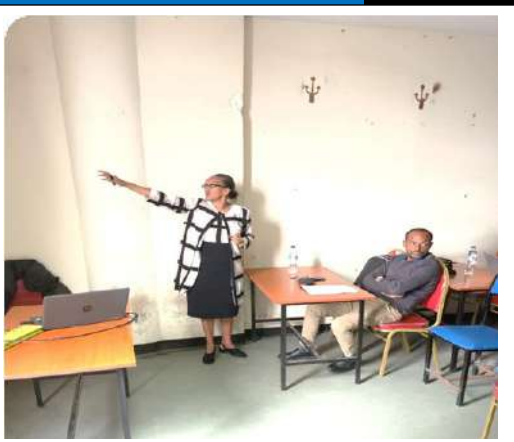


Africa Medical College



Proceedings of the Second Annual Research Conference on

*“Improving the Provision of Quality
and Equitable Health Services”*



June 27, 2024
Addis Ababa



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Africa Medical College

Proceedings of the Second Annual Research Conference

**“Improving the Provision of Quality and Equitable
Health Services”**

June 27, 2024

Addis Ababa

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Proceedings of the Second Annual Research Conference on “Improving the Provision of Quality and Equitable Health Services”, June 27, 2024

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PREFACE

Africa Medical College, as a privately owned organization, is mandated to promote and enhance research focusing on knowledge and technology transfer consistent with the country's priority needs. To discharge these duties, it has to undertake and encourage relevant study, research, and community services in national and local priority areas (Higher Education Proclamation No. 1152/2019, Articles 4.2 and 8.3).

Accordingly, Africa Medical College organized and launched, through the Research and Publication Office (RPO), two annual research seminars and two annual conferences.

Research seminars

The first research seminar, marked by a one-day training session for the academic and support staff, was conducted on 22 August 2022. The training was offered by Professor Abraham Haileamlak, a prominent cardiologist serving at Jimma University. During the second seminar, which took place on February 9, 2024, three research papers were presented and deliberated on by the academic staff of the College. The Seminar gathered more than 27 participants.

Annual research conferences

The First Annual Research Conference was held on the theme "Evidence for Health-Related Sustainable Development Goal" on February 17, 2023. Its aims were encouraging relevant research works that contribute to improving research practices in national and local priority areas,

disseminating research findings, and fostering awareness of academic and administrative staff about research and development activities on health and medical education. RPO strongly believes that the experience RPC gained through organizing the first conference was immensely important to hold the Second Annual Conference on 27th June 2024 on the theme "Improving the Provision of Quality and Equitable Health Services". Its main purposes were encouraging relevant research works, improving research practices in national and local priority areas, disseminating the findings of the study, and developing awareness of the academic and administrative staff of AMC about research and development activities on health and medical education.

After the College had announced a Call for Papers, the College received an adequate number of research papers from higher education institutions. The Research and Publication Committee therefore then selected four of them using a Review Score Sheet developed by the Ethiopian Academy of Sciences. However, one researcher informed the Research and Publication Committee that he was unable to come to the conference after he had submitted his paper. The Committee, thus, decided to go ahead with only the three selected documents.

Publications

The RPO has prepared and published reports and proceedings for the seminars and conferences and disseminated them to stakeholders in soft and hard copies. The

Office has also published seven issues of highly informative quarterly newsletters and distributed them to stakeholders in hard and soft copies. The soft copies are sent out through emails and telegram accounts. Additional copies of the documents can be obtained from the Research and Community Service Office in hard and soft copies and accessed at africollege@amc.edu.et and +251 911 14 70 23, +251 911 66 30 41, +251 115 50 11 99, and +251 911531142.

The Research and Publication Committee would like to thank those who willingly submitted their papers when the Call for Papers was announced and those who came forward after their research works had been selected. The Committee is also grateful to the management of Africa Medical College, specifically Dr. Berhane W/Georgis, President of AMC, and Dr. Mekonnen Belay, V/President of AMC, who foresaw

the importance of such academic practices to our College and made everything possible to make the Conference a reality.

Africa Medical College is of the view that the Conference provided an effective forum for the College's academicians and researchers to advance their knowledge of research. The Guest of Honor, Dr. Eyob Ayenew, Private Higher Education Institutions Services Desk Head, at MoE, who has a great deal of experience in higher education and quality assurance, in particular, was believed to have motivated and encouraged participants to engage in research and community services. He underlined research as one of the pillars of higher education institutions and the basis for academic staff promotion and, therefore, there is no way to go around it.

Kassahun Kebede (PhD),

Research and Community Service Head

OPENING MESSAGE FROM DR. MEKONNEN BELAY, V/P AFRICA MEDICAL COLLEGE



Dr Mekonnen Belay, Vice President of the College

Dear Dr. Eyob Ayenew, Private Higher Education Institutions Services Desk Head, Ministry of Education, Guest of Honor and Keynote Speaker of the Conference,

Dear colleagues, lecturers, researchers, ladies, and gentlemen.

On behalf of African Medical College, I would like to express my sincere gratitude and welcome you to this Second Annual National Conference to be held on the theme “Improving the Provision of Quality and Equitable Health Services”.

Ladies and gentlemen,

Africa Medical College gives due consideration to research and community services. In the current academic year, it has set aside considerable budget to fund researches and community services that may be undertaken by the academic and support staff. Some of the College’s academic staff members have undertaken many relevant studies and community services.

The College nonetheless believes more has to be done in the future to increase the number of staff members who are engaged in research and community service activities. That is one reason for organizing this conference. The agenda of this Conference covers interesting topics related to theoretical and practical aspects of health and medical practices and encourages both experienced and novice researchers of the College to present their papers and share their insights and research findings with the internal and external research community. The College also encourages our female colleagues to make their level best in making their appearance on such events. One of the presenters, for instance, is a female scholar who presented a study entitled “Reaching those at risk: Active Case Detection and Tracing of Household Contacts in A Leprosy Hotspot Woreda, Kokosa, Oromia Region, Ethiopia.

I hope the methods of scientific analysis used by the presenters will help those who are and who will want to engage in research activities in the future. It is therefore my hope that this conference will achieve its objectives by providing an effective forum for academicians, researchers, and health practitioners to advance knowledge.

I would like to end my speech by thanking and appreciating the President and owner of the College, Dr. Berhane W/Georgis, for his unreserved support for all planned activities and extend my thanks to the Research and Community Service Head and Research and Publication Committee members who are

working hard to create scientific platforms on which the academic and support staff of the College can participate in and contribute to. I would also like to say thank you to the Guest of Honor, Dr. Eyob Ayenew who honored us with his attendance despite his crowded work schedule and shared his invaluable experience and expertise with us.

Finally, I wish participants a very productive conference with exciting and encouraging discussions and exchange of knowledge.

Thank you.

**KEYNOTE ADDRESS BY THE GUEST OF HONOUR, DR. EYOB
AYENW, MOE, PRIVATE HIGHER EDUCATION INSTITUTIONS
SERVICES DESK HEAD**

Honorable Dr.
Mekonen Belay,
V/President of
Africa Medical
College,

Distinguished
Guests,
Participants, and
ladies and
gentlemen,

I am pleased to
be here among
scholars who have dedicated their time and
energy to teaching learning and scientific
research.

Dear Participants,

A well-organized research activity is not only important as an academic practice but also an essential engagement for a country's development. As an official from the Ministry of Education, I must inform you that research is one of the pillars of a higher education institution and the government of Ethiopia believes research undertaken by higher education institutions is one of the vehicles of social, economic and technological development of the country. Any research conducted by the academic staff, therefore, should solve societal problems and boost our economic and technological capacity.

In my opinion educational research helps individual educators to teach more comprehensively and effectively, enhance



student learning,
attract students to
STEM professions,
and increase
professional
satisfaction.

Higher education
research improves
educational practice
by analyzing and
understanding the
world of education
by helping explore

issues, share policy, and improve practices. I firmly believe conducting research in health and medical areas and disseminating the results to stakeholders is vital to influencing policymakers to make data-driven decisions and encourage researchers to do research activities in certain thematic areas.

As you are well aware, the focus of research in health areas is guided by the Ministry of Health and higher education institutions. engaged in education and training health professionals. Nevertheless, there is a shortage of funds to adequately support research in thematic areas a lack of multidisciplinary perspectives and an absence of strong research institutions are among some of the bottlenecks of research and development in health areas in Ethiopia. The Ministry of Education has thus developed a National Research Policy and Strategy which has identified certain research thematic areas to guide the research

and development sector in Ethiopian higher education institutions.

Finally, I want to end my speech by wishing you a successful annual research conference.



OESOPHAGEAL CANCER PATIENT IN ADDIS ABABA, ETHIOPIA: COST OF ILLNESS AND FACTORS ASSOCIATED 1 WITH COST VARIABILITIES

Berhe Dessalegn¹



Abstract

Background

Oesophageal cancer, the sixth leading cause of cancer-related deaths globally, causes over half a million deaths annually. Higher morbidity and mortality rates are found in Eastern African countries, including Ethiopia. However, no studies have been conducted in Ethiopia on the costs of illness and factors associated with the cost variability of the disease.

Objective

The aim of the study was to estimate the cost of illness and factors contributing to cost variability among oesophageal cancer patients at health facilities in Addis Ababa, Ethiopia.

Methods and materials

The study was conducted from February 2019 to August 2020 using a cross-sectional study design to estimate the costs of illness for oesophageal cancer in six healthcare facilities in Addis Ababa. A total of 338 oesophageal cancer patients aged 18 years and above were included in the study. Epi-Info version 7 was used for data entry, and the cleaned data were

transferred into SPSS version 23 for analysis. Descriptive statistics were carried out to provide a summary of each of the study variables. Percentages and frequencies were used for the categorical variables. However, the data violated linear regression assumptions, so non-parametric Kruskal-Wallis (>2 independent variables) and Mann-Whitney (2 independent variables) were used to compare mean ranks. A p -value of <0.05 was declared significant.

Results

The study found that the median (interquartile range) outpatient cost was Ethiopian Birr (ETB) 11,380.40 (6,700.0, 17,200.0). The total direct medical cost was ETB 4,358,135.0, and the median (interquartile range) investigation cost was ETB 7,689.0 (4,000.0, 12,000.0), respectively. The total (direct medical and direct non-medical) and median outpatient direct costs were ETB 4,981,337.0 and 12,750.0, respectively. The total direct inpatient cost was ETB 1,769,002.0, and the median (interquartile range) direct inpatient cost was ETB 9,450.0 (6,016, 14,275.0). The study identified that surgical procedures, stage at diagnosis, gender, and number of visits to medical facilities were the causes for cost variability predictors of oesophageal cancer treatment.

Conclusions

This study found that the cost of illness for oesophageal cancer was higher, and several factors were identified that determined the cost of illness. These factors include surgical procedures, stage at diagnosis, gender, and frequency of visits to health facilities. The study found that these factors had an impact on the overall costs associated with oesophageal cancer care.

Keywords

Oesophageal cancer, cost of illness, cost, Addis Ababa, Ethiopia

¹

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Introduction

Oesophageal cancer is a common type of cancer worldwide, with over half a million new cases diagnosed each year, making it the seventh most common cancer. Unfortunately, it is also a leading cause of death, with more than half a million people dying from the disease, making it the sixth leading cause of death. The prognosis for esophageal cancer is poor, with only about 20% of patients living for five years [1]. The aggressive nature of oesophageal cancer has made it a significant public health concern globally [2].

In many rural areas of developing countries, healthcare coverage is insufficient, and as a result, many esophageal cancer patients die without receiving timely treatment. Studies showed that more than half of all cancer cases occurred in low- and middle-income countries. Esophageal cancer is the most common disease in Eastern Africa, and the reason is due to various factors, including the aging of the population and an increase in risk factors such as substance abuse and obesity [3].

Oesophageal cancer is responsible for most cancer-related morbidity and mortality in sub-Saharan African nations. The highest incidence rate extends from Ethiopia to South Africa, with Eastern Africa showing disproportionately higher incidence rates [4].

According to the global cancer database of 2002, Ethiopia had the highest incidence of oesophageal cancer patients. The data estimated that there were 28 cases of oesophageal cancer in Ethiopian men and 10 cases in women for every 100,000 people. Ethiopia ranked first and tenth for

male and female cases of oesophageal cancer, respectively [5].

Oesophageal cancer has the highest overall treatment cost compared to many other cancer types. This is mainly associated with an increase in the average cost of the disease, which is influenced by several factors, including clinical stages, treatment types, patients' residency, number of hospital visits, gender, age at the time of diagnosis, and pathologic types [6]. A study conducted in Ethiopia has shown that the cost of oesophageal cancer diagnosis and treatment is much higher than other cancer types [7].

Cancer treatment can be expensive and the cost can vary depending on the type, stage, and length of the tumor. Therefore, cost assessment is an important activity for both decision and policy makers as well as the patients themselves to make their own fair decision regarding the treatment of oesophageal cancer. Early diagnosis and treatment of cancer can improve patients' quality of life and reduce cancer mortality rates. However, underdeveloped countries have disproportionately limited resources, despite accounting for more than half of all cancer cases worldwide [8].

In comparison to other cancer types, such as breast and colorectal cancer, the cost of illness for esophageal cancer is higher. In addition, the cost of illness of the disease varies between genders and stage at diagnosis. According to studies, the costs of illness of the disease surpassed people's entire incomes and impacted overall health expenditures [6,9,10].

