

Pre-analytical Factors Influencing Blood Sample Rejection Rate in the Hematology Laboratory of the Philippine General Hospital from 2018 to 2022: A Cross-sectional Study

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ABSTRACT

Background and Objective. Blood collection errors are one of the most common causes of laboratory sample rejection in the pre-analytical phase of the testing process. This study aims to determine the frequency and identify the pre-analytical factors that lead to rejection of samples meant for the hematology laboratory.

Methods. This cross-sectional, retrospective study analyzed blood samples received and rejected by the Hematology Division of the University of the Philippines – Philippine General Hospital from 2018 to 2022. Data were extracted from the Division's annual reports and sample rejection logbooks. The causes and frequency of sample rejections, as well as the hospital locations of the patients involved were presented using frequency tables.

Results. Out of 1,072,366 blood samples received during the study period, 61,935 (5.78%) were rejected. The most common cause of rejection was clotted blood samples for both routine hematology (86.31%) and coagulation (44.43%). Clotted samples were the predominant cause of sample rejection across most age groups, with the exception of the neonatal and infancy groups, where inadequate sample quantity was the primary issue. The highest rejection rate was seen in the emergency department (65.71%) and intensive care units (9.68%).

Conclusion. The rejection rate in our institution was higher than reported in previous global studies. The main causes of rejection were identified as clotted blood samples and inadequate blood volume for routine hematology and coagulation testing. Notably, the highest rejection rates for hematology-related requests occurred in critical areas, including the emergency department, intensive care units, and obstetrics and gynecology.

Keywords: blood sample collection, pre-analytical phase, hematology test, rejection rate, coagulation test

INTRODUCTION

The role of the clinical laboratory is underscored by its provision of high-quality test results to patients and clinicians.^{1,2} These test results provide crucial information that may confirm a clinical diagnosis, detect an otherwise obscured disease process, determine prognosis, decide the best treatment option, and recognize the success of a therapeutic intervention. The complex process of generating such results warrants a distinct medical specialty (Clinical Pathology) accompanied by trained personnel (e.g., pathologists, medical technologists), sophisticated laboratory techniques, and automation. This intricate operation is generally divided into pre-analytical, analytical, and post-analytical phases, and the culmination is an accurate and precise laboratory

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result reflective of the patient's status at one point during sample collection.²

Despite advancements in the analytical and post-analytical phases, the pre-analytical phase requires rather focused attention. Studies demonstrate that up to 70% of errors originate in this phase, leading to an erroneous testing process and negative downstream effects on patient care.³ Errors include patient misidentification, labelling errors, inappropriate sample containers, missing samples, and errors in sample collection.⁴⁻⁶

The process to produce test results is divided into three phases: the pre-analytical phase, the analytical phase, and the post-analytical phase. Lippi et al. compares the total process to a virtual loop wherein errors may occur throughout the complex cycle.⁷

The pre-analytical phase occurs before a sample is analyzed and a particular analyte of interest is determined. It is important to emphasize that the pre-analytical process is notably intricate. In fact, according to a paper by Plebani, the pre-analytical phase should be divided into a "pre-pre-analytical phase" and a "true" pre-analytical phase. The former is defined as the initial procedures performed or with partial involvement of the clinical laboratory and its personnel. In contrast, the latter is defined by the steps required prior to sample testing processed by the laboratory personnel.⁸ Examples of errors in the "pre-pre analytical phase" are inappropriate test requests, order entries, patient misidentification, sample collection (e.g., a sample collected from infusion route, hemolysis, insufficient volume), handling (e.g., inappropriate containers), storage (e.g., freezing), and transportation. Meanwhile, sample sorting and routing, pour-off, aliquoting, pipetting, labelling, and centrifugation are considered as errors in the "true" pre-analytical steps.⁹

The University of the Philippines - Philippine General Hospital (UP-PGH) stands at the forefront of this challenge, with the Department of Laboratories providing approximately 340,000 tests and procedures annually. A portion of these services are delivered by the Division of Hematology, which examines blood samples to help diagnose erythrocytic and leukocytic disorders, as well as disorders in hemostasis and thrombosis. The Department of Laboratories is not exempt from pre-analytical errors. It is fortunate that the Division of Hematology has excellent record keeping and supports studies to identify possible causes of such errors. To our knowledge, there are no comparable studies to elucidate on these errors in our institution, specifically in the Division of Hematology. This study, therefore, aimed to identify the pre-analytical factors that lead to sample rejection in the Philippine General Hospital – Division of Hematology from January 1, 2018, to December 31, 2022. Specifically, this study aimed to determine the frequency of pre-analytical errors leading to sample rejection, categorize these errors based on their nature (e.g., improper sample collection, labelling errors, and inappropriate sample documentation) and by the hospital areas where they occur.

