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ORIGINAL ARTICLE

An audit of pre-analytical errors and specimen rejection in the haematology laboratory of a tertiary care transplant center: Clinical and financial impact: Root cause analysis of specimen rejection in haematology laboratory.

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ABSTRACT… Objective: To identify specific problems regarding pre-analytic processes susceptible to errors and their impact on sample rejection in a haematology laboratory. **Study Design:** A retrospective audit. **Setting:** The study was conducted at the Haematology laboratory of the Pakistan Kidney and Liver Institute and Research Center (PKLI&RC). **Period:** The audit covered a four-year period from 2019 to 2022. **Methods:** A retrospective audit of all samples rejected in the Haematology laboratory was performed. The reasons for rejection and the potential clinical impact of these rejections were investigated. The study was approved by the Institutional Review Board (IRB) of PKLI&RC (Ref No.: PKLI-IRB/AP/110, Approval date: 28 March 2023). **Results:** Out of 250,000 samples received, 568 specimens were rejected, yielding a rejection rate of 0.22%. The most common reasons for rejection were clotted samples (n=274, 48%), results not matching the patient's given history (n=142, 25%), hemolyzed samples (n=40, 7%), insufficient quantity (QNS) (n=34, 5.9%), vial defects (n=15, 2.6%), patient identification errors (n=6, 1%), and sample switches (n=4, 0.7%). **Conclusion:** The implementation of a barcoding system and positive patient ID can help prevent mislabelling and patient ID issues. Proper training and continuing education for all healthcare professionals involved in collecting, handling, and transporting patient samples is crucial to the mitigation of pre-analytical errors. Standardization of processes and procedures can efficiently prevent pre-analytical errors.

Key words: Audit, Financial Impact, Haematology Laboratory, Patient Care, Pre-analytical Errors, Rejection Rate, Turnaround Time.

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INTRODUCTION

Specimen rejection is not only a laboratory problem but it has direct negative affects on patient care jeopardizing patient safety. Not only that it is an inconvenience and discomfort for the patient but the accompanying delay can compromise the safety window we have for ideal patient care.[1] Q- probe analysis by CAP found out that there is an average lag of 65 minutes in availability of test results, implying that the safe time period of conveying the critical value and the golden hour in our septic patients or other life threatening conditions can potentially lead to increase in mortality.[2] A study by Green Et al suggested that financial consequences rise up to around 1 lac PKR per patient and this comprises 1.2% of total hospital operating cost. Based on above dire consequences it was imperative that we as a resource constrained institute, in otherwise constrained country, need to save such hefty amounts. These resources can have a much better utilization and also saving time and energy can be effectively availed for better opportunities. We conducted an audit to serve the following purposes:

1. Identify and subsequently prevent the common causes of specimen rejection.
2. The depreciation cost threshold to be brought to minimum.
3. Capacity building of our staff to work with more precision.
4. Re-evaluation our practices to reject or accept the sample.

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In haematology laboratory the sample stability is the matter of huge concern as we are dealing with cellular elements and long storage by freezing is not possible therefore, samples do get rejected due to following reasons[3,4,5,6,7,8,10]:

1. Clotting
2. Hemolysis
3. Insufficient quantity
4. Mislabeling
5. Broken vials
6. Wrong vials

METHODS

This audit was conducted at our PKLI, which is a 450 bedded medical center which serves as tertiary care transplant center. Samples are also accepted from the community by walk-in patients. The following departments are mainly function Nephrology and Kidney transplant, Hepatology and Liver transplant, Pulmonology, ICU and Pediatric unit. Although specimens are collected by Phlebotomist and Nurses. The study was approved by the Institutional Review Board (IRB) of PKLI&RC (Ref No.: PKLI-IRB/AP/110, Approval date: 28 March 2023). This retrospective research to identify all phlebotomy specimens were received in our Haematology laboratory during last 3.5 years i.e. June 2019 till December 2022. These samples included Haematology, coagulation, and hemoglobin study tests. The total number of specimens collected as well as rejected were tabulated as Type of Sample Rejected (Table-I), Reason of rejection (Table-II), Location of patient or from where the sample was taken (Table-III), Rejection rate per year (Table-IV).

Most test require minimum volume of 1ml and have to be received in appropriate tube. After taking samples, the hematology samples specially CBC are placed on rotator to prevent clotting and adequate mixing of anticoagulant until the sample is transported to the laboratory. The samples are transported in a transportation box forming all biosafety principles and ensured that temperature does not fluctuate. The ideal time for sample transportation which is also a Key Performance Indicator of Lab administration is 30 minutes. An evaluation was performed for comparing specimen rejection rate with every passing year. Data assessment and statistical analysis were performed using Microsoft excel.

