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DEPARTMENTOF MEDICAL LABORATORY SCIENCES

ASSESSING THE QUALITY PERFORMANCE IN PRE-ANALYTICAL PHASE OF HAEMATOLOGY AND SEROLOGY SAMPLES AT KIBOGORA DISTRICT HOSPITAL, RWANDA

Undergraduate research thesis submitted in the fulfilment of the requirements for Bachelor's Degree in Biomedical Laboratory Sciences with Honours at Kibogora Polytechnic

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DECLARATION

We, UWIMBABAZI Dative and TWAJAMAHORO Gilbert hereby declare that this our own original work and not a duplication of any similar academic work. It has therefore not been previously or concurrently submitted for any other degree, diploma or other qualification to Kibogora Polytechnic or any other institution. All materials cited in this paper which are not our own have been duly acknowledged.

Signed……

Date…….

And

Signed……

Date…….

Declaration by the Supervisor

I declare that this work has been submitted for examination with my approval as KP Supervisor

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ABSTRACT

Clinical laboratory results are critical components of the patient management process, affecting treatment decisions as many as 70% of medical cases. Delayed or incorrect laboratory results resulting from poor sample quality constitutes a potential factor that leads to delayed or erroneous diagnosis, thus treatments. The purpose of the present study was to assess quality performance in pre-analytical phase of haematology and serology samples at Kibogora district hospital. Specific objectives of the study were: (1) to describe best practices during pre-analytical phase for haematology and serology sample processing at Kibogora District Hospital, Rwanda; and (2) to identify potential errors during pre-analytical phase for haematology and serology sample processing at Kibogora District Hospital, Rwanda. A quantitative approach and descriptive survey design were used in this study to collect data by use of a checklist for laboratory performance and questionnaire to survey nurses.

The number of respondents was 72 nurses, and 165 samples were observed. Over half of nurse participants were females, 38 (52.8%) and males were 34 (47.2%). Education categories were Advanced diploma, 27(37.5%), and Bachelor degree45 (62.5%). Identified best practices were that all nurses, 72 (100%) had good knowledge on correct patient, correct test request, correct request form, correct container for haematology and serology samples, correct labelling, correct volume for haematology and serology samples, correct storage of haematology and serology samples and correct sample transportation. However, there were gaps in providing trainings, SOPs, and quality assurance evaluation by laboratory staff, 23(31.9%), 21(29.2%), and1.4%respectively. In laboratory all 165 samples that were observed, the laboratory technicians had best practices at 100% adherence to standards of checking patient identification, requested tests, right patient sample and labelling of sample. Gaps were on mention of the physician's name,25(15%), origin of sample 10(6%), sample collection date and time 50(30%), appropriateness of the container10 (6%), sufficiency of the sample 45(27%), ratio of blood and anticoagulant 50(30%), clotting of sample 45 (27%), haemolysis of sample 60(36%), proper storage 40(24%) and proper transportation 40(24%).

In the light these results, intentions to improve the quality of laboratory technicians are recommended. Moreover, nurses need to keep their good performance through regular trainings.

DEDICATION

To the almighty God

To our parents

To our sister and brother

To our classmates and friends

This research work is dedicated

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We are grateful to almighty God for giving us strengths during our studies without which the completion of the present work could not be possible.

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LIST OF ABBREVIATIONS AND ACRONYMS

ISO: International Organization for Standardization

TTP: Total testing process

QIs: Quality indicators

IOM: Institute of Medicine

IFCC WG-LEPS: International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory errors and patient safety.

AST: Aspartate amino transferase

LDH: Lactate dehydrogenase

GPs: General practitioners

SPSS: Statistical package for social science

SOPs: Standard operating procedures

CHAPTER ONE: GENERAL INTRODUCTION

1.0.INTRODUCTION

Clinical laboratory results are considered as one of critical components of the patient management process, affecting treatment decisions as many as 70% of medical cases. Delayed or incorrect laboratory results resulting from poor sample quality or other pre-analytical factors have the potential to lead to delayed or erroneous diagnosis or treatments, which can impact patient treatment outcomes (Erdal et al., 2017). This is the main interest of this study. This first chapter describes the background of the study, Problem statement, Purpose of the study, objectives of the study, research questions, significance of the study, limitations of the study, and the scope of the study.

1.1 BACKGROUND OF THE STUDY

There is claim which stated that 70% of clinical decisions depend on laboratory testing. This claim is supported by recent surveys of specialist clinicians in Germany and the USA which found that 60-70% of clinical decisions were affected by laboratory test results, both in the hospital setting and outside. Furthermore, surveys of evidence based clinical guidelines show that at least 80% of guidelines which are aimed at establishing a diagnosis or managing disease require laboratory testing (Sikaris & Sikaris, n.d., 2017). Though the clinical laboratory results have a huge impact in clinical decisions, errors in total testing process may result in erroneous diagnosis or treatment of patients. Of all errors that occur in total testing process affecting laboratory results, the pre-analytical errors occupy 46 – 68.2% and a study by an ISO 9002:1994 certified clinical laboratory, reported that 84.5% of errors detected in their laboratory occurred in the pre-analytical phase (Mukherjee & Patra, 2013).To minimize those errors and improve patient outcomes, Quality and safety in diagnostic testing, on the other hand, are critical to achieving the objective of high quality and safe healthcare, with no other disciplines playing such an important role in the patient safety solution as laboratory medicine (Tola et al., 2022).

In developed countries, a survey done in China in different laboratories evaluating pre-analytical errors on haematological samples showed that 0.11% of samples were rejected and the main reason was clotting of samples 57% (Ye et al., 2018). Another study done in Sheffield in England on pre-analytical errors reported that of the total samples received

during the period of the study 20.8% were unlabelled (Ayoola, 2017). In a study conducted in Brazil in one federal laboratory in a period from 2013-2014 reported that of 304,361 samples, 0.62% needed to be recollected and of the reasons for sample rejections, insufficient sample represented 21.9%, coagulated sample 18.1% and haemolysed sample 11, 9% (Coriolano et al., 2016). Another study conducted in North India reported that of the total of 2000 samples that were studied and followed, a total of 5.3% samples were rejected and the main reason of rejection was due to inadequacy of specimen collection by the paramedical staff. (Dr.Abhineet Mehrotra, 2013).

In sub Saharan Africa like in South Africa, a study conducted in a primary health care provider in Capetown showed that pre-analytical errors rate was 0.79% (Abbas et al., 2017). A study conducted in Nigeria reported that among errors that led to sample rejection, incomplete specimen labelling and clotted specimens were the commonest reasons and accounted for 59.8% and 30.3% respectively(Musa & Ndakotsu, 2020).This problem also was found in Ethiopia where in a research conducted at one hospital in haematology laboratory, pre-analytical errors represented 21,6% of total testing process errors(Tadesse et al., 2018) . A study conducted in Kenya reported that pre- analytical errors in clinical laboratory occupied 42.8% of total errors and among these, 13.5% samples were in wrong tubes, 4.7% contaminated specimen bottles and 2.0% wrong specimens (Kimengech et al., 2017).Another study in a clinical laboratory in Tanzania reported that of all sample rejected due to pre-analytical errors, haematology samples occupied 33.3% and serology samples occupied 14.5%, wrong sample container 15.38% and clotted sample 14.10%(Mosha& Kabanyana, 2021).

In Rwanda, there is a program which aimed to strengthen laboratory toward accreditation which in a period of 2012 -2017 showed that only one laboratory progressed from four to five stars and this indicates the improvement in quality performance. However, other four laboratories dropped which means they have decreased in quality performance (Rusanganwa et al., 2018). Another study done in referral laboratories on challenges and strategies to sustain laboratory quality management system reported that there was insufficient knowledge in laboratory quality management system and ownership by laboratory workforce (Rusanganwa et al., 2019). There is no published work showing the status of quality performance during laboratory pre-analytical phase at Kibogora District Hospital.

1.2 PROBLEM STATMENT

Laboratory diagnostic service is an integral part of modern health care service. Quality of laboratory result helps for proper patient care. However, occurrences of clinical laboratory errors impair clinical decision-making process. Such errors are supposed to be high in resource-poor countries. Laboratory errors in any level of the process have an influence on total patient care, which might include misdiagnosis and mismanagement (Tola et al., 2022). Though the errors can occur in any part of the total testing process which is the entire process

from ordering of a test to the interpretation of test result as subdivided into three phases which are pre-analytical phase, analytical phase and post-analytical phase(Naz et al., 2012), the pre analytical phase is the most complex process. The effect of this process frequently appears in the analytical and the post analytical phase. The number of errors mostly depends on the management of samples and the handling of samples, such as sample collection, storage and transportation which is part of pre-analytical phase and is mostly managed out of the Clinical laboratory (Englezopoulou et al., 2016).