To obtain high-quality test results, the total error in all three phases of the testing process must be kept to a minimum, especially during the pre-analytical phase where the majority of the laboratory errors take place. The knowledge obtained from this study can help develop appropriate error detection programs and corrective measures to mitigate unnecessary procedures to patients, wastage of hospital resources, and operating costs that will result in negative effects in healthcare delivery and the overall healthcare system.

METHODS

Study Design

This cross-sectional, retrospective study investigated pre-analytical factors leading to sample rejection within the Hematology Division of the Department of Laboratories. The study focused on factors such as improper sample collection, labeling errors, and inadequate sample documentation.

Improper sample collection includes the use of wrong tubes, insufficient blood volume, hemolysis, diluted samples, clotted samples, use of wrong tube, underfilled tubes, overfilled tubes, and submission of empty tube. Labelling errors include mislabeled or unlabeled sample tubes. Inappropriate sample documentation includes incomplete request forms, incorrect patient data, and lack of patient data in the laboratory information system (LIS).

Study Site and Population

The study was conducted in the UP-PGH Department of Laboratories - Hematology Division and involved all rejected samples from January 1, 2018, to December 31, 2022 registered in the sample rejection logbooks of the division.

The study included all samples from the Division of Laboratory Information and dedicated for testing by the Hematology Division of the Central Laboratory. These samples must have included key data such as age, sex, the date received, the test requested, the reason for sample rejection, and the patient's location at the time of sample collection. Conversely, samples processed by other laboratory divisions prior to testing in the Hematology Division and samples lacking complete data were excluded.

Data Collection

Data were obtained from the sample rejection logbook of the Division of Hematology from January 1, 2018, to December 31, 2022. Total enumeration of all rejected samples was recorded and analyzed. Patients' age and gender, the date the sample was received, requested tests, the reason for sample rejection, and the patient's location were obtained. Retrieved data were encoded and organized into a spreadsheet using Microsoft Excel 2021. The division's annual and monthly census for received samples were likewise retrieved and recorded. All data were collected during office hours and within the premises of the UP-PGH Department of Laboratories to prevent potential loss of physical records and possible

breach of patient confidentiality. Logbooks were stored in a secure storage area within the Hematology Division, which was managed by the division supervisor. Permission to access the documents was coursed through the division supervisor and division head. Patients' privacy and confidentiality were followed according to hospital's guidelines.

Data Analysis

The sample rejection rate was computed by dividing the total number of rejected samples by the total number of samples received during the specified period. The samples were further stratified based on the indicated reason for rejection, the test request, the patients' age group, and location.

Collected data were tabulated, organized, and analyzed using the pre-programmed formulas in Microsoft Excel 2021. Descriptive statistics (i.e., mean, median, range, and percentage) were used based on the frequencies and proportions from the summarized categorical data. Graphs and tables were used to organize data and show relationships.

Ethical Considerations

The study protocol was reviewed and granted ethical approval by the University of the Philippine - Manila Research Ethics Board (UPMREB 2023-0433-01). The primary investigator was supervised by the co-investigator, serving as the research adviser to ensure the ethical conduct of the study.

Table 1. Blood Samples Received at and Rejected by the Hematology Division from 2018 - 2022

Year	Blood samples received, n	Blood samples rejected, n	Sample rejection rate (% of total)
2018	228,438	12,956	5.67
2019	264,873	15,569	5.88
2020	143,439	5,451	3.80
2021	191,762	12,227	6.38
2022	243,854	15,732	6.45
Total	1,072,366	61,935	5.78

RESULTS

The study retrospectively collected information from the Division of Hematology of the UP-PGH from 2018 to 2022. A total of 1,072,366 were received for various hematology-related tests. Of these, 61,935 samples were rejected (Table 1). This comprised a mean of 5.78% of all blood samples received over a period of five years. Data showed a decrease in samples received during the onset of the COVID-19 pandemic in 2020, with an increase in numbers in the following years.

Table 2 shows the frequency distribution and reasons for rejection relative to each routine hematology test. Clotted sample (n=17,828, 86.31%) was the most common reason for rejection across all routine hematology tests. This was followed by improperly labeled samples (n=1294, 6.26%) and an inadequate quantity of samples (n=1176, 5.69%).

