

ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF NURSING AND MIDWIFERY
DEPARTMENT OF MEDICAL LABORATORY SCIENCES



Cost- analysis of malaria screening to identify transfusion transmissible malaria in Hawassa regional blood bank, Hawassa, Ethiopia

By: Seblewongel Tsehay (BSc)

Advisors: Fatuma Hassen (MPH, PhD candidate)

Kassu Desta (MSc, PhD candidate)

Zinegnaw Abiy (PhD)

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ADDIS ABABA UNIVERSITY
SCHOOL OF GRADUATE STUDIES

This is to certify that the thesis prepared by **Seblewongel Tsehay**, entitled: **Cost- analysis of malaria screening to identify transfusion transmissible malaria in Hawassa regional blood bank, Hawassa, Ethiopia** and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality assurance) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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External Examiner _____ Signature _____ Date _____

Internal Examiner _____ Signature _____ Date _____

Advisor _____ Signature _____ Date _____

Advisor _____ Signature _____ Date _____

Advisor _____ Signature _____ Date _____

Chairman of the Department or Graduate Program Coordinator

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Abbreviations /Acronyms

ABC	Activity Based Costing
DRERC	Departmental Research and Ethics Review Committee
ELISA	Enzyme Linked Immuno Sorbant Assay
FMOH	Federal Ministry of Health
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTLV	Human T-cell lymphotropic viruses
LDHELISA	Lactase Dehydrogenises Enzyme Linked Immuno Sorbent Assay
P. Falciparum	Plasmodium Falciparum
P. Vivax	Plasmodium Vivax
PCR	Polymerase Chain Reaction
RDT	Rapid Diagnostic Test
SNNPR	Southern Nation Nationality and People
SSA	Sub Saharan Africa
TTI	Transfusion Transmissible Infection
TTM	Transfusion Transmissible Malaria
WHO	World Health Organization
ETB	Ethiopian Birr

Abstract

Back ground: The transmission of malaria by blood transfusion is one of the first recorded incidents of transfusion-transmitted infection (TTI). To reduce the risk of transmission transmissible infection effective screening for the presence of the most common and dangerous transfusion transmissible pathogens should be practiced in transfusion centers. Blood transfusion services should therefore establish efficient systems to ensure that all donated blood is correctly screened for specific transfusion transmissible infection.

Objective: To determine the magnitude of transfusion transmissible malaria and to compute the sum cost of screening blood donors for malaria in comparison to other transfusion transmissible infection in Hawassa regional blood bank, Hawassa, Ethiopia.

Methods: A cross sectional study was conducted from April-May 2018, blood samples of donors was screened for malaria using rapid diagnostic test method as well thick smear microscopy as confirmatory test. In addition to this the cost of malaria screening was calculated using activity based costing method. 414 donors were included in the study and the donors were selected conveniently.

Results: From the total number of 414 blood units collected 29 donors were positive for any of the TTI tested giving an overall positivity rate of 7%. 2(0.5%) of the donors were positive for malaria. 2 donors were deferred due to malaria symptom but both of them were negative for malaria. The total cost of each test is \$5.91 for HIV, \$5.48 HBV, \$5.98 HCV and \$5.62 Syphilis. The cost per test for malaria is \$4.73 which is the least in comparison to the others and the cost to be added for malaria screening with marginal cost of \$11,025.36 which is 4.58%.

Conclusion: The overall prevalence of malaria during the study is 0.5% but in the other way the cost for malaria screening computed to be the least compared to other TTI screening and also the cost to be added for malaria screening is minor compared to the complication caused by transfusion transmissible malaria for non immune patients. So, screening of malaria in endemic countries is beneficial. More studies are needed to infer this recommendation to endemic places as routine practice.

Key words; **cost-analysis, transfusion-transmitted infections, malaria, donor blood screening**

1 Introduction

1.1 Background

Transfusion-transmitted malaria was the first transfusion transmissible infection to be reported, it was reported for the first time in 1911 (1). Malaria is a protozoan infection with indirect transmission by female anopheles mosquito as intermediate host, In addition to the transmission by the bite of female anopheles mosquito malaria could also be transmitted by blood transfusion of infected donor. *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale*, and *Plasmodium malariae* are the species of plasmodium genus which causes malaria in human. Malaria could be caused by one or more of plasmodium species. Malaria is one of the commonest diseases in the world. Malaria endemic areas include Africa, part of Asia, Central and South America, Oceania, and the Caribbean, in sub Saharan Africa (2).

The infection of malaria always begins with intra venous inoculation of sporozoite which invade the hepatocytes in the liver and undergo multiplication, then after a week thousands of merozoites rupture the cell and invade the erythrocytes which leads to pathogenesis stage. In this stage the amplification of the parasite and differentiation to gametocyte may occur. Because *P. falciparum* has the ability to adhere the venular endothelium the erythrocytes attached to the endothelium until merozoites formed and invade other erythrocytes (3).

Ethiopia is one of sub-Saharan malaria endemic country with high morbidity and mortality record. The first malaria survey was conducted in 1936 and 1941. The epidemiology of malaria in the country is unstable due to socio economical pattern, topographical and climatic features (4). 68% of Ethiopian population lives in malaria endemic areas and its transmission is unstable so the malaria endemic areas are in serious public health emergencies. In highland it's seasonal and has longer transmission duration. The main plasmodium species in the country are *P. falciparum* and *P. vivax* which account for 60% and 40% of all malaria cases respectively. *Anopheles arabiensis* and *Anopheles pharoensis* are the major transmission vectors. . Because Ethiopia is one of malaria endemic area in the sub Saharan Africa the rate of mortality and morbidity increases 3 to 5 fold during endemics (5).

Blood transfusion is an intervention used to save the life of patients who need blood. In order to protect the health of donors and recipients, all blood banks screen the donated blood for Human

Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and Syphilis. For screening of the major TTI the minimum requirement is HIV-1/2 antibodies screening target for HIV, Hepatitis B surface antigen (HBsAg) for Hepatitis B, anti-HCV anti-body for Hepatitis C, specific treponemal antibodies for syphilis (6). Based on epidemiological evidence screening of blood donation for Malaria, Chagas disease and Human T-cell lymphotropic viruses should be practiced to control further spread of the diseases and to prevent the morbidity and mortality of blood recipients caused by Transfusion transmissible infection (7).

Malaria screening alternatives for blood donors are deferral of donors based on history of exposure, microscopic investigation of stained blood smear, antibody detection test, malaria antigen test and PCR technique. All these tests are not suitable due to sensitivity, specificity and economic feasibility issues, but malaria antigen test is effective compared to the others though it is costly (8).

There is wide variation in malaria prevalence in donors across SSA so, malaria screening policy must be customized to the country in low TTM prevalence areas so the exclusion of malaria positive blood would not cause a major impact in the amount of blood to be discarded. In most all Sub-Saharan African countries transfusion services which screen malaria use microscopic evaluation method for TTM screening (9).

