Frequency of Sample Rejection and Associated Factors Among Clinical Specimens Referred for Diagnostic Testing to Adama Regional Public Health Laboratory, Adama, Ethiopia.

By

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Jimma, Ethiopia.

Jimma University

Institute of Health

Faculty of Health Sciences

School of Medical Laboratory Sciences

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Abbreviations

AOR = Adjusted Odds Ratio

APHRL = Adama public health Regional Laboratory

CD4 = Cluster of Differentiation 4

CSF = Cerebro Spinal Fluid

DBS = Dried Blood Spot

EID = Early Infant Diagnosis

HIV = Human Immunodeficiency Virus

LIS = Laboratory Information system

LQMS = Laboratory Quality Management System

ISO = International Organization for Standardization

NHS = National health Laboratory Service

OR = Odds Ratio

QI = Quality Indicators

SPSS = Statistical Package for Social Sciences

WHO = world Health Organization

Abstract

Background: *There are occasions when laboratory tests could not be performed in site where the specimens have been collected and these specimens need to be transported to referral laboratories for diagnostic testing. The majority of laboratory errors emerge from the physically intensive activities of the pre analytical phase, mainly those related to collection, handling, transportation, preparation and storage of diagnostic specimens. So, sample rejection was one of quality indicators that compromise quality that compromise quality laboratory and patient's satisfaction.*

Objective: *The main aim of this study was to determine the frequency of specimen rejection and assess associated factors among specimens that were referred through the referral network to the Adama regional public health laboratory for laboratory testing, Adama, Ethiopia*.

Method: *A prospective cross-sectional study were done to determine the frequency of specimen rejections and the association factors. All of specimens sent from september1/2021G.C for one month sent from referring sites to Adama public Regional laboratory for investigation was reviewed for its quality and reason for rejections prospectively. Data was entered to EpiData version 3.1then transferred to SPSS for analysis. Association of dependent variable and independent variables will be analyzed using binary logistic regression and for those with p-value less than 0.25 multiple binary logistic regression was conducted and P values less than 0.05 were taken as statistically significant when looking for association between dependent and independent variables and results were presented by figure and tables.*

Result: *All 3320 of specimens were observed for quality and 65 (1.96% %) of specimens were rejected due to different rejection criteria. The highest specimen rejection rate 18.3% (19/104) were seen among whole blood specimen type referred for CD4 count, plasma samples for viral load test were the highest number of rejected and not maintained cold chain was the most reason for specimen to reject. Work experience of specimen collector(p=0.000) and both training of specimen collectors(p=0.000) and transporter(p=0.031) had statistically significant association to rejection of specimen.*

Conclusion and recommendation: *The overall rejection rate was 2% and Our finding show maintaining cold chain was the most cause of sample to reject and training of specimen transporter and collector, experience of collector and distance of health facility were statistically significant significantly associated with sample rejection.*

Key *Words*: *Referred specimen, referral network, sample rejection, Adama public regional health laboratory*.

1 Introduction

1.1 Back ground

Clinical laboratories are a crucial and essential a part of all health structures and their goal to enhance health. Reliable and timely results from laboratory investigations are important elements in Decision-making in almost all components of health services and disease prevention and management programs. To make certain top preparation for clients, quality laboratory contributions are mandatory by way of establishing and retaining an exceptional control device for all parts of laboratory services. This include proper arrangement of requests, preparation of patient and identity, collection, transportation of specimen, processing and testing with proper interpretation and reporting(1).

Specimen referral system was a coordinated system that permits a health facility or laboratory lacking capacity to do tests to securely send patients specimen to higher level laboratory with ability to perform the referred or requested tests (2).

Approximately 70% of the blunders in the laboratory happen in pre-analytical step of the laboratory phase. Sample collection is one of the pre-analytical processes that guarantees correct, reliable and timely patient test results. In any case, inappropriate collection of tests may delay time due to unnecessary re-collection and prolonged remedial and preventive activity exercises. This might disappoint customers in addition to time and asset wastage within the laboratory facility(3,4).

Usually, samples are collected outside of the laboratory facility, and transported for testing. In this case, transport must be overseen carefully in arrange to preservation of samples needed, temperature in order to keep integrity needs, extraordinary transport holders, and time barriers. Staff who bundle or transport the specimen should be prepared approximately the right strategies, both for security and for great support of tests(5).

The ultimate goal of creating the laboratory network and specimen referral system is to handle the overall public demand at big for and provision of quality health service. The reason includes the provision of and perpetuating adequate, reliable, and satisfactory laboratory identification inside the ever-expanding health care system. Communication, information and ability sharing among the networked laboratories will even contribute to reinforce the quality of their services. In

addition, this would possibly facilitate an honest allocation and distribution of accessible resources (6).

In health facilities lower standard laboratories were not equipped to perform all of the essential laboratory tests, and this necessitate referring specimens to their higher-tiered laboratories so as to be ready to perform. In sub-Saharan Africa, irregular specimen referral networks within health structure and the Acquired Immuno Deficiency Syndrome (AIDS) epidemic showing easily broken. The absence of this structure resulted in inappropriately time-consuming for laboratory results. Providing laboratory result on time is the key component of improving and prolong the lives of patients, particularly for those HIV and Tuberculosis diagnosis, treatment and monitoring services(7).

The quality of the work a laboratory produces is just nearly as good because the quality of the samples it uses for testing. The laboratory should be proactive in ensuring that the samples it receives meet all of the necessities required to produce correct look at results. Appropriate management of samples is important to the accuracy and reliability of testing, and, therefore, to the self-assurance in laboratory diagnosis. Laboratory results affect therapeutic choices and may have vital impact on patient care and outcomes. It is important to supply correct laboratory leads to order to assure sensible treatment. Inaccuracies in testing will influence length of hospital stays, still as hospital and laboratory prices. Inaccuracies can even have an effect on laboratory effectiveness, resulting in repeat testing with resultant waste of personnel time, supplies, and reagents(8)

As articulated in the international organization for standardization (ISO, 2012), clinical laboratories should set their own specimen rejection and acceptance criteria. The issues with patient or sample identification, sample instability because of delay in transport or inappropriate container(s), insufficient sample volume, clotted sample and hemolyzed sample are a number of the instance of rejection criteria. The licensed laboratory management ought to review sporadically the quantity of rejected specimens and reasons for rejection to develop laboratory quality improvement set up and to conduct coaching on specimen assortment, handling and transportation as wanted(9)

The strategy to propose network between the different laboratories in the health care system and implementing specimen referral system is to improve a problems seen in routine testing laboratory

types performed in most health facilities especially in resource limited countries due to materials, financial and trained personnel constraints(6,10).

In emerging countries many laboratories are today choosing for accreditation protocols with the benefit that it is improving their standards and at the same time these standards are making the laboratory results acceptable as globally. In the pre examination phase, in order to get quality sample, certain criteria are arranged by the laboratory management systems to make that only good quality of samples should be accepted by the laboratory. Thus, the frequency of specimen rejection is one of the quality indicators and can be used to monitor improvement in the pre examination phase(11,12).

Problem related with developing valuable and sustainable sample referral system is the prerequisite for management in establishing a fully integrated and tiered laboratory system, with facilities and staff equipped and trained at each stage of the network to handle specimens properly, safely, and securely(13)

Even if it is difficult to reject a sample, the reference laboratory should set up rejection criterion since poor sample will not produce accurate results and they should have to take responsibility to enforce its policies on specimen rejection consequently that patient care is not compromised. Reason for rejection, type of sample, Transport handling systems, characteristics of postal personnel & laboratory workers are some the key components of the examples of specimens should be rejected. The management should frequently evaluate the number of rejected specimens & the reasons for rejections, give training on gap identified, and improve written procedures for specimen management as needed(14,15).

In Ethiopia Since 2008 E.C laboratory specimen referral network has been established to improve access of the community with adequate and specialized laboratory services. In this network system samples are collected by trained personnel from any health facility and transported with appropriate courier system to reference laboratories where the testing service is on hand(6,7).