Frequency and reasons for rejection relative to each of the coagulation studies offered by the laboratory is shown in Table 3. Clotted sample (n=18,342, 44.43%) remained the most common reason for rejection. This was followed by an inadequate quantity of samples (n=13,255, 32.11%) and overfilled blood collection tubes (n=7,222, 17.5%).

The majority of rejection criteria were related to improper sample collection. These issues included clotted samples, inadequate volumes, diluted samples, incorrect tubes, underfilled or overfilled tubes, and the submission of empty tubes. Specifically, 93.11% of rejected samples for hematology testing and 97.35% for coagulation testing were due to these collection problems. A smaller proportion of rejections were due to labeling errors (6.26% for hematology tests and 2.41% for coagulation tests) and inappropriate sample documentation (0.62% for hematology tests and 0.24% for coagulation tests).

Table 4 shows the frequency distribution of rejected samples for testing according to age and reasons for sample rejection in UP-PGH from 2018-2022. The majority of rejected samples were from young and middle-aged adults at 34.53% (n=21,388), followed by older adults and pediatric patients at 24.97% (n=15,465) and 20.04% (n=12,412), respectively. Clotted blood samples were the most frequent

Table 2. Frequency Distribution of Rejected Samples for Routine Hematology Tests from 2018 - 2022

	Complete Blood Count, n	Erythrocyte Sedimentation Rate, n	Reticulocyte Count, n	Peripheral Blood Smear, n	Hemoglobin and Hematocrit, n	Total, n (%)*
<i>Clotted</i>	16237	374	550	554	113	17828 (86.31)
<i>Improperly labeled samples</i>	1139	81	22	20	22	1294 (6.26)
<i>Inadequate quantity of sample</i>	682	438	22	12	22	1176 (5.69)
<i>Diluted</i>	110	14	6	2	4	136 (0.66)
<i>No LIS entry</i>	88	18	6	5	12	129 (0.62)
<i>Hemolyzed</i>	22	5	0	5	0	32 (0.15)
<i>Inappropriate blood collection tube</i>	15	7	5	1	0	28 (0.14)
<i>Underfilled blood collection tube</i>	22	0	0	0	0	22 (0.11)
<i>No blood in tube</i>	9	1	0	1	0	11 (0.05)
Total	18324	938	611	600	183	

*Percentage of rejected samples per specified reason over total number of rejected samples.

Table 3. Frequency Distribution of Rejected Samples for Coagulation Tests from 2018 – 2022

	Prothrombin Time	Activated Partial Thromboplastin Time	D-dimer	Fibrinogen	Protein S	Protein C	Factor VIII	Factor IX	Total, n (%)*
<i>Clotted</i>	9032	8691	496	30	32	32	16	13	18342 (44.43)
<i>Inadequate quantity of sample</i>	6600	6358	286	11	0	0	0	0	13255 (32.11)
<i>Overfilled blood collection tube</i>	3608	3432	110	41	12	11	5	3	7222 (17.5)
<i>Improperly labeled samples</i>	462	415	78	27	6	6	2		996 (2.41)
<i>Underfilled blood collection tube</i>	418	396	103	14	2	2	2	2	939 (2.27)
<i>Hemolyzed</i>	110	102	33	5	1	1	2	1	255 (0.62)
<i>Inappropriate blood collection tube</i>	56	49	15	1	0	0	0	0	121 (0.29)
<i>No LIS entry</i>	44	40	6	2	1	0	1	1	95 (0.23)
<i>Diluted</i>	24	21	5	4	0	0	0	0	54 (0.13)
Total	20354	19504	1132	135	54	52	28	20	

*Percentage of rejected samples per specified reason over total number of rejected samples.

Table 4. Frequency Distribution of Sample Rejection according to Patients' Age Group

Reason for rejection	Neonates and infants (0-1 years)	Pediatric (2-18 years)	Young and Middle-aged adults (19-44 years)	Older adults (45-64 years)	Elderly (65 years old and above)
<i>Clotted</i>	634	5976	13239	10434	5887
<i>Inadequate quantity of sample</i>	2021	5541	2320	2571	1978
<i>Overfilled</i>	0	335	4265	1550	1072
<i>Improperly labeled</i>	157	324	954	436	419
<i>Underfilled</i>	102	96	256	304	203
<i>Hemolyzed</i>	30	36	114	44	63
<i>Diluted</i>	34	41	57	35	23
<i>No LIS entry</i>	11	43	91	58	21
<i>Inappropriate blood collection tube</i>	8	18	87	31	5
<i>No blood in tube</i>	1	2	5	2	1
Total, n (%)	2998 (4.84)	12412 (20.04)	21388 (34.53)	15465 (24.97)	9672 (15.62)

*Percentage of rejected samples per age group over total number of rejected samples.

cause of rejection across most age groups, with the exception of the neonatal and infancy groups, where inadequate sample quantity was the primary reason for rejection.