Ethiopia laboratory diagnosis of malaria includes microscopy and RDT chromatography. In microscopic examination using Giemsa stain the parasite would be demonstrated while the RDT is a chromatographic technique to detect plasmodium-specific antigens. RDTs are mostly used in peripheral health sectors which do not have laboratories for microscope investigation for treatment guiding (10). Though pre transfusion screening is cost effective in most malaria endemic areas of sub-Saharan Africa, malaria screening is not performed because of lack of an effective and affordable method and lack of evidence about the clinical impact of TTM (11).

Cost analysis in laboratories is used to measure the clinical significance of a test and its monetary value in a laboratory. ABC costing model is one of the costing methods which help to compute the cost incurred accurately based on the activity involved in the health sector. Since there is wide variation in clinical laboratory test expenditures for all tests computing the cost of each test is essential in order to introduce new tests in laboratories (12).

1.2 Statement of the Problem

Though malaria screening for donated blood is recommended by WHO for endemic countries as it causes serious complication for recipients, very few blood centers implemented it due to lack of evidence about the cost for malaria screenings and lack of sensitive, specific and economically feasible method in the sub Saharan Africa (13).

Malaria control program of endemic countries suggests that laboratory confirmation of malaria must precede the treatment but its common practice in hospitals in endemic areas to prescribe anti malaria drugs for post transfusion fever. Since malaria control program and blood transfusion service has responsibility in prevention of transfusion transmissible malaria the policy of one must not contradict the other (14). In addition to this, the cost effectiveness of pre transfusion screening is better than post transfusion anti malaria prophylaxis treatment of the recipient, for this reason further studies are needed to maintain safe transfusion services in sub Saharan Africa blood bank setting in prevention of TTI and implementation of TTM screening (15).

Since testing donors blood for TTI must be using standard methods peripheral smear and rapid test are recommended to screen blood donors for malaria in endemic areas (16, 17). The current malaria screening mechanism in Ethiopia is deferral of donors based on history though the country is endemic and studies conducted in southern and northern Ethiopia showed the prevalence of TTM to be 0.3% and 1% respectively the blood banks do not screen donors blood for prevention of TTM. Southern Ethiopia is one of the endemic regions for malaria so the donors are more susceptible for malaria since they are part of the population too but there is no donor blood screening test in the blood bank (18, 19).

Even if rapid diagnostic test have a great role in reduction of mortality and morbidity of malaria in African countries, most blood transfusion services in the continent do not use this test for malaria screening (20).

1.3 Significance of the Study

In malaria endemic countries like Ethiopia screening donor blood for transfusion transmissible malaria is not practiced due to lack of evidence about cost for screening. So, this study will provide the magnitude of the infection, the cost of screening and witnessed the cost to be added for the screening will be less compared to the complication malaria causes to recipients.

This study helps recipients to be protected from malaria infection via transfusion so it reduces the risk of morbidity and mortality of immune compromised and non immuned patients due to TTM, for physicians to diagnose other post transfusion febrile reaction easily instead of monitoring post transfusion fever with anti-malaria treatment and for donors to be diagnosed asymptomatic malaria early.

In addition to this blood transfusion services or blood banks deliver infection free blood for recipients so the quality of the blood will be improved and malaria control and prevention program will obtain data about magnitude of asymptomatic malaria in donors. Blood bank and malaria control program also obtain the computed marginal cost of the lab per year and the cost per malaria test to include the test as routine practice.

In conclusion pre transfusion screening of donor blood is helpful for all stakeholders in malaria endemic countries blood banks. So, donors, recipients, physicians, transfusion services and malaria prevention and control programs will be benefited.

2 Literature review

Various studies were conducted on the prevalence of TTI and specifically on the prevalence of other endemic pathogens in different countries like for Malaria, Chagas disease, and other transfusion transmissible infections which are rare but may cause serious health outcome. The cost analysis of screening TTI is also studied by different authors.

2.1 Prevalence of transfusion transmissible infection in blood bank

A retrospective study conducted in china blood banks for 10 years showed over all prevalence of TTI to be 0.08%, 0.86%, 0.51% and 0.47%, for HIV, HBV, HCV and syphilis respectively. The study concludes that the prevalence of TTI was reduced in the country for past 10 years (21).

A cross sectional retrospective study conducted in Zambia in 2015 showed the prevalence of TTI in the study period as 2.9% for HIV, 6.0% for HBV , 0.6% for HCV, and 1.2% for syphilis .In the study Hepatitis B remains the most common TTI (22).

A retrospective study conducted at Yirgalem regional blood bank southern Ethiopia for 5 years showed that the prevalence of TTI was significant. In this study the prevalence of HIV, HBV, HCV, and syphilis were 1.6%, 4.8%, 0.6%, and 0.5%, respectively .The prevalence of HIV and HCV was higher among replacement donors than volunteer and the study conclude that volunteer donors are associated with lower risk of TTIs (23).

2.2 Prevalence of transfusion transmissible malaria in endemic countries

A study conducted in two teaching institutes of Bangladesh between 1st January and 30th April 2003 showed that 0.76% of the donors were found to be malaria positive .In this study the blood samples were examined under microscopy by preparing thick blood smear. The study proves that there is risk of transmission of malaria parasites in blood transfusion among the voluntary and professional blood donors (24).

A prospective cohort study was conducted in Pakistan from January 2013 to June 2015 to determine the prevalence of TTI and to evaluate the demographic characteristic of blood donors; thick blood microscopy was performed for malaria test and found that 0.07% of positivity. The study suggested that in blood banks there should be strict selection of donors and the prevention of TTI must be the main goal of the policy makers (25).

Another study from Nigeria conducted from 2012 to 2014 showed that there is a great number of malaria infection in blood donors, majority, 67.5 % of the donors were infected by malaria specifically *Plasmodium falciparum* species. As a solution the study recommended the screening of donor blood prior to transfusion and the improvement of blood banks policy for free will of donors to increase the amount of malaria free blood (26).

A cross sectional study was also conducted in Cameroon in 2015. A total of 179 donors were included in the study of which 27.54% of them were infected with the parasite. The blood sample was tested by microscopical investigation. It suggested that microscopic examination is less sensitive and specific so there should be adequate policies for pre transfusion screening of TTM in endemic areas of Africa (27).

In the study conducted in Northern Ethiopia from December 2002 to February 2003 four blood banks were involved the prevalence of TTI including malaria was studied. In this study for malaria investigation light microscopy was used and the prevalence of malaria from total 600 blood donors was found to be 6 which is 1% (18).

Another study from Ethiopia which was conducted in the southern region of the country from April 2015 to May 2015 it was across sectional study to assess the prevalence of the four TTI and malaria. In this study different assays were used and for malaria thick smear microscopy detection was used. The total no of donors in the study period was 384 of which 0.3% of malaria positivity reported .The study suggests that since the southern region of the country is malaria endemic pre transfusion malaria screening is mandatory (19).

