

ST. PAUL'S HOSPITAL MELLINIUM MEDICAL COLLEGE DEPARTMENT OF PUBLIC HEALTH

ETHIOPIA FIELD EPIDEMIOLOGY TRAINING PROGRAM (EFETP)

COMPILED BODY OF WORKS IN FIELD EPIDEMIOLOGY

BY: JEMAL HASSEN

A BODY OF WORK SUBMITTED TO THE DEPARTMENT OF PUBLIC HEALTH IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER'S OF PUBLIC HEALTH IN FIELD EPIDEMIOLOGY

JANUARY 2018

ADDIS ABABA, ETHIOPIA

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Dedicated To

My wife Yasmu, and my Kids Rahmu, Kal and Sitru(KalSitRah)

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Abbreviations/Acronym

^{o}C	Degree centigrade
µl	Microliter
3TC	Lamivudine
AAUSP	Addis Abeba University School of Public Health
AFB	Acid Fast Bacilli
AIDS	Acquired Immuno- Deficiency Syndrome
ANC	Ante Natal Care
AOR	Adjusted Odds Ratio
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATT	Anti-Tuberculosis Treatment
AZT	Azidothymidine/Zidovudine
BCD_4	Baseline Cluster of Differentiation 4
BCG	Bacillus Calmette Guerin
BHL	Bekoji Hospital Laboratory
BMI	Body Mass Index
BPVL	Baseline Plasma Viral Load
BSL	Bio safety Level
BTB	Baseline Tuberculosis

CART	combination Antiretroviral Therapy
CBC	Complete Blood Count
CD_4	Cluster of Differentiation 4
CD_8	Cluster of Differentiation 8
CDC	Centers for Disease Control and Prevention
CFR	Case Fatality Rate
CHW	Community Health Worker
CHW	Community Health Worker
CI	Confidence interval
CM	Centimeter
CMV	Cytomegalo Virus
CPR	Contraceptive Prevalence Rate
CPR	Contraceptive Prevalence Rate
CSA	Central Statistical Agency
CSA POP PROJ	Central statistics agency, population projection
CSF	Cerebro-Spinal Fluid
CSM	Circulation, Sensation, and Movement
d4T	Stavudine
DALYs	Disability adjusted life years
Df	Degree of freedom
DPT	Diphtheria, Pertussis, and ,Tetanus

DR Congo	Democratic republic of Congo
DST	Drug Susceptibility Test
EC	Ethiopian calendar
EFETP	Ethiopian Field Epidemiology Training Program
EOS	Enhanced Outreach Strategy
EPHI	Ethiopian Public Health Institute
EPI	Extended program on immunization
EPI Info	Epidemiological Information
Epi link	Epidemiologic link
EPRP	Epidemic preparedness and response plan
EQA	External Quality Assessment
ETB	Ethiopian Birr
ETB	Ethiopian Birr
etc.	et cetera
EVF	Efavirenz
FA	Follow up
Feb	February
Fig	Figure
FM	Florescence microscope
GIS	Geographic Information System
GPI	Gender Parity Index

HAART	Highly Active Antiretroviral Therapy
HEP	Health extension program
HEWs	Health Extension Workers
HF	Health Facility
HGB	Hemoglobin
HIT	Health Information Technology
HIT	Health Information Technology
HIV	Human Immune deficiency Virus
HIV/AIDS	Human immune-deficiency virus / Acquired immune-deficiency syndrome
HMIS	Health management information system
HR	Hazard Ratio
HSV	Herpes Simplex Virus
ID	Identification
IEC	Information, Education, Communication
IgM	Immunoglobulin M
IQC	Internal Quality Control
IQR	Interquartile Range
IRS	Indoor Residual Spray
ISO	International Organization for Standardization
IT	Information Technology

ITN	Insecticide Treated Net
Jan	January
K.G	Kindergarten
KM	Kilo Meter
KOH	Potassium Hydroxide
LIS	Laboratory Information System
LPF	Low power field
MAC	Mycobacterium Avium Complex
MCH	Mother and Child Health
MCV	Measles containing vaccine
MDG	Millennium development goals
MOH	Federal Ministry of Health
MRN	Medical Record Number
MSF	Médecins Sans Frontières
MTB	Mycobacterium Tuberculosis
MUAC	Mid Upper Arm Circumference
MV	Measles vaccine
NGO	Non-governmental Organizations
NVP	Nevirapine
^{o}F	Degree Fahrenheit
OI	Opportunistic Infection

OPD	Outpatient Department
OPHRCBQAL	Oromia Public Health Research Capacity Building & Quality Assurance Laboratory
OR	Odds ratio
ORHB	Oromiya Regional Health Bureau
ORS	Oral rehydration salt
OTP	Outpatient Therapeutic Program
P. jiroveci	Pneumocystis jirovecii
PF	Plasmodium Falciparum
PFSA	Pharmaceutical fund support agency
PHEM	Public Health Emergency Management
PI	Protease Inhibitors
PLW	Pregnant and Lactating Women
PLW	Pregnant and Lactating Women
PLWHA	People Living With HIV/AIDS
PMTCT	Preventing Mother to Child Transmission
PNC	Post natal Care
PPE	Personal protective equipment
PV	Plasmodium Vivax
PVL	Plasma Viral Load
QC	Quality Control

QM	Quality Manual
QMS	Quality Management System
QSE	Quality System Essential
RDT	Rapid Diagnostic Test
REQA	Regional External Quality Assessment
RHB	Regional Health Bureau
RIF	Rifampin
RNA	Ribonucleic Acid
RT-PCR	Real Time Polymerase Chain Reaction
SEC	Squamous epithelial Cells
SF	System form
Sig	Significance
SMS	Short message service
SNNP	Southern Nations Nationalities and Peoples
SNNPR	Southern nation's nationalities and people's region
SOP	Standard operating procedure
SPHMMC	Saint Paul's Millennium Medical College
SPSS	Statistical package for social science
SSA	Sub Saharan Africa
STI	Sexually Transmitted Infection
T. gondi	Toxoplasma gondii

TAT	Turn- around Time
TB	Tuberculosis
TBA	Traditional Birth Attendant
TF	Technical form
TLC	Total Lymphocyte Count
TT	Tetanus Toxoid
TTBA	Traditional Trained Birth Attendant
TTC	Tetracycline
TV	Television
UNAIDS	Joint United Nations Programme on Human Immuno-Deficiency Virus/ Acquired Immuno- Deficiency Syndrome
VCR	Video Cassette Recorder
VCT	Voluntary Counseling and Tasting
VL	Viral Load
WHO	World Health Organization

Executive summary

The Ethiopia Field Epidemiology Training Program (EFETP) is a two year an in-service training program in field epidemiology adapted from the United States Centers for Disease Control and Prevention (CDC) Epidemic Intelligence Service (EIS) program. The program is designed to assist the Ministry of Health in building or strengthening health systems by recruiting promising health workers and building their competencies through on-the-job mentorship and training.

Because trainees work in active public health teams that are tackling the most serious and acute problems of the population, their work is exciting and leads to improvements in program implementation even as the trainees are learning. The EFETP program has two main components, each of which contributes to the award of the Master's degree (MPH) in Field Epidemiology. A classroom-teaching component (25%) and practical attachment or field placement component (75%) consisting of disease investigations, surveillance evaluations, surveys, and applied research on national health problems.

This body of work contains six chapters. The first chapter contains thesis report on Median time of HIV Plasma viral load suppression after ART in East Shoa zone, Oromiya region. The second chapter details Measles Outbreak Investigation and Response in Danno Woreda, West Shewa Zone, Oromiya Region. In this outbreak investigation, Measles outbreak had been confirmed by Epidemiological link and laboratory investigation. The third chapter includes Malaria surveillance data analysis in East shoa zone, Oromiya region. Malarial case was analyzed based on three categories of data available from East Shewa zone health department. The cases are clinical malaria, confirmed Plasmodium falciparum and Malaria other than Plasmodium falciparum. The fourth chapter was all about surveillance system evaluation in Gimbichu woreda, East Shoa zone, Oromiya region. Surveillance system in this wereda was evaluated by observing activities related to surveillance from community level to zonal health department and includes observation from other sectors outside health. Chapter five describes health profile of Bora woreda East shoa zone, Oromiya. Parameters that describes health status of the woreda has been discussed in details. Additional output activities were included in chapter six that includes preparation of quality manual for Bokoji Hospital, EQA standard operating procedure for OPHRCBQA lab, and laboratory practical summary report in OPHRCBQA lab

CHAPTER I

1. Outbreak Investigation

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Abstract

Introduction

Measles is a highly contagious acute viral disease characterized by fever, coryza (runny nose), cough, irritability, conjunctivitis/ lacrimation, enanthema (Koplik's spots) on the buccal and labial mucosa; and maculo-papular rash. Incidence rate for Confirmed measles cases in Ethiopia in 2014 was 11.1%. The objective of the study was to investigate suspected outbreak of Measles in Dano Woreda , West shewa zone, Oromia Regional State, Ethiopia.

Method: The study area was Dano woredas in the Oromia Region of Ethiopia. Part of the West Shewa Zone, Dano is bordered on the southwest by the Jimma Zone, on the north by Cheliya, and on the southeast by Nono; part of the boundary with the Jimma Zone is defined by the Gibe River. Outbreak was investigated from January 1, 2017 to February 10, 2017. Community based case-control study was employed to study the outbreak. Sample size was 248. We collected data directly from study participants by using standardized and structured questionnaire. Four blood samples were collected from measles suspected patients from Danno woreda in 06/01/2017 and sent to the Polio/Measles laboratory in Ethiopian Public Health Institute, Addis Abeba, Ethiopia for confirmation. All four (100%) specimens were tested positive for measles IgM during the specified outbreak period. Based on this result we concluded that Measles outbreak has occurred in Danno woreda, West Shewa zone, Oromiya, Ethiopia in February 2017.

Result: We identified 129 measles cases from 12 Jan 2017 to 17 February 2017 from twelve Kebeles in Danno woreda. There were one community deaths reported (CFR=0.77). The median age for measles cases was 4.5 –years and for controls was 2 years old. Of total cases 61 (47.2%) were females and 68(52.8%) were males. Fathers Occupation, P-value 0.023, (OR 7.026, CI, 1.301-37.955), Mothers education, P-value .009, (OR 0.038, CI, 0.003-0.447) Patients Cases age in months, P-value 0.000, (OR

1.043, CI, 1.020-1.067) Sex P-value 0.002, (OR 0.055, CI, 0.009-0.339), vaccine doses received, P-value 0.000, (OR 87.448, CI, 8.312-920.013) number of family in the house P-value 0.000, (OR 0.002, CI, 0.000-0.026), presence of other measles case in the household, P-value 0.000, (OR 0.003, CI, 0.000-0.061) was found to be risk factors for measles disease in the study area.

Conclusion: Measles outbreak was confirmed with both laboratory and epidemiological link in Danno woreda, West Shewa Zone, Oromiya, Ethiopia in February 2017.

1.1 Introduction

Background

Measles is a highly contagious acute viral disease characterized by fever, coryza (runny nose), cough, irritability, conjunctivitis/ lacrimation, enanthema (Koplik's spots) on the buccal and labial mucosa; and maculo-papular rash appearing in a shower distribution over a period of 3 days, first erupting successively over the head, neck & face then progressing to involve the body (trunk), arms & legs progressing down wards to reach the feet on the third day and accompanied by a high fever (1).

Measles is caused by a virus in the paramyxovirus family and it is normally passed through direct contact and through the air. It is a human disease and is not known to occur in animals. The first sign of measles is usually a high fever, which begins about 10 to 12 days after exposure to the virus, and lasts 4 to 7 days. A runny nose, a cough, red and watery eyes, and small white spots inside the cheeks can develop in the initial stage. After several days, a rash erupts, usually on the face and upper neck. Over about 3 days, the rash spreads, eventually reaching the hands and feet. The rash lasts for 5 to 6 days, and then fades. On average, the rash occurs 14 days after exposure to the virus (within a range of 7 to 18 days). Most measles-related deaths are caused by complications associated with the disease. Complications are more common in children under the age of 5, or adults over the age of 20. The most serious complications include blindness, encephalitis (an infection that causes brain swelling), severe diarrhoea and related dehydration, ear infections, or severe respiratory infections such as pneumonia. Severe measles is more likely among poorly nourished young children, especially those with insufficient vitamin A, or whose immune systems have been weakened by HIV/AIDS or other diseases. The virus remains active and contagious in the air or on infected surfaces for up to 2 hours. It can be transmitted by an infected person from 4 days prior to the onset of the rash to 4 days after the rash erupts (2).

During epidemics, it is responsible for killing an estimated three to five percent of children with the disease, and it contributes to childhood mortality rates of ten percent or above in malnourished populations. Case fatality rates (CFRs) may be higher in complex emergencies. Measles usually peaks during the dry season (October to March in the northern tropics, and April to September in the southern tropics). First dose of measles through routine vaccination to be given by nine months. 90% coverage to be achieved with 95% reduction in mortality (3).

Outbreaks of measles occur when the accumulated number of susceptible individuals is greater than the critical number of susceptible individuals for a given population to sustain transmission. Approximately 15% of children vaccinated at nine months of age and 5%of those vaccinated at 12 months of age fail to seroconvert, and are thus not protected after vaccination (4).

Measles is one of the most devastating infectious diseases for humans and has caused millions of death worldwide each year before introduction of measles vaccine (MV). The incidence rate of measles in China in 2010 was 2.68 per 10 0000 people (5).

Measles is one of the most contagious diseases in the world and is a leading cause of vaccine-preventable death among children. More than 60% of the 21.5 million children who did not receives one dose of measles vaccine in 2013 comes from only from six countries, India, Nigeria, Pakistan, Ethiopia, Indonesia and D.R Congo. A household in Ethiopia can lose one month's income if one child is sick from measles. Despite the fact that a safe and effective vaccine has been available for over 50 years, 400 children die every day, 16 children dies every hour. Each year: Globally 267,000 measles cases reported and 146,000 estimated deaths, mostly children (6).

Measles transmission is dependent on several factors including population vaccination coverage rates. Individuals without a history of natural immunity or not successfully immunized against measles are considered to be at increased risk of acquiring measles. Measles complications disproportionately affect persons suffering from malnutrition, immunodeficiency and pregnant women. Adults born prior to 1970 are at lower risk of measles infection because they are presumed to have natural immunity to measles. Additionally, children born to mothers with a naturally acquired immunity inherit immunity for longer periods of time than infants born to mothers with vaccine induced immunity. A high risk contact is one that is at an increased risk of measles complications (7).

Measles vaccination is one of the most cost-effective interventions available. Since measles vaccine was developed in 1958, it has saved the lives of millions of children throughout the world. Measles vaccine is made from a live attenuated virus. When children are correctly administered 0.5 ml of potent live attenuated measles vaccine subcutaneously, serologic studies have demonstrated that measles vaccines induce sero-conversion of 85% at 9 months and above 95% after 12 months of age. The peak antibody response occurs 6 to 8 weeks after infection or vaccination. Immunity conferred by vaccination against measles has been shown to persist for at least 20 years and is generally thought to be life-long for most individuals (4).

Routine EPI coverage for Measles in 2014 in Ethiopia was 84%. Incidence rate for Confirmed measles cases (laboratory and epi-linked), in Ethiopia in 2014 was 11.1% (4).

Statement of the problem

While measles deaths have dropped by an astounding 71 per cent since 2000, an estimated 158,000 children died of measles-related complications. In 2011, about 430 child deaths a day, from a virus that can be countered with an effective, inexpensive vaccine.(8) In developing countries measles is one of the leading causes of childhood deaths, most of which follow complications such as pneumonia, diarrhea and malnutrition (9).

With effective childhood immunization programs, such as in Europe and North America, Measles cases have dropped markedly and are generally limited to older age groups. However, it still remains to be common in countries with low immunization coverage, such as sub-Saharan Africa. Approximately 30 million measles cases are reported annually to World Health Organization. Most reported cases are from Africa. In 1998, the reported cases of measles per 100,000 total population reported to the World Health Organization was 1.6 in the Americas, 8.2 in Europe, 11.1 in the Eastern Mediterranean region, 4.2 in South East Asia, 5.0 in the Western Pacific region, and 61.7 in Africa. In these areas relatively younger children and infants are affected frequently. Measles epidemics occur every 2-3 years in population with large susceptible groups (10).

Risk Factors for Increased Fatality in Measles are Age at infection, Malnutrition, Type and severity of complications, Lack of immunization services, Maternal Immunity, Vaccine Induced Immunity (10).

Measles in sub-Saharan Africa is endemic and cyclical. During epidemics, it is responsible for killing an estimated three to five percent of children with the disease, and it contributes to childhood mortality rates of ten percent or above in malnourished populations. Case fatality rates (CFRs) may be higher in complex emergencies. Measles usually peaks during the dry season (October to March in the northern tropics, and April to September in the southern tropics) (3).

Due to intensified measles immunization efforts, measles mortality has decreased substantially worldwide, particularly in Sub-Saharan Africa (SSA). The World Health Organization (WHO) estimated a 92% decrease in measles-related deaths in the WHO AFRO region for the period 2000–2008. Recently, the AFRO region established a measles pre-elimination goal and experts have suggested engaging in a measles eradication campaign at the global level. However, recent large-scale outbreaks in many Sub-Saharan African countries present a challenge to measles control efforts (11).

Improved measles vaccine coverage has led to a decreased measles incidence and a reduced death rate. The World Health Organization (WHO) estimates from 2014 show a 72% reduction in cases and a 75% reduction in deaths since 2000. The WHO estimates 74% to be the coverage figure for the first dose of measles-containing vaccine (MCV1) in the African region, and only 7% for routine coverage with the second dose of measles containing vaccine (MCV2). Many countries rely on supplementary immunization activities to administer additional doses. The WHO targets for 2015 include MCV1 coverage at 90% nationally, and at least 80% in every district, with a national incidence of less than 5 per 1 000 000 population, and supplementary immunization exceeding 95% in every district (12).

Incident rate in Africa was less than 5 per million in 2012. In Ethiopia, 2013, measles incidence rate was 7.2 cases per 100,000 populations. A total of 243 measles outbreaks were confirmed in 2013 compared to 146 in 2012 with a total of 192 affected woredas (districts) in 2013 compared to 125 in 2012. Based on the epidemiology of measles in Ethiopia and burden of disease modeling, it is estimated that more than 1.5 million cases of measles (all age) and 70,000 deaths (assuming 4% case fatality ratio) would occur in Ethiopia annually. For many years the average number of measles cases reported to the Ministry of Health by the region ranged from 500-2000 annually (13).

In Ethiopia, a seasonal pattern of occurrence of measles has been observed over the years, with increased number of measles cases during the late-early part of the year (December to February). Due to the low sub national routine measles vaccine coverage and prevailing poor living and nutritional conditions, measles outbreaks continue to occur frequently in different parts of the country, most especially in Oromia and SNNPR (southern) Regions where the density of the population is relatively high . The number of confirmed measles cases steadily increased from 73 in 2003 to a peak of 3,511 in 2008, following which there was a decline to 1,944 cases in 2009. Even though measles incidence rate has showed significant increase in the country since 2010 a dramatic increase is observed from 2012 up to 2014. Case based measles surveillance in a few selected administrative zones of Ethiopia in 2002 revealed that a shift of measles cases from children under five to those above five years of age. A total of 931 measles cases were registered during the surveillance period, of which 52.4% were children 5 to 14 years and the remaining 42.5% being a child under five years (13).

This indicates the effectiveness of the vaccination campaigns which mainly focused on providing and boosting immunization in under five children. Based on this fact subsequent measles supplemental immunization activities broadened the age range to children under 15 years of age. Measles outbreaks

continue to occur in most parts of the country with nearly 70% of the reported cases among children less than 15 years. Epidemiologic data from the past several years show a decreasing proportion of measles cases in children under 5. This age group made up 56 % of measles cases reported in 2008 but only 30% of cases in 2014 [Ethiopia National Expanded Programme on Immunization (2015) comprehensive multiyear plan, 2016-2020; Federal Ministry of Health, Addis Ababa]. Ethiopia incidence rate of measles in 2017 was 20.9% (8).

Rational Of the study

Index cases of measles were seen in 01/12/2016 in Danno woreda and treatd in Danno woreda Seyo health center. Danno woreda Health office report suspected outbreak of measles in 03/01/2017 to West shewa zonal health department, The West Shewa Health department report the outbreak to Oromiya Region Health office. The regional Health beauro notify the suspected outbreak of measles for Oromiya Regional Laboratory. The lab sends us to investigate the existence of an outbreak and Response.

The main aim of this outbreak investigation was to identify the causative agent, major mode of transmission, the magnitude and risk factor of Measles outbreak in Dano Woreda, W/shewa zone, Oromia Regional State Ethiopia 2017.

1.2 Objectives

General Objective

- To investigate of Measles in Dano Woreda , West shewa zone, Oromia Regional State, Ethiopia 2017.

Specific Objective

- To confirm Existence of an suspected outbreak of measles
- To identify causative agent for the outbreak
- To identify major risk factors of the outbreak
- To provide recommendation for public health authorities in the area

1.3 Methods

Study area

Dano is one of the woredas in the Oromia Region of Ethiopia. Part of the West Shewa Zone, Dano is bordered on the southwest by the Jimma Zone, on the north by Cheliya, and on the southeast by Nono; part of the boundary with the Jimma Zone is defined by the Gibe River. The major town and the place where administrative structures located are in Sayo town. As Central statistics agency projection for 2017, the woreda total population is 125,759 with male 62,621 and female 63,138. (CSA POP PROJ, 2014-2017). The majority of the inhabitants said they were Protestant, with 53.43% of the population reporting they observed this belief, while 37.1% of the population practiced Ethiopian Orthodox Christianity, and 8.2% were Muslim (14).

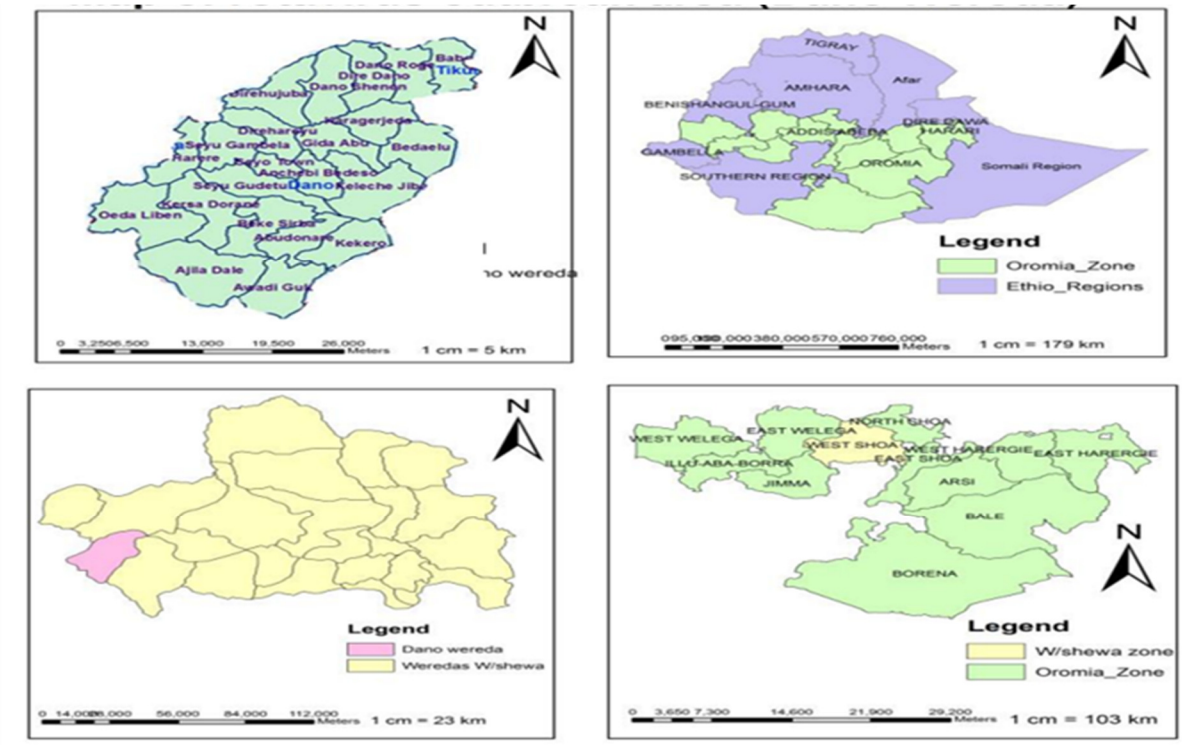


Figure 1. Administration map of Danno woreda, West Shewa Zone, Oromiya, February, 2017

Based on figures published by the Central Statistical Agency in 2005, 3.87% of its populations are urban dwellers, which is less than the Zone average of 12.3%. With an estimated area of 667.19 square kilometers, Dano has an estimated population density of 123.8 people per square kilometer, which is less than the Zone average of 152.8.

The two largest ethnic groups reported in Dano were the Oromo (92.24%), and the Amhara (7.56%); all other ethnic groups made up 0.96% of the population. Oromiffa was spoken as a first language by 94.43%, and 5.53% spoke Amharic; the remaining 0.04% spoke all other primary languages reported (14).

Study period

Outbreak was investigated from January 1, 2017 to February 10, 2017.

Study design

Community based case-control study was employed to study the outbreak of measles in Danno woreda, West Shewa Zone, Oromiya Ethiopia, from January 1, 2017 to February 10, 2017.

Sample size

Sample size was calculated by unmatched case control formula (Epi Info 7.1.4), one case to two controls and the prevalence of Measles for control taken from WHO estimate for Ethiopia in 2017 was 20.9. (15). Based on Fleiss with continuity correction formula, total number of 42 cases and 83 controls, with 10% contingency results in total number of sample size 138. But for convenience purpose larger number of sample size was taken and a total of 248 study participants (129 cases and 119 control) were studied.

$$n = \frac{r+1}{r} \frac{\bar{p}(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Where:

n1= total number of cases

n2= number of controls

r= proportion of n2 and n1 (n2/n1)

p1= prevalence of measles in a community

p2= estimated attack rate of measles during outbreak (expertise judgment)

ṕ= (p1+rp2)/ (1+r)

Data collection method

Data was collected by using standardized and structured questionnaire. We also interviewed study participants and their surrogates to elicit factors for measles outbreak in the woreda. Surrogates have been asked to provide evidence when a case cannot produce valid information about the cases during interview. We interviewed woreda health experts and observe registration of the woreda health office for different variables including immunization status of the woreda and current and previous years coverage of immunization of the woreda.

Laboratory investigation

The principal investigator collected four bloods samples with minimum volume of 10 milliliter samples from measles suspected patients and send to Ethiopian Public health Institute (EPHI) polio and measles laboratory. Samples were transported in 2-8OC until they reach the laboratory.

Data analysis

Data was analyzed by place (kebeles), person (age, sex, other socio-demographic information) and time (date of onset). It was also analyzed to identify risk factors by using Microsoft Excel, Epi Info 7.1.4 and SPSS 21.0 version software.

Case definitions

Cases

Community case definition: A person of any age and sex group with rash and fever.

Suspected measles case: Any person with fever and maculo-papular (non-vesicular) generalized rash and cough, coryza or conjunctivitis (red eyes) OR any person in whom a clinician suspects measles.

Confirmed measles case: A suspected case with laboratory confirmation (positive IgM antibody) or epidemiologically linked to confirmed cases in an outbreak.

Epidemiologically linked case: A suspected measles case that has not had a specimen taken for serologic confirmation and is linked (in place, person and time) to a laboratory confirmed case; i.e., living in the same or in an adjacent district with a laboratory confirmed case where there is a likelihood of

transmission; onset of rash of the two cases being within 30 days of each other. When a cluster of three or more cases from a woreda or health-facility catchment area (potentially including the neighboring woreda) is laboratory confirmed, subsequent cases from that woreda, occurring within 30 days are considered confirmed by epidemiological linkage, and further blood sample collection is not required. However, all cases should be line listed with the prepared format, submitted to the next level, and stored in the database.