Figure 1 shows the proportion of the rejected samples relative to the different clinical services from which the samples were collected. The highest proportion of rejected samples are from the Emergency Room Complex (65.71%), Intensive Care Units (9.68%), Obstetrics and Gynecology (7.79%), Pediatrics (5.71%), Surgery (3.44%), and Medicine (2.61%). The lowest proportion came from the Psychiatry ward (0.01%).

DISCUSSION

In the clinical laboratory, errors during the pre-analytical phase can contribute to as much as 75% of total laboratory errors. Of these, 26% can negatively impact

patient care which may lead to unnecessary investigations and expenditure, inappropriate treatments, longer hospital stays, and overall dissatisfaction with healthcare services.¹⁰ The need to identify and categorize errors based on their most common causes allows for the identification of those that need urgent attention for quality improvement. This approach helps in implementing corrective and preventive measures to mitigate these errors.¹¹

The current study showed that the mean overall rejection rate in the Department of Laboratories - Hematology Division is 5.78%. This is significantly higher compared to other laboratories worldwide with reported rejection rates between 0.44% and 3.19%, as mentioned in different studies. In a meta-analysis of 26 studies from across the globe done by Getawa et al., a high level of heterogeneity in rejection rates was observed with a minimum prevalence of 0.11% in China to 10.58% in India. A subgroup analysis revealed a 3.19%

