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INVESTIGATION OF THE IMPACT OF SOME PRE-ANALYTICAL VARIABLES ON HEMATOLOGY SAMPLE REJECTION RATES AT MASVINGO PROVINCIAL LABORATORY, ZIMBABWE (2024)

BY

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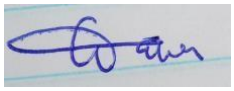
ABSTRACT

The investigation aimed to assess the impact of pre-analytical variables on hematology sample rejection rates at Masvingo Provincial Laboratory in Zimbabwe. High rejection rates can compromise patient care and laboratory efficiency, necessitating a thorough understanding of contributing factors. A retrospective cross-sectional study design was employed, analysing data from all haematology samples submitted over a one-year period in 2024. The study included both accepted and rejected samples, leveraging historical records to identify patterns. Key informant interviews with laboratory personnel and healthcare providers supplemented the quantitative data. A standardized data extraction form, validated through expert consultations and pretesting, captured information on specimen collection, handling, and transportation conditions. Ethical approval was secured prior to the study. Monthly rejection rates fluctuated between 0.2% and 3.0%, with the highest rates observed in June, July, and October. Clotted samples emerged as the primary cause of rejection (28%), followed by incorrect tube usage (18%) and lip emic samples (14%). Analysis revealed that the majority of rejections originated from the paediatric ward, highlighting specific areas for improvement. The findings underscore the critical role of pre-analytical factors in sample rejection rates. Recommendations include enhancing training for staff on specimen handling and collection techniques, particularly in high-rejection wards. Implementing systematic reviews of procedures may further reduce rejection rates, ultimately improving patient outcomes and laboratory efficiency.

DECLARATION

I, Gracious Garira, student number 210517 do hereby declare that this proposal is my original work except where sources have been cited and acknowledged. This work has never been submitted by anyone, nor will it ever be submitted to another university for the award of a Bachelor of Science degree.

Gracious Garira 

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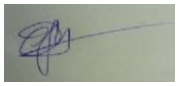
Prof. Emmanuel Obeagu Ifeanyi 

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AWKNOLEDGEMENTS

First and foremost, I would like to express my gratitude to the Almighty for guiding me to this point. In the process of preparing this dissertation, I am especially thankful to my supervisor, Professor Emmanuel Obeagu, for his continuous support and guidance. I also wish to acknowledge my father, Mr. Garira. My sincere appreciation goes to the Masvingo Provincial Hospital Laboratories for permitting me to carry out this research, as well as to their staff for their steadfast support throughout my project.

DEDICATION

I dedicate this dissertation proposal to my father, Mr. Garira for being there for me always with his unwavering support and prayers.

TABLE OF CONTENTS

Table of Contents

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

CHAPTER ONE: INTRODUCTION

1.0 Background of the study:

Hematology laboratory testing plays a critical role in the diagnosis, monitoring, and management of various health conditions. It provides crucial insights into a patient's health status, aiding in the diagnosis and management of various conditions such as anaemia, infections, and hematologic malignancies (Hoffbrand et al., 2016). The reliability and accuracy of hematology test results are heavily dependent on the quality of the collected samples. Pre-analytical phase refers to all steps from preparing the patient for collection of the specimen to processing of the specimen prior to the analytical step. This phase includes specimen collection, handling, labeling, and transportation (Cheesbrough, 2010). In hematology, the pre-analytical phase is particularly crucial due to the sensitivity of blood samples and the potential for variations that can affect test results. Proper and accurate management during this phase is essential to ensure accurate test results. However, it is susceptible to errors that can compromise the integrity of hematological samples and result in high sample rejection rates. Specimens are rejected by the laboratory if they do not meet predefined technical requirements for each specific analysed. Factors such as improper sample collection techniques can lead to sample rejection and inaccurate results (Hoffbrand et al., 2016). Blood samples must be labelled correctly to ensure they are identified with the right patient and tests. Any inconsistencies between the requisition form and the sample labels can lead to confusion and incorrect results. Using the incorrect tube can impact the preservation of blood components, affecting tests such as coagulation or cell counts. Blood samples that are not processed

within appropriate time frames can degrade, particularly affecting parameters like cell counts and morphology. Also, if the blood sample is too small, it may not provide enough material for comprehensive testing.

Furthermore samples that are haemolysis (breakdown of red blood cells) or Lip emic (excess fat in the blood) can yield unreliable results, particularly impacting tests like haemoglobin measurement. Leaking tubes or contamination from improper handling can cause skewed results. Ensuring proper procedures in the preanalytical phase is essential in hematology to minimize rejection rates. Adequate training for staff, strict adherence to protocols, and attention to detail can help maintain the quality of blood samples, directly impacting patient diagnosis and treatment. (Klein & Zaleski, 2017). High rates of sample rejection pose challenges in laboratory operations, leading to increased turnaround times, repeat sample collection, and potential delays in diagnosis and treatment. Understanding the factors contributing to sample rejection is crucial for quality improvement initiatives. Investigating the impact of pre-analytical variables on hematology sample rejection rates at Masvingo Provincial Laboratory in Zimbabwe was essential for identifying specific areas of improvement in sample handling practices and implementing targeted interventions to enhance the quality and efficiency of laboratory services. The current state of pre-analytical practices at Masvingo Provincial Laboratory and the prevailing sample rejection rates served as a baseline for the study, highlighting existing challenges and areas for enhancement.

1.1 Statement of the Problem:

Despite the critical role of hematology testing in patient care, Masvingo Provincial Laboratory in Zimbabwe has been experiencing elevated rates of sample rejection in hematology testing procedures (Masvingo Provincial Laboratory, 2022). In the context of laboratory operations, a sample rejection rate of 2% or higher is considered a nonconformity and raises significant concerns regarding the quality of pre-analytical processes .This issue also raises concerns about the quality and reliability of laboratory results, potentially leading to delays in diagnosis, treatment, and patient care (Sibanda, Katambo, & Ngazimbi, 2021). The laboratory had been consistently encountering a high volume of rejected hematology samples, which indicated underlying issues in preanalytical processes that needed to be identified and addressed. High sample rejection rates can strain laboratory resources, increase turnaround times for test results, and impede the timely delivery of diagnostic information to healthcare providers and patients. Inaccurate or delayed test results due to sample rejection can compromise the quality of patient care, leading to potential misdiagnoses, inappropriate treatments, and suboptimal health outcomes. Repeat sample collection and retesting due to sample rejection not only escalate costs for the laboratory but also consume valuable time and resources that could be redirected towards other critical laboratory activities. Moreover, re-drawing of blood from a patient is uncomfortable, and complications such as hematoma and iatrogenic anemia are potential risks (World Health Organization, 2020).There was a pressing need to investigate the specific pre-analytical variables contributing to sample rejection at Masvingo Provincial Laboratory and to develop targeted strategies for enhancing sample quality, reducing rejection rates, and improving overall laboratory performance. In light of these challenges, a comprehensive examination of the impact of pre-analytical variables on hematology sample rejection

rates at Masvingo Provincial Laboratory was indispensable to identify root causes, implement corrective measures, and elevate the standard of laboratory services to ensure optimal patient care and diagnostic accuracy. In addition, it was necessary to identify whether there is an influence between the knowledge and practice of nursing officers who collect blood samples on the rejection rate.