TABLE-I

Types of specimens rejected

Type of Samples Rejected	Number of Samples Rejected (Total 568)	Percentage of Samples Rejected
Complete Blood Count	238	42%
Coagulation Profile	330	58%

TABLE-II

Reasons and proportions of specimen rejected

Reasons of Rejection	Rejected Specimen (N) (Total 568)	Percentage (%) of rejected Specimen
Clotting	274	48.2%
Results mismatched with the History of Pt	194	34.1%
Hemolysis	40	7%
Insufficient Quantity	34	5.9%
Vial Defects	15	2.6%
Mislabeling	6	1%
Sample switch	4	0.7%

TABLE-III

Location of the specimen collection

Site of Service	Number of Samples Rejected (total 568)	Percentage of Samples Rejected
Inpatient Department	255	44.8%
Outpatient Department	104	18.3%
ICU	99	17.4%
SICU	6	1.05%
MICU	24	4.2%
PICU	4	0.7%
Emergency Department	30	5.28%
Dialysis Unit	5	0.8%
Blood Bank	11	1.9%
HPTC	30	5.28%

ICU: Intensive Care Unit; SICU: Surgical Intensive Care Unit; MICU: Medical Intensive Care Unit; PICU: Paediatric Intensive Care Unit; HPTC: High Point Treatment Center.

TABLE-IV	
Per year specimen rejection rate	
Year	**Number of Samples Rejected per year**
2019 (June-Dec)	36
2020	42
2021	206
2022	284

DISCUSSION

This quality improvement audit highlights the impacts of specimen rejection on patient's clinical care and financial burden on our institute. As of now we are an on-site laboratory where distance is not an issue and identifying the pre analytical factors leading to sample rejection need to be corrected sooner than later. This will help us to predict problems when we expand our services to outside collection centers in the future. The studies mentioned here include centers with outsource services and therefore the rate of rejection is expected to be higher than our on-site laboratory, though the sample size is pretty comparable. Every laboratory might have their own specimen rejection pattern. Few studies have reported that clotting is the predominant cause of specimen rejection 10. At PKLI&RC Clotted sample comprise (48.2%) of rejected samples (Table-II). Our study indicates that pre-analytical errors including mislabeling and insufficient volume are also one of the major causes this is a preventable issue and educational counselling can be provide adequate support mitigating these reasons (Table-II). A very important aspect shows that specimen acceptability can be variable within the hospital and amongst the technologists. Our usual method to determine the clotting of sample is a stick method and for hemolysis its naked eye interpretation. Difficult sampling in pediatric patient accounted for (0.7%) of sample rejection due to insufficient volume. These methods need to be standardized among laboratories. Currently no standard is being followed by most of the laboratories and there is an element of biasedness. The college of American Pathologist[1] consider specimen acceptability as one of laboratory quality measure whereas most of preanalytical variables including sample quantity and labeling occur outside the laboratory therefore, this measure should be viewed as a multidisciplinary measure for healthcare institution right from patients bedside physician to the person uploading patient report on HMIS. A collaboration between laboratory and nursing staff and other hospital patient care provider group is essential. The chain from sample taking to sample analysis involves multiple hands and frequent links and mismanagement at any single point can spoil the entire chain.[9] Continuous monitoring and tracking on performance improvement can be helpful.

In reference to Table-I, the types of samples studied were Complete Blood counts, Coagulation Profile, Thrombophilia work up and Hemoglobin studies. Out of which only CBC and Coagulation Profile Samples were rejected comprising of more weightage to the Coagulation profile i.e. 58% while 42% samples of CBC were rejected. most of the samples rejected were collected from the inpatient departments i.e. 44.8% (Table-III) where staff nurses draw the samples, while the sample rejection proportion is less in OPDs in which samples are taken by Phlebotomists. So in reference to this study, problem lies mostly at the end of nursing staff for which we can arrange educational sessions for the proper sampling techniques.

Our Rejection Rate per year is being consistent (Table-IV). As there was Pandemic going on in 2020, less samples were received so is the rejection rate.

Our 568 samples were rejected that cost us 0.38 million PKR. Our rejection rate is way below than even the most renowned centers. It is attributed to because most of our samples are inpatient and no remote sampling, our phlebotomy staff is experienced, however deviation from normal rejection parameters to reject a sample need to be looked at.

Although we are already doing much better than most of the centers however with the expansion of services and opening of collection centers this rate is expected to rise exponentially. To improve our ongoing services and preempt the expected problems with outsourcing of services we suggest the following mechanisms:

1. Design a customized educational plan for each role.
2. Standardize the acceptance and rejection

criteria.
3. Design effective workflow practices and devising methods for effective phlebotomy with vessel scan in difficult patients.

CONCLUSION

This audit shows that even small pre-analytical errors like clotted or mislabelled samples can delay care, increase costs, and cause unnecessary discomfort for patients. Although our rejection rate is low, most issues came from inpatient areas, highlighting where better training and support are needed. By improving sampling techniques, strengthening identification systems, and standardizing our processes, we can make testing safer, faster, and more reliable for our patients. As our services grow, these improvements will be essential to maintaining high-quality care.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Mussawair Hussain:** Manuscript writing.
2	**Hira Hassan:** Data analysis.
3	**Unaiza Qamar:** Formatting.
4	**Fayyaz Hussain:** Data collection.
5	**Asif Ali Shah:** Referencing.
6	**Murad Ali:** Writing, methodology.
7	**Shukrya Khan:** Reviewing.