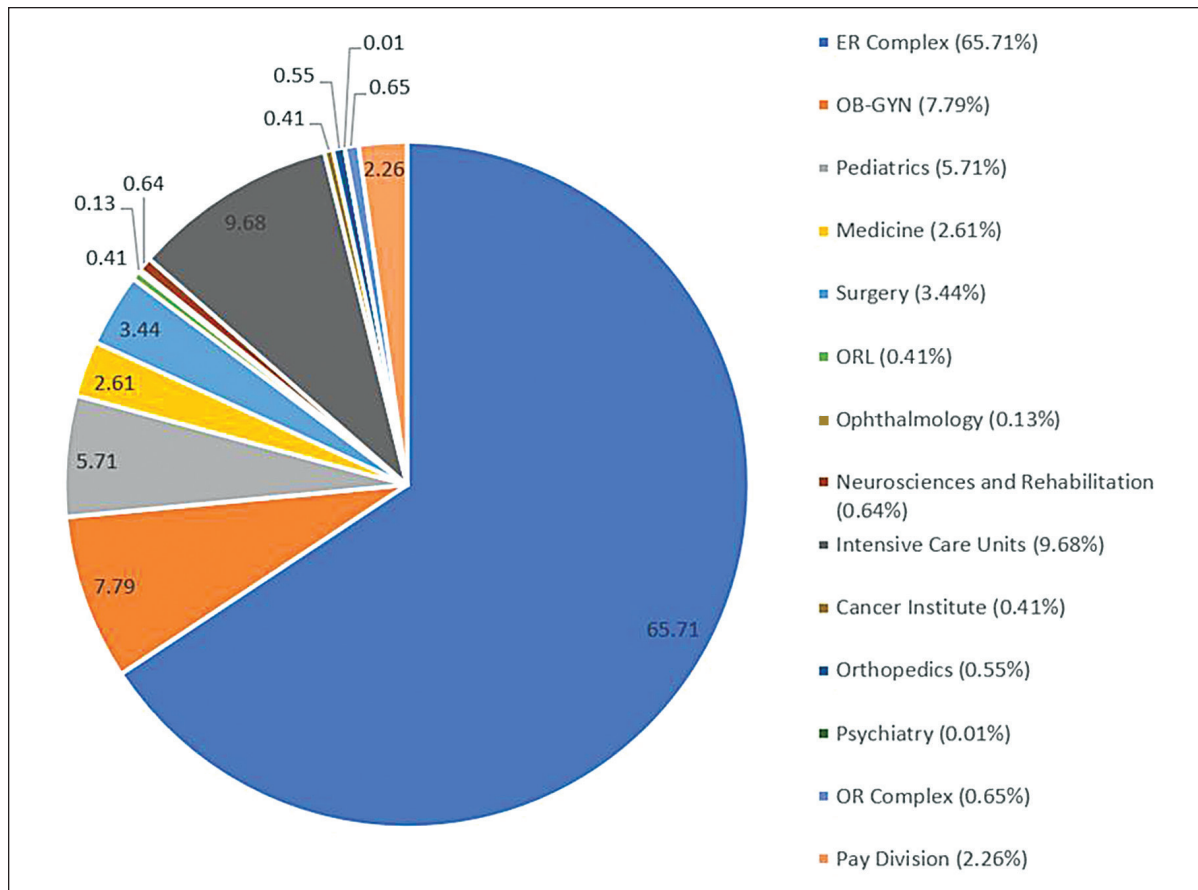


Figure 1. Sample rejection rate based on the distribution of the rejected samples for testing according to department.

rejection rate in Southeast Asia, which is lower than the rate observed at our institution.² Lippi et al. also reported an overall incident rate of 1.22% gathered from 59 participating laboratories worldwide.⁹ A study done in a private laboratory in Pakistan which processes an estimated 690,000 blood samples a year reported a rejection rate of 5.15%.¹² Their rates were still slightly lower than the findings of this study despite processing three times the volume of samples. The significant difference in reported rejection rates may be due to a number of reasons including staffing concerns, experience and expertise of staff, nature of services offered in institutions, among others. Additionally, varying levels of understanding of operational procedures and laboratory quality standards among staff could also contribute to this discrepancy.

Despite the difference in numbers, the most common causes of blood sample rejection reflect the same findings across the different studies and settings: clotted blood and insufficient sample volume. One of the possible factors leading to the high rate of clotted blood in our laboratory is inadequate blood mixing during sample collection. According to the Clinical and Laboratory Standards Institute (CLSI) manual, blood collected in tubes containing ethylenediaminetetraacetic acid (EDTA) and citrate for routine hematologic and coagulation testing requires immediate, gentle, adequate

mixing by tube inversion for approximately 8 and 3-4 times, respectively. Inadequate mixing leads to clot formation, making the blood sample unsuitable for analysis.¹³ Another cause of clotted blood samples is slow blood draw, especially among patients with non-visible and non-palpable blood vessels. Delay in the transfer of blood in blood collection tubes during syringe collection is another reason to be considered, as closed-system blood collection is not commonly utilized.¹³

Inadequate sample was the second most common cause of sample rejection across all hematology tests and was also the most common cause for sample rejection among the neonates and infants in this study. Insufficient sample volume often arises when multiple tests are requested and need to be analyzed across different laboratory areas or testing platforms. This issue is particularly common in pediatric patients, especially neonates, where only a small amount of blood is collected in microtainer tubes for testing. Possible causes may also be due to unsatisfactory phlebotomy techniques and poor patient preparation.¹⁴

Overfilled tubes was the third most common cause of rejection in coagulation tests in this study. Sodium citrated tubes must be filled up to 90% of the nominal volume or to the mark noted on the tube if provided. The required ratio of sodium citrate to whole blood is 1:9.¹⁵ This finding contrasts

with previous reports, which commonly identify under-filling of tubes as a leading cause of rejection in coagulation testing.¹⁵ The discrepancy observed in our study may be attributed to the specific type of blood tubes utilized at our institution.

Other causes of rejection under improper sample collection were also encountered in this study. Diluted samples are caused by drawing blood from veins with intravenous lines.¹⁶ Hemolyzed samples are encountered due to poor sample collection (poor venous access, poor extraction technique, traumatic venipuncture, small needle size, forced passage of blood through the needle) and inappropriate sample preparation (inappropriate centrifugation conditions, freeze/thaw), handling, and transportation (excessive shaking of tube, delay in processing, exposure to extreme temperatures).¹⁷ Our study noted a very small percentage of rejection for use of wrong tubes (0.14-0.29%) in contrast to previously reported studies (1.8 – 8.1%).¹⁸ This may be attributed to the presence of trained phlebotomists at our institution as opposed to higher rejection rates in studies where samples were collected by physicians and nurses from various hospital units.¹⁸