1.2 Justification of the Study:

The proposed study was essential for several reasons. Elevated hematology sample rejection rates can indicate underlying issues in pre-analytical processes that compromise the accuracy and reliability of laboratory results. By investigating the impact of pre-analytical variables on rejection rates, the study aimed to identify root causes and develop targeted interventions to improve sample quality and reduce rejection incidents, ultimately enhancing the overall quality of laboratory services. Also, high sample rejection rates can strain laboratory resources, increase turnaround times, and impede the timely delivery of diagnostic information to healthcare providers and patients (Hoffbrand et al., 2016). Understanding the implications of rejection rates on operational efficiency is crucial for optimizing workflows, resource allocation, and costeffectiveness within the laboratory setting. Besides that, Inaccurate or delayed test results due to sample rejection can have detrimental effects on patient care, leading to potential misdiagnoses, inappropriate treatments, and compromised health outcomes. By addressing sample rejection issues, the study aimed to improve the quality of patient care by ensuring the timely and accurate delivery of diagnostic information. Moreover repeating sample collection and retesting due to rejection not only incur additional costs for the laboratory but also consume valuable time and resources. By reducing rejection rates through targeted interventions, the study had the potential to generate cost savings, optimize

resource utilization, and enhance the overall cost-effectiveness of laboratory operations. Investigating the impact of pre-analytical variables on sample rejection rates contributed to the existing body of knowledge on laboratory quality assurance practices. The study findings informed best practices and guidelines for improving pre-analytical processes not only at Masvingo Provincial Laboratory but also in similar healthcare settings, promoting continuous quality improvement and standardization in laboratory testing procedures.

1.3 Research Objectives:

1.3.1: Broad Objective:

- To investigate the preanalytical factors influencing hematology sample rejection rates at Masvingo Provincial Laboratory ,Zimbabwe

1.3.2: Specific Objectives:

- To determine the prevalence of sample rejection in hematology testing at Masvingo Provincial Laboratory.
- To identify the most common reasons for sample rejection at Masvingo provincial hospital laboratory.
- To evaluate the impact of sample rejection on laboratory operations and patient care.

1.4 Research Questions:

1. What is the prevalence of sample rejection in hematology testing at Masvingo Provincial Laboratory?

2. What are the most common reasons for sample rejection at Masvingo Provincial Hospital?

3. What are the implications of sample rejection on the quality of patient care and clinical decision-making?

1.5 Limitations of the Study

The study's delimitations encompassed its focus on Masvingo Provincial Laboratory in Zimbabwe, potentially limiting the generalizability of findings, while time constraints may have affected the depth of data analysis and intervention sustainability. This was a retrospective study and patient information was obtained from the folders stored at medical records. Resource limitations impacted the study's ability to implement comprehensive interventions or conduct extensive analyses, and data quality issues or ethical considerations restricted access to certain information. Staff cooperation and engagement, as well as external factors like policy changes, could influence the effectiveness and sustainability of proposed interventions. Lifestyle influences on preanalytical variables and sample rejection rates, such as dietary habits or access to healthcare services, were not extensively explored due to the study's focus on laboratory processes. These delimitations underscored the need to interpret the study results within

the specific context of Masvingo Provincial Laboratory, recognizing the constraints and potential impact of these factors on the study's outcomes and recommendations.

1.6 Delimitations of the study:

This study examined the prevalence and causes of sample rejection in hematology testing specifically at Masvingo Provincial Laboratory in Zimbabwe. The research covered a detailed analysis of pre-analytical variables that contribute to sample rejection, including labeling accuracy, collection techniques, and transport conditions. The study utilized data collected throughout the year to reflect current operational practices and identify areas for improvement. Additionally, the research assessed the impact of sample rejection on laboratory efficiency and patient care, focusing on how delays in testing can affected diagnosis and treatment outcomes. By concentrating on hematology testing, the findings provided insights specifically relevant to this field, although they could offer additional implications for overall laboratory practices. The study did not encompass other laboratory areas, such as biochemistry or microbiology, neither did it consider factors beyond the pre-analytical phase, ensuring a clear and focused investigation within the defined parameters. This study focused exclusively on sample rejection rates within hematology testing at Masvingo Provincial Laboratory in Zimbabwe, limiting the scope to this specific geographical location and type of laboratory testing. The research analyzed data from samples collected throughout the year, ensuring relevance to current practices while excluding historical data. It specifically investigated pre-analytical variables such as labeling errors and sample collection techniques, without addressing post-analytical or analytical phases. The target population included laboratory staff involved in sample collection and processing, as well as healthcare providers affected by sample rejection, while perspectives from patients and administrative staff was not

included. This focused approach aimed to provide a comprehensive understanding of the challenges related to sample rejection in this context, though findings may not be broadly applicable to other settings.

1.7 Summary:

The research study is focusing on the impact of pre-analytical variables on hematology sample rejection rates at Masvingo Provincial Laboratory in Zimbabwe, the scope and justification of the study are outlined. The chapter discusses the significance of investigating rejection rates, emphasizing quality improvement, operational efficiency, patient care, cost savings, and knowledge advancement as key motivators. Limitations are also presented, including the study's single-center focus, time and resource constraints, data availability and quality issues, ethical considerations, staff cooperation, and external factors. The geographical scope, lifestyle influences, and challenges specific to Masvingo Province are highlighted as factors that may impact the study's generalizability and applicability.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction:

The increasing complexity of healthcare demands that laboratory services maintain high standards of accuracy and reliability, particularly in hematology testing, where timely and precise results are critical for effective patient management. Elevated rates of sample rejection pose significant challenges to laboratory operations, leading to delays in diagnosis and treatment. The preanalytical phase is crucial in the laboratory workflow and this is also the phase where many errors stem from. This preanalytical phase encompasses all processes that occur before the actual analysis of a laboratory sample, including patient preparation, specimen collection, handling, transportation, and processing. However, research indicates that this phase significantly influences the quality of laboratory results, particularly in hematology. Rejection of hematology samples can lead to delays in diagnosis and treatment, emphasizing the need to understand the factors contributing to these rejections. This literature review aims to explore the various factors contributing to sample rejection, focusing on pre-analytical variables. By examining existing research, guidelines, and case studies, this review also highlighted the implications of high rejection rates on laboratory efficiency and patient care outcomes. Additionally, it helped in identifying gaps in the current literature and suggest areas for further investigation, ultimately emphasizing the importance of optimizing pre-analytical processes to enhance the quality of laboratory services. Understanding these dynamics is essential for developing targeted strategies to reduce rejection rates and improve diagnostic accuracy, thereby ensuring better health outcomes for patients.