Several studies reported that of all errors that occur in total testing process affecting laboratory results, the pre-analytical errors occupy 46 – 68.2% and a study by an ISO 9002:1994 in a certified clinical laboratory, reported that 84.5% of errors detected in their laboratory occurred in the pre-analytical phase (Mukherjee & Patra, 2013). Haematological and serology samples processing are also prone to pre-analytical errors as shown in one study conducted in Ethiopia where pre-analytical errors on haematology samples represented 21,6% of total testing process errors (Tadesse et al., 2018). Although some studies have been conducted to assess the quality proficiency in clinical laboratory in Rwanda like one which reported non-conformances in quality system in four laboratories which disqualified them to be accredited (Rusanganwa et al., 2018), there isn't any research that look into details of critical areas in clinical laboratory as part of clinical diagnosis and the reason of this research is to bridge that gap.

1.3 PURPOSE OF THE STUDY

The purpose of this research is to assess quality performance in pre-analytical phase while processing haematological and serological samples as part of better clinical diagnosis. In this

research good practices and potential pre-analytical errors on haematological and serology samples during sample collection and handling will be evaluated. The research will also evaluate the knowledge of phlebotomist on haematology and serology samples collection and handling.

1.3.1 General objective

To assess the quality performance in pre-analytical phase of haematology and serology samples at Kibogora District Hospital, Rwanda.

1.3.2 Specific objectives

1. To describe best practices during pre-analytical phase for hematology and serology sample processing at Kibogora District Hospital, Rwanda; and
2. To identify potential errors during pre-analytical phase for hematology and serology sample processing at Kibogora District Hospital, Rwanda.

1.4 RESEARCH QUESTIONS

1.4.1 General Research question

What is the quality performance in pre-analytical phase of haematology and serology samples at Kibogora District Hospital, Rwanda?

1.4.2 Specific Research questions

1. What are observed best practices during pre-analytical phase for hematology and serology sample processing at Kibogora District Hospital, Rwanda?
2. What are potential errors during pre-analytical phase for hematology and serology sample processing at Kibogora District Hospital, Rwanda?

1.5 SIGNIFICANCE OF THE STUDY

The main aim of this research is to describe best practices on hematological and serological samples processing during pre-analytical phase and to identify potential pre-analytical errors on hematology and serology sample which may lead to erroneous results resulting in poor diagnosis and treatment. Once gaps are identified practices to reduce them will follow and

this will help in improving patient care because better diagnosis leads to better patient management.

Not only patients will benefit from this research but also the hospital because once the sample is rejected, the sample will be recollected and it leads to an extra cost of all consumables used during sample collection not forgetting the time it takes to repeat sample collection. This research will help in reducing that extra cost. After this research, this evaluation may be used as a basic to evaluate other hospital laboratories in Rwanda since all district hospitals are taken to give the same level of quality. This research will help decision makers at the hospital and in Nyamasheke district plus the western province to change mind towards the quality of service given by Kibogora District hospital laboratory. Further studies in the future will refer to this study; therefore, the research is vital for future education.

1.6 LIMITATIONS OF THE STUDY

The limitations were the delay of starting data collection because it took time to get approval from Kibogora District Hospital. Another limitation is the limited time; we would have observed more samples but we had to reduce the sample due to the short time.

1.7 SCOPE OF THE STUDY

This is a prospective quantitative research work that will be conducted in Nyamasheke district Western province, Kanjongo sector, at Kibogora District Hospital clinical services, laboratory specifically in Haematology and serology services in a period of one week of working hours from 15/06/2022 to 22/06/2022.

CHAPTER TWO: LITERATURE REVIEW

2.0.INTRODUCTION

The chapter two concerns the existing literature on pre-analytical errors in clinical laboratory but more specifically on haematology and serology samples. The different publication, books, journals, websites and articles was used to make the content of this chapter.

2.1 GENERALITY ON LABORATORY PRE-ANALYTIC PHASE

In clinical laboratories, there are three testing processes: pre-analytical, analytical, and post-analytical phases, in a collective way it all those steps are resumed as total testing process (TTP). According to definition by ISO 15189:2007, Pre-analytical components are defined as steps beginning with the clinician's request, examination requisition, patient preparation, collection of the primary sample, transportation to and inside the laboratory, and ending when the analytical examination procedure begins(Tola et al., 2022).

2.2 QUALITY STANDARDS IN LABORATORY PRE-ANALYTICAL PHASE

2.2.1 Sample collection and transportation in clinical laboratory

After the sample is collected according to the SOPs, the transportation of blood samples is a major part of the pre-analytical pathway. When sample transportation is not done at right time it leads to delaying laboratory results to the clinicians. Due to increasing demands from the clinicians, it is important to have the primary venous specimen collection tubes transported to the laboratory as fast as possible to be able to measure analytes within the established stability time to maintain fast turnaround times and ensure sample integrity. Furthermore, the transportation process itself must be firmly controlled to assure that the analyses requested are not affected by temperature, agitation, or other physical or biological influences(Nybo et al., 2019)

Transportation logistics must be well arranged to satisfy sample flow from hospital wards to the laboratory. Physicians while at work must do the exercise of matching sample reception with the workflow at the laboratory in terms of numbers of samples, peak arrival during

daytime, etc. Any delay from blood collection to centrifugation and analysis or any deviation from standard transportation conditions could potentially alter laboratory results and subsequently have a negative impact ton patient outcome (SF.Green, 2013).

It is important to note that the impact of transportation time and conditions on test results is highly dependent on the analytes requested, time to centrifugation as well as on the analytical method applied. Multiple sample stability studies are available for separated as well as whole blood samples, though not necessarily for every analyte(Henriksen et al., 2014). All these aspects make sample transportation a complex, challenging and often overlooked task that needs thorough planning and resources taking into account. The profound understanding of which pre-analytical factors that could alternate the test results has to be shared among all parties involved in the transportation process (e.g., clinicians, nurses, phlebotomists, carriers, etc.).

2.2.2 Acceptance and sample rejection in clinical laboratory

The proper collection and handling of clinical specimens is essential for obtaining quality test results from a clinical laboratory. As we have seen approximately 70% of laboratory errors occur during the pre-analytical phase of the laboratory process. This situation highlights the importance of testing proper samples with accurate and precise techniques at the earliest possible moment. Specimen adequacy is a crucial pre-analytical factor affecting the accuracy and usefulness of test result. Laboratories usually establish a guideline for evaluating the acceptance of submitted specimens, and specimens not meeting the criteria of acceptability are rejected. Data on rejected samples due to various types of pre-analytical errors are one of laboratory medicine pre-analytical quality indicators (Ye et al., 2018).

Though the quality indicators in pre-analytical phase are not harmonized in all laboratories, errors that can lead to haematology and serology sample rejection are almost the same in pre-analytical phase, the difference may occur only on the sample container as haematology samples have to be collected in a tube containing anticoagulant while serology samples may be collected in an anticoagulant containing tube or in a dry tube. Different anticoagulant agents are used depending on the type of test required.

2.3 QUALITY INDICATORS IN CLINICAL LABORATORY

As defined by the Institute of Medicine (IOM) to quality in healthcare, the identification of reliable quality indicators (QIs) is a crucial step in enabling users to quantify the quality of a selected aspect of care by comparing it with a defined criterion. A quality indicator is defined as an objective measure that potentially evaluates all critical care domains as defined by the IOM (patient safety, effectiveness, equity, patient-centeredness, timeliness and efficiency). Those domains can be implemented and evaluated in a consistent and comparable manner across settings and over time (Chawla et al., 2010).

As stated by the ISO 15189:2012, "The laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post examination processes. The process of monitoring QIs shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement."(Plebani et al., 2017). Therefore, when assessing the quality of laboratory services using QIs, it is important to ensure systematic and consistent data collection and analysis by using a comprehensive set of indicators that addresses all stages of the TTP and focuses on the areas with an important impact on patient care and health outcomes (Plebani, 2012).

2.3.1 Specific quality indicators in pre-analytical phase

As stated above, the pre-analytical phase should be subdivided into a 'pre-pre-analytical phase' and a 'true' pre-analytical phase, which is undertaken within the laboratory walls after specimen reception. The former phase, which comprises initial procedures usually performed neither in the clinical laboratory nor undertaken, at least in part, under the control of laboratory personnel, includes test requesting, patient and sample identification and sample collection. The latter involves the steps required to prepare samples for analysis (centrifugation, aliquoting, and sorting). In a patient-centred scenario, QIs should be designed to cover all steps of the pre-analytical phase, including the appropriateness of test selection, which is a key issue in projects aiming to ensure clinical effectiveness.

Table 2.1 Quality indicators in the pre-analytic phase.