Measles death: For surveillance purposes, a measles death is defined as any death from an illness that occurs in a confirmed case or epidemiologically linked case of measles within one month of the onset of rash. The immediate and delayed complications of measles (like pneumonia, persistent diarrhea) may manifest and lead to death much later after the disappearance of the rash.

Controls: Any child under 15 years of age without sign symptoms of measles disease and resident of Dano Woreda within period of January 1, 2017 to February 10, 2017

Inclusion criteria

Cases: Any person with generalized, maculopapular rash lasting ≥3 days; and temperature ≥101°F or 38.3°C; and cough, coryza, or conjunctivitis and resident of Dano Woreda within period of January 1, 2017 to February 10, 2017.

Controls: resident of Dano Woreda within period of January 1, 2017 to February 10, 2017.who did not develop signs and symptoms of measles and agreed to be interviewed were included.

Exclusion criteria

Participant who are not willing to participate in the study

Ethical consideration

Approval letter were written from regional health bureau to Danno woreda Health office. Each participant were told the objective of the investigation and asked verbal permission for interview. Those who accept the request will be interviewed and those who refuse the request will not be interviewed.

1.4 Result

Outbreak of Measles in Danno woreda, West Shewa Zone, Oromiya Regional State was investigated from 07/01/2017-19/02/2017.



Figure 2.Confirmed Measles case in Danno Woreda, West Shewa Zone, Oromiya, Ethiopia, and February 10, 2017

Laboratory Investigation

Four blood samples were collected from measles suspected patients from Danno woreda in 06/01/2017 and sent to the Polio/Measles laboratory in Ethiopian Public Health Institute, Addis Abeba, Ethiopia for confirmation. All four (100%) specimens were tested positive for measles IgM during the specified outbreak period. Based on this result we concluded that Measles outbreak has occurred in Danno woreda, West Shewa zone, Oromiya, Ethiopia in February 2017.

Based on Ethiopian national guideline on measles surveillance and outbreak management there is no need to perform additional laboratory tests for measles cases in Danno woreda in February 2017. We link other cases of measles epidemiologically by the fact that: A suspected measles case that has not had a specimen taken for serologic confirmation and is linked (in place, person and time) to a laboratory confirmed case; i.e., living in the same or in an adjacent district with a laboratory confirmed case where there is a likelihood of transmission; onset of rash of the two cases being within 30 days of each other. When a cluster of three or more cases from a woreda or health-facility catchment area (potentially including the neighboring woreda) is laboratory confirmed, subsequent cases from that woreda, occurring within 30 days are considered confirmed by epidemiological linkage, and further blood sample collection is not required. However, all cases should be line listed with the prepared format and submitted to the next level and stored in the database.

Four blood samples were collected from active cases and transported by triple package to EPHI for RT-PCR analysis. The results demonstrate that all blood samples transported were positive for IgM antibody.

Table 1. List of measles cases from which Blood samples were collected from Danno woreda, West Shewa Zone, Oromiya, Ethiopia, February 2017

ID number	Name of patient	Age (years)	Region	Zone	Wereda	HF_Name	Date of onset	Date specimen collected	Measles IgM	Rubella IgM
ETH-ORO-WSH-17-0164	Feysa Tamene	5	Oromia	W Shoa	Dano	Sayyo H/c	05-01-17	06-01-17	1	4
ETH-ORO-WSH-17-0165	Dawit Abdeta Bogale	5	Oromia	W Shoa	Dano	Sayyo H/c	04-01-17	06-01-17	1	4
ETH-ORO-WSH-17-0166	Simbo Teshome Mekonen	3	Oromia	W Shoa	Dano	Sayyo H/c	04-01-17	06-01-17	1	4
ETH-ORO-WSH-17-0167	Amanuel Feysa Kidane	6	Oromia	W Shoa	Dano	Sayyo H/c	05-01-17	06-01-17	1	4

Table 2. Laboratory result of measles cases from Danno woreda, West Shewa Zone, Oromiya, Ethiopia, February, 2017.

nno woreda	Expected Cases	Reported Cases With blood specimen	Reported Measles Cases	% With Blood Specimen	Measles Detection Rate	Specimen Adequacy rate	Measles Igm+ Cases	% measles Igm	Measles Discarded cases
2	3	4	4	100	23.1	50	4	100	0

Descriptive epidemiology

We identified a total of 129 measles cases from 12 Jan 2017 to 17 February, 2017 from twelve Kebeles in Danno woreda. There were one community deaths reported (CFR=0.77). The median age for measles cases was 4.5 –years and for controls was 2 years old. Of total cases 61 (47.2%) were females and 68(52.8%) were males.

Index case

The index case was seen in Gidu Abu Kebele on 12 Jan 2017 . The case was a 8 months old boy with unknown vaccination history. The case was treated at seyo health center in 18-01-17. There was travel history with his mother in Dire ujuba Kebele weeks before onset of rash. The case was alive.

The outbreak occurred between 12 Jan 2017 to 17 February 2017 with several peaks and stayed for about 4 weeks. The index case was seen so early at health facility but the district health office had started intervention lately. Additionally, late notification of the outbreak to the zonal level which in turn delayed early intervention that results a prolonged type of outbreak.

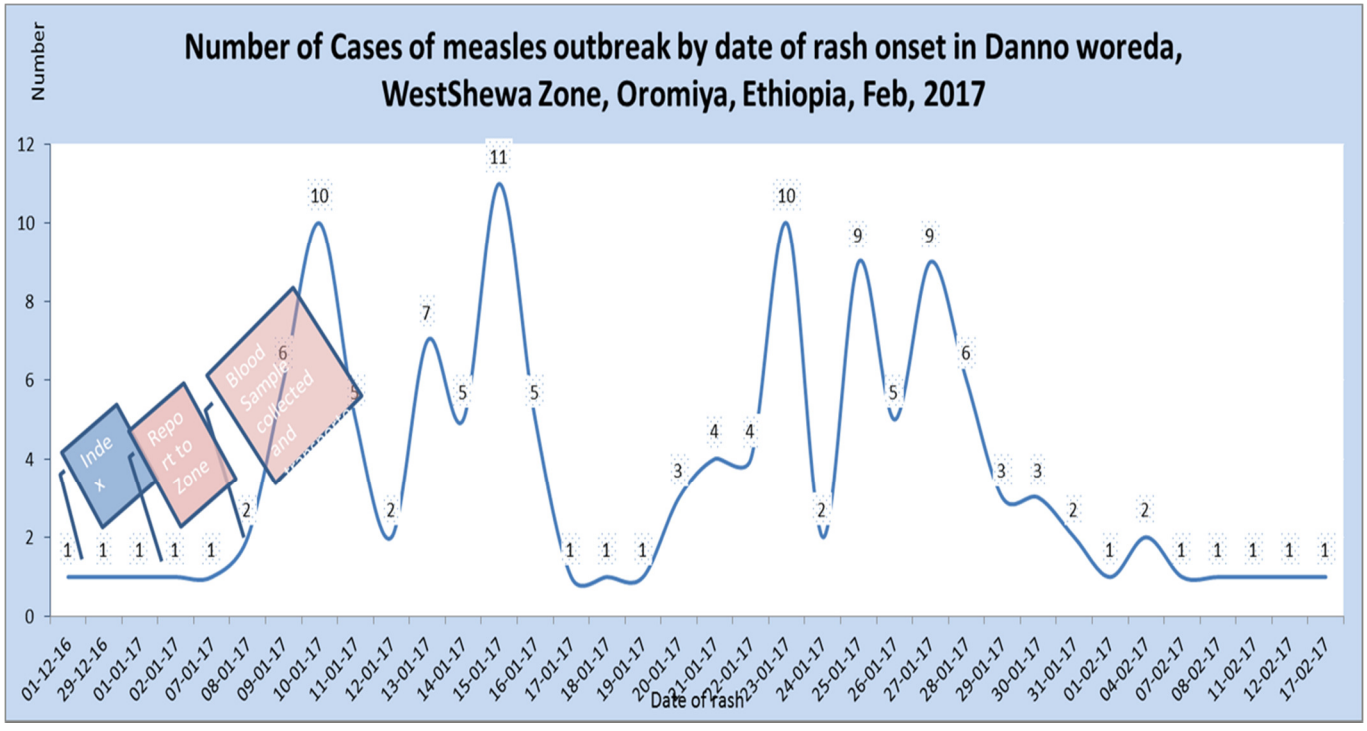


Figure 3. Epidemic curve for the outbreak of measles in Danno woreda, West Shewa Zone, Oromiya, Ethiopia, February, 2017

Vaccination status of the measles cases and controls

Out of total cases 4% were vaccinated at nine months, 19% at 12 months or above and 77% of all cases was not vaccinated at all or unknown vaccination history.

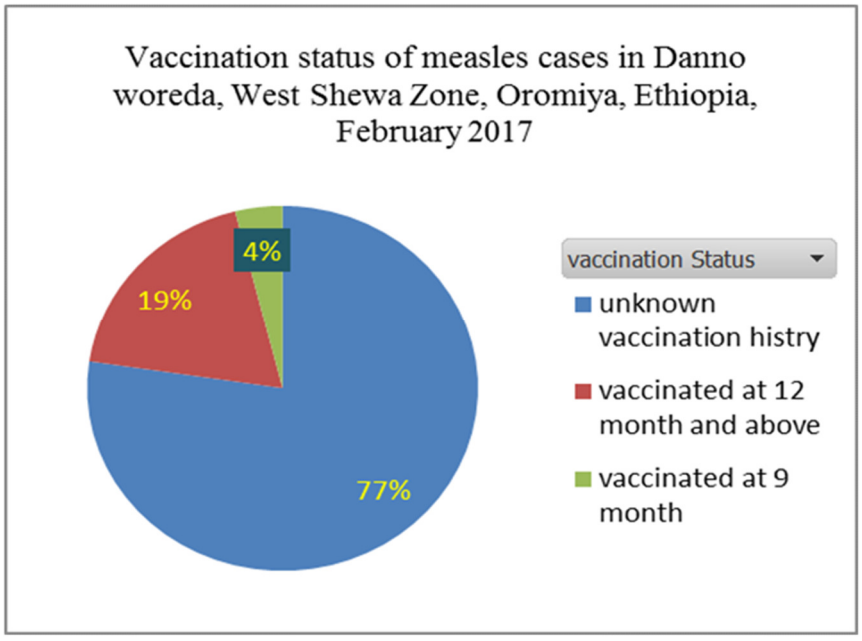


Figure 4. Vaccination status of measles cases in Danno woreda, West Shewa zone Oromiya, February 2017.

Out of total control for measles outbreak, 72% were vaccinated at nine months, 7% at 12 months or above and 21% of all cases were not vaccinated at all or unknown vaccination history. Vaccination status was asserted using immunization card and surrogate's oral witnesses.

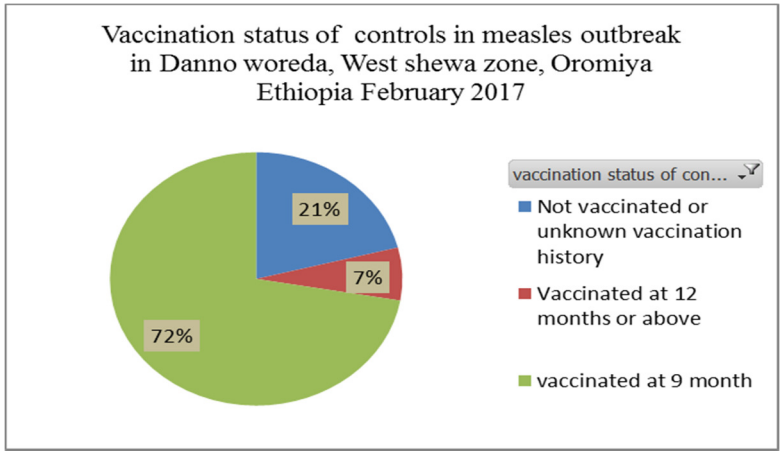


Figure 5. Vaccination status of controls for measle outbreak investigation in Danno woreda, West Shewa zone Oromiya, February 2017.

Complications developed by study participants in the outbreak includes Diarrhea in 47.3% of cases and 6.7% of controls, Ear infection , in 6.2% of cases and 0% in controls, cough in 95.3% of cases and 5% of controls.

There are also Sign symptoms in which the case and controls showed. These includes Koplic spot in 23.3 % of cases and 0% in controls, Running nose in 100% cases and 5.8% controls, red eye in 93% cases and 5% control, and rash in 96% cases and 5.8% of controls.

Table 3. Proportion of Sign symptoms and complication developed in measles cases in Danno woreda, West Shewa zone Oromiya, February 2017.

		Diarrhea		Koplic spot		fever		Running nose		Ear infection		cough		Red eye		rash		Convulsion	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Cases	number	61	68	30	99	121	20	129	0	8	121	123	6	120	9	124	5	0	129
	%	47.3	52.7	23.3	76.7	93.8	6.2	100	0	6.2	93.8	95.3	4.7	93	7	96	4	0	100
Control	number	8	111	1	118	6	113	7	112	0	119	6	113	6	113	7	112	0	119
	%	6.7	93.3	0.9	99.1	5	95	5.8	94.2	0	100	5	95	5	95	5.8	94.2	0	119

Cold chain management

The cold chain management of zonal health department and district health offices for drug and vaccine storage was good during our visit. The temperature monitoring chart for cold chain was done on a regular manner. However, there was no precise temperature measurement that there is shortage of

temperature monitoring devices; refrigerators temperature was read by only built in digital reading; this may not ensure the correct temperature.

Characteristics of measles cases by Place of residence

Most cases were reported from Dire Hujuba Kebele with an Attack Rate of 64 cases per 1000 population followed by Dire Areyu with 31 cases per 1,000 populations. The least affected Kebeles are Dire Ujumo, Oda Liben, S/ Gam, S/ Gambela, And S/ Gam with 1 in 1,000 cases per population.

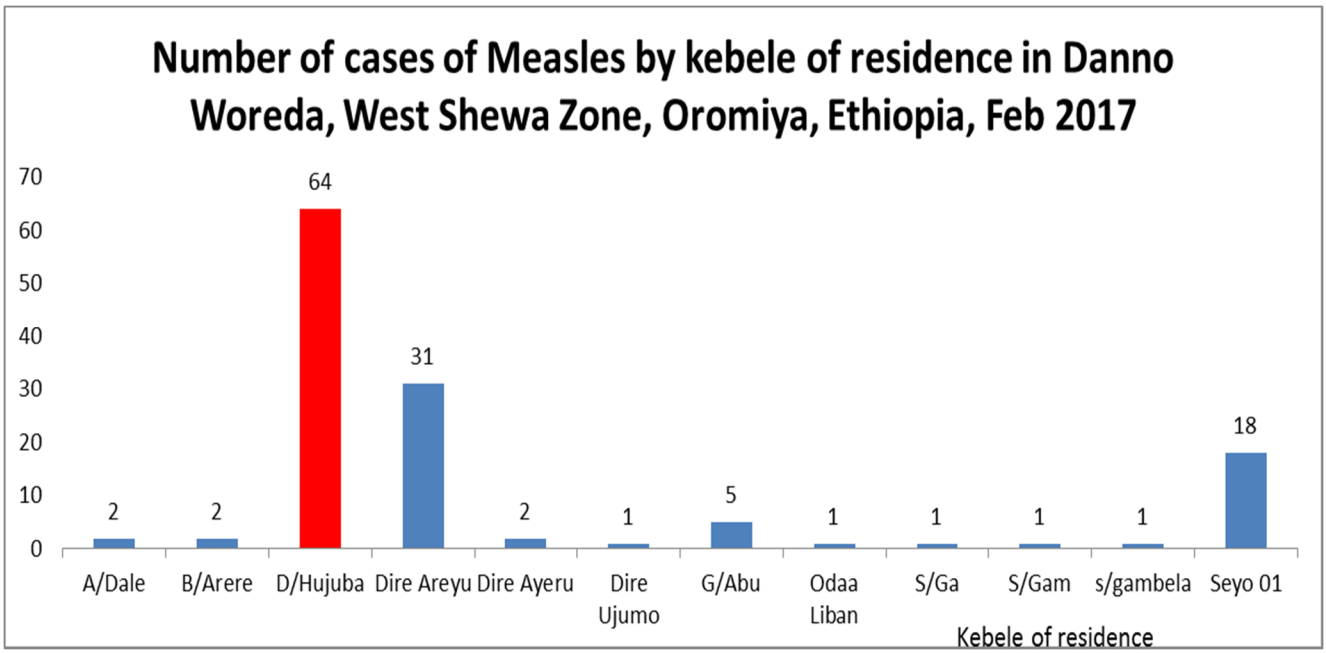


Figure 6. Number of measles cases by kebele in Danno woreda, West Shewa zone Oromiya, February 2017.

Characteristics of the outbreak by person

Most cases 18(13.9%) were age 60-64 months followed by age group 20-24 months of age with 13(10%).

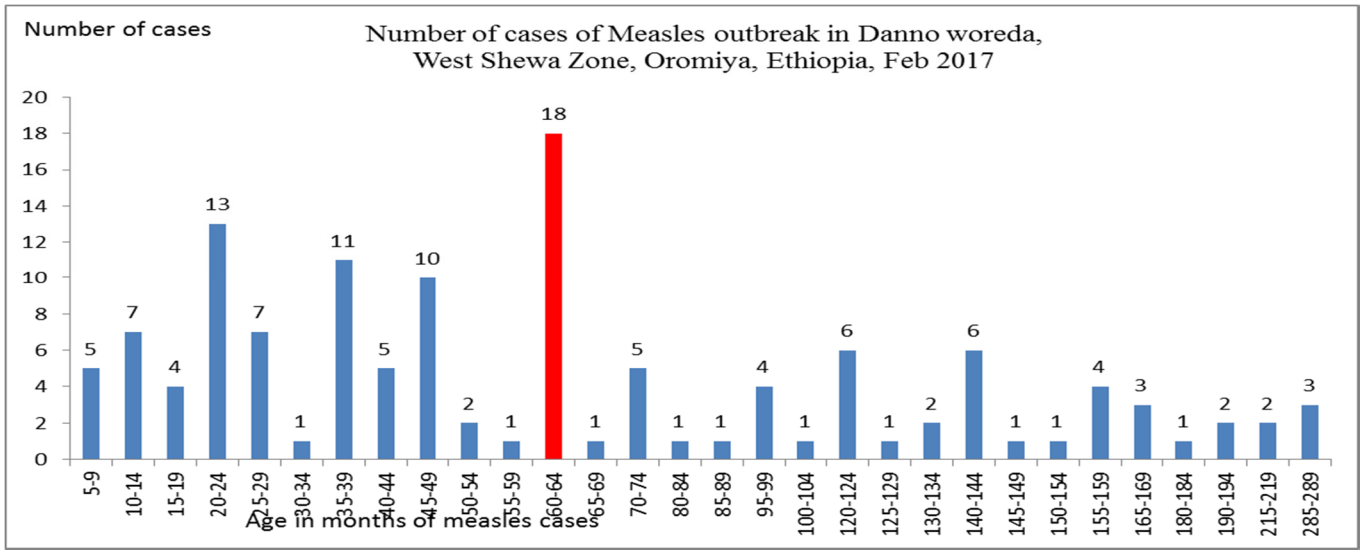


Figure 7. Number of measles cases by Age group in Danno woreda, West Shewa zone Oromiya, February 2017.

The overall Attack rate during the outbreak was 100 cases per 1000 population and 90 cases per 1000 population for females and 100 cases per 1000 population for males.

Attack rate was high in age group of 60-64 months with 140 cases per 1000 population. The next age group most affected was 20-24 months with 10.1. Least affected age group was age group between 30-34, 55-59, 80-84, 85-89, 100-104, 125-129, 145-149, 150-154 and 180-184 months of age group.

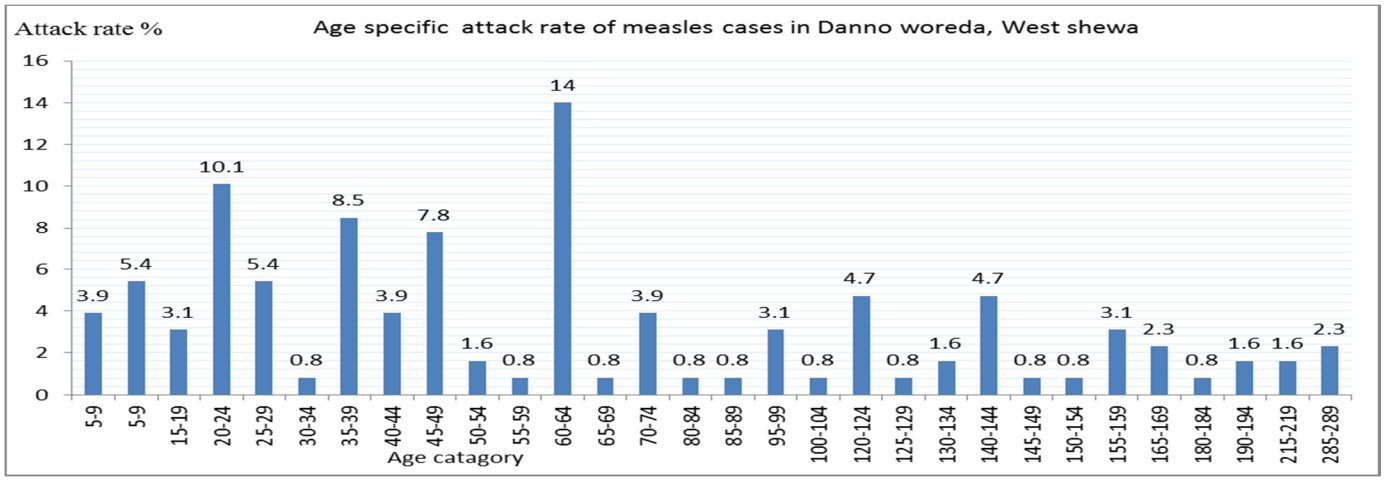


Figure 8. Age specific attack rate of measles cases in Danno woreda, West Shewa zone Oromiya, February 2017.

The highest attack rate was recorded in age group between 60-64 months of age and the second highest attack rate was observed in age group 20-24 months of age.

The most affected sex group during outbreak was males with 68%

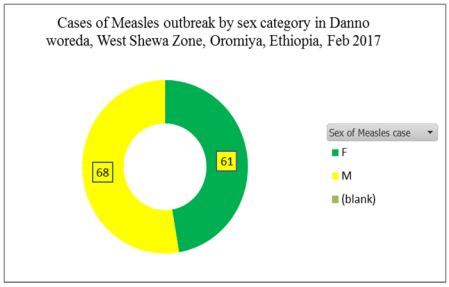


Figure 9. Proportion of measles cases by sex in Danno woreda, West Shewa zone Oromiya, February 2017.

Analytical Epidemiology

In this study, we have included "status of study subjects" as response variable and we consider Patients/Cases age in months, presence of radio in the household, Fathers Occupation, Mothers education, Fathers education, Attend school, sex, Ethnicity, religion, vaccination status, number of family in the house, presence of other measles case in the household, previous contact with measles case and travel history as predictor variables. The statistical package used for analysis was Statistical Package for the Social Sciences (SPSS) version 21.0 and Microsoft Excel 2010. We used binary logistic regression model for variable selection which contribute to the response variable: status of study subject.

From the parameter estimate table, we have found that presence of radio in the house, fathers education, attending school, Ethnicity, religion, contact with measles cases and traveling history does not have statistically significance with development of measles disease in this outbreak .Fathers Occupation P-value 0.023, (OR 7.026, CI, 1.301-37.955), Mothers education, P-value .009, (OR 0.038, CI, 0.003-0.447) Patients Cases age in months, P-value 0.000, (OR 1.043, CI, 1.020-1.067) Sex P-value 0.002, (OR 0.055, CI, 0.009-0.339), vaccine doses received, P-value 0.000, (OR 87.448, CI, 8.312-920.013) number of family in the house P-value 0.000, (OR 0.002, CI, 0.000-0.026), presence of other measles case in the household P-value 0.000, (OR 0.003, CI, 0.000-0.061).

The model

84% of variance /variability in the status of study subject was explained by our factors included in our study than the model explained by intercept only.

The variability/variance explained by variables in the equation is 84%. That is 84% of variance is explained by the factors in the model which is a good proportion.

Table 4.summary of table for variance explained by risk factors included in the measles outbreak investigation in Danno woreda, West Shewa zone Oromiya, February 2017

Pseudo R-Square	
Cox and Snell	.585
Nagelkerke	.841
McFadden	.739

The constructed model fits significantly than the null model constructed with intercept only model with p-value 0.000.

Universal model fitting summary table indicates that model with variables show significance (p-value 0.000) compared to model with intercept only .

Table 5. Universal model fit summary of risk factors included in the measles outbreak investigation in Danno woreda, West Shewa zone Oromiya, February 2017

Model Fitting Information				
Model	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood	Chi-Square	df	Sig.
Intercept Only	291.938			
Final	73.752	218.185	13	.000

$y = \exp(\beta 0+\beta 1x1)/ 1+\exp(\beta 0+\beta 1x1)$, where " y" be a binary response variable "x1, x2 x3…."" be a set of explanatory variables which can be discrete, continuous, or a combination

$\beta 0$ represent the intercept

$\beta 1, 2, 3\ldots$ stands for Coefficient for each explanatory variable

Predicting the response variable (status of study subjects)

Let's represent out predictor variables for simplicity of analysis

Patients/Cases age in months =A

Fathers Occupation=B

Mothers education=C

Sex=D

vaccination status=E

number of family in the house=F

presence of other measles case in the household=J

Then:

$y = \exp^{(\beta 0+\beta 1x1)}/ 1+\exp^{(\beta 0+\beta 1x1)}$

$y = \exp(14.405+\beta AxA+ \beta BxB+ \beta CxC+ \beta DxD +\beta ExE+ \beta FxF+ \beta JxJ)/ 1+\exp(14.405+ \beta AxA+ \beta BxB+ \beta CxC+ \beta DxD +\beta ExE+ \beta FxF+ \beta JxJ)$

Status of study subject= $\exp^{(14.405+.042\text{Patients/Cases age in months} + 1.950\text{Fathers Occupation} -3.264\text{Mothers education} -2.894\text{Sex} +4.471\text{vaccination status} -6.033\text{number of family in the house} -5.868\text{presence of other measles case in the household})}/ 1+\exp^{(14.405+.042\text{Patients/Cases age in months} + 1.950\text{Fathers Occupation} -3.264\text{Mothers education} -2.894\text{Sex} +4.471\text{vaccination status} -6.033\text{ number of family in the house} -5.868\text{presence of other measles case in the household})}$.

The table below summarizes factors which associated in the development of measles disease in Danno woreda, West Shewa zone Oromiya, February 2017.

Table 6. Summary of table variables in the model in the measles outbreak investigation in Danno woreda, West Shewa zone Oromiya, February 2017.

Respondent category	B	Sig.	Exp(B)	95% Confidence Interval for Exp(B)	
				L/ Bound	U/Bound
Intercept	14.405	.000			
Patients Cases age in months	.042	.000	1.043	1.020	1.067
Does you household have a radio	-.969	.218	.379	.081	1.774
Fathers Occupation	1.950	.023	7.026	1.301	37.955
Mothers education	-3.264	.009	.038	.003	.447
Fathers education	-.665	.400	.514	.109	2.423
Attend school	-1.788	.115	.167	.018	1.550
Sex-female	-2.894	.002	.055	.009	.339
Ethnicity	0[b]	.	.	.	.
Religion	-.206	.759	.814	.218	3.031
What is the number of vaccine doses received	4.471	.000	87.448	8.312	920.013
How many people slept in your house last night	-6.033	.000	.002	.000	.026

Is there other persons with measles symptoms in your household	-5.868	.000	.003	.000	.061
Did you have contact with measles case	-1.498	.148	.224	.029	1.704
Have you travelled	-1.162	.593	.313	.004	22.306

Outbreak Response

Active cases surveillance was carried out house to house to prevent further spread of the disease. Supportive treatment such as antibiotics, tetracycline eye ointment, oral rehydration salt (ORS), and vitamin A was also distributed. Strengthening Routine surveillance system was also enhanced supported daily with team members from National down to Woreda level. House to house health education was given to 200 households.