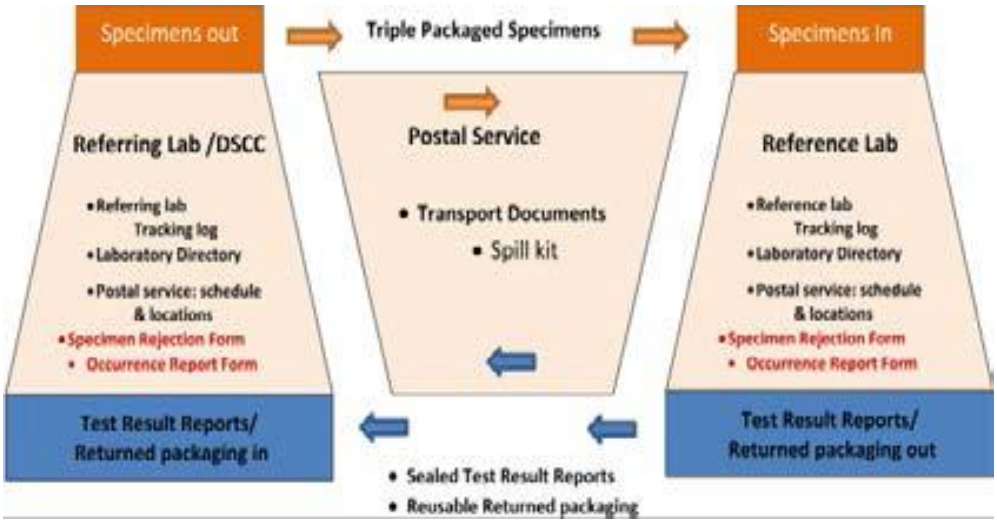

Fig 1 specimen referral system in ethiopia,2017 G.C

Source: Specimen referral system training module of the African Center for Integrated Laboratory training(16).

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1.2 Statement of the problem

The adequacy of a specimen is a very important issue that affects the accuracy and quality of laboratory results. For this reason, most laboratories have guidelines for evaluating specimens submitted for laboratory testing. If specimens fail to fulfill these criteria of adequacy, it should be necessary to obtain another specimen from the patient that causes delay, discomfort, and increased price(7,17).

Specimens' rejection has a lot of consequences. Recollecting of venous blood for a patient is uncomfortable, and there's a risk of complication like hematomas and induced anemia. Similarly, there's a difficulty in recollecting for sputum and body fluid like CSF (17).Specimens which do not fulfill the required quality will be rejected as the specified the rejection standards of the reference laboratory and this may be good practice for reference laboratories. However, this seen as poor practice of pre pre-analytical to referring laboratory(18).

A research conducted on referred specimens in Ethiopia also, confirmed that there was a big problem associated to specimen collection, managing and transportation of specimen due to exclusive reasons like wrong package, presence of clots, not centrifuge, hemolysis and incorrect use of tube(4)

Despite the existing problem, scientific research concerning frequency of specimen rejection and related elements mainly at Regional (reference) laboratories is limited. That is why this research will be designed to examine the specimen rejection rate and associated factors amongst referred specimen to Adama Regional Laboratory.

Adama regional laboratory is one of the regional laboratories to which the Surrounding health facilities refer diagnostic specimens for laboratory testing especially for viral Load, gene expert for tuberculosis (TB), Early Infant diagnosis (EID) for HIV test, CD4 test, culture and so on. However, there is no study conducted in the area and also limited as a country to get comprehensive information relating to the rate of specimen rejection and the main factors that causes the specimen to be rejected. For that reason, intend of this study was to determine the specimen rejection rate and its associated factor among Referred specimens to Adama Regional laboratory

1.3 Significance of study

The result of this study will add a value on information of rejected referred samples as a quality improvement plan for both reference laboratory and periphery laboratory to develop laboratory quality improvement plan. May use for researchers as a baseline data and may increase patients and health professional satisfaction rate.

The study may give emphasis by identifying a gap on the sample referral system to conduct training and allocation of budget for the government and stake holders or responsible body. Generally, the study will give benefit to patients, health professionals and for large community.

2 Literature review

Appropriate running of specimen at the time of collection, transport and storage must be managed according to the standard operating procedures. In each laboratory quality of sample acceptability criteria should developed and those sample that don't fulfill the adequacy criteria should be rejected(10,19,20).

In 2019 G.C study conducted in Malaysia for ten months in specimen rejection data on the hematology & transfusion medicine unit shows that from total of 17996 samples submitted to the laboratory about 644 (3.57%) specimens were rejected, about 3.38% from hematology and 5.7% in transfusion unit. From this clotted samples were the leading cause of rejection in hematology and hemolyzed samples transfusion unit. The rejection rate was increased by 0.45 %, 0.6% for hematology and 0.31% in transfusion unit when compared to previous year (2018G.C)(21)

A descriptive, cross-sectional study conducted in Iran at Imam Teaching hospital in 2014G..C noted that about 6.3% samples were rejected due to rejection criteria by the reference laboratory and majority of errors were related to human factors like personnel skill in sample collection(22).

According to a prospective observational study done in India, with in a period of two months 19,002 samples were received and 401(2.11%) were rejected due to pre-analytical specimen rejection criteria and the highest error was noted as due to hemolysis (64.0%)(23).

A analytical cross-sectional study conducted in Zimbabwe shows that from 34,950 DBS samples sent to laboratory ,1291(4%) specimens were rejected .the study conducted for 12 months and the trends of rejection rate where almost increasing from month to month ,the proportion of rejected samples were ranged from 3%to 6% within the maximum rejection rate seen in September. Insufficient specimen volume was the major reason for rejection which accounts about 909(72%) and the missing request form is the next, 133(11%)(24).

A retrospective study done in Kenyatta national hospital indicate CD4 test samples for HIV/AIDS patients submitted from health facility shows 2% rejection rate of samples. The delayed arrived samples were the mainly cause of samples to reject and incorrect container tube is the least prevalent reason for sample rejection(25)

In the period of first year of implementation of LQMS, retrospective study done on sample rejection rate done by Gupta V et al in the tertiary care medical center laboratory of developing

world shows that from the 54603 samples received in the period of study, about 3936(7.2%) were rejected. The issues associated to reason for rejection of sample and request form gives for nearly fifty (50%) of rejections(11).

According to study done on clinical consequences of specimen rejection in a college of American pathologist, 86.8% of rejected blood samples led to recollection and 13.8% of rejected sample need for re collection of new samples. This recollection of procedures correlated to inconvenience and discomfort of the patient. Both them bring for potential complications. In addition, specimen rejection led to the median specimen processing delay of about 65minutes with range of 41minutes to 93minutes. This indicate massive delays in accessibility of critical and urgent results (26).

A retrospective audit conducted for two-week period at the chemistry and hematology laboratories of the NHLS of Tygerberg hospital, in the western cape province of south Africa shows that from 1.5% of rejected samples, only 51.7% specimens were repeated and the average time repeat specimen to reach the laboratory was about five days or 121hour. In addition, this study pointed out from the repeated specimens 5.1% of the result is in the critical value range (27). This report displays how much inappropriate sample negatively affects patient health outcomes

A retrospective cross-sectional study conducted in Amhara public health institute in 2018 G.C shows that from total of 42,923 referred specimens, 221 (0.5%) were rejected because of poor quality of the specimens that didn't conform the mandatory requirements to be tested. HIV Viral load 192 (0.6%) and CD4 19 (0.7%) were among the majority of rejected samples due to wrong packages which accounts about 84.2% , errors related to samples and characteristics of personnel(4).