2.3 Cost -Analysis of screening endemic transfusion transmissible infection in blood banks

A study conducted in India for 5 years using thick and thin smear microscopy and ELISA. For microscopy thin and thick smear were made simultaneously at the same time and were stained and examined for 10 minutes by experienced investigators and for the ELISA the LDH ELISA assay was used. The result showed that from 187,564 donors 168 of them are positive for malaria using ELISA which is 0.08% of the total and 164 of the total are positive for malaria in the case of microscopy and in the study 97% slide positivity occur .the study suggested that the cost per test for malaria is the same as other TTI tests (28).

A study which was conducted in endemic and non endemic areas of Kenya from September 2004 to February 2005 found that the prevalence of malaria was 8.63% and 0.67% respectively .The study compared the cost per case prevented of Prophylactic administration of anti-malarial and pre screening of the blood for TTM. The result found that cost of preventing transfusion associated malaria (TAM) using recipient anti-malarial prophylaxis is considerably higher than if pre-transfusion screening using an automated technique is adopted (cost of anti malaria was US\$1.4 and US\$ 0.69 for adult and pediatric respectively while the cost of screening was US\$ 0.03) and suggested the pre transfusion screening is cost effective (29).

2.4 Cost –Effective malaria test in malaria endemic countries

A study was conducted in Brazil between May 2008 and May 2009.The objective of this study was to evaluate the efficacy of RDT for malaria screening in blood banks. Two types of RDT and microscopy were used and all the 3 types of malaria screening showed the same result of malaria positivity (30).

Another study was conducted in Afghanistan to compare the cost-effectiveness of clinical symptom, RDT and microscopy using decision model and undertaken incremental cost effectiveness analysis and founded that RDT was cost effective in scarce resource setting (31).

In Iran a study was conducted to evaluate three methods of malaria testing Microscopy, RDT and real time PCR. A total 100 samples were collected 50 were from endemic and 50 from non endemic area of Iran and the result was all samples were negative by microscopy and RDT while 2 samples from endemic region were positive using PCR the study concluded that real-time PCR could be used in endemic area blood banks detect asymptomatic carriers of malaria and suggested that rapid and correct diagnosis could be gained from RDT (32).

2.5 Prevalence of malaria in endemic areas of Ethiopia

Institution based, cross sectional study was conducted in the southern Ethiopia health facilities from October to December 2014. Thick smear microscopic investigation for malaria screening was done and 16% of malaria infection (33).

Another Cross sectional study was conducted in East Shewa zone of Oromia region, Ethiopia from October to December 2012 .In this study 25% of the study participants were malaria positive. Microscopical investigation was the confirmatory test for the cases so all of the positive cases were found have microscopically confirmed malaria (34).

2.6 Conceptual frame work

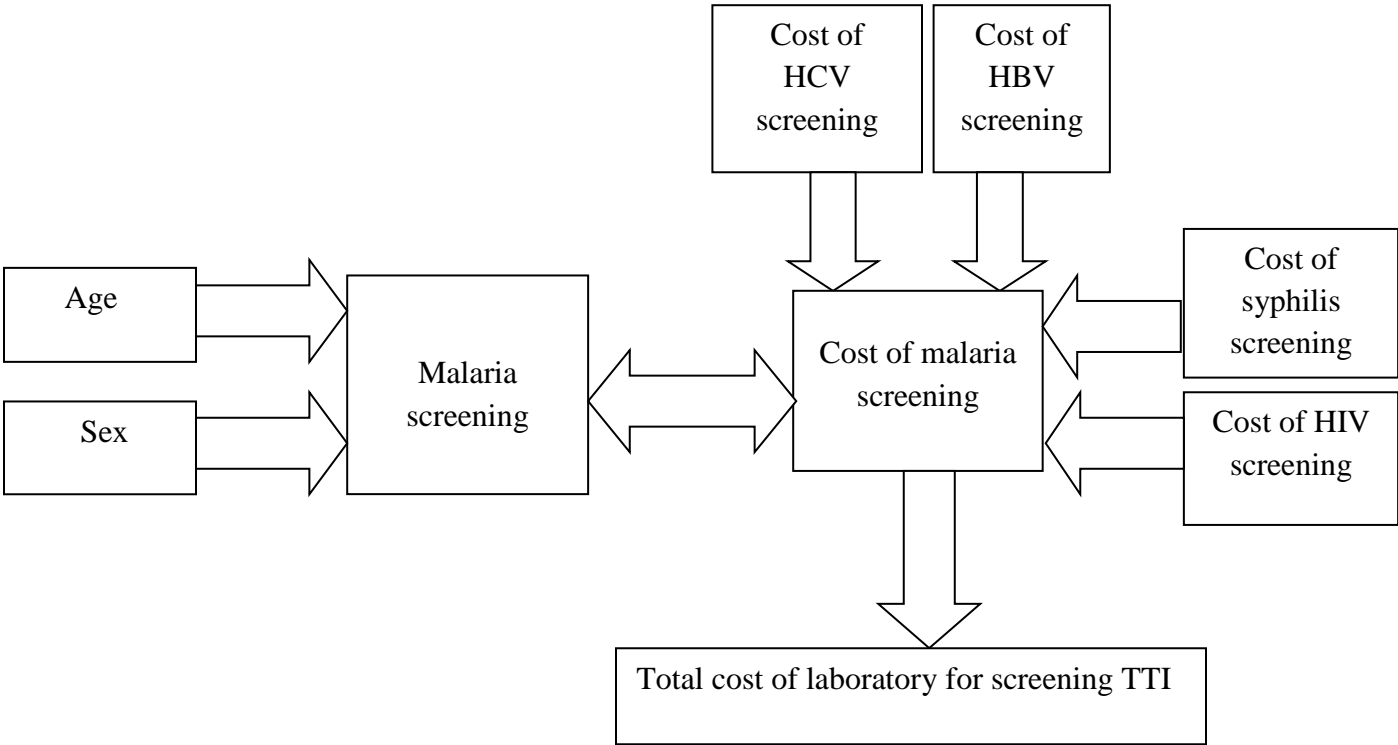


Figure 1- Conceptual frame work

3 Objective

3.1 General Objective

- To determine the magnitude of TTM and to compute the sum cost of screening blood donors for malaria in comparison to other transfusion transmissible infection in Hawassa regional blood bank, Hawassa, Ethiopia.

3.2 Specific Objectives

- To determine the rate of transfusion transmissible infection including malaria
- To compute the cost of all TTI tests and to compare it with cost of malaria screening
- To assess the effectiveness of donors deferral based of malaria symptom

4 Material and method

4.1 Study area

The study was conducted Hawassa Regional blood bank service center in SNNPR, Ethiopia .This center serves as the center of blood bank for the region and it is located in the capital of SNNPR, Hawassa city. Hawassa blood bank was established in May 2013 with \$209,609.16 cost for building and serves for those public and privet hospitals found in Sidama zone, Gedio zone and Halaba special woreda. In the blood bank HIV, HBV, HCV and Syphilis screening had undertaken prior to distribution to hospitals and health centers. SNNPR is one of malaria endemic area of the country so the donors in Hawassa blood bank are from susceptible source population.