QI-1: Appropriateness of test request	Number of requests with clinical question (%)
QI-2: Appropriateness of test request	Number of appropriate tests with respect to the clinical question (%)
QI-3: Examination requisition	Number of requests without physician's identification (%)
QI-4: Examination requisition	Number of unintelligible requests (%)
QI-5: Identification	Number of requests with erroneous patient identification (%)
QI-6: Identification	Number of requests with erroneous identification of physician (%)
QI-7: Test request	Number of requests with errors concerning test input (%)
QI-8: Samples	Number of samples lost/not received (%)
QI-9: Samples	Number of samples collected in inappropriate containers (%)
QI-10: Samples	Number of samples haemolysed (haematology, chemistry) (%)
QI-11: Samples	Number of samples clotted (haematology, chemistry) (%)
QI-12: Samples	Number of samples with insufficient volumes (%)
QI-13: Samples	Number of samples with inadequate sample-anticoagulant ratio (%)
QI-14: Samples	Number of samples damaged in transport (%)
QI-15: Samples	Number of improperly labelled Samples(%)
QI-16: Samples	Number of improperly stored samples (%)

The IFCC WG-LEPS developed 16 QIs for the pre-analytic phase (Table 2.1). A preliminary evaluation of data collected by several laboratories worldwide, underlined the need for an improved specification of some QIs. For example, the QI number of requests with errors concerning patient identification/total Number of requests should be split into two categories: a) true patient misidentification and/or miss-match, and b) minor errors in patient identification like age, gender or requesting physician recorded erroneously that do not significantly compromise patient safety (Plebani, 2012).

The violation of each one of the above mentioned QIs in pre-analytical phase may lead to sample rejection, one study on haematological sample rejection in China reported that

about85% of rejections were attributed to the five reasons: specimen clotted (57%), insufficient specimen volume (14%), inappropriate specimen anticoagulant volume ratio (6.9%), incorrect container type (4.2%) and inadequately labelled(2.9%).Of the 11,447 rejected specimens, laboratory staff were unable to obtain information about measures taken. Of 562 (4.9%) specimens, requested 9563 (83.6%) specimens to be recollected, and asked for 479 (4.2%) specimens to be relabelled, and 2.6% rejected specimens were abandoned by the laboratory and provider. Besides, 541 (4.7%) rejection were classified as "other", which participants did not believe fit into one of the provided actions(Ye et al., 2018).

2.4 PRE-ANALYTICAL ERRORS

Pre-analytical phase is an important component of laboratory medicine. The pre-analytical phase comprises all the processes occurring before the sample being processed in the laboratory, it includes specimen collection, handling and processing variables, physiological variables, and endogenous variables(BJ & C, 2019). Certain pre-analytical variables, namely, specimen variables can be controlled; whereas knowledge of uncontrollable variables needs to be well understood in order to be able to separate their effects from disease-related changes affecting laboratory results. Different reports indicate that pre-analytical errors occupy 46 – 68.2% of the total testing process. These include errors in specimen preparation which involves all activities to render a sample suitable for analysis.The reported types of pre-analytical error are ordering tests on the wrong patient, misidentifying the patient, ordering the wrong test, missing sample and/or test request, wrong or missing identification, contamination from infusion route, haemolysed, clotted, and insufficient samples, inappropriate containers, improper labelling of containers, inappropriate blood-to-anticoagulant ratio, inappropriate transport and storage conditions (Arul et al., 2018).

All of the above-mentioned errors are to be cared for and efforts to minimize them have to be made so that the results of any diagnosis in clinical process may lead to the desired diagnosis as it is the target for clinical laboratory to help in better management of the patient. Most studies demonstrated that a large percentage of laboratory errors occur in the pre and post analytical phases, with fewer mistakes occurring in analytical phase (Naz et al., 2012).

2.4.1 Frequent errors in pre-analytical phase and their possible consequences in clinical diagnosis

2.4.1.1 Inappropriate Laboratory Test Requisition

Many studies indicate the importance of the pre-analytical phase. Misuse of laboratory services through requesting inappropriate laboratory test is under scrutiny worldwide because of its impact on total costs, and the inherent increased risk of medical errors and injury. The estimations of inappropriate laboratory tests vary from 11% to 70% for general biochemistry and haematology tests, 5% to 95% for urine screens and microbiology and 17.4% to 55% for cardiac enzymes and thyroid tests (Salinas et al., 2018)

2.4.1.2 Incomplete Laboratory Request Forms

One important source of pre-analytical error is incorrect or incomplete information on the test request or labels which have been found in more than two thirds of all rejected samples in the laboratory(A et al., 2011) Several other studies confirm that test requests can be a clinically important source of errors. Paper based test requests are risky as they can be incompletely filled, placed in the wrong collection box, or simply be lost. Incomplete laboratory requests forms are rarely rejected at the service point and in many instances the reception staff in the laboratory may not know the significance of the missing data. Specific missing information included the physician's name, misidentification of patient and requested tests (Burnett et al., 2004).

2.4.1.3 Wrong Patient Identification

Correct patient identification is the most important task in all medical procedures. Therefore, efforts to ensure compliance with standardized identification routines should be prioritized. Mistakes in patient identification before specimen collection is responsible for up to 25% of all pre-analytical errors. Mistakes in patient identification often occur during manual tasks which can be avoided using electronic technologies like barcodes; radiofrequency identification and wristbands. Wristbands have patient's name and identification number, and sometimes also have a barcode. Studies have reported error rates of 0.3–11% for identification wristbands mostly comprising of missing or incomplete wristbands, and wrongwristband on the patient(Parisi, 2003)

2.4.1.4 Wrong Labelling of the Containers

Labelling of specimen containers is one of the most important identifications in laboratory. It is the only way used to differentiate samples of the patients as specimen containers used in laboratory are many times identical and wrong identification or non-identification may result in giving wrong result report to the wrong patient. Labelling of specimen containers should always be done immediately before sample collection while, labelling them after sample collection increases the risk of the specimen collection from the wrong patient. Mislabelling is responsible for 50% of all identification errors (Kahn, 2005).

2.4.1.5 Potential Outcomes of Collection Errors

Proper sample collection is an important part of good laboratory practice and improper collection can lead to delays in reporting, unnecessary re-draws/retests, decreased customer satisfaction, increased costs, incorrect diagnosis / treatment, injury and occasionally death. Studies have shown the importance of checking for specimen adequacy as a critical factor in test result accuracy and usefulness. Samples that are missing, coagulated, haemolysed, insufficient or wrong due to inappropriate specimen collection and handling account for a large percentage of pre-analytical mistakes (Lippi et al., 2006) Inadequate Volume

Insufficient volume is a major factor leading to rejection of samples. The main reason for this anomaly is the ignorance of the phlebotomist, difficult sampling as in paediatric patients, debilitated cases, those on chemotherapy and those with difficult to localize veins. Insufficient sample constituted the most frequent cause of sample rejection in a study done in out-patients department (Saloni & Mittal, 2020).

2.4.1.6 Incorrect Phlebotomy Practices

Incorrect phlebotomy practices are also one of the main reasons behind pre-analytical errors which occur due to lack of knowledge or heavy workload. Ideal phlebotomy practices should be adopted by all health care workers(World Health Organization, 2010).

2.4.1.7 Lipemic Samples

Lipemic samples are often seen following collection after heavy meals or the due to pre-existing metabolic disorder like hyperlipoproteinemia. Some of these errors can be avoided

by collecting samples after an overnight fast or by mentioning the metabolic disorder in the requisition slip. Fat interferes with optical reading of the instrument and can affect electrolyte values. Too many lipemic samples are often due to non-dissemination of information regarding patient preparation by the clinicians, non-compliance and/or miscomprehension by the patient (Naz et al., 2012). It is the responsibility of the clinicians and the phlebotomists to ensure that proper patient preparation is instituted before sample collection.

2.4.1.8 Hemolysis

Samples haemolysis occurs when blood is forced through a fine needle during vein puncture, shaking the tubes vigorously, and centrifuging the sample specimens before clotting. Haemolysis accounts for the majority of rejections in specimen received in the laboratory. The introduction of vacuum tubes along with the closed system of blood collection has madeblood collection efficient and easy. But lack of staff training engaged in phlebotomy is an impediment for expediting sample collection and transport. Red top vacutainers without any anticoagulant should not be shaken after the sample has been collected, and vacutainers for plasma should be gently inverted a few times so the anticoagulant mixes with the blood. Freezing and thawing of blood specimens also causes massive haemolysis. A study reported that over 95% of the haemolysed samples were due to incorrect sampling procedure or transportation (Lexington Medical Center, 2011). Haemolysis leads to the extravasations of intracellular contents into the plasma, leading to false high values different analytes like potassium, aspartate amino transferase (AST) and lactate dehydrogenase (LDH).