In 2020 G.C cross-sectional study done in Debre Markos Referral Hospital shows about 1.57% of specimens were rejected due to different pre-analytical errors. The highest sample rejection rate among sample referred was seen in CD4 count which account about 5.41% (118) and the least rejection rate 4(0.2%) was seen for gene expert test. In a four-consecutive year the rejection rate decreasing from year to year, 2.30%, 1.59%, 1.42% and 1.26 % respectively from 2016 G.C to 2019 G.C(28).

Cross-sectional study done by Habtamu Molla in "St. Paul Hospital Millennium Medical College'' noted that 116(1.4%) of samples were rejected from total of 8063 specimens because of their unable to fulfill acceptance criteria of the laboratories. The study noted that the most reason for sample rejection were hemolytic (27.66%), clotted (16.4%), unlabeled samples (16.4%), and insufficient specimens (14.7%)(29).

All the above scholars confirmed that the problem relating to laboratory sample handling, collection and transportation is among the key challenges faced in every clinical laboratory setting.

In Ethiopia with the accomplishment of laboratory quality management system to manage specimen acceptability for the required laboratory testing, several clinical laboratories are trying to build up their own specimen rejection criteria.

However, there were only limited studies conducted in regarding to specimen rejection rate at some health facilities of Ethiopian laboratories. Concerning to the frequency of sample rejection and associated factors particularly for referred sample require further study that used for quality laboratory improvement plan. For that reason, this study filled these gaps and investigates comprehensive information on referred specimens.

2.1 Conceptual frame work

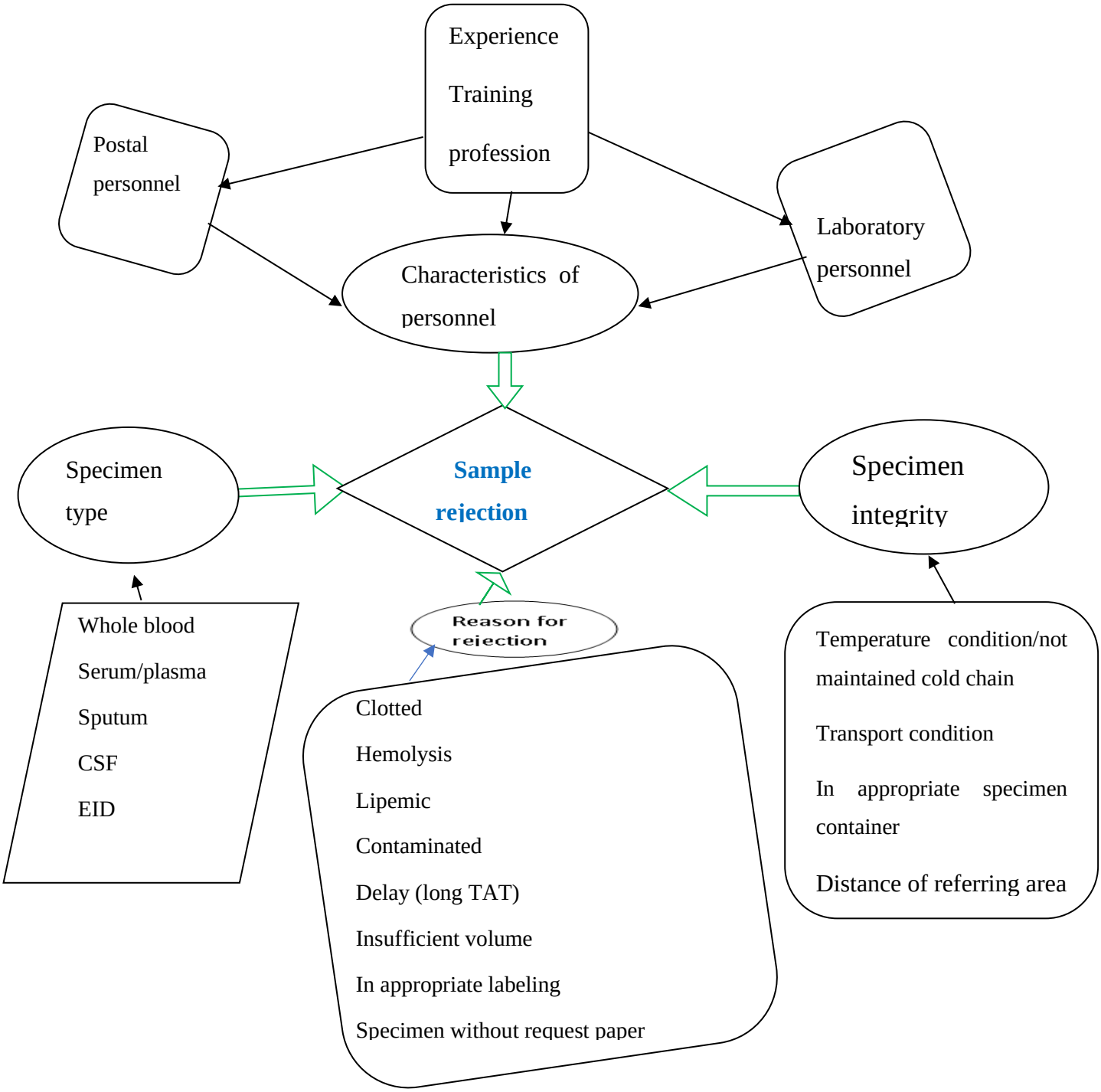

Figure 2 Conceptual frame work of the frequency of specimen rejections and associate factors among referred specimens through referral network to the Adama PH regional laboratory for laboratory testing.

3 Objectives

3.1 General objectives

- To determine frequency of sample rejections and associate factors among referred specimens through referral network to the Adama PH regional laboratory for laboratory testing, Adama, Ethiopia.

3.2 Specific objectives

- To asses specimens rejected frequently among referred specimens through referral network to the Adama regional laboratory for laboratory testing, Adama, Ethiopia.
- To assess the frequently rejected test ordered among referred specimens through referral network to the Adama regional laboratory for laboratory testing, Adama, Ethiopia.
- To identify associated factors of rejection among referred specimens through referral network to the Adama regional laboratory for laboratory testing, Adama, Ethiopia.

4 Methodology

4.1 Study area.

The study was conducted in Oromia region Adama city administration. Adama city administration is one of the cities located in East Shewa Zone. It is located at 8.54°N 39.27°E at an elevation of 1712 meters, 99 km southeast of Addis Ababa. The Adama city administration consisting of 14 urban and four rural kebeles with total population 388,257(30)

Adama public health regional laboratory was found in Adama town. It was one of regional laboratory in Oromia and serve as reference for many laboratories in Oromia region specially in central Oromia.

4.2 Study period

The study was conducted from September 1/2021 G.C to October 1/2021 G.C.

4.3 Study design

A cross-sectional study design was applied prospectively.

4.4 Population

4.4.1 Source of population

All clinical specimens transported to Adama public research regional laboratory for different laboratory testing were the source of population.

4.4.2 Study population

All specimens referred for CD4count, viral load, culture (sputum), gene expert, and EID to APHRL with in the study period was used as study population.

4.5 Inclusion and exclusion criteria

4.5.1Inclusion Criteria

All referred specimens ordered within study period was included in the study.

4.5.2 Exclusion Criteria

Specimens not referred for CD4, DBS, Viral load, Gene expert and Culture.

4.6 Study variables

4.6.1 Dependent variables

Frequency of specimen rejection

4.6.2 Independent variables

Laboratory and postal personnel characteristics (training status, profession, experience & educational level), specimen type, requested laboratory test type, sample integrity (temperature, condition of transportation,….) and reason for rejection which include insufficient volume, hemolysis, clotted, Lipemic, unlabeled, specimen with no request paper, delayed time, inappropriate specimen container.

4.14 Operational definition

Specimen rejection: a judgment by laboratory personnel, that specimens are unsuitable for analysis based on the specimen rejection criteria set by the laboratory.

Specimen rejection rate: the proportion of rejected specimens among the total number specimens received from the referring laboratories

Insufficient volume: quantity of specimen less than the minimum required volume

Hemolyzed: breakdown of red blood cells which is visible as a reddish color in the clear

Serum/plasma due to the presence of free hemoglobin.