4.2 Study design and period

Institutional based cross-sectional study was conducted among blood donors who donate blood in malaria endemic season of the region. The study was conducted from April 2018-May 2018.

4.3 Population

4.3.1 Source population

All potential donors who volunteer to donate blood in Hawassa regional blood bank

4.3.2 Study population;

All potential donors who fulfill the inclusion criteria and volunteer to donate blood in Hawassa regional blood bank on the study period

4.4 Inclusion and exclusion criteria

4.4.1 Inclusion criteria

- All Potential donors who fulfill the criteria of national blood bank. (Annex 4)
- Potential blood donors who are deferred due to malaria symptom.

4.4.2 Exclusion criteria

- Blood donors deferred due to being incapable of donating blood other than malaria symptom.

4.5 Study variables

4.5.1 Dependent variable;

- Magnitude of TTM
- Cost of laboratory screening TTM

4.5.2 Independent variable;

- Socio-demographic characteristics (age, sex, residency, occupation)
- Prevalence of TTI other than malaria
- Cost of screening TTI other than malaria
- Total cost of the laboratory

4.6 Sample size calculation and Sampling method

4.6.1 Sample size calculation

The required sample size for the study is determined using single population proportion formula considering the prevalence of malaria in the area. In previous study the prevalence of malaria in the area was 16% (33). The sample size calculated based on the formula with 95% confidence interval and 5% margin of error.

$$n = \frac{(z\alpha/2)^2 p(q)}{d^2}$$
$$n = \frac{(1.96)^2 \cdot 0.16(1-0.16)}{(0.05)^2}$$
$$n = 207$$

Where **n**: The desired sample size

z: The value of level of significance at 95%

p: Estimated proportion of malaria in the area

q: 1-p

d: Marginal error = 5%

Since blood donors are healthy looking population malaria will be rare so by doubling the sample size found to be **414**

4.6.2 Sampling method

Convenient sampling technique was used in malaria endemic season of the year in Hawassa regional blood bank since it is found in southern region of the country which is endemic to malaria. Blood donors who are eligible for donation plus donors who deferred due to malaria symptom were taken.

4.7 Measurement and Data collection

4.7.1 Data collection procedure

The national blood bank information sheet, consent form and questioner were adopted in the study. Socio demographic status of the donor obtained from the questioner of the blood bank and the result of TTI was obtained from laboratory result log.

4.7.2 Laboratory procedures

Whole blood sample was collected from donors for malaria RDT and microscopy diagnosis. Then tested using RDT the test was done using the procedure of the kit. For microscopy thick smear was used as standard reference. Standardized thick and thin smear were prepared after drying the thin smear was fixed with absolute methanol then the slides stained with 10% Giemsa for 10 minutes.

4.7.3 Work flow

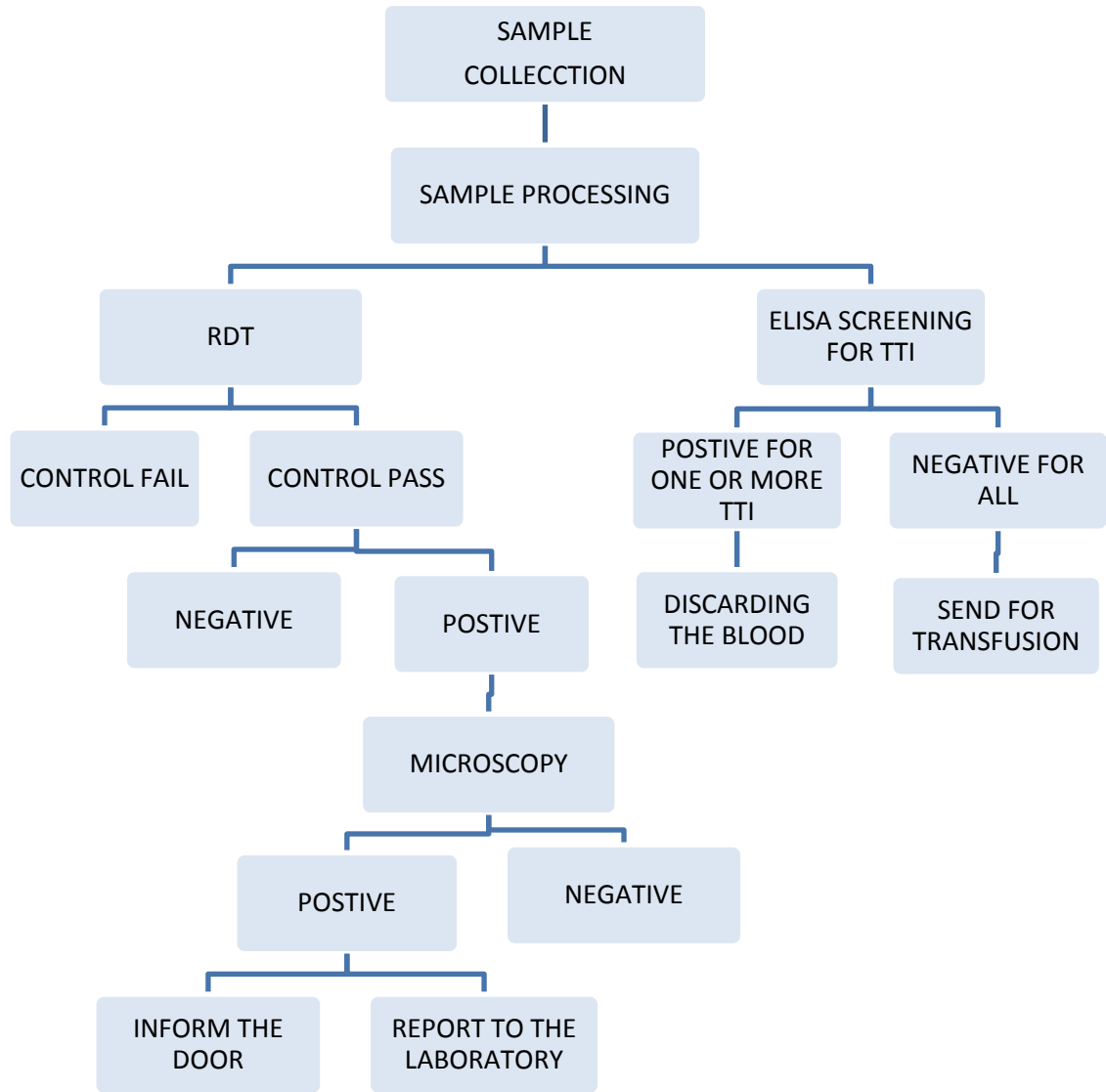


Figure 2- Work flow

4.7.4 Cost analysis procedure

All direct variable and fixed cost were computed. Fixed costs include building equipment and personnel salary, while variable cost includes the cost of the materials and the supplies .Cost of plant asset was computed by deducting the depreciation cost from the original cost of the asset and the overhead cost assigned using appropriate allocation rate.