2.4.1.9 Delayed Transport of Specimen

Transport delays to the laboratory can give rise to clinically important errors if transport conditions are not optimized. It is stated that sample transportation needs to be considered as well, as it was identified as one of the source of pre-analytical errors that is commonly ignored and needs to be improved as there is an increasing trend towards a need for sample transport over long distances with the flourishing of laboratory facilities(Hamid et al., 2019).

2.4 Errors in Specimen Preparation

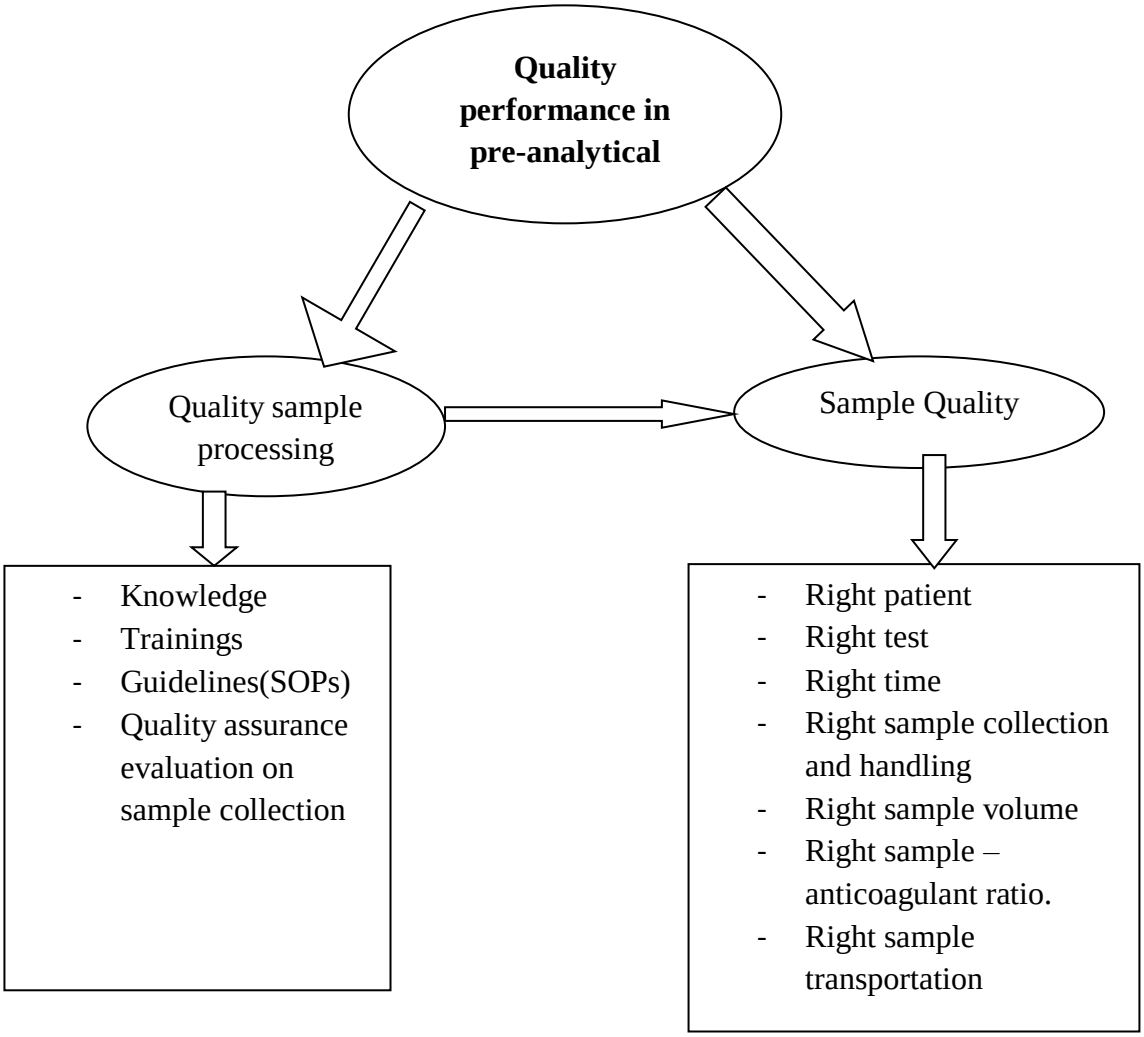
The specimen preparation steps contribute to approximately 19% of the overall cost of analysing a single specimen and are time-consuming (37% of time spent in producing result).

Being infectious, manual handling of samples are a well-recognized hazard to laboratory staff. Patient identification is probably the most important task in sample collection and error in this crucial step could have mild to life threatening consequence. Therefore, efforts to ensure compliance with standard identification procedures should be prioritized. Similarly wrong container labelling could also result in mild to severe life threatening consequence (Naz et al., 2012).

2.5 CONCEPTUAL GRAMEWORK

The conceptual framework gives a graphical representation of the independent variables and dependent variables. In this study the independent variable is the quality sample processing. Quality sample processing is achieved through giving required knowledge, trainings on sample processing to nurses, availing and following SOPs and monitoring their adherence to standards with periodic quality assurance evaluations.

The dependent variable is sample quality. Once the nurses are equipped with the knowledge, trainings; follow SOPs and periodically evaluated on quality assurances on quality sample processing, the outcome will be the sample quality. Now they will be able to provide right sample, right test to the right patient at right time. They will know the right sample volume, right ratio of sample to the anticoagulant, right sample storage and right sample transportation.


Quality performance in pre-analytical
Quality sample processing
Sample Quality
- Knowledge
- Trainings
- Guidelines(SOPs)
- Quality assurance evaluation on sample collection
- Right patient
- Right test
- Right time
- Right sample collection and handling
- Right sample volume
- Right sample – anticoagulant ratio.
- Right sample transportation

CHAPTER THREE: RESEACH METHODOLOGY

3.0 INTRODUCTION

Methodology in research is the part in which the researcher decides the systematic ways he will be used to solve the research problem. In it various steps that are generally adopted by a researcher in studying his research problem along with the logic behind them are studied (Ranjit Kumar, 2011). In this part we have seen how the research was designed, how data were collected, the size of the sample and how data were analysed.

3.1 STUDY AREA

The study was conducted at Kibogora District Hospital located in Kanjongo sector, Nyamasheke District Western province. The hospital serves 374,481people; it has 275 beds, 880 hospitalizations per year. It has 92 nurses, 19 midwifes and 11 lab technicians. Our target population were nurses who participate in sample collection. On laboratory quality performance, patient samples from six wards at Kibogora District Hospital (Maternity, Internal medicine, paediatrics, emergency, surgery and isolation) from which the clinician requested tests related to haematology and serology to be performed at Kibogora District Hospital laboratory during the period of the research were observed.

3.2 RESEARCH DESIGN AND APPROACH

An observational descriptive survey was adopted in evaluating the quality assurance practices in pre-analytical phase and potential pre-analytical errors that occur during laboratory pre-analytical phase at Kibogora District Hospital laboratory. A quantitative approach was used to collect data for each research objective. The study used non-probability convenience sampling technic to select the respondents.

3.3 TARGET POPULATION

The target population were nurses who participate in phlebotomy of laboratory samples and all patient samples from the six wards at Kibogora District Hospital (Maternity, Internal medicine, paediatrics, emergency, surgery and isolation) from which the clinician requested tests related to haematology and serology to be performed at Kibogora District Hospital

Laboratory during the period of the research. Also, laboratory technicians were assessed on the quality performance on the samples they received from different hospital wards.

3.4 SAMPLING TECHNIQUE

In this study a non-probability, convenience sampling was used to select the respondents and the samples to be evaluated. Convenience sampling method as one of non-probability sampling is when units are selected in an arbitrary manner with little or no planning involved. This sampling assumes that the population units are all alike, then any unit may be chosen for the sample.(Rant, 2013)**.**After the calculation of the desired sample size using a formula, The samples were selected based on who have been asked for haematology and/or serology tests during the period of the study. Regarding nurses, participants were selected based on who is on duty at the time of data collection.

3.4.1 Sample size

To determine the size of the sample, this study used Yamane simplified formula to calculate sample size (Adam, 2020). A single population proportion formula used for determination of the sample size for nurses and samples considered the following assumptions: A 95% confidence level and P = 0.5. The sample size was calculated based on 880 people who are hospitalized per year at Kibogora district hospital. In laboratory, the sample size was calculated based on 220 people who are hospitalized per quarter at Kibogora district hospital. For nurse respondents, the sample size was calculated based on 88 nurses who perform blood sample collection as part of their daily activities at Kibogora District hospital.