Labelling errors, specifically improper labelling of tubes, were the second most common cause of sample rejection in hematology tests (6.26%) observed in this study. This issue can arise during sample collection due to misidentification of patients, the use of illegible handwritten labels, or mishandling occurring before or after the collection process. Such problems can result in delayed diagnoses, the need for additional laboratory tests, or incorrect treatment for the patient.¹⁸

This study also highlighted the specific areas where sample rejection was most prevalent. Consistent with Getawa et al. (2023), the highest rejection rates were observed among patients in the emergency and critical care units, surgical, pediatric, and obstetric and gynecological wards. High rejection rates in critical areas, such as the emergency department, intensive care units, and obstetric and gynecological cases may be linked to rapid patient turnover, high pressure situations, and variability in patient conditions. These factors can result in lost time that could otherwise be used for life-saving clinical decisions based on accurate laboratory results. Additionally, repeated blood draws can place an extra burden on already compromised patients and add to the workload of clinicians and other healthcare professionals involved in their care.

Laboratory errors significantly impact patient care and sometimes lead to unacceptable adverse events. Plebani reports that the risks of inappropriate care due to laboratory errors range from 6.4% to 12%, and 20% to 30% of these errors proceed to significant patient care problems, causing patient discomfort and increased costs in the healthcare system.⁸ Green stresses that the average cost of pre-analytical errors in North America ranges from 0.23% to 1.2% of the total hospital operating cost – approximately \$1,199,122

annually.¹⁰ Furthermore, the impact on efficiency is also identified, with an estimated 24,027 total patient hours lost. Of these, approximately 10% was due to laboratory redraw/processing, while 90% was due to additional patient treatment. Given all these figures, errors in the healthcare sector should be kept minimal, and if possible, these events should not occur. However, since human errors cannot be eliminated, compliance with best practices may help these endeavors.

Various studies have proposed several interventions during the pre-analytical phase to reduce laboratory errors. One of these is the introduction of pre-analytic workstations wherein automation is incorporated in the sorting, labeling, and aliquoting of samples. This was proven to improve the integrity of sample handling throughout laboratory processes. Furthermore, education with competency validation of involved personnel based on established guidelines and standard operating procedures has translated into higher-quality samples coming into the laboratory. Lastly, appropriate error detection programs and measures for error reduction must be in place to determine the effectiveness of corrective actions. Currently, our institution does not have these measures in place. The standard operating procedures only specify rejection criteria and provide detailed instructions for proper collection, transport, and storage. Implementing additional protocols as described could potentially improve rejection rates at our facility.

Given that the laboratory department is pursuing International Organization for Standardization (ISO) 15189 accreditation, it is essential to integrate and rigorously enforce hospital and laboratory quality indicators, including effective management and monitoring of laboratory sample rejection, to achieve accreditation from international organizations. Causes of rejection should be communicated well with the respective clinical services, and the hospital should likewise address feedback through the laboratory department. Laboratory reports should also contain information regarding affected analytes when the samples are compromised to promote vigilance from the clinician or personnel collecting laboratory samples. As the patients' well-being is at the center of quality laboratory services, results of customer feedback and surveys should be discussed during meetings to formulate and implement strategies to improve blood sample collection procedures.

A significant limitation of this study is its exclusive focus on samples processed within the central laboratory, thereby excluding samples handled by other divisions. This limitation restricts the scope of our findings and implies that the reported rejection rate may not fully represent broader laboratory practices of our institution. Observer and temporal bias may have also affected the manner of documentation of rejected samples. Future studies should consider including samples from all divisions to offer a more comprehensive perspective on the pre-analytical challenges encountered within the healthcare setting. The current study relied solely on record

reviews and did not incorporate focus group discussions or key informant interviews. Consequently, factors such as staffing concerns, personnel experience, personnel training, temporal patterns, and interdepartmental issues were not examined.

CONCLUSION

This study revealed that the rejection rate in the Department of Laboratories - Division of Hematology was notably higher compared to previous global reports. The primary causes of rejection were clotted blood samples and insufficient blood volume for both routine hematology and coagulation testing. Additionally, the highest rejection rates for hematology-related requests were observed in critical areas such as the emergency department, intensive care units, and obstetrics and gynecology. However, factors such as staffing and personnel, training, temporal patterns, and interdepartmental issues were not examined in this study. Future research should incorporate these elements to gain a comprehensive understanding of areas for improvement and to effectively reduce pre-analytical errors and subsequent sample rejection.

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Statement of Authorship

Both authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

Both authors declared no conflicts of interest.

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