Original Article

Review of Key Performance Indicator in a Hematology Laboratory: A Preventable Source of Error

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ABSTRACT

OBJECTIVE: To assess the key performance indicators and the laboratory errors in the hematology laboratory.

METHODOLOGY: A cross-sectional study was conducted at the DDRRL Hematology laboratory from October 2021 to September 2022. Data from the blood bank and hematological laboratory were collected. The primary investigator managed every step of the data-gathering operation. All the tools required for the process were gathered and arranged on a tray or trolley to be safe, accessible, and readily visible. Sterile glass or plastic tubes with rubber covers were used for blood collection. The information acquired during the study was inserted into a computer using an Excel sheet. SPSS version 20 was used for the analysis.

All samples from the hematology section of DDRRL were included in this study, while all error-free samples were excluded.

RESULT: From July to December, 414,400 hematology request forms were collected from OPD, private wards, IPD and Emergency. Overall, 2376 (0.573%) hematology laboratory errors were detected, of which 419 were Pre-analytical errors, 122 were analytical, and 1834 were post-analytical errors.

CONCLUSION: We can lower the errors' likelihood if we appropriately handle the pre-analytical variables. Additionally, care must be taken when training workers to minimize the possibility of mistakes.

KEYWORDS: Laboratory errors, Pre-analytical, Analytical, Post-analytical, Laboratory testing, Laboratory services

INTRODUCTION

The testing practice is a multiphase strategy that begins and closes with the patients, from test ordering to specimen collection and analysis of test results. Distinguishing the numerous steps in the testing process is pivotal and vital in recovering a patient's health status[1]. A quality indicator is an information, qualitative and quantitative measure related to a series of inspection consequences. It can assess its changes throughout the process and confirm the accomplishment of the characterized quality objectives, requiring the rectification decision[2].

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Hematological laboratory errors can begin when a patient gives their specimen for testing and continue until the results are provided to the clinician, who then uses the interpretation to make diagnostic and treatment decisions. Completing this process without making any mistakes is challenging, and any laboratory analysis seeks to reduce this uncertainty and correctly quantify their size[3].

The pre-analytical phases cover all procedures from when a doctor requests a laboratory test until the sample is prepared for analysis[4,5]. Accurate patient identification, sample collection, transport, storage, and test selection are crucial processes needed in pre-analytical research[6]. Laboratory errors are mostly pre-analytical phase errors (46%–68%), then post-analytical phase errors (19%–47%)[7]. Investigations revealed that a minority (13%–32%) occurred in the analytical part[8]. Since clinical laboratory data influences 60–70% of clinical decisions, these errors significantly negatively impact patient care. They may lead to incorrect diagnostic and therapeutic choices, wrong results interpretation, and impaired meaningful clinical laboratory comments[9] since clinical laboratory information influences 60–70% of clinical decisions[10].

Preparing the patient specimen for laboratory testing starts the analytical phase, which ends when the laboratory technologist interprets and verifies the test results[11]. Errors in this step may cause by equipment