2.2 Literature Review

2.2.1 Prevalence of hematology sample rejection at Masvingo Provincial Hospital laboratory:

The prevalence of sample rejection is a significant concern in laboratory settings. In a study conducted at various healthcare facilities, it was found that sample rejection rates can vary widely, often ranging from 5% to 20% (Karp et al., 2020).The Malaysian

Society for Quality in Health (MSQH), in its 2017 5th edition of the MSQH Hospital Accreditation Standards, recommended a rejection rate of less than 1%, as one of the quality indicators in the medical laboratories (Malaysian Society for Quality in Health, 2017). There is no standard method to set the target rejection rate. However, the College of American Pathologists (CAP) suggests that each institution compare its internal rates of specimen rejection to benchmarks from multi-institutional studies. The institution should specify a low threshold for action if the rejection rates increase very much. Achieving a rejection rate of less than 1% would be quite a daunting task for our institution (Jones, 1997).In the context of Masvingo Provincial Laboratory, understanding the local prevalence is essential for benchmarking against national and international standards. High rejection rates can point to systemic issues in sample handling and processing, which, if unaddressed, could lead to compromised patient care. For instance, a study by López and Colomer (2015) highlights that laboratories with rigorous quality control measures tend to have lower rejection rates, emphasizing the importance of continuous monitoring and evaluation. At the Masvingo Provincial Laboratory, a sample rejection rate greater than or equal to 2% is considered a nonconformity. If our annual rejection rate is more than 2%, it is a critical challenge that can significantly impact patient care and the efficiency of healthcare delivery to the local population. The cause of rejection is closely linked to the type of test and the location of the specimen. Gunnur, Pinar, and Akbiyik (2015) found that the ratio rejected specimens

was higher in the emergency departments (40%) compared to intensive care units (ICU) (30%) and inpatient services (28%). They have also identified that clotted samples (35%) and insufficient samples (13%) as the leading causes of rejection for coagulation tests, blood gas analyses and complete blood count (CBC) (Gunnur, 2015). Rooper et al, (2017) also found emergency departments to have the highest number of rejected samples, which contributed about 26.9% of all rejected samples. Their study showed that the highest rate of rejection was from neonatal ICU. The outpatient locations had 2.85% specimen rejection compared to inpatient locations (13.03%) (Rooper et al., 2017). Stark et al. (2007) found that the specimens rejected from ED and inpatient services were 2fold and 5-fold higher than for the outpatient services (Stark et al., 2007). In the context of Masvingo Provincial hospital, most rejected samples are from the paediatric wards, antenatal clinic, post natal ward and out-patient department. This particularly concerning due to the vulnerability of these patient populations. Addressing these high rejection rates was imperative for enhancing laboratory performance and ensuring that patients receive timely and accurate diagnostic information.

2.2.2 Most common reasons for sample rejection at Masvingo provincial hospital laboratory:

Sample rejection in clinical laboratories often stems from a variety of preventable errors. The most commonly cited reasons include improper labelling, discrepancies between the requisition form and specimen information, and insufficient specimen volume (López & Colomer, 2015). Klein and Zaleski (2017) further identify the use of incorrect collection tubes and delayed processing as significant contributors to rejection rates. The importance of training and adherence to protocols cannot be overstated; research shows that well-trained and competent staff are less likely to commit these errors. At Masvingo Provincial Hospital,

we utilize specific codes for rejecting samples. Samples are rejected for several reasons: if they are improperly labelled, if there are discrepancies between the specimen information and the requisition form, if the test is not specified, if the wrong sample tube is used, if the specimen is too old, or if the tube is leaking. Additionally, we may reject samples that have insufficient quantity, are Lip emic, are grossly haemolysed, lack a hospital number, have no proof of payment, or when both the form and specimen are soiled. We also discard samples that are unlabelled, presented in an empty tube, or consist only of the form (MPHL-MS-PR20-F-01 Specimen Rejection log). There are many causes of sample rejection, and these vary between institutions. But some criteria are common to all laboratories such as haemolysed, and clotted samples, insufficient and overfill, repetitive order and test not indicated. Generally, the causes of sample rejection include clotted and lysed samples or no sample received in the laboratory; samples are inadequately labelled or insufficient (Dale CJ., 2002). Clotted and haemolysed samples were the most common causes of sample rejection. Studies have linked these causes to inadequate or incorrect knowledge and skill at performing venipuncture and advocated the use of trained phlebotomists (Bolenius, 2013).Additionally, environmental factors such as temperature fluctuations during transport can compromise sample integrity, leading to rejection (Austrian & Chen, 2019). By identifying and addressing these common reasons, laboratories can implement targeted interventions to reduce rejection rates. The rejection rate reflects the preanalytical process of the laboratory path of workflow, which includes sample collection and transport. It has been reported that preanalytical errors account for up to 70 % of total laboratory errors. In a review on risk management in the pre-analytical phase of laboratory testing, the absolute prevalence of pre-analytical problems ranged between 0.2% – 0.75 %. The most common problems were hemolysis, inappropriate clotting, insufficient volume, inappropriate containers and misidentification.

- Sample collecting techniques:

The integrity of hematology samples begins at the point of collection. Various studies have shown that improper venepuncture techniques can lead to haemolysis, contamination, and other issues that result in sample rejection. Venepuncture is the first step in the sample collection process, and errors at this stage are common. Karp et al. (2020) highlight that improper technique such as using a needle that is too small or inadequately stabilizing the vein can lead to haemolysis, contamination, or insufficient sample volume. Haemolysis can artificially elevate the levels of potassium and other intracellular components, skewing analytical results and potentially leading to misdiagnosis. Facilities using the service of laboratory-administered phlebotomists reported higher success rates than facilities with the non-laboratory-administered phlebotomist (Karcher, 2014).Karp et al. (2020) emphasized that adherence to standardized collection methods, such as using appropriate tourniquet techniques and avoiding excessive manipulation of the collection equipment, can reduce rejection rates significantly. The application of a tourniquet is a critical step that requires careful timing. Lippi et al. (2018) found that prolonged tourniquet application can cause hem concentration, where larger molecules are retained while smaller ones are diluted. Also, prolonged tourniquet time can lead to an increase in various chemistry analytes, including serum protein, potassium and lactic acid due to hem concentration of blood at the puncture site. This can lead to inaccuracies in results, particularly for tests measuring proteins, lipids, and electrolytes. The study recommends limiting tourniquet application to less than one minute to minimize this risk. Using the incorrect sample tube for collection is another significant source of preanalytical errors. Each type of blood test requires specific

anticoagulants or additives to preserve the integrity of the sample. For instance, sodium citrate tubes are used for coagulation tests, while EDTA tubes are preferred for hematological analyses. Plebani et al. (2019) emphasize that using the wrong tube can lead to clot formation, inappropriate anticoagulation, or contamination with additives that interfere with test results. This can result in inaccurate laboratory findings and ultimately affect clinical decision-making. ● Sample Handling:

After blood collection, proper mixing of anticoagulants is essential to prevent clot formation. Plebani et al. (2019) emphasize that inadequate mixing can result in clots that not only lead to sample rejection but also impair the accuracy of hematological analyses, such as complete blood counts (CBC). It is critical that samples are gently inverted multiple times immediately after collection to ensure homogeneity. The time between collection and processing can significantly influence sample integrity. Wang et al. (2020) found that samples processed within two hours of collection exhibited markedly lower rejection rates compared to those processed after extended delays. Delays can lead to cellular degradation and changes in analytes concentrations, which are particularly detrimental for tests that measure unstable components, such as certain enzymes and electrolytes.