Clotted specimen: a specimen with red cells, white cells, platelets and fibrin strands are forming a clot.

Cold chain: temperature-controlled transportation condition (mostly 2-8 0C)

Delayed time: a specimen is received at laboratory after beyond the minimum specimen storage duration.

Associated factors: aspects that have direct or indirect impact on specimen rejection

Contaminated specimen: specimen with visible leakage due to breakage or uncapped specimen container

In appropriate specimen container: specimen collected by wrong tube or transported by unstandardized container tube

Referral: It is an official procedure that activates the need for a specimen of health service seeker to be transferred to a facility of a higher level with aim of getting specialized care.

4.7 Sample size and sampling technique

All specimens referred to APHRL through referral network and submitted within the one month was included and convenient sampling technique was applied.

4.8 Data collection

Short term training or orientation on data collection checklist for data collectors was given and permission will be obtained from APHRL. Then the data was registered on inspection record logbook of the laboratory by principal investigator and laboratory personnel of the organization. The inspection logbook contains the variable like; specimen type, requested laboratory tests and reasons for rejection. Data collection check list was used for study to collect characteristics of personnel like profession, experience, educational level, distance of referring facility and training status to identify associated factors for rejection.

4.9 Data quality assurance

To maintain quality of data, the data collection tool was pre tested in Bishoftu General Laboratory hospital. The collected data was checked by the principal investigator for completeness, clarity and consistency by the performance indicator. Data was entered using double data entry to minimize transcription errors. Lastly, data cleansing and missing data was checked at the end phase of data quality assurance.

4.10 Data analysis and interpretation

Specimen rejection rate was calculated by the number of rejected specimens per total specimens.. Descriptive analytical analysis SPSS software was done. The rejected specimen was analyzed to identify the reasons and factors led to rejections. Percent of rejected specimen was summarized separately by type laboratory test. All statistical tests were done by using SPSS version 20 software. Association of dependent variable and independent variables was analyzed using binary logistic regression and for those with p-value less than 0.25 Multivariate logistic regression were conducted and P values less than 0.05 were taken as statistically significant when looking for association between dependent and independent variables.

4.11 Ethical consideration

Before collecting data, proposal approval was obtained from Institute of Health; School of Medical Laboratory Sciences and ethical clearance was obtained from Jimma University Institutional Review board committee. Letter of permission was obtained from head of APHRL and agreement between research team of the organization was done. Then informed consent was made with responsible body of the referring facilities that the study was kept confidential and used only for research purpose.

4.12 Dissemination plans.

The findings of the study will be forwarded to the School of medical laboratory sciences: Post graduate program, Jimma University. I intend to present the findings to the Adama regional laboratory with the hope that it will encourage the responsible individual to reflect on the issue of specimen rejection and decide on quality of specimens. I also propose to submit the study for publication in Medical Journals.

5. Result

All 3320 of specimens were observed for quality and about 65 (1.96% %) of specimens were rejected due to different pre analytical errors. The highest specimen rejection rate 18.3% were seen among whole blood specimen type referred for CD4 count, plasma samples for viral load test were the highest number of rejected and the sputum samples sent for gene expert test were the not rejected specimens' type (Table 1).

Table 1 Cross tabulation result of status of specimen and type of specimen referred to Adama public Health regional Laboratory from September 1/2021 G.C to October 1/2021 G.C.

		Type of specimen				Total
		Whole blood	Plasma	Sputum	DBS	
Status of specimen for testing	0	85	2771	264	135	3255
	1	19	40	4	2	65
Total		104	2811	268	137	3320

0 = Not rejected 1= Rejected

During our study highest frequency of specimen 84.7% (2811) were plasma specimen send for viral load test and the least 3.1% (104) were whole blood samples which send for CD4 count tests. Specimens ordered for whole blood were 18.3% which was the highest frequently rejected and specimens type ordered for plasma were 1.42 % ,1.5% for sputum & 1.46 % for DBS. Tests ordered for CD4were the most frequently rejected ,18.3% and tests ordered for viral load were the least frequently rejected ,1.42% (Figure 3)

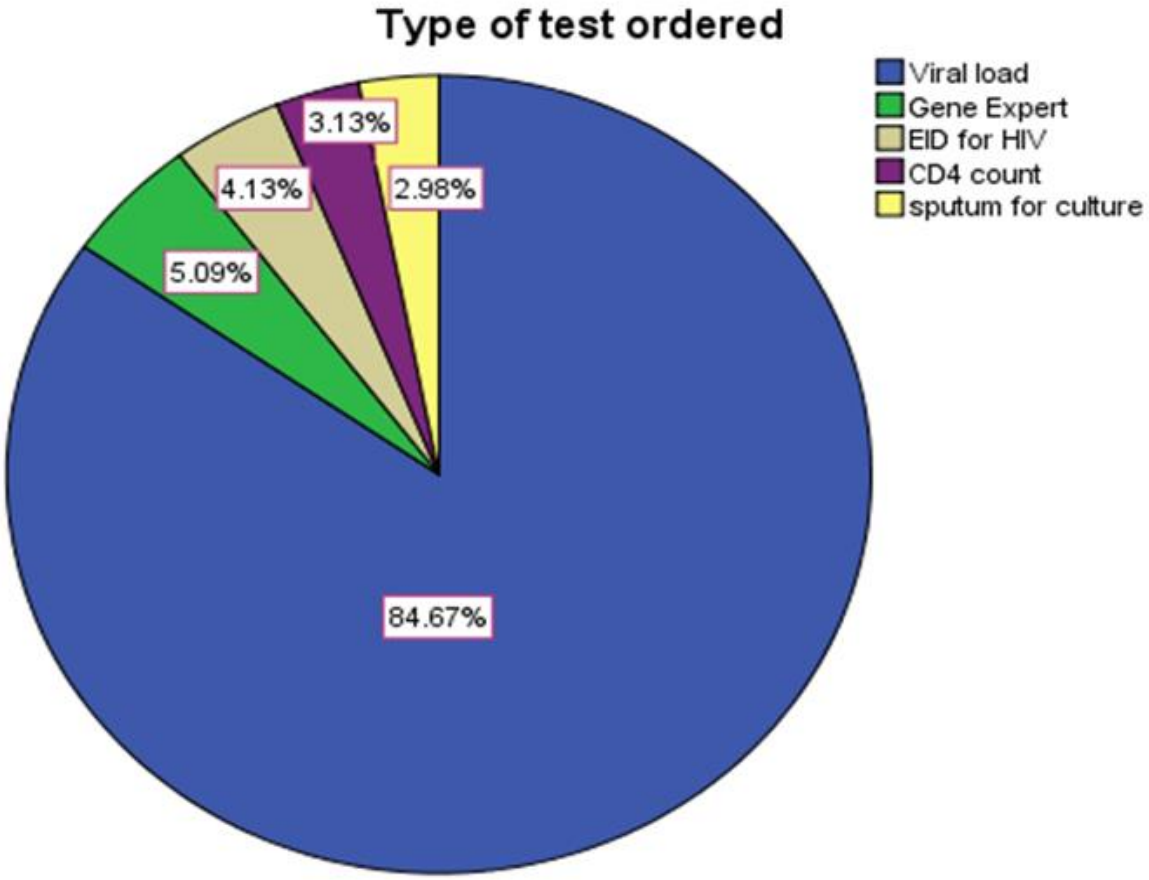

Figure 3 Type of test ordered rejection rate among referred specimens to the Adama public health regional laboratory for laboratory testing, Adama, Ethiopia.

5.1. Health professional and sample transporter related variables among specimens referred to the Adama public health regional laboratory for laboratory testing, Adama, Ethiopia.