Training on active case surveillance, data collection, organization and analysis such as case monitoring by using Epidemic curve was given for the woreda health experts.

1.5 Discussion

There were an outbreak of measles in Danno woreda, West shewa zone from 12 Jan 2017 to 17 February, 2017. The outbreak spread to twelve Kebeles in the woreda in put 127,002 people at risk. The picture of measles in this study resembles descriptions of the disease to be found in the older literature.

Male accounted for 52.7% of confirmed measles. This figure is the same as the finding in an article published by James L. Goodson (16) in which the proportion of male in an outbreak was 52%.(16) Analysis of measles case distribution by age reveals that 22.6% of the confirmed cases were aged less than one years old, 28.6% was aged between 1-5 years of age and 48.8% of the cases were aged greater than 5 years of age. In our study, The peak attack rate was seen in age group greater than 5 years of age but in similar study in India, the highest attack rate was observed in children aged 1-4 years of age (17). (Munesh k sharma). 3.8% of confirmed cases were vaccinated against measles at the age of 9 months. While 18.6% were vaccinated at 12 months of age or above and 77.6% of confirmed cases, their vaccination status was either not known or unvaccinated. Most age group affected was those between 5-10 years old children with Attack rate of 47.7%. This finding is similar with a study done in Nepal which cites the most affected age group as 5-14 years of age with attack rate of 56%.(18)

The overall attack rate in this outbreak was 100 cases per 1000 population which is higher than the attack rate reported in similar study in India with attack rate of 51.3%. (17) Age specific attack rate was high in 5-10 years old children with 24.2%. The median age for measles case was 4.5 years.

Case fatality rate (CFR) was 0.77%. This rate was small compared with other studied such as study mentioned above in which the case fatality rate was 5%(James L. Goodson),7.2% by another study (Akalu, measles burden in Ethiopia) and 1.1% in Nepal.(18)

Fathers Occupation P-value 0.023, (OR 7.026, CI, 1.301-37.955), Mothers education, P-value .009, (OR 0.038, CI, 0.003-0.447) Patients Cases age in months, P-value 0.000, (OR 1.043, CI, 1.020-1.067) Sex P-value 0.002, (OR 0.055, CI, 0.009-0.339), vaccine doses received, P-value 0.000, (OR 87.448, CI, 8.312-920.013) number of family in the house P-value 0.000, (OR 0.002, CI, 0.000-0.026), presence of other measles case in the household P-value 0.000, (OR 0.003, CI, 0.000-0.061).

Some of the risk factors identified in our study was similar with a study such as being < 5 years old, being unvaccinated against measles, (18) and a study by moss(19) but disagree with the finding that being female was found to be associated with the disease.(18)

Complication developed by measles patient includes cough in 95.3%, Ear infection in 6.2%, Diarrhea 47.3% of measles cases. Sign symptoms developed by measles cases includes Koplic spot in 23.3%, Fever in 93.8%, Running nose in 100% rash in 96% and red eyes in 93% of cases.

Limitation

Absence of child immunization card at household level poses difficult to get exact date of vaccination.

Index case was not followed appropriately for data mining

Conclusion

Measles outbreak was confirmed in Danno woreda, West Shewa Zone, Oromia,Ethiopia in February 2017.The outbreak was ruled out for Rubella by laboratory which has similar characteristics as measles.

Risk factors for the outbreak was fathers occupation , mothers education, Sex being male, absence of immunization, large number of family in the house, presence of other measles case in the household.

Recommendation

- Strengthen routine immunization through awareness creation on the importance and benefits of routine immunization services.
- Improve measles active surveillance by training the health workers on active surveillance system.
- Immunization campaign should be planned for age group of 6 month up to 10 year.

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1.7 Annex

A NAME OF OUTBREAK _____UNIQUE ID----------

Hello, my name is _____. I work for ORHB. We are doing an investigation of a measles outbreak. The purpose of these questions is to get information for public health action. Would you be willing to participate?

If YES, ask screening questions. If NO, thank the person for their time (FINISHED).

What is the name of the case or control? _____ (First/Last name)

What is your relation to (NAME)? ☐ Mother ☐ Father ☐ Other (specify) _____

SCREENING QUESTIONS:

Has (NAME) had any of the following symptoms over the past three months?

Rash:	☐ Yes ☐ No	Fever:	☐ Yes ☐ No
Runny nose:	☐ Yes ☐ No	Red eyes:	☐Yes ☐ No
Cough:	☐ Yes ☐ No	Joint pain:	☐Yes ☐ No
Conjunctivitis:	☐ Yes ☐ No	Large lymph nodes:	☐Yes ☐ No
		Pain behind your eyes:	☐Yes ☐ No

If (name) has had fever and rash with cough, or conjunctivitis or coryza in the past three months, they can be a CASE

If (name) has not had these symptoms at the same time, they can be a CONTROL. Confirm that they have never had these symptoms that is saying of the potential control has previously had measles, they cannot be a control.

QUESTIONS AND FILTERS, CODING CATEGORIES

Respondent category ☐ Case ☐ Control

Data collector name----------

Date of data collection ----------/----------/----------Month/Day/Year

Kebele----------

Got----------

Latitude----------

Longitude----------

CLINICAL PRESENTATION *(for case ONLY)*

What is the date (NAME) first saw a rash on his/her body? ----------/----------/---------

Was (NAME) in their home village when became ill? ☐ Yes (skip to Q11) ☐ No (go to next question)

Where was (NAME) when the illness started._____ Purpose of trip:_____

Did (NAME) visit a health facility for this illness? ☐ Yes (date went to facility____/____/____) ☐ No (skip to Q14)

How long was (NAME) sick before visiting the health facility? _____ in days/hours

Was (NAME) admitted to a health facility? ☐ Yes --- date admitted:_____/___/___ (Month/ Day/ Year) ☐ No

At the health facility, was (NAME) given treatment? ☐ Yes (go to Q15)☐ No (skip to Q16

Was the respondent given(READ ALL)

Outcome of the case ☐alive ☐ death

Did (NAME) have any of the following complications when (NAME) was sick with measles or in the month after the rash? (READ ALL)

Diarrhea: ☐ yes ☐ No

Convulsions ☐ yes ☐ No

Blindness: ☐ yes ☐ No

Pneumonia:☐ Yes ☐ No

Ear infection: ☐ yes ☐ No

Change in vision: ☐ yes ☐ No

other: _____

How old is (NAME)? _____months ____ years

What sex is (NAME)? ☐ Male ☐ Female

Has (NAME) ever attended school? ☐ Yes ☐ No OR ☐ Not Applicable (mark N/A on Q24, Q25, then go to question 26)

What is the highest level of education (NAME) has completed? (Read answers):

☐ KG ☐ Primary ☐ Secondary ☐ Tertiary ☐ Not applicable

When the last time (NAME) went to school? ____day ____weeks ____ months ago or date: ___/___/_____(Month/ Day/ Year)

What is (NAME)'s occupation?

☐ Farmer ☐ Merchant ☐ Housewife ☐ Unemployed

☐ Government ☐ Pastoralist ☐ Not applicable ☐ other _____

What is (NAME)'s ethnicity? ☐ Oromo ☐ Tigre ☐Amhara ☐Gurage

☐ Other (specify) _____

What is (NAME)'s religion? ☐ Orthodox ☐ Protestant ☐ Muslim ☐ Catholic ☐ Other_____

What is the education level of the FATHER of (NAME)?

☐ Illiterate ☐ Primary ☐ Secondary ☐ Tertiary ☐ Don't know

What is the education level of the MOTHER of (NAME)? ☐ Illiterate ☐ Primary ☐ Secondary ☐ Tertiary☐Don't know

What is the main material of the roof? RECORD OBSERVATION

o No roof

o Thatch/leaf/mud

o Rustic mat/plastic sheets

CHAPTER II

2. Malaria surveillance data analysis in East Shewa zone, Oromia Region, Ethiopia, 2017.

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Abstract

Introduction

Background: Malaria continues to be one of the most devastating infectious diseases of our time, rivaling HIV and tuberculosis as a killer disease in tropical and subtropical regions, Around 3.2 billion people are at risk of malaria each year with around 500 million people proceeding to clinical disease.

Methods: Data on malaria indicators were collected from the East shewa zone Health management and information system database from 2003 EC to 2007 EC . The data was analyzed to indicate the trend of malaria incidence rate in the Zone. Data were analyzed in terms of place and person.

Results: Malarial case was analyzed based on three categories of data available from East Shewa zone health department. The cases are clinical malaria, confirmed Plasmodium falciparum and Malaria other than Plasmodium falciparum. The total numbers of cases in East shewa zone in the last five years (from 2003EC – 2007EC) were 89180 with highest cases registered in Adama and Boset woredas. The Incidence rate of malaria in East shewa zone, 2003EC-2007EC ranges from the lowest 5 cases per 10,000 populations in 2003EC to 254 cases per 10,000 populations in 2004 EC. Of the total 89,180 malaria cases reported to Zonal PHEM, on average 19,529 (21.89%) were clinically and 38534 (43.2%) laboratory confirmed PF and 31117(34.89%) laboratory confirmed malaria other than PF cases.

Conclusion: Malaria continued to be a major cause of ill health in East shewa zone. Therefore, the zonal health department should evaluate again their weakness and strength on malaria control and prevention strategy.

2.1 Introduction

Malaria, the oldest and cumulatively the deadliest of the human infectious diseases seeped into our very earliest human history (1). 40% of the world's population is at risk and 500 million of malaria cases each year with 1-2 million deaths, mostly in sub-Saharan Africa. (2) About 90% of all malaria deaths in the world today occur in Africa south of the Sahara. Malaria affects the lives of almost all people living in the area of Africa defined by the southern fringes of the Sahara Desert in the north, and latitude of about 28° in the south (9).. In Africa alone, malaria kills 1 in 5 children (3).

Ethiopia , with two-thirds of the country's population at risk, This makes malaria the number one health problem in Ethiopia with an average of 5 million cases a year [3] and 9.5 million cases per year between 2001-and 2005 .The disease causes 70,000 deaths each year and accountant for 17% of outpatient visits to health institutions. It also accounts for 15% of admissions and 29% of inpatient deaths" (4).

About 75% of the landmass of Ethiopia is malarious and 68% of the Ethiopian population, estimated at about 74 million in 2010, lives in malaria risk areas. The distribution of malaria in Ethiopia is not uniform. There are areas where the risk of malaria is high and there are areas where the risk is low. There are even areas, 25% of the country, that are malaria free.(10). The overall trend is one of a gradual progression from around four-fifths of a million confirmed cases a year in 1990 to almost a million and a half in the year 2005-06 reporting period. This represents an increase of about 80 percent. The turn of the century (1999-00) marked the worst decade of malarial infections in recent history with the number of confirmed cases exceeding one and a half million a year (4).

Malaria is a risk in the western and eastern lowlands and central midlands. However, it is absent or the risk is low in the central highlands, where the altitude (or elevation) is 2,000 metres or more above sea level, the reason is the effects of altitude on the habitat of the mosquito vector, and the development of the parasite inside the mosquito. The exact number of people getting sick and dying of malaria every year in Ethiopia is not known. However, it is known that millions of people get sick and tens of thousands of people die due to malaria every year, and that rates of mortality (death) and morbidity (illness) dramatically increase during epidemics. The distribution

of malaria in Ethiopia is not uniform. There are areas where the risk of malaria is high and there are areas where the risk is low. There are even areas, 25% of the country, that are malaria free (7).

Statement of the problem

According to WHO and the World Bank, malaria is responsible for an annual loss of 35 million disability adjusted life years (DALYs) worldwide, it has furthermore been estimated that about 40% of all fever episodes in SSA are caused by malaria (5).

Malaria continues to be one of the most devastating infectious diseases of our time, rivaling HIV and tuberculosis as a killer disease in tropical and subtropical regions , Around 3.2 billion people are at risk of malaria each year with around 500 million people proceeding to clinical disease, The burden of morbidity and mortality is biased towards young children, not yet immune to clinical symptoms and pregnant women where parasites are sequestered in the placenta (6). Ethiopian adults, unlike their counterparts in more endemic areas, have relatively little protective immunity and are vulnerable to malaria (4).

Pregnancy reduces women's immunity to malaria, which can lead to adverse health outcomes for the mother, including anemia, involuntary abortion, intrauterine growth retardation, cerebral malaria, and even death . On the other hand, severe anaemia due to malaria increases the risk of maternal mortality. The health and survival chances of the infant are also affected by malaria, which increases the risk of stillbirth and low birth weight (6).

The number of malaria cases globally was estimated to be 214 million in 2015, most cases (88%), are estimated to have occurred in the WHO African region. The number of malaria deaths globally is estimated to be 438 000 in 2015 (7).

Where it is the leading cause of death for children under 5 years of age(4) (7). Six hundred thousand African children, most under the age of five, died from malaria in 2010. Malaria is the cause of 25 percent of all childhood deaths in Africa (8).

The burden of malaria contributes significantly to perpetuating global poverty and underdevelopment. Africa's economy alone is estimated to lose $12 billion annually to malaria. (4).

In all malaria-endemic countries in Africa, 25–40% (average 30%) of all outpatient clinic visits are for malaria (with most diagnosis made clinically). In these same countries, between 20% and 50% of all hospital admissions are a consequence of malaria. With high case-fatality rates due to late presentation, inadequate management, and unavailability or stock-outs of effective drugs, malaria is also a major contributor to deaths among hospital inpatients (11).

Significance of the study

Unstable and largely unpredictable malaria epidemiology makes surveillance, information management and logistics for vector control and pharmaceuticals of paramount importance (4).

Malaria remains as the major causes of morbidity as well as mortality in the country. A study conducted in year 2001 indicated that only 31% of cases of fever seen in health facilities were properly managed; only 7 % of children with malaria received early diagnosis and treatment and the case fatality rate was 5.2%.

Even though the target of Millennium Development Goal (MDG) 6 "to have halted and begun to reverse the incidence of malaria" has been achieved, Slower declines in malaria in high-burden countries, Gaps in intervention coverage, Weaknesses in health systems in countries with the greatest malaria burden, Economic burden of malaria on health systems, Insecticide resistance, antimalarial drug resistance still possess great treat to malaria prevention and control program.(7).

2.2 Objectives

General Objective

The main objective of this malaria surveillance data analysis was to collect, organize and analyze five year trends (2003-2007EC) of secondary data on malaria in Oromia Region East shewa zone to have recent and epidemiologically described malaria surveillance information which provide for future control and prevention of the disease

Specific Objective

- To determine the magnitude of malaria morbidity and mortality in the Region
- To analyze the malaria cases trends by year and month in East shewa zone from 2003-2007 EC
- To analyze malaria prevalence by woreda, sex and age in 2003-2007EC
- To identify gaps in malaria control and prevention efforts, so as to provide practical and appropriate recommendation for the zone.

2.3 Methods and materials

Case Definition

Suspected malaria case: Clinical diagnosis of malaria is made in a patient who has fever or history of fever in the last 48 hours and lives in malaria-endemic areas or has a history of travel within the last 30 days to malaria-endemic areas.

Presumed (not tested) malaria case: In a suspected malaria case, the patient did not receive a diagnostic test for malaria but was nevertheless treated for malaria. Such cases have also been referred to as 'probable' cases; however, in most settings, the chance that a suspected case will be confirmed is < 50%, and therefore use of the term 'probable' is inappropriate. Such cases are also sometimes referred as 'unconfirmed' cases. In this guide, the term used is 'presumed malaria case'.

Confirmed malaria case: A suspected case of malaria in which malaria parasites have been demonstrated, generally by microscopy or a RDT, becomes a confirmed case.

Not malaria (confirmed not to be malaria): Patients with suspected malaria for whom a diagnostic test was negative would usually be given a diagnosis other than malaria.

Study setting/area

East Shewa zone is one of the Zones of the Ethiopian Region of Oromia. East Shewa is located in the middle of Oromia, connecting the western regions to the eastern ones. This zone is bordered on the south by the West Arsi Zone, on the southwest by the Southern Nations, Nationalities and Peoples Region, on the west by South west Shewa and Oromia Special Zone Surrounding Finfinne, on the northwest by North Shewa, on the north by the Amhara Region, on the northeast by the Afar Region, and on the southeast by Arsi; its westernmost reach is defined by the course of the Bilate River. Towns and cities in East Shewa include Bishoftu (Debre Zeit), Metehara, and Ziway. The town of Adama was separated from East Shewa and is a special zone now. Based on the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA), this Zone has a total population of 1,424,727 (2008 EC projected by 2.9 from 2007 EC population) with an area of 8,370.90 square kilometers, East Shewa has a population density of 162.03. While 340,225 or 25.08% are urban inhabitants, a further 664 or 0.05% are pastoralists.

A total of 309,726 households were counted in this Zone, which results in an average of 4.38 persons to a household, and 296,342 housing units. Concerning health, 21% of the zone is exposed to malaria, and 49% to Tsetse fly. There are 10 district and 2 town administration in East Shewa zone. These includes Ada'a, Adama Zuria, Adami Tullu and Jido Kombolcha, Bishoftu (town), Bora (woreda), Dugda (woreda), Boset, Fentale, Gimbichu, Liben, Lome (woreda), Ziway (town) (3).

East Shewa zone is one of the zones found in Oromiya region. It has 10 woredas and three town administrations.

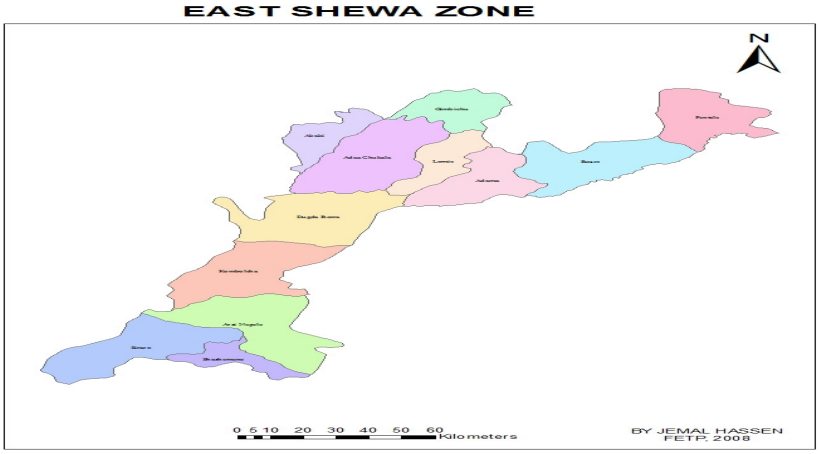


Figure 10. Administrative map of East Shewa zone, Oromiya, Ethiopia, 2008 EC.

Study unit: individual malarial diseased person from zonal surveillance data base, woreda in East shewa zone and East shewa zone.

Study period: The study was conducted from April 1/2008- June 10/2007.

Study design: Descriptive retrospective cross sectional study design were used to assess data from PHEM reporting format which includes malaria items encompassing total malaria cases (clinical and confirmed) for out-patients by species.

Incidence estimates for summary malaria indicators by year and month were obtained by summing the appropriate indicator over the time period in question using the relevant population denominator (population at malaria's area) for each reporting unit.

Source population: this Zone has a total population of 1,424,727 with population density of 162.03. While 340,225 or 25.08% are urban inhabitants, a further 664 or 0.05% are pastoralists. A total of 309,726 households were counted in this Zone, which results in an average of 4.38 persons to a household, and 296,342 housing units. People with malaria disease registered on zonal HMIS registration with clinical and laboratory diagnosis.

Inclusion criteria: All study units registered of malaria disease on HMIS and reported in surveillance form.

Exclusion criteria: study unit with missing data was excluded.

Sample size determining: all subjects which are reported from July 1/2003- June 30/2007 included in the study

Data collection: Using different format from East shewa zone health department HMIS registration and surveillance database. Principal investigator collected the data.

Operational definition

Source Population: population from which the study subjects are drawn

Study Sample/Group: Consists of the individuals (animals or groups of animals) that end up in the study.

Disability adjusted life years: The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.

Mortality rate: is a measure of the number of deaths (in general, or due to a specific cause) in a particular population, scaled to the size of that population, per unit of time.

Morbidity rate: The number of cases of a particular disease in a unit of population Health management information system: is information management applied to health and health care. It is the practice of acquiring, analyzing and protecting digital and traditional medical information vital to providing quality patient care.

Data analysis: Data were collected by different format and descriptively analyzed by using Microsoft Excel 2007. The data entered was analyzed in terms of

Time: The data were analyzed by time in terms of month and year for the past 5 years.

Place: malaria Surveillance Data were analyzed in East Shewa zone by Woreda

Person: malaria Surveillance Data were analyzed in terms of different category of age and sex

2.4 Result

Data was analyzed for its quality before going to analysis. The quality of data obtained from East shewa zone HMIS department shows satisfactory data quality in terms of completes of data except the year 2003 EC. Completeness of data in 2003 EC was 61%. The Following table summarizes data completeness in East shewa zonal health department from 2003EC to 2008EC.

Table 7. HMIS Data quality in East Shewa zone Health Office from 2003 EC to 2008 EC

S.No	Year, EC	Completeness, %	Remark
1	2003	61	
2	2004	92	
3	2005	100	
4	2006	100	
5	2007	100	

Malarial case was analyzed based on three categories of data available from East Shewa zone health department. The cases are clinical malaria, confirmed Plasmodium falciparum and Malaria other than Plasmodium falciparum. The total numbers of cases in East shewa zone in the last five years (from 2003EC – 2007EC) were 89180 with highest cases registered in Adama and Boset woredas. The least malarial cases registered in the last 5 years were from Gimbichu and Adaa woreda.

Table 8. Total population by Age and Sex in East shewa zone from 2003 EC to 2007 EC

S.No	Year, EC	Total Population			<5 years		>5 years	
					Population	Malaria case, all form	Population	Malaria case, all form
1	2003	1,367,819	Male	692,116	224,735	835	1,143,084	4432
			Female	675,702				
2	2004	1,367,776	Male	692,094	224,725	5714	1,143,050	25625
			Female	675,681				
3	2005	1,408,627	Male	712,765	231,437	3536	1,117,190	14425
			Female	695861				
4	2006	1,416,402	Male	716,699	235,714	3001	1,183,687	14540
			Female	699,702				
5	2007	1,467,534	Male	742,572	241,115	2496	1,226,418	14576
			Female	724,961				

The table below depicts malaria case in under five age group. High number of malaria case in <5 children was recorded in 2004 with total malaria case of 5714 up by 4879 case or a 684% increase from the previous year malaria cases.

Table 9.Malaria case in under five and in age group > 5 years old, East shewa zone, 2003EC-2007EC

S.No	case type	2003		2004		2005		2006		2007		Remark
		<5 years old	>5 years old	<5 years old	>5 years old	<5 years old	>5 years old	<5 years old	>5 years old	<5 years old	>5 years old	
1	Clinical diagnosis	361	2174	2057	9264	612	2541	165	1512	100	743	
2	Lab confirmed PF	324	1638	1392	6973	1419	6613	1554	7648	1551	9422	
3	Lab confirmed malaria other than PF	150	620	2265	9388	1505	5271	1282	5380	845	4411	
4	Total case	835	4432	5714	25625	3536	14425	3001	14540	2496	14576	89180

The Incidence rate of malaria in East shewa zone, 2003EC-2007EC ranges from the lowest 5 cases per 10,000 populations in 2003EC to 254 cases per 10,000 populations in 2004 EC.

Table 10. Incidence rate of malaria cases in under five and age group > 5 years of age, East shewa zone, 2003 EC-2007 EC

S.No	Year	Age category	Case classification	Clinical	Lab confirmed PF	Lab confirmed malaria other than PF	Total	Remark
1	2003	<5	Number of case	361	324	150	835	
			T/population	224,735				
			I/ Rate per 10,000 population	16	14	6	37	
		>5	Number of case	2174	1638	620	4432	
			T/population	1,143,084				
			I/ Rate %	19	14	5	38	
2	2004	<5	Number of case	2057	1392	2265	5714	
			T/population	224,725				
			I/ Rate %	91	61	100	254	

		>5	Number of case	9264	6973	9388	25625	
			T/population	1,143,050				
			I/ Rate %	81	61	82	224	
3	2005	<5	Number of case	612	1419	1505	3536	
			T/population	231,437				
			I/ Rate	26	61	65	152	
		>5	Number of case	2541	6613	5271	14425	
			T/population	1,117,190				
			I/ Rate	22	59	47	129	
4	2006	<5	Number of case	165	1554	1282	3001	
			T/population	235,714				
			I/ Rate	7	65	54	127	
		>5	Number of case	1512	7648	5380	14540	
			T/population	1,183,687				
			I/ Rate	12	64	45	122	
5	2007	<5	Number of case	100	1551	845	2496	
			T/population	241,115				
			I/ Rate	4	64	35	103	
		>5	Number of case	743	9422	4411	14576	
			T/population	1,226,418				
			I/ Rate	6	76	35	118	

Of the total 89,180 malaria cases reported to Zonal PHEM, on average 19,529 (21.89%) were clinically and 38534 (43.2%) laboratory confirmed PF and 31117(34.89%) laboratory confirmed malaria other than PF cases. The following table present details of cases of malaria in East Shewa zone from 2003EC – 2007 EC. The most affected age and sex group was Male aged >= 15 years old with five year total cases of 28,319.

Table 11. All cases of malaria disease by age and sex in East Shewa zone from 2003 EC – 2007 EC

Disease_Facility	Male<=4	Male5-14	Male>=15	Female<=4	Female5To14	Female>=15	Total
Total Malaria case	8619	13984	28319	6963	11647	19648	89180
Adaa Woreda Health Office	71	168	244	54	100	157	794
Adama Woreda Health Office	1140	2622	5529	862	2286	3846	16285
Adami Tulu Jido Kombolcha Woreda Health	1663	1872	2472	1297	1615	2319	11238

Office							
Bora Woreda Health Office	421	693	1155	316	495	1044	4124
Boset Woreda Health Office	1243	2421	5910	1089	2036	3887	16586
Dugda Woreda Health Office	654	1178	2140	563	943	1317	6795
Fentale Woreda Health Office	685	1531	4500	520	1211	2186	10633
Gimbichu Woreda Health Office	2	7	9	1	2	5	26
Liben Woreda Health Office	873	1412	1717	661	1106	1186	6955
Lume Woreda Health Office	379	470	1514	364	330	1097	4154
Mojo Town Woreda Health Office	148	133	453	109	101	287	1231
Metehara Town Woreda Health Office	508	664	1416	396	602	956	4542
Zeway Batu Town Woreda Health Office	832	813	1260	731	820	1361	5817

In this five year period, Boset woreda and Adama woreda experienced the highest burden of malaria cases while Gimbichu and Adaa woreda registered the list cases.