- Transport Conditions:

Temperature is a crucial factor during sample transport. Vassallo et al. (2022) report that exposure to extreme temperatures can alter cell morphology and stability, leading to increased rejection rates. For instance, blood samples should

ideally be transported at temperatures between 2°C and 8°C. Deviations from this range can result in hemolysis or degradation of cellular components. The duration of transportation also affects sample quality. Lippi et al. (2018) noted that samples experiencing delays during transport often yield unreliable results. Efficient logistics and prompt delivery to the laboratory are essential to minimize the time samples spend outside optimal conditions, thereby enhancing the reliability of test outcomes.

- Storage conditions:

  Storage conditions play a crucial role in preserving sample integrity. Chawla et al. (2021) found that samples stored at incorrect temperatures can lead to degradation of analytes. For example, storage of blood samples at room temperature can cause the breakdown of certain enzymes and proteins, leading to falsely low or high results. Adherence to recommended storage protocols is critical for maintaining sample quality. The duration of sample storage prior to testing is equally important. Research indicates that blood samples should ideally be tested within a specific timeframe (usually within 24 hours) to prevent deterioration of cellular components (Friedman et al., 2021). Prolonged storage can lead to changes in cell morphology and loss of certain analytes, compromising the reliability of results.

- Sample Labelling and Documentation:

  Inadequate or incorrect labelling remains a significant source of preanalytical errors. A survey by Karp et al. (2020) found that nearly 30% of rejected samples were due to labelling errors. These errors can lead to misidentification and incorrect test results, highlighting the need for standardized and clear labelling

practices across clinical settings. In addition to labelling, incomplete documentation can hinder sample processing. Proper documentation includes patient identifiers, test orders, and relevant clinical information. Plebani et al. (2019) emphasize that meticulous record-keeping is essential for accurate analysis and interpretation of results, and lapses in this area can complicate patient care.

- Patient-Related Factors:

  The fasting status of patients can significantly influence results, particularly for tests such as glucose and lipid profiles. Wang et al. (2020) stressed the importance of ensuring that patients adhere to fasting protocols before sample collection. Also, blood should not be collected from patients just after exercise or just after walking long distances. This may result in false results. Noncompliance can lead to erroneous results, impacting clinical decision-making. Medications taken by patients can interfere with laboratory results, leading to misleading interpretations. Chawla et al. (2021) highlighted the importance of obtaining a comprehensive medication history prior to sample collection to ensure that any potential interferences are accounted for in the interpretation of results.

2.2.3 The implications of sample rejection on the quality of patient care and clinical decision-making:

Patient safety has been the focus of numerous recent publications. It has become progressively more important in laboratory medicine. The effective patient management depends on the accuracy of laboratory results. Sample rejection can affect patient management. Repeated venepuncture causes inconvenience and discomfort for both the

patient and the healthcare worker, as it causes pain, consumes time and increases workload. Moreover, it creates a delay in obtaining laboratory result. Delays in obtaining reliable test results due to rejected samples can hinder timely diagnosis and appropriate treatment, potentially compromising patient outcomes (Hoffbrand et al., 2016). For instance, in cases of critical conditions such as anaemia or infections, delayed results can lead to worsened health states or even fatalities. The conditions often treated in these settings can be urgent. For example, paediatric patients may present with acute illnesses that require rapid diagnosis to initiate treatment. If the repeated test result is abnormal, it can cause further delay in the commencement of the correct treatment for the patient. Sample rejection can also lead to the abandonment of the test. A study reported that as many as 48.3% of rejected tests were never being redrawn and reported (Jacobsz, 2011). Sample rejection is something the laboratory has to do to ensure quality. Moreover, repeat sample collections not only increase healthcare costs but also cause patient discomfort and anxiety (Gunderson & Gulliksen, 2020). High rejection rates can lead to repeated blood draws, which can be particularly distressing for children and new mothers. This not only causes physical discomfort but can also heighten anxiety and stress for both patients and their families. The financial burden on healthcare systems is exacerbated by the need for additional resources to manage rejected samples, which diverts attention and funds from other critical areas of patient care. It is also costly and inconvenient for outgoing patients. High rejection rates from the paediatric wards, antenatal clinic, postnatal ward, and outpatient department are particularly critical for several reasons. Patients in paediatric wards and antenatal/postnatal clinics represent vulnerable populations. Children and pregnant women require timely and accurate testing to monitor their health and that of their babies. Delays due to sample rejections can lead to serious health risks and complications. Moreover, delays the releasing of results, and

decreases patient satisfaction. Inadequate monitoring and delayed diagnoses due to sample rejection can adversely affect health outcomes, particularly for conditions like gestational diabetes, infections, or developmental disorders in children. The laboratory has to make sure that all its results are reliable, accurate and timely. The inaccuracy of the result can be caused by the limitation of the test, machine and operator when making a measurement.

2.3 Theoretical Framework:

The theoretical framework for this chapter integrates the Quality Assurance (QA) Model, Patient-Centered Care (PCC) Model, Systems Theory, and Root Cause Analysis (RCA) to address high sample rejection rates in hematology testing at Masvingo Provincial Laboratory. The QA Model emphasizes systematic monitoring and evaluation of laboratory processes to minimize errors in specimen collection and handling. The PCC Model highlights the importance of patient involvement and satisfaction, advocating for processes that reduce patient discomfort and anxiety associated with repeated blood draws. Systems Theory views the laboratory as part of a larger healthcare system, focusing on how interrelated components—such as staff training and departmental communication—affect operational efficiency. Finally, RCA provides a structured approach to identifying the root causes of sample rejections, enabling targeted interventions. Together, these frameworks guide the research methodology and inform recommendations for improving laboratory practices, ultimately enhancing patient outcomes.

2.4 Summary:

Addressing preanalytical errors through standardized protocols, staff training, and effective logistics ways essential for improving sample quality and ensuring reliable laboratory results, ultimately enhancing patient outcomes and clinical decision-making.

CHAPTER 3: METHODOLOGY

3.1 Introduction:

This chapter set out a guard-line that was followed as we sought to answer the research questions previously outlined.

3.2 Research design and its appropriateness:

A retrospective cross-sectional study design was utilized for this research. This approach was the most appropriate as it allowed for the analysis of existing data over a defined period, facilitating the examination of preanalytical variables and their association with sample rejection rates. By analyzing historical data, the study was able uncover patterns and trends without the need for prospective data collection.

3.3 Study setting and rationale for selection:

The research was conducted at Masvingo Provincial Laboratory, a prominent healthcare facility in the Masvingo region selected due to its significance in hematology testing and the observed variability in sample rejection rates. The laboratory serves a diverse patient population, providing an ideal context to study the impact of preanalytical factors on sample quality through historical records.

3.4 Study population:

The study population consist of all patient samples submitted for hematology testing at Masvingo Provincial Laboratory over a one-year period. This means it included samples that were accepted and those that were rejected due to various preanalytical errors. The study incorporated key informant interviews to gather qualitative insights from three laboratory

personnel and three other healthcare providers. By including both accepted and rejected samples, the study aimed to provide a comprehensive understanding of the factors contributing to sample rejection.