Oesophageal cancer is a common type of cancer in Ethiopia, but the costs associated with the disease have not been adequately

estimated. This includes direct, indirect, and other expenditures. The study conducted by the authors was the first of its kind to estimate the costs of illness of the disease in Ethiopia. The results of this study can provide valuable insights for health professionals, programmers, politicians, and other researchers to design appropriate strategies on how to minimize costs associated with the illness, particularly for people who are struggling financially.

Materials and Methods

Study design and Setting

A cross-sectional study design was conducted at six health facilities in Addis Ababa, the capital city of Ethiopia, between February 2019 and August 2020. The study facilities were selected based on caseloads and the availability of cancer diagnostic and treatment services. To determine the sample size, single population mean formula was used. The preliminary assessments and expert opinions revealed 3,500 and 700 Ethiopian Birr as the mean and standard deviation (δ), respectively. However, due to the minimal cases follow of the disease, all the participants were recruited using a consecutive sampling method and it took 18 months to recruit eligible cases.

A structured questionnaire that was both closed-ended and partially open-ended was utilized to assess the financial burden of the cases. The interviews were conducted face-to-face, and direct costs were divided into direct medical and direct non-medical costs based on patient recalls and available receipts. The indirect costs of illness were calculated by measuring productivity lost during outpatient and inpatient visits. The

interviews were conducted in Amharic, which is the official working language of the Federal Democratic Republic of Ethiopia. The tools were initially designed in English, then translated into Amharic by language translators, and then back into English to ensure consistency between the Amharic and English translations. To enhance the questionnaire's validity, cancer research professionals evaluated it. A pretest was also conducted to improve the study tools' applicability.

The supervisor and data collectors received two days of training on the purpose of the study. The data collectors were selected based on their prior participation in cancer research, moral integrity, and academic preparation. Additionally, the primary investigator continuously oversaw the process of data collection and checked for completeness of the data regularly. Epi-Info version 7 was used for data entry, and the cleaned data were transferred to SPSS version 23 for analysis.

Descriptive statistics were used for each of the study variables, and percentages and frequencies were employed to present categorical variables.

The normality of the data was assessed using normality plots, Q-Q plots, histograms, Kolmogorov-Smirnov, and Shapiro-Wilk statistical tests. For normally distributed data, the mean and standard deviation were calculated, while for skewed data, the median and interquartile ranges were estimated. The results were presented using texts, tables, and graphs. The population parameter was estimated using a 95% confidence interval. The direct cost was calculated using a micro-costing bottom-up approach, which is the

most common cost estimate in healthcare [11], and the human capital approach was applied for estimating the indirect costs of illness [12].

The prevalence-based cost-of-illness analysis was used for estimating the total costs of illness. It considered all medical costs incurred during a specified time and provides decision-makers with a way to quantify the economic burden of diseases and injuries in monetary terms. The cost-of-illness approach divides the gross economic impact of an illness into direct and indirect costs, which can be used to inform policy and planning[13].

The normality assumptions of linear regression were violated by the data distribution. Even after performing a log transformation, the data continued to violate the normality assumptions.

Therefore, non-parametric tests were used to compare the means of the two groups. The Kruskal Wallis test was used for variables with more than two independent groups, and the Mann-Whitney test was used for variables with only two independent variables. Statistical significance was declared at p-values of <0.05 (95% CI).

Results

Socio-demographic and economic characteristics of study participants

This study involved 338 patients with histologically confirmed and clinically staged oesophageal cancer, which represents approximately 96.3% of the patients who were approached for participation. The mean age of the

participants was 54.30 (± 12.49) years, and female participants accounted for about 47.6% of the study participants. More than 93% of participants were above the age of 35, and 52% were above the age of 55.

Approximately two-thirds of the research participants were from rural areas and were illiterate or unable to read and write. Muslims and farmers made up 52% and 38% of all participants, respectively. At the time of data collection, more than 75% of the participants were married. Additionally, half of the participants earned less than one dollar per day, or 28.0 Ethiopian Birr. About 73% of the participants had to travel long distances to receive cancer-specific care, and almost all of them had to spend more than \$7 USD or 198 Ethiopian Birr on a single trip for transportation costs. Furthermore, almost 75% of the patients who took part in this study covered their own medical expenses or paid from their own pockets.

Direct outpatients' cost

In the study area, patients diagnosed with oesophageal cancer incurred a median cost of 11,380.40 Ethiopian Birr (ETB) or \$404 USD for outpatient direct medical expenses. The range of costs for outpatient care varied from 6,700.0 to 17,200.0 ETB or \$238 to \$610 USD. The total amount paid by participants for direct medical expenses was approximately 4,358,135.0 Ethiopian Birr or \$154,534 USD. Most of these costs were attributed to investigation and treatment expenses, which amounted to 2,870,539.0 ETB and 1,390,209.0 ETB or \$101,793 and \$49,298.2 USD, respectively. The investigation cost had a median (IQR) of 7,689.0 ETB (4,000.0,

12,000.0) or 272.7 USD (142, 426 USD), respectively. Consultation fees were paid by approximately 96% of the participants, with a median cost of 100 ETB or 3.6 USD per participant. The total direct non-medical cost was 745,080.0 ETB or 26,421.3 USD, and the median (IQR) costs was 1,690.0 ETB or 60 USD (690.0, 3090.0 ETB) or (24.5, 110 USD), respectively. Transportation fees were the

largest component of the direct non-medical costs, with a median and interquartile range of 500.0ETB or 18 USD (300.0, 800.0) ETB or (11.0, 28.4 USD), respectively. The median and interquartile range of the direct costs (medical and non-medical) was 12,750.0 (7,927.5, and 18,650.0), respectively (Table 1).

Table 1: Oesophageal cancer, patients' side direct outpatient costs in Addis Ababa, Ethiopia from February 2019 to August 2020.

Direct costs in Ethiopian Birr	Sum	Median	IQR
Direct medical cost (323)	4,358,135.0	11,380.0	(6,700.0,17,200.0)
Consultation Fees (n=323)	97,387.0	100.0	(40.0,450.0)
Investigations Fees (n=307)	2,870,539.0	7,689.0	(4,000.0,12,000.0)
Treatments and disposable supplies(n=285)	1,390,209.0	3,900.0	(2,000.0,5,950.0)
Direct non-medical cost(n=337)	745,080.0	1,690.0	(690.0,3090.0)
Transportation Fees (n=312)	249,480.0	500.0	(300.0,800.0)
Non-prescribed medicine (n=309)	149,293.0	200.0	(10.0,900.0)
Accommodations (n=156)	346,307.0	1,900.0	(1,400.0,2,500.0)
Total direct cost (n=327)	4,981,337.0	12,750.0	(7,927.5,18,650.0)
Indirect outpatients' patients side costs	1,868,598.0	10,000.0	(5,000.0,15,000.0)

The median duration of outpatient treatment for oesophageal cancer was 6.0 months, with an interquartile range of (5.0, 8.0) months. A total of 2,450 outpatient visits were recorded for diagnosis and treatment services. Patients

who missed work due to the disease had a median of 120.0 days (interquartile range of 79.0 to 200.0 days). The total indirect cost of oesophageal cancer over the outpatient period was approximately 1,868,600,800 Ethiopian Birr or 66,270.0 United States dollars (Table 2).

Table 2: Oesophageal cancer, patient side indirect outpatient costs in Addis Ababa, Ethiopia from February 2019 to 2020.

Patient side indirect cost	Sum	Median	IQR
Duration of stay as outpatient (in months)	2,219.0	6.0	(5.0,8.0)
Number of outpatient visits	2,458.0	6.0	(4.0,9.5)
Days remained out of work	46,467.0	120.0	(79.0,200.0)

Direct patient-related inpatient costs

Out of all the participants in the study, 157 patients (46.5%) had been hospitalized for at least one day in a public or private healthcare facility. Of these hospitalizations, 82 (52.6%) were male and 74 (47.4%) were female oesophageal cancer patients. Approximately 85.3% of the 157 patients hospitalized for oesophageal cancer had paid for the direct medical costs or paid out of pocket for treatment and investigation. The total cost for hospitalization of these patients was 1,279,005.0 Ethiopian Birr or 45,355 USD. The median cost was 6,702.0 ETB or 238 USD, with an interquartile range of 3,839.0 to 11,011.3 ETB or (136.2, 390.5 USD). The median cost of medical treatment and consumables was 2,300.0 Ethiopian Birr or 82 USD, with a range of 1,500.0 to 4,500.0 ETB or 53.2 to 159.6 USD.

Most of the direct medical costs of the illness were due to the cost of investigation,

which amounted to 745,008.0 Ethiopian Birr. The median cost was 4,000 Ethiopian Birr, and the interquartile range was 2,075.0-8,000. The total direct non-medical cost was 489,997.0 Ethiopian Birr, with a median cost of 2,538.0 Ethiopian Birr and interquartile ranges of 1,561.0 and 3,950.0 Ethiopian Birr. The cost of accommodation was the second highest direct non-medical cost, totaling 180,826.0

Ethiopian Birr, with a median cost of 900.0 Ethiopian Birr and an interquartile range of 500.0 to 1,500.0 Ethiopian Birr. The total direct medical and non-medical costs amounted to 1,769,002.0 Ethiopian Birr (Table 3).

Table 3: Oesophageal cancer patients' hospitalization costs in Addis Ababa, Ethiopia, from February 2019 to August 2020

Direct costs in Ethiopian birr	Sum	Median	IQR
Direct medical cost (n=152)	1,279,005.0	6,702.0	(3,839.0,11,011.3)
Consultation	33,630.0	60.0	(10.0,200.0)
Investigations	745,008.0	4,000.0	(2,075,8,000.0)
Treatment and disposable supplies	500,367.0	2,300.0	(1,500.0,4,500.0)
Direct non -medical cost (n=153)	489,997.0	2,538.0	(1,561.0, 3,950.0)
Non-prescribed medicine	187,833.0	900.0	(407.0,1,500.0)
Accommodations	180,826.0	900.0	(500.0, 1,500.0)
Other expenses	121,878.0	800.0	(500.0,1,000.0)
Total (n=152)	1,769,002.0	9,450.0	(6,016,14,275.0)

Indirect costs for hospitalization, radiotherapy, chemotherapy, and surgical treatment costs

The total amount of Ethiopian Birr (ETB) lost from hospitalized patients was 363,899.0 Birr. The median amount lost was 1000.0 Birr, and the interquartile range

was 900.0 to 2,400.0 Birr. These lost wages were a result of 2,897 wasted working days, with a median of 15 days and an interquartile range of 10.0 to 25.0 days.

The average hospital stay for the 122 patients was 34 days. Overall, there were 2,499.0 days of hospitalization with a

median of 13 days and an interquartile range of (7.0, 20.0). The combined cost of radiotherapy, chemotherapy, and surgery was 545,342.0 ETB, with a median cost of 1,750.0 ETB and an interquartile range of 1,100.0 and 4,200.0 ETB. Chemotherapy alone cost 348,308.0 ETB, with a median cost of 2,500 ETB and an interquartile range of 1,850 and 12,060.0 ETB. Surgery alone costs 161,091.0 ETB, with a median cost of 1,500.0 ETB and an interquartile range of 900.0 and 2,500.0 ETB.

Factors associated with variation in oesophageal cancer patients' costs of illness

The study revealed that there was no significant difference in the median outpatient costs of illness between male and female oesophageal cancer patients. However, a statistically significant difference was observed between male and female oesophageal cancer patients in the case of inpatient median rank of costs of illness. Female oesophageal cancer patients were subjected to pay more compared to male cases, with a p-value of < 0.003 (Table 4).

Based on the findings of the study, the following variables, marital status,

residency, comorbidities, and prior awareness about oesophageal cancer, did not have a statistical difference on the median rank of costs of illness in both outpatient and inpatient categories. However, a significant statistical median cost difference was observed in outpatients oesophageal cancer patients who were accompanied by family members. The patients who were accompanied were subjected to pay more than those who did not accompany, with a p-value of < 0.049 (Table 4).

In the case of oesophageal cancer patients, no statistically significant median cost was estimated in the variables of ever health facility admission, administration of chemotherapy, and radiotherapy as treatment options for the disease, both in outpatient and inpatient settings.

However, the median costs incurred for surgery in both outpatient and inpatient oesophageal cancer patients showed a statistically significant difference. Those who underwent surgery paid more than those who did not, with p-values of < 0.008 and < 0.002, respectively (Table 4).

Table 4: Oesophageal cancer patients' median, mean rank, and factors that affect costs in Selected healthcare facilities from February 2019 to August 2020, Addis Ababa, Ethiopia.