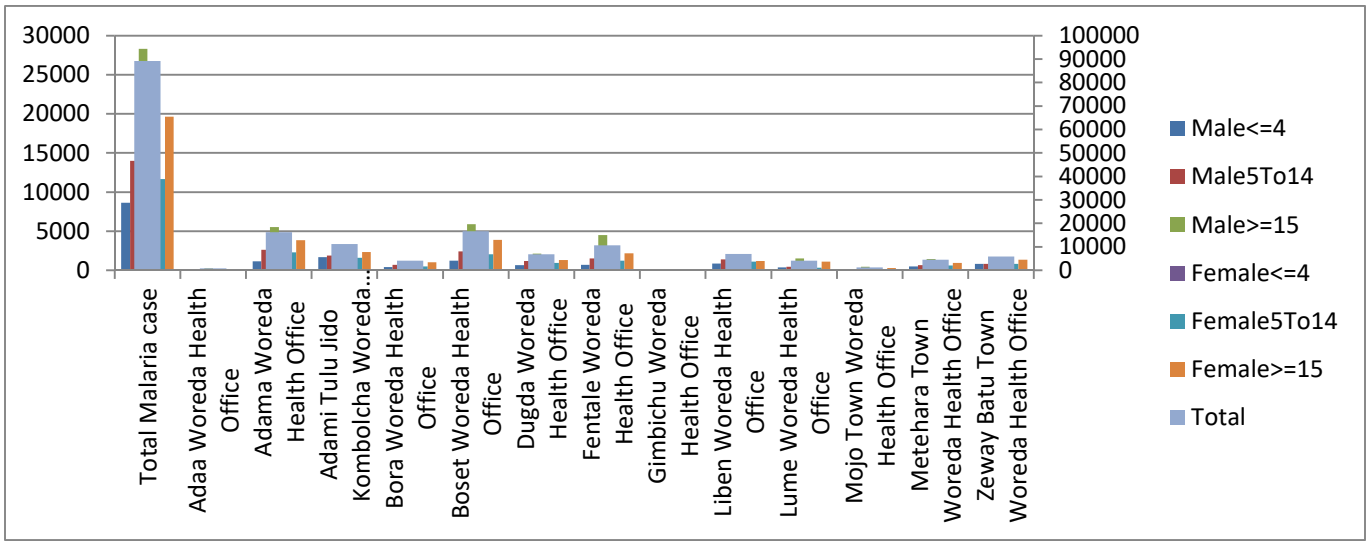


Figure 11. All cases of malaria disease by age and sex in East Shewa zone from 2003 EC – 2007 EC

The highest malaria case as seen in 2004 with total malarial cases of 31,339, of which 11,321 cases were clinical, 8,365 cases were PF lab confirmed and 11,653 cases were lab confirmed other than PF. The lowest malarial cases were recorded in 2003 EC with total malarial cases of 5,267 of which 2,535 cases were clinically diagnosed cases, 1962 cases were lab confirmed PF and 770 cases were lab confirmed malaria other than PF.

Epidemic Threshold determination

In order to detect the occurrence of malaria epidemics as early as possible, regular monitoring of the number of malaria cases at peripheral health facilities is essential. In order to detect a malaria epidemic as early as possible, the weekly number of malaria cases for each year during the last five years should be compiled. Among the data for the five years, determine the largest number of cases, and the 2nd largest number of cases for each week , then plot a line graph (in permanent ink) for 2nd largest number of cases against each week. This line graph will serve as a reference for comparing data for subsequent years. The line represents the upper normal limit of number of cases seen at the health facility. During subsequent years, plot the weekly number of malaria cases on the reference graph. If a weekly number of cases exceeds a point on the original

reference line graph or the upper normal limit. it indicates the beginning of an epidemic. After detecting the epidemic, the health worker should find out from which localities most of the cases came.

In this data analysis, data based on epidemiologic week were not available. So occurence of epidemic was unable to describe in the last five years of my data analysis.

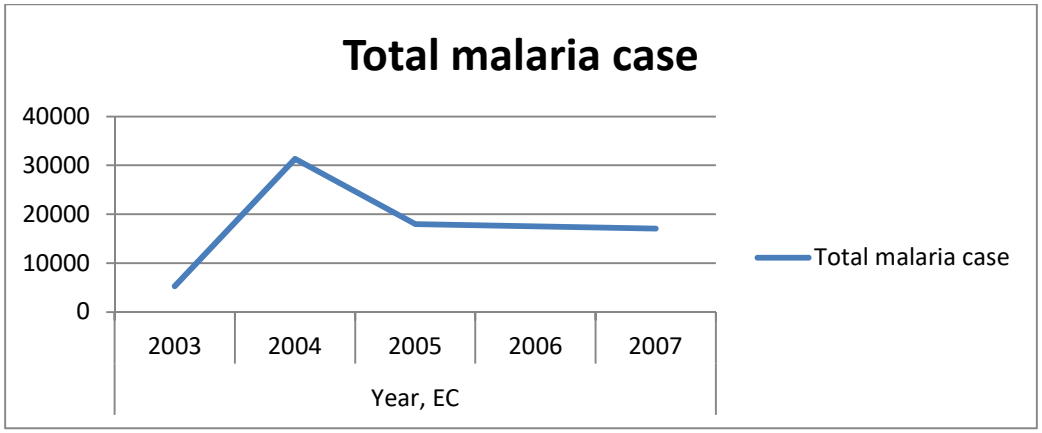


Figure 12. Five Year Trend of Total malarial cases in East Shewa zone, from 2003EC – 2007 EC

The graph below shows malaria case by species and sex of malaria cases. Males tend to be more infected than females in all years we have collected data.

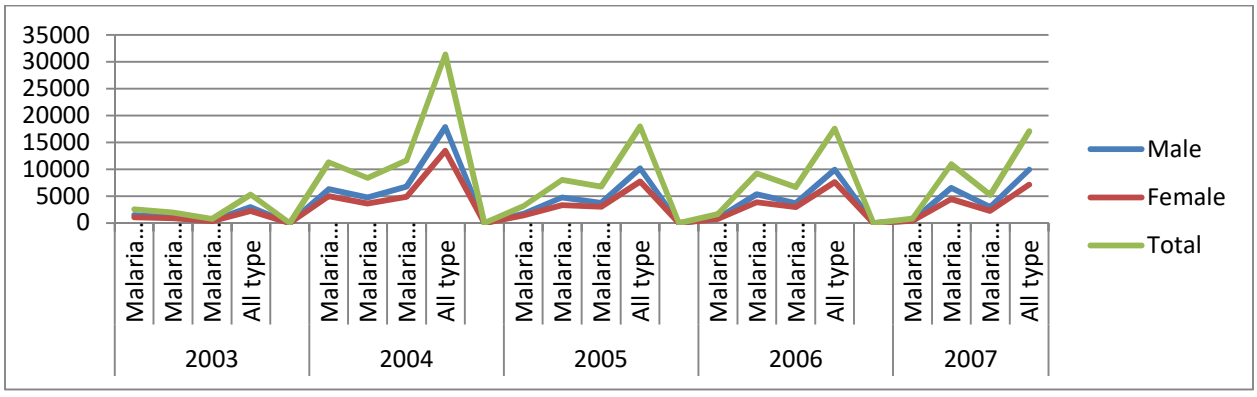


Figure 13. All Malaria cases by year, East Shewa zone, from 2003EC – 2007 EC

In the year 2003 EC -2007 EC, the incidence of malaria decrease except the case in an increase of Lab confirmed malaria; this can be partially attributed to the increase in quality of laboratory service which can be attributed to training given to lab personnel by Adama regional lab.

Table 12. Incidence of malaria by diagnosis and year per 10,000 populations East shewa zone from 2003 EC to 2007 EC

S.No	Year	Incidence of Total malaria case	Incidence of clinical malaria case	Incidence of Lab confirmed PF	Incidence of Lab confirmed Malaria other than PF	Remark
1	2003	38	18	14	5	
2	2004	229	82	61	85	
3	2005	127	22	57	48	
4	2006	123	11	64	46	
5	2007	116	5	74	35	

Lab confirmed malaria is becoming increasingly the main diagnosis than clinical diagnosis. This shown a shift of diagnosis from clinical to laboratory confirmation.

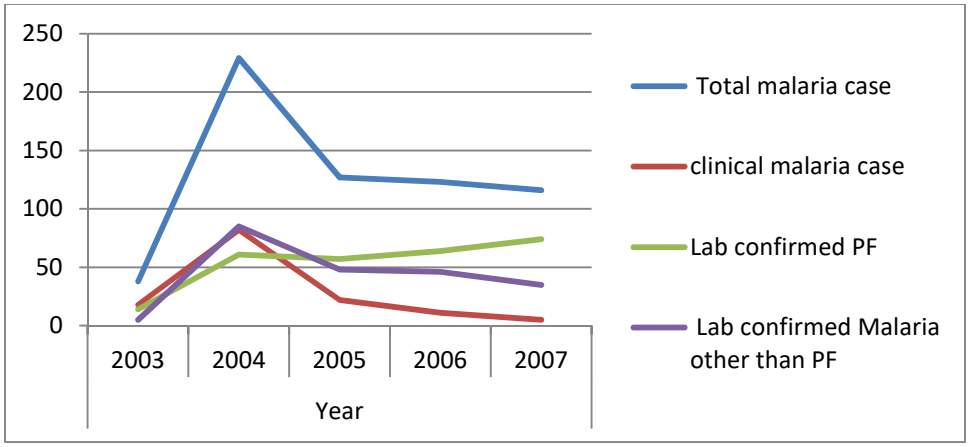


Figure 14. Trends of all cases of malaria in East Shewa zone, from 2003EC – 2007 EC

The incidence rate of total malaria decreases from 2004 to 2007. The incidence rate of all malaria cases slightly decreased from 229 cases per 10,000 populations to 116 cases per 10,000 populations in 2007. Meanwhile the incidence rate Lab confirmed PF increases from 61 cases per 10,000 population in 2004 to 74 cases per 10,000 population in 2007. incidence rate Lab confirmed malaria other than PF was higher in 2004 by 85 cases per 10,000 thought the completeness of data in 2003 EC is 61%.

To determine the emergence of epidemic in the last 5 years in East Shewa zone , we need to have data in collected in Epidemiological week. The epidemic threshold determination takes in to account the knowledge of the second largest cases of malarian in week. If the weekly number of

cases exceeds a point on the reference line graph or upper normal limit, it indicates the beginning of an epidemic.

The most affected woreda from East shewa zone from in 2003 EC was Boset woreda with 2070 all malaria cases with other 8 woredas reporting zero or no report. While in 2004 EC, Adama woreda health office report the largest number of malaria cases with 8325 cases of all forms of malaria with Boset woreda the second largest cases. In the same year, Gimbichu woreda report the least number of malaria cases with only 3 malaria cases. In 2005 Adami Tulu Jidu Kombolcha reported the largest number of cases with 2911 with Boset woreda being the second largest reporter of the ceses. In 2006 EC, Boset woreda and Gimbichu woreda Health offices report the largest and the least malaria cases. In the year 2007 EC Fentale woreda reported 3522 cases of malaria with gimbichu reporting the least cases with 5 cases per year. The following table summarizes the total number of cases reported from 2003 EC to 2007 EC in East shewa zone Oromiya Region.

Table 13. Total cases of malaria by woreda in East shewa zone from 2003 EC to 2007 EC

Disease_Facility	2003	2004	2005	2006	2007
Total Malaria case	5267	31339	17961	17541	17072
Adaa Woreda Health Office	0	312	260	163	59
Adama Woreda Health Office	0	8325	1553	2628	3779
Adami Tulu Jido KomWoreda Health Office	0	4852	2911	1987	1488
Bora Woreda Health Office	598	1656	854	609	407
Boset Woreda Health Office	2070	5324	2803	2810	3579
Dugda Woreda Health Office	949	2291	1728	1590	237
Fentale Woreda Health Office	0	2962	1579	2570	3522
Gimbichu Woreda Health Office	0	3	10	8	5
Liben Woreda Health Office	1595	937	1712	1739	972
Lume Woreda Health Office	0	1441	943	911	859

Mojo Town Woreda Health Office	0	492	318	158	263
Metehara Town Woreda Health Office	55	1642	1128	1023	694
Zeway Batu Town Woreda Health Office	0	1102	2162	1345	1208

In Adaa, Adama, Adami Tulu Jidu Kombolcha, Bora, Boset and Dugda, woredas, the largest number of cases were reported in 2004 EC with 312, 8325,4852,1656,5324,2291 malarial cases respectively ,while the number of cases in fentale was higher in 2007 with 3522 cases, in Gimbichu in 2005 with 8 cases and in Liben woreda the highest number of cases were in 2006 with 1739 cases of all forms of malaria.

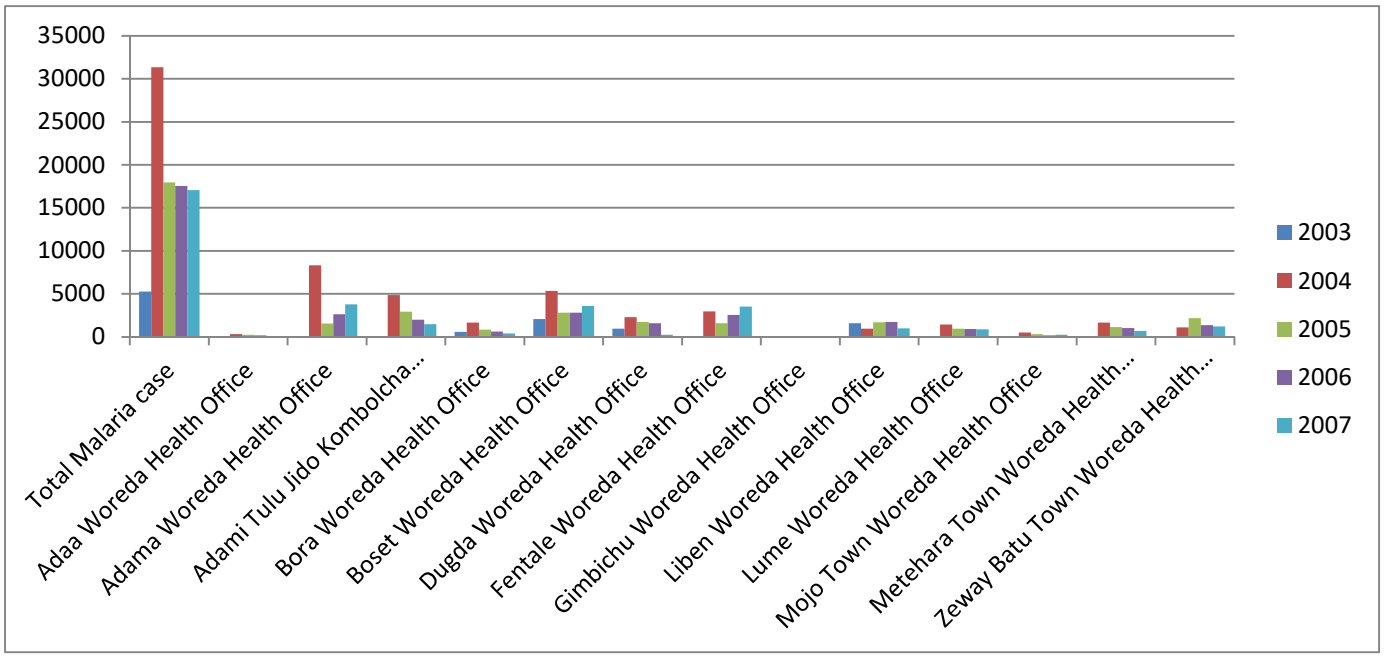


Figure 15 Graph representing the total number of cases of malaria by woreda, East Shewa zone, from 2003EC – 2007 EC

In all age categories, it is evident that males are more affected by malaria than females

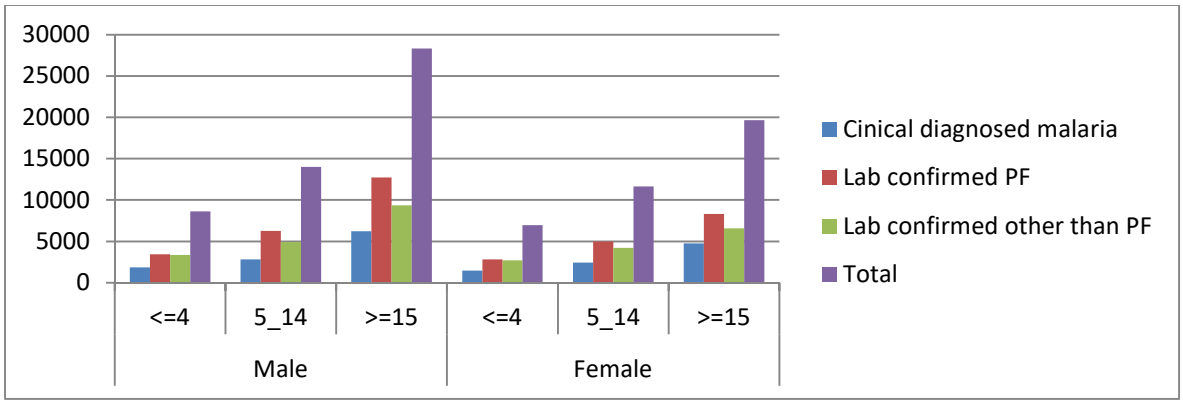


Figure 16. Cases of malaria by Age and Sex East shewa zone from 2003 EC to 2007 EC

Of all cases of malaria, Lab confirmed PF was the largest number of cases of malaria reported in East shewa zone from 2003 EC-2007 EC with clinically diagnosed being the least. Males were 75% more affected by malaria than Females, while the most affected age group was >=15 years old from in both Female and Male sex category.

Table 14 Cases of malaria by sex, age and diagnosis East shewa zone from 2003 EC to 2007 EC

S.No	Cases of malaria	Male			Total, Male	Female			Total, Female	Grand Total
		<=4	5_14	>=15		<=4	5_14	>=15		
1	Cinical diagnosed malaria	1843	2806	6231	10880	1452	2432	4765	8649	19529
2	Lab confirmed PF	3430	6274	12710	22414	2810	4985	8325	16120	38534
3	Lab confirmed other than PF	3346	4904	9378	17628	2701	4230	6558	13489	31117
4	Total	8619	13984	28319	50922	6963	11647	19648	38258	89180

Cases of malaria in under 5 years of age

Children under five years of age are especially vulnerable to malaria .Total number of malaria cases in under 5 years of age in East shewa zone from 2003EC to 2007 EC was 15582 with male being affected more than Females. In the both sex category, lab confirmed PF was the largest number to be registered with 3430 cases per 5 yeas period in males and 16120 cases in Female.

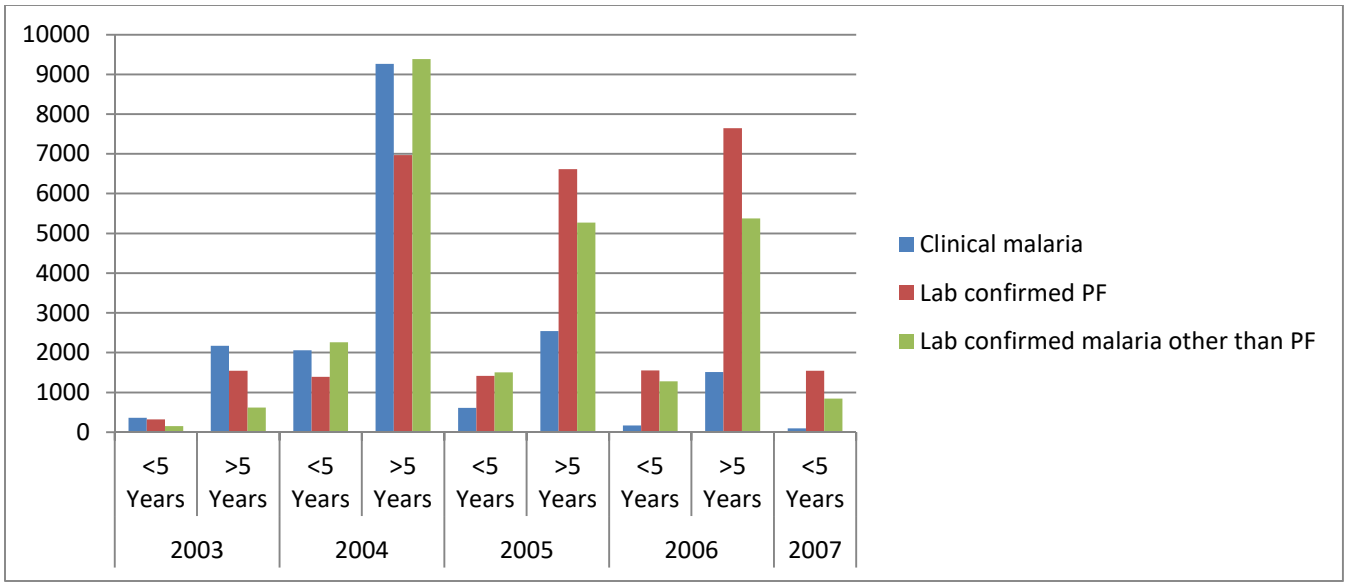


Figure 17. Cases of malaria by sex, age and diagnosis East shewa zone from 2003 EC to 2007 EC

2.5 Discussion

The annual malaria total Incidence rate for the calendar years 2007 was 118/10,000 population and reaches its highest point in 2004 with 224/10,000 population is relatively two fold higher than that of 2007. In addition to this, the confirmed PF malaria Incidence rate in this zone was similarly raised from 14/10,000 in 2003 to 76/10,000 population in 2007. The increases in both result might be due to the increment of the facilities or the strengthen of malaria surveillance activities at each level in the zone or else there might be increased risk of malaria transmissions to the higher altitude and lower altitude. Of the total 89,180 malaria cases reported to Zonal PHEM, on average 19,529 (21.89%) were clinically and 38534 (43.2%) laboratory confirmed PF and 31117(34.89%) laboratory confirmed malaria other than PF cases. The following table present details of cases of malaria in East Shewa zone from 2003EC – 2007 EC. The most affected age and sex group was Male aged >= 15 years old with five year total cases of 28,319. The highest malaria case as seen in 2004 with total malarial cases of 31,339, of which 11,321 cases were clinical, 8,365 cases were PF lab confirmed and 11,653 cases were lab confirmed other than PF. The lowest malarial cases were recorded in 2003 EC with total malarial cases of 5,267 of which 2,535 cases were clinically diagnosed cases, 1962 cases were lab confirmed PF and 770 cases were lab confirmed malaria other than PF. The most affected woreda from East shewa zone from in 2003 EC was Boset woreda with 2070 all malaria cases with other 8 woredas reporting zero or no report. While in 2004 EC, Adama woreda health office report the largest number of malaria cases with 8325 cases of all forms of malaria with Boset woreda the second largest cases. In the same year, Gimbichu woreda report the least number of malaria cases with only 3 malaria cases. In 2005 Adami Tulu Jidu Kombolcha reported the largest number of cases with 2911 with Boset woreda being the second largest reporter of the ceses. In 2006 EC, Boset woreda and Gimbichu woreda Health offices report the largest and the least malaria cases. In the year 2007 EC Fentale woreda reported 3522 cases of malaria with gimbichu reporting the least cases with 5 cases per year.

Limitations

Secondary data source were used to analyze the data. Data was not found in Epidemiologic week that enable us to analyze data in terms of Time and to determine epidemic threshold. Data

was not complete for the year 2003. No PHEM data were available compiled in a form than enable us analyze data in terms of time, place and person.

Conclusion

The incidence and cases of all malaria cases were decreased by about half from 2004 EC to 2007 EC. However, the incidence of Lab confirmed PF increased from 61 person per 10,000 to 74 person per 10,000. But this increase can partially be attributed to quality training given by Adama regional lab on Malaria diagnosis. So the zonal health department should strengthen the activities previously taken to even more decrease the incidence of malaria in the zone.

Recommendations

The zonal health department should conduct training for the woreda PHEM officers especially on how to report the data timely.

The recent reporting format lacks some important indicator variables such as different age category for analysis.

Close follow up and technical assistance Should be needed when no reports are coming from the woreda. Having complete report helps the analysis and interpretation to be more meaningful and acceptable.

Not the least but the last, PHEM office in the zone were not recording , documenting and reporting well as of expected enough to detect the outbreak early as far as possible. The malaria surveillance data were not well integrated so as to monitor the occurrence of outbreak .

Further study should be plan for prevention and control to come to elimination

Dissemination of findings: finding of the surveillance data analysis were distributed to advisor, supervisor, zonal health department, and regional laboratory(2).

2.6 Reference

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10. (http://moodle.digital campus.org/mod/page/view.php?id=14803)

11. (https://www.againstmalaria.com/downloads/RBMBurdenMalariaAfrica.pdf)

2.7 Annex

Data collection format

Table 1: Population of East shewa projected from 2007 census, Oromia, Ethiopia, February 2008

S.NO	Name of woreda	Malarious Status							Remark
			2004	2005	2006	2007	2008		
1									
2									
3									

Table 2: Age and sex distribution of the population of East shewa zone, Oromia Regional State, Ethiopia, February 2008

Population group		2004		2005		2006		2007		2008	
		Relative proportion	Total Popu	Relative proportion	Total Popu	Relative proportion	Total Popu	Relative proportion	Total Popu	Relative proportion	Total Popu
	< 1 yr										
	1_4										
	5_9										
	>10										
	< 1 yr										
	1_4										
	5_9										
	>10										
	Pregnant and Lactating Mother										

Table 3: Distribution of malaria Death (2004-2008) by age and sex, East shewa zone, Oromia Regional State, Ethiopia, February 2008

Year	Age groups (years)				Sex groups			Total
	< 1 yr	1_4	5_9	≥10	Male	Female		
						Pregnant	others	
2004								
2005								
2006								
2007								
2008								

Table 4: Distribution of malaria Case (2004-2008) by age and sex, East shewa zone, Oromia Regional State, Ethiopia, February 2008

Year	Age groups (years)				Sex groups			Total
	< 1 yr	1_4	5_9	≥10	Male	Female		
2003						Pregnant	others	
2004								
2005								
2006								
2007								
2008								

Table 5: Basic Information of East shewa zone Oromia Regional State, Ethiopia, February 2008.

Year	Number of HHs with at least 1 ITN	Number of HHs utilizing ITNs properly	Malaria breeding site reduction in M 2	Health institution							
				Governmental			NGO and Private				Total
				Total hospitals	Total H.C	Total H.Post	Total hospitals	Total H.C	Total H.Post	Clinics	

2003											
2004											
2005											
2006											
2007											
2008											
Total											

Table 8:- Burden of Malaria by age group and Sex in East shewa zone, Oromia, Ethiopia, January 2004- January 2008 .

Variables		Age				Sex			Total
		<1	1_4	5_9	>10	Male	Female		
							PW	PW	
Mortality	All Cause								
	Malaria								
Morbidity	All Cause								
	Malaria								
Admission	All Cause								
	Malaria								

Table 9: Reported cases of malaria by woreda, East shewa zone Oromia Regional State, Ethiopia, 2004-2008 EC

S, No	Woreda	2004			2005			2006			2007		
		Clinically treate	Malaria cases	Total cases	Clinically treate	Malaria cases	Total cases	Clinically treate	Malaria cases	Total cases	Clinically treate	Malaria cases	Total cases

		dmalariacases						dmalariacases						dmalariacases						dmalariacases				
			Pos.	PF	PV	PF+PV			Pos.	PF	PV	PF+PV			Pos.	PF	PV	PF+PV			Pos.	PF	PV	PF+PV	

Budget Breakdown

Table10. Budget Breakdown

Sr. No.	Item	unit	Quantity	Unit cost	Total cost in Eth. Birr	Remark
1	Duplicating paper	box	3	150	450	
2	Toner	each	1	1350	1350	
3	Pen	each	3	5	15	
4	Pencil	each	5	2	10	
5	Flash Disk	Each of 16 GB	1	200	200	
6	Hard Disk	Each of 1TB	1	2500	2500	
	Grand total				4525	

CHAPTER III

3. Malaria Surveillance System Evaluation in Gimbichu woreda, East Shewa Zone, Oromiya, Ethiopia, March 2017

Authors: Jemal Hassen Ali[1], Yemesrach Abeje[2] , Mesrach Ayalew[2] Daba Muleta[3]

Affiliation: [1]Ethiopia Field Epidemiology Training Program; [2]St. Paul's Hospital Millennium Medical College Department of Public Health; [3]Oromiya Public Health Research, Capacity Building, Quality Assurance Laboratory

Abstract

Background: Disease surveillance is the ongoing systematic collection, analysis, and interpretation of outcome specific data for use in planning, implementing and evaluating public health policies and practices. The evaluation of a surveillance system promotes use of data collection resources and assures that systems operate effectively.

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected female Anopheles mosquitoes. This study evaluats malaria surveillance system and provide possible recommendation for action in Gimbichu woreda, East Shewa Zone,

Methods: Descriptive cross sectional study design was employed on secondary data from 01-30, March 2017. The study was conducted, in Gimbichu woreda East Shewa Zone in Oromia Regional State. The study units were the nine health facilities and two health offices. Data was collected using questionnaire specifically designed to collect data for surveillance. The principal investigator using the WHO protocol for the assessment of national communicable disease surveillance and response systems, collected data. Descriptive analysis was used to estimate achievement in the woreda. Tables and graphs were used to summarize the finding.

