

KIBOGORA POLYTECHNIC

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF BIOMEDICAL LABORATORY SCIENCE

ASSESSMENT OF LABORATORY SPECIMEN REJECTION RATES

Case study: Kibogora district hospital

A Research Paper submitted in partial fulfillment of the requirements for the Bachelor's degree
with honor in Biomedical Laboratory Sciences

PREPARED BY:

NDATABAYE NGABO Fredy

Reg.Nº 1600290

KUBWIMANA Marie Jeanne

Reg. Nº 1600221

SUPERVISOR:

Dr HABUMUREMYI Sosthene

Kibogora September, 2019

DECLARATION

Declaration by the Candidate

We, **NDATABAYE NGABO Fredy** and **KUBWIMANA Marie Jeanne** hereby declare that this is our own original work and not a duplication of any similar academic work. It has therefore not been submitted to any other institution of higher learning.

All materials cited in this paper which are not our own have been duly acknowledged.

Signed:

NDATABAYE NGABO Fredy:.....

And

KUBWIMANA Marie Jeanne:.....

Date.....

Declaration by the Supervisor

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

SUPERVISOR’S NAME: Dr HABUMUREMYI Sosthene

SIGNED.....

DATE.....

ABSTRACT

This study was about evaluating the rate of specimen rejection in Kibogora DH. This study considered the following objectives; to assess the cause and rates of specimen rejection in Kibogora DH, to investigate the criteria of specimen rejection in Kibogora DH and to evaluate clinical consequences of specimen rejection on patients in Kibogora DH.

Some studies investigate the magnitude of rejection among received specimens through sample referral network. GeneXpert for TB drug resistance testing, HIV viral load, CD4 and EID specimens were among the rejected specimen types. It was also evaluated the rejection reasons and trends of rejection whether the problem was improved through time or continued as it was. The considered total sample in 95621 periods of 2018 where rejected sample was of 66.

Referring to objective one, was summarized in table 1 shows that along study period the specimen which were received in Kibogora D H were 95621 and among them 66 which represented 0.069% were rejected due to different causes. table 2 illustrates that the types of rejected samples were blood which were 64 which represented 96.97%, urine which represented 1.51% and 1.51% were TB samples. Referring to objective two, it was summarized in table 3 demonstrates that samples were rejected due to clotting where 60.6% of samples were rejected due to this reason, 12.12% were rejected due to missed request form , 4.54% were rejected because they were in inappropriate tube, 3.03% were rejected as they mislabeled, 3.03% were rejected as they were hemolyzed sample, 4.54% were rejected as they delayed transport time and sample processing ,3.03% were rejected due to wrong labeled and 9.09% were rejected due to insufficient sample. Objective three showed that; in the table 6 highlights that high rate of recollection of specimen was a major consequence of sample rejection as it was caused by 42.42% of sample rejection, 18.18% of sample rejection caused repeated phlebotomy, causing discomfort and potential complications in the affected patients was 18.18% of sample rejection, 21.21% of sample rejection caused by delay in availability of test results.

By conclusion, is clear the comprehensive analysis of specimen acceptability criteria and specimen rejection detailed in this study emphasized that specimen rejections for various reasons are a continuous challenge for hospitals and other laboratories. Detailed analyses of specimen rejection rates and related issues, allowed to formulate an inter-disciplinary and efficient plan targeted to decrease specimen rejection rates at institution.

DEDICATION

we dedicate to this work:

To our family,

To our friends and

Classmates

ACKNOWLEDGEMENTS

Thanks go to the almighty God. It is under his mercy that we have been able to complete all our undergraduate studies especially the dissertation of this final research project.

We greatly recognize the encouragement from the KIBOGORA POLYTECHNIC, especially all staff and lecturers of Faculty of health sciences who, in diverse ways, provided the highly valued and appreciated knowledge and skills that considerably contributed to the completion of this work.

We are highly indebted to our supervisor Dr **HABUMUREMYI Sosthene** for his tireless guidance, critical comments and his valuable scientific advice on our work. Your great academic strength, devotion, competence and conscientiousness provided us the inspiration we needed most.

We would like to extend our gratitude to all our class-mates, for their help, critical contribution and cooperation, in various cases, to the realization of undergraduate four years studies as well as this dissertation.

Our thanks also go to management of Kibogora district Hospital located in Nyamasheke district for their kindness, contribution tirelessness and commitment that they showed during field data collection.

To our family, we express our special thanks for your love, care, encouragement and all the continuous support that made our studies successful. Any kind of contribution is of great recognition.

Be blessed all!

LIST OF ABBREVIATON

APHI	:	Amhara Public Health Institute
CBC	:	Complete Blood Count
CD4	:	Cluster of differentiation 4
DH	:	District Hospital
ED	:	Emergency Departments
EID	:	Exposed Infant Diagnosis
HIV	:	Human immunodeficiency virus
ICU	:	Intensive Care Unit
ISO	:	International Organization for Standardization
SRR_s	:	sample rejection ratios
TAT	:	short turnaround time
TB	:	Tuberculosis
TDM	:	therapeutic drug monitoring
TTP	:	total testing process

