not received in our setup. To minimise these types of errors, measures should be taken to educate the medical staff regarding haemolysis and its avoidable causes and adoption of correct sampling procedures for the correct patient at the correct time in a correct tube with correct transportation measures. It is important that correct phlebotomy techniques are practised to minimise pre-analytical errors. Medical staff need to be sensitised on this subject by awareness programs, implementation of standard operation procedures and regular training sessions. These measures and awareness will lead to betterment in the quality of laboratory service.

CONCLUSION

KPIs aided as a tool to monitor and improve process performance in the laboratory. Six Sigma metrics are an efficient way of monitoring quality in the clinical chemistry laboratory. Haemolysed samples and lost-not-received samples were the leading causes of pre-analytical errors. Specimen rejections for various reasons are a continuous challenge for laboratories. Laboratory errors should be treated seriously as they adversely affect patient safety.

Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

AAG & MUM: Data acquisition, data analysis, critical review, approval of the final version to be published.

ZHH, MY: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

MA & SIK: Concept, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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