$n = N / [1 + N (e)^2]$

Sample size in laboratory: $n= [220/1+220(0.05)^2]= 141$

Nurse respondents sample size: $n= [88/1+88(0.05)^2] = 72$

Where; n = the sample size

N = the finite population

e = the level of significance or limit of tolerable error

1 = unit or a constant

3.5 INCLUSION CRITERIA

Laboratory request forms and blood samples for haematology and serology from maternity, internal medicine, paediatrics, emergency, surgery and isolation were part of this study. Rejected samples for serology and haematology during the period of the study were part of this study. Nurses in the above-mentioned services who participate in blood collection in their daily activities were also part of the study.

3.6 EXCLUSION CRITERIA

Other blood samples rather than serology and haematology samples and request forms were not included in this study. Request forms and samples to be examined outside of Kibogora District hospital were not included in the research. Rejected samples outside of the period of research will not be evaluated. Nurses who do not perform blood collection in their daily activities were not part of the study.

3.7 DATA COLLECTION METHOD

A check list designed for the evaluation of Quality indicators in pre-analytical phase was elaborated and used during the data collection in laboratory, while a questionnaire to collect social demographic and knowledge of the nurses were elaborated and distributed to nurses for self-report by the nurses. Data were collected from laboratory request forms, sample containers and logbook for sample rejection. Nurses were given a questionnaire and responded to mentioned questions.

3.7.1 Data collection instrument

The researcher elaborates a checklist comprising quality indicators in pre-analytical phase to be evaluated in laboratory and a questionnaire for nurses. The checklist has three sections. The first section has five questions concerning the evaluation of the completeness of the request form. The second has nine questions related to the quality of the sample. The third has two questions which evaluated whether the sample is accepted or rejected.

The questionnaire for nurses consisted of five questions. The first question has eleven elements evaluating the knowledge of the respondents on hematology and serology sample processing. Other four questions are related to trainings, use of SOPs and quality assurance evaluations.

3.7.2 Administration of data process

After obtaining the permission from the concerned authorities, the data were collected by the researchers. Because the researcher would collect samples in laboratory, a laboratory lab coat

as personal protective equipment was worn during data administration process. Laboratory staff and nurses were explained about the research in order to facilitate the data collection. These explanations were given through giving them the information sheet and allowing them to ask questions. Nurses were given a consent form, signed it and then given the questionnaires for self-report. Laboratory technician was observed by the data collector while receiving samples and the data collector wrote the observation on the checklist. After data collection, all raw data from checklist and questionnaires were transcribed to an excel sheet before analysis.

3.7.3 Validity and reliability of data collection instrument

The data collection instruments were checklist and a questionnaire designed by the researcher comprising all pre-analytical quality indicators related to the study objectives and research questions and all-important information related to the present study were incorporated on the checklist and the questionnaire.

3.8 DATA ANALYSIS

During data analysis, three steps were used which are description, analysis and interpretation. The data were analysed using SPSS (Statistical Package for Social Sciences) version 23. In order to summarize all the information obtained from data collection tool, descriptive statistics were used and findings presented using frequency tables.

3.9 ETHICAL CONSIDERATION

During this study, the University policy related to research was followed. Plagiarism was avoided. Prior to data collection, ethical clearance was obtained from Institutional Review Board of Kibogora Polytechnic. The participants were informed that participation is voluntary and that they have the right to refuse to participate or stop from participating in the study any time they may experience any discomfort without any consequence. Those who accepted to participate signed the consent form attached herewith (Appendix1) they have been ensured the anonymity and confidentiality of the information that they had provided.

CHAPTER FOUR: DATA PRESENTATION, ANALYSISAND INTERPRETATION

4.0 INTRODUCTION

This chapter consists of presenting; analysing and interpretation of data from questionnaires and checklists used during the data collection in this study. Guided by the study objectives, this chapter includes the discussion of the results in the light of existing evidences that have been found in the same area of interest. The data analysis was done using the Statistical Package for Social Sciences (SPSS) version 23 and the results were presented using descriptive statistics in the form of tables. Analytical statistics were used to compare independent and dependent variables in order to establish the relationship between these variables.

4.1 DEMOGRAPHIC CHARACTERISTICS OF THE RESPONDENTS

The Table 4.1 illustrates demographic characteristics of the respondents.

Table 4.1 Demographic characteristics of the respondents (***N=72)***

Characteristic	**Frequency**	**Percentage (%)**
Gender		
Male	34	47.2%
Female	38	52.8%
Age		
Between 20-30 years	25	34.7%
Between 31-40 years	45	62.5%
More than 40 years	2	2.8%
Marital Status		
Single	13	18.1%
Married	59	81.9%
Widow	0	0%
Divorced	0	0%
Educational level		
Advanced Diploma	27	37.5%
Bachelor Degree	45	62.5%
Master Degree	0	0%
Working Experience		
Less than two years	5	6.9%
Between 2-5 years	33	45.8%
Above 5 years	34	47.2%

The number of respondents in this study was 72 nurses. Over half of participants were female 38 (52.8%) and male 34 (47.2%). Age group varied in three groups, between 20 to 30 years 25(34.7%), between 31-40 years 45 (62.5%) and above 40 years 2 (2.8%). The majority was married 59 (81.9%) while single was 13 (18.1%), No divorced or widow among the participants. The educational background of the participants was in two categories, Advanced diploma 27(37.5%), Bachelor degree45 (62.5%). Concerning working experience, the participants were subdivided in three categories, less than 2 years of working experience 5(6.9%), between 2 and 5 years33 (45.8%) and above 5 years34(47.2%).

4.2 KNOWLEDGE OF LABORATORY SAMPLING PROCESSING AMONG NURSES AT KIBOGORA DH

About the knowledge of the nurses on laboratory samples collection and handling (Table 4.2), following the responses of all respondent, the study showed that all the nurses 72 (100%) had knowledge on correct patient, correct test request, correct request form, correct container for haematology and serology samples, correct labelling, correct volume for haematology and serology samples, correct storage of haematology and serology samples and correct sample transportation.

Table 4.2 Knowledge of laboratory sampling processing among nurses at Kibogora DH

Characteristics	Frequency (n=72)	Percentage (%)
Correct patient		
Yes	72	100%
No	0	0%
Correct Test		
Yes	72	100%
No	0	0%
Correct request form		
Yes	72	100%
No	0	0%
Correct container for serology samples		
Yes	72	100%
No	0	0%
Correct container for hematology sample		
yes	72	100%
No	0	0%
Correct Labeling		
Yes	72	100%

No	0	0%
Correct volume for hematology samples		
Yes	72	100%
No	0	0%
Correct volume of Serology Samples		
Yes	72	100%
No	0	0%
Correct storage of serology samples		
Yes	72	100%
No	0	0%
Correct storage for hematology samples		
Yes	72	100%
No	0	0%
Correct transport of blood samples		
Yes	72	100%
No	0	0%

4.3 TRAINING AND QUALITY ASSURANCE EVALUATION

Concerning trainings and quality assurance evaluation, the study showed gaps in every standard evaluated as summarized in (Table 4.3), the study showed that 49(68.1%) have been trained on blood sample collection and handling while 23(31.9%) lack the training on blood sample collection and handling. 51(70.8%) nurses confirmed of having SOPs on blood collection and handling while 21(29.2%) reported the non-availability of SOPs. Only 7(9.7%) participants confirmed that there is a periodic quality assurance evaluation from laboratory and 65(90.3%) said there is no periodic quality evaluation. Of 7 nurses who responded to have periodic quality assurance evaluation, 1(1.4%) said it is monthly, 5(6.9%) said it is quarterly, 1(1.4%) did not indicate the periodicity while none reported of yearly quality assurance evaluation.

Table 4.3 Training and quality assurance evaluation

Characteristic	Frequency (n=72)	Percentage (%)
Trained on blood samples collection		
Yes	49	68.1%
No	23	31.9%
Availability of SOPs on blood collection and handling		
Yes	51	70.8%
No	21	29.2%
Periodic quality assurance Evaluation		
Yes	7	9.7%
No	65	90.3%
Frequency of evaluation (n=6)		
Monthly	1	1.4%%
Quarterly	5	6.9%
Yearly	0	0%
Not responded the frequency	1	1.4%

4.4 SAMPLE QUALITY CHECK BY THE LABORATORY TECHNICIAN

As summarized in (Table 4.4), the study showed that laboratory technicians had fully best practices on different quality indicators including checking patient identification, requested tests, right patient sample and labelling of sample, where among 165 samples evaluated, the adherence to those standards was 100%. Among other quality indicators assessed, though it was at different proportions, the study showed gaps at each quality indicators as follow: the physician name checking 140(85%), 25(15%) no checking of physician name, samples to which the origin of sample is checked 155(94%), 10(6%) with no checked origin; checking of sample collection date and time 115(70%), 50(30%) date and time of collection not checked; appropriate tube checked 155(94%), 10(6%) not checked; sufficient sample checked 120(73%),45(27%) not checked; ratio of blood and anticoagulant checked 115 (70%), 50(30%) not checked; Clotting of sample checking 120(73%), 45(27%) not checked; checking for sample haemolysis 105(64%),60(36%)haemolysis not checked; checking of proper storage of the sample 125(76%),40(24%)with proper storage not checked; checking for proper transportation 125(76%), 40(24%) not checked for proper transportation; all 165(100%) samples were accepted.