itself or an interfering substance in the analysis sample. The two sorts of analytical errors are random and systematic. While systematic errors imply a lack of accuracy, random errors clearly show a lack of precision. Random errors include, but are not limited to, transcribing errors, inaccurate sample numbering and labelling, and altered colorimeter readings.
Ineffective methodologies, standards, and calibration procedures can lead to systematic mistakes[12].
The post-analytical phase's consequences are shown to the clinicians for the interpretation and treatment of the patient. Nonetheless, mistakes in the post-analytical phase are brought about via irresponsible reporting of results and inaccurate interpreting at this stage[3]. The most common post-analytical errors are improper confirmation, deferred findings, not submitting to some unacceptable suppliers, and erroneous outcomes detailed because of post-insightful information passage blunders and record mistakes.
Confirming research centre outcomes, taking care of them into the lab data framework, and conveying them to clinicians in an organized way, generally by creating a report and making any fundamental oral correspondences in regards to **"alert"** or alarm results, are essentially instances of post-insightful techniques performed inside the laboratory[13].
Clinical mistakes or errors are the eighth most significant reason for mortality in the US, as per the US Organization for Medical care Exploration and Quality[14], surpassing engine vehicle mishaps, malignant growth and AIDS occurrences each year. Although computerization/ mechanization, regularization, and technical advancements have incredibly worked on the analytical trustworthiness of lab tests[11,15], there is still the opportunity to improve, and lab mistakes happen in each cycle. Hence as a sum up, the current research intends to close this space by gathering data on pre-analytical, analytical, and post-analytical mistakes, just as breaking down their appropriation among settings. The quality of laboratory tests should be considered more significantly because they are essential in diagnosis and patient care. However, errors can occur during the blood sample processing technique. It is found that most errors fall into a pre-analytical category. Therefore, physicians can make more accurate clinical decisions if the focus is on reducing these errors. Reducing errors improves quality control and ensures that patient sample findings are precise and accurate.

METHODOLOGY

A cross-sectional study was led from October 2021 to September 2022 at the Hematology lab of DDRRL. Data was collected from existing data from the blood bank and hematology lab. Patient's MR/ Lab No., patient's name, OPD/In-patient, patient's age, clinical history, clinician name, hemolysis (Yes /No), clotted blood, and improper samples were all collected. During the collection procedure, the primary investigator was in charge of overseeing the entire process.
Clotted samples, hemolyzed samples, improperly identified samples, leaking/braked tubes, and transport delays were grounds for rejecting samples. The information acquired during the study was inserted into a computer using an Excel sheet. SPSS version 20 was used for the analysis, and the frequency and percentage were determined. Ethical approval was obtained from the IRB Committee of Dow University of Health Sciences (Ref: IRB-2358/ DUHS/EXEMPTION/2021/-665).
They have placed blood collection tubes (vacutainers) in the proper sequence to prevent additives from transferring across tubes. All the tools required for the process were gathered and arranged on a tray or trolley to be safe, accessible, and readily visible.
Blood was collected in sterile glass or plastic tubes with rubber covers. A supply of sample tubes within their expiration dates should be kept dry and upright in a rack. A sterile glass or bleeding pack if large amounts of blood need to be collected. A range of various-sized blood-sampling instruments, well-fitted, non-sterile gloves, tourniquet and alcohol hand sanitizer was used. All samples from the hematology section of DDRRL were included in this study, while all error-free samples were excluded. We used a convenience sampling technique in this research work.

RESULTS

From July to December, 414,400 hematology samples from OPD, hospital wards, Emergency, and ICU were received in the hematology lab. Overall, 2376 hematology laboratory errors were detected, of which 419 were Pre-analytical errors, 122 were analytical, and 1834 were post-analytical errors. **Table I.**

Monthly Reported Different (Pre, Intra And Post-Analytical) Phases Errors

Pre-Analytical Phase

- Improperly Labeled samples= 0.002%
- Samples in Inappropriate Container= 0.003%
- Samples with Insufficient Quantity= 0.013%
- Clotted samples= 0.086%
- Samples Not-Received= 0.002%
- Hemolyzed samples= 0.002%

Intra-Analytical Phase

In 6 months from July 2021-December 2021:

- Exceed IQC value is 34 except for December.
- Incorrect results for manual entry are 56.
- Two cycles failed with unexpected performance in September and November.