Result: There was shortage of standard reporting format in the last six months. The number of district reporting weekly and immediately to the zone in 2017 was 11**.** Completeness of data reporting in the woreda was 96.9% of which in the month October only 74 facility report was reported on time. The woreda health office allocates budget for malaria control and prevention for the year 2017. Total budget allocated was ETB 817950.00. Most health facilities report timely in the last nine months. But in the month November 2016, only 66% of the health facility was reported timely due to absence of reporting format in the reporting health facility.

Conclusion: The surveillance system in the woreda was good. It enables prevention and early detection of public health problems in the study area.

3.1 Introduction

Disease surveillance is the ongoing systematic collection, analysis, and interpretation of outcome specific data for use in planning, implementing and evaluating public health policies and practices. A communicable disease surveillance system serves two key functions; early warning of potential threats to public health and programme monitoring functions which may be disease specific or multi-disease in nature (1).

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected female Anopheles mosquitoes. In 2015, 91 countries and areas had ongoing malaria transmission. The disease is preventable and curable, and increased efforts are dramatically reducing the malaria burden in many places (5).

There were 212 million new cases of malaria worldwide in 2015 (range 148–304 million). The African Region accounted for most global cases of malaria (90%), followed by the South-East Asia Region (7%) and the Eastern Mediterranean Region (2%).In 2015, there were an estimated 429 000 malaria deaths (range 235 000–639 000) worldwide. Most of these deaths occurred in the African Region (92%), followed by the South-East Asia Region (6%) and the Eastern Mediterranean Region (2%).Children under 5 are particularly susceptible to malaria illness, infection and death. In 2015, malaria killed an estimated 303 000 under-fives globally, including 292 000 in the African Region. Between 2010 and 2015, the malaria mortality rate among children under 5 fell by an estimated 35%. Nevertheless, malaria remains a major killer of under-fives, claiming the life of 1 child every 2 minutes (6).

Ethiopia has been implementing the Integrated Disease Surveillance and Response (IDSR) strategy for strengthening communicable diseases surveillance in the country since the year 2000. More recently, IDSR has been incorporated as one pillar in the Public Health Emergency Management (PHEM) system under the foresight of the Ethiopian Public Health Institute (EPHI), a specialized agency of the Federal Ministry of Health (2).

In 2004, 87 original (integrated disease surveillance and response) IDSR units existed nationwide reporting on "zonal" level statistics. These increased to 108 by 2008–2009 through the splitting of zones and the addition of referral hospitals and towns. The increase in reporting units enhance surveillance data flow from grass root level to the MOH (3).

The evaluation of a surveillance system promotes the best use of data collection resources and assures that systems operate effectively. Surveillance system evaluation allows us to define

whether a specific system is useful for a particular public health initiative and is achieving the overarching goals of the public health program and the data collection objectives. Any evaluation should include recommendations for improving the quality and efficiency of the system and a timeline for implementing changes based on available resources (4).

In EFY 2007, the total number of laboratory confirmed plus clinical malaria cases were 2,174,707. In particular, the monthly pattern showed an increase in the first five months of the fiscal year reaching the highest peak in November, followed by a decrease until April. A total of 662 deaths were recorded in the same period, with a Case Fatality Rate (CFR) of 0.03%.Out of the total 2,174,707 malaria cases reported in the fiscal year, 1,867,059 (85.9%) were confirmed by either microscopy or rapid diagnostic tests (RDT), out of which 1,188,627 (63.7%) were Plasmodium falciparum (PF) and 678,432 (36.3%) were Plasmodium vivax (PV). The monthly pattern showed an increase in the first five months of the fiscal year reaching the highest peak in November, followed by a decrease until April. In EFY 2007, the highest number of laboratory confirmed plus clinical malaria cases was reported from Amhara (610,486), followed by Oromia Region (430,969 cases), and SNNP Region (375,746 cases) . In general, there was a decrease on the number of laboratory confirmed plus clinical malaria cases at national level (5).

There are identified 20 disease and conditions in Ethiopian national disease surveillance system classified in to two reporting periods depending on their epidemic potential, diseases targeted for elimination and eradication. They are immediately reportable and weekly reportable disease. Immediate reporting: Currently 13 diseases are identified to be reported immediately to next reporting level. For the immediately reportable diseases, a single suspected case is considered as a suspected outbreak. This disease includes Polio, Pandemic Influenza A, Anthrax, Rabies, Avian Human Influenza, Smallpox, Cholera, Sever Acute Respiratory Syndrome, Guinea worm Viral Hemorrhagic Fever, Measles, Yellow fever and Neo Natal Tetanus. In addition to immediately reportable disease the reporting protocol also lists disease or conditions to be reported weekly. This includes Dysentery, Severe acute Malnutrition, Malaria, Typhoid fever, Meningococcal Meningitis, Typhus and Relapsing fever. Woreda report to zone/region every Tuesday till midday; Reporting of the total number of cases and deaths seen within a week (Monday to Sunday) and should be reported to the next level , Zone report to region every Wednesday till midday (6).

Rationale for Surveillance System Evaluation

Public health surveillance systems should be evaluated periodically to assure the effectiveness and efficiency of the systems. this study was conducted to determine the status of core activities of the surveillance system in Gimbichu woreda East Shewa zone, Oromiya, Ethiopia. Malaria is one of the leading causes of morbidity and mortality in Ethiopia. Therefore, this study will be conducted to evaluate whether the system is in a way of performing to the set objective and to identify the gap for improving the surveillance system. Malaria surveillance system has been useful in providing information of malaria trends and it provides magnitude of morbidity and mortality due to malaria in the woreda. The finding of this evaluation will be utilized for planning, effective health interventions and procure of equipment that helps for diagnosis, treatment and prevention of malaria cases.

3.2 Objectives

General objective

- To assess malaria surveillance system in Gimbichu woreda, East Shewa Zone, Oromia region, 2017

Specific Objectives

- To assess the Performance of the surveillance system, in early detection of outbreaks, morbidity and mortality of malaria disease
- To evaluate the key attributes of surveillance system and explain the challenges of quality of surveillance system
- To provide recommendation based on findings of the surveillance system in the woreda

3.3 Methods and Materials

Study Area

The study was conducted, in Gimbichu woreda, East Shewa Zone in Oromia Regional State**.** Gimbichu is one of the woredas in the Oromia Region of Ethiopia. Part of the East Shewa Zone, Gimbichu is bordered on the south by Lome, on the southwest by Ada'a Chukala, on the northwest by the Amhara Region, and on the east by the Afar Region. The administrative center is Chefe Donsa. Most parts of this woreda are more than 2300 meters above sea level; Gara Bokan is the highest point. Rivers include Wedecha and Belbela, both tributaries of the Modjo. A survey of the land in Gimbichu shows that 37.6% is arable or cultivable, 14.2% pasture, 2.6% forest, and the remaining 45.6% is considered degraded or otherwise unusable. Lentils, chickpeas and fenugreek are important cash crops. About 6% of the rural, 100% of the urban and 11% of the total population has access to drinking water. The woreda has two town and 33 rural kebeles. The study units includes one woreda health office (Gimbichu woreda Health office), one health center(Chefe Donsa Health center), and eight health posts (H/Seftu, L/Chefe, A/Gole, Kersa, Buii, Germama, M/Gora, and M/Tade). All health facilities and health office were studied (7)(8).

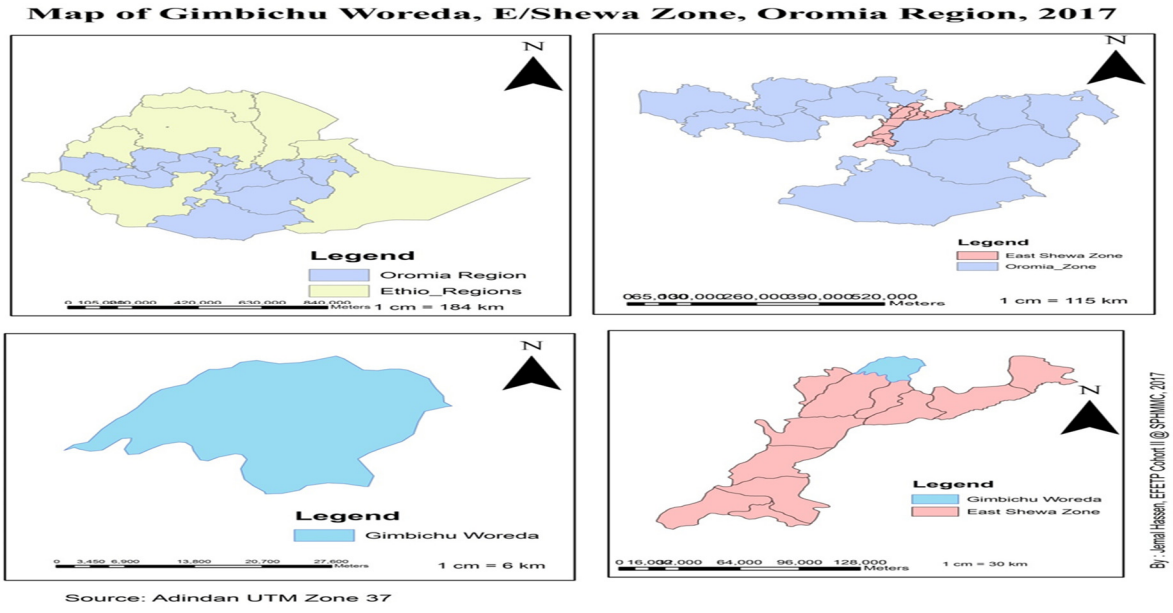


Figure 18. Administrative Map of Gimbichu woreda, East Shewa Zone, Oromiya Region, Ethiopia, February, 2017.

Study design and period

Descriptive cross sectional study was conducted to assess effectiveness of surveillance system for early detection of on retrospective data in Gimbichu woreda from 01-30, March 2017.rertospective data will be analysed for system evaluation.

Study unit

The study units were nine health facilities (one Health Centers, and eight Health Posts) and one Woreda Health Office.

Sample Size and Sampling Technique

From East shewa zone, Gimbichu woreda health office was selected purposely, then one health centers from this woreda and eight health posts from this health centers catchment were selected for the study. A total of 9 health facilities were included in this surveillance system evaluation. Three focal persons from East Shewa Zone, Gimbichu woreda health office and Chefe Donsa health center were interviewed.

Data collection Method

Data was collected using standardized questionnaire (Annex 1-4). Data was collected by the principal investigator using the WHO guidelines and protocol for the assessment of national communicable disease surveillance and response systems. Questionnaires were reviewed for completeness after pretesting at A/Gole and Kersa health posts.

Data analysis

The primary study outcome was assessment of malaria surveillance system in the woreda. Descriptive analysis was used to compare achievement by the study unit against national standards set by Federal ministry of health. Figures, Graphs and tables were used to summarize data obtained by questionnaire using Microsoft office excel-2007. Data were describes in terms of percent, absolute numbers and ratios.

Data Dissemination

After completing the surveillance system analysis, the report were be forwarded primarily to my advisor in Saint Paulo's Hospital Millennium Medical College Public Health Department. The other recipient will be my field mentor at Oromiya regional laboratory. East Shewa zone PHEM

department and Gimbichu woreda health office will also receive the report to help them plan based on the finding.

Case definition

According to National PHEM guideline the case definition for malaria categorized in to two, Clinical and community case definition.

- **Clinical case definition:** Any person with fever, headache, back pain, chills, sweats, myalgia, nausea and vomiting diagnosed as malaria clinically.
- **Community case definition:** Any person with fever OR fever with headache, back pain, chills, sweating, muscle pain, nausea and vomiting OR suspected case confirmed by RDT.

Operational definition

- **Flexibility:** is the ability of the system to adapt to changing needs with little additional time, persons or allocated funds. A flexible public health surveillance system can adapt to changing information needs or operating conditions with little additional time, personnel, or allocated funds. Flexible systems can be easily integrated with other systems.
- **Timeliness**: is the ability of the system to trigger appropriate action in time. The surveillance system must provide information in time to control communicable diseases.
- **Representativeness**: is the ability of the system to describe health events accurately in terms of time, place and person. A public health surveillance system that is representative accurately describes the occurrence of a health-related event over time and its distribution in the population by place and person.
- **Simplicity**: The simplicity of a public health surveillance system refers to both its structure and ease of operation. Surveillance systems should be as simple as possible while still meeting their objectives.
- **Acceptability**: reflects the willingness of persons and organizations to participate in the surveillance system.
- **Sensitivity**: is a surveillance system can be considered on two levels. First, at the level of case reporting, sensitivity refers to the proportion of cases of a disease (or other health-related event) detected by the surveillance system. Second, sensitivity can refer to the

ability to detect outbreaks, including the ability to monitor changes in the number of cases over time.

- **Stability**: refers to the reliability (i.e., the ability to collect, manage, and provide data properly without failure) and availability (the ability to be operational when it is needed) of the public health surveillance system.

3.4 Result

Presence of national manual and reporting formats for surveillance

There is the latest version of (version 2012) national manual for surveillance in the zone for malaria. They have standard case definition for malaria reporting format provided by ministry of health. But there were shortage of standard reporting format in the last six months. The number of district reporting weekly and immediately to the zone in this year was 11. That is 56 health center, 289 health post and five NGO's.

Trends of malaria disease in the woreda in the last five years show that there was no suspect of outbreak of malaria. Highest cases of malaria were observed in 2013 and the lowest cases of malaria was observed in 2017.

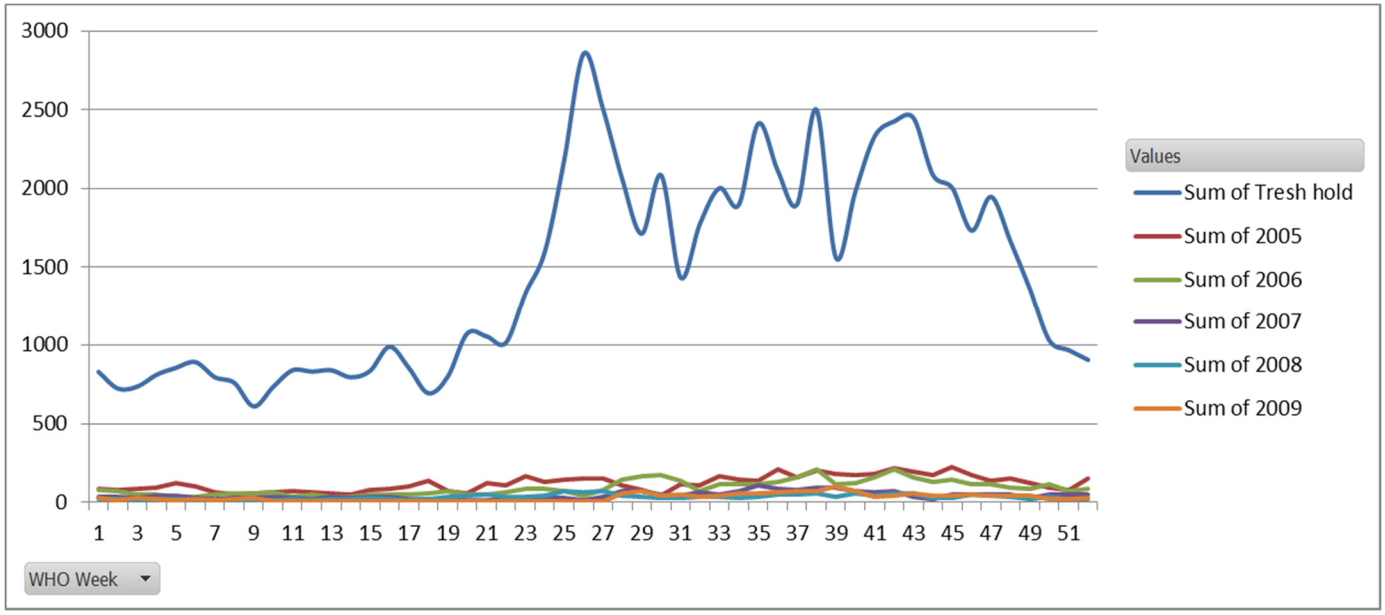


Figure 19. Five year trends of malaria disease by WHO weeks in Gimbichu woreda, East Shewa zone, Oromiya, Ethiopia, March 2017.

Budget allocation for surveillance

The woreda health office allocates budget for malaria control and prevention for the year 2017. Total budget allocated was ETB 817950.00. This budget was allocated by government ETB 95000.00 NGO's ETB 458950.00 and from public 264000.

Weekly surveillance data Reporting Health facilities

Most health facilities report timely in the last nine months, But in the month November 2016, only 66% of the health facility was reported timely due to absence of reporting format in the reporting health facility. The reporting system for all health facility was based on telephone report followed by hard copy sent to the next higher level.

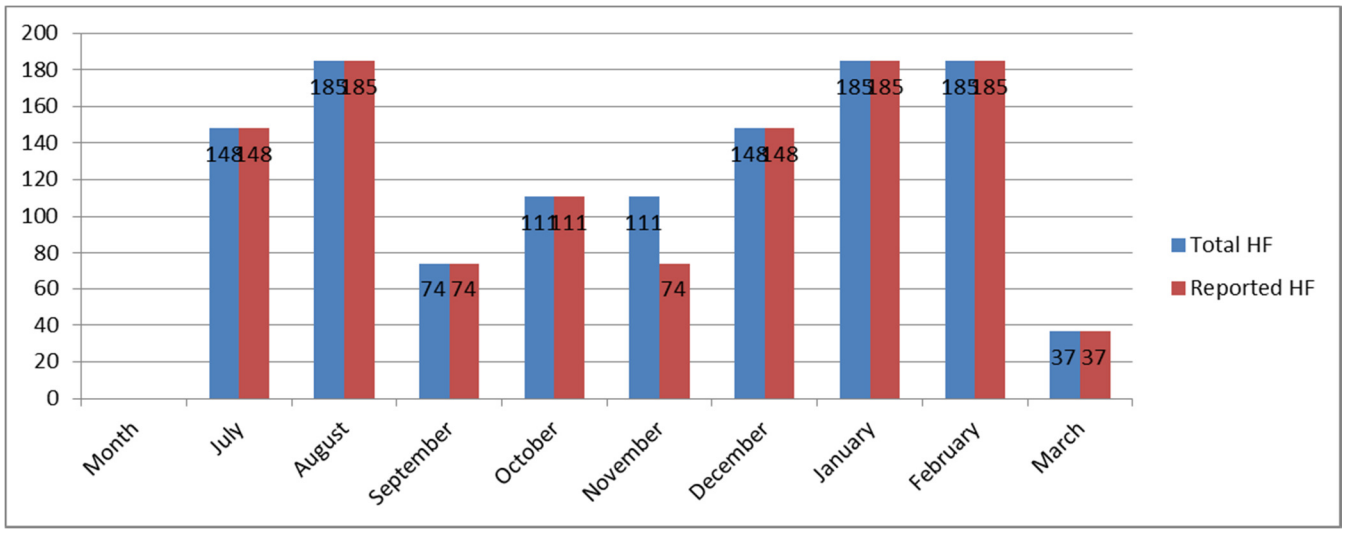


Figure 20. .completeness of weekly surveillance data reporting (condensed in months) in Gimbichu woreda, East Shewa zone, Oromiya, Ethiopia, March 2017

Malaria cases in Gimbichu Woreda

There was hike in blood film examination of malaria in the month January to February of 2017, but confirmed blood film was not increases in those times indicating probability of occurrence of other febrile illness in the woreda in which typhoid fever was a suspect in this time and woreda.

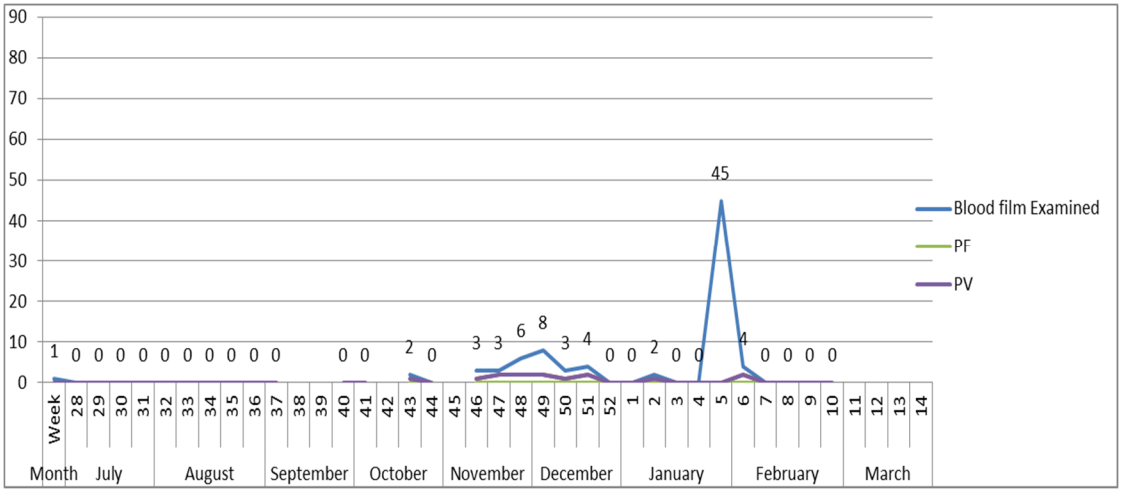


Figure 21.Cases of malaria and blood film examined in WHO weeks of Gimbichu woreda, East Shewa zone, Oromiya, Ethiopia, March 2017.

Trends of malaria cases in Gimbichu woreda from 2013-2016.

The number of cases of malaria was high in March, 2014. The lowest malaria cases were recorded in 2013. Trend analysis was also performed in the woreda health for other disease such as Typhoid fever and Typhus.

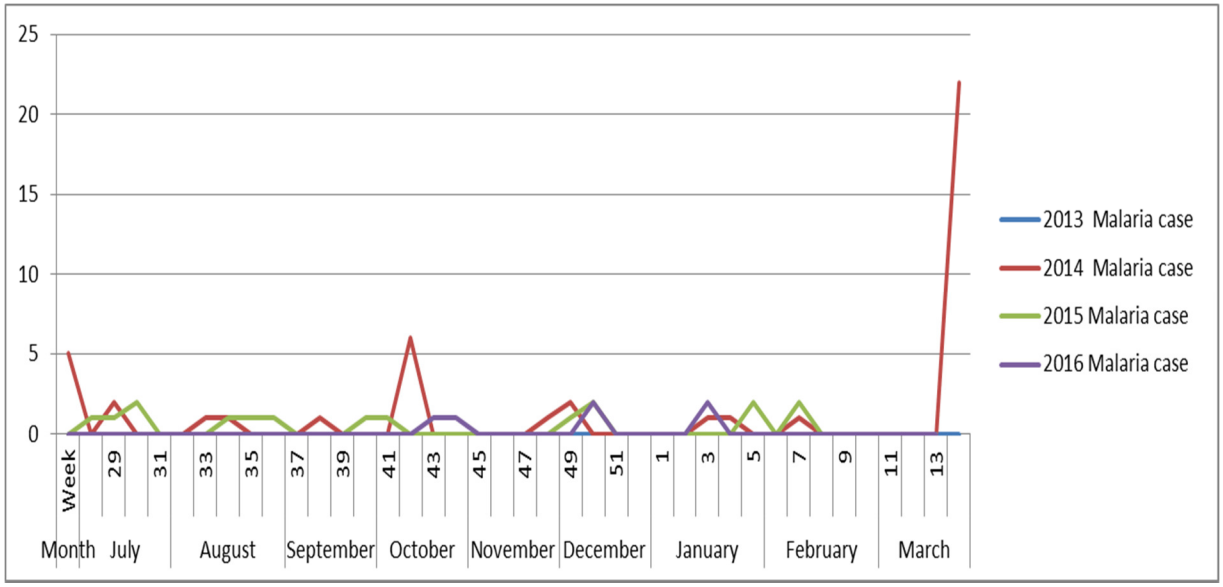


Figure 22.Five year trends of malaria disease in Gimbichu woreda, East Shewa zone, Oromiya, Ethiopia, March 2017.

Case confirmation

Case/outbreak confirmation refers to the epidemiological and laboratory capacity for confirmation of this notifiable disease in the woreda. The Capacity of the referral linkage between health facility for case confirmation, appropriate specimen transportation and collection like stool, sputum and blood for routine activities in the zone in the health center was 100%. visited health center in the woreda was incapable to collect and transport the CSF specimen for further confirmation.

Data analysis

There were appropriate population denominator for data analysis in all health facility and office visited. From Visited 9 health facility and one woreda health office, only the Gimbichu woreda health office used to analyze malaria data obtained from the health facility over the past four years by time, place and person and used to analyze trend over time. Moreover, all health facilities and woreda health office did not established acceptable threshold level for the monitoring of malaria situation in the woreda. There were two health worker professionals trained in surveillance data management in the woreda health office. However, no staff were trained other than these two personnel. Trained Public health management officers of the Gimbichu woreda health office analyzed data.

Epidemic management committee

Epidemic management committee in the woreda was established some five years ago. The committee consists of Woreda administrator, health office head, and agriculture, education, water and finance and economy office heads. There were a communiqué written some years ago, no recent minutes were seen during the visit. The health office told us that the epidemic management committee held meeting only if outbreak occurs of if only there is imminent risk of an outbreak is identified. There are other teams in the woreda and health centers established in response to an outbreak. One of the team is rapid response team for outbreak. In the health center, The team members includes health center head, laboratory personnel, pharmacy personnel, mother and child focal person, and surveillance focal person.

Epidemic Response activity

The woreda established epidemic management committee for a response to possible outbreak in the woreda. In the previous year, 2016, there was a suspected outbreak of typhoid fever. But in the last five years there were no suspected outbreak of malaria in the woreda. In the past year, the district health office did not implement prevention and control measures based on malaria data obtained from health facility. The epidemic management committee of the woreda did not (in minutes) evaluate their performance in epidemic preparedness and response activity.

Surveillance data report Feedback

Neither The woreda health office nor the health centers in the woreda did not produce regular feedback bulletin. But there were feedback reports produced regularly from the woreda health office to the health centers and from the health centers to health posts in the woreda. The woreda health office produced 16of 16 expected feedbacks (100%) in 2016 and eight feedback in 2017 of expected eight feedbacks (100%) for the two quarters. Chefe Donsa health center produced feedback report every month for health posts in its catchment. In 2016 the health center produces 96 feedbacks for eight health posts.

Resource

Resources for data management, communication, and other logistics were available at the woreda level. But there were scarcity of standard reporting form to the zonal health office. However, they all became limited down in the hierarchy. The woreda public health emergency management focal person has their own computer for effective data management and analysis. There is also computer dedicated to data management of public health emergency in Chefe donsa health center. The rest of the health facilities have no computers. The Woreda has Vehicle/ambulance for emergency management transportation.

Training

Training on disease surveillance, outbreak investigation, Surveillance data analysis and response is the back bone for early detection and confirmation of the cases, consequently two woreda health professionals trained in public health management organized by East Shewa zone health

department and 75% of workers in the health post were given orientation on surveillance organized by woreda health office

Description of Quality and attributes of surveillance system

Malaria is among the major public health problems of the 20 priority diseases under surveillance in Ethiopia. Malaria surveillance is integrated with all other priority diseases which include laboratory support and passive surveillance which becomes active during outbreaks. We assessed system attributes including usefulness, simplicity, flexibility, data quality, acceptability, sensitivity, timeliness, stability and representativeness and usefulness.

Usefulness

Usefulness Early detection of epidemics of diseases under surveillance and assessment of the effect of prevention and control programs were common understanding of all the respondents as the major use of the surveillance system. However, this well understood use of the surveillance system has many challenges in the area of case detection, reporting and response In general, the users of the surveillance system, though they understood the usefulness in this regard, are not satisfied with the system and the utility of the system was very low.