TABLE OF CONTENTS

DECLARATION	i
ABSTRACT	ii
DEDICATION.....	iii
ACKNOWLEDGEMENTS.....	iv
LIST OF ABBREVIATON.....	v
LIST OF TABLES	x
LIST OF APPENDICES	xi
CHAPTER ONE: GENERAL INTRODUCTION	2
1.0. INTRODUCTION	2
1.1. BACKGROUND OF THE STUDY	2
1.2. STATEMENT OF THE PROBLEM.....	3
1.3. PURPOSE OF THE STUDY	3
1.4. OBJECTIVES OF THE RESEARCH	3
1.5. RESEARCH QUESTIONS.....	3
1.6. SIGNIFICANCE OF THE STUDY	4
1.6.1. To researcher.....	4
1.6.2. To lab workers	4

1.7. SCOPE OF THE RESEARCH.....	4
1.7.1. Content scope.....	4
1.7.2. Geographic scope	4
1.2.3. Time scope.....	4
CHAPTER TWO: LITERATURE REVIEW.....	5
2.1. RATE AND CAUSES OF LABORATORY SPECIMEN REJECTION.....	5
2.2. CRITERIA OF SAMPLE REJECTION	6
2.3. CLINICAL CONSEQUENCES OF SPECIMEN REJECTION.....	6
CHAPTER THREE: MATERIALS AND METHODS.....	8
3.0. INTRODUCTION	8
3.1. RESEARCH APPROACHES AND DESIGN.....	8
3.1.1. Quantitative approach.....	8
3.1.2. Qualitative approach.....	8
3.1.3. Research design.....	8
3.2. STUDY AREA DESCRIPTION	8
3.3. TARGET POPULATION	9
3.3.1. Inclusion criteria.....	9
3.3.2. Exclusion criteria.....	9
3.4. SAMPLE SIZE.....	9

3.5. SAMPLING PROCEDURES.....	9
3.6. MATERIALS AND EQUIPMENT.....	9
3.6.1. Materials and equipment.....	9
3.6.2. Data collection methods	9
3.7. DATA ANALYSIS PROCEDURES.....	10
3.7.1. Editing	10
3.7.2. Coding	10
3.7.3. Tabulation	10
3.8. ETHICAL CONSIDERATION.....	10
3.9. RELIABILITY AND VALIDITY MEASURES	11
CHAPTER FOUR: DATA PRESENTATION, ANALYSIS, INTERPRETATION AND SUMMARY.....	12
4. 0. INTRODUCTION	12
4.1. DATA PRESENTATION AND INTERPRETATION	12
4.1.1. Results regarding causes and rejection rate of specimen.....	12
4.2. Discussion of findings.....	15
4.2.1. Cause and rates of specimen rejection in study area.	15
4.2.3. Clinical consequences of specimen rejection on patients in study area	17
4.3. Summary of findings.....	18

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS	19
5.0 Introduction	19
5.1. Conclusion.....	19
5.2 . Recommendation	20
5.3 Suggestions for further study	20
REFERENCES	21
APPENDICES	25

LIST OF TABLES

Table 1: Rejection rate of specimen.....	12
Table 2: Rejected sample by type of specimen	13
Table 3: Reasons or rejection criteria of samples in study area	13
Table 4: Rejected sample by site of services	14
Table 5: Specimen Rejection by Type of Healthcare provider Collecting Specimen	14
Table 6: Clinical consequences of sample rejection	15

LIST OF APPENDICES

Appendices 1: Introduction letter.....	26
--	----

CHAPTER ONE: GENERAL INTRODUCTION

1.0. INTRODUCTION

This chapter concern on describing the background of the study, problem statement, purpose of the study, objectives of the study, hypothesis and scope of the study.

1.1. BACKGROUND OF THE STUDY

Precision, accuracy, and short turnaround time (TAT) are important in effective emergency laboratory services. The type of laboratory errors is classified as pre-analytical, analytical, and post-analytical, depending up on the time of presentation. Laboratory specialists have been demonstrated that 70% of errors occur in the pre-analytical phase which is an important component of laboratory medicine (Carraro P et Al, 2007).

Plebani *et al* (2012) state that the pre-analytical phase includes test request, patient or sample identification, sample collection, handling and transport, sample preparation for analysis such as centrifugation, aliquoting and sorting. It has been demonstrated that most errors occur in the pre-analytical phase by healthcare personnel who are not under the control of the laboratory. For the prevention of pre-analytical error, the most reliable approach is to construct pre-analytical standardization (Lippi G, Guidi GC., 2006).

Quality in laboratory medecine has been defined as the guarantee that each single step throughout the total testing process (TTP) is correctly performed. Due to the improvements in analytical techniques and instrumentation, a 10-fold reduction in the analytical error rate has been achieved in the past decades. However, the pre-analytical errors have been found to be much more vulnerable in the TAT (Plebani M., 2010).

Normally, shortening turn-around-time(TAT) is one of the quality indicators in emergency laboratories. It is obvious that the improvement in TAT is related with correct pre-analytical phase procedure, receiving the appropriate sample from the right patient on time is necessary to achieve reliable laboratory results and promote patient safety.

1.2. STATEMENT OF THE PROBLEM

The rejection of phlebotomy specimens may be considered a clinical laboratory problem, but it has a wide range of direct negative implications for patient care. On the most obvious level, rejected specimens lead to inconvenience and discomfort of repeated specimen collection, with accompanying delay in reporting test results. Specimen rejection leads to median lag of 65 min in availability of test results (Karcher DS, et al 2014), potentially postponing the availability of critical values, the ability to make diagnose, and the initiation or cessation of treatment. Because of the many negative consequences of specimen rejection, monitoring of specimen acceptability is an important quality assurance measure within the clinical laboratory. Many studies have evaluated this issue in individual laboratories and have reported rejection rates ranging from 0.1% to 3.49% (Alsina MJ, 2008).