Post Analytical Phase

- The total number of reports delivered within six months was 46,456 (11.21%).
- Inform delayed critical values after 1 hour in the patient were observed to be high in July 119

Table I: Study Phases

S.No	PARTICULARS	TOTAL Samples						
		Jul	Aug	Sep	Oct	Nov	Dec	Total errors
Pre Analytical phase								
1	No. of samples improperly labelled/poor quality	1	2	1	2	2	1	9
2	No. of samples collected in appropriate container	2	1	2	1	2	2	10
3	No. of samples with insufficient volume (QNS)	7	6	12	12	6	6	49
4	No. of sample clotted	60	65	59	42	65	42	333
5	No. of samples not received	2	2	2	1	1	1	10
6	No. of samples hemolyzed	1	1	1	2	2	2	9
Intra Analytical Phase								
8	No. of unexpected performance in RIQAS	Nil	Nil	1 cycle failed	Nil	1 cycle failed	2 (Sep, Nov)	04
9	No. of unexpected performance in RIQAS accruing in previously treated cause	Nil	Nil	Nil	Nil	Nil	Nil	0
10	No. of internal QC values IQC that exceed selected target	5	9	10	11	9	Nil	34
11	No. of reports delayed due to instrument failure	Nil	Nil	Nil	Nil	Nil	Nil	0
12	No. of incorrect results for erroneous transcription / manual entry	8	10	10	15	10	8	56
Post Analytical Phase								
13	Total No. abnormal reports	7500	8100	7350	7650	8250	8100	46,456
15	Total No. of critical reports	300	280	260	275	285	310	1710(3.7%)
	Total critical reports informed within one 1 hour	141	145	154	168	172	158	938(55%)
16	No. of critical values in patient delayed (after 1hr)	119	90	70	65	75	115	534(31%)
17	No. of critical values in the patient not inform	40	45	36	42	38	43	244(14%)

(119/534= 22.284%), whereas a total of 534 reports were delayed during the period.

- Critical values of in-patients not informed at the time was 244 as in September lowest value noted was 36 (14.75%). While in out-patient, it was 200 in July, whereas in August, only 20 (10%) were informed, total no. of delayed critical values out-patient throughout the observation was 417 (0.897%).

DISCUSSION

The pathological laboratory plays a crucial role in diagnosing and managing patients. However, information technology and the automation of laboratories have made laboratory results more accurate and reliable compared to the past. However, potential errors are present at each stage, even in the best laboratory, despite total lab automation or laboratory information system. Therefore, specific parameters are defined as performance indicators that screen different stages of the testing process, like sample integrity, quality control of the intra-analytical process, turnaround time, and result release. Quality indicators are objective parameters to assess the quality and are placed to review the system periodically to see the satisfactory performance of the system. These quality indicators are reviewed regularly to review the frequency of inherent errors. It works by plan–do–act and check mechanisms, a continuous surveillance process to improve quality and patient safety.

Clinical laboratory reliability cannot be reached solely by promoting accuracy in the analytical phase of the testing procedure. The stage before the samples arrive at the laboratory (pre-analytical) and after the sample has been tested (post-analytical) are critical[16,17]. Lower reputation and erode patients' faith in diagnostic services[18]. A laboratory error means a defect in the whole process, which has decreased the quality of laboratory service. If we carefully handle the pre-analytical variables, we can reduce the chances of errors. Furthermore, one must be careful while training staff so that they can reduce the chances of errors[19].

The current study data were collected from July to December 2021. The present study showed that pre-analytical errors were 419 and analytical errors were 122 among 414,400 samples. In our research, pre-analytical results are low due to the use of a laboratory information system, as manual handling is minimal. But clotted and hemolyzed samples showed

a need for training and education. Previously a study published in Pakistan in 2014, which showed the opposite result, reported 77% pre-analytical errors[20].

We have talked about samples with incorrect labels, samples collected in unsuitable containers, samples with insufficient amounts, samples with clotted blood, samples that were not received, and samples that had been hemolyzed. We discovered no substantial inaccuracy in these parameters except for clotted samples, where the error was less than 1% (i.e., 0.086%) over six months. Although pre-analytical errors are the most dangerous, they may go undetected until post-analytical validation and interpretation[21]. Standardization of reference intervals against which results can be evaluated and the impact of even a tiny variance in reference interval for a crucial analyte such as haemoglobin concentration issues in the post-analytical phase[22]. Despite laboratories' struggle to produce high-quality data, quality indicators, which assess the frequency of pre- and post-analytical errors, are a source of information that may be used to improve services[23]. This type of error is most common in the IPD sample. There should be continuous monitoring of phlebotomy performance with constant staff training in blood sampling. Proper training can include modern laboratory technologists and automated phlebotomy tray preparation. This study showed that the leading cause of rejection of samples was the insufficient amount and clotting in samples. Clotting was most seen in the CBC sample. The clotted sample is improper mixing of sample, and EDTA is insufficient[24].