3.5 Sample size and sampling procedure:

Sample size measures the number of individual samples measured or observations used in a survey or experiment (Zambani, 2018). All patient samples that were run per month were reviewed, comprising both accepted and rejected samples.

3.6 Data collection instruments, their validity and reliability:

Data was collected using a standardized data extraction form designed to capture relevant information regarding preanalytical variables, including specimen collection techniques, handling, and transportation conditions. The data extraction form was developed based on existing literature and expert consultations to ensure content validity. Its reliability was assessed through a pilot test, aiming for a Cohen's kappa coefficient of 0.78 or higher, indicating substantial agreement among reviewers.

3.7 Pretesting of instruments:

Pretesting of the data extraction form was conducted with a subset of 20 patient records prior to the main data collection. This process allowed for the identification of potential issues in the form's clarity and relevance. Feedback from the pre-test lead to necessary revisions, enhancing the instrument's effectiveness in capturing accurate data.

3.8 Inclusion criteria:

In this study, we focused on a diverse group of patients whose samples are collected at Masvingo Provincial Hospital Laboratory. This included both adults and children, allowing us to capture a wide range of demographics that reflect our community. The time frame for the data collection extended throughout the year 2024, which allowed for a comprehensive analysis. This study only focused on hematology samples, such as those for complete blood counts and coagulation tests, to keep our focus sharp and relevant. The main interest lied in the preanalytical phase, which includes patient preparation, specimen collection, handling and transportation. By examining these factors, the main aim was to uncover how they affect sample rejection rates in the lab.

3.9 Exclusion Criteria:

Any samples that were rejected before January 2024 were not be included, as they fell outside our study's timeframe. Certain patient populations were excluded, particularly those with known hematological disorders, since their conditions could skew our results. Furthermore, the research did not consider analytical and post-analytical variables, such as those related to actual test performance and interpretation of results, as the primary focus was on the pre-analytical phase.

3.10 Data collection procedure:

Data collection was carried out over a four-week period. Trained research assistants reviewed the laboratory’s historical records and extracted relevant data from the selected patient files. They ensured meticulous attention to detail to maintain the accuracy and integrity of the data collected. The data was organized systematically for analysis, with all identifying information anonymised to protect patient confidentiality

3.11 Ethical consideration:

Ethical approval was be obtained from the institutional review board prior to the commencement of the study. Given the retrospective nature of the research, informed consent from patients was not required. However, confidentiality was maintained throughout the process, with all data anonymised and securely stored to protect patient privacy. The study will adhered to ethical guidelines for research involving human subjects. Also, approval to carry out the study was obtained from the management at

Masvingo provincial hospital laboratory.

CHAPTER 4: DATA PRESENTATION AND ANALYSIS

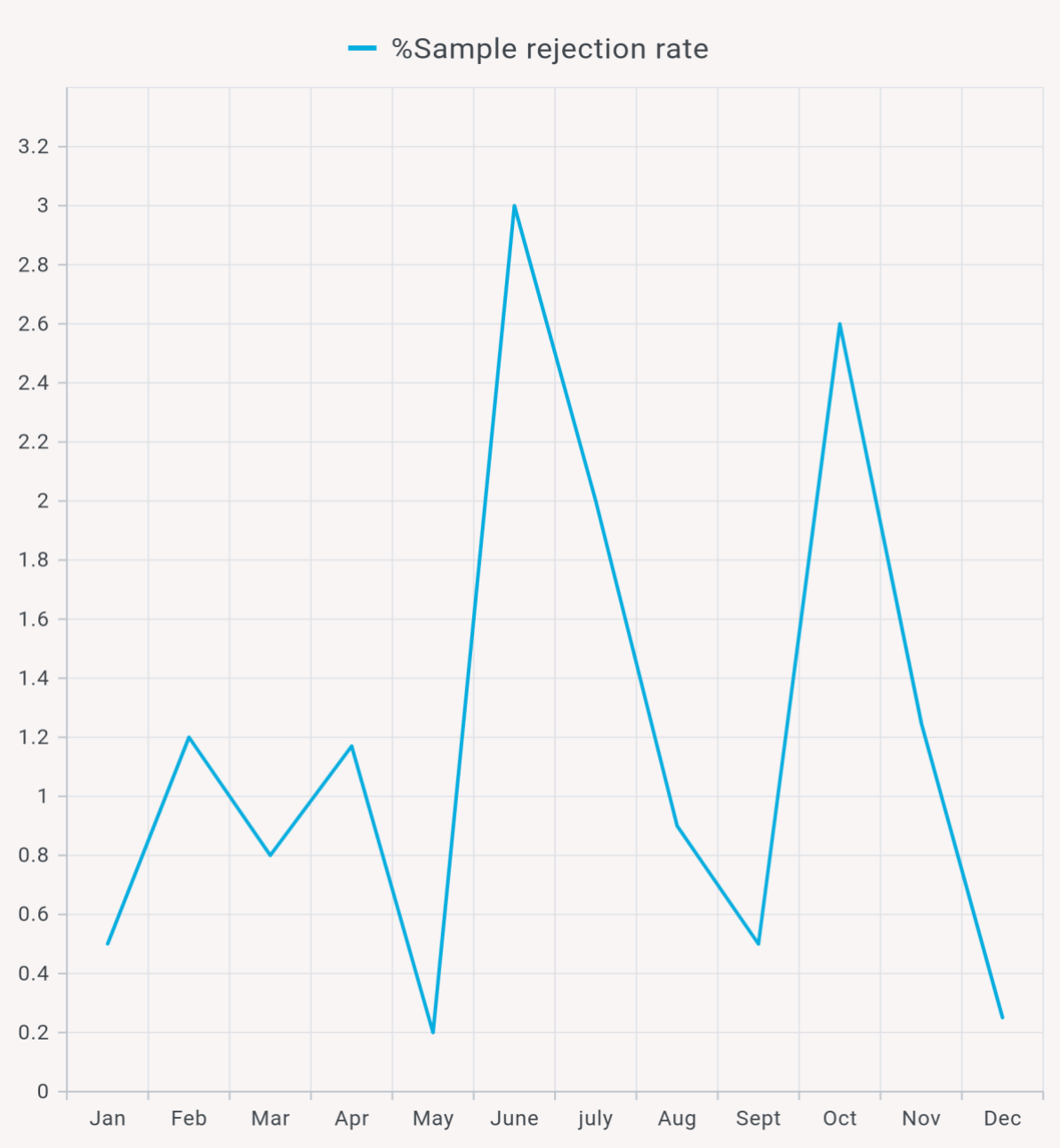
4.0 INTRODUCTION:

This chapter presents the findings of the study investigating the impact of preanalytical variables on haematology sample rejection rates in 2024 at Masvingo provincial hospital laboratory. It includes a detailed analysis of the data collected, followed by a discussion of the implications of these findings.