In our study the highest frequency of samples 93.1 % were collected by laboratory professional and the least 6.9% were by other health professionals. Whereas 41.8% (1389) and 58.2% (1931) of samples were collected by diploma and degree respectively. The highest frequency of samples 41.9% were collected by 4-6 years of experienced professionals and 85.8 % of sample collectors had training (Table 2). All samples sent to ARL were transported by postal service and 84.5% of them had training and 67% of sample transporter were 1-3 year experienced (Table 3).

Table 2 Frequency rate and number of rejected samples of Specimen collector related variables among referred specimens to the Adama public health regional laboratory for laboratory testing from September 1/2021 G.C to October 1/2021 G.C

Variable	Frequency	percentage	Number of rejected samples
Profession of Sample collectors			
Laboratory professional	3092	93.1	59
Other health professional*	228	6.9	6
Educational level of sample collectors			
Diploma	1389	41.8	15
Degree	1931	58.2	50
Work experience of specimen collector			
< 1 year	74	2.2	7
1-3 year	672	20.2	39
4-6 year	1390	41.9	14
>6years	1184	35.7	5
Training status of specimen collector			
yes	2849	85.8	19
No	471	14.2	46

* Nurses &health officers

All samples sent to ARL were transported by postal service and 84.5% of them had training and 67% of sample transporter were 1-3 year experienced (Table 3).

Table 3 Frequency rate and number of rejected samples of Specimen collector related variables among referred specimens to the Adama public health regional laboratory for laboratory testing from September 1/2021 G.C to October 1/2021 G.C

Variable	Frequency	percentage	Number of rejected samples
Educational level of sample transporter			
Twelve complete	760	22.9	27
Certificate	1393	42.9	29
Diploma	1093	32.9	8
Degree	74	2.2	1
Experience of sample transporter			
< 1 year	646	19.5	23
1-3 year	2225	67.0	36
4-6 year	357	10.8	3
>6years	92	2.8	3
Training status of sample transporter			
Yes	2805	84.5	36
No	515	15.5	29

Table 4 Frequency of specimen rejection rate and distance of health facility from reference laboratory among referred specimens to the Adama public health regional laboratory for laboratory testing from September 1/2021 G.C to October 1/2021 G.C.

Variable	Frequency	percentage	Number of rejected samples
Distance of health facility			
1km - 20 km	134	4.04	5
21km-40km	301	9.06	7
41km-60km	339	10.2	6
61km- 80km	1126	33.9	16
>81km	1420	42.8	31
Total	3320	100%	65

5.2. Specimen and health facility related characteristics for specimens referred to the Adama public health regional laboratory for laboratory testing, Adama, Ethiopia.

During our study the highest number 43.2% (1433) of samples were referred from >81 km distance from the APHRL and 3.9% (129) of samples were referred from 1-20 km distance (Figure 4)

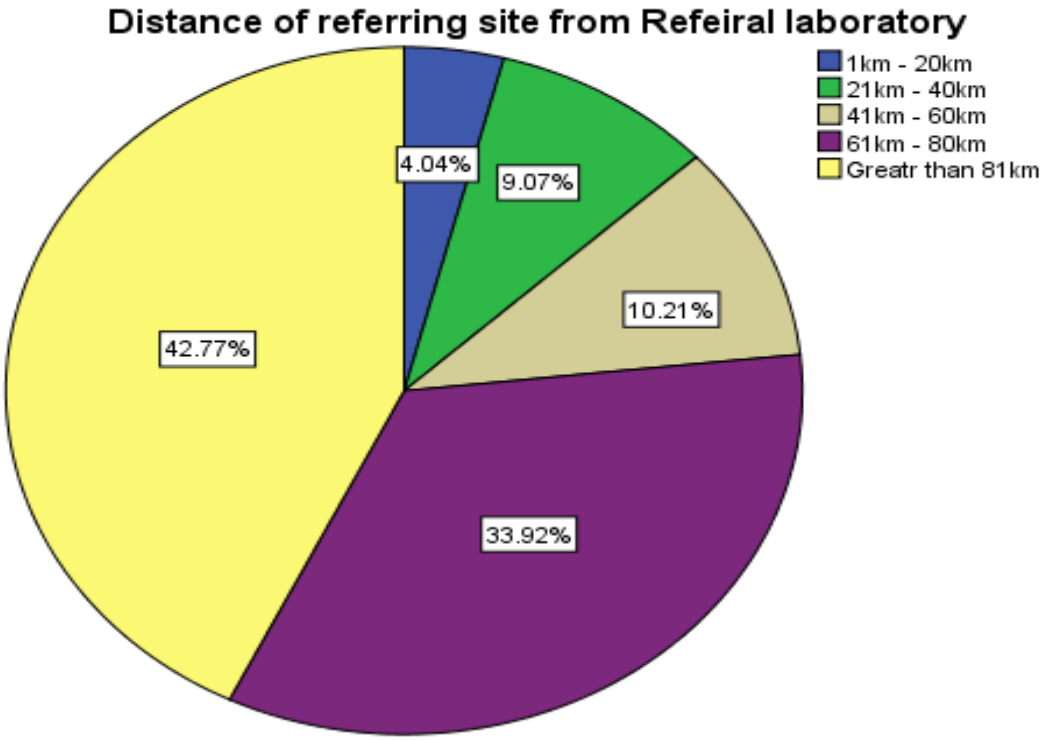

Figure 4 specimen rejection rate by their distance of referring site from referral laboratory among referred specimens to the Adama public health regional laboratory for laboratory testing, Adama, Ethiopia

5.3 Reason of specimen rejection among specimens referred to the Adama public health regional laboratory for laboratory testing, Adama, Ethiopia.

Further analysis of data shows that not maintained cold chain (49.2%), in appropriate specimen container (23.07%), hemolysis (7.7%) and the specimen without request paper (7.7%) were the major reasons the specimens to be rejected. Meanwhile wrongly labeled specimen (6.15%), insufficient volume of sample (3.07%), contaminated (1.54%) and not communicated referral samples (1.54%) were also the other reasons for specimen rejection (Table 5).

Table 5 Reason of specimen rejection among specimens referred to the Adama public health regional laboratory for laboratory testing from September 1/2021 G.C to October 1/2021 G.C.

Reason of specimen rejection.	Frequency of rejection	plasma	Whole blood	DBS	Sputum	% of rejection
Insufficient volume of sample	2	0	0	2	0	3.07
Wrongly labelled specimen	4	0	2	0	2	6.15
Specimen without request paper	5	4	0	0	1	7.7
Hemolyzed	5	4	1	0	0	7.7
Not maintained cold chain	32	32	0	0	0	49.2
Contaminated	1	0	0	0	1	1.54
In appropriate specimen container	15	0	15	0	0	23.07
Not communicated referral sample	1	0	1	0	0	1.54
Total	65	40	19	2	4	100%

5.4 Association of outcome variables with independent variables among specimens referred to the Adama public health regional laboratory for laboratory testing, Adama, Ethiopia.

Bivariate logistic regression shows that sample collectors' profession and Educational level of sample transporter were not eligible for further multivariate analysis with greater than 0.25 P-value. Whereas the other independent variables were qualified for next multivariate analysis to see the association of independent variables with outcome variables with less than 0.25 P-value (Table 6).

Table 6 Bivariate logistic regression analysis of specimen rejection among referred specimens through referral network to the Adama regional laboratory for laboratory testing from September 1/2021 G.C to October 1/2021 G.C.