So, this study was designed to highlight the extent at which the specimen is rejected and the negative consequences to the patient in the hospital considered as study area.

1.3. PURPOSE OF THE STUDY

This study will concentrate on evaluating the rate of specimen rejection in Kibogora DH.

1.4. OBJECTIVES OF THE RESEARCH

This study will consider the following objectives:

1. To assess the cause and rates of specimen rejection in Kibogora DH.
2. To investigate the criteria of specimen rejection in Kibogora DH.
3. To evaluate clinical consequences of specimen rejection on patients in Kibogora DH.

1.5. RESEARCH QUESTIONS

1. What are the cause and rate of specimen rejection in Kibogora DH?
2. What are the criteria of specimen rejection in Kibogora DH?
3. What are clinical consequences of specimen rejection on patients in Kibogora DH?

1.6. SIGNIFICANCE OF THE STUDY

The present research is of great importance to diverse careers; in fact, the researcher and lab workers.

1.6.1. To researcher

The findings of the study will be beneficial to the researcher in being experienced to carry out the research and the research will stand as partial fulfillment for the requirement of an award of Bachelor degree in biomedical laboratory.

1.6.2. To lab workers

The research will help the community the adoption of policies which could help them in reducing specimen rejection

1.7. SCOPE OF THE RESEARCH

1.7.1. Content scope

This study will interest on assessment of rate of specimen rejection.

1.7.2. Geographic scope

This study will take place in Kibogora hospital located in Nyamasheke district.

1.2.3. Time scope

This study will be conducted in 12 months of 2018.

CHAPTER TWO: LITERATURE REVIEW

2.1. RATE AND CAUSES OF LABORATORY SPECIMEN REJECTION

About 70% of the errors in the laboratory occur during pre- analytical phase of the laboratory processes. Specimen collection is the one of pre- analytical processes that ensure to provide accurate, reliable and timely results to patients. However, improper collection of samples could delay patient results due to unnecessary specimen re-draws and elongated corrective and preventive action activities.

A retrospective study conducted by Clinical Laboratory Standards Institute (2010) to identify the proportions of rejected specimens at the emergency laboratory. It was detected that an overall specimen rejection rate of 6% in our emergency laboratory. The results have shown that the most important rejection cause in our emergency laboratory is fibrin clots (28%) for biochemistry tests, additionally blood sample clot (35%) for coagulation tests, complete blood count (CBC) and blood gas analyses.

The most commonly reported types of pre-analytical errors in the stat laboratory were hemolyzed samples (46.4% in biochemistry), clotted samples (43.2% in hematology), lost samples (6.4%), inadequate sample-anticoagulant ratio (2.9%), patient misidentification (0.7%), samples collected in wrong blood collection tubes (0.3%) and missing test requests (0.1%) (Steindel SJ, 2001). It was have previously reported the sample rejection ratios of the core laboratory; the most frequent reason was the clotted specimen (55.8% of total rejections), followed by inadequate volume (29.3% of total rejections), similar to the emergency laboratory data. Most of the clotted specimens were received from adult hospital inpatient services (54.3%), followed by pediatric hospital inpatient services (26.8%) (Sinici Lay I, 2014).

2.2. CRITERIA OF SAMPLE REJECTION

Hemolysed specimens should not be used in coagulation testing because of possible clotting factor activation, which may also produce inaccurate results.

According to the International Organization for Standardization (ISO), clinical laboratories should develop criteria for acceptance or rejection of samples. However, when the sample is clinically critical or irreplaceable, the laboratory chooses to process the sample, and the final report should indicate the nature of the problem and, where applicable, that caution is required when interpreting the result (International Organization for standardization, 2012).

In Ethiopia, laboratory testing is through sample referral to more advanced reference laboratories using the established referral networking system (Kebede Y, 2016). A study conducted in Gondar University hospital showed that specimen rejection contributed 3.8% of the total pre-analytical errors for clinical chemistry tests (Ambachew S., 2018).

Moreover, hemolysis could influence test results by falsely elevating the analytes (Narayanan S, 200). Vigorous mixing of the specimen, pneumatic tube transport of the specimens, or forcing of blood through a large-bore needle of a syringe may cause the red blood cells to rupture, resulting in hemolysis (Carraro P, 2000).

The evaluated main rejection criteria which were identified are; improper test requests (incomplete, duplicate, errors in test input, inconsistent information), inappropriate transport (transport temperature, light exposure, delayed transport time), specimens without barcodes or unsuitable barcodes misidentification (unlabeled, mislabeled or mismatched samples), improper container or tube (including precious samples such as cerebrospinal fluid), insufficient specimen volume (inappropriate blood/anticoagulant ratio).

2.3. CLINICAL CONSEQUENCES OF SPECIMEN REJECTION

The previous studies clearly documents the consequences of laboratory specimen defects and resulting specimen rejection. Prospective analysis performed by 78 institutions of a total of 2 054 702 specimen accessions revealed an overall specimen rejection rate of 0.2%. This is generally in line with the rate reported in past studies in past studies of specimen

rejection, which have typically shown rates of less than 0.3% and up to 0.75% with lower rejection rates reported in more recent studies (Zarbo RJ, 2002).

The study carried out by the joint commission (2013) showed that the first and most direct consequence of specimen rejection is the need to collect a new specimen from the patient. In this study, 86.8% of rejected blood specimens led to repeated phlebotomy.