Table 4.4: Sample quality check by the Laboratory technician

Sample quality check by the Laboratory technician (n=165)	Frequency and Percentages			
	Yes	Percentage	**No**	Percentage
Patient identification	165	100%	0	0%
Physician name	140	85%	25	15%
Requested tests	165	100%	0	0%
Origin (ward) of the sample	155	94%	10	6%
Date and time of sample collection	115	70%	50	30%
Right patient sample	165	100%	0	0%
Appropriate tube	155	94%	10	6%
Sample labelled	165	100%	0	0%
Sufficient sample	120	73%	45	27%
Ratio of blood and anticoagulant	115	70%	50	30%
Clotted sample	120	73%	45	27%
Haemolysed sample	105	64%	60	36%
Proper storage	125	76%	40	24%
Proper transportation	125	76%	40	24%
Sample accepted?	165	100%	0	0%

4.5 DISCUSSION OF FINDINGS

The current study had the main purpose of assessing the quality performance in pre-analytical phase of haematology and serology samples at Kibogora District Hospital, Rwanda. It had to describe the knowledge of nurses on serology and haematology samples collection and handling and administrative support with periodic quality assurance evaluation. Another aspect was to describe the best practices of laboratory technicians while receiving serology and haematology samples. The majority of respondent females 52.8% and the majority of age is between 31 – 40 years 62.5%. This differ from the survey on health care workers regarding knowledge on clinical sample collection, storage and transportation in India were the majority was male 53.5% with most age group of 21 -30 years 60% while 31 -40 years was 30.6%(Sharma, 2019).

The study showed that the all respondents 100% had knowledge on laboratory blood sample processing including correct container for haematology samples, correct storage and correct volume, this concord with the findings of another study conducted in Turkey on the awareness of nurses on blood and urine sample collection procedures which showed that all the participants 100% who responded said they are aware of haematology samples collection

container but differ from the awareness blood sample storage 75% and correct sample volume 97%(Kaplan & Azizoglu, 2014).This shows that though there are different necessary knowledge among nurses on blood sample collection, still efforts should be made to sustain this knowledge for better management of patients relying on reliable laboratory results. This study showed that among the respondents only 68.1% had training on blood collection samples, the results of a study conducted on nursing students showed a higher percentage because it showed that 87% received practical training on blood sample collection(Alves & Jouffroy, 2018), the two research findings shows that more trainings are needed in order to help nurses to keep on performing phlebotomy according to standards and this contribute a lot to the quality of service rendered to patients and reducing pre-analytical errors related to phlebotomy errors.

The current study showed that the laboratory technicians have best practices on some pre-analytical quality indicators including checking patient identification, requested tests, right patient sample and labelling of sample, where the adherence to these standards was 100%, these are good laboratory practices and efforts are needed to maintain these best practices. Contrary to the best practices mentioned, this study showed some weaknesses on other pre-analytical indicators like checking the date and time of sample collection where 50(30%) samples were not checked, not checking the date and time of sample collection might lead to errors in diagnosis due to delaying of transporting the sample to the laboratory, a study in Iraq reported that 39% of samples delayed to be transported to laboratory(Najat, 2017) and most of the time delays of samples transportation to the laboratory results in sample rejection because some artefacts resulting to delays may affect the laboratory results.

Another aspect that was shown by this study is that checking of haemolysis of the sample was not at a good level because 60(36%) samples were not checked for haemolysis; this is considered as a potential source of pre-analytical errors as there is a study done in Sweden which reported that 31.1% of samples from emergency department at a primary health care presented haemolysis(Söderberg et al., 2009); it also showed that the laboratory technicians did not check for ratio of blood and anticoagulant for 50(30%) samples and 45(27%) samples were not checked for clots, this might be a source of pre-analytical errors as shown in a study conducted in Brazil in one federal laboratory where 18.1% of samples were rejected due to coagulation(Coriolano et al., 2016). Regarding the proper storage and transportation of blood samples this study showed that 40(24%) samples were not checked for proper transportation.

Proper storage and transportation of blood sample has a major role in reducing pre-analytical errors and this must be not neglected by laboratory technicians.

4.6 SUMMARY OF FINDINGS

On the assessment of knowledge of nurse on blood sample processing, the total number of respondents in this study was 72, over half of participants were female 38 (52.8%) and male 34 (47.2%). The educational background of the participants was in two categories, Advanced diploma 27(37.5%), Bachelor degree45 (62.5%). As best practices the study showed that all the nurses 72 (100%) had knowledge on correct patient, correct test request, correct request form, correct container for haematology and serology samples, correct labelling, correct volume for haematology and serology samples, correct storage of haematology and serology samples and correct sample transportation, but the study showed gap in providing trainings SOPs and quality assurance evaluation by laboratory staff because 23(31.9%) participants said they have not been trained, 21(29.2%) said not having SOPs and periodic quality assurance evaluations were very low 1.4%.

As shown by study, among 165 samples assessed, laboratory technicians had best practices of 100% adherence to standards of checking patient identification, requested tests, right patient sample and labelling of sample, on the other side, the study showed gaps at each quality indicators as follow: the physician name checking 140(85%), 25(15%) no checking of physician name, samples to which the origin of sample is checked 155(94%), 10(6%) with no checked origin; checking of sample collection date and time 115(70%), 50(30%) date and time of collection not checked; appropriate tube checked 155(94%), 10(6%) not checked; sufficient sample checked 120(73%),45(27%) not checked; ratio of blood and anticoagulant checked 115 (70%), 50(30%) not checked; Clotting of sample checking 120(73%), 45(27%) not checked; checking for sample haemolysis 105(64%),60(36%)haemolysis not checked; checking of proper storage of the sample 125(76%),40(24%)with proper storage not checked; checking for proper transportation 125(76%), 40(24%) not checked for proper transportation; despite all the gaps, all samples were accepted by laboratory technicians.

CHAPTER FIVE: CONCLUSION ANDRECOMMENDATIONS

5.0 INTRODUCTION

The chapter presents the study conclusion and recommendations, based on the study objectives and research questions, and the chapter ends up by the suggestions on future research studies for laboratory quality improvement

5.1 CONCLUSION

As conclusion, this study showed that nurses have certain knowledge on sample collection but refresher trainings to sustain this knowledge is needed to maintain the good performances. The study revealed that the use of SOPs in related to laboratory sample collection and handling is not satisfying and periodic quality assurance evaluation by laboratory is one of the areas that need improvement.

The laboratory showed some best practice by checking samples on patient identification, requested tests, right patient sample and labelling of sample before accepting them but there are weaknesses on checking the physician's name, origin of sample, sample collection date and time, appropriateness of container, sufficiency of sample, ratio of blood and anticoagulant, clotting of sample, sample haemolysis, proper storage and proper transportation. All the negative treats can be minimized by quality assurance implementation in all aspect related to sample processing both in laboratory and other clinical services.

5.2 RECOMMANDATIONS

Quality assurance implementation is the key in improving the quality of service delivered to the patients including better diagnosis and better diagnosis cannot be obtained without reliable laboratory results. That is why the following must be implemented:

- **To Kibogora District hospital**
    - The administration of Kibogora District hospital needs to provide all the necessary so that refresher trainings of laboratory samples are done to help nurse in providing the quality while processing laboratory samples.

- The Quality focal point at Kibogora District Hospital must ensure that SOPs are available and followed during daily activities including laboratory sample processing.
- Planning and implementation of quality assurance evaluation are needed as way of monitoring the adherence to quality standards.

5.3 SUGGESTION FOR FURTHER STUDIES

Our study did not associate the knowledge of the nurses and their quality performance; quality indicator to detect pre-analytical errors and reduction of pre-analytical error in the laboratory. Further studies would try to show the association of knowledge, training and periodic quality evaluation with good performance and bad performance.

Our study assessed if the laboratory checks for potential pre-analytical errors before sample reception and did not go far and evaluation the outcome after checking, further studies will try to evaluate the quality of the samples after each checking.

The followings are suggested studies:

- Prevalence and types of pre-analytical errors in hematology laboratory at Kibogora District Hospital, Rwanda.
- Knowledge attitudes and practices of nurses on blood samples collection at Kibogora District Hospital, Rwanda.
- Analysis of blood samples acceptability and rejection and identifying needed interventions at Kibogora District Hospital, Rwanda.