Variables	Frequency	Specimen status		COR	95 %CI	P-value
		rejected	Not rejected			
Sample collector's profession						
Laboratory professional	3092	59	3092	1		
Other health profession	228	6	222	1.39	.593-3.253	.449
Educational level of sample collectors						
Diploma	1389	42	1,347	.411	.230-0.734	.003
Degree	1931	58	1,873	1		
Work experience of specimen collector						
< 1 year	74	2	72	24.6	7.62-79.67	0.000
1-3 year	672	20	652	14.5	5.7-37	0.000
4-6 year	1390	42	1,348	2.4	0.86-6.7	0.094
>6years	1184	36	1,148	1		
Training status of specimen collector						
yes	2849	86	2,813	1		
No	147	14	133	16.1	9.4-27.7	0.00
Educational level of sample transporter						
Twelve complete	760	27	733	2.7	0.36-20.1	0.34
Certificate	1393	29	1364	1.5	0.21-11.5	0.67
Diploma	1093	8	1,085	0.54	0.06-4.4	0.56
Degree	74	1	73	1		

Variables	Frequency	Specimen status		COR	95 %CI	P-value
		rejected	Not rejected			
Experience of sample transporter						
< 1 year	646	23	623	1.09	0.32-3.7	0.88
1-3 year	2225	36	2189	0.49	0.15-1.6	0.24
4-6 year	357	3	354	0.25	0.05-1.28	0.094
>6years	92	3	89	1		
Training status of sample transporter						
Yes	2805	36	2,7689	1		
No	515	29	486	4.59	2.78-7.5	0.00
Type of specimen ordered						
Whole blood	104	19	85	15.08	3.43-66.4	0.00
Plasma	2811	40	2771	0.97	0.23-4.07	0.97
Sputum	268	4	264	1.01	0.18-5.65	0.98
DBS	137	2	135	1		
Type of test ordered						
Viral load	2811	40	2771	0.34	0.12-0.98	0.045
Gene expert	169	0	169	0.00	0.00	0.99
EID for HIV	137	2	135	0.352	0.63-1.96	0.23
CD4 count	104	19	85	5.3	1.74-16.2	0.003
Sputum for culture	99	4	95	1		
Distance of health facility						
1km - 20 km	134	5	129	1		
21km-40km	301	7	294	0.614	0.19-1.97	0.614
41km-60km	339	6	333	0.465	0.14-0.1.55	0.212
61km- 80km	1126	16	1,110	0.372	0.13-1.03	0.057
>81km	1420	31	1389	0.576	0.22-1.51	0.261

5.5 Factors associated with specimen rejection among specimens referred to the Adama public health regional laboratory for laboratory testing, Adama, Ethiopia.

Multivariate logistic analysis shows that work experience of specimen collectors, both training status of collectors (p-value = 0.000) and transporter (p-value = 0.031), and distance of referring facility from referral site were significantly associated with rejection of the specimen (Table 7). Educational level of sample collectors was not significantly associated with dependent variable with 0.053 p-value (Table 7).

Specimen collectors who had <1years work experience had 41.3 times higher contribution for the specimen to be rejected than those who had >6years of work experience. Specimen collectors who had 1-3-year experience had 22.02 times more contribution for the specimen to be rejected than those who had > 6years experience and collectors who had 4-6-year work experience had 3.87 times more contribution for the specimen to be rejected than those who had higher work experience (Table 7).

The odd of specimen rejection was 15.8 times higher among specimen collectors who hadn't training than those who had trained on specimen collection and odds of specimen rejection was 2.02 times among specimen transporter who hadn't trained than those who had trained (Table 7).

Table 7 Multivariate logistic regression analysis of specimen rejection among referred specimens through referral network to the Adama regional laboratory for laboratory testing from September 1/2021 G.C to October 1/2021 G.C

Variables	Status of specimen		COR	AOR	95 %CI	P-value
	rejected	Not rejected				
Educational level of sample collectors						
Diploma	42	1,347	.411	0.53	0.23-1.007	0.053
Degree	58	1,873	1			
Work experience of specimen collector						
< 1 year	2	72	24.6	41.3	10.44-163.07	.000**
1-3 year	20	652	14.5	22.02	8.06-60.45	.000**
4-6 year	42	1,348	2.4	3.87	1.3-11.3	.013**
>6years	36	1,148	1			
Training status of specimen collector						
Yes	86	2,813	1			
No	14	133	16.1	15.85	8.4-30	0.000**
Training status of sample transporter						
Yes	36	2,7689	1			
No	29	486	4.59	2.02	1.067-3.83	0.031**

** significantly associated variables with p-value < 0.05

6 Discussion

From all total specimens (3320) send to APHRL about 1.96% of specimens were rejected due to different reasons of quality defect. The finding from this study suggested that work experience on specimen collectors and both training status of specimen collector and transporter had evidence of statistically significant association to the rejection of referred specimen in a study period.

Almost three fourth of errors in laboratory occurred in pre laboratory examination process, in our cross sectional prospective study we aimed that frequency of specimen rejection and their association send from peripheral laboratory for CD4 count(104), viral load(2811) ,gene expert(169) ,DBS(137) and sputum culture(99) test by assessing their quality. High number of rejections were scored for plasma samples send for viral load test (40) and whole blood for CD4 test were high rejection rate (18.3%).

The rate of rejection was almost similar with prospective study observational study conducted in India were out of 19,002 samples about 2.1% of specimens rejected(23) and also the same as the cross sectional study conducted in Kenyatta hospitals done on referral rejection rate of CD4. The only difference was their study were conducted retrospectively and our study done prospectively(25). Specimen submission more than 48 hours was the most frequent cause of rejection and clotted specimens, incorrect vacutainer and poor specimen labelling bring the least sample rejection according to the study done in Kenyatta hospital but in our study not maintained cold chain was the most cause ,and contaminated and not communicated referral samples were the least cause of samples rejection(25).

The rate of rejection in our study was much lower than study conducted in Malaysia in 2019G.C which was 3.57% of specimen samples were rejected and the leading cause of rejection were clotted specimen but in our study not maintained cold chain was the leading cause of rejection (21).

According to descriptive cross-sectional study conducted in Iran at Imam Teaching hospital about three-fold(6.3%) more than our study(2%) of the samples send to reference laboratory were rejected due to refence laboratory's' rejection criteria(22). and also a prospective cross-sectional study conducted in Zimbabwe shows that about 4% DBS sample of specimen sent to laboratory were rejected, this finding also more than two fold of our study and the difference between our

study and in this study insufficient volume of samples were the major leading cause of rejection and the study was studied only for DBS , unlikely in our study not maintained cold chain was the leading cause of rejection and the study was studied about five referral samples including DBS (24).

A retrospective cross sectional study done in Amhara public health institute shows that from total of referred specimens 0.5% of samples were rejected due to poor quality of specimens that didn't conform the mandatory requirement to be tested and this study shows more likely less than our finding which was 2% of rejection and in both finding the majority of the rejected samples were due to un maintained cold chain or wrong packaging of samples and characteristics of personnel. Here also in both finding whole blood samples send for CD4 test were the highest frequency scored(4).

A retrospective and prospective cross-sectional study done in Debre Markos referral hospital laboratory shows sample collector experience and training status had significant association with specimen rejection rate(28). Our study also concluded that work experience of specimen collectors and both training of specimen collectors and transporter had significant association with sample rejection rate. In our result training of sample transporter and distance of referring health facility were also significantly associated in our study.

A cross-sectional study done by Habtamu Molla in "St. Paul Hospital Millennium Medical College' shows from 8063 of samples 1.4% of samples rejected which was much lower than our study and the difference may be due to the sample size and the number of data collection site and their study shows that sample collected by non-laboratory professionals were statistically associated with sample rejection (29). However, our study shows that profession of sample collectors has no association to sample rejection rate. The difference may be due to duration of study which was one month in our study.

7 Limitation

Data were collected by direct observing that may have been accurate which may not have missing registration of necessary information. Besides, the short observation period could be a limitation to our study which can't asses the trend of rejection to see improvement. The study can't touch on influences of sample rejection on financial, social and health of individual patient and community at large.

8 Conclusion and recommendation

8.1 conclusion

The present study showed that the overall specimen rejection rate was 1.96% and the main reasons for specimen the specimen to be rejected were not maintained cold chain, in appropriate sample container, hemolysis, request paper without sample, wrongly labeled specimen, insufficient volume of sample, contaminated and not communicated referral samples.