Variables		Outpatient cost in		Inpatient cost in ETB	
		Median	Mean	Median	Mean rank
Gender	Male	12,890.0	169.0	8,405.0	68.0
	Female	12,160.0	168.0	11,580.0	90.0
Marital status (current)		Mann-Whitney U (p <		Mann-Whitney U test (p <	
	No	12,980.0	171.0	8,725.0	70.0
	Yes	12,692.0	168.0	10,052.0	81.0
Residency		Mann-Whitney U (p <		Mann-Whitney U test (p <	
	Urban	13,360.0	178.0	10,877.0	86.0

Variables		Outpatient cost in		Inpatient cost in ETB	
		Median	Mean	Median	Mean rank
	Rural	12,125.0	163.0	8,750.0	73.0
Comorbidity		Mann-Whitney U (p <		Mann-Whitney U test (p <	
	No	12,900.0	170.0	10,100.0	82.0
	Yes	11,902.0	164.0	7,775.0	67.0
Prior awareness about oesophageal cancer		Mann-Whitney U (p <		Mann-Whitney U test (p <	
	No	12,599.0	165.0	9,450.0	79.0
	Yes	14,115.0	182.0	10,181.0	80.0
Presence of companion		Mann-Whitney U		Mann-Whitney U test	
	No	12,025.0	155.0	6,656.0	55.0
	Yes	12,900.0	170.0	9,912.0	81.0
Ever admitted		Mann-Whitney U		Mann-Whitney U	
	No	12,400.0	159.0	4183.0	23.0
	Yes	12,950.0	179.0	9550.0	79.0
Underwent surgery		Mann-Whitney U		Mann-Whitney U	
	No	12,052.0	161.0	7,987.0	68.0
	Yes	15,705.0	196.0	11,180.0	91.0
Chemotherapy		Mann Whitney		Mann-Whitney U	
	No	12,345.0	166.0	10,084.0	81.0
	Yes	15,131.0	186.0	8,496.0	72.0
Radiotherapy		Mann-Whitney U		Mann-Whitney U	
	No	7,890.0	108.0	9,500.0	79.0
	Yes	7,650.0	102.0	10,300.0	74.0

Statistically significant variations in illness costs were observed for outpatients with oesophageal cancer based on the stage of the disease at the time of diagnosis ($P < 0.0001$). Patients diagnosed at advanced stages (III and IV) experienced higher illness-related costs compared to those diagnosed at early stages (I and II), with a statistically significant median difference. On the other hand, there was no statistically significant difference in illness costs for inpatient oesophageal cancer patients ($P < 0.12$) (Table 5).

In the case of the outpatient category, a statistical difference in costs was observed among those who initiated their treatment at late stages. This means that those who started their treatment at advanced stages paid more money ($p < 0.0001$). However, this was not true in the case of the inpatient

category ($p < 0.36$). Age was not found to be an important factor in bringing a statistically significant difference in median cost of illness for outpatient and inpatient patients (Table 5).

The study found that the employment status of patients had a statistically significant association with the median difference of the costs of illness in the inpatient categories (p -value < 0.007), but not in the outpatient categories ($P < 0.16$). On the other hand, the monthly income and educational status of oesophageal cancer patients had significant differences in median outpatient cost at p -values of < 0.011 and < 0.036 , respectively, but this did not apply to the inpatient participants (Table 5).

The study found that for outpatient patients, the types of health facilities that participants first visited, the frequency of

facility visits, and traveling a long distance to Addis Abeba from regional states were statistically significant for costs variabilities, with p-values of < 0.0001 , < 0.0001 , and < 0.026 , respectively. However, there was no statistically significant variation in the median costs for hospitalized patients (Table 5).

Table 5: Addis Ababa health facilities, Addis Ababa, Ethiopia: Median, Mean Rank, and Factors Associated with Costs of Illness from February 2019 to August 2020

	Variables	Outpatient cost in		Inpatient cost in ETB	
		Median	Mean rank	Median	Mean
Age categories	<35	15,400.0	198.0	9,050.0	75.0
	35-44	11,500.0	149.0	11,056.0	76.0
	45-54	11,750.0	158.0	8,250.0	78.0
	>55	13,330.0	175.0	10,052.0	81.0
Stage at time of diagnosis		Kruskal Wallis test		Kruskal Wallis test (p<0.95)	
	Stage I	6,900.0	103.0	4,805.0	54.0
	Stage II	8,302.0	120.0	7,470.0	67.0
	Stage III	12,900.0	175.0	9,677.0	80.0
	Stage IV	16,575.0	208.0	11,200.0	90.0
	Unknown	12,640.0	172.0	13,040.0	82.0
Stage at time of treatment initiation		Kruskal Wallis test		Kruskal Wallis test (p<0.12)	
	Stage I	7,495.0	107.0	4,805.0	55.0
	Stage II	8,450.0	126.0	8,402.0	71.0
	Stage III	12,900.0	173.0	9,550.0	80.0
	Stage IV	16,962.0	201.0	10,800.0	86.0
	Unknown	10,483.0	158.0	9,113.0	74.0
Occupational status of participants		Kruskal Wallis test		Kruskal Wallis test (p<0.36)	
	Farmers	12,200.0	153.0	7,470.0	66.0
	Gov't	15,690.0	188.0	10,827.0	85.0
	House wife	11,970.0	171.0	12,395.0	96.0
	Merchant	13,310.0	186.0	8,496.0	63.0
	Private	13,025.0	188.0	8,887.0	72.0
Monthly income in Ethiopian Birr (ETB)		Kruskal Wallis test		Kruskal Wallis test (p<0.007)**	
	< 1000 ETB	12,700.0	170.0	9,612.0	79.0
	1001-3000	11,952.0	159.0	9,050.0	77.0
	3001-5000	12,725.0	162.0	9,550.0	73.0
	> 5000 ETB	24,548.0	245.0	11,600.0	93.0
Educational status of participants		Kruskal Wallis test		Kruskal Wallis test (p<0.76)	
	Unable to read and write	11,783.0	156.0	9,002.0	74.0
	1-8 (Grade)	15,200.0	190.0	10,131.0	81.0
	9-12 (Grade)	14,430.0	187.0	9,820.0	94.0
	Diploma and	12,650.0	185.0	8,402.0	65.0
Region		Kruskal Wallis test		Kruskal Wallis test (p<0.23)	
	Addis Ababa	14,355.0	182.0	12,180.0	96.0
	Oromia	12,035.0	160.0	9,220.0	73.0
	Amhara	16,180.0	197.0	11,610.0	86.0
	SNNP	10,705.0	141.0	8,000.0	71.0
	Somali	24,348.0	261.0	19,899.0	113.0

	Variables	Outpatient cost in		Inpatient cost in ETB	
		Median	Mean rank	Median	Mean
	*Others	20,135.0	228.0	11,255.0	83.0
Level of health facility at first presentation		Kruskal Wallis test		Kruskal Wallis test (p<0.13)	
	Health post	13,300.0	182.0	7750.0	62.0
	Health center	11,102.0	147.0	9335.0	78.0
	Private clinic	18,225.0	209.0	10,200.0	83.0
	Private	14,550.0	189.0	12,797.0	99.0
	Public hospital	13,125.0	179.0	8,725.0	73.0
First contacted health professional		Kruskal Wallis test		Kruskal Wallis test (p<0.16)	
	Health	12,950.0	174.0	8,190.0	72.0
	Nurse	12,880.0	175.0	10,577.0	84.0
	Health officer	12,110.0	152.0	9,450.0	76.0
	Medical	13,330.0	179.0	10,200.0	80.0
Distance to Addis Ababa in Kilometer (km)		Kruskal Wallis test		Kruskal Wallis test (p<0.76)	
	<100 km	12,990.0	163.0	11,400.0	91.0
	100-300 km	11,096.0	152.0	9,060.0	75.0
	301-500 km	12,749.0	174.0	9,820.0	78.0
	>500 km	13,750.0	185.0	9,627.0	77.0
Number of health facilities visited		Kruskal Wallis test		Kruskal Wallis test (p<0.55)	
	<3	12,300.0	168.0	6,202.0	105.0
	3-6	12,800.0	157.0	9,450.0	77.0
	7-10	12,915.0	177.0	10,158.0	76.0
	>10	12,499.0	185.0	11,550.0	85
Frequency of health facilities visited		Kruskal Wallis test		Kruskal Wallis test (p<0.44)	
	<4	11,300.0	154.0	9,250.0	80.0
	4-10	12,300.0	164.0	10,163.0	77.0
	11-17	16,150.0	201.0	8,496.0	72.0
	>17	16,165.0	198.0	12,100.0	96.0

Kruskal Wallis test (p<0.024)**Kruskal Wallis test (p<0.53)

*Others: “Tigray, Gambella, Dire dawa, Harar” and ** “Significant at 95% confidence level”

Discussion

This study was the first of its kind to systematically estimate the costs of illness associated with oesophageal cancer in Ethiopia. The study aimed to estimate the costs of illness for the disease over a period of 18 months. The illness was much more expensive than other cancer types, and the study had identified cost variability determinates, including the frequency of health facility visits, residential area of the

participants, and stage at the time of diagnosis.

According to the study, the median outpatient cost of illness was \$452.2 (IQR=\$281.1, \$661.3), and the total cost of illness over 18 months was \$176,643.0. The overall cost of hospitalization was \$62,730.0, with the median and IQR of \$335.1 (IQR= (\$213.3, 506.2), respectively. The cost of illness for oesophageal cancer in this study was

significantly lower than the costs estimated in China[6].

There are several possible explanations for the variation in the study results. One reason could be the differences in the two populations' or communities' service purchasing ability and willingness to pay medical costs, as well as the difference in socio-economic status. Another reason is that the Chinese study had a longer duration of about ten years, while our study only lasted for 18 months or 1.6 years. Additionally, differences in research settings and study durations could also contribute to the variation in the results.

Most of the overall expenses were attributed to the direct medical costs of illness. Specifically, the bulk of medical expenses for both inpatient and outpatient patients were related to the cost of the investigation. The median medical cost of illness was \$776.1, which was higher than the \$407.0 median cost of cervical cancer in the same settings [14] . Patients with oesophageal cancer may require additional qualified experts or specialists, such as dieticians, compared to patients with cervical cancer. This can lead to a cost of illness disparity between the two patient groups.

Our estimations suggest that the median cost of care varies depending on the stage of diagnosis.

Patients diagnosed at stages III and IV have higher costs than those diagnosed at stages I and II.

As the cancer's stages advance, its costs continue to rise. Our estimate is comparable with this study, as the cost of illness increases with the stage at the

time of diagnosis. However, our estimated cost was lower than the cost of illness estimated by this study [15]. The cost variability can be attributed to several factors, including the ability and willingness to pay for medical services and the socio-economic status of the two populations or communities.

The cost of cancer care depends on various factors, including the type, stage, and duration of the illness. Compared to other cancer types, the cost of illness for oesophageal cancer is higher. The cost of illness not only affects the patient but also their family members, society, healthcare providers, and the productivity of the entire economy of the country [10,16]. According to a Chinese study, esophageal cancer has caused financial pressure in communities and at patients' households in high-incidence areas [17]. Our study's findings are consistent with several previous studies conducted elsewhere in the world.

Due to the complexity of the methods used for diagnosing and treating esophageal cancer, which include surgery, chemotherapy, radiotherapy, neoadjuvant therapy, and various laboratory investigations, the cost of illness for this disease is higher than other cancer types. Additionally, there can be follow-up visits after treatment, which would increase the cost of the illness [9,18,19].

Our study found that the cost of investigation was higher than other costs, which is consistent with a similar study conducted in China [20]. After conducting estimations, we found that the investigation costs had a significant impact on the overall costs of illness. Previous research has shown that

estimating the costs of illness can help programmers and policymakers allocate resources based on evidence and ensure fairness [15]. Contrary to our study, a different study revealed that the cost of illness for the disease was higher for the costs of treatments than for investigation [6].

The cost of treating oesophageal cancer varies depending on the stage of the disease at the time of diagnosis. Patients in stages III and IV had to pay more compared to stages I and II [20]. In addition, according to a study, the cost of oesophageal cancer treatment has been steadily increasing from year to year [21]. The study we conducted align with previous research, which demonstrated that the cost of illness increases as the disease progresses through its stages.

Patients with advanced oesophageal cancer incurred higher costs compared to those in the early stages of the disease [18]. Furthermore, a comparable study revealed similar findings to ours, indicating that patients with stage I and stage IV oesophageal cancer had the lowest and highest costs, respectively [15].

Patients diagnosed at stages III and IV experienced a twofold increase in healthcare costs compared to those diagnosed at stages I and II [22]. Our estimation is in line with earlier studies, which have found that the cost of illness for a disease increases as it becomes more complicated and worsens.

This study further strengthens our findings that as a disease progresses, multiple treatment methods may be required, leading to an increase in the cost of illness [23]. This study supports our finding that early

diagnosis of esophageal cancer can lead to lower medical costs [6]. Patients with esophageal cancer often must travel long distances to access cancer care health facilities, as cancer diagnosis and treatment require cancer experts and advanced medical equipment. This can result in additional expenses for patients, including transportation costs such as gas, tolls, and parking fees. Patients with esophageal cancer often must travel long distances to access cancer care health facilities, as cancer diagnosis and treatment require cancer experts and advanced medical equipment. This can result in additional expenses for patients, including transportation costs such as gas, tolls, and parking fees [24]. Our study is like a previous study in that most of our patients were from rural areas and had to pay considerable travel and other fees to come to Addis Ababa.

Strengths and Limitations

Our study in Ethiopia was the first of its kind to quantify the societal burden of oesophageal cancer-related medical costs. We also determined the factors that contribute to the variability in costs of illness. However, there are some limitations to our study. We only used data from patients and their companions to estimate the costs of illness, which means we did not include extra costs that may be associated with oesophageal cancer. Additionally, the cost of illness estimated in our study may be underestimated due to recall bias in self-reported data.

Conclusion

Patients with oesophageal cancer face significant financial burdens due to the high cost of illness associated with this

cancer type. In addition, patients often had to travel long distances to receive medical treatment. The median cost of illness is significantly associated with the stage at the time of diagnosis, surgical procedures, stage at which diagnosis and treatment were begun, and the number of hospital visits. As the stage of the diagnosis and the treatment advance, the entire expense of oesophageal cancer increases. To address this issue, the implementation of a subsidy system for the costs of oesophageal cancer care, specifically treatment and investigation fees, is recommended. However, it is important to note that the study was cross-sectional and may be prone to recall bias, and follow-up studies are recommended to include all costs of illness.