REFERENCES

A, A. O., A, I. A., & A, J. O. (2011). Incomplete laboratory request forms as a contributory factor to preanalytical errors in a Nigerian teaching hospital. *African Journal of Biochemistry Research*, *5*(3), 82–85. http://www.academicjournals.org/AJBR

Abbas, M., Mukinda, F. K., & Namane, M. (2017). The effect of phlebotomy training on blood sample rejection and phlebotomy knowledge of primary health care providers in Cape Town: A quasi-experimental study. *African Journal of Primary Health Care and Family Medicine*, *9*(1), 1–10. https://doi.org/10.4102/phcfm.v9i1.1242

Adam, A. M. (2020). Sample Size Determination in Survey Research. *Journal of Scientific Research and Reports*, *June*, 90–97. https://doi.org/10.9734/jsrr/2020/v26i530263

Alves, B., & Jouffroy, R. (2018). *Nursing and Health Care Training of French Nursing Students on Drawing Blood Culture : Results from a Broad Electronic Survey*. 1–6. https://doi.org/10.23937/2469-5823/15100104

Arul, P., Pushparaj, M., Pandian, K., Chennimalai, L., Rajendran, K., Selvaraj, E., & Masilamani, S. (2018). Prevalence and types of preanalytical error in hematology laboratory of a tertiary care hospital in South India. *Journal of Laboratory Physicians*, *10*(02), 237–240. https://doi.org/10.4103/jlp.jlp_98_17

BJ, S., & C, S. (2019). Study on "Pre-analytical Errors in a Clinical Biochemistry Laboratory:" The Hidden Flaws in Total Testing. *Biochemistry & Analytical Biochemistry*, *08*(01), 1–6. https://doi.org/10.35248/2161-1009.19.8.374

Burnett, L., Chesher, D., & Mudaliar, Y. (2004). Improving the quality of information on pathology request forms. *Annals of Clinical Biochemistry*, *41*(1), 53–56. https://doi.org/10.1258/000456304322664708

Chawla, R., Goswami, B., Singh, B., Chawla, A., Gupta, V. K., & Mallika, V. (2010). Evaluating laboratory performance with quality indicators. *Laboratory Medicine*, *41*(5), 297–300. https://doi.org/10.1309/LMS2CBXBA6Y0OWMG

Coriolano, N. L., Silva, I. C. R., & Lamounier, T. A. C. (2016). Analysis of the frequency of biological sample recollections as quality indicators in a clinical laboratory of Distrito Federal, Brazil. *Jornal Brasileiro de Patologia e Medicina Laboratorial*, *52*(1), 11–16. https://doi.org/10.5935/1676-2444.20160002

Dr.Abhineet Mehrotra, D. A. M. (2013). An Evaluation of Laboratory Specimen Rejection Rate in a North Indian Setting-A Cross-Sectional Study. *IOSR Journal of Dental and*

Medical Sciences, *7*(2), 35–39. https://doi.org/10.9790/0853-0723539

Englezopoulou, A., Kechagia, M., Chatzikiriakou, R., Kanellopoulou, M., Valenti, M., & Masedu, F. (2016). Pre Analytical Errors as Quality Indicators in Clinical Laboratory. *Austin Journal of Public Health and Epidemiology*, *3*(5), 1–8.

Erdal, E. P., Mitra, D., Khangulov, V. S., Church, S., & Plokhoy, E. (2017). The economic impact of poor sample quality in clinical chemistry laboratories: results from a global survey. *Annals of Clinical Biochemistry*, *54*(2), 230–239. https://doi.org/10.1177/0004563216651647

Hamid, I., Ramnath Pai, V., U, R., & H. Sheriff, M. (2019). Pre-analytical errors in clinical biochemistry-a comparative study. *International Journal of Clinical Biochemistry and Research*, *6*(2), 182–189. https://doi.org/10.18231/j.ijcbr.2019.042

Henriksen, L. O., Faber, N. R., Moller, M. F., Nexo, E., & Hansen, A. B. (2014). Stability of 35 biochemical and immunological routine tests after 10 hours storage and transport of human whole blood at 21°C. *Scandinavian Journal of Clinical and Laboratory Investigation*, *74*(7), 603–610. https://doi.org/10.3109/00365513.2014.928940

Hobson, G. E. (2015). *A Sheffield Hallam University thesis*.

Kahn, S. E. (2005). *Specimen mislabeling: A significant and costly cause of potentially serious medical errors*. *April*, 8.

Kaplan, I., & Azizoglu, M. (2014). *A questionnaire study among nurses : awareness of blood and urine sample collection procedures*. *April 2015*. https://doi.org/10.1515/cclm-2013-1118

Kimengech, K. K., Waithaka, S. K., Onyuka, J., & Kigondu, C. S. (2017). Determination of errors that compromise the quality of laboratory service in a tertiary hospital. *Asian Journal of Medical Sciences*, *8*(1), 64–70. https://doi.org/10.3126/ajms.v8i1.14740

Lexington Medical Center. (2011). *Department of Pathology and Laboratory Medicine SPECIMEN COLLECTION , HANDLING , and TRANSPORT*. 1–6.

Lippi, G., Bassi, A., Brocco, G., Montagnana, M., Salvagno, G. L., & Guidi, G. C. (2006). Preanalytic error tracking in a Laboratory Medicine Department: Results of a 1-year experience [11]. *Clinical Chemistry*, *52*(7), 1442–1443. https://doi.org/10.1373/clinchem.2006.069534

Mosha, V. V., & Kabanyana, C. (2021). The Rate of Sample Rejection and Pre-Analytical Errors at KCMC Clinical Laboratory in Moshi, Kilimanjaro. *East Africa Science*, *3*(1), 116–122. https://doi.org/10.24248/easci-d-20-00005

Mukherjee, B., & Patra, S. (2013). *PRE-ANALYTICAL ERRORS IN THE CLINICAL*

LABORATORY AND HOW TO MINIMIZE THEM Quality control View project. *May 2014*. https://www.researchgate.net/publication/236020318

Musa, A. U., & Ndakotsu, M. A. (2020). Pattern of Blood Specimen Rejection at a Nigerian Public Clinical Laboratory. *Cross Current International Journal of Medical and Biosciences*, *2*(4), 55–59. https://doi.org/10.36344/ccijmb.2020.v02i04.003

Najat, D. (2017). Prevalence of pre-analytical errors in clinical chemistry diagnostic labs in Sulaimani City of Iraqi Kurdistan. *PLoS ONE*, *12*(1), 1–13. https://doi.org/10.1371/journal.pone.0170211

Naz, S., Mumtaz, A., & Sadaruddin, A. (2012). Preanalytical Errors and their Impact on Tests in. *Pakistan Journal of Medical Research*, *51*(1), 27–30.

Nybo, M., Cadamuro, J., Cornes, M. P., Gómez Rioja, R., & Grankvist, K. (2019). Sample transportation - An overview. *Diagnosis*, *6*(1), 39–43. https://doi.org/10.1515/dx-2018-0051

Parisi, L. L. (2003). Patient Identification: The Foundation for a Culture of Patient Safety. *Journal of Nursing Care Quality*, *18*(1), 73–79. https://doi.org/10.1097/00001786-200301000-00010

Plebani, M. (2012). Quality indicators to detect pre-analytical errors in laboratory testing. *Clinical Biochemist Reviews*, *33*(3), 85–88.

Plebani, M., Sciacovelli, L., & Aita, A. (2017). Quality Indicators for the Total Testing Process. *Clinics in Laboratory Medicine*, *37*(1), 187–205. https://doi.org/10.1016/j.cll.2016.09.015

Rant, M. B. (2013). Research methodology. In *Hidden Champions in CEE and Turkey: Carving Out a Global Niche* (Vol. 9783642405). https://doi.org/10.1007/978-3-642-40504-4_2

Rusanganwa, V., Gahutu, J. B., Evander, M., & Hurtig, A. K. (2019). Clinical Referral Laboratory Personnel's Perception of Challenges and Strategies for Sustaining the Laboratory Quality Management System. *American Journal of Clinical Pathology*, *152*(6), 725–734. https://doi.org/10.1093/ajcp/aqz092

Rusanganwa, V., Gahutu, J. B., Nzabahimana, I., Ngendakabaniga, J. M. V., Hurtig, A. K., & Evander, M. (2018). Clinical Referral Laboratories in Rwanda. *American Journal of Clinical Pathology*, *150*(3), 240–245. https://doi.org/10.1093/ajcp/aqy047

Salinas, M., Flores, E., López-Garrigós, M., & Leiva-Salinas, C. (2018). Laboratory test inappropriateness: lessons revisited and clarified in seven questions. *Journal of Laboratory and Precision Medicine*, *3*, 34–34. https://doi.org/10.21037/jlpm.2018.03.10

Saloni, & Mittal, N. (2020). Study of pre analytical errors in clinical biochemistry laboratory in rural area of Punjab. *Panacea Journal of Medical Sciences*, *10*(2), 135–138. https://doi.org/10.18231/j.pjms.2020.029

Sharma, D. N. (2019). Post sensitization assessment of knowledge attitude and practice regarding clinical sample collection, storage and transportation among Health care workers at a tertiary care Hospital in central Madhya Pradesh. *Journal of Medical Science And Clinical Research*, *7*(12), 91–95. https://doi.org/10.18535/jmscr/v7i12.63

Sikaris, K. A. (2017). Enhancing the clinical value of medical laboratory testing. In *Clinical Biochemist Reviews* (Vol. 38, Issue 3).