Work experience of specimen collector and training status of both specimen collector and transporter are the scientifically significant associated independent variables of specimens to be rejected. Every time a specimen is rejected, a new specimen has to be collected which increases turnaround time and thus disturbs patient care and customer satisfaction. Not only this specimen rejection may have impacts on economic, social and health of individuals and the community at large. Hence, make to be collected by experienced health professional, give training to both collector and transporter and give attention by top managers on changing and motivating the skills of workers participating on sample referrals could improve the problem of specimen rejection in a referral network.

8.2 Recommendation

To improve specimen rejection rate among referral samples all postal personnel who transport samples and laboratory professionals working at the referring health facility should have trained on how to maintained cold chain, appropriate container, collection, handling and transportation of referred test specimens. Furthermore, the feedback given by reference laboratory is not enough to improve this draw back strict follow and written feedback is mandatory to improve specimen referral rejection rate.

Moreover, responsible bodies like, reference laboratory, regional health bureau, stake holders, and all top-level managers should strongly participate on preventive and corrective actions periodically and make improvement plan with workers who participate on referral samples to improve on identified gaps in specimen rejection. Finally, we recommend that more studies need on impacts of specimen rejection on economic, social and health of patients and it is good if research done long duration to see the trend of specimen rejection to see improvement of the facility on given fee back.

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10 Annexes

10.1 Consent form (English version)

Code ----------

My name is Jiregna Fikadu; I am Medical Laboratory Msc student in Clinical laboratory Science specialty in laboratory management. Now I am going to conduct research entitled the Frequency of specimen rejection and associated factors among referred specimen through referral network to Adama Regional Laboratory for laboratory testing, Adama, Ethiopia. For this study true and direct information is needed to fill the data collection checklist and a sample quality observation will be performed.

A. Volunteer, Continue _____

B. Not Volunteer, stop _____

The aim of the study was explained to me. It is therefore with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use the information gathered within the laboratory regarding specimens. I have also been informed that the benefit of the laboratory is identifying factors affecting specimen quality so as to design appropriate intervention strategies to improve the quality of the laboratory service.

Code of respondent----------Signature---------- Date----------

Please direct any question or problems that you may face.

Name: Jiregna Fikadu

Mobile: +251-9-23-39-19-59

E-mail: fjiregna9@gmail.com

Consent form (Afaan oromo Version)

Uunka 1 Foormii waliigaltee afaanii daataa Funaanuu dura fudhatamu

Walbaruu: Maqaankoo _____jedhama. Jireenyaa Fikaduu qo'annoo isaan baayyina saamuuda gara laaborattorii Adaamaatti ergame keessaa hangamtu qorannoo fi fudhatama dhabee fi rakkoolee isaaf sababa taan adda baasuuf hojjetan irraatti yaada (daataa) keessan akka nuuf laattaniifidha.. Inni qo'annoo maastersii isaaf haa hojjetu malee bu'aansaa qorannoon garaa garaa akka hojjetamuuf akka hundeetti waan gargaaruuf gaaffilee kana amanammumadhan akka deebistani isin gaaffadha. Deebiin keessan eenyuufuu dabarfamee hin kennamu.Maqaan keessan foormii kana irratti hin barraa'u akkasumas odeeffannoo kennitaniif rakkoon isinitti dhufu hin jiru. Gaaffii deebisuu hin barbaanne dhiisuu dandeessu akkasumas otoo gaafatamaa jirtannii adda kutuun mirga. Hirmaannaa isin gaaffilee jiraniif deebisuun hirmaattaniif guddaa isin galateeffanna. Gaaffilee kana guutuuf gara daqiiqaa digdamaa isin fudhatti.

Irratti hirmaachuuf fedhii qabduu? 1. Eyyee itti fufi

2. Lakki dhaabi

Data collection format

Specimen ID----------

I. Type of specimen

1. Whole blood

2. Serum/plasma

3. Sputum

4. CSF

5. DBS

II. For what test the specimen was referred

1. Viral load

2. Gene expert

3. EID for HIV

4. CD4 count

5. Sputum for culture 6. Others specify…….

III. Status of specimen

0. not rejected

1. Rejected

IV. If rejected, why the specimen was rejected?

1. Insufficient volume

2. Wrongly labeled

3. Specimen without request paper

4. Hemolysis

5. Clotted

6. Delayed time

7. Not maintained cold chain

8. Contaminated

9. Inappropriate specimen container

10. Request paper without sample

11. Lipemic specimen

13. Not communicated referral samples

V. Corrective measures taken at the reference laboratory

1. Written feedback for referring site

2. Phone feedback for referring site

3. No feedback

VI. Profession of Specimen collector

1. Laboratory professional

2. Laboratory aid

3. Other health professionals

VII. Educational level of Specimen Collector

1. Twelve complete

2. Certificate

3. Diploma

4. Degree 5. Other

VIII. Working experience on specimen collection or related clinical services

1. < 1 year

2. 1-3 years

3. 4-6 years

4. > 6 years

IX. Training status on specimen collection.

1. Yes

2. No

X. The specimen is transported by

1. Laboratory personnel

2. Postal service

3. With others, specify----------

XI. Is the sample transporter have training?

1. Yes

2. No

XII. Experience on sample transportation

1. < 1 year

2. 1-3 years

3. 4-6 years

4. > 6 years

XIII. Educational level of sample transporter.

1 Twelve complete

2. Certificate

3. Diploma

4. Degree

XIV. Distance of referring site from ARL.

1. 1km - 20 km
2. 21km-40km
3. 41km-60km
4. 61km- 80km
5. >81km

Uunka Gaafannoo Afaan Oromoo(Afan oromo version)

1 Gosa saamuudaa

a. Dhiiga hin calalamiin

b. Dhiiga Calalmaa

c. Tufaatii ykn Aakkee

d. Saamuuda kan dugda keessaa warabame

e. Saamuda dhiiga daa'iman irraa fudhame

f. Kan biro, adda baasi_____

2 Saamudichi qorannoo maaliif ergame

a. qorannoo baayyina vaayirassif

b. qorannoo kan aakkeef

c. vaayirasii HIV kan daa'immanii adda baasuuf

d. baayyina 'CD4'qaama keessa jiru adda baasuuf

e. Kan biro, adda baasi_____

3 Sadarkaa saamudichi irra jiru

a. qorannoodhaaf fudhatama argateera

b. qorannoodhaaf fudhatam hin arganne(haqameera)

4 haqameera yoo ta'e, **saamudichi maalif haqame?**

a. hangi isaa xiqqaachuu

b. mallayyoon adda baasuu hin kennamneefii

c. samuudichii waraqaa ajajaa malee dhufe

d. qabiiyye seelota dhiigaaa caccabaniiru

e. saamudichii ni ititeera

f. yeroon kan itti darbedha

g. tempirecharaa sirriidhaan eegamee hin dhufne

h. waan hin barbaachifnee waliin makameera ykn “bakkalameera”

i. qodaa sirrii hin taaneen baatamee dhufe

j. waraqaa ajajaa tu saamuuda malee dhufeera

k. mallayyoon adda baasuuf irra deddebiin kennameera

l. dhiiga coomni itti baayyate.

m. mallayyon kenname wal hin fakkaatu

n. Kan biro, adda baasi_____

5 Tarkaanfii sirreefamaa bakka laboratoorii ergameetti fudhame

a. Duub-deebii barreefamaa erguu

b. Duub-deebii bilbilaan kennuu

c. Duub-deebiin tokkoyyuu hin kennamne

6 Ogummaa nama saamuuda sassaabee

a. ogeessa laboratoorii

b. gargaarra/tuu laaboratoorii

c. ogeessa fayyaa kan biraa

6.2 Sadarkaa barnootaa

a. ‘Seertifikeetii’ kan qabu/du

b. Dippiloomaa kan qabu/du

c. Digrii jalqabaa kan qabu/du

d. Digrii lammaffaa kan qabu/du

7 Muxxanno saamuuda sassaabuu irratti qabu/du

a. waggaa tokkoo gadii

b. wagga 1-3 ttii

c. wagga 4-6 ttii

d. wagga jahaa oli

8 Haalli leenjii saamuda saassabuu

a. kennameerrafii

b. hin keennamneefii

9 Saamuudichii eenyuun geejibsiifame yk gara laaborattorii geessame

a. Ogeessa laaboratooriidhaan

b.Tajaajila postaadhaan

c. Kan biro, adda baasi_____

11 Haalli leenjii saamuda saassabuu

a. kennameraf

b. hin kennamneefii

10 Muxannoo nama saamuuda geejibsiisee

a. waggaa tokkoo gadii

b. wagga 1-3 ttii

c. wagga 4-6 ttii

d. wagga jahaa oli

NB: please use instruction below to fill the inspection log book.