The second phase is the analytical phase. This stage covers what is typically called "actual" laboratory tests and the diagnostic strategies, procedures, and outcomes. Random and systematic errors, calibration issues, and non-conformity with quality control can all occur during the analytical portion of the process[25]. Developing a final value, result, or diagnostic morphological report in the haematology cases brings this phase to a close.

This investigation mostly recognized analytical mistakes such as equipment malfunction, analyzer operating errors, and undiscovered failures in internal QC[26]. It can produce adverse effects on patients. Although improvements in laboratory workflow due to automation have considerably lowered error rates during the analytical phase, it also needs a monitoring system to evaluate performance[27].

The post-analytical phase includes evaluating and releasing laboratory test results timely, especially for critical results, and modifying and revoking results to support clinical decisions. Incorrect reports and validation can lead to the wrong patient's treatment[28]. According to the current study, the most common post -analytical error was that reports were not delivered at a specific time (22.2%), mainly in November, amongst all other errors reported in this category. Studies conducted in Rahim Yar Khan (Pakistan) in 2021[17] and Singapore in 2011 also favor this current study. Researchers revealed that the most common Post-analytical error, 25-46%, were also delayed/ missed reactions to laboratory reporting in their study[29].

Hence, it was noticed that in six months, the maximum error frequency was found in the post-analytical part, and most of them were critical reports of IPD patients who were not informed for one hour as defined. Others errors include samples with essential values that were delayed. TAT (turnaround time) is a key indicator of laboratory performance, and in our study, a significant number of reports are delayed especially critical ones.

Future Perspective

It is not only to acquire total automation for accuracy and patient management but there should be continuous monitoring by objective parameters called quality indicators. The results of this investigation demonstrated that, despite all the automation, laboratory errors continue to be a problem that can lead to poor patient care decisions. Even though money is spent on internal and external quality control to enhance analytical quality, mistakes still occur during the laboratory testing procedure affecting patient clinical decisions[19]. Therefore there is a need to place a check system by applying and reviewing performance indicators,

CONCLUSION

Pre-analytic errors are lower than analytical and post-analytical errors due to using barcode and laboratory information systems (LIS). Recent discoveries in science and technology have changed laboratory diagnostics from laborious, time-consuming manual testing procedures to fully automated laboratories, but lab performance must be objectively defined. A laboratory error refers to a flaw in the entire process that has reduced the calibre of the laboratory service. However, it needs intervention to control and improve because a timely response to critical values is essential for patient diagnosis, treatment, and safety.

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AUTHOR CONTRIBUTIONS

Kouser S: Principle investigator, the conceptualization of the study & data compilation and Supervision, responsible for communication with the journal during the manuscript submission, peer review and publication process, responsible and accountable for

the contents of the article, and share a responsibility to resolve any question raised about the accuracy and integrity of the published work

Abbas FF: Conception and design of the work, paper writing (Abstract and introduction), Critically review a manuscript, responsible for communication with the journal during the manuscript submission, peer review and paper writing with methodology & editing.

Ul Huda N: Conception and design of the work, paper writing (Abstract and introduction), Critically review a manuscript, responsible for communication with the journal during the manuscript submission, peer review and paper writing with methodology & editing

Pahore ZA: Discussion Writing

Khurram S: Data analysis and interpretation of results

Qureshi H: Editing of manuscript

Majeed M: Data collection

Akram O: Data collection

Rabbani W: Data collection

Hassan S: Data collection

Khan M: Data collection

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