Completeness

A report is said to be complete if all the reporting units within its catchments area has submitted the reports on time. A report (from a reporting unit) is said to be on time, if it reaches the designated level within the prescribed time period. If it reaches later, then the report is considered to be late. The timeliness of a reporting unit can be calculated by assessing how many of its expected reports have come on time. Completeness of reporting in Gimbichu woreda health office was 96.9%

Simplicity

The case definitions of malaria for identification of suspected cases are easy to understand and apply by all levels of health professionals. Though forms are easy to complete, it was noted that the system was not simple due to lack of functional communication mechanisms making it difficult to get weekly report from health facilities. The respondent agreed that additional data

could be collected with the existing reporting form by adding some information. Cases were detected using case definition and confirmed with RDT at health post level and microscopy at health center level. Most of report forms were easy to complete. Weekly reports were communicated by telephone from Districts to next level. The time it takes to complete the reporting form was greater than 15 minutes. The person who completes the reports also commented that training is needed to understand and complete new formats.

Flexibility

The reporting form can be modified to include other variables to report other newly occurring health events without much difficulty, and the formats are assumed to be easy and comprehensive. The standard reporting formats for suspected & confirmed malaria cases and standard epidemic reports were integrated into PHEM, which make the system flexible.

Data quality

The data quality was also assessed on the basis of completeness of the reporting format and timeliness of the report. The data collection format for the priority disease is clear and easy to feel for data collectors. There were some missed variable in reporting formats like week number, the expected number of health facilities to report, and blank variables rather to fill zero cases, especially in health posts. The major reasons are not considering some of the variable as important. Training for surveillance data collection was given at zonal level. The reporting sites and data collectors are also supervised regularly to check the quality of reporting and address concerns on reporting.

Acceptability

The acceptability of the surveillance system was assessed based on the engagement of the reporting agents and active participation in the case detection and reporting. In Gimbichu woreda the engagement of the reporting facilities was good and the reporting rates were 100% in the last quarter.

Sensitivity

The sensitivity of the surveillance system of malaria in the detection of the cases and outbreaks were seen separately.

The surveillance system to detect cases of malaria

The surveillance system is based in the health facilities; the capacity of the surveillance system to capture cases in the community is dependent on different reasons: one reason could be the health seeking behavior of the community- which was generally commented as poor, though there is improvement with the health extension workers and the community health worker. The other reason is lack of case management capacity of the health posts; the health posts record and report those whom they can give treatment like anti- malaria. otherwise, cases are not recorded and reported if they are not given any drug. Hence, the number of cases reported from the health post will be high when they have anti-malaria and rapid diagnostic test at hand. The third reason could also be the technical and logistic capacity of the health facilities in detection and laboratory confirmation of cases.

The surveillance system to detect an outbreak of malaria

The capacity of the surveillance system to detect an outbreak is influenced by the definition of the outbreak. There was no regular analysis of the collected data, however, the sensitivity of the system increases once the number of cases is higher or death starts to occur, i.e. the surveillance system would be sensitive for high epidemics.

Predictive value positive

It was not possible to measure the PVP of the surveillance system in this assessment of the surveillance of these diseases. Because, laboratory confirmation of all suspected cases using case definition was not done .

Timeliness

The reporting rates of the health facilities in the District were good. But of those which reported, the number of facilities which reported timely was difficult to know exactly; since the date reports were received were not recorded.

Stability

The surveillance system was not fully stable based on available information from the woreda. There was shortage of standard reporting format in 0ne health facility. However, activities by woreda health office to integrated surveillance of malaria with other disease contributed some kind of stability for the malaria disease surveillance.

Representativeness

Thirty-five health posts report weekly surveillance report to the woreda. There were four health centers reporting to the woreda regularly representing the whole woreda. The reporting facility represents 100% of the facilities that were expected to report to the woreda.

Usefulness of surveillance

All of the participants agreed up on that the surveillance system is helpful to detect the outbreak of priority diseases early, to estimate the magnitude of morbidity and mortality related to these diseases, including identification of factors associated with these diseases. Even though there was no malaria epidemics, all health officers in health facilities in the District believe that outbreaks should be investigated and response given within 48 hours of occurrence. The Districts has prepared written epidemics preparedness and response plan (EPRP). The challenge of all assessed area was none of epidemic management committee evaluated their preparedness and response activities. At District level the data from representative and complete sources transmitted to the next level. In general the system was useful and utilizes the existing health system to provide evidence based information for action.

3.5 Discussion

Surveillance activities are critical to detect nationally identified diseases and obtaining information to help prevent and control disease of public health importance. Robust and responsive information systems are critical for successful malaria control and elimination. Surveillance must be an intervention where data collection, analysis, output, and response occur quickly to identify symptomatic and asymptomatic cases, prevent onward transmission, and reduce vectorial capacity. The best way to ensure that this occurs rapidly and efficiently is to work with information systems designed to support malaria surveillance and response (2).

The PHEM at woreda and zonal level of the health system could raise warning "flags" signaling the need for increased level of alertness, preparedness and proactive interventions working with local, regional and national level to prevent occurrence of malaria outbreak. The system should also collaborate with sectors outside health such as meteorological organization to predict for the anticipated fluctuation in climate which could trigger an outbreak (9). However, we could not find any data that shows utilization and communication of organizations that can provide useful data for the malaria prevention and control effort at zonal and woreda health office.

In Ethiopia Malaria, epidemics are serious public health emergencies. In most situations, malaria epidemics develop over several weeks, allowing some lead-time to act proactively to avoid larger numbers of illnesses and to prevent transmission. Approximately 52 million people (68%) live malaria-endemic areas in Ethiopia, chiefly at altitudes below 2,000 meters. Malaria is mainly seasonal in the highland fringe areas and of relatively longer transmission duration in lowland areas, river basins and valleys. But in our study area, Gimbichu woreda, the altitude is found to be 2431 meters above sea level. So the severity of malaria is not that much compared to other part of the region (9).

The feasibility of preventing epidemic occurrences within the available lead-time depends on the level of decentralized responsibility through the health system and the capacity of the health system to make use of available data at each level to early detect malaria, if not forecast epidemics. Since 2005, Ethiopia has strengthened the health system with the establishment and subsequent expansion of the Health Extension Program (HEP), allowing closer monitoring of epidemic-precipitating factors at the local level. The fact on the ground was different. Capacity

building at grass root level was not substantiated and need to be improved to achieve proper malaria prevention and control activities (9).

Once malaria has been suspected or established as the cause of an epidemic or significant case buildup, notification by telephone or short-message-sending (SMS) should occur as soon as possible to all higher levels of the health system, such as the health extension worker (HEW) supervisor, health center, district health office, zonal or regional health bureau (RHB). Each health care worker should have the contact number of his/her supervisors. Weekly and immediately report of malaria surveillance is communicated by phone call followed by hard copy report to the next higher level (9).

Surveillance data analysis and interpretation is a crucial part that guides responses to public health emergencies. The analysis provides key information for taking prompt public health actions. Data analysis provides Frequency count by reporting units, information for predicting changes of disease rates over time, Disease rates change over time and the most appropriate and timely control measures during outbreak. Surveillance data analysis is performed at zonal and to some extent at woreda level in our study area (6).

Completeness of data reporting in the woreda for the year 2016/2017 is 96.9% of which in the month October only 74 facility report was received on time, however the expected number of facilities to report was 111 (6).

Thresholds are markers that indicate when something should happen or change. They help surveillance and program managers answer the question, “When will you take action, and what will that action be?” Ethiopian national public health emergency management guidelines recommend two types of thresholds: an alert threshold and an action threshold for the diseases under surveillance. No threshold has been set in the health post, health center and woreda level. However both types of threshold for malaria disease has been set at zonal level (6).

Conclusion

The overall system set up of the surveillance system in the woreda was good. Reporting hierarchy was also well established, synchronized and timely. The surveillance system of malaria was useful to detect outbreaks, estimate magnitude of the morbidity and mortality of the disease in the area.

Recommendation

- Give Training for health facilities on data analysis to secure early detection and immediate action of outbreak.
- Post and use the case definitions of all identified priority diseases and report accordingly.
- Avail weekly and immediately reporting format for health facilities.
- Epidemic management committee of the woreda should evaluate their performance in epidemic preparedness and response activity at least yearly.

Limitation of the evaluation

- We use convenience-sampling technique to evaluate woreda health surveillance system. This sampling technique may not provide representative sample for generalize for the woreda.

3.6 Reference

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3.7 Annexes

Annex 1. Zonal Level Questionnaire for Surveillance System Evaluation

_____

Identifiers

Date __/___/_____ Region _____

Respondent Name _____ Zone _____

Interviewer _____

_____

General

I. **Availability of a National Surveillance Manual;**

1. Is there a national manual for surveillance?

a. Yes b. No c. Unknown

If yes, describe (last update, diseases included, case definitions, surveillance and control, integrated or different for each disease):

_____

II. **Case Detection and Registration;**

2. Do you have standard case definitions for Malaria?

a. Yes b. No c. Unknown d. Not applicable

If yes, observe the standard case definition _____

_____

III. **Data reporting:**

3. Who is responsible for providing you reporting formats of surveillance?

a. Federal Ministry of Health PHEM unit.

b. NGOs

c. Others _____

4. Have you encountered shortage of appropriate surveillance forms at any time during the last 6 months? a. Yes b. No c. Unknown
5. What are the reporting entities for the surveillance system?
    a. Public health facilities
    b. NGO health facilities
    c. Military health facilities
    d. Private health facilities
    e. Others_____

6. Number of districts has reported weekly and immediately report in the last 3 months compared to expected number? _____

7. Number of Health post, Health centers, Hospitals, NGO health facility, Others (private) sent weekly report in the last three months?

Weekly: _____

Immediately: _____

8. **On time (use national deadlines)**

Number of districts has sent weekly reports on time in the last 3 months: _____

9. Was there any report of the immediately reportable diseases in the past 1 month?

a. Yes b. No

If yes, with in what time is the report received after detection of the case/ diseases?

a. Less than 1 hour
b. 2-24 hour
c. 1- 2 days
d. 3- 7 days
e. After 1 week
f. Other_____

10. How do you report to the next level?

a. Mail
b. Fax
c. Telephone
d. Radio
e. Electronic
f. Other

IV. **Data analysis**

11. Do you describe data by person (case based, outbreaks, and sentinel)?

a. yes b. no c. don't know

If yes, observe analyzed data by person: _____

12. Do you describe data by place?

a. yes b. no c. don't know

If yes, Observe description of data by district (tables, maps)

_____

13. Do you describe data by time?

a. yes b. no c. don't know

If yes, observe description of data by time:

_____

14. Do you perform trend analysis?

a. yes b. no c. don't know

If yes, observe line graph of cases by time

_____

List disease(s) for which line graph is observed

_____

_____

V. **Availability of defined threshold;**

15. Do you have defined threshold level for Malaria?

a. yes b. no c. don't know

If yes, observe _____

16. Who is responsible for the analysis of the collected data? _____

17. How often do you analyze the collected data?

a. Daily
b. Weekly
c. Every 2 weeks
d. Monthly
e. Quarterly
f. As needed……..

18. Have you an appropriate denominators?

a. Yes b. No c. don't know

If yes, observe presence of demographic data (E.g. population by district and hard to reach groups)

_____

VI. **Outbreak Investigation**

19. Number of outbreaks suspected in the past year:_____

20. List the diseases: _____

21. Of those suspected/detected, how many of them were investigated? _____

(Observe reports and take copies if possible) _____

22. Number and percentage of outbreaks in which risk factors were looked for:_____

23. Number and percentage of outbreaks in which findings were used for action:_____

[Observe report]

24. Number of districts that looked for risk factors [observe in reports] _____

25. Number of districts that used the data for action [observe in final report] _____

VII. **Epidemic preparedness(relevant for epidemic prone diseases)**

26. Is there Zonal plan for epidemic preparedness and response?

a. Yes B. No c. Unknown

If yes, observe a written plan of epidemic preparedness and response

_____

27. Has the zone had emergency stocks of drugs, vaccines, and supplies at all times in past 1 year?

a. Yes b. No c. Unknown

28. Has the zone experienced shortage of drugs, vaccines or supplies during the most recent epidemic (or outbreak)?

a. Yes b. No c. Unknown

29. Are there standard case management protocols for Malaria?

a. Yes b. No c. Unknown

If yes, list the exists protocols, _____

Observe the existence of a written case management protocol for at least 1 priority disease

_____

VIII. **Presence of a budget line for epidemic response;**

30. Is there a budget line for epidemic response?

a. Yes b. No c. Unknown

If yes, describe total budget allocated and utilized in the past last year _____

IX. **Existence of zonal epidemic management committee;**

31. Is there established zonal epidemic management committee?

a. Yes b. No c. Unknown

If yes, observe minutes (or report) of meetings of epidemic management committee

_____

32. Has epidemic management committee evaluated its preparedness and response activities during the past year?

a. yes b. no c. don't know

If yes, observe written report to confirm _____

_____

X. **Zonal rapid response team for epidemics;**

33. Does the zone have a rapid response team for epidemic?

a. Yes b. No c. Unknown

34. Is there any notification of recently reported outbreak to which you had response within 48 hrs?

a. Yes b. No c. Unknown

If yes, observe that the zone responded within 48 hours of notification of most recently reported outbreak (from written reports with trend and intervention)

a. Yes b. No c. Unknown

XI. **Feedback;**

35. How many feedback bulletin or reports has the regional level produced in the last year? _____

Observe the presence of a report or bulletin that is regularly produced to disseminate surveillance data _____

_____

XII. **Supervision;**

36. How many supervisory visits have you made in the last 6 months compared to expect? _____(%)

37. If no supervision was not made during the past 6 months, please mention the reasons, _____

XIII. **Training on surveillance activities;**

38. What percent of your subordinate personnel have been trained in surveillance? _____

39. On what topics have you gave training in the last 6 months? _____

40. What are your stakeholders those supporting you in giving training? _____ _____

41. Major challenges during and after training activities _____

_____

Strengths during and after training _____

_____

XIV. **Resources**

Do you have;

42. **Data management equipment**

Computer_____

Printer _____

Photocopier _____

Data manager _____

Statistical package _____

Stationary _____

43. **Communications:**

Telephone service _____

Fax _____

Radio call _____

Mobile phone _____

Computers that have modems _____

44. **Budget line (from donors)** _____

XV. **Surveillance Networking**

45. Do you have functional computerized surveillance network at this level?

a. Yes b. No c. Unknown

XVI. **Budget for surveillance**

46. Is there a budget allocated for surveillance activities from the Regional Health Bureau budget (governmental source)?

a. Yes b. No c. Unknown

If yes, what is the proportion of this budget from total allocated budget for other activities? _____(%)

47. How could surveillance be improved?

_____

XVII. **Surveillance Co-ordination**

48. Is there a focal unit for surveillance at the this level?

a. Yes b. No c. Unknown

If yes, observe organogram of the zone to confirm _____

49. What opportunities are there for integration of surveillance activities and functions (core activities, training, supervision, guidelines, resources etc.)?

_____

Questionnaire for Attributes and level of Usefulness:

a. Total population under surveillance_____
b. In 2012/13, what is the incidence / Prevalence of:

- Malaria incidence _____ prevalence _____Deaths _____

I. Level of Usefulness of the Surveillance System for these selected priority diseases

Does the surveillance system help;

c. To detect outbreaks of these selected priority diseases early? Yes/ No
d. To estimate the magnitude of morbidity and mortality of these diseases, including identification of factors associated with these diseases? Yes/ No
e. Permit assessment of the effect of prevention and control programs? Yes/ No

Observe (confirmation):

- interventions and diseases trends analyzed _____

_____

II. Description of Each System Attributes:

i. Simplicity:

1. Is the case definition of Malaria easy for case detection by all level health professionals? a. Yes b. No c. Unknown
2. What are the organizations which need to receive reports of the surveillance data? _____
3. Do you feel that additional data collected on cases are time consuming?

a. Yes b. No c. Don't know

4. How long it takes to fill the reporting format?

a. <5 minutes b. 10-15 minutes c. >15 minutes

Overall comments of on the above points _____

_____

ii. Flexibility:

1. Can the current reporting formats be used for other newly occurring health event (disease) without much difficulty? a. Yes b. No c. Don't know
2. Do you think that any change in the existing procedure of case detection, case definition, allocating funds, report forms, and formats will make difficult to implement? a. Yes b. No c. Don't know

Overall comments on the above points :_____

iii. Data Quality: (Completeness of the reporting forms/and validity of the recorded data)

1. Are the data collection formats for these priority diseases clear and easy to fill for all the data collectors/ reporting sites? a. Yes b. No
2. Have you ever gave training for data collectors on data quality management?

a. yes b. no. c. don't know

3. Are the reporting site and data collectors supervised regularly? a. Yes b. No
4. **Observe:** Review the last month report of selected diseases

A. Average number of ***unknown or blank responses*** to variables in each of the reported forms

_____

B. Percent of reports which are complete(that is with no blank or unknown responses) from the total reports

_____

iv. Acceptability:

1. Do you think all the reporting agents accept and well engaged to the surveillance activities? a. Yes b. No

If yes, how many are active participants (of the expected)?_____

If no, what is the reason for their poor participation in the surveillance activity?

A. Lack of understanding of the relevance of the data to be collected

B. No feedback or recognition given by the higher bodies for their contribution; i.e. no dissemination of the analysis data back to reporting facilities

C. Reporting formats are difficult to understand

D. Report formats are time consuming

E. Cost of data reporting

F. Other:

_____

2. Are all stakeholders are fully participate in surveillance system strengthening?

a. yes b. no c. don't know

If no, what are the reasons make them discomfort?_____

_____

v. Representativeness:

1. What is the health service coverage of the zone? _____%
2. Do you think that the populations under surveillance have good health seeking behavior for these diseases? Yes / No
3. Whom do you think is well represented by the surveillance data? a. the urban b. the rural c. equal

vi. Timeliness:

1. Do you think that the existing surveillance system is timely detecting the outbreak? a. yes b. no c. don't know

Comment _____

_____

2. During the most recent outbreak of malaria, meningitis and measles within how many days these outbreaks were reported to the region after the first case/index case/

   _____

3. Is enough information is available for control of selected diseases during outbreak? a. yes b. no c. don't know

Comment_____

4. How long does it take to have laboratory confirmation of Malaria_____

vii. Stability:

1. Was there lack of resources that interrupt the surveillance system? Yes/No

ANNEX 2. Woreda Level Questionnaire for Surveillance System Evaluation

Identifiers

Date ___/___/____ Region _____

Interviewer _____ Zone _____

Respondent_____ District _____

Availability of national surveillance manual

1. Is there a national manual for surveillance at this site?

a. Yes b. No c. Unknown

If yes, observe national surveillance manual _____

I. Case confirmation

2. Does the district have the capacity to transport specimens to a higher-level lab?

a. Yes b. No c. Unknown d. Not applicable

3. Does the district have guidelines for specimen collection, handling and transportation to the next level?

a. Yes b. No c. Unknown c. Not applicable

II. Data reporting

4. Have you got shortage forms recommended for the country at any time during the last 6 months?

a. Yes b. No c. Unknown

5. Number of health facilities (Health posts, Health centers, Private/NGO) sent weekly reports in the last 3 months compared to expected number

Weekly: _____ /12 times the number of health facilities

Immediately: _____/----- times the number of health facilities

On time (use national deadlines)

6. Number of weekly reports submitted on time: ____/12 times the number of health facilities
7. Number of immediately reports submitted on time: _____/3 times the number of health facilities
8. How do you report to the next level:
    a. Mail
    b. Fax
    c. Telephone

d. Radio

e. Electronic

f. Other

Strengthening reporting

9. How can reporting be improved?

_____

III. ***Data analysis for Malaria***

10. Have you appropriate denominators (<5 years children, total population, population by kebeles, and so on)

a. yes b. no c. Don't know

If yes, Observe for each denominators _____

11. Do you describe data by person (case based, outbreaks, sentinel)?

a. Yes b. No c. Unknown

Observe description of data by age and sex_____

12. Do you describe data by place (locality, village, work site etc)?

a. Yes b. No c. Unknown

Observe description of data by place _____

13. Do you describe of data by time?

a. Yes b. No c. Unknown

If yes, observe the description _____

14. Do you perform trend analysis (line graph of cases by time) for malaria?

a. Yes b. No c. Unknown

If yes, Observe and list diseases _____

IV. Availability of threshold level for selected diseases

15. Do you have an action threshold for any of the country priority diseases?

a. Yes b. No c. Unknown

If yes, for which diseases and mention what are their threshold levels _____

_____

16. Who is responsible for data analysis? _____

17. How often do you analyze the collected data?

a. Daily
b. Weekly
c. Every 2 weeks
d. Monthly
e. Quarterly
f. As needed……..

V. Outbreak investigation

18. Number of outbreaks suspected in the past 6 months: _____

Observe the investigations (Observe reports and take copies if possible): _____

_____

19. Has your district ever investigated an outbreak?

a. yes b. No c. Unknown

VI. Epidemic preparedness

20. Is your district has a plan of epidemic preparedness and response?

a. yes b. no c. Unknown

*If yes, o*bserve a written plan of epidemic preparedness and response _____

_____

21. Has the district had emergency stocks of drugs and supplies at all times in past 1 year?

a. yes b. no c. unknown

If yes, observe the stocks of drugs and supplies at time of assessment _____

_____

22. Has the district experienced shortage of drugs, vaccines or supplies during the most recent epidemic (or outbreak)?

a. Yes b. No c. Unknown

If yes, how did you solve the problem at that time? _____

_____

23. Is there a budget line or access to funds for epidemic response?

a. Yes b. No c. Unknown

VII. Epidemic management committee

24. Is established epidemic management committee at district level?

a. yes b. no c. unknown

If yes, observe minutes (or report) of meetings of epidemic management committee

_____

25. Does the district have a rapid response team for epidemics?

a. Yes b. No c. Unknown

VIII. <u>Responses</u>

26. Has the district implemented prevention and control measures based on local data for at least one reportable disease or syndrome?

a. Yes b. No c. Unknown

27. Is your district responded with 48 hours of notification of most recently reported outbreak?

a. yes b. no c. don't know

If yes, observe that the district responded within 48 hours of notification of most recently reported outbreak (from written reports) _____

_____

28. What were the case fatality rates during most recent outbreak mainly for malaria? _____

Observe that the district achieved an acceptable case fatality rate for most recent outbreak (Observe from outbreak report) _____

29. Has epidemic management committee evaluated their preparedness and response activities during the past year?

a. Yes b. No c. Unknown

If yes, observe written report to confirm _____

_____

IX. <u>Feedback</u>

30. How many feedback written reports has the district produced in the last year?

_____

Observe the presence of a written report that is regularly produced to disseminate surveillance data for health facilities, _____

_____

31. How many feedback bulletin or reports has the district received in the last year from zone/region? _____

Observe at least 1 report or bulletin at district from a higher level during the past year on the data they have provided _____

X. Supervision

32. How many times had you supervise health facilities in the last 6 months?

_____

Observe supervision report or any evidence of supervision in last 6 months _____

_____

33. Is appropriate review of surveillance practices were done during supervision?

a. yes b. no don't know

If yes, observe supervision report or any evidence for appropriate review of surveillance practices _____

_____

34. If not all the required supervisory visits were conducted, mention the reasons.

Reason 1_____

Reason 2_____

Reason 3_____

XI. Training

35. Number of health personnel trained in disease surveillance

_____

36. What percent of your personnel in the district have been trained in surveillance and epidemic management? _____

XII. Resources

37. Is your district has enough logistics for surveillance activities?
    a. Electricity
    b. Bicycles
    c. Motor cycles
    d. Vehicles
38. Data management
    a. Stationery
    b. Calculator
    c. Computer

d. Printer

e. Statistical package

39. Communication

a. Telephone service

b. Fax

c. Computers that have modems

40. **Information education and communication materials**

a. Posters

b. Megaphone

c. Flipcharts or Image box

d. VCR and TV set

e. Generator

f. Screen

g. Projector (Movie)

h. Other:

41. **Hygiene and sanitation materials**

a. Spray pump

b. Disinfectant

XIII. Surveillance co-ordination:

42. Is there a surveillance co-ordination focal point within the district epidemic management committee?

a. yes b. no c. don't know

If yes, observe some documents _____

XIV. Satisfaction with surveillance system

43. Are you satisfied with the surveillance system?

Yes No Unknown Not applicable

44. ***If no***, how can the surveillance systems is improved?

_____

XV. Opportunities for integration

45. **What opportunities are there for integration of surveillance activities and functions (core activities, training, supervision, guidelines, resources etc?)**

ANNEX 3. Health Center Level Questionnaire for Surveillance System Evaluation

Identifiers

Date ___/___/_____ Region _____

Interviewer _____ Zone _____

Respondent_____

District _____

Name of health facility _____

I. Availability of national surveillance manual

1. Is there a national manual for surveillance at this site?

a. yes b. no don't know

If yes, observe national surveillance manual _____

II. Case detection and registration

2. Within what time interval (between date of onset and reach health facility) have you detected the most recent malaria outbreak? _____
3. Is there clinical register at this facility?

a. yes b. no c. Unknown

If yes, observed the existence of a clinical register _____

4. Is clinical register is filling correctly?

a. yes b. no c. unknown

Observe the last month filled clinical register if correctly done _____

_____

5. Do you have a standard case definition for Malaria?

a. Yes b. No c. Unknown

Observe the standard case definition _____

_____

6. Are you using standardized case definitions for malaria?

a. yes b. no c. don't know

Observe the respondent correctly diagnosing of the diseases using a standard case definition

_____

III. Case confirmation

7. Are you able to collect sputum Y N U N/A

Stool Y N U N/A

Blood Y N U N/A

CSF Y N U N/A

Observed the presence of materials required to collect

Stool Y N U N/A

blood/serum Y N U N/A

CSF Y N U N/A

8. Do you have the capacity to handle sputum, stool, blood/serum and CSF until shipment at this facility?

a. Yes b. No c. Unknown d. Not applicable

If yes, observe presence of functional cold chain at health facility _____

_____

9. Observe presence of packing materials for shipment of specimens at health facility

_____

IV. <u>Data reporting</u>

10. Have you lacked appropriate surveillance forms at any time during the last 6 months?

a. Yes b. No c. Unknown

11. Can you report accurately cases from the registry into the summary report to send to higher level?

a. yes b. no c. don't know

Observe that the last monthly report agreed with the register for malaria;

Y N U N/A

12. How many times have you sent surveillance report in the last three months?

Number of reports in the last 3 months compared to expected number

Weekly: ____ /12 times the number of sites

Immediately: /-- times the number of sites

13. **On time (use national deadlines)**

Number of weekly reports submitted on time:-_____ /12 times the number of sites

Number of immediately reports submitted on time: ___/____ times the number of sites

14. How do you report?

a. Mail
b. Fax
c. Telephone
d. Radio
e. Electronic
f. Other

15. **Strengthening reporting**

How can reporting be improved?

_____

V. Data analysis

16. Do you describe data by person (outbreaks, sentinel)?

a. yes b. no c. Don't know

If yes, Observe description of data by age and sex _____

17. Do you describe data by place (locality, village, work site etc)?

a. yes b. no c. don't know

If yes, Observe description of data by place _____

18. Do you describe data by time?

a. yes b. no c. don't know

If yes, Observe description of data by time _____

19. Do you perform trend analysis?

a. yes b. no c. don't know

If yes, Observe line graph of cases by time _____

20. Who is responsible for data analysis? _____

21. How often do you analyze the collected data?

a. Daily
b. Weekly
c. Every 2 weeks
d. Monthly
e. Quarterly
f. As needed……..