Straight line deprecation method is used to compute the current value or book value of the assets, for the building the useful life is estimated by the engineers to be 50 years and \$209,609.16 was the budget to build it. The useful life for all equipments is estimated by biomedical engineers and the cost of purchasing is the original cost, the original cost of equipments supplies and materials were found from the respective voucher and current market value.

Table 1- Accumulated Depreciation-Assets of Hawassa regional blood bank, Hawassa, Ethiopia, 2013-2018.

Asset	Life span	Cost	Accumulated Depreciation year				Book value
			2014	2015	2016	2017	
Building	50	209,609.16	4,192.18	8,384.36	12,576.54	16,768.72	192,840.43
ELISAreader	7	1,648.15	235.45	470.9	706.35	941.8	706.35
ELISAwasher	7	1648.15	235.45	470.9	706.35	941.8	706.35
Autoclave	12	1055.55	87.96	175.3	263.88	351.85	703.7
Incubator	10	1037.04	103.70	207.4	311.1	414.8	622.24
Shaker	10	814.80	81.48	162.96	244.44	325.92	488.88
Refrigerator	12	925.93	77.16	154.32	231.48	308.64	617.29
	12	1,481.48	123.46	246.91	370.38	493.83	987.65

Micro pipette	10	55.55	5.56	11.12	16.68	22.22	33.33
Water bath	10	1055.55	105.56	211.2	316.68	422.4	633.15
Centrifuge	7	740.74	74.07	148.14	222.21	296.28	444.46

Direct labor cost like salary of laboratory technologists and laboratory technicians, indirect labor cost like the salary of CEO, cleaner and security is distributed for the tests done per month to find salary per test.

Table 2- Labor Cost of Hawassa regional blood bank, Hawassa, Ethiopia, May2018

	A	B	$C=(A*b)/30$	D	$E=C/D$
Professionals salary	Salary	N^o of staff	Salary per day	N^o of tests per day	Salary per test
Salary of CEO	371.26	1	12.37	30	0.41
Salary of Laboratory technologist	298.4	3	29.84	30	0.99
Salary of Laboratory technician	144.78	1	4.82	30	0.16
Salary of Cleaner	42.67	3	4.27	30	0.14
Salary of Security	42.67	4	5.69	30	0.19

Utility expense is computed by dividing the annual budget by months of the year to find the estimated utility per month. Then the average expense of the month will be distributed for number of sample per day to find utility per test.

Table 3- Utility expense of Hawassa regional blood bank, Hawassa, Ethiopia in 2018

Utility	Annual expense	Average expense	Test done per day	Utility per test
Electricity	703.70	58.64	30	1.96
Water	555.56	46.30	30	1.54
Telephone	954.00	79.50	30	2.65

Variable cost of each TTI includes materials and supplies used by each tests, variable cost varies for each tests. The variable unit cost is computed by dividing the total cost by the quantity needed materials or supplies per test.

Table 4 -Variable cost Hawassa regional blood bank .Hawassa, Ethiopia, May 2018

Materials and supplies	Quantity	Total Cost	Quantity per test	Unit cost
RDT kit	25	21.60	1	0.86
HIV ELISA kit	96	70.00	1	0.73
HCV ELISA kit	96	77.00	1	0.80
HBV ELISA kit	96	28.80	1	0.30
Syphilis ELISA kit	96	42.00	1	0.44
EDTA tube	50	8.96	1	0.18
Micro pipette tips	500	35.00	1	0.07

4.7.4.1 Cost per test of screening.

Cost of HIV screening per test = Fixed cost per test + Variable cost per test of HIV

Cost of HBV screening per test = Fixed cost per test + Variable cost per test of HBV

Cost of HCV screening per test = Fixed cost per test + Variable cost per test of HCV

Cost of syphilis screening per test = Fixed cost per test + Variable cost per test of syphilis

Cost of malaria screening per test = Fixed cost per test + Variable cost per test of malaria

4.7.4.2 Cost to be added for malaria screening

The cost of TTI per case would be deducted from total laboratory cost per case to get the cost of malaria screening

Total cost for malaria screening = Total cost of the laboratory – Total cost of TTI screening

4.8 Data quality assurance

Both RDT and microscopy method were done by following SOP. Quality was assured by well trained professionals and training. Supervision during sample processing and onsite correction was done. The completeness and accuracy of the data was rechecked.

4.9 Data analysis and interpretation

Data entered into excel and exported to SPSS version 20 for analysis. Both dependent and independent variables and also proportion was used to determine the prevalence of TTI and the cost analysis computed using ABC costing method.

4.10 Ethical consideration

Ethical approval and permission was obtained from the DRERC of the Addis Ababa University, Department of Medical Laboratory Science. Then official letter of support was written to Hawassa blood bank and regional laboratory. Donors were included after they signed the consent form of the blood bank and all results of the donors were kept confidential.

4.11 Dissemination of result

The result founded by the study will be presented in the school of medical laboratory science. And it will be disseminated to the scientific community through scientific presentation and different journals. The result of the study will also be sent to malaria control program and blood transfusion services in the country.

4.12 Operational definition

Activity Based Costing: a costing which provides decision-making information by computing the cost of a product /test by focusing on assigning the costs contributing to specific test and by allocating over head costs accordingly.

Fixed costs: costs that do not vary with the number of goods or services a company produces.

Variable costs: costs that fluctuate as the level of production or service changes.

Depreciation: the physical deterioration of an asset over a period of time that spans a number of years.

Book value: the current value of the asset after deducting the accumulated depreciation from the original cost of the asset.

Blood transfusion : a process of collection of blood from voluntary non-remunerated blood donors at low risk of infections, screening of the blood for infectious agents which can be transmitted through blood and blood products and transfuse the blood to recipient.

Transfusion transmissible malaria: a malaria infection caused by transfusion of infected blood and blood products by plasmodium specious and transfusing the infected blood to recipients

5 Results

5.1 Socio demographic characteristics of study participants

During the study period a total of 414 blood donors were screened of them 228(55.1%) were female, 87.4% of the donors were students while the rest are employee. Blood was collected from different collection sites, 61.6% of the blood was collected from Hawassa which accounts the higher number of donors and the rest collection is from Halaba, Dilla and Yirgalem. The majority of the donors are youths because blood bank has a schedule of collecting blood from schools, church fellowships and different events. The median age of the donors was 20 (range 18-48years) 37.9% of the donors were at the age18, 52% of the donors were at age range 19-24 while the rest 10.1% of the donors were 25 years and above.