A troubling finding in this study was the very high rate of mislabeled specimens that were the result of allowing providers and other patient care team members to relabel specimens that were received in the laboratory improperly labeled. Of the participating institutions, 45% allow relabeling of blood specimens and 37% allow relabeling of urine specimens. Among the institutions allowing specimen relabeling, this was reported to be allowed at higher rates for incompletely labeled specimens, but 59% and 38% of participating institutions allow correction of mislabeled or unlabeled blood specimens, respectively.

In summary, specimen rejection leads to a high rate of recollection of specimens, including repeated phlebotomy and recatheterization for urine, causing discomfort and potential complications in the affected patients. Specimen rejection also leads to frequent abandonment of the test(s) originally ordered, more so with nonstart tests and urine specimens. Finally, the practice of allowing relabeling of improperly labeled specimens is associated with little clinical benefit but introduces a significant likelihood of specimen mislabeling and potential harm to the patient.

CHAPTER THREE: MATERIALS AND METHODS

3.0. INTRODUCTION

This chapter presented different methods and materials which were used to collect the data to assess the rate of specimen rejection in Kibogora DH.

3.1. RESEARCH APPROACHES AND DESIGN

As this research need to know the several kind of information several arguments was considered (argument which are in type of statements and arguments which are in type of number). Then present research put into consideration used two approaches to collect all kind of data: qualitative (for collecting information in type of statement) and quantitative (to collect data in type of number).

3.1.1. Quantitative approach

This approach helps the researcher to collect the information in numerical data to investigate traits and situations in data collection and data were analyzed using statistical methods to arrive at results which were interpreted to give meanings of the study.

3.1.2. Qualitative approach

It emphasizes on description where people's event views and arguments to give different ideas and arguments about the study.

3.1.3. Research design

A retrospective study was conducted for 12 months of 2018. Participants were recruited from Kibogora district hospital and sample of specimens will be collected.

3.2. STUDY AREA DESCRIPTION

Mission Organization: General Missionary Board, Free Methodist Church

Location: Kibogora hospital is found in Rwandan country western province precisely in Nyamasheke district in Kanjongo sector.

Specialties Needed: GS, ORS, OBG, IM/FP, EM, U, GE, OTO, OPH, PED ORS, PS, PD, AN, Dentist, Physical Med, & Rehab, Derm, Neurologist, Neonatology, Rheumatology, Nephrology,

CVS, TS, Hematologist, Geriatrics, Allergy and IMM, CARD, RAD, Oral & Maxillofacial Surgeon, PD SURG, NS

Profile: Kibogora Hospital is a 279 bed facility that includes: (75) Post-surgery, (64) Pediatric, (51) Internal Medicine, (45) Maternity, (6) Neonatal, (7) Emergency room, (18) Isolation and (13).

3.3. TARGET POPULATION

The target population of this study was sample of specimen from all units found in Kibogora district hospital in the period of 12 months in 2018 which were 95621.

3.3.1. Inclusion criteria

All specimen collected inside Kibogora district hospital.

3.3.2. Exclusion criteria

Specimen from outside of Kibogora district hospital.

3.4. SAMPLE SIZE

In this study, the data about the samples sent to the emergency laboratory during 12 months from were evaluated.

3.5. SAMPLING PROCEDURES

A convenient sampling strategy was used to gather participants. This was achieved in collaboration with Kibogora district hospital, the purpose of this study was explained to the study population and encourage them to participate in all scenario that were conducted within that period.

3.6. MATERIALS AND EQUIPMENT

3.6.1. Materials and equipment

Records of specimens, Logbooks and laptop machine to enter data.

3.6.2. Data collection methods

The methods which was used is a retrospective method.

3.7. DATA ANALYSIS PROCEDURES

In addition various activities were performed to ensure a better processing of data. This analysis was effectively run by focusing on the use of software.

Sample rejection ratios (SRRs) will be calculated according to different test groups (biochemistry, CBC, blood gases, coagulation, TDM, cardiac markers, hormones and anemia panel) and analyzed according to the site of services (ED, inpatient services). The distribution frequencies between the point of collection and the specimen rejections were evaluated by descriptive statistical analyses.

3.7.1. Editing

This involved the identification and corrections of errors found in log book and attitude scale responses. It was done immediately after such responses are cross-checked to make sure that accuracy, completion and uniformity are purposefully reinforced.

3.7.2. Coding

Coding was applied for the transformation of gathered results from the field study into categories converted into codes for easy qualitative and quantitative analysis.

3.7.3. Tabulation

After carrying out editing and coding, frequency distribution tables were used. Tables were constructed according to the main themes in the log book summarized all the findings of the study. Therefore, the results were presented in terms of frequencies and percentages.

3.8. ETHICAL CONSIDERATION

Confidentiality was of great importance while gathering information. This is the reason why the identity of individuals from whom the information was drawn was not permeated. Informants were not pressured to become a subject of the research. This was done to ensure the safety, social and psychological of both people and local leader respondents.

Then after, the researcher tried to get data from respondents; the information given will have to be treated with confidentiality and anonymity.

3.9. RELIABILITY AND VALIDITY MEASURES

Validity and reliability of the instruments to be used in this study will be given assurance in the way the researcher will give to his supervisor such instruments for the necessary corrections.

To ensure the validity of the instrument, research will check the log book for the consistency of the items, intelligibility and clarity, for adjustment and realignment purposes. As for reliability, the concept refers to the degree to which the same results would be obtained in repeated attempt of the same tests.