Abbreviations

SD: Standard Deviation

IQR: Inter Quartile Range

USD: United States Dollar

ETB: Ethiopian Birr

EC: Oesophageal cancer

Ethics approval and informed consent

The Institutional Review Board (IRB) of Addis Ababa University College of Health Sciences granted ethical clearance for the study with a protocol number of 080/18/SPH. The study followed the basic ethical principles of the Helsinki Declaration for medical research involving human participants. The Helsinki Declaration emphasizes the right of research subjects to make informed decisions, the recognition of vulnerable groups, and the importance of respecting the privacy and confidentiality of the patient's information [25]. All participants in the study were informed about the

purpose and procedure of the research, as well as their right to withdraw from the study at any time. Each participant provided oral informed consent. The participants agreed that the findings of the study would be subject to publication. They were also informed not to disclose their information to a third party. The information was kept secure and confidential by the first author.

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EFFECT OF NUTRITION BEHAVIOR CHANGE COMMUNICATION ON NUTRITIONAL STATUS AND GESTATIONAL WEIGHT GAIN OF PREGNANT ADOLESCENTS IN WEST ARSI, CENTRAL ETHIOPIA, A CLUSTER RANDOMIZED CONTROLLED TRIAL

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Abstract

When pregnancy occurs in adolescence, the growth and development of the mother and fetus may be hampered due to strong competition for nutrients between the still-growing adolescent and her fetus. Pregnant adolescents remain an underserved population; they lack adequate nutrition knowledge and have low antenatal care attendance; therefore, this study investigated the effect of nutrition behavior change communication (NBCC) through alliance for development (AFD) on nutrition status and gestational weight gain (GWG) of pregnant adolescents. A two-arm parallel cluster randomized controlled community trial was conducted in West Arsi Zone, central Ethiopia,

from August 2022 to July 2023. The nutritional status of the pregnant adolescent was assessed using mid-upper arm circumference. Weight was measured at baseline and at the end of intervention. A total of 207 and 219 pregnant adolescents participated in intervention and control clusters, respectively. The intervention started before 16 weeks of gestation and the intervention group attended four NBCC sessions. NBCC was based on the health belief model (HBM) and it was given at the participants' homes with their husbands. NBCC intervention was delivered by AFDs, community-level health actors. Pregnant adolescents in the control group got routine nutrition education from the health care system. A Linear mixed-effects model and difference in difference (DID) were used to measure the intervention effect after adjusting for potential confounders. After the implementation of the trial, the mean mid-upper arm circumference (MUAC) in the intervention arm significantly increased from the baseline, $P = < 0.001$), the mean MUAC difference in difference (DID) was 1.89 ± 2 , with $P = < 0.001$); the mean GWG in the intervention arm has been significantly increased from the baseline; the mean GWG among intervention group was 9.4 kg and among control group 5.14 kg and the difference in difference was 4.23 kg and this was statically significant $P = < 0.001$). This study demonstrated that NBCC using HBM delivered through AFD was effective in improving the nutritional status and GWG of pregnant adolescents. The results imply the need for the design of model-based nutrition counseling guidelines through front line community health actors to improve nutritional status of pregnant adolescents and associated birth outcomes.

Key words: Pregnant adolescent, Alliance for development, nutrition behavior change communication, nutritional status

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Introduction

When pregnancy occurs in adolescence, the growth and development of the mother and fetus may be hampered due to strong competition for nutrients between the still-growing adolescent mother and her fast-developing fetus, commonly known as "nutrient partitioning"^{1,2}. Alternative theories that may be used in conjunction with nutrient partitioning include the idea that due to gynecological immaturity, safe delivery is sacrificed to allow for optimal fetal growth^{3,4}.

The desirable amount of weight to be gained is associated with optimal outcomes for the mother and infant. A Joint FAO/WHO/UNU Expert Consultation report recommended that healthy, well-nourished women gain 10 to 14 kg during pregnancy, with an average of 12 kg, to increase the likelihood of giving birth to full-term infants with an average birth weight of 3.3 kg and to lower the risk of fetal and maternal complications^{5,6}.

Behavior change communication (BCC) refers to the methodical application of communication that has positive impact on people's understanding, attitudes, and behaviors. This encourages people to take charge of their own health. BCC can promote dietary improvement; and account for individual health beliefs and practices⁷. NBCC (Nutrition behavior change communication) is an approach to change nutrition related behaviors using different strategies, techniques, and teaching materials to bring about practice change that leads to better health through optimal feeding practices and improved dietary habits⁸. BCC is a straightforward strategy for altering behavior. It differs from traditional IEC (Information Education Communication) because, in contrast to BCC, IEC only considers spreading awareness and providing information⁹.

In low- and middle-income (LMIC) countries, as of 2019, there were about 21 million pregnancies among teenagers aged 15 to 19¹⁰. Regarding the magnitude of child marriage in Eastern and

Southern Africa, Ethiopia is among the top three nations. The vast majorities gave birth during adolescence after getting married as children¹¹⁻¹³. The intergenerational effect of malnutrition has been recognized as a major contributing factor to Ethiopia's inclusion among countries with the highest rates of maternal and newborn mortality in the world^{14,15}.

Pregnancy presents a variety of challenges, including nausea, vomiting, fatigue, heartburn, constipation, hemorrhoids, food cravings and aversions¹⁶. These problems may be alleviated by NBCC. Many expectant mothers in developing nations restrict their food intake because of different reasons such as the false belief that smaller babies will have lower delivery complications and the belief that cultural influences will make fetus large and difficult to deliver^{17,18}. This illustrates the lack of adequate information and false beliefs about dietary behaviors among expectant mothers¹⁹⁻²¹.

AFD [Alliance for development], originally known as Women development army [WDAs] are community health volunteers; who are in charge of 30 houses, each of which has one to five networks under them. Six different one-to-five connections formed one WDA²². Ethiopia is an excellent example of a community health initiative with a well-structured health-extension package. The country's primary healthcare unit (PHCU) is at the forefront of PHC²³. A study conducted on contribution of women's development Army or by its new name, AFDs to maternal and child health showed that, they have contributed to the improvement of child immunization service use, minimizes maternal mortality, improved skilled delivery attendance and skilled ANC²⁴, an experience that can be extended to nutrition education, and other developing countries might adapt it.

A systematic review and meta-analysis study conducted in 2021 showed that, the pooled estimated prevalence of teenage pregnancy in Ethiopia was 23.59%²⁵. There are efforts from the government of Ethiopia, to solve adolescent

health and nutrition problems, to mention some; adolescent, and youth health (AYH) programs, including those focused on sexual and reproductive health (SRH) and youth development, have gained attention²⁶ the national adolescent and youth reproductive health (AYRH) strategy of 2007²⁷, comprehensive national adolescent and youth health (AYH) strategy of 2016²⁸ and National nutrition program (NNP II) 2016-2020²⁹; however, they were not effective in the expected level; because, adolescents and youth-related interventions in Ethiopia are uncoordinated, fragmented under various ministries, lack effective policy implementation, underfunded, project-oriented, and lack meaningful engagement of young people³⁰

Compared to adult women, pregnancy at any age during adolescence is associated with a greater possibility of facing eclampsia, puerperal endometritis anaemia, systemic infections, low birthweight, preterm delivery, and neonatal mortality³¹⁻³³. Pregnant adolescents remain underserved population and therefore they can benefit greatly from receiving prenatal health and nutrition education. Adolescents often enter unplanned pregnancy. Different studies showed as few as 27% pregnant adolescents receive ANC services^{34,35} and this makes them even more vulnerable to undernutrition and other adverse health outcomes. To the best of our knowledge there is no community based interventional study which investigated effect of behavioral change model based NBCC through community level health volunteers [AFDs] on nutritional status and weight gain among pregnant adolescents; therefore, this study sets out to generate which can help policymakers and planners at local and national levels to improve nutrition counseling practices.

Methods

Study design, setting and participants

This study was a cluster randomized controlled community trial with a two-arm parallel design

that lasted for a year. This study was conducted in the West Arsi Zone, Oromia region, Central Ethiopia; 250 km from Addis Ababa, the nation's capital. There are 16 Districts in West Arsi Zone (13 rural districts and three towns). A total of 2,929,894 people were estimated to live there by mid-2022. A total of 12,556 square kilometers makes up the zone, which has a climate of 45.5% highland, 39.6% medium land, and 14.9% lowland³⁶. According to the Zonal report of 2022, there are 417 public health facilities of which 5 are hospitals, 324 are health posts, 88 are health centers, and 203 are private medium and higher clinics including one non-governmental hospital and two private hospitals giving health services. Utilization of at least one sexual and reproductive health (SRH) services in the zone, in 2019 was 58.6%³⁷. The study was conducted between August 2022 and July 2023. This trial included pregnant adolescents before 16 weeks of pregnancy who intended to remain in the study region until delivery. Adolescent pregnant who refused to give their informed consent were not included in the study.

Sample size determination and sampling technique

The sample size was calculated using the G*Power 3.0.10. The required sample size was determined using the following assumptions: a 95% confidence interval, a 5% margin of error, 80% power, and an intracluster correlation (ICC) of 0.03 (based on a comparable published study ICC)³⁸ for the difference between two independent means (two groups). A 10% loss to follow-up was considered, and a design effect of two was employed. A total of 488 people constituted the computed sample sizes. As a result, both intervention and control groups of 244 pregnant adolescents were included. 28 clusters were used, and the preliminary report's average cluster size was 19. Single-stage cluster sampling technique was applied in this study.

Recruitment, randomization and intervention allocation

Five of the zone's 16 districts had nutritional education interventions; thus, they were excluded from the study. Four districts namely Dodola Rural, Adaba, Gedeb Hasasa, and Siraro—were chosen from among the remaining eligible districts by simple random sample (SRS) technique. Samples of non-adjacent kebeles (clusters) from the four districts were chosen using SRS. Six clusters each from the Dodola Rural and Adaba districts, as well as eight clusters each from the Gedeb Hasasa and Siraro districts were selected based on proportion to size allocation and considering cluster allocation in the intervention and control groups. Kebeles (the smallest administrative entity in Ethiopia) were used as the randomization unit (clusters). Clusters for the intervention and control groups were distributed using the lottery (SRS) approach. The Consolidated Standards of Reporting Trials (CONSORT) guidelines were used to report the results (Fig. 1).

A cluster randomized trial was used to avoid message contamination because pregnant teenagers in the same cluster were likely to communicate and discuss intervention messages. To avoid information leaking, all pregnant adolescent who fit the criteria in one cluster were enrolled in the same arm (either the intervention or control arm). Buffer zones (non-selected clusters) were additionally positioned^{39,40}.

House-to-house survey was done and pregnant teenagers who met the criteria were screened by being asked about the first date of their last menstrual period and based on a pregnancy test to confirm their pregnancy. Urine-based pregnancy test, urine HCG was used. The procedure involved dipping a test strip into a urine sample, the test strip contains chemicals that react to the presence of the pregnancy hormone HCG (human chorionic gonadotropin) if it is present in the urine. The results were displayed as lines on the test strip. The study included all pregnant teenagers who met the inclusion criteria. The study participants were screened and enrolled by nurses, and the clusters were randomly assigned.

Intervention

The intervention strategy used in this study was a community-based nutrition behavioral change communication intervention (NBCC) based on the HBM (Health Belief Model). Recommendations of World Health Organization, the blended training module on nutritional counseling developed by the Federal Ministry of Health of Ethiopia, EFDRE/MOH, and related interventional researches⁴¹⁻⁴⁴, served as the basis for preparing the intervention package. Additionally, the baseline study, conducted at the start of this study served as a direction for the development of intervention tools; the NBCC included the husbands of the pregnant teens, and a demonstration of how to prepare meals. A training manual for nutrition counselors, a manual for nutrition counselors, leaflets with the key messages for pregnant adolescents and their families, and counseling checklist cards were among the intervention items.

The intervention method was pilot tested for one week in an environment similar to the research site and adjustments were made in light of the results. The counseling manual's core contents included eating a range of foods, especially iron-rich foods, animal products, fruits, and vegetables, and increasing meal frequency and portion size as gestational age increased. The main components of counseling guidance also included taking iodized salt and iron/folic acid supplements. Additional messages of the core components included reduced workload, day rest, the use of impregnated bed nets, and the use of medical services.

It was also emphasized, how undernutrition can harm a person's development and how vulnerable pregnant adolescents need to eat. The benefits of eating enough meals that are diverse and the challenges to maintaining a balanced diet were also highlighted in the NBCC guidebook. Throughout her pregnancy, each pregnant adolescent attended four counseling sessions. Personalized NBCC based on trimester was

provided during home visits. Counselors used a client-centered approach to identify specific dietary preferences and needs. Before allowing the teenagers to choose guidance that was easily accessible, agreeable, and affordable in their location, counselors took into account the needs of the pregnant adolescents, their household income, and any gaps they had discovered. Counseling was conducted using the GALIDRAA approach (Greet, Ask, Listen, Identify, Discuss, Repeat, Agree, and Appoint)⁴⁵.

A counseling guide card that comprised the necessary information was used to conduct each counseling session for the NBCC, which lasted 45-60 minutes. The first appointment concentrated on the basics of nutrition, food groups, selecting foods that provide a balanced diet, showing how to prepare meals, frequency of meals, and use of iodized salt before 16 weeks of pregnancy. The second and third counseling sessions, which covered the whole of the counseling manual were offered in second trimester. Final counseling, which focuses on weight gain and incorporates all the module's important messages, was provided based on the gaps that were discovered during the previous trimesters of pregnancy.

Each pregnant adolescent in the intervention arm received a leaflet containing the key themes in Afan Oromo and Amharic (local languages) and appropriate images. Anyone at home who could read was asked to read the leaflet to the pregnant adolescent, if the adolescent couldn't read.