4.1Prevalence of haematology sample rejection at Masvingo Provincial Hospital laboratory:

Using sample rejection= (total rejected sample ÷total number of samples) × 100 :

FIG 4. 1: Haematology sample rejection at Masvingo Provincial Hospital



Annual sample rejection rate =(total rejected samples÷ total hematology samples) ×100

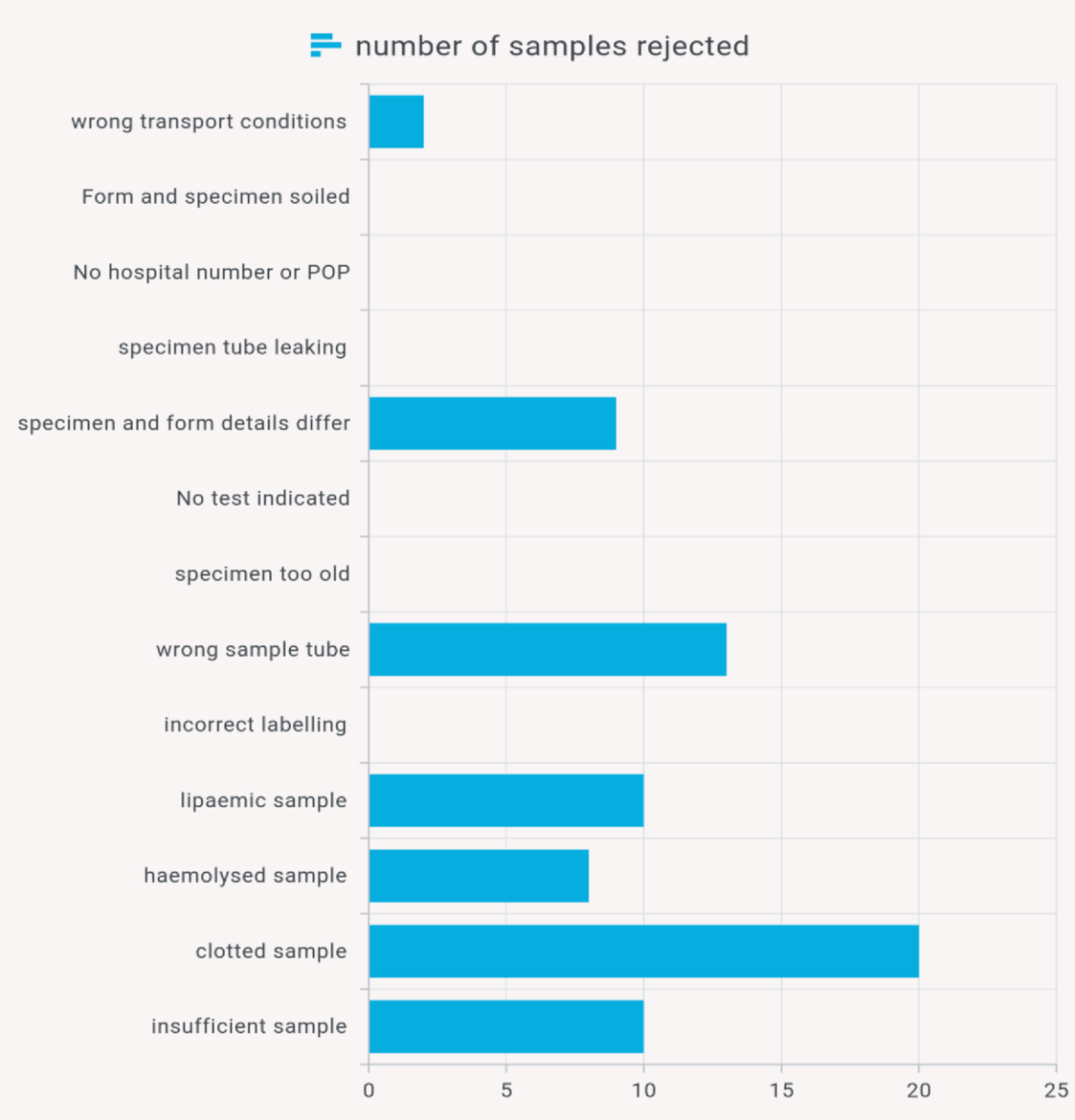
= (72÷6364) ×100

=1.13%

The monthly rejection rates for Hematology fluctuated between 0.2% and 3.0%. The highest rejection rates were in June, July and October 2024, whereas the lowest rejection rate was in May **2024.**

4.2 Most common reasons for sample rejection at Masvingo Provincial Hospital Laboratory:

FIG 4. 2: Most common reasons for sample rejection at Masvingo Provincial Hospital



Clotted samples were found to be the leading cause of rejection in hematology with a total of 20 samples, which constitute 28% of all rejected samples. This was followed by wrong sample tubes (18%), lipaemic samples (14%) and insufficient samples (14%). Eight samples were rejected because they were hemolyzed. Also, nine samples were rejected because specimen and form details differed and another two samples were rejected because of wrong transport conditions. There were no samples rejected because the hospital number or proof of payment was missing, incorrect labelling, specimen tube was leaking, form and specimen were soiled, no test was indicated and specimen was too old.

4.3Implications on Patient health

Table 4.3.1 Analysis of the locations of blood taking

WARD	NUMBER OF SAMPLES REJECTED	PERCENTAGE OF REJECTION
Paediatric Ward	23	32
Antenatal Clinic	14	19
Post Natal Ward	10	14
Out-Patient Department	10	14
Other Wards	15	21

Analysis of the locations of blood taking showed that most of the rejected samples came from the paediatric ward followed by the antenatal Clinic. Others such as Post Natal Ward and the outpatient department contributed to 10 and 8 rejected samples. The rest of the wards at the hospital had 20 rejected samples combined

CHAPTER 5: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 DISCUSSION

5.1.1 Prevalence of Hematology Sample rejection at Masvingo Provincial Hospital laboratory

At the Masvingo Provincial Laboratory, a sample rejection rate greater than or equal to 2% is considered a Non-Conformity(NC).The monthly rejection rates fluctuated between 0.2% and 3.0%, with notable peaks in June, July, and October 2024. Our rejection rates in these months were more than 2%, which is much higher than the recommended rate set in the 2022 Masvingo provincial hospital laboratory quality management system (MPHL-QMS) recommendation. Many studies reported a rejection rate of less than. 1%, but there were not as many studies that reported a similar rate as ours. For example, a study done in Turkey reported a 2.7% rejection rate, in which clotted samples contributed 55.8% of total rejection (Lay, 2014). Another study done in India reported a rejection rate of 1.54%, in which haemolysis was the leading cause of rejection (Atay, 2014). In our case, the annual sample rejection rate was 1.13 % in which clotted samples were the reason for most rejection.