CHAPTER FOUR: DATA PRESENTATION, ANALYSIS, INTERPRETATION AND SUMMARY

4. 0. INTRODUCTION

The data of this survey were presented following the objectives of the study and this chapter was divided into three sub chapters including; data presentation and interpretation, discussion and summary of findings.

4.1. DATA PRESENTATION AND INTERPRETATION

This section is organized into three subsections which were prepared as follows, findings relating to first objective, findings relating to second objective and findings relating to third objective.

4.1.1. Results regarding causes and rejection rate of specimen

4.1.1.1. Rejection rate of specimen

While carrying out this study, the researcher considered the data about rejected samples available in 2018.

Table 1: Rejection rate of specimen

Category of specimen	Frequency	Percentage
All specimen	95621	100
Rejected specimen	66	0.069

Source: Secondary data, July, 2019

Table 1 shows that along study period the specimen which were received in Kibogora D H were 95621 and among them 66 which represented 0.069% were rejected due to different causes.

4.1.1.2. Rejected sample by type of specimen

The rejected sample were found to be of different types.

Table 2: Rejected sample by type of specimen

Type	Frequency	Percentage
Blood	64	96.97
Urine	1	1.51
TB	1	1.51
Total	66	100

Source: Secondary data, July, 2019

Table 2 illustrates that the types of rejected samples were blood which were 64 which represented 96.97%, urine which represented 1.51% and 1.51% were TB samples.

4.1.2. Reasons or rejection criteria of samples in Kibogora DH

In study area samples were found to be rejected due to different reasons.

Table 3: Reasons or rejection criteria of samples in Kibogora DH

Reasons	Frequency	Percentage
Clotted samples	40	60.6
Missed request form	8	12.12
Inappropriate tube	3	4.54
Mislabeled sample	2	3.03
Hemolyzed Sample	2	3.03
Wrong labeled	2	3.03
Insufficient sample	6	9.09
Delayed transport time and sample processing	3	4.54
Total	66	100

Source: Secondary data, July, 2019

Table 3 demonstrates that samples were rejected due to clotting where 60.6% of samples were rejected due to this reason, 12.12% were rejected due to missed request form, 4.54% were rejected because they were in inappropriate tube, 3.03% were rejected as they mislabeled, 3.03% were rejected as they hemolyzed sample, 4.54% were rejected as they delayed transport time and

sample processing,3.03% were rejected due to wrong labeled and 9.09 were rejected due to insufficient sample.

4.1.2.1. Rejected sample by site of services

Table 4: Rejected sample by site of services

Reasons	Frequency	Percentage
Emergency	8	12.12
Mat	10	15.15
Neo	5	7.57
Surgery	15	22.72
Ped	10	15.15
Internal medicine	16	24.24
SO	1	1.51
NC	1	1.51
Total	66	100

Source: Secondary data, July, 2019

Table 4 demonstrates that samples which were rejected from emergency was 12.12%, 15.15% were rejected from mat, 7.57% were rejected from neo, 22.72% were rejected from surgery,15.15 were rejected from ped,24.24% were rejected from internal medicine, 1.51% were rejected from SO and 1.51% were rejected from NC

4.1.2.3. Specimen Rejection by Type of Healthcare Provider Collecting Specimen

The samples which were rejected from different type of healthcare provider collecting specimen.

Table 5: Specimen Rejection by Type of Healthcare provider Collecting Specimen

Type	Frequency	Percentage
Registered nurse	64	96.96
Patient care technician	1	1.51
Licensed practical nurse	1	1.51
Total	66	100

Source: secondary data, July, 2019

Table 2 illustrates that the types of healthcare provider where rejected samples were from are registered nurse where 64 which represented 96.96% were from them, patient care technician delivered 1.51% rejected samples and 1.51% were from licensed practical nurse.

4.1.3. Clinical consequences of sample rejection

The rejection of samples was found to have various clinical consequences to the patients.

Table 6: Clinical consequences of sample rejection

Type	Frequency	Percentage
High rate of recollection of specimens	28	42.42
Repeated phlebotomy	12	18.18
Causing discomfort and potential complications in the affected patients	12	18.18
Delay in availability of test results	14	21.21
Total	66	100

Source: Secondary data, July, 2019

Table 6 highlights that high rate of recollection of specimen was a major consequence of sample rejection as it was caused by 42.42% of sample rejection, 18.18% of sample rejection caused repeated phlebotomy, causing discomfort and potential complications in the affected patients was 18.18% of sample rejection, 21.21% of sample rejection caused by delay in availability of test results.

4.2. Discussion of findings

4.2.1. Cause and rates of specimen rejection in study area.

While carrying out this study, the researcher considered the data about rejected samples available in 2018.

Table 1 shows that along study period the specimen which were received in Kibogora D H were 95621 and among them 66 which represented 0.069% were rejected due to different causes.

Table 2 illustrates that the types of rejected samples were blood which were 64 which represented 96.97%, urine which represented 1.51% and 1.51% were TB samples.

About 70% of the errors in the laboratory occur during pre-analytical phase of the laboratory processes. Specimen collection is one of the pre-analytical processes that ensure to provide accurate, reliable and timely results to patients. However, improper collection of samples could delay patient results due to unnecessary specimen re-draws and elongated corrective and preventive action activities. This could dissatisfy customers in addition to time and resource wastage in the laboratory.

A retrospective study conducted by Clinical Laboratory Standards Institute (2010) to identify the proportions of rejected specimens at the emergency laboratory. It was detected that an overall specimen rejection rate of 6% in our emergency laboratory.