Table 5- Demographic characteristics of blood donors donate blood in Hawassa regional blood bank, Hawassa, Ethiopia, April-May 2018

Variable	Number	%
Age in years		
=18	157	37.9
19-24	215	51.9
>25	42	10.1
Sex		
Male	186	44.9
Female	228	55.1
Address		
Hawassa	255	61.6
Dilla	47	22.2
Halaba	92	11.4
Yirgalem	20	4.8
Occupation		
Student	362	87.4
Employee	52	12.6

5.2 Transfusion Transmissible infections

From the total number of 414 blood units collected 29 donors were positive for any of the TTI tested giving an overall positivity rate of 7%. During the study period there was no co infection and none of the donors were positive for HIV or HCV. Twenty three (5.6%) of the donors were positive for HBV, four (1%) of the donors were positive for syphilis and two (0.5%) of the donors were positive for malaria. There were two donors who were deferred due to malaria symptom using the deferral of donors based on malaria symptom which is currently implemented as malaria screening in blood banks but both of them were negative for malaria. Positivity

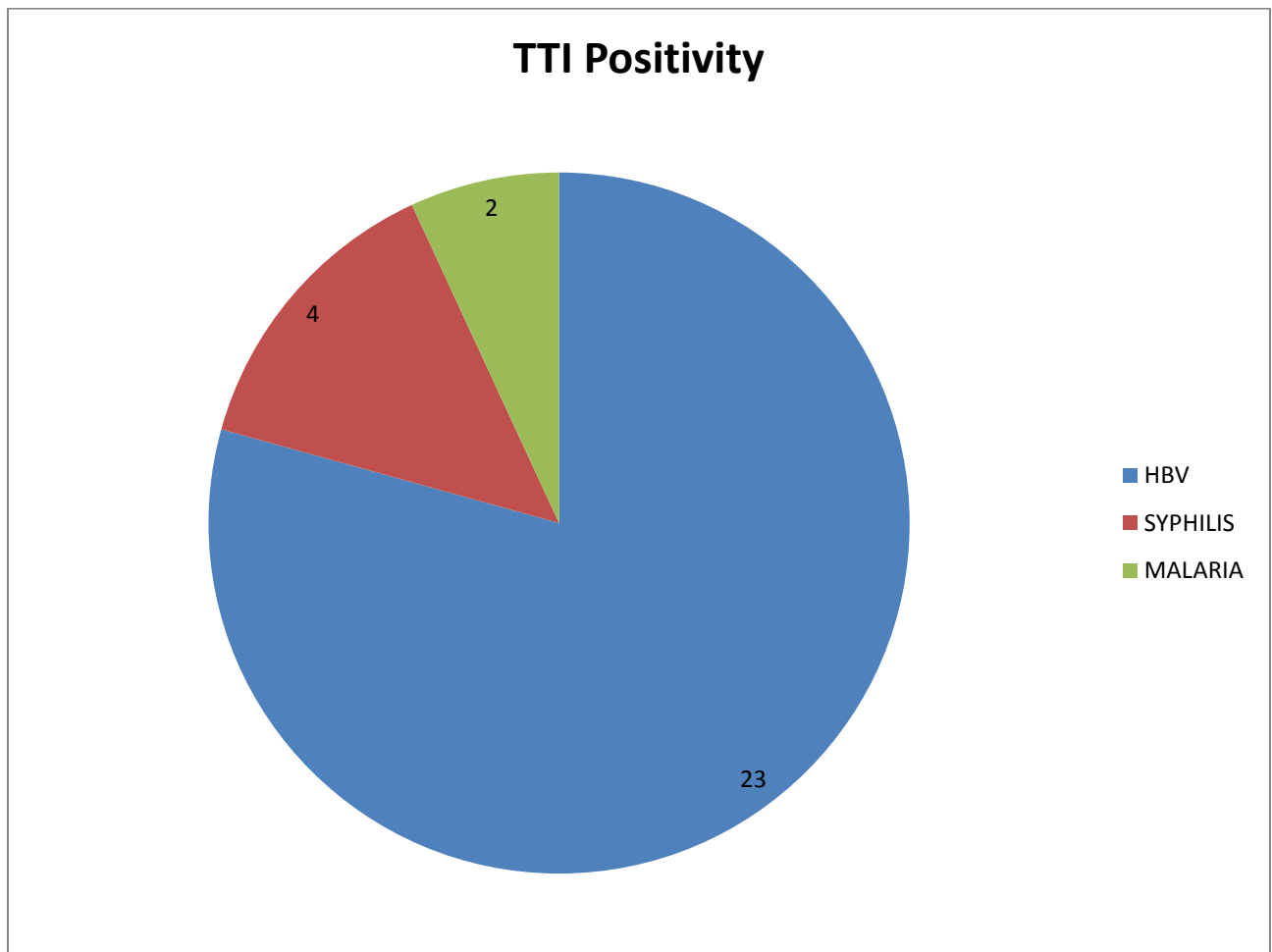


Figure 3- TTI positive blood donors who donate blood in Hawassa regional blood bank, Hawassa, Ethiopia, April-May 2018.

5.3 Cost of laboratory for tests

The current cost of the building (book value) was estimated to be \$192,840.43. So the cost of the building for each sample was calculated for each sample by dividing the book value by the total number of samples per year and found to be \$17.6. Since the building cost is distributed for all tests then the cost per test of the building for all TTI including malaria was \$3.52. Other fixed cost of equipments was calculated based on the test utilization and most of the TTI tests use the equipments equally so the cost was distributed for the TTIs except malaria test which don't need any equipment for analysis. The cost of all equipment was calculated and the book value was distributed to the test they used since all equipment used in the analysis of the TTI in the same amount the cost of all equipments for each test was found to be \$0.14 per test or \$ 0.54 per sample. \$1 was changed around 27 Ethiopian birr during the study period so for the study all the costs were declared with 1\$ which is equal to 27 Ethiopian birr.

The indirect cost like salary paid for the CEO and supportive staff was distributed all TTI and malaria and found to be \$0.15. Other labor cost for the TTI was calculated to be \$ 0.44 and for malaria screening the estimated labor cost will be \$0.30. Utility expense for TTI was \$0.88. Variable cost of each test was found to be \$0.73 HIV, \$0.8 HCV, \$0.2 HBV, \$0.44 Syphilis and \$0.86 for malaria, variable cost of materials used for all TTI including malaria was \$0.05. So, the cost per test for each TTI was \$5.91 for HIV, \$5.48 HBV, \$5.98 HCV and \$5.62 Syphilis. The cost per test for malaria was \$4.73 which was the least in comparison to the others.