Health extension workers chose 14 AFDs [formerly known as WDAs] counselors based on their performance and prior involvement with public health services. The 14 AFDs were carefully supervised by four BSc nurses. Role-playing exercises and fieldwork using the training handbook were part of rigorous one-week training for counselors and supervisors. After the intervention had been in place for two months, the supervisors and counselors received three more days of training to ensure that the

providers continued to adhere to standardized practices.

Intervention fidelity

Criteria were created to assess the integrity of the intervention based on the best practice suggestions developed by the National Institutes of Health Behavioral Change Consortium⁴⁶. The criteria⁴⁷, included checklists to assess the intervention design, counselor training, counseling process, receipt of the intervention, and implementation of the skills picked up during the intervention. Nonadjacent clusters were selected to prevent information contamination. The intervention and control groups had an equal number of clusters from each district to balance differences.

The intervention strategy was tested before the experiment. Additionally, each pregnant adolescent received the same number and frequency of counseling sessions, and the lengths of interactions within the intervention group were comparable to standardize the method. Counselors training was given in a group environment using a training booklet, role-playing, and simulated counseling sessions. Tests administered before and after training as well as, a practical evaluation, were utilized to evaluate counselors' skills and knowledge. The process observer graded the counselors using a "yes/no" rating system and looked at things like using a counseling guide, covering the whole subject, the duration and frequency of counseling, preparation, accuracy, and the counselor's ability to respond to questions appropriately. Pregnant adolescents' understanding of food throughout pregnancy was assessed using checklists through interviews on their knowledge of the intervention's main components.

Participants, counselors, and data collectors were blinded to the study's objective; participant allocation concealment was impractical given the nature of the intervention. Until the analysis was complete, the groups were given a unique non-

identifiable number that also served to blind the data entry clerk. The counseling process was supervised by the main investigator and counseling supervisors.

Data collection procedure and measurements

The primary outcome of this study was nutritional status as measured by MUAC, while the secondary outcome was GWG. The mid upper arm circumference (MUAC) is the recommended assessment tool for nutritional status because of its simplicity and sensitivity in detecting undernutrition. In low-resource settings, where girls have minimal subcutaneous fat, it is the preferred measurement method because changes in MUAC are more likely to reflect changes in muscle mass⁴⁸. It has been demonstrated that low maternal MUAC is useful for detecting unfavorable delivery outcomes, such as intrauterine growth restriction, preterm birth, and asphyxia at birth⁴⁹. The left mid-upper arm circumference (MUAC) was measured at the anatomical landmark at the midpoint of the acromion and olecranon processes of the non-dominant hand, with the palm facing upward and the women's elbows flexed to 90°. The measurements were taken twice, by employing inelastic MUAC tape and interpreting the measurements to the nearest 0.1 cm.

A pre-tested structured questionnaire was used to obtain data. Socio-demographic characteristics, meal frequency, use of medical services, types of diet, and the Household Food Insecurity Access Scale (HFIAS) were collected. Six clinical nurses and two MPH (masters of public health) holders worked as data collectors and supervisors, respectively. Pregnancy tests were performed by three female laboratory technologists. The data collectors conducted in-person interviews with the participants at their homes to administer the questionnaire. To the best extent possible, the adolescent's privacy was protected by prohibiting access to the site where the interviews took place.

According to the Food and Nutrition Technical Assistance (FANTA) III recommendation from the United States Agency for International Development (USAID) and the Food and Agricultural Organization (FAO), dietary intake was determined using 24-hour recalls⁵⁰. The objective was to ascertain whether the meals of pregnant teenagers were varied. Grain, dairy, meat, white roots and tubers (peas, beans, and lentils), nuts and seeds, eggs, dark green leafy vegetables, poultry and fish, plantains, other fruits and other vegetables, and other fruits and vegetables high in vitamin A are among the ten food groups listed in the recommendations. If a pregnant adolescent had eaten at least five of the foods on the aforementioned lists in the 24 hours before the data collection period, she was considered to have a sufficiently varied diet^{51,52}. Every meal the participants had during the previous 24 hours, both inside and outside the home, were asked to be remembered. The participants were also asked if they could remember any between-meal snacks they may have consumed. Food items received a "1" rating if consumed during the reference period, and a "0" rating if not.

The HFIAS (Household Food Insecurity Access Scale) Guideline⁵³ was used to assess food security. The HFIAS were used to evaluate the household's level of food security with 27 questions. Prior to this, the questions were validated for use in developing nations⁵⁴. Food-secure households experienced fewer than the first two food insecurity indicators. Households that experienced between two and ten, eleven to seventeen, and more than seventeen food insecurity indicators were considered mildly, moderately, and severely food insecure households, respectively.

The household's wealth index was derived using Principal Component Analysis (PCA), taking into account access to a latrine, a water source, household items, and agricultural land. The responses to the non-dummy variables were all split into three groups. A code of 1 is allocated to the highest rating. The two smaller digits,

however, were given a code of 0. Using variables with a commonality value larger than 0.5, PCA factor scores were produced. The first primary component score for each family is kept in order to calculate the wealth score. Quintiles of the wealth score were created in order to classify households as, poorest, poor, medium, rich, and richest⁵⁵.

The autonomy of the pregnant adolescent was evaluated using eight questions. Code one was provided for each question when a decision was taken by the girl, by herself or jointly with her husband; otherwise, code zero was provided. The mean was used to classify the pregnant adolescent's decision-making capacity⁵⁶.

Data management and analysis

The data was entered using Kobo Toolbox and exported to SPSS version 25 for analysis. The baseline variations in the two groups' socio-demographic characteristics were examined using a chi-square test. Paired t test and independent t test were used to see within and between group differences.

The effect of the intervention on changes in the nutritional status and gestational weight gain of pregnant adolescents over time was estimated using a linear mixed-effects model. This model was chosen; due to the repeated assessments (pre- and post-intervention) and the clustering of individuals, it allowed us to explain how the results were correlated. The Akaike information criterion (AIC) was employed to help us choose the best statistical model. The model that displayed the lowest AIC was selected. The bivariate linear mixed regression model's variables with $p < 0.2$ were chosen as potential candidates for the multivariate linear mixed

model analysis. By analyzing how time and the intervention interacted, the effectiveness of the intervention was evaluated.

Participants were examined as random effects during model fitting. Linear mixed-effects model also makes it possible to manage the impact of various confounding variables. The intra-cluster correlation coefficient at the final model was 0.04, indicating that constructing a third level model was not necessary. The intercept-only model was created initially. To take into consideration time-invariant variables at the individual level, the two-level model was fitted. The effect of intervention was estimated by testing the interaction term between treatment allocation and time.

Results

The overall follow-up of study participants through the trial was summarized by the CONSORT guideline flow chart (Figure 1).

Socio-demographic characteristics of pregnant adolescent

Out of the 459 participants initially sampled 426 (IG = 207, CG = 219) pregnant teenage participants in this study followed the protocol exactly and were accounted for in the analysis. The mean follow-up weeks of participants were 15 weeks. The socio-demographic features of the intervention and control groups did not differ significantly at baseline, chi-square test ($P > 0.05$). The baseline characteristics of the pregnant adolescents are shown in Table 1.

Table 1: Socio-demographic characteristics of pregnant adolescents in West Arsi Zone, central Ethiopia, 2022-2023

	Variables	Intervention group (n1=207) Frequency %	Control group (n1=207) Frequency %	P value
	Number of clusters	14	14	
Age	Middle adolescent	51 (24.7)	46 (21)	0.37
	Late adolescent	156 (75.3)	173 (79)	
Family size	< 5 persons	148 (71.5)	173 (79)	0.07

	>= 5 person	59 (28.5)	46 (21)	
Marital status	Married	174 (84)	188 (85.8)	0.60
	Unmarried/ divorced	33 (16)	31 (14.2)	
Educational status	No formal education	20 (9.6)	30 (13.6)	0.20
	Can read & write	27 (13)	26 (11.8)	
	Primary level education	113 (54.5)	102 (46.5)	
	Secondary education	35 (16.9)	52 (23.7)	
	College & above	12 (5.7)	9 (4)	
Occupation	House wife	71 (34.3)	64 (29.2)	0.9
	Student	77 (37)	86 (39.3)	
	Merchant	34 (16.4)	39 (17.8)	
	Daily labourer	7 (3.4)	9 (41)	
	Farmer	9 (4.3)	9 (41)	
	Government job	9 (4.3)	12 (5.4)	
Wealth index	Poorest	42 (20)	46 (21)	0.67
	Poor	32 (15.4)	48 (21.9)	
	Medium	32 (15.4)	17 (7.7)	
	Rich	59 (28.5)	70 (32)	
	Richest	42 (20.3)	38 (17.3)	

Health belief model constructs score and their correlation with MUAC and GWG

women, except perceived barrier ($p < 0.05$) (Table 2).

At baseline, there was no significant difference between the HBM constructs score of the intervention and control groups. All the HBM constructs had a significant positive correlation with nutritional status and GWG of the pregnant

Table 2: Correlation of the health belief model constructs with MUAC and GWG among pregnant adolescents in West Arsi, central, Ethiopia, 2022- 2023.

	Perceived Susceptibility	Perceived severity	Perceived benefits	Perceived Barriers	MUAC	GWG
Perceived Susceptibility	1					
Perceived severity	0.943**	1				
Perceived benefits	0.917**	0.869**	1			
Perceived Barriers	0.09	0.107	0.164	1		
MUAC	0.145**	0.150**	0.191**	-0.211	1	
GWG	0.173**	0.181**	0.194**	0.068	0.190**	1

GWG Gestational weight gain, MUAC mid-upper arm circumference,

* Correlation is significant at the 0.05 level (2-tailed) and ** Correlation is significant at the 0.01 level (2-tailed)

Effect of nutrition behavioral change communication on the nutritional status of pregnant adolescents

At the baseline, there was no statistically significant difference in the mean MUAC (23.19 ± 2.1 Vs 23.49 ± 2.1 , $P = 0.20$) between the two groups. After the implementation of the trial, the mean MUAC in the intervention arm has been significantly increased from the baseline, $P = < 0.001$), (Table 3).

The variance of the individual-level residual errors or variability of the average MUAC across individuals was 2.79, which was statistically

significant ($p = < 0.001$). The intra-individual correlation coefficient was 0.55; this indicated the importance of accounting individual level time-invariant variables (fitting two-level model). After controlling for food security, wealth index, DDS, and meal frequency, the intervention group showed a significant improvement in nutritional status at the end of the study trial ($p < 0.01$) (Table 4).

Table 3 Differences between baseline and end line MUAC and gestational weight gain, and difference of the differences [DID] between intervention and control groups.

Variable	Study period	Intervention group Mean($\pm$ SD)	Comparison group Mean($\pm$ SD)	DID Mean($\pm$ SD)
MUAC	Baseline	23.19 $\pm$ 2.1	23.49 $\pm$ 2.1	1.89 $\pm$ 2***
	End-line	25.06 $\pm$ 2.9	23.56 $\pm$ 2.0	
	Difference (EL-BL)	1.87 $\pm$ 1.67	0.7 $\pm$ 0.4	
Gestational weight gain	Baseline	51.54 $\pm$ 4.7	52.86 $\pm$ 5.27	4.23 $\pm$ 0.34**
	End-line	60.98 $\pm$ 4.6	58 $\pm$ 5.3	
	Difference (EL-BL)	9.44 $\pm$ 4.48	5.14 $\pm$ 3.7	

BL Baseline, EL End-line, SD standard deviation; CI, confidence interval; MUAC, mid-upper arm circumference, ** $p < 0.01$, *** $p <$

0.001 Table 4 Linear mixed-effects model predicting MUAC of pregnant adolescent in West Arsi Zone, Central Ethiopia, 2022/2023.

		Model 1		Model 2		Model 3	
		Estimate (SE)	95% CI	Estimate (SE)	95% CI	Estimate (SE)	95% CI
Fixed effect	Intercepts	23.78(0.1)	23.5 - 23.9	24.7(0.33)	24 - 25.37	23.7(0.7)	22.3, 25.13
	Intervention effect			0.65(0.2)	0.27, 0.83	0.65(0.2)	0.27, 0.83
	Baseline MUAC			-0.253(0.3)	-0.4, -0.14	-0.253(0.3)	-0.4, -0.14
	End-line MUAC			-0.72(0.27)	-0.92, -0.47	-0.36(0.27)	-0.53, 0.28
	DDS					0.6(0.29)	0.06, 1.2
	Wealth index					-0.01(0.06)	-0.14, 0.12
	Food security					0.13(0.2)	0.08-0.27
	Meal frequency					0.08(0.24)	-0.4, 0.13
Random effect	Level 2 Variance	2.79(0.3)		2.78(0.25)		2.26(0.18)	
	ICC	0.55		0.53		0.04	

		Model 1	Model 2	Model 3
	AIC	3796	3791.9	3796

AIC Akaike information criterion, DDS Dietary diversity score, ICC Intraclass correlation, SE: Standard error, CI: Confidence interval

Effect of nutrition behavioral change communication on gestational weight gain [GWG] of pregnant adolescents

At the baseline, there was no statistically significant difference in the mean GWG in kg. (52.86 ± 5.27 Vs 51.54 ± 4.7 , $P = 0.34$) between the two groups. After the implementation of the trial, the mean GWG in the intervention arm has been significantly increased from the baseline, The mean weight gain among intervention group was 9.4 kg and among control group 5.14 kg and the difference in difference was 4.23 kg and this was statically significant $P = < 0.001$), (Table 3).

The variance of the individual-level residual errors of the average GWG across individuals was 5.53, which was statistically significant ($p = < 0.001$). The intra-individual correlation coefficient was 0.139; this indicated the importance of accounting individual level variables (fitting two-level model). After controlling for Age, occupation, DDS, Female decision making and meal frequency, the intervention group showed significant improvement in GWG at the end of the study trial ($\beta=5/59$, $p < 0.01$) (Table 5).

Table: 5 linear mixed-effects model predicting Gestational weight gain of pregnant adolescent in West Arsi Zone, Central Ethiopia, 2022-2023,

		Model 1		Model 2		Model 3	
		Estimate (SE)	95% CI	Estimate (SE)	95% CI	Estimate (SE)	95% CI
Fixed effect	Intercepts	55.85(0.23)	55.4 – 56.3	55.9(0.23)	55.46 – 56.4	55.97(1.6)	52.8, 59.2
	Intervention effect			5.59(0.7)	4.1, 6.98	5.59(0.7)	4.1, 6.98
	Female decision making					-0.85(0.57)	-1.99, 0.28
	DDS					2.42(0.63)	1.17, 3.67
	Age					-0.12(0.4)	-1, 0.8
	Occupation					0.028(0.16)	-0.28, 0.34
	Meal frequency					0.55(0.5)	-0.53, 1.64
Random effect	Level 2 Variance	5.53(1.89)		3.26(1.57)		3.04(0.83)	
	ICC	0.139		0.066		0.03	
	AIC	5546		5357.5		4838.5	

AIC Akaike information criterion, CI Confidence interval, ICC Intraclass correlation, SE Standard error,

Discussion

This study found that nutritional status and GWG of pregnant adolescents were improved by NBCC delivered through AFDs using HBM. The mean MUAC and GWG of adolescents in the intervention group were significantly greater in comparison to adolescents in the comparison

group. These results persist after controlling for the potential confounders.

The finding on improvement of nutritional status is consistent with that of (East Shoa Zone, Ethiopia ⁵⁶, West Gojjam Zone, Ethiopia ⁵⁷, Lahore, Pakistan ⁵⁸, Iran ⁵⁹), which reported significant improvement in the nutritional status of pregnant who attended nutrition education; a possible explanation for this is human behavior can be changed by well-designed adequate nutrition education which ultimately leads to improvement in nutritional status and better health.

Another important finding is, that the NBCC resulted on significant improvement of GWG of pregnant adolescents within recommended weight gain range, and these results were consistent with other research ⁶⁰⁻⁶², this might be because NBCC made participants to change perception and increased proper understanding of good nutrition.

From HBM constructs, perceived barrier was the main problem among participants and perceived benefit brought more significant change. This is consistent with other studies ⁶³⁻⁶⁵, perceived barriers are often the most predictive constructs and often more difficult to change compared with other constructs; therefore, more attentions need to be given to perceived barrier. Addressing perceived barriers often requires considering and addressing the broader context in which the behavior occurs. Perceived barriers are influenced by various contextual factors, such as social, cultural, economic, and environmental factors ^{66,67}.

The findings from this study provide some evidence that carefully selected, intensively trained, and closely supervised AFDs can be used actively in the health care system for NBCC and other similar health care services, thereby decreasing the overload on health care providers. These are promising findings especially for developing countries, where health care provider to population ratio is very small ⁶³,

and community level actors like AFDs can play great roles.

It is not possible to solve nutritional problems in a sustainable way through supplementation in the form of capsules or tablets or nutrition therapeutic interventions. It would be too difficult to organize and costs would be too high; therefore, such model based NBCC intervention will bring sustainable improvement in nutritional status and overall health of mothers and their fetus. Community health workers (CHWs) or AFDs are a critical link in improving access to different health services, as it is revealed in this study that they can contribute significantly on NBCC interventions and health policy makers, government and non-government organizations needs to continue actively involving them in organized way with periodic performance measurement and improvement of their knowledge and skills.

There are several possible explanations which may resulted in significant improvement of nutritional status and GWG by the NBCC intervention in this study; these include; the use of HBM, husband participation in education sessions, employing GALIDRAA counseling technique, teaching aids like leaflets, cooking demonstration techniques and giving trimester-based nutrition education.

Once a pregnancy happens in adolescence, it is great to successfully manage it by proper nutrition and all ANC services; however further studies, about delaying or preventing teenage pregnancy and early marriage need to be undertaken. Further studies are required to explore what other behavioral change communication models can be used. The findings have wider practical implications on the need for implementing adolescent nutrition guideline to prevent intergenerational cycle of malnutrition that sets is during adolescent pregnancy ⁶⁸. The results also imply the great potential for leveraging the existing community levels structures such as the AFDs in improving adolescent nutrition during pregnancy.

The strengths of this study are; it is community based, theory based NBCC was used, cooking demonstration, the involvement of husbands of pregnant adolescent in NBCC; whereas the limitations are all of the responses, except measurement of MUAC, were based on the pregnant adolescent's recall, self-report, and honesty in answering to the questions.

Conclusion

This study demonstrated that HBM based NBCC with husband involvement given through AFDs was effective in improving nutritional status and gestational weight gain of pregnant adolescents. Utilizing AFDs makes the NBCC sustainable and low-cost intervention. Thus, it is recommended to include the HBM to nutrition counseling guidelines. This reproducible NBCC intervention may be scaled up and sustained with low cost through the existing health systems and community structures.

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REACHING THOSE AT RISK: ACTIVE CASE DETECTION OF LEPROSY AND CONTACT TRACING AT KOKOSA, A HOT SPOT DISTRICT IN ETHIOPIA

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Abstract

Introduction

Leprosy is a chronic mycobacterial disease of public health importance. It is one of the leading causes of permanent physical disability. The prevalence of leprosy in Ethiopia has remained stagnant over the last decades. The aim of the study was to identify new leprosy cases and trace household contacts at risk of developing leprosy by active case detection. The study area was Kokosa district, West Arsi zone, Oromia region, Ethiopia.

Method

A prospective longitudinal study was conducted from June 2016-September 2018 at Kokosa district. Ethical approvals were obtained from all relevant institutions. Health extension workers

screened households by house-to-house visits. Blood samples were collected and the level of anti-PGL-I IgM measured at two-time points.

Results

More than 183,000 people living in Kokosa district were screened. Dermatologists and clinical nurses with special training on leprosy confirmed the new cases, and their household contacts were included in the study. Of the 91 new cases diagnosed and started treatment, 71 were recruited into our study. Sixty-two percent were males and 80.3% were multibacillary cases. A family history of leprosy was found in 29.6% of the patients with cohabitation ranging from 10 to 30 years. Eight new leprosy cases were diagnosed among the 308 household contacts and put on multi-drug therapy. The New Case Detection Rate increased from 28.3/100,000 to 48.3/100,000 between 2015/2016 and 2016/2017. Seventy one percent of leprosy patients and 81% of the household contacts' level of anti-PGL-I IgM decreased after treatment. In conclusion, the results of the study showed the importance of active case detection and household contact tracing. It enhances early case finding, and promotes early treatment, thereby interrupting transmission and preventing potential disability from leprosy.

Introduction

At the end of 2021, the World Health Organization (WHO) reported globally 127,396 new cases of leprosy. Of these 7,198 had grade-two disability (G2D) and 8,629 were new child leprosy cases. Ethiopia reports greater than 1000 new cases of leprosy yearly. The registered new cases in 2020 numbered 2,591. Ethiopia ranks 7th among the 23 global priority countries and 3rd in Africa with 390 new child cases and 384 G2D cases per year [1].

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Early diagnosis and treatment are the cornerstones of leprosy management, preventing permanent disabilities and reducing transmission. Continuous long-term follow-up contributes to early diagnosis. WHO member countries adopted the global 2016–2020 strategy which moves towards a leprosy-free world [2]. This was recently updated in the “Towards zero leprosy (2021–2030)” strategy [3], which includes active case detection (ACD) as one of its pillars. The scale-up of leprosy control through ACD is achievable, leading to interruption of transmission and potential elimination of disease [3].

The risk of developing leprosy increases among persons with prolonged contact, with diagnosed cases, but also in particular with new untreated leprosy patients. In addition, risk increases when contacts live with the patients [4]. Studies show the contacts of leprosy cases are 6 fold more likely to develop disease than those in the general population. Contacts of multibacillary (MB) patients have 8-fold increased risk compared to the paucibacillary (PB) contacts [5]. Hence, screening household contacts (HHCs) is crucial for possible early case detection.

Serum anti-PGL-I antibody levels in HHCs of leprosy patients contribute to ACD. Studies from Brazil demonstrated the usefulness of serum anti PGL-I antibody levels in HHCs. Spencer et al. showed that many HHCs developed increased titers over time and this was associated with development of borderline lepromatous leprosy (BL) after two years routine follow-

up [6]. However, anti-PGL-I antibody levels are higher in MB than PB leprosy patients, which may limit the usefulness of anti-PGL-I as a prognostic biomarker to MB patients.

In 2003, Ethiopian Federal Ministry of Health (FMOH) initiated a new program, “Accelerated Expansion of Primary Health Care”, which promoted the use of Health Extension Workers (HEWs) to provide basic package health services to the rural community.

In this study, the engagement of HEWs was vital to conduct the house-to-house screening and contact tracing. The HEWs assigned to work in the community were trained to identify patients with the major signs and symptoms of leprosy. Leprosy suspects were referred to health centers for further screening, confirmation and management.

This study designed to demonstrate the implementation of ACD in identifying new leprosy patients and fill the gap observed by passive case detection. Additionally, we aimed to determine whether early management of leprosy patients will reduce the risk of developing leprosy complications. This study was conducted at one of the leprosy hotspot areas of the country.

Materials and methods

A prospective longitudinal study was conducted in Kokosa district. The study period was from June 2016 to September 2018. The district is located in the West Arsi Zone, Oromia region.

Oromia is the largest region of Ethiopia. It accounts for 36.7% of the population but comprises 57% of new cases of leprosy in the

country [7]. When the study began the district had a population of 183,685 with 36,495 HHCs (Source: West Arsi Zone Health Bureau). There were 8 health facilities. They include Hogiso, Hebano, G/Hurufa, Boro, Bokore, Kokosa, Ararso, and Kokosa hospital. The hospital participated in the diagnosis of some of the leprosy cases who were referred back to the nearest study health centers for treatment, proper management, and follow-up.

The source population was all individuals with dermatological complaints from Kokosa district. Leprosy suspects were screened and referred to health centers for further examinations and confirmation. Consenting HHCs of the confirmed leprosy patients were included in the follow-up study. A pre-structured questionnaire was completed and blood samples from patients and HHCs collected. Slit skin smear (SSS) was collected from patients only. Tuberculosis (TB) and leprosy screened endemic controls (ECs) were recruited from the same population.

Definition of terms

New leprosy patient: a patient with MB or PB leprosy who has never had previous treatment for leprosy [8].

Treatment completed: a patient who has completed the full regimen of MDT within the prescribed period; the full regimen is 12 months of therapy within a 15 month period for MB cases and 6 months of therapy within a 9 month period for PB patients [8].

Household contacts (HHCs): individuals who have been living at least 6 months or more with an index case, and without signs and symptoms of leprosy at enrolment.

Endemic controls (ECs): apparently healthy individuals who have lived in the district for 2 years. ECs have had no contact with an index case and no previous treatment history of leprosy or TB.

Biological samples preparation

At the first-time point, a total of 149 blood samples were collected from 24 leprosy patients, 100 HHCs, and 25 ECs. 103 blood samples were collected from 88 HHCs and 15 leprosy patients during the second visit. Nine patients and 12 HHCs were lost to follow-up. Clinical samples that included Slit skin smear (SSS) and biopsy samples from confirmed leprosy patients were collected. Also, blood samples from leprosy patients, HHCs, and ECs were collected.

Slit skin smear (SSS) reading was done at the Armauer Hansen Research Institute (AHRI).

Three SSS from lesions of each leprosy patients were taken. The smears were stained with Ziehl-Nelson. The average number of bacilli per microscopic field was termed bacterial index (BI) and used for reporting. An oil-immersion objective was used for microscopy.

The Up-converting Phosphor Lateral Flow Assay (UCP-LFA) was used to analyze anti-PGL-I IgM antibodies for both time points, and was performed by Leiden University Medical Center (LUMC).

Anti-PGL-I IgM was measured before and after treatment for leprosy patients. It was also done for HHCs before and after their paired index cases completed treatment. The measurement helps to identify the biomarker signature specific for leprosy disease. IgM antibodies against *M. leprae* PGL-I were

detected using conjugate antigen comprised of the natural disaccharide of PGL-I linked to human serum albumin (NDO-HSA 500 ng/well in 50 μ l). The anti-gens provided

incubation was for 120 minutes in flat-bottomed microtiter plates (Nunc) coated with NDO-HSA. After washing, diluted enzyme-linked secondary antibody solution used. The solution (anti-human IgG/IgM/IgA–HRP; Dako, Heverlee, Belgium; 50 μ l/well) was added to all wells for 120 minutes at room temperature. After washing, diluted TMB solution (50 μ l/well) was added to all wells and plates were incubated in the dark for 15 minutes at RT. The reaction was stopped by adding 50 μ l/well 0.5 N H₂SO₄. Absorbance was determined at a wavelength of 450 nm. Samples with a net optical density at 450 nm (OD) above 0.149 were considered positive.

Positive and negative control serum samples was used to check ELISA performance. The diagnostic potential of anti-PGL-I IgM was evaluated based on the clinical classifications. UCP-LFA results of anti-PGL-I IgM assay is displayed as the Ratio value (R) of patient to control sample. After one year, the Ratio of anti-PGL-I IgM in HHCs was determined for the first and second time screening. High responses were defined as those with optical density (OD) value above 1.195.

Case record forms were used to collect personal and clinical data, and all data was double entered into an MSAccess database. Epi-info software was used for verification and cleaning. STATA/SE version 15 (College Station, TX, USA) used for statistical analysis.

through the NIH/NIAID Leprosy (Contract N01-AI-25469) as described earlier [9]. Serum dilutions (50 μ l/well; 1:800) were incubated at room temperature (RT). The

The study proposal evaluated and approved by multiple ethical review boards, including AHRI/ALERT Ethical Review Committee (AAERC PO37/2014), the National Health Research Ethics Review Committee (NHRERC 3-10/014/2015), the College of Health Sciences Institutional Review Board, Addis Ababa University (AAU,002/15 DMIP), and the Oromia Regional Health Bureau Ethical Review Committee (BEFO/HBTFFH/1-8/2416).

Study participants were informed about the study objectives, and each participant signed informed consents. Parents of children aged 12–17 signed consent forms if their children were willing.

Results

Dermatologists and leprosy experts' clinical assessment were used as the main diagnostic criteria. FMOH guidelines defined the diagnosis, based on the three cardinal signs of leprosy: hypopigmented or reddish lesions with loss of sensation; enlarged peripheral nerves and acid fast bacilli (AFB) identified in SSS.

During the study period, 91 new leprosy cases were confirmed out of 1,769 suspects. Seventy-one patients were detected through active household level screening and contact tracing. The other 20 patients' self-presented at health facilities seeking treatment. After proper orientation 71 were enrolled in the study. Blood samples were collected before starting leprosy treatment (Fig 1).

Of the 71 new cases, 308 HHCs (77%) were screened. Of these, eight new leprosy cases from six index leprosy cases were diagnosed and initiated on MDT. Most of the HHCs (51.4%) were below the age of 15. 26.2% of the HHCs were from Hebeno kebele and the male to female proportion was almost equal.

The age and sex distribution of patients affected by leprosy is depicted in Fig 2. Of the new diagnosed cases starting treatment, 62% (44/71) were males and 38% (27/71) were females (Fig 2). The age ranged from 4 to 70 years and 42.3% (30/71) of the patients were

aged between 16 and 30 years Sociodemographic and PGL-I Raw Data 1 in S1 File.

Nearly all patients, 95.8% (68/71), resided in remote rural areas; three lived in rural towns. 59.2% (42/71) were illiterate. Most of the leprosy patients, 88.7% (63/71), were diagnosed at the health centers. 11.2% (8/71) were diagnosed at the Kokosa hospital. Among the 71 index cases, 59.1% of them had a household size from six to ten consistent with crowding (Table 1).

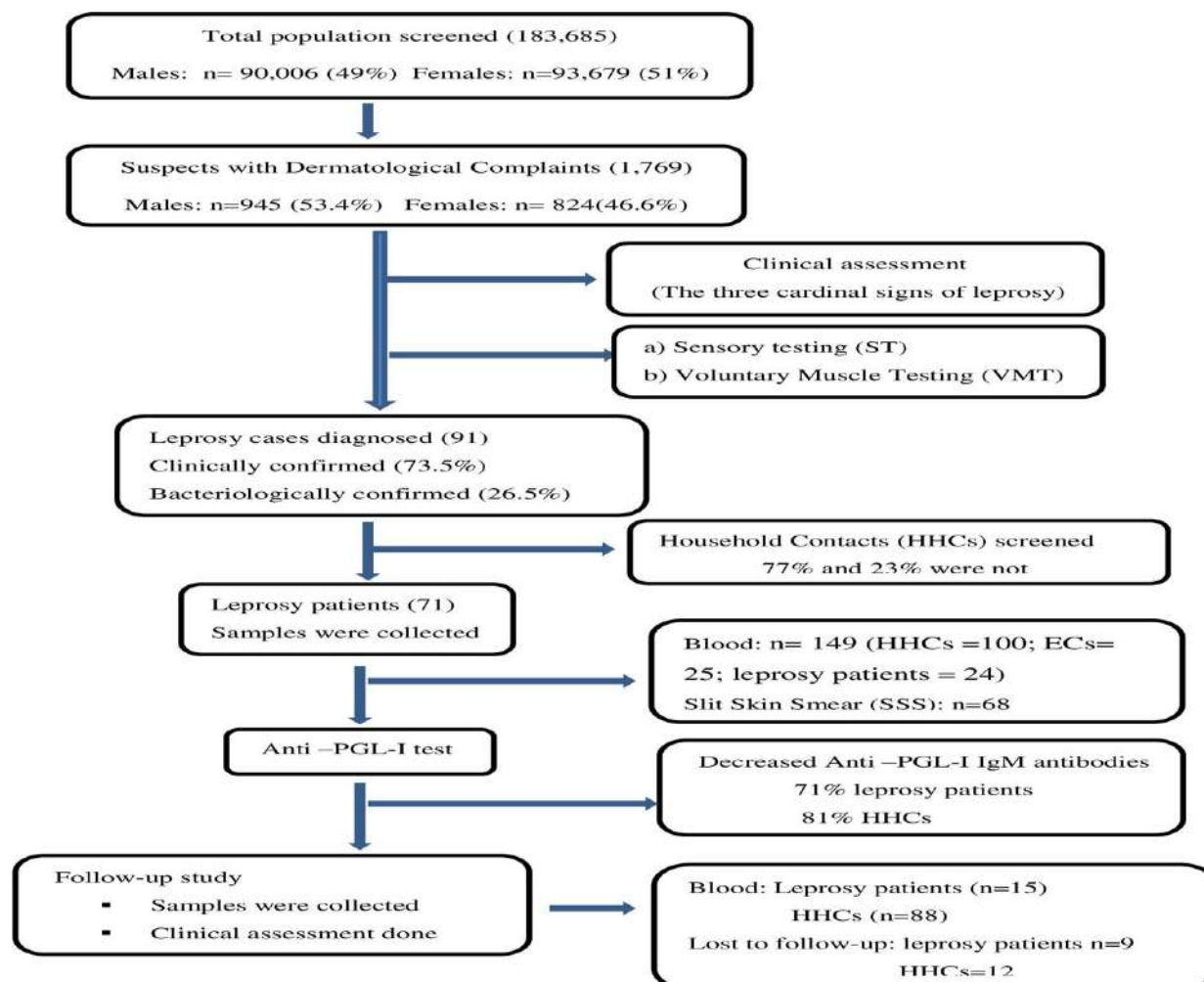


Fig 1. Flow diagram of study participant's recruitment at Kokosa District.

<https://doi.org/10.1371/journal.pone.0264100.g001>

Clinical features of persons affected by leprosy

Among the 71 enrolled patients, 80.3% (57/71) were MB while the remaining 19.7% (14/71) were PB according to WHO classification (Fig 3).

Most of the patients (72.9%) presented with numbness and 39.4% had patches. Very few

(9.5%) reported having pain at the hypopigmented lesion. 5.9% had difficulties closing their eyes and 9.9% presented with leprosy reactions. Five of them had Type I reactions (T1R) and two had Erythema Nodosum Leprosum (ENL) reactions (Fig 4).

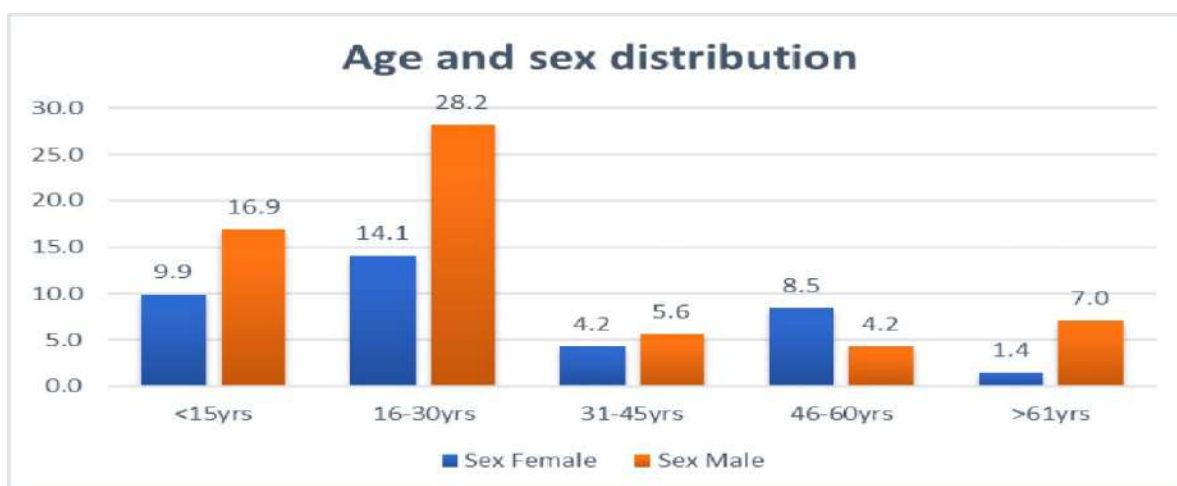


Fig 2. Age and sex distribution of patients affected by leprosy in Kokosa District. X-axis represents age group and Y-axis represents frequency.

<https://doi.org/10.1371/journal.pone.0264100.g002>

Disabilities observed at diagnosis. Disability is one of the complications of leprosy that includes impairment, activity limitation, or participation restriction affecting a person (Fig

5). Most disabilities and deformities due to leprosy result directly or indirectly from loss of peripheral nerve function secondary to infection of the nerves supplying the eyes, hands, and/

Table 1. Socio-demographic characteristics of patients affected by leprosy at enrollment, Kokosa district, 2016–2017.

Variables		Frequency n = 71	Percent (%)
Age in years	<15	19	26.8
	16–30	30	42.3
	31–45	7	9.9

	46–60	9	12.7
	>61	6	8.5
Sex	Male	44	62
	Female	27	38
WHO classification	Multibacillary (MB)	57	80.3
	Paucibacillary (PB)	14	19.7
Residence	Urban	3	4.2
	Rural	68	95.8
Education	Not able to read & write	42	59.2
	Able to read and write	5	7.04
	Primary	16	22.5
	Secondary	7	9.9
	College	1	1.4
Household size number	<5	23	32.4
	6–10	42	59.1
	11–15	0	0
	16–20	5	7.1
	>21	1	1.4

<https://doi.org/10.1371/journal.pone.0264100.t001>



Fig 3. Leprosy patients enrolled in Kokosa ACD study. A and B = MB patients >5 cutaneous lesions; C = PNL, no cutaneous lesions; D = MB (LL) with numerous nodules; E = PB with < 5 cutaneous lesions [(Photos by Tsehaynesh Lema (PI)].

<https://doi.org/10.1371/journal.pone.0264100.g003>

including 2 MB and 1 PB patients. 21.1% (15/71) of the patients had grade 2 disabilities (G2D), 2 PB, 3 pure neural leprosy (PNL) and 10 MB patients.

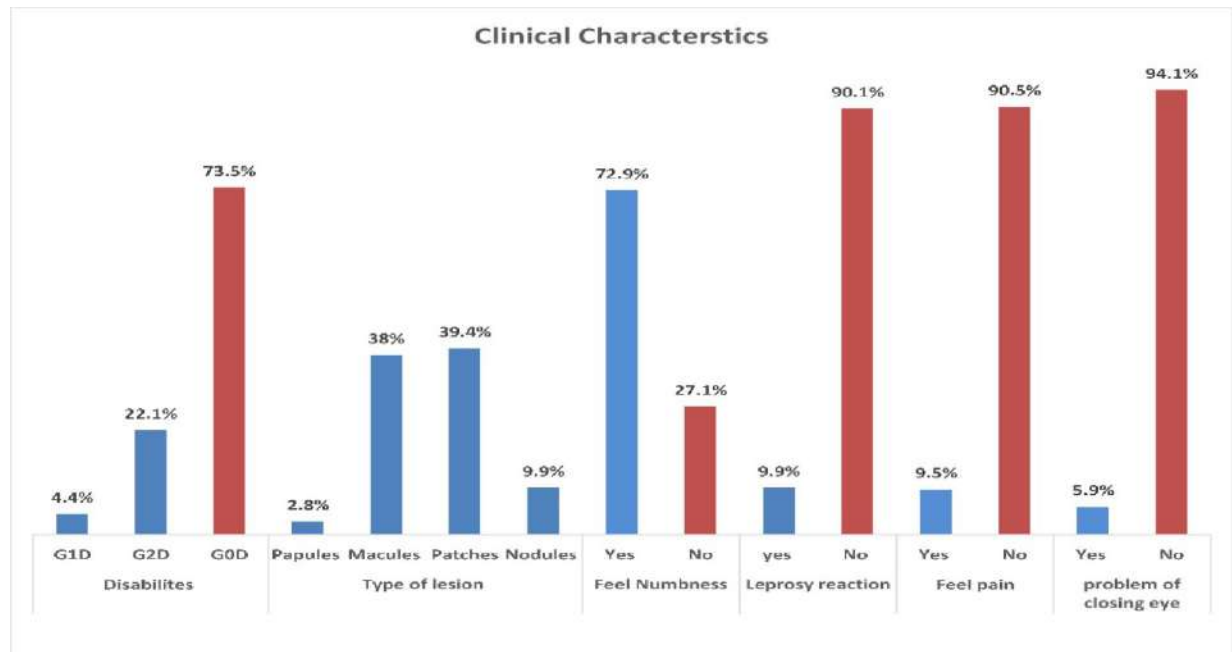
Slit-skin smears. In this study, the positive SSS was 26.5% (18/68) with BI ranging from 1–6. Half of the smears were negative (34/68). Of which 3 were from PNL patients, 9 were from PB patients and 22 were from MB patients. SSS was not done for 23.5% (16/68) of the leprosy patients among which 5 PB, 4 PNL, and 7 were MB patients.

or feet. In this study, 4.2% (3/71) of the patients had grade 1 disabilities (G1D),

Anti-PGL-1 IgM antibody. A total of 149 whole blood samples were collected from the cross-sectional study and 103 from the longitudinal study. Both sample sets were analyzed by assays that included an anti-PGL-I-IgM antibody assay. The level of

demographic and PGL-1 raw data 2 in S1 File) showed decreased levels. Most of the

Fig 4. Clinical characteristics of patients at enrolment. G0D = grade 0 disabilities, G1D: Grade 1 disabilities, G2D: Grade 2 disabilities,



anti-PGL-I IgM decreased after treatment. 71% of the leprosy patients (Fig 6A) and 81% of the HHCs (Fig 6B and Socio-

***9.9% of the patients are PNL cases without cutaneous manifestations.
<https://doi.org/10.1371/journal.pone.0264100.g004>

Fig 5. Leprosy patients diagnosed with G2D in Kokosa ACD study [(Photos by Tsehaynesh Lema (PI)].
<https://doi.org/10.1371/journal.pone.0264100.g005>



participants' anti-PGL-I-IgM antibodies levels were below 0.5 O.D. In contrast, three patients had significant expression of anti-PGL-I-IgM antibody (O.D> 1.2) at baseline, and these levels decreased substahntially after MDT.While most HHCs showed lower levels of anti-PGL-I-IgM antibodies at baseline than index cases, one HHC showed elevated levels.

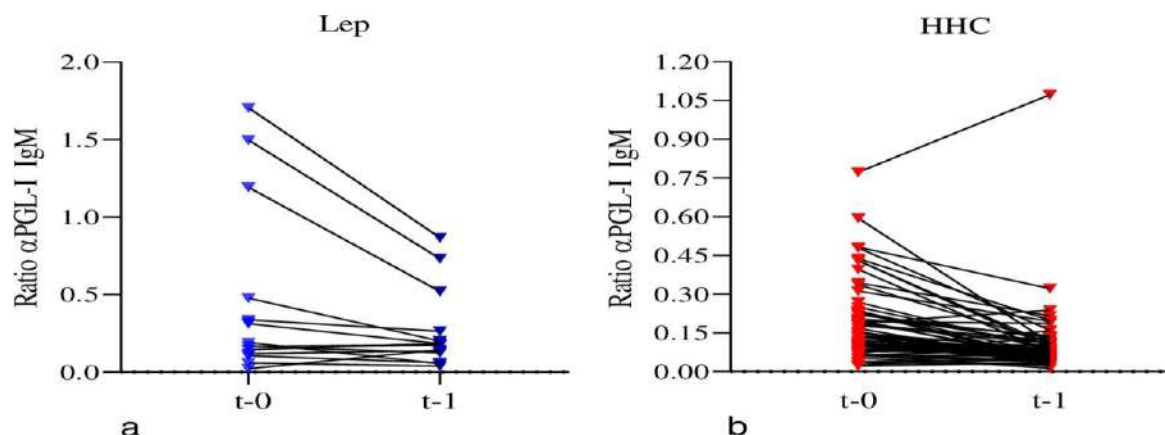
Discussion

Active case detection (ACD) of leprosy is a key intervention, reaching affected patients early and hence prevents the disease spread. We used a house-to-house screening approach for ACD which appeared to be highly effective. Whereas 52 new cases were reported in the year prior to the study initiation (2015/2016), 91 new cases were reported in the 12 months of this study (2016/2017). However, in the years following the survey, when active case detection was no longer being performed, the new case detection showed a declining trend. In 2017/2018, 2018/ 2019, 2019/2020 reports, 54, 21 and 24 new patients were registered, respectively. This dramatic spike in case detection in the study year strongly suggests the importance of ACD through the active involvement of HEWs. A very recent study in the Eastern Hararghe applied ACD and contact screening, also revealed the importance of active rather than passive case detection [10].

The current study indicated 29.6% of the diagnosed patients had at least one leprosy family contact, with HHCs remaining in contact with varying duration ranging from < 10 to 30

Fig 6. Level of biomarkers before and after treatment. a) The levels of anti-PGL-I IgM in the plasma of leprosy patients before and after MDT. b) The levels of anti-PGL-I IgM among HHCs at enrollment and after a year (after the index patients completed MDT, 12 months for MB and 6 months for PB).

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years. Previous studies have shown that HHCs have 4–9 times increased risk of acquiring the disease. In one study, two contact-related factors mentioned, including closeness and intensity of the contact to the index leprosy case [5].

In this study, eight of the 308 HHC screened were diagnosed with leprosy, a much greater prevalence that was expected from the population at large. This shows the importance of close exposure to the leprosy patient as an important risk factor. Our findings are in agreement with other studies showing the importance of both ACD and contact tracing [11–13] compared with passive case finding [11].

Among the 71 indexes, 59.1% of them had a household size from six to ten, indicating crowding (Table 1). The study of Kiribati et al have emphasized the importance of crowding, with at least 7 persons in a household considered as a risk for leprosy infection [14]. Another study, however, did not observe significant associations with crowding and leprosy acquisition [15]. The reasons for these discrepancies may reflect the nature of the disease, in particular the lengthy incubation period which may lead to underestimations of contact risk.

There is a lack of rapid and field-friendly tools for early disease detection. Levels of anti- PGL-1 IgM antibodies showing exposure or infection from *M. leprae* could be a candidate tool to support early diagnosis. While evidence is lacking that anti-PGL-I IgM antibodies alone can be used for leprosy infection in HHCs, some studies have observed that anti-PGL-I IgM anti- body

positive contacts are at increased risk of developing leprosy [5, 16].

An increased level of anti- PGL-I IgM noted in one of our HHC. Despite the opposing views mentioned above, it helped the diagnosis (Fig 6B). Our result showed similarity to the study findings of Spencer and his colleagues. Their finding had shown many HHCs with progressively elevated antibody titers. One HHC developed borderline lepromatous leprosy (BL) after two years routine follow-up [6]. But the Bangladesh study opposed the above statement. The study stated its insufficiency when used alone. According to that study, it needs other markers for early detection of leprosy and onset of the disease [4].

In our study PGL-I results decreased after MDT in the majority of our patients and HHCs. This finding is in line with Spencer and Brennan's study. The study showed decreased seropositivity even after the first MDT administration. This is due to bacilli destruction where the

PGL-I synthesis is also reduced. Measuring PGL-I IgM serum level after instilling MDT considered for monitoring. It helps in checking the effectiveness of MDT in leprosy especially in patients with BI >3 [17].

Anti-PGL-I IgM antibodies in adjunct with other biomarkers improved the diagnostic accuracy of PB leprosy, and improved resolution has also been obtained with a combination of both humoral and cellular markers [18, 19]. A point of care multiplex biomarker analytical test using up to 6 biomarkers has also been recently developed which

includes anti-PGLI IgM anti- bodies as a component. It is easy to use under field conditions and has the potential to distinguish both MB and PB leprosy patients from controls [20].

A recent improved test has also been developed by Dijk et al., [21]. This point-of-care test uses synthetic phenyl glycolipids as an antigen component and can detect *M.leprae* IgM anti- bodies. The test will be applicable in future field studies in low resource leprosy endemic areas [21].

Several challenges encountered during conducting the ACD included the increased responsibility of the HEWs and knowledge gap on leprosy. Additionally, high turnover and rotation of trained health workers constrained leprosy management. Lack of awareness, stigma and low perception of the community were also challenges. The HEWs program has not been implemented in hospitals and this was an obstacle for the ACD implementation which in our study required individuals experienced in ACD and contact tracing [22].

A limitation of this study was that we were unable to screen all HHCs, 23% were not screened. Political instability in the region was an obstacle and with greater stability we could have been able to improve case detection.

Conclusion

This study showed that ACD and HHC tracing successfully identified many unsuspected leprosy cases in the Kokosa district during the study period. Through ACD and HHC tracing, prevention of potential disability can be

achievable through early diagnosis. Our work is in line with the current leprosy strategy to interrupt transmission “Towards zero leprosy, 2022– 2030”.

ACD helps in interrupting transmission of the disease within the family and beyond. Introducing similar efforts in other leprosy hotspot districts are applicable. Thus, ACD and contact tracing are proven strategies, contributing to early detection of leprosy and decreasing transmission. Ethiopia has established a good health extension program (HEP). Through this existing HEP, ACD is applicable with little investment and should be considered by public health authorities as avenue for early and better case finding, contributing to leprosy elimination.

Author Contributions

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THE SECOND ANNUAL RESEARCH CONFERENCE IN PICTURES









Appendices

Appendix 1- Conference Schedule

Africa Medical College Second Annual Research Conference June 27, 2024 <u>Addis Ababa</u>			
Time	Activities	Responsible person	Facilitators
8:30 AM- 8:55 AM	Registration	Ms. Bizen / Ms. Enuka	Dr. Mekonen Belay, V/P of Africa Medical College
	Opening Speech	Dr Berhane W/Giorgis	
8:55 AM- 9:00 AM	Keynote Speech	Dr. Esubalew Tesfahun	
9:00 AM- 9:20 AM	Presentation 1: Effect of Nutrition Behavior Change Communication on Nutritional Status and Gestational Weight Gain of Pregnant Adolescents in West Arsi, Central Ethiopia, A Cluster Randomized Controlled Trial Using GEE and LMM	Mr. Adane Tesfaye	Ato Ephrem
9:20 AM- 9:40 AM	Presentation 2: Reaching Those at Risk: Active Case Detection and Tracing of Household Contacts in A Leprosy Hotspot Woreda, Kokosa, Oromia Region, Ethiopia	Dr. Tsehaynesh Lemma	Ato Ephrem
9:40 AM- 10:10 AM	Discussion and reflections		Mr. Sisay F. Mr. Ephrem T
10:10 AM- 10:35 AM	Health Break		
10:35 AM- 10:55 AM	Presentation 3: Establishment of Local Diagnostic Reference Levels for Common Adult CT Examinations: A Multicenter Survey in Addis Ababa	Mr. Marema Jebessa	Mr Teklehaimanot
10:55 AM- 11:15 AM	Presentation 4: Oesophageal Cancer Patients in Addis Ababa, Ethiopia: Cost of Illness and Factors Associated with Cost Variability	Mr. Berhe Dessalegn	Mr Teklehaimanot
11:15 AM- 11: 40 AM	Discussions and reflections	Mr. Teklehymanot	
11:40 AM- 11: 55 AM	Concluding remarks	Mr. Bizuayehu	

11:55 AM- 12: 20 PM	Recognition and certification	Dr. Mekonnen	
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Appendix 2- Call for Paper



Call for Papers

2nd Annual Research Conference

"Improving the Provision of Quality and Equitable Health Services"

Africa Medical College invites researchers to submit research abstracts on the following sub-themes and related areas:

- *Prevention and Control of NCDs and Mental Health Problems*
- *Patient Care*
- *Scientific Research in Health and Health Related Areas*
- *Quality and Equity of Health Services*
- *Motivated, Competent and Compassionate Health Workforce*

Deadlines:

Submission of abstract: *May 20, 2024/Ginbot 12, 2016*

Submission of full paper: *May 29, 2024/Ginbot 21, 2016*

Authors should observe the following in their submissions:

· <i>Name and updated CV of the author</i>	· <i>Abstract (not more than 200 words)</i>
· <i>Title of paper</i>	· <i>Email address</i>
· <i>Affiliation of the author</i>	· <i>Mobile phone number</i>

Send your abstracts to:

· *Dr. Kassahun Kebede, Email: kassahunkb@yahoo.com
Mobile Phone: +251 91 153 1142*

N.B

· *Modest honorarium will be paid to authors whose papers will be selected and presented.*

Appendix 3- Attendance

June 27, 2024 Addis Ababa					
No	Name	Institution	Email	Phone No.	Signature
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4.	Netsared Gregawi			0913405030	
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Africa Medical College Second Annual Research Conference
June 27, 2024
Attending Physician

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3	Dr. Michael C. Johnson	UK		0044-161-234-5678	[Signature]
4	Dr. Sarah D. Evans	UK		0044-123-456-7890	[Signature]
5	Dr. Robert F. Green	UK		0044-123-456-7890	[Signature]
6	Dr. Emily G. White	UK		0044-123-456-7890	[Signature]
7	Dr. David H. Black	UK		0044-123-456-7890	[Signature]
8	Dr. Lisa I. Brown	UK		0044-123-456-7890	[Signature]
9	Dr. James K. Taylor	UK		0044-123-456-7890	[Signature]
10	Dr. Anna L. Hill	UK		0044-123-456-7890	[Signature]
11	Dr. Thomas M. Scott	UK		0044-123-456-7890	[Signature]
12	Dr. Rachel N. Adams	UK		0044-123-456-7890	[Signature]
13	Dr. William O. Baker	UK		0044-123-456-7890	[Signature]
14	Dr. Victoria P. Clark	UK		0044-123-456-7890	[Signature]
15	Dr. Benjamin Q. Lewis	UK		0044-123-456-7890	[Signature]
16	Dr. Sophia R. Walker	UK		0044-123-456-7890	[Signature]
17	Dr. Daniel S. Hall	UK		0044-123-456-7890	[Signature]
18	Dr. Olivia T. King	UK		0044-123-456-7890	[Signature]
19	Dr. Noah U. Wright	UK		0044-123-456-7890	[Signature]
20	Dr. Isabella V. Green	UK		0044-123-456-7890	[Signature]