Insufficient samples are the second most common reason (22%) for sample rejection in our emergency laboratory. We know the difficulty of collecting sufficient blood sample from newborns, children, oncology and ICU patients. The performance of venipuncture especially in infants and children requires special training and skill. The pediatric population also has a risk for anemia due to frequent blood draws necessitating small specimen volumes (Schnabl K, 2008). Lippi *et al.* (2012) have identified a clinically significant bias in test results when tubes are drawn at less than 89% of total fill for activated partial thromboplastin time (aPTT), less than 78% for fibrinogen, and less than 67% for coagulation factor VIII, whereas prothrombin time (PT) and activated protein C resistance remain relatively reliable even in tubes drawn at 67% of the nominal volume. Hence, under-filled citrated tubes containing less than 80% of target volume failed our acceptance criteria.

4.2.2. Criteria of specimen rejection in study area.

Table 3 demonstrates that samples were rejected due to clotting where 60.6% of samples were rejected due to this reason, 12.12% were rejected due to missed request form, 4.54% were rejected because they were in inappropriate tube, 3.03% were rejected as they mislabeled, 3.03% were rejected as they hemolyzed sample, 4.54% were rejected as they delayed transport time and sample processing, 3.03% were rejected due to wrong labeled and 9.09% were rejected due to insufficient sample.

Hemolyzed specimens should not be used in coagulation testing because of possible clotting factor activation, which may also produce inaccurate results.

According to the International Organization for Standardization (ISO), clinical laboratories should develop criteria for acceptance or rejection of samples. Problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s) and insufficient sample volume are some of the examples of rejection criteria.

4.2.3. Clinical consequences of specimen rejection on patients in study area

The rejection of samples was found to have various clinical consequences to the patients.

Table 6 highlights that high rate of recollection of specimen was a major consequence of sample rejection as it was caused by 42.42% of sample rejection, 18.18% of sample rejection caused repeated phlebotomy, causing discomfort and potential complications in the affected patients was 18.18% of sample rejection, 21.21% of sample rejection caused by delay in availability of test results.

The previous studies clearly document the consequences of laboratory specimen defects and resulting specimen rejection. Prospective analysis performed by 78 institutions of a total of 2 054 702 specimen accessions revealed an overall specimen rejection rate of 0.2%. This is generally in line with the rate reported in past studies of specimen rejection, which have typically shown rates of less than 0.3% and up to 0.75%, with lower rejection rates reported in more recent studies (Zarbo RJ, 2002).

An additional significant consequence of laboratory specimen rejection is abandonment of the ordered test(s). Such abandonment may occur when the laboratory fails to request recollection or relabeling/correction of a defective specimen (laboratory abandonment) or when the provider or patient care team fails to comply with such a request (provider abandonment). The overall specimen abandonment rate in this study was 11.2%, meaning that these patients received *no* result(s) for the test(s) originally ordered. The laboratory abandonment rate was lower (median rate = 1.3%) than when the provider abandoned the specimen (median rate = 5%), but still significant. Specimen abandonment rates were significantly higher for all non-stat tests and for urine specimens.

4.3. Summary of findings

The findings of this study were summarized referring to objectives which were; to assess the cause and rates of specimen rejection in Kibogora DH, to investigate the criteria of specimen rejection in Kibogora DH and to evaluate clinical consequences of specimen rejection on patients in Kibogora DH.

Referring to objective one, was summarized in table 1 shows that along study period the specimen which were received in Kibogora D H were 95621 and among them 66 which represented 0.069% were rejected due to different causes.

Table 2 illustrates that the types of rejected samples were blood which were 64 which represented 96.97%, urine which represented 1.51% and 1.51% were TB samples.

Referring to objective two, it was summarized in table 3 demonstrates that samples were rejected due to clotting where 60.6% of samples were rejected due to this reason, 12.12% were rejected due to missed request form , 4.54% were rejected because they were in inappropriate tube, 3.03% were rejected as they mislabeled, 3.03% were rejected as they hemolyzed sample, 4.54% were rejected as they delayed transport time and sample processing,3.03% were rejected due to wrong labeled and 9.09% were rejected due to insufficient sample.

Objective three showed that; in the table 6 highlights that high rate of recollection of specimen was a major consequence of sample rejection as it was caused by 42.42% of sample rejection, 18.18% of sample rejection caused repeated phlebotomy, causing discomfort and potential complications in the affected patients was 18.18% of sample rejection, 21.21% of sample rejection caused by delay in availability of test results.

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

5.0 Introduction

This research concentrated on assessment the rate of specimen rejection in Kibogora DH. Samples available in the year of 2018 were considered to evaluate the rate of sample rejection in Kibogora DH. Data were collected using retrospective data collection methods where different argument were gathered, presented analyzed and interpreted.

5.1. Conclusion

By conclusion, based on the objective of this study which were; to assess the cause and rates of specimen rejection in Kibogora DH, to investigate the criteria of specimen rejection in Kibogora DH and to evaluate clinical consequences of specimen rejection on patients in Kibogora DH.

Referring to objective one, it was concluded in table 1 shows that along study period the specimen which were received in Kibogora D H were 95621 and among them 66 which represented 0.069% were rejected due to different causes.

Table 2 illustrates that the types of rejected samples were blood which were 64 which represented 96.97%, urine which represented 1.51% and 1.51% were TB samples.

Referring to objective two, it was concluded that table 3 demonstrates that samples were rejected due to clotting where 60.6% of samples were rejected due to this reason, 12.12% were rejected due to missed request form , 4.54% were rejected because they were in inappropriate tube, 3.03% were rejected as they mislabeled, 3.03% were rejected as they hemolyzed sample, 4.54% were rejected as they delayed transport time and sample processing,3.03% were rejected due to wrong labeled and 9.09% were rejected due to insufficient sample.

Objective three showed that; in the table 6 highlights that high rate of recollection of specimen was a major consequence of sample rejection as it was caused by 42.42% of sample rejection, 18.18% of sample rejection caused repeated phlebotomy, causing discomfort and potential complications in the affected patients was 18.18% of sample rejection, 21.21% of sample rejection caused by delay in availability of test results.

In conclusion, the comprehensive analysis of specimen acceptability criteria and specimen rejection detailed in this study emphasized that specimen rejections for various reasons are a continuous challenge for hospitals and other laboratories. Detailed analyses of specimen

rejection rates and related issues, allowed to formulate an inter-disciplinary and efficient plan targeted to decrease specimen rejection rates at institution. While it was experienced that an immediate decrease in rejection rates initially following the educational intervention, it was found during continued monitoring of rejection rates for a 12-months period no sustained significant decrease in specimen rejection rates.

5.2 . Recommendation

The rejection rate in kibogora district hospital was high in internal medicine department where 16 which represented 24.24% samples were rejected and surgery department where 15 which represented 22.72% were rejected. so, were encouraged to follow standard operation procedure during collection of sample, transport and labelling in order to reduce rejection of specimen, for laboratory department check the sample matching with lab request form before receive, collection of specimen and follow the criteria of specimen rejection and acceptability.

5.3 Suggestions for further study

Further studies should be performed on a larger sample rejection and its impact on patients' life and the measures which could be adopted to alleviate sample rejection in hospitals.

REFERENCES

- African Society of Laboratory Medicine. (2018). *Ensuring Specimen Integrity for Viral Load Testing*.
- Alsina MJ, Alvarez V, Barba N, et al. (2008) Pre-analytical quality control program – An overview of results (2001–2005 summary). *Clin Chem Lab Med*; 46:849–854.
- Ambachew S, Adane K, Worede A, Melak T, Asmelash D, Damtie S, Baynes HW, Abebe M, Biadgo B. (2018). *Errors in the total testing process in the clinical chemistry laboratory at the University of Gondar Hospital, Northwest Ethiopia*. *Ethiop J Health Sci.* ;28(2):235–244. doi: 10.4314/ejhs.v28i2.15.
- Atay A, Demir L, Cuhadar S, Saglam G, Unal H, Aksun S, Arslan B, Ozkan A, Sutcu R. (2014) Clinical biochemistry laboratory rejection rates due to various types of preanalytical errors. *Biochem Med.* ;24(3):376–382. doi: 10.11613/BM.2014.040.
- Bonini P, Plebani M, Ceriotti F, Rubboli F. (2002). *Errors in laboratory medicine*. *Clin Chem.*;48:691–8.
- Carraro P, Plebani M. (2007). *Errors in a stat laboratory: Types and frequency 10 years later*. *Clin Chem.*;53:1338–42. 10.1373/clinchem.2007.088344.
- Carraro P, Servidio G, Plebani M. (2000). *Hemolyzed specimens: a reason or rejection or a clinical challenge?* *Clin Chem.* ;46:306–308.
- Clinical Laboratory Standards Institute. (2008). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays*. CLSI H21-A5 document. Wayne, PA: Clinical Laboratory Standards Institute.
- Clinical Laboratory Standards Institute. (2010). *Procedures for the handling and processing of blood specimens for common laboratory tests*. CLSI H18-A4 document. Wayne, PA: Clinical Laboratory Standards Institute.
- Da Rin G. (2009) Pre-analytical workstations: a tool for reducing laboratory errors. *Clin Chim Acta.* ;404:68–74. doi: 10.1016/j.cca.2009.03.024.
- Dasgupta A, Dean R, Saldana S, Kinnaman G, McLawhon RW. (1994). *Absorption of therapeutic drugs by barrier gels in serum separator blood collection tubes*. Volume- and time-dependent reduction in total and free drug concentrations. *Am J Clin Pathol.*;101:456–61.

- Ethiopian Public Health Institute. (2016). *Specimen Collection, Handling, Transportation and Storage Manual*.
- Green SF. (2013). The cost of poor blood specimen quality and errors in preanalytical processes. *Clin Biochem*; 46:1175–1179.
- International Organization for standardization. (2012). Medical laboratories- Requirements for quality and competence, International standard ISO 15189.
- International Organization for standardization. (2012). Medical laboratories- Requirements for quality and competence, International standard ISO 15189.
- International Organization for Standardization. ISO. (2012). 15189:2012: *medical laboratories: particular requirements for quality and competence*. Geneva, Switzerland: International Organization for Standardization.
- Jacobsz LA, Zemlin AE, Roos MJ, Erasmus RT. (2011) Chemistry and haematology sample rejection and clinical impact in a tertiary laboratory in Cape Town. *Clin Chem Lab Med*; 49:2047– 2050.
- Karcher DS, Lehman CM.(2014). Clinical consequences of specimen rejection a College of American Pathologists Q-probes analysis of 78 clinical laboratories. *Arch Pathol Lab Med*; 138:1003-1008.
- Kebede Y, Fonjungo PN, Tibesso G, Shrivastava R, Nkengasong JN, Kenyon T, Kebede A, Gadde R, Ayana G. (2016). *Improved specimen referral system and increased access to quality laboratory services in Ethiopia: the role of the public-private partnership*. *J Infect Dis.* ;213(Suppl 2): S59–S64. doi: 10.1093/infdis/jiv576.
- Lillo R, Salinas M, Lopez-Garrigos M, Naranjo-Santana Y, Gutiérrez M, Marin MD, et al. (2012). *Reducing preanalytical laboratory sample errors through educational and technological interventions*. *Clin Lab.*; 58:911–7.
- Lima-Oliveira G, Lippi G, Salvagno GL, Brocco G, Gaino S, Dima F, et al. (2014). *Processing of diagnostic blood specimens: is it really necessary to mix primary blood tubes after collection with evacuated tube system?* *Biopreserv Biobank.*;12:53–9. 10.1089/bio..0043.
- Lippi G, Banfi G, Buttarello M, Ceriotti F, Daves M, Dolci A, et al. (2007). *Recommendations for detection and management of unsuitable samples in clinical laboratories*. *Clin Chem Lab Med.*; 45:728–36. 10.1515/CCLM.2007.174.