Specimen type *
1. Whole blood
2. Serum/plasm
3. Sputum
4. CSF
5. DBS

Prof**
1. Laboratory professional
2. Laboratory aid
3. Other health professional

C. Edu***
1. Twelve complete
2. Certificate
3. Diploma
4. Degree
5. Other

C. Exp****
1. <1year
2. 1-2 year
3. 3-5 year
4. >5year

C. Tr*****
1.yes
2. No

Transported by ******
1.Lab. Personnel
2. Postal personnel
3. Others, specify

T. Edu***
1. Twelve complete
2. Certificate
3.Dippiloma
4. Degree

C. Exp****
1. <1year
2. 1-3 year
3. 3-5 year
4. >5year

T. Tr*****
1. Yes
2. No

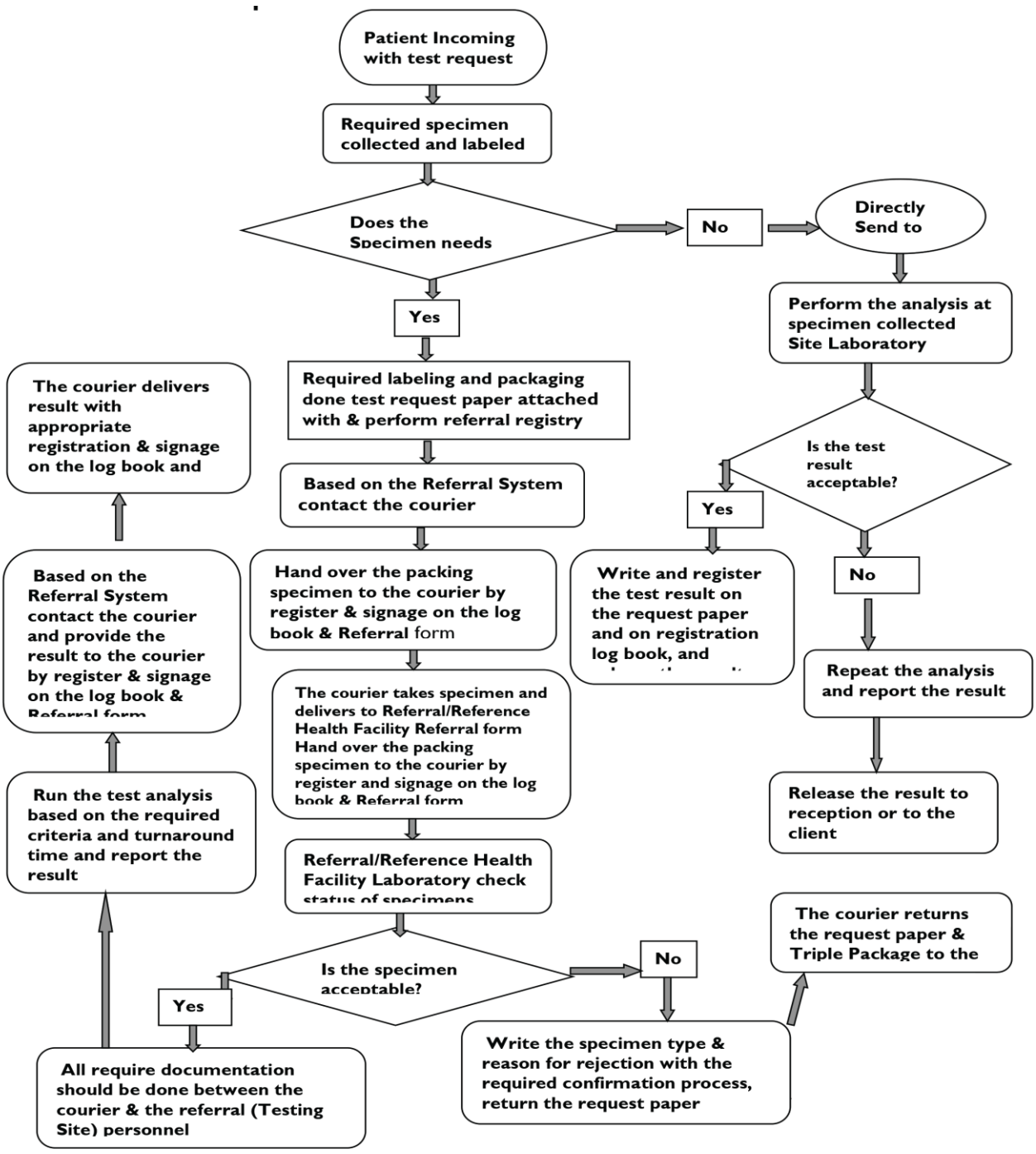
Distance*******
1. 1km – 20 km
2. 21km – 40km
3. 41km – 60km
4. 61km – 80km
5. >81 km

Test ordered
1. Viral load
2. Gene expert
3. EID for HIV
4. CD4 count
5.Sputum for Culture
6. Other

Inspection log book used for data collection of specimens referred to Adama regional laboratory

Test ordered	Specimen type *	Status of specimen		sample collector characteristics.				sample transporter characteristics				Km	Ordered test.	RE
		Rejected	Not rejected	Prof**	C.Edu***	C.Exp****	C.Tr*****	Transported by ******	T. Edu***	T.Exp****	T.Tr*****	Distance *******		
Viral load														
Gene expert														
EID for HIV														
CD4														
Culture														

Specimen Referral Flow Process.



Source: Specimen Referral Flow Process Guide Line For specimen Referral System in Ethiopia,2018(6)

STATEMENT OF AUTHOR

First, I declare that this thesis is my own work and that all sources of materials used for writing it have been duly acknowledged. This thesis has been Submitted to the School of Medical Laboratory Sciences, Jimma University, in Partial Fulfillment of the Requirements for the Degree of Master of Sciences (MSc) in Clinical Laboratory Science (specialty Laboratory Management) and is deposited at the library of the school to be available to students under the rules and regulations of the library. I declare that I have not submitted this thesis to any other institution anywhere for the award of any academic degree, diploma or certificate.

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Signature: _____

Place: Jimma University

Date of submission: _____

JIMMA UNIVERSITY

School of graduate studies

This is to certify that a thesis prepared by JITEGNA FIKADU, entitled:

Frequency of Specimen Rejection and Associated Factors of specimens Referred for diagnostic Testing to Adama Regional public health Laboratory, Adama Ethiopia and submitted in partial fulfillment of the requirements for degree of Masters in Clinical Laboratory Sciences (laboratory management) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Signed by the Examining Committee:

Examiner _____ Signature _____Date _____

Examiner _____ Signature _____Date _____

Advisor _____ Signature _____Date _____

Advisor _____ Signature _____Date _____

Head of Department or Graduate Program Coordinator

DECLARATION

I the undersigned agree to accept responsibility for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the Jimma University, Institute of health in effect at the time of grant is forwarded as the result of this application

Name of the investigator: **Jiregna Fikadu (BSc)**

Signature _____ Date_____

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Name: Mr. Edosa Tadasa (MSc)

Signature _____ Date _____

Approval of department head

Name: _____

Signature _____ Date _____