5.1.2 Discussion of most common reasons for sample rejection at Masvingo Provincial Hospital Laboratory:

There are many criteria used for sample rejection, and the criteria vary between institutions. We had specified about 13 criteria in our sample rejection form. All rejected samples were captured according to test requested, reason for rejection and location (ward) of the samples. In another study, Cao et al. reported contamination by IV fluid or TPN solution as being the most common cause of rejection, followed by inappropriate collection container/tube and quantity not sufficient as the second and third

most frequent cause of rejection (Cao, 2016). This study found that the most common causes of sample rejection were due to sample clot, lipaemia, wrong sample tube, insufficient sample, specimen and form details differ, wrong transport conditions and haemolysis. Blood clot often interfere with the interpretation of results by automatic analysers. For example, a blood clot can cause false thrombocytopenia, in which case the platelet count cannot be released. Clots can be readily seen under the microscope or through direct inspection of the sample before machine analysis can also detect clot in the tube. Lip emic sample (defined as an abnormally high concentration of lipids in the blood, usually in the form of very low density lipoproteins) also interfere in the interpretation of tests in and could cause wrong results particularly haemoglobin (Hb) measurement, leading to falsely elevated Hb, MCH, and MCHC. Using the wrong blood collection tube for a haematology test can lead to inaccurate results, potentially causing delayed or incorrect diagnoses and treatments. Haemolysed sample can cause spurious hyperkalaemia. This should not be mistaken for in vivo haemolysis that could be caused by an actual pathological condition such as intravascular haemolysis. All collection tubes must be filled with the required volume since they contain an additive. Insufficient sample means less blood is drawn into the tube. If less blood than required is drawn into the tube, the amount of additive present may interfere with the accuracy of test Wrong transport conditions can affect the integrity of the sample. Environmental factors such as temperature fluctuations during transport can compromise sample integrity, leading to rejection (Austrian & Chen, 2019). Sample collection techniques significantly influence rejection rates, with improper methods leading to issues such as haemolysis, which damages red blood cells and can mislead test results. This was highlighted by Jones et al. (2020), who reported haemolysis rates as high as 10% due to improper venepuncture.

Contamination from unsterilized equipment or incorrect procedures can render samples unsuitable. Insufficient sample volume can hinder comprehensive testing and may occur due to incorrect tube sizes or inadequate blood draw techniques. Using the wrong sample tube can introduce chemical interference or sample degradation, while clotted samples often result from delays in processing, inadequate mixing, or the use of inappropriate tubes. Samples should be gently, not vigorously, inverted at least one to two times immediately after blood collection. Post-collection handling errors, such as inadequate sealing of specimen tubes leading to leaks, can cause contamination or loss of volume. Transport conditions are critical; samples exposed to extreme temperatures or delays are more likely to be rejected, with Patel (2021) noting a 20% higher rejection rate under adverse conditions and Adams et al. (2019) emphasizing the impact of temperature fluctuations on sample quality. Proper storage is essential; factors like deterioration due to inadequate conditions or exceeding recommended storage timelines can compromise sample integrity, supported by findings from Carter et al. (2020) and the Clinical Laboratory Standards Institute guidelines. Accurate labelling and documentation are vital for traceability; issues such as missing test indications or patient identifiers can lead to significant delays and rejections. Finally, patient-related factors like age and physiological differences can also affect sample quality and suitability for analysis.

5.1.3 Impact on patient health

Samples received from the paediatric ward, antenatal Clinic, outpatient department and postnatal wards contributed most of the rejected samples compared to other Wards. The Paediatric Ward and Other Wards recorded the highest number of rejected samples, each with 20 cases (27.78% of the total). The Antenatal Clinic followed with 14 rejected samples

(19.44%), while the Post Natal Ward and Out-Patient Department had lower rejection rates, with 8 (11.11%) and 10 (13.89%) rejected samples, respectively. Blood samples in the wards were mainly taken by the medical officers, rather than medical assistants and phlebotomists. This finding could reflect the blood taking skill or technique used by the staff. Other explanation could be that inpatients were sicker compared to outpatients and made blood-taking more difficult, in which prolonged venous stasis can lead to blood clot formation. Insufficient sample contributed to the causes of sample rejection from these sites, especially in long-staying patients who had multiple venepunctures. Sample rejection can result in delayed treatment. It also increases the economic burden especially to those patients in the Out-Patient Department because they have to travel back to the hospital for re-collection.

5.2 Implications of findings to public health:

The implications of haematology sample rejection for public health are significant and multifaceted, leading to delayed diagnosis and treatment, which can postpone the identification of conditions like anaemia or leukaemia and worsen health outcomes due to disease progression. Additionally, rejected samples increase healthcare costs through the need for repeat testing, diverting resources from critical patient care areas. Compromised public health data results from these rejections, distorting epidemiological studies and leading to ineffective public health policies. Inconsistent data can also result in inappropriate treatment protocols, posing patient safety risks. Furthermore, the wastage of laboratory resources and increased workload on healthcare professionals can lead to burnout. Patients may experience anxiety from repeated testing, and frequent issues with sample handling can erode trust in healthcare systems. Lastly, high rejection rates may indicate systemic quality control problems within laboratories, highlighting the need for improved processes and training.

5.3 Limitations of the study:

All rejected samples were captured according to test requested, reason for rejection and location (ward) of the samples. Patient-related factors like age and physiological differences, which can affect sample quality, were not adequately explored. The study focus solely on haematology samples, which restricts its applicability to other laboratory sections, such as clinical chemistry or microbiology. Also, the laboratory does not have direct control over pre-analytical processes like sample collection and transportation, which are often performed by non-laboratory personnel. This limitation is common in studies of this nature and can lead to variability in results due to external factors. The study relied on retrospective data collection, therefore it was prone to errors in documentation or incomplete records regarding rejected samples. Prospective studies often provide more accurate insights into real-time challenges

5.4 Study conclusion:

The study revealed a concerning sample rejection rate at Masvingo Provincial Hospital, particularly during certain months where rates exceeded the recommended threshold. The predominant causes of rejection were identified as clotted samples, lipaemia, wrong sample tube, insufficient sample, specimen and form details differ, wrong transport conditions and haemolysis. These findings highlight the need for improved training and protocols for blood sample collection and handling, especially in high-rejection wards such as paediatrics and antenatal clinics. The impact of sample rejection extends beyond laboratory operations, potentially delaying patient treatment and increasing economic burdens on patients. Future efforts should focus on standardizing collection techniques,

enhancing staff training, and implementing stricter adherence to protocols to reduce rejection rates and improve overall patient care.

5.5 Recommendations:

- Training and Education:

  Continuous education programs for healthcare staff involved in blood collection are essential to ensure compliance with best practices regarding specimen handling, labelling, and transportation. At our institution, the availability of trained phlebotomists was limited, with only a few on staff.

- Patient Preparation:

  Implementing clear guidelines for patient preparation before blood draws can help minimize lip emic samples and other related issues.

- Standard Operating Procedures:

  Establishing strict protocols for blood collection, processing timelines, and transport conditions will help reduce instances of clotted or haemolysed samples. Other measures of improvement include the use of better phlebotomy equipment such as using straight needles rather than butterfly devices or syringes. Some

studies suggested the use of larger needles, i.e. size 19 to 21 gauge; and primary vacuum tubes to prevent haemolysed sample.

- Quality Control Measures:

  Regular audits on sample handling practices within wards can identify areas needing improvement while fostering a culture of accountability among staff.