- Lippi G, Becan-McBride K, Behulova D, Bowen RA, Church S, Delanghe J, et al. (2013). *Preanalytical quality improvement: in quality we trust*. Clin Chem Lab Med.;51:229–41. 10.1515/cclm-2012-0597.
- Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, et al. (2009). *Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics*. Clin Chem Lab Med.; 47:143–53. 10.1515/CCLM.2009.045.
- Lippi G, Guidi GC. (2006). *Preanalytic indicators of laboratory performances and quality improvement of laboratory testing*. Clin Lab.; 52:457–62.
- Lippi G, Guidi GC. (2007). Risk management in the preanalytical phase of laboratory testing. Clin Chem Lab Med.; 45:720–727.
- Lippi G, Salvagno GL, Montagnana M, Lima-Oliveira G, Guidi GC, Favaloro EJ. (2012). *Quality standards for sample collection in coagulation testing*. Semin Thromb Hemost.;38:565–75. 10.1055/s-0032-1315961.
- Lippi G. (2009). *Governance of preanalytical variability: Travelling the right path to the bright side of the moon?* Clin Chim Acta.;404:32–6. 10.1016/j.cca.2009.03.026.
- Lowe G, Stike R, Pollack M, Bosley J, O'Brien P, Hake A, et al. (2007). *Nursing blood specimen collection techniques and hemolysis rates in an emergency department: analysis of venipuncture versus intravenous catheter collection techniques*. J Emerg Nurs. 2008;34:26–32. 10.1016/j.jen..02.006.
- Manor PG. (1999). Turnaround time in the laboratory: a review of the literature. Clin Lab Sci.; 12:85–9.
- Narayanan S. (2000). *The preanalytic phase: an important component of laboratory medicine*. Am J Clin Pathol. ; 113:429–452. doi: 10.1309/C0NM-Q7R0-LL2E-B3UY.
- Parentmark A, Landberg E. (2011). *To mix or not to mix venous blood samples collected in vacuum tubes?* Clin Chem Lab Med.; 49:2061–3. 10.1515/CCLM.2011.705.
- Plebani M. (2010). *The detection and prevention of errors in laboratory medicine*. Ann Clin Biochem.;47:101–10. 10.1258/acb.2009.009222.
- Plebani M. (2012). *Quality Indicators to Detect Preanalytical Errors in Laboratory Testing*. Clin Biochem Rev.; 33:85–8.
- Rana SV. (2012). *No Preanalytical Errors in Laboratory Testing: A Beneficial Aspect for Patients*. Indian J Clin Biochem.;27:319–21. 10.1007/s12291-012-0271-2.

- Schnabl K, Chan MK, Gong Y, Adeli K. (2008). *Closing the Gaps in Pediatric Reference Intervals: The CALIPER Initiative*. Clin Biochem Rev.; 29:89–96.
- Sheppard C, Franks N, Nolte F, Fantz C. (2008). *Improving quality of patient care in an emergency department: a laboratory perspective*. Am J Clin Pathol.;130:573–7. 10.1309/DGXYTH0VNTTQRQHD.
- Simundic AM, Lippi G. (2012). *Preanalytical phase – a continuous challenge for laboratory professionals*. Biochem Med (Zagreb).;22:145–9. 10.11613/BM.2012.017.
- Sinici Lay I, Pınar A, Akbıyık F. (2014). *Classification of reasons for rejection of biological specimens based on pre-preanalytical processes to identify quality indicators at a university hospital clinical laboratory in Turkey*. Clin Biochem. 2014; 47:1002–5. 10.1016/j.clinbiochem.04.024.
- Snyder SR, Favoretto AM, Derzon JH, Christenson RH, Kahn SE, Shaw CS, et al. (2012). *Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: A Laboratory Medicine Best Practices systematic review and meta-analysis*. Clin Biochem. 2012; 45:988–98. 10.1016/j.clinbiochem.06.019.
- Steindel SJ, Howanitz PJ. (2001). *Physician satisfaction and emergency department laboratory test turnaround time*. Arch Pathol Lab Med.; 125:863–71.
- Valenstein PN. (1990). *Pre-analytic delays as a component of test turnaround time*. Lab Med.; 21:448–51.
- World Health Organization. (2012). *Laboratory Quality Management System (LQMS) training toolkit*.

APPENDICES