Table 6- Cost per test of fixed assets in Hawassa regional blood bank, Hawassa, Ethiopia, 2018

Name of the asset	Book value	N ^o of days per year	N ^o of tests per day	Cost per sample	N ^o of tests use it	Cost per test
Building	192,840	365	30	17.6	5	3.52
ELISAreader	706.35	365	30	0.064	4	0.016
ELISAWasher	706.35	365	30	0.064	4	0.016
Autoclave	703.7	365	30	0.064	4	0.016
Incubator	622.24	365	30	0.06	4	0.014
Shaker	488.88	365	30	0.04	4	0.010
Refrigerator	1,604.94	365	30	0.14	4	0.040
Micro pipette	33.33	365	30	0.004	4	0.002
Water bath	633.15	365	30	0.058	4	0.014
Centrifuge	444.46	365	30	0.04	4	0.010

Table 7 Total cost per test of all TTI and Malaria in Hawassa regional blood bank.,Hawassa, Ethiopia, 2018.

Test	Building cost	Equipment cost	Indirect cost	Labor cost	Utility expense	Material cost	Variable cost	Total cost
HIV	3.52	0.14	0.15	0.44	0.88	0.05	0.73	5.91
HCV	3.52	0.14	0.15	0.44	0.88	0.05	0.80	5.98
HBV	3.52	0.14	0.15	0.44	0.88	0.05	0.30	5.48
Syphilis	3.52	0.14	0.15	0.44	0.88	0.05	0.44	5.62
Malaria	3.52	–	0.15	0.16	–	0.05	0.86	4.73

5.4 Cost to be added for malaria screening

The total cost the laboratory incurred for screening TTI except malaria is estimated to be \$229,923.02 per year. If malaria screening is added to the laboratory, the cost becomes \$240,948.38. So, the total cost incurred by the lab increases by \$11,025.36 which is 4.58% of the total cost.

Table 8- Cost to be added for malaria screening in Hawassa regional blood bank. Hawassa, Ethiopia, 2018.

Cost	Total fixed Cost	Variable Cost per year	Total
Estimated cost of the lab per year	202,707.02	27,216.00	229,923.02
Total cost of the lab per year	204,444.38	36,504.00	240,948.38
Cost to be added for malaria per year	1,737.36	9,288.00	11,025.36

6 Discussion

Even if blood transfusion is an intervention used to save the life of patients who need blood, the blood may also carry risks of infections which can be transmitted by blood transfusion hence to reduce the risk of these infections all blood banks screen the donated blood for HIV, HBV, HCV and syphilis. And also based on epidemiological evidence screening of blood donation for infections which are endemic to the area should be practiced to control further spread of the diseases and to prevent the morbidity and mortality of blood recipients caused by TTI (6, 7).

In the study screening blood donors for TTI in addition to malaria was performed and the overall prevalence TTI was 7%. of which positivity rate 5.6% for HBV, 1% for syphilis and no HIV and HCV, HBV was detected more than others like other studies, the prevalence of TTI in this study is higher than the study in China but much less than a study conducted in Zambia (21, 22). This could be in the Chinese study large number of donors were involved in Zambia the study participants were small in number. The prevalence of TTI in a study conducted in the southern Ethiopia showed prevalence of TTI to be similar but in the study the prevalence of HIV and HCV decreases in this study. The reason for decrease of HIV and HCV positivity is implementation could be voluntarily blood donation instead of replacement donation which is unsafe (23).

The prevalence malaria was significant which accounts 0.5% of the total blood donors which is much less than Nigerian prevalence of 67.5% and Cameroon 27.54% (26, 27). This huge variation of malaria prevalence in donors could be due to the prevalence of malaria in Nigeria and Cameroon is much greater than Ethiopia. The result is closer to study result in Bangladesh and in northern Ethiopia which was 0.76% and 1% respectively (24, 17). But the prevalence is greater than the study conducted in same area, southern Ethiopia in 2015 which was 0.3% and 0.07% of positivity in Pakistan, the reason could be both studies used microscopy which is less sensitive than RDT (25, 19).

In all previous studies the investigation was using thick smear giemsa stained microscopy though malaria antigen test is effective compared to the other malaria screening alternatives for blood

donors like deferral of donors based on history of exposure, microscopic investigation of stained blood smear, antibody detection test and PCR technique (8) .

In this study two donors were deferred due to malaria symptom but both of them were negative for malaria, this shows that out of 100,000 blood donors 483 donors who deferred will donate blood if malaria screening is implemented in the blood bank so that 483 additional units of blood will be secured.

The number of malaria positive donors in this study is two this implies that per 10,000 donors 48 donors will be malaria positive. If pre transfusion malaria screening malaria is not applied in blood banks 48 malaria positive blood will be transfused for recipient which will be risk for mortality and morbidity due to TTM. The outcome of this could be fatal for pediatric and gynecology unit blood recipients since this group are more susceptible to infection.

In this study we use RDT kit and thick smear microscopy as confirmatory test and both of screening showed the same result which is the same as study conducted in Brazil found that RDT kit and thick smear microscopy has the same efficacy for blood bank (30). A study conducted in Afghanistan showed RDT was cost effective in resource limited areas this study also the cost added for malaria screening is 4.58% which the blood bank could easily afford (31). Another study showed that malaria RDT test is cost effective than clinical symptom and microscopy (32). In this study also there were two donors deferred based on clinical symptom but they were negative for the test so even if the RDT screening is costly, it is effective than other malaria screening alternatives like deferral of donors based on exposure.

In this study the cost was computed using ABC costing method since this costing method provide more accurate method of service costing and it also enable allocating costs easily. To analyze the cost of fixed assets of the blood bank straight line depreciation method was used and the cost was allocated for each test based on utilization. Other costs like labor cost, utility expense and indirect costs were computed using the appropriate cost driver so the cost of each test was analyzed precisely.

The cost per test for malaria is less than other TTI. The cost per test for each TTI was \$5.91 for HIV, \$5.48HBV, \$5.98 HCV, and \$5.62Syphilis and, for malaria it was \$4.73. So the cost per test for HCV was most expensive while the cost for malaria was the cheapest. The result of this

study is in comparable with the study conducted India which showed the cost per test of malaria is the same as other TTI cost per test this could be because the method they use was microscopy which is labor intensive and the supplies for the test are costly so that the cost for malaria screening is as costly as other tests (28). When this study is compared with another study conducted in Kenya the study computed the cost per test of malaria screening to be \$ 0.03 which is much less than the result of this study, this may occur because automation analyzer was used in the study which run many hematological parameter including malaria so malaria screening accounts the ratio of other this makes the cost incurred for malaria least (29).

This study was conducted from April to May and finds 0.5% which is the moderate transmission season and finds 0.5% of malaria positivity which have an implication there could be higher magnitude malaria if the study was conducted after the rainy season (October to January) of the country. Other studies conducted in this season showed that the magnitude of malaria 16% southern region and 25% in Oromia region of Ethiopia (33, 34). The huge variation could be in the current study our study population is from healthy population while the other studies were conducted health sector so the study populations are susceptible to malaria in addition to seasonal variation.

7 Limitation

In the study we only analyze the cost of malaria RDT which is one of malaria screening but there are alternative malaria screenings which are much more sensitive and specific than RDT.

Second limitation of this study is convenient sampling technique which is non probability sampling technique was used for donor's selection.

The other limitation is study was conducted April to May which moderate malaria transmission season of the country.

8 Conclusion

The overall prevalence of malaria during the study was 0.5% which is significant and in the other way the cost for malaria screening was computed to be the least compared to other TTI tests and the complication caused by transfusion transmissible malaria for non immune patients. The marginal cost or cost to be added for malaria screening is only 4.58% of the total cost the laboratory incurs per year.

9 Recommendation

- Less cost incurred for malaria compared to other TTI showed malaria screening could be done in Ethiopia blood banks, so after large scale studies the country blood banks should have a strong policy in pre transfusion malaria screening.
- The positivity rate of malaria shows the TTM exist. So malaria control and prevention program should take part in reduction of malaria transmission by this route of transmission.
- The donors deferral based on malaria symptoms is not effective so it has to be replaced by malaria screening in malaria endemic areas
- Further studies are needed to implement routine Malaria screening among blood donors at least in Malaria endemic places

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11 Annexes

Annex 1: Information sheet

Hello; my name is. Seblewongel Tsehay

I am MSC student at Addis Ababa university health since college medical laboratory department. I am doing a research entitled Cost- analysis of malaria screening to identify transfusion transmissible malaria in Hawassa regional blood bank. Hawassa, Ethiopia

Background to the study

Screening malaria in blood banks in the endemic areas is mandatory since the malaria transmitted during transfusion may harm the recipient's health and may also cause serious complication in recipients health. In the other hand this screening also helps to inform infected donors and counsel them to go health centers for treatment. So screening malaria prior to transfusion is mandatory in malaria endemic areas of the country.

Why the study is important

Analyzing the cost of screening malaria and assessing the magnitude of malaria in blood bank helps to inform all stakeholders about the infection and to show the cost screening to be added to save the life of donors and recipients .If you agree you will give me information about the costs incurred in the organization, allow me to use some socio demographic information and result of donors in the study period. And the study assures that all the data would be kept strictly confidential.

What are the risks of the organization participating in the study?

There is no risk related to participating in the study.

Seblewongel Tsehay (PI)

Department of Medical Laboratory Sciences, College of Health Science

Addis Ababa University

Addis Ababa, Ethiopia.

Email: seble1325@gmail.com

Tel: +251913145568

Signature: _____

Date: _____

Annex 2: Consent form

I, the undersigned, have read the provided information and understood that the study is useful without major risks to the organization and donors. So I agreed to let the organization participate in the study by giving the necessary information accordingly

Signature of participant: _____

Occupation _____

Job Position: _____

Date : ____ / ____ / ____

Annex 4: National blood bank donors exclusion criteria

- **Age:** In blood bank donors who are only in the age range of 18-60years are included those who not in this range will be deferred.
- **Weight:** The acceptable weight for blood donation is 45kg and above, donors who are less than 45kg will be deferred.
- **Anemia:** Hematocrit of donors is measured prior to donation so those donors who have low hematocrit will be deferred.
- **Abnormal blood pressure:** The blood pressure of the donors should also be in the normal range hypertensive donors will be excluded
- **Previous infection of TTI:** Donors who are known to be positive for any of TTI will be deferred.
- **Surgery history:** Donors which have Surgery recently will be deferred
- **Malignancy history:** Donors which have any malignancy will be deferred
- **Lactating or pregnant women**
- **Malaria symptom :** Donors who has malaria symptom and assumed to have malaria will be deferred

Annex 5: Standard operating Procedure of malaria microscopy

Purpose and scope

To describe the recommended procedure for malaria microscopy blood films .the procedure mentioned here are mandatory for all microscopist working health laboratories performing malaria microscopy.

Back ground

Correct labelling of malaria blood films, proper smearing, staining and identification of malaria parasite is important for clinical management of patients and for epidemiological survey and control programmes .Therefore malaria diagnosis with microscopy must be correct and accurate.

Supplies and materials and equipment

- Microscope
- Giemsa stain (10% solution)
- Methanol
- Water
- Slide
- Timer
- Lead pencil
- Immersion oil

Procedure

1. Label the slide by the laboratory code, date of collection
2. Make a thick and thin blood Smear in the slide
3. Allow the smear air dry
4. Fix the thin smear using methanol
5. Air dry the smear
6. Cover the slide with 10% geimsa for 10 minuets
7. Wash the slide

8. Air dry the slide
9. Place a drop of immersion oil and examine the slide using light microscopy
10. Report the result founded

Annex6: Standard operating procedure for rapid diagnostic malaria test

Purpose and scope;

To describe the recommended procedure for rapid diagnostic test for malaria, the procedure mentioned here are mandatory for all health professional working health laboratories performing rapid diagnostic test.

Back ground

Practicing safe blood collection and proper testing using RDT for malaria parasite is important clinical management of patients and for epidemiological survey and control programmes therefore malaria diagnosis with RDT must be using the procedure of the manufacturer.

Principle

The test contains a membrane strip which is pre-coated with two monoclonal antibodies as two separate lines across the test strip .one monoclonal antibody (test line pv) is specific to plasmodium lactate dehydrogenase (pLDH) for *P.vivax* while the other monoclonal antibody (test line for Pf.) is specific to histidin rich protein 2(HRP2) for *P.falciparum*.so the test is designed to differentiate diagnosis of *P.vivax* and *P.falciparum*

Supplies and materials

- Care Start TM Malaria HRP2/pLDH
- Micropipette
- Pencil
- Glove
- Timer

Procedure

1. Put a new pair of glove
2. Label the kit
3. Collect 5µl of blood sample

4. Add the 5 μ l of the blood to the sample well
5. Add 60 μ l of buffer to the buffer well
6. Read the result at 20 minutes
7. Report the result founded

Annex 7: ABC costing procedure

Scope of activity-based costing

ABC is complementary method to the two traditional costing techniques. It considers all the costs associated with a single infection test, regardless of whether they fall under the headings of labor or materials or something else.

Steps to perform ABC

1. Analyze all Activities performed in the laboratory
2. Gather all the Costs incurred in the period to perform TTI tests.
3. Trace Costs to the activities/tests
4. Allocate the overhead costs using allocation rate
5. Analyze the Costs

Declaration

I, the undersigned, declare that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been duly acknowledged.

M.Sc. candidate: Seblewongel Tsehay (B.Sc.)

Signature: _____

Date of submission_____

This thesis has been submitted with our approval as advisors.

Advisor: Signature: Fatuma Hassen (MPH, PhD candidate)

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: Kassu Desta (MSc, PhD candidate)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: Zinegnaw Abiy (PhD)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.