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Appendices:

Appendix 1: AUREC approval

"Investing in Africa's future"

AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC)

P.O. Box 1320 Mutare, Zimbabwe, Off Nyanga Road, Old Mutare-Tel (+263-20) 60075/60026/61611 Fax: (+263 20) 61785 Website: www.africau.edu

Ref: AU 3649/25

4 March, 2025

GARIRA, GRACIOUS
C/O Africa University
Box 1320
MUTARE

RE: ***INVESTIGATION OF THE IMPACT OF SOME PRE-ANALYTICAL VARIABLES ON HEMATOLOGY SAMPLE REJECTION RATES AT MASVINGO PROVINCIAL LABORATORY, ZIMBAMBWE (2024)***

Thank you for the above-titled proposal you submitted to the Africa University Research Ethics Committee for review. Please be advised that AUREC has reviewed and approved your application to conduct the above research.

The approval is based on the following.

a) Research proposal

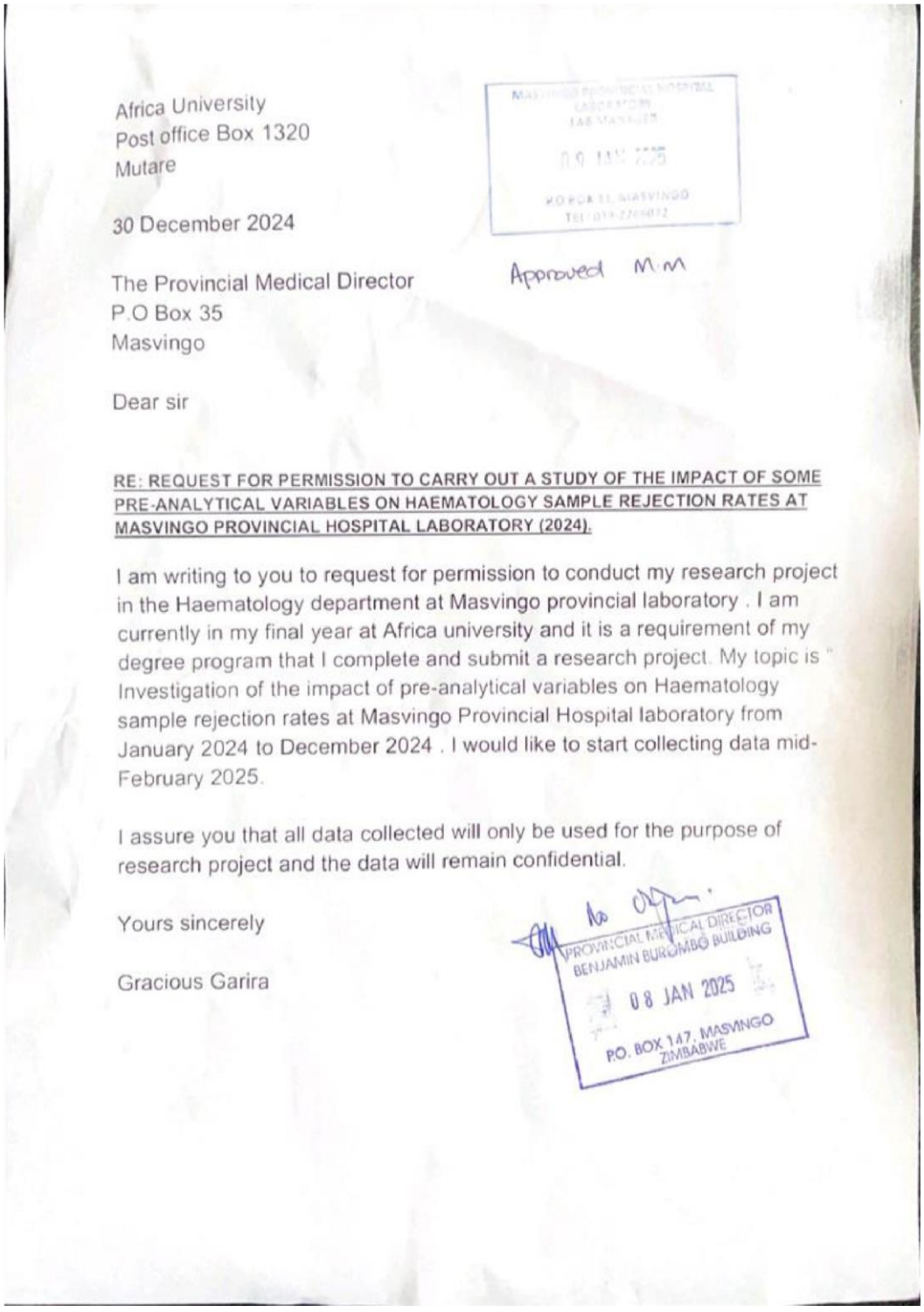
- **APPROVAL NUMBER** AUREC 3649/25
  This number should be used on all correspondences, consent forms, and appropriate document
- **AUREC MEETING DATE** NA
- **APPROVAL DATE** March 4, 2025
- **EXPIRATION DATE** March 4, 2026
- **TYPE OF MEETING**: Expedited
  After the expiration date, this research may only continue upon renewal. A progress report on a standard AUREC form should be submitted a month before the expiration date for renewal purposes.
- **SERIOUS ADVERSE EVENTS** All serious problems concerning subject safety must be reported to AUREC within 3 working days on the standard AUREC form.
- **MODIFICATIONS** Prior AUREC approval is required before implementing any changes in the proposal (including changes in the consent documents)
- **TERMINATION OF STUDY** Upon termination of the study a report has to be submitted to AUREC.

AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC) APPROVED P.O. BOX 1320, MUTARE, ZIMBABWE

Yours Faithfully

MARY CHINZOU
FOR CHAIRPERSON
AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE

Appendix 2: Study Site Approval



Africa University
Post office Box 1320
Mutare

30 December 2024

The Provincial Medical Director
P.O Box 35
Masvingo

Approved M.M

Dear sir

RE: REQUEST FOR PERMISSION TO CARRY OUT A STUDY OF THE IMPACT OF SOME PRE-ANALYTICAL VARIABLES ON HAEMATOLOGY SAMPLE REJECTION RATES AT MASVINGO PROVINCIAL HOSPITAL LABORATORY (2024).

I am writing to you to request for permission to conduct my research project in the Haematology department at Masvingo provincial laboratory . I am currently in my final year at Africa university and it is a requirement of my degree program that I complete and submit a research project. My topic is " Investigation of the impact of pre-analytical variables on Haematology sample rejection rates at Masvingo Provincial Hospital laboratory from January 2024 to December 2024 . I would like to start collecting data mid-February 2025.

I assure you that all data collected will only be used for the purpose of research project and the data will remain confidential.

Yours sincerely

Gracious Garira

PROVINCIAL MEDICAL DIRECTOR
BENJAMIN BUROMBO BUILDING
08 JAN 2025
P.O. BOX 147, MASVINGO
ZIMBABWE

Appendix 3: Budget allocation

MATERIAL	**QUANTITY**	**COST (USD)**
TRANSPORT	-	10.00
FLASH DISK	1	25.00
INTERNET BUNDLES	8Gb	10.00
REFRESHMENTS	-	20.00
TOTAL	**-**	**65.00**

Appendix 4: Timeline for the research project

2024 to 2025						
Activities	**September 2024**	**October 2024**	**November 2024**	**January 2024**	**March 2025**	**April 2025**
Submit a project proposal to the supervisor						
Submit a project proposal to AUREC.						
Data collection						
Data analysis						
Project writing						
Submit a project to the African University						