22. Have you appropriate denominators?

a. yes b. no c. don't know

If yes, Observed presence of demographic data at site (E.g. population <5 yr., population by village, total population) _____

_____

VI. Availability of threshold levels for each priority disease

23. Do you have an action threshold levels for any of the Country priority diseases?

a. Yes b. No c. Unknown

VII. Epidemic preparedness

24. Is your health facility has a standard case management protocol for epidemic prone diseases?

a. yes b. no c. don't know

If yes, observed the existence of a written case management protocol for 1 epidemic prone disease _____

VIII. Epidemic response

25. Has the health facility implemented prevention and control measures based on local data for at least one epidemic prone disease?

a. Yes b. No c. Unknown

26. Did your facility achieve acceptable case fatality rates (e.g. 10% for Meningococcal CSM 1% for Cholera) during the most recent outbreak?

a. Yes b. No c. Unknown d. Not applicable

Observe case facility rate for most recent outbreaks _____

_____

IX. Feedback

27. Have you received a report or bulletin from a higher level during the past year on the data they have provided?

a. yes b. no c. Don't known

28. How many feedback bulletin or reports has the health facility received in the last year?

_____

Observe at least 1 report or bulletin at the health facility from a higher level during the past year on the data they have provided _____

29. Have you conducted at least semi-annual meetings with community members to discuss results of surveillance or investigation data?

a. yes b. no c. don't know

If , yes how many meetings has this health facility conducted with the community members in the past six months? _____

Observe the minutes or report of at least 1 meeting between the health facility team and the community members within the six months _____

X. Supervision:

30. How many times have you been supervised in the last 6 months?_____

Observe supervision report or any evidence of supervision in last 6 months _____

_____

31. Is appropriate review of surveillance practices were done during the past supervision activities?

a. yes b. no c. don't know

Observe supervision report or any evidence for appropriate review of surveillance practices

_____

_____

XI. Training

32. Number of health personnel trained in disease surveillance and epidemic management _____

33. On what topics of surveillance they trained? _____

_____

34. Are they any training, which is relevant to your job that facility's personnel did not get yet? _____

XII. Resources

Have you:

35. **Logistics**

    a. Electricity

b. Bicycles

c. Motor cycles

d. Vehicles

36. **Data management**

a. Stationery

b. Calculator

c. Computer

d. Software

e. Printer

f. Statistical package

37. **Communications**

a. Telephone service

b. Fax

c. Radio call

d. Computers that have modems

38. **Information education and communication materials**

a. Posters

b. Megaphone

c. Flipcharts or Image box

d. VCR and TV set

e. Generator

f. Screen

g. Projector (Movie)

h. Other:

39. **Hygiene and sanitation materials**

a. Spray pump

b. Disinfectant

40. **Protection materials (list) _____ _____ _____**

XIII. <u>Satisfaction with surveillance system</u>

41. Are you satisfied with the surveillance system?

a. Yes b. No c. Unknown d. Not applicable

42. If no, how can the surveillance system is improved? _____

What opportunities are there for integration of surveillance activities and functions (core activities, training, supervision, guidelines, resources etc.) _____

ANNEX 4 Health Post Level Questionnaire for Surveillance System Evaluation

Identifiers

Date ___/___/_____ Region _____

Interviewer _____ Zone _____

Respondent_____

District _____

Name of health facility _____

I. Availability of national surveillance manual

1. Is there a national manual for surveillance at this site?

a. Yes b. No c. Unknown d. Not applicable

If yes, observe national surveillance manual _____

II. Case detection and registration

2. Have you clinical register?

If yes, observe the existence of a clinical register

a. Yes c. No c. Unknown d. Not applicable

3. Do you correctly register cases?

a. Yes b. No c. Unknown d. Not applicable

If yes, observed the correct filling of the clinical register during the previous 30 days_____

_____

III. Presence of standardized case definitions for the country's priority diseases

4. Do you have a standard case definition for Malaria?

a. Yes b. No c. Unknown d. Not applicable

If yes, observed the standard case definition for malaria.

a. Yes b. No c. Unknown d. Not applicable

IV. Using standardised case definitions for the country's priority diseases

Observe the respondent correctly diagnosing one of the country's priority diseases using a standard case definition _____

_____

(Select one of the priority diseases in the facility's clinical register and ask how they diagnosed it — interviewer should have the standard case definition from MoH

V. Data reporting

5. Have you lacked appropriate surveillance forms at any time during the last 6 months?

a. Yes b. No c. Unknown d. Not applicable

6. Have you reported accurately cases from the registry into the summary report to go to higher level?

a. yes b. no c. don't know d. Not applicable

Observe that the last monthly report agreed with the register for 4 diseases (1 for each targeted group [eradication; elimination; epidemic prone; major public health importance])

a. Malaria Y N U N/A
b. Meningitis Y N U N/A
c. Measles Y N U N/A

7. Number of reports sent to the next higher level during the past 3 months;

Weekly: ____ /12 times the number of sites

Immediately: /-- times the number of sites

8. On time (use national deadlines)

Number of weekly reports submitted on time:-_____ /12 times the number of sites

Number of immediately reports submitted on time: ___/-- times the number of sites

9. How do you report?

a. Mail
b. Fax
c. Telephone
d. Radio
e. Electronic
f. Other

10. Strengthening reporting

How can reporting be improved?

_____

VI. Data analysis

11. Describe data by person (outbreaks, sentinel)

a. Yes b. No c. Unknown d. Not applicable

If yes, Observed description of data by age and sex _____

_____

12. Describe data by place

a. Yes b. No c. Unknown d. Not applicable

If yes, observed description of data by place (locality, village, work site etc) _____

_____

13. **Describe data by time**

a. Yes b. No c. Unknown d. Not applicable

If yes, observe description of data by time _____

_____

14. Did you perform trend analysis?

a. Yes b. No c. Unknown d. Not applicable

If yes, Observe line graph of cases by time _____

_____

VII. Epidemic response

15. Has the health facility implemented prevention and control measures based on local data for at least one epidemic prone disease?

a. Yes b. No c. Unknown d. Not applicable

VIII. Feedback

16. have you received a report or bulletin from a higher level during the past year on the data they have provided?

a. Yes b. No c. Unknown d. Not applicable

How many feedback bulletin or reports has the health facility received in the last year? ___

17. Have you conducted meetings with the community members in the past six months on surveillance activities?

a. Yes b. No c. Unknown d. Not applicable

If, Observe the minutes or report of at least 1 meeting between the health facility team and the community members within the six months

IX. Supervision:

18. How many times have you been supervised in the last 6 months?_____

Observe supervision report or any evidence of supervision in last 6 months _____

_____

19. Is appropriate surveillance practices were reviewed by higher level during supervision?

a. yes b. no c. Don't know d. Not applicable

If yes, observe supervision report or any evidence for appropriate review of surveillance practices _____

_____

X. Training

20. Number of personnel trained in disease surveillance and epidemic management

_____

Topics on which training were given _____

_____

By whom you were trained? _____

_____

XI. Resources

Have you:

21. Logistics

a. Electricity
b. Bicycles
c. Motor cycles
d. Vehicles

22. Data management

a. Stationery
b. Calculator
c. Computer
d. Software
e. Printer
f. Statistical package

23. Communications

a. Telephone service
b. Fax
c. Radio call

d. Computers that have modems

24. **Information education and communication materials**

a. Posters

b. Megaphone

c. Flipcharts or Image box

d. VCR and TV set

e. Generator

f. Screen

g. Projector (Movie)

h. Other:

25. Hygiene and sanitation materials

a. Spray pump

b. Disinfectant

26. Protection materials (list) _____ _____ _____

_____

XII. Satisfaction with surveillance system

27. Are you satisfied with the surveillance system?

a. Yes b. No c. Unknown d. Not applicable

28. If no, how can the surveillance system be improved? _____

_____

What opportunities are there for integration of surveillance activities and functions (core activities, training, supervision, guidelines, resources etc.)

_____

CHAPTER IV

4. Bora Woreda Health Profile Report, East Shoa zone, Oromia, Ethiopia, 2008 EC

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Abstract

Introduction: The major diseases prevailing in Bora Wereda include Urticaria, Malaria, Intestinal Parasites, Skin Disease, Eye Disease, Diarrhea, and Anemia. The major causes of morbidity are respiratory infection, malaria, skin infections, diarrheal and intestinal parasitic infections. In addition to the government service, in Alam Tena, the Catholic Church established a clinic in 1995. The number of patients visited the facilities in 1999 was reported to be 29,900 for first visit, and 31,900 for the repeated. The general objective of this health profile description was to describe key aspects of the health status and demographics of Bora Woreda.

Method: The study design was Cross-sectional descriptive studies. The study population consists of total population in Bora woreda, East Shewa zone, Oromiya region. Data was collected using different format and responsible persons from relevant office were interviewed.

Result: The total household in the Woreda was 15912 with an average family size of 4.8.Cultivation was the major agricultural practice with 27550 hectare cultivated areas. The health sector takes 12.77 % (7,290,646 ETB) of the Woreda total budget of 57,083,370 in the year 2008 E.C. In the year 2008 EC, the numbers of students enrolled were 14, 264 of which 7168 were male &7096 were female students. Safe water supply and improved latrine coverage in the Woreda was 59% and 24.9% respectively. The health coverage in the woreda was 100%. The Woreda has a total of 92 health centers. Acute febrile illness and pneumonia were the top leading causes of OPD visit for adults and <5 years in 2008 EC in the area. The Woreda TB and HIV/AIDS prevalence was 170 per 100,000 population and 50 per 100,000 populations respectively, while the incidence for new HIV infection was 4 per 100,000 populations.

Conclusion: In Bora woreda, almost all children get most of the vaccination at their intended target and time. Except for Measles and fully immunization parameter, all immunization service provided by the woreda meet their intended target for 2008 EC.

4.1 Introduction

The overall prevalence of malaria in East Shewa in 2005 EC was 20% (1). The Malaria microscopic laboratory result in East Shewa zone indicated that 52.6 of the total malaria case were PF and 47.4% was due to PV. Regarding the time interval between the onset of malaria illness and treatment seeking behavior, only 25.5% of patients visited the laboratory within two days while the remaining 74.5% come to the laboratory after three or more days following the onset of illness (2).

The major diseases prevailing in Dugda Bora Woreda include Urticaria, Malaria, Intestinal Parasites, Skin Disease, Eye Disease, Diarrhea, and Anemia. A large portion of the population neither has access to safe water nor sanitation facilities, which is afflicted by water-borne diseases. The major causes of morbidity are respiratory infection, malaria, skin infections, diarrheal and intestinal parasitic infections. In addition to the government service, in Alam Tena, the Catholic Church established a clinic in 1995. The number of patients visited the facilities in 1999 was reported to be 29,900 for first visit, and 31,900 for the repeated (3).

Perception of malaria prevention, from the total respondents 809(97.5%) considered malaria as a major health problem. Nearly all (97%) of the respondents said malaria is curable disease (4).

Rationale of the study

Health description is important for prioritizing health and health related problems of the community at any level. In related to this there is no organized, completed and well-documented profile data in Bora woreda of East Shewa zone oromia region. Therefore describing the health profile of the woreda is helpful to give evidence based information for prioritizing and instituting appropriate public health intervention in the woreda.

4.2 Study Objectives

General Objective

The main objective of this woreda health profile was to describe the health status of Bora woreda residents to have recent and epidemiologically describable health profile which can provide for future plan for the woreda public health authorities.

Specific Objective

- To analyze the health status indicators of the woreda 2008 EC
- To asses immunization coverage of the woreda in 2008 EC
- To determine the status of primary health care components of the woreda in 2008 EC
- To determine the total safe water coverage of the woreda in 2008 EC

4.3 Study Methods and materials

Study setting/area

Bora is one of the woreda in the Oromia Region of Ethiopia. It was part of the former woreda of Dugda Bora. Part of the Misraq Shewa Zone it is located in the Great Rift Valley. The administrative center of Bora is Bote (Alem Tena).

The 2007 national census reported a total population for this woreda of 58,748, of whom 30,487 were men and 28,261 were women and the projected total population of the woreda in 2008 is 76384 of whom 37810 were males and 38574 were females. In 2008 EC, the number of people lives in the urban areas was 15043 with 7446 male and 7597 female population dwellers.



Figure 23. Administrative map of Bora woreda, East Shewa Zone, Oromiya Ethiopia, 2016.

Study period*:* The study period was from May 10/2008 to May 20/2008 EC.

Study design: Quantitative, Cross-sectional descriptive studies was conducted to address the objectives stated above

Source population: East Shewa zone total population was taken as source population

Study population: Bora woreda total population was taken as study population

Sample size: No sample size calculation was not needed since all study unit were included.

Data collection*:* Using different format developed from Bora woreda administration, finance, culture and tourism, transport agriculture telecommunication, Ethiopian power supply office, Ethiopian post office, government communication office, education office and health office

experts and relevant personals were interviewed and or observed. The Principal investigator collected the data.

Variables

Dependent

- Total safe water coverage
- Ratio of health institution to population
- Health service coverage
- Top ten leading cause of morbidity
- Infant Mortality Rate (IMR)
- Child Mortality Rate
- Crude Birth Rate
- Crude Death Rate
- Maternal Mortality Rate
- ANC rate
- Percentage of deliveries attended by skilled birth attendants

Independent Variables

Main income, Educational status, Bank telecommunication, Power supply and Transportation.

Data analysis: The Data were collected by different format and descriptively analyzed by using manually and Microsoft Excel 2007. The analysis included calculation of rates and ratios.

Ethical consideration: Permission was secured from zonal health department in written letter to undertake the study in Bora woreda. Permission letter was secured from East shewa zone health office to Bora woreda health office. Then Bora woreda health office communicated to relevant sectors in the woreda to enable me collect necessary data.

Dissemination of findings: finding of the surveillance data analysis was distributed to advisor, supervisor, zonal health department, and Adama regional laboratory.

4.4 Results

Historical aspect of the woreda

The woreda name is Bora. Bote town is the place where woreda administration and other sector office found. The name was derived from the name of mountain found in Jima Bora kebele in Bora woreda. This name was given in 1999 after the Dugda Bora woreda split in to Dugda and Bora woreda in 1999 EC.

Geography and climate

Bora woreda is located 109 KM south east of Addis Abeba and 54 KM South –West of Adama town which is East Shewa zonal town. It is Located in 8^0 24' 02N Latitude and 39^0 07' 58E Longit Mean monthly air temperature varies from 18.8 •C in December to 22 •C in May. Period from March to June is relatively warmer, when the mean temperature is generally above 21 • C. The air relative humidity is 66% on average. Average annual potential evapotranspiration is 1,658 mm, which is more than two times the annual rainfall. The annual rainfall in the woreda is 774 mm and temperature averages 20.3 ^{o}c.

About 64% of the annual rainfall is recorded during the period from June to September. The drier months are from November to February, only 8% of the annual rainfall is recorded during this period. The heaviest precipitation usually falls during August with as much as 21% of the annual precipitation occurring during this period.

The woreda boundary is Liben chukala and Lume woreda in the North, Arsi zone and Dugda woreda in the South, Arsi zone and Lume woreda in the East and Dugda woreda and South West shewa zone in the West.

Administrative and Political Organization

In the Woreda there were a total of 20 kebeles of which 18 kebeles are rural and 2 Town kebeles. The Woreda has its own council and representative in the Federal Parliament. All governmental sector offices were found in the Town of Bote.

Demography

According to the 2000 EC census and projections in the year 2008EC, the size of Bora Woreda population, including 18 rural kebeles and two town kebeles total population is 76,384 of which 37,810 (49.4%) male and 38,574 (50.6%) female and the population of urban in the woreda is 15,043 of which 7,446 were male and 7,597 females and those of rural residents were 61341 of which 30364 were males and 30977 were female residents.

Figure 24. Total population of Bora woreda by kebele, Bora woreda East Shewa Zone, Oromia region, Ethiopia, 2008 EC

S.No	Name of kebele	Total population	Male	Female	Remark
1	Bote 01	7621	3765	3857	
2	Bote 02	7422	3666	3756	
3	Bite Dhaba	5709	2672	3037	
4	Dodo Wedera	6034	2981	3053	
5	Mallima Bari	5143	2541	2602	
6	Gora Lemmen	1402	693	709	
7	Illen	2852	1409	1443	
8	Tube Suti	3367	1663	1704	
9	Lafisa Garmaji	2473	1222	1251	
10	Barta Sami	3407	1683	1724	
11	Tuqa Langano	2057	1016	1041	
12	Jirma Bora	3226	1594	1632	
13	Dalota Mati	3421	1690	1731	
14	Sori Dolesa	2890	1428	1462	
15	Qiltu Ombole	4497	2222	2275	
16	TUte Qoremtu	3795	1875	1920	
17	Doyo Lamman	3087	1525	1562	
18	Gosa Korke	3470	1714	1373	
19	Huluko Keshi	2372	1172	3572	
20	Tuchi Daku	2342	1157	1185	

Table 25. Population size by age category, Bora woreda East Shewa zone, Oromia region, Ethiopia, 2008 EC

S.No	Population category	Number	Male	Number	Remark
1	Under 1 years	2460	1215	1245	
2	Under 5 years	12,539	6194	6345	
3	Under 15 years	36,333	17948	18385	
4	Women aged 15-49 years	14,050	6941	7109	
5	Average House hold size	15912	-	-	
6	Annual population growth rate	2.9%	-	-	

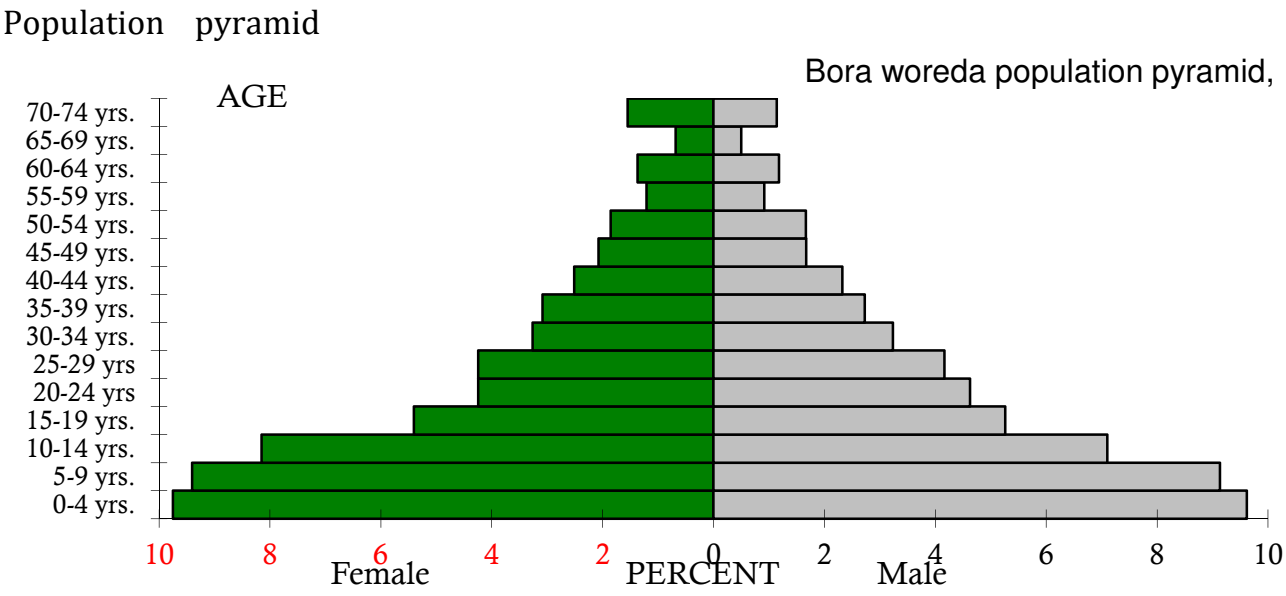


Figure 26. Population pyramid of Bora woreda Population Bora woreda East Shewa Zone, Oromia region, Ethiopia, 2008 EC

Economic situation

Agriculture is the main livelihood of the woreda. A total of 48,756 hectares of land available in the woreda of which, 27,550 Hectares of land used for cultivation, 13,886 for grazing area and 1,073 hectares of land is covered by water. The land density is 1.56 persons per hectare of land. In Bora woreda there are a total of livestock 161,504 of which 53,548 are cattle, 49,760 goats, and 46,718 poultry, 731 bee farm and 10,747 equine livestock available.

Education

Education is a key determinant of individual opportunities, attitudes, and economic and social status. Studies have consistently shown that educational attainment has a strong effect on

reproductive behavior, fertility, infant and child mortality and morbidity, and attitudes and awareness related to family health, use of family planning, and sanitation[3]. In the year 2008,in the Woreda there were6(K.G) grade-level of school. Similarly there were 37 government and 3 private primary school, 2 government and 1 private high school, 1 preparatory school and 1 TVET(Technical and vocational education and training) school .

14,264 students of which 7168 (50.25%) students were males whereas 7096(49.75) students were female students enrolled in 2008 in the woreda.

Gender Parity Index (GPI) is balanced in almost all school categories. The number of male students in all categories except from school category 5-8, outnumbers the number of female students.

Woreda facility

There is dry weather road to all health facility and kebeles and 6 health facilities enjoy all weather road access. 343 residents have access to land line telephone access, with 80% mobile network coverage. There is one post office, one bank (Commercial bank of Ethiopia) and 2188 Households have access to Electricity power.

Water Supply coverage

Bora Woreda is found in the Rift Valley, which is characterized by high temperature, low and unreliable distribution of rainfall. Despite this fact, the Woreda has no enough surface and ground water (thought to be the effect of fluoride) resources. Awash River does act as the main source of water supply to the community. Total safe water supply coverage in the Woreda was59% based on the Woreda Water and Energy Bureau.

Health service

Woreda Health Office Structure

The woreda health system structure has 6 core processes: Health and health related service, HIV prevention and control, Human resource, Health extension support, Purchasing and finance, and health information core process owners.

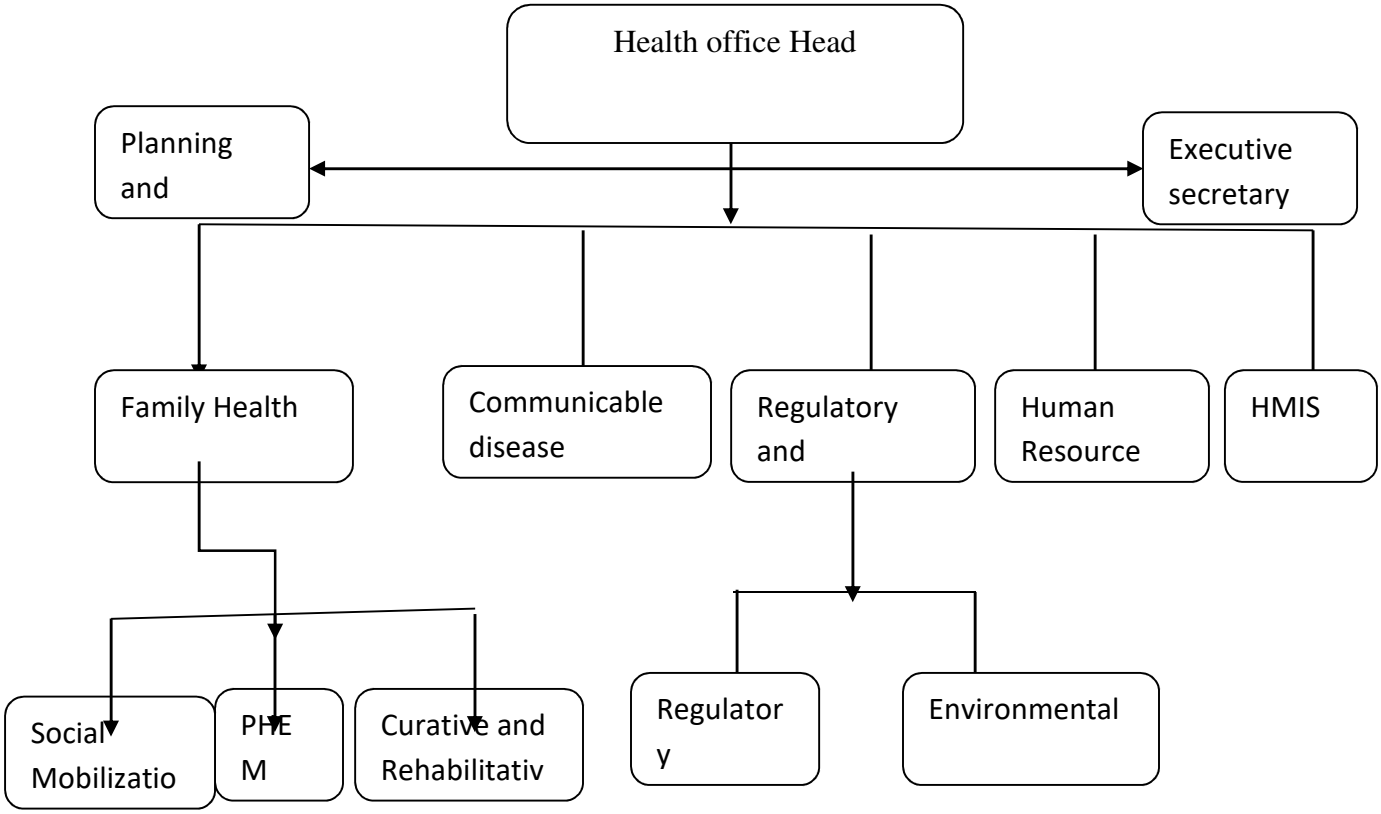


Figure 27. Organizational structure of Bora woreda health office, Bora woreda, East Shewa Zone, Oromia region, Ethiopia, 2008 EC

At the woreda level, there is health management team composed of deputy woreda health office head as chairperson, MCH coordinator, regulatory coordinator, communicable disease coordinator and HMIS focal person as members. This team has responsibility to oversee the overall activities of health sector in the woreda.

Concerning Non- governmental organization working in the woreda, there is one organization called “MULU HIV PROJECT” which works on prevention of HIV in the woreda. No data were available on vital statistics in the woreda.

Health Infrastructure

The numbers of health institutions administered under the woreda Health sector that directly provide services to all people of the Woreda is 40. No Hospital is found in the woreda. The nearest Hospital is found some 30 KM away from the woreda in Batu town. Three government

and 1 private health centers, 18 health posts, 13 clinics of all type, three diagnostic lab and 02 drug stores provide service to the woreda population.

The health population to Hospital ratio is 0, while health center to population ration is 1:25,461 which is in line with the government policy of 1:25,000 ratios. The health post to population ratio is 1:4,244 with standard of 1:5,000 ratios. The total health service coverage in the woreda is 98%.

Table 15. Type and number of health institution in Bora woreda, Oromia regional state, Ethiopia, 2008 EC

S.No	Type of institution		Number	Number of beds	Remark
	Government Hospitals		0	0	
	Government health centers	Type A	01	06	
		Type B	02	08	
	Private Health facility	All types of clinics	13	0	
		Diagnostic lab	03	0	
		Drug store	02	0	
	Government health post		18	0	
	Non-governmental Health institutions	Health posts	0	0	
		Health centers	0	0	
		Hospitals	0	0	
		Clinics	01	0	
	Facility under construction		0	0	

Human resource, health workers

The Woreda had a total of 91 health workers and 21 supportive employees. The health workers distribution is listed below in a table.

Table 16. Health professionals in Bora woreda, Bora woreda East Shewa Zone, Oromia region, Ethiopia, 2008 EC

S.No	Type of Professionals	Number	Remark
1	Specialist	0	
2	General practitioner	0	
3	Health officer	07	
4	Nurse(Degree and Diploma)	20	
5	Laboratory(Degree and Diploma)	04	
6	Pharmacy(Degree and Diploma)	07	
7	Environmental Health(Degree and Diploma)	03	
8	Health Information technician	02	
9	Health extension workers	44	
10	Radiologists	0	
11	Anesthesia	0	
12	Clinical pharmacy	0	
13	Ophthalmologists	0	
14	Psychiatry	0	
15	Others	21	
16	Health education	0	
17	Mid wife	05	

Health indicators

The number of pregnant women attended the First and the fourth anti natal care in the woreda in 2008 EC is 3533 and 1929 respectively. The number of pregnant women attended by skilled birth attendant was 103.

Immunization coverage

In Bora woreda, almost all children get most of the vaccination at their intended target and time. Except for Measles and fully immunization parameter, all immunization service provided by the woreda meet their intended target for 2008 EC. The table below summarizes the types of immunization and the number of children and mother getting immunization.