Söderberg, J., Jonsson, P. A., Wallin, O., Grankvist, K., & Hultdin, J. (2009). Haemolysis index - An estimate of preanalytical quality in primary health care. *Clinical Chemistry and Laboratory Medicine*, *47*(8), 940–944. https://doi.org/10.1515/CCLM.2009.227

Tadesse, H., Desta, K., Kinde, S., Hassen, F., & Gize, A. (2018). Errors in the Hematology Laboratory at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia. *BMC Research Notes*, *11*(1). https://doi.org/10.1186/s13104-018-3551-y

Tola, E. K., Dabi, Y. T., & Dano, G. T. (2022). Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia. *Pathology and Laboratory Medicine International*, *Volume 14*(March), 1–6. https://doi.org/10.2147/plmi.s351851

World Health Organization. (2010). WHO best practices for injections and related procedures toolkit. *Safe Injection Global Network (SIGN)*, 1–51.

Ye, Y., Wang, W., Zhao, H., He, F., Zhong, K., Yuan, S., Du, Y., Chen, B., & Wang, Z. (2018). Haematology specimen acceptability: A national survey in Chinese laboratories. *Biochemia Medica*, *28*(3), 1–10. https://doi.org/10.11613/BM.2018.030704

APPENDICES

Appendix 1: QUESTIONNAIRE FOR DATA COLLECTION AMONG NURSES

Title: Assessment of quality performance in pre-analytical phase for haematology and serology samples at Kibogora District Hospital, Rwanda.

SECTION A: SOCIAL DEMOGRAPHIC INFORMATION OF PARTICIPANTS

Nurses or midwives
Gender Male ☐ female ☐
Marital status Single ☐ Married ☐ Divorced ☐ Widow ☐
Age group 20-30 ☐ 31-40 ☐ more than >40 ☐
Educational level Advanced Diploma ☐ Bachelor degree ☐ Master's degree ☐
Working experience Less than 2 years ☐ Between 2-5 years ☐ Above 5 years ☐

1. **KNOWLEDGE**

Do you have knowledge on the following thing to be cared of while dealing with serological and haematological samples?

Knowledge	**YES**	**NO**
1. Correct patient		
2. Correct test request		
3. Correct request form		
4. Correct container for serological samples		
5. Correct container for hematological samples		
6. Correct labeling		
7. Correct volume for hematological samples		
8. Correct volume for serological samples		
9. Correct storage of serological samples		
10. Correct storage of hematological sample?		
11. Correct transport of blood samples		

2. Have you been trained on blood sample collection? Yes ☐ No ☐
3. Do you have a standard operating procedure (SOP) on blood sample collection and handling? Yes ☐ No ☐
4. Do you have a periodically quality assurance evaluation on laboratory sample collection? Yes ☐ No ☐
5. If yes, how many time does the quality assurance evaluation is done?
    1) Monthly ☐
    2) Quarterly ☐
    3) Yearly ☐

CHECK LIST FOR LABORATORY TECHNICIAN

Does the lab technician check for the followings when receiving haematological and serological samples?

1. **INFORMATION ON REQUEST FORM**
   1) Patient identification Yes ☐ No ☐
   2) Physician name Yes ☐ No ☐
   3) Requested tests Yes ☐ No ☐
   4) Origin (ward) of the sample Yes ☐ No ☐
   5) Date and time of sample collection Yes ☐ No ☐
2. **SAMPLES**
   1) Wright patient sample Yes ☐ No ☐
   2) Sample collected in appropriate tube Yes ☐ No ☐
   3) Sample labeled Yes ☐ No ☐
   4) Sufficient sample volume Yes ☐ No ☐
   5) Ratio of blood and anticoagulant Yes ☐ No ☐
   6) Clotted sample Yes ☐ No ☐
   7) Hemolysed Sample Yes ☐ No ☐
   8) Proper storage Yes ☐ No ☐
   9) Proper transportation Yes ☐ No ☐

3. **SAMPLE ACCEPTANCE AND REJECTION**
   1) Is the sample accepted? Yes ☐ No ☐
   2) If not, was the sender notified? Yes ☐ No ☐

APPENDIX 2: INFORMATION SHEET

Dear Participant,

We invite you to participate in a research study entitles: Assessing quality performance in pre-analytical phase of haematology and serology samples at Kibogora District Hospital, Rwanda. We are currently enrolled in the biomedical laboratory sciences at Kibogora polytechnic in Nyamasheke district, Rwanda, and we are in the process of writing our research project as a requirement for obtaining bachelor degree. The purpose of the research: To assess the quality performance in pre-analytical phase of haematology and serology samples at Kibogora District Hospital, Rwanda as required to obtain accurate and reliable laboratory testing results.

The enclosed questionnaire has been designed to collect information on: performance of phlebotomist, sample receptionist and social demographic as well.

Your participation in this research project is completely voluntary. You may refuse to participate. There are no known risks of participating other than those encountered in your everyday work life as health professional. Your responses will remain confidential and anonymous. Data from this research will be protected and reported only as collective combined totals. No one other than the researchers will know your individual answers to this questionnaire.

If you have any questions about this project, feel free to contact *TWAJAMAHORO Gilbert: 0788810856 and UWIMBABAZI Dative: 0780570319*

Thank you. We are happy to work with you.

Sincerely yours,

UMUGEREKA B: AMAKURU AJYANYE N'UBUSHAKASHATSI

Tubatumiye mu gufatanya natwe mu bushakashatsi bufite inyito: Igenzurary'imikorere myiza ikwiye mbere yuko hatangiragupimwa ibizamin iby'amaraso muri serivise za hematoroji na seroroji muri laboratwari y'ibitarobya Kiogora mu karere ka Nyamasheke.

Twe abakora ubu bushakashatsi twiga mu ishami ry'ubuzima mubijyanye no gusuzuma indwara muri laboratwari mu ishuri rikuru rya Kibogora ribarizwa mu karere ka Nyamasheke mu Rwanda.Turigukora ubu bushakashatsi murwego rwo kuzuza ibisabwa mbere yo guhabwa impamyabushobozi y'icyiciro cya kabiri cy'amashuri ya kaminuza. Ikigenderewe muri ubu bushakashatsi ni :Igenzura ry'imikorere myiza ikwiye mbere yuko hatangira gupimwa ibizamini by'amaraso muri serivisi za hematoroji na seroroji muri laboratwari y'ibitaro bya Kibogora mu rwego rw'uko laboratwari itanga ibisubizo byizewe .

Turifuza gukora iryoge nzura kumikorere ya buri munsi kubafata ibizamini by'amaraso bijyanwa muri laboratwari ndetse no kubyakira muri laboratwari y'ibitaro bya Kibogora mu karere ka Nyamasheke .

Kugira uruhare muri ubu bushakashatsi, no gutanga amakuru akenewe biva kubushake, ntagahato.Ntan'ingaruka zaba kumuntu waba yumva adahisemo kwemera gutanga ayomakuru. Amakuru yatanzwe ni ibanga rikomeye, ntawundi muntu utari mu bushakashatsi uzabimenya.

Hagize ikibazo mufite uburenganzira bwuzuye kubaza ikibazo cyose mufite kubyerekeranye n'ubu bushakashatsi. Bibaye ngombwa mwahamagara:*TWAJAMAHOROGilbert:0788810856 na UWIMBABAZI Dative: 0780570319.*

Turabashimiye byimazeyo ko mwemeye gufatanya natwe muri ubu bushakashatsi.

APPENDIX C: CONSENT

I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to participate in this study.

Participant's signature …….... Date…….

UMUGEREKA D: KWEMERA KUBA MU BUSHAKASHATSI

Nasobanuriwe ibijyany en’amakuru asabwa mukeneye mu bushakashatsi bwanyu.Nahawe n’amahirwe yogusobanuza ibyo ntari nsobanukiwe.Nasobanukiwe ko ari ubushake kandi ko nshobora kureka gutanga umusanzu wange nta bwisobanuro nta nikiguzi. Nemeye kubushake bwanjye gutanga amakuru akenewe muri ubu bushakashatsi.

Umukono……. italiki……