Table 17. Immunization coverage in Bora woreda, East Shewa Zone, Oromia region, Ethiopia, 2008 EC

S.No	Types of immunization	Plan	Performance	Coverage in %	Remark
1	BCG	2210	2310	104.5	
2	OPV 1	2050	2431	118.5	
3	OPV 3	2050	2202	107.4	
4	Penta 1	2050	2431	118.5	
5	Penta 3	2050	2202	107.4	
6	PCV 1	2050	2431	118.5	
7	PCV 2	2050	2151	104.9	
8	Measles	2050	2049	99.9	
9	Fully immunized	2050	2013	98.2	
10	PW TT2+	2210	2345	106.1	
11	PAB	2050	2422	118.1	

Ten top causes of morbidity

The total number of disease case presented to health facilities in Bora woreda in 2008 EC was 14,077 of which 7452(52.93) were adult and 6625(47.07%) cases were under 5 years of age. This indicates high burden of disease in under five children.

In the woreda Acute Febrile Illness, Upper respiratory infection, Helmenthiasis and Pneumonia contribute to most of the disease in the woreda both in adults and children under five years of age. Malaria UTI accounts for small number of disease compared to the above mentioned disease.

Table 18. Ten top causes of morbidity as registered in Bora woreda health facilities, Bora woreda East Shewa Zone, Oromia region, Ethiopia, 2008 EC

Adult				Under 5 years of age			
Rank	Cause of Morbidity	Count	Percent	Rank	Cause of Morbidity	Count	Percent
1	Acute Febrile Illness	1410	18.92	1	Pneumonia	1491	30.08
2	Upper Respiratory Infection	1091	14.64	2	Diarrhea(Non-Bloody)	1214	24.58
3	Helmenthiasis	871	11.69	3	Upper Respiratory Infection	814	16.42
4	Trauma	737	9.89	4	Helmenthiasis	320	6.46
5	Typhoid Fever	724	9.72	5	Acute Febrile Illness	266	5.37
6	Epidemic Typhus	718	9.63	6	Diarrhea with Dehydration	260	5.25
7	PF confirmed	654	8.78	7	Infection of the skin and Sub-Cutaneous	194	3.91
8	Diarrhea(Non-Bloody)	452	6.07	8	Dysentery(Bloody Diarrhea)	160	3.23
9	Urinary Tract Infection	451	6.05	9	PF confirmed	123	2.60
10	Malaria Other than PF	344	4.62	10	Unspecified Disease of the Respiratory	108	2.18

Health budget allocation

The 2008 EC Bora woreda total budget was 57,083,370 ETB of which, 7,290,464 ETB was allocated for health sector. Compared to the previous year health sector budget were 5,094,797 this year's budget has an increment of 43%.

Status of primary health care components

Proper medical attention and hygienic conditions during delivery can reduce the risk of complications and infections that can cause the death or serious illness of the mother and/or the

newborn baby. An important component of efforts to reduce health risks to mothers and children is increasing the proportion of babies that are delivered in health facilities.

Pregnant mothers who attending the first visit in the woreda health facilities were 3656(165%), and those who attend the fourth ANC visit were 1961(88%). pregnant mothers who attends the fourth visit also attends PNC service. The coverage of Oral contraceptive in the woreda stands at 11.9% with 1370 mothers got the service, while 4799(41.8%) uses inject able contraceptive. Implant contraceptive users in the woreda were 2513(21.9%) while IUCD users were 13(0.01%). The contraceptive prevalence rate in the same year in the woreda were 22%, calculated by total number of women aged 15-49 divided by total women population in the woreda.

Environmental health and sanitation

Environmental health programme is one of the main components of the current National Health Policy as it is evident that environmental factors are major determinants of public health outcomes. The main objective of the programme is to contribute to the attainment of a significant reduction in morbidity and mortality due to environmental health related conditions. Ensuring adequate sanitation facilities is another Millennium Development Goal that Ethiopia shares with other countries.

Overall household with latrine in the woreda is 6055(38%), while the standard (improved) latrine coverage in the woreda is 24.9% with 3967 household used improved type household. For the Solid waste management, 4710 households dug well for management of dry waste.

Endemic disease

Malaria

All kebeles in the woreda (20 kebeles) and all population in the woreda (76384) are at risk of malarial disease. The prevalence of malaria of all cases in the woreda was 1.8 %. The ITN coverage in the woreda is 100% i.e all household got access to at least on ITN in their home. A total of 42150 ITN has been distribute in 2008 and the year before. Eleven kebeles got indoor residual spray in 2008. Total number of malarial case (both clinical and lab confirmed case) in the woreda in 2008 EC was 1436 with no death registered in health facility in both adult and

under 5 years of age. A total of 1212 adult cases and 214 under five cases registered in the woreda in the same year.

Tuberculosis/Leprosy

The Woreda TB prevalence rate was 179 per 100,000 populations with the mortality rate due to TB was 5.8% and other TB indicators are listed below in table 13.

Table 19. TB/Leprosy indicators, bora woreda Oromia region Ethiopia 2008 EC

S.N	TB indicators	count	Coverage by %
1	Tuberculosis detection rate	70/63	111.1
2	TB treatment completion rate	65/74	88
3	Tuberculosis cure rate	42/45	93
4	TB treatment success rate	43/45	96
5	Total TB patients screened for HIV	137	
6	Total leprosy case on treatment	0	
7	Death on TB treatment	8	
8	TB defaulter	2	
9	Extra PTB	34	
10	PTB Negative	33	
11	PTB Positive	70	

HIV prevention and control

The priority intervention area in the Woreda in relation to HIV/AIDS to date were IEC/BCC, condom promotion and distribution, voluntary counseling and testing (VCT), management of sexually transmitted infections (STIs), prevention of mother to child transmission of HIV (PMTCT), management of opportunistic infections, blood safety, infection prevention/universal precaution, care and support to the infected and affected.

Total number of people screened for HIV in the year 2008 EC is 6605. The number of people screened for HIV by VCT is 927, in PICT 5678 in PMTCT 3750.HIV prevalence in the woreda

is 0.5% while the incidence rate is 0.04%. The number of pregnant women living with HIV/AIDS is 6. From a total HIV positive people, 352 patients are on ART and 35 were on Pre-ART.

Nutrition, Food Shortage and any Other Disasters

Vegetables are the main food source of the area since the Awash River crosses this woreda, Onion, Cabbage, carrot, tomato and other vegetables produced in the woreda. Not all family has access to Awash River irrigation chance. There are kebeles where food shortage is common and food supplement provided by the government.

To distribute these supplements the woreda has 22 OTP sites with total admission of 379 in the year 2008 EC. No new sick child sites opened this year beside the previous year's 3 sites. Total admission in the SC sites in 2008 is 50 children. There is also targeted supplement feeding program in the woreda. Total community based nutrition program 2683.

Essential drugs shortage

According to the Woreda Health Office, budget for drugs and other medical supplies was not clearly known, however, the Woreda Health Office pharmacist reported that there was shortage of some essential drugs in the year 2008 E.C.

4.5 Discussion

The age structure of the household population in Ethiopia is typical of a society with a young population. In my study also the pyramidal age structure reflects the large number of children under age 15. Children under age 15 account for nearly half of the total population, a feature of populations with high fertility levels, while only about 4 percent of Ethiopians are over age 65. This population distribution is similar to that observed in the 2000 and 2005 surveys (5).

Immunization coverage is one of the most important indicators used to monitor progress towards the reduction of child morbidity and mortality, as it is one of the most cost-effective public health interventions for reaching these goals. In Bora woreda immunization coverage has increased over the past years and well ahead from the regional and national coverage. The percentage of BCG, and fully immunized children in the woreda in 2008 EC was 104.5%and 98.2% respectively well over the regions average of 65.2% and 21.7% respectively (5).

The contraceptive prevalence rate for all women in the woreda aged 15-49 is 22 percent. This rate is almost similar with the regional contraceptive prevalence rate of 20%. The most common modern method used by age group of women is injectable, currently used by 41.8 percent of all women, followed by IUCD with 13%. This finding is same with oromiya regional usage of contraceptive methods by women of which usage rate was high for injectable with 14% (5) .

The quality of antenatal care (ANC) can be measured by the qualifications of the provider and the number and frequency of ANC visits. Antenatal care quality can also be monitored through the content of services received and the kinds of information given to women during their visits. These services raise awareness of the danger signs during pregnancy, delivery, and the postnatal period. Under normal circumstances, the World Health Organization (WHO) recommends that a woman without complications should have at least four antenatal care visits, the first of which should take place during the first trimester. Eithy eight percent of women made their first ANC visit in 2008 EC and 16.5% of the followed up to fourth ANC visit in the woreda compared to 58.3% and 32.1% for the first and fourth visit in the region (5) .

The woreda total latrine coverage is found to be 38% with improved latrine coverage of 24.9%. This coverage is far more than the regions average coverage of latrine and with improved latrine

coverage of 4.5 % (5). .Children and female household members are the most vulnerable to the risk of malaria (6).

Malaria parasite prevalence was 2.4% in Ethiopia and 0.9% in Oromiya, and in my study the prevalence of malaria in the woreda was 1.8% which is not markedly differ from both the national and regional prevalence rate of malaria (7). .

A total of 137 cases of all forms of TB cases were registered in the woreda in 2008 EC. Among the 137 cases of all forms of TB, a total of 70 (51.09%) were identified as pulmonary TB patients based on Acid Fast Bacilli microscopic result. the prevalence of all forms of TB in the woreda in 2008 EC was 179 cases per 100,000 population. This finding does not match with a study conducted by Mulugeta Belay in his study of "Prevalence of tuberculosis, HIV, and TB-HIV co-infection among pulmonary tuberculosis suspects in a predominantly pastoralist area, Ethiopia" in 2015, the prevalence of TB was 13.5 % (8).

According to the 2014 WHO report, the prevalence and incidence of all forms of TB are 211 and 224 per 100,000 of the population, respectively so the prevalence of Tuberculosis in the woreda is not significantly different from that of the prevalence of TB in the country (9). In this study HIV incidence and prevalence rate in the woreda in 2008 was 0.04% and 0.5% respectively.

HIV prevalence is low in Ethiopia, with 1.5 percent of the population age 15-49 HIV positive (EDHS 2014). According to the 2014 HIV estimates, the national HIV prevalence in Ethiopia is 1.14%, indicating the country has more than achieved the Millennium Development Goal 6 target of 2.5%. The rate I have found is less than that of the national HIV prevalence rate (10).

Conclusion

In Bora woreda, almost all children get most of the vaccination at their intended target and time. Except for Measles and fully immunization parameter, all immunization service provided by the woreda meet their intended target for 2008 EC.

Recommendation

- The Woreda immunization coverage should be registered and documented

- Important health indicators like maternal mortality, infant mortality and child mortality should also be registered and documented.
- Health education to the population is needed regarding environmental health, personal hygiene and the importance of ITN and IRS
- To alleviate malnutrition in the Woreda people should shift from pastoralist to agro-pastoralist and should have access to modern technology to maximize the agricultural product.
- Clean water, Road, Transport, Telecommunication and power supply should be available and there is a needed to maximize their coverage in the Woreda.

4.6 Reference

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4.7 Annex

Data collection tool

Health profile assessment questionnaire Bora Woreda, Oromia Regional State 2008

1. Historical aspects of the Woreda

- Woreda Name
- How & why the name given
- How and when the Woreda was formed_____
- Any other historical aspect about the Woreda_____

2. Geography and Climate

Woreda map_____

- Location(distance) ----------Direction ----------
- Altitude
- Surface Area ----------
- Town __rural (land)

Geographical coordinate

- Latitude
- Longitude
- Annual rain fall(average)
- Annual temp(average)
- Climatic zones

3. Woreda boundaries

	Kebeles	Total Population	Sex		Residency	
S.N			Male	Female	Urban	Rural

4. Population pyramid

Population data by age and sex								
Male								
Female								
Total								

Characteristics	Frequency	Percentage
Ethnic/language		
Oromo		
Amhara		
Tigre		
Garage		
Others		
Religion		
Orthodox		
Muslim		
Protestant		
Others		
Occupation		
House Wife		
Student		
GOV employment		
Merchant		
Others		
Water Source		
Pipe		
River		

Wale		
Others		

5. Economy (mainstay of the economy, average income levels etc)

Main income sources

- Agriculture
- Cultivated area_____
    - Grazing area_____
- Cropping seasons_____
- Land density_____
- Livestock
- Tourism
- Trade
- Other business

House hold income source

- Agriculture_____ (#)
- Government Employer_____(#)
- Private Employer_____(#)
- Daily Laborer (#)
- Different business_____ (#)
- Jobless (#)
- **Average Income per year_____**

Characteristics	**Frequency**	**Percentage**
Educational institution		
K.G		
Primarily School (1-8)		
Secondary (9-10)		
Preparatory(11-12)		
College/ University		

TVET		
School health activities: Number of schools with Water supply		
Schools with functional latrines Male Female		
Schools with HIV/other Health clubs		

6.Educational Status

School Enrolment	**Sex**				
	Male		**Female**		**Total**
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**
Illiterate					
KG					
1_8					
9_12					
TVT					
Collage/University					
School Age Children (target)					
Coverage					
School dropout in 6 months or year 2005					

7. Water coverage

Characteristics	**Frequency**	**Percentage**
Total safe water coverage		
Safe water supply coverage by kebeles		
Main source of water supply		
Kebeles getting safe water		

Population getting safe water		
Daily water consumption per day per person		

Other Facilities

Characteristics	Frequency	Percentage
Transport		
Accessibility (main roads)		
Type of road		
How many kebeles have access to transportation		
Flow of transportation per day		
Telecommunication		
How many people have access to fixed telephone		
How many people have access to mobile phone (coverage)		
Post Office		
Bank		
Power supply		
How many house hold get power supply		

8. Disaster situation in the Woreda

- Was there any disaster (natural or manmade) in the Woreda in the last one year?
- Any recent disease outbreak/other public health emergency
- If yes cases_____ and deaths_____

9. District health system

-The general health system structure of the Woreda (flow chart)

-Is there health management team (HMT) at Woreda levels? Yes/no

-If yes, describe the HMT in detail (composition, functions, etc)

- Do you have non-governmental organizations working on health and heath related issues? yes/no
- List the NGOs (and what they are doing) working on health and health related issues in your Woreda

10. Vital Statics and Health Indicators

- Infant Mortality Rate (IMR) _____(total <1 yr deaths this 2005yr)
- Child Mortality Rate_____(this year's total <15 yr deaths)
- Crude Birth Rate_____
- Crude Death Rate_____ (total deaths 2005yr _)
- Maternal Mortality Rate_____(2005 total maternal deaths_____)
- Contraceptive prevalence rate
- Contraceptive acceptance rate _____
- ANC rate (how many of the total expected pregnancies attended ANC)
- Percentage of deliveries attended by skilled birth attendants
- Percentage of deliveries attended by HEWs
- Percentage of deliveries attended by TBA
- PNC rate(how many of the total expected Mothers attended PNC)
- Average family size

11. Immunization Coverage

S.N	Type of Vaccine	Vaccination Status			
		PLAN TO VACCINATE	ACHIEVEMENT	PERCENTAGE	RANK
1	BCG				
2	Penta 1				
3	Penta 3				
4	Measles				
5	PCV 1				

6	PCV 3				
7	Fully immunized				
8	TT2+NPW				
9	PAB				

12. Health Service

Type and Number of Health Institution

Type		**Number**	**Total No. of beds**	HF: Population Ratio
Gov. Hospital				
Gov. Health center	Type A			
	Type B			
Private H.Fs (clinics/diag. lab/drug stores)	Clinics (all type)			
	Diag. Lab.			
	Drug store			
Gov. Health posts				
NGOs	H.Ps			
	H.Cs			
	Hospitals			
	Clinics			
OGOs	Hospitals			
	Clinics			
Health service coverage				

Type and Number of health professionals

Type	**Frequency**	**Percentage**	Health Professional: Population Ratio

Specialist			
G.P			
HO			
Nurses (Deg. and Dip.)			
Mid wife (Deg. and Dip.)			
Lab. (Deg. and Dip.)			
Pharmacy (Deg. and Dip.)			
Env. Health (Deg. and Dip.)			
HIT			
Health education			
HEWs			
Total			

13. Top causes of morbidity

Top ten leading causes of OPD visit (morbidity)

	DISEASE (2003)	No of cases	%
1	Acute upper respiratory infection		
2	Diarrhea non-blood		
3	Trauma		
4	Malaria clinically		
5	Disease of musculoskeletal system and connective tissue		
6	Acute febrile illness		
7	Urinary tract infection		
8	Dyspepsia		
9	Pneumonia		
10	Helminthes		

No	DISEASE(2004)	No of cases	%

1	Acute upper respiratory infection		
2	Diarrhea non-blood		
3	Acute febrile illness		
4	Malaria clinically		
5	Disease of musculoskeletal system and connective tissue		
6	Urinary tract infection		
7	Pneumonia		
8	Dyspepsia		
9	Malaria confirmed with PF		
10	Helminthes		

No	DISEASE(2005)	No of cases	%
1	Acute upper respiratory infection		
2	Malaria confirmed with FP		
3	Helminthes		
4	Diarrhea non-blood		
5	Acute febrile illness		
6	Urinary tract infection		
7	Trauma		
8	Pneumonia		
9	Malaria Clinical		
10	Disease of musculoskeletal system and connective tissue		

Top ten causes of admissions (Morbidity)

No	DISEASE(2005)	No of cases	%
1	Pneumonia		
2	Malaria confirmed with PF		
2	Diarrhea non blood		
4	Acute upper respiratory infection		
5	Dyspepsia		
6	Urinary tract infection		
7	Trauma		
8	Asthma		
9	Malaria other than PF		
10	AIDS		

14. Health budget allocation

Government

- Total budget allocated for the Woreda _____(consecutive 5 years)
- Total budget allocated for health _____ (____ %)

years	Woreda budget	Health budget	%
2003			
2004			
2005			
2006			

Funds from NGO

- Total ____unknown_____ (purpose/programs)_____

15. Community Health Services

Status of services provided by community health workers namely:

- No. of TBAs/TTBA_____ and their responsibility

- No. of CHWs/CHPs and their responsibility
- Responsibility of HEWs
- Others;

16. Status of Primary Health Care Components – with focus on the eight PHC elements and MDG

- MCH (Delivery, ANC, PNC)

_____

Family Planning Methods

Methods	Frequency	Percentage
Oral Contraceptive		
IUCD		
Implant		
Injection		
Condom		

Is their EPI (outreach service?)

- Yes
- No

Conduct cold chain or vaccine management supportive supervision

- Yes
- No

If yes, do you have checklist?

- Yes
- No

Environmental Health and Sanitation

- Latrine coverage & utilization rate

Type of Latrine

Type of Latrine	**Frequency**	Percentage
Open field		
Pit Latrine		
Ventilated Pit Latrine		
Others		

Solid waste management

Is their solid waste container?

- Yes
- No

Is their solid waste container loader?

- Yes
- No

If yes, frequency of solid waste collection_____

- Liquid waste management only in Metehara sugar factory camp
- others_____
- Health Education (what, when, where, how and who conducted health education)_____

17. Endemic diseases

Malaria:

- Total malarious kebeles & Pop at risk
- ITNs coverage (including current dist) Total requirement

- Is there IRS this year(No of kebeles)
- Total cases/yr deaths/yr 0,<5yr cases_____ deaths_____
- Malaria supplies (Coartem, RDT, etc) shortage
- Other issues_____

TB/Leprosy:

- Total TB cases
- PTB negative
- PTB positive
- Extra PTB
- TB detection rate
- TB Rx completion rate
- TB cure rate
- TB Rx success rate
- TB defaulter
- Death on TB Rx
- Total TB patients screened for HIV
- Total Leprosy cases on Rx_____

HIV/AIDS

- Total people screened for HIV (last one year)
- VCT PIHTC PMTCT

- HIV prevalence_____
- HIV Incidence (new cases/yr)_____
- Total PLWHA
- On ART on Pre-ART
- Other HIV prevention activities_____

Nutrition

- Total OTP sites , total admissions to OTP/yr_____
- Total SC sites,_____, Newly opened/yr_____, total admissions to SC/yr_____
- Is there TSF (targeted supplementary feeding) program in the Woreda
- CBN program PSNP _____other_____

18. Essential drugs (shortage)

CHAPTER V

5. Manuscript for peer reviewed Journal

Time to viral load suppression and its associated factors in cohort of patients taking antiretroviral treatment in East Shewa Zone, Oromiya, Ethiopia, 2018

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Affiliation: Ethiopian Field Epidemiology Training Program[1], St. Paul's Hospital Millennium Medical College Department of Public Health[2]

Abstract

Background: A key goal of ART is to achieve and maintain durable viral suppression. Thus, the most important use of the viral load is to monitor the effectiveness of therapy after initiation of ART. The main objective of the study was to determine the time for virological suppression and its associated factors among people living with HIV taking antiretroviral treatments in East shewa zone, Oromiya, Ethiopia.

Methods: Patients diagnosed with human immunodeficiency virus presenting to the study health centers between October 3, 2011 and March 1, 2013 were included in the study given the following criteria: age 18 years or greater, eligible to start ART. All patients with baseline viral load measurement were included in the study. Interaction between explanatory variables with the response variable was analyzed by using cross tab features of SPSS, IBM Inc. Significance group comparison was done by Kaplan Meier log rank test. Cox proportional hazard model was used to select significant factors to the variability between groups.

Result: plasma viral load was suppressed below detection level in 72% of individuals taking different regimen of ART. The median HIV-1 plasma viral load in the cohort was estimated to be log 5.3111 copies/ml. Survival curve difference were observed in category of marital status (p-value 0.023) and baseline CD4 values (p-value 0.023). Estimated median time to PVL suppression was 181days (CI: 140.5-221.4) with the age group of 30-39years having minimum time to achieve suppression with 92 days (CI: 60.1-123.8) and the maximum time required to reach the level was age group between 50-59 years.

Conclusion: Estimated time to achieve PVL after taking ART was found to be 181 days. Factors affecting time to suppression level was marital status and baseline CD4.

5.1 Introduction

Human immuno-deficiency virus (HIV) is a virus spread through different body fluids that attacks the body's immune system, specifically the CD4 cells, often called T cells (1). Acquired immunodeficiency syndrome (AIDS) is a chronic, potentially life-threatening condition caused by the human immunodeficiency virus (HIV) (2).

The world has committed to end the AIDS epidemic by 2030 as part of the sustainable Development goals (4). Momentum is now building towards a new narrative on HIV treatment and a new, final, ambitious, but achievable target: By 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have viral suppression. When this three-part target is achieved, at least 73% of all people living with HIV worldwide will be virally suppressed – a two- to three-fold increase over current rough estimates of viral suppression. Modeling suggests that achieving these targets by 2020 will enable the world to end the AIDS epidemic by 2030, which in turn will generate profound health and economic benefits (5, 6).

Viral load is the most important indicator of initial and sustained response to ART and should be measured in all HIV-infected patients at entry into care, at initiation of therapy, and on a regular basis thereafter (7). Viral load (HIV-RNA copies/mL of blood plasma) as a surrogate marker for disease progression was first developed enrolling male patients and is currently considered highly predictive of the clinical course of infection (8).The main objectives of this study was to determine the time to virological suppression and its associated factors among people living with HIV taking antiretroviral treatments in East shewa zone, Oromiya, Ethiopia, 2018.

5.2 Methods

Settings: The study was conducted in East Shewa zone Oromiya Region, Ethiopia in 2018. Study was conducted on those patients who take ART treatment in five Health centers in East Shewa zone.

Study Design: Retrospective cohort study design was used to conduct the study.

Source population: The source population was all people with confirmed HIV positive status in East Shewa Zone, Oromiya region Ethiopia.

Study population: Patients who have started ART since inclusion constitute the study population for the current study, with follow-up data collected until data abstraction on December 31, 2013.

Sample size determination and sampling

Two hundred forty three study participants with base line viral load measurement were included in the study. All patients in cohort with baseline Plasma viral load was included in the study.

Data collection tools & procedures

The study used secondary data from a long-running community-recruited prospective cohort of patients of HIV. Trained clinicians at the start of the study collected demographic and clinical data, including physical examination details by using structured questionnaires. Interview was also used to collect data from patients. After informed consent, data was collected and checked for completeness.

Eligibility criteria

Human immunodeficiency virus(HIV)-positive patients presenting to the study health centers between October 3, 2011 and March 1, 2013 were eligible for inclusion given the following criteria met: age 18 years or greater and residency in the catchment area of any of the study sites. Patients with current or previous ART, as well as patients on ATT for more than 2 weeks before inclusion, were excluded. This cohort has since been continuously followed. Patients who have started ART since inclusion constitute the study population for the current study, with follow-up data collected until data abstraction on December 31, 2013.

Exclusion criteria: age less than 18 years old, with current or previous ART, as well as patients on ATT for more than 2 weeks before inclusionwere excluded.

Data Quality: Training was given for two data clerks on data management of secondary data obtained from previous study. Pretest of data collection tools was done before actual data collection procedure. Double entry of data made by using EPIINFO 7 to minimize error in data management and will be analyzed by SPSS version 21.

Data Analysis

Once data is collected, it was analyzed descriptively to determine the demographic characteristics and distribution of time to PVL. Time to undetectable viral load level was calculated by using Kaplan–Meier to estimate the distribution of PVL in time, and differences between the survival curves was evaluated with the use of the log-rank test, which is useful for comparing potentially unequal follow up times of study participants. Cox proportional-hazards regression analysis used to relate covariates with response variable with 95% confidence intervals.

Ethical considerations

Ethical approval was obtained from Saint Paul's Hospital Millennium Medical college public health department ethical review committee. Then the approval letter was forwarded to Oromiya regional health beauro. Finally, the approval letter from regional health bureau submitted to Adama regional laboratory where the actual study was done. Study participants provided written informed consent. Informed consent were received from illiterate study participants in the previous study (35).

5.3 Result

Laboratory analysis

All laboratory analyses, except TB cultures, were performed at Adama Regional Laboratory. CD4 cell counts were analyzed using BD FACSCalibur cytometer (Becton Dickinson, San Jose, CA). Sputum and FNA samples were analyzed with direct smear microscopy using Ziehl-Neelsen staining and Xpert MTB/RIF (Cepheid, Sunnyvale, CA) for polymerase chain reaction. Liquid cultures for TB were performed at International Clinical Laboratories, Addis Ababa, using a BACTEC MGIT 960 (BD Diagnostics, Franklin Lakes, NJ). Plasma HIV-RNA levels were determined using Abbott Real- Time HIV-1 assay (Abbott Molecular Inc., Des Plaines, IL) with a detection limit of 40 copies/ml. External quality assurance of the regional laboratory is regularly performed by the Center for Disease Control and Prevention (Atlanta, GA).

Study participant Characteristics

Study participants were recruited from Adama, Dhera, Geda, Modjo and Wolenchiti health centers taking ART and selected according to eligibility criteria. The minimum age included in the study was 18 years and the maximum age was 69 years

old. The mean, median and mode of participant age was 34, 32 and 30 years of age respectively. Forty five percent of the participants age was between 20-29 years old and minimum category was observed in <20 years old with 1.6 percent. Sex distribution of the study participant was 41% male and 59% female participants. most of the study participants (41%) was married but widowed participant represent only 10 % of the participant. With regard to baseline viral load in which the measurement was taken when the study participants enrolled in to the study, 13% of them were with plasma viral load less than 10,000 copies/µl. plasma viral load was suppressed in 72% of individuals taking different regimen of ART treatment. The median HIV-1 plasma viral load in the untreated cohort was log 5.3111 copies/ml. Nine percent of participant complete higher education while 36% of them were illiterate. Study participants nutritional status was also assessed by the study. Six participants (2.46%) were classified as having acute malnutrition while 71(29.2%) Participants classified as having moderate malnutrition and the rest166 (68.3%) were classified as normal. Baseline CD4 count was determined at the beginning of the study. Based on the data 140(57.6%) of the participants have BCD4 count of <200 cells/µl, 77(31.7%) have BCD4 count 200-350 cells/µl and 26(10.7%) have BCD4 count of >350 cells/µl. Tuberculosis disease screened among participants before enrollment and 189(77.8%) were positive for MTB by AFB light microscopy smearing and culture (MGIT and LJ). Viral rebound was observed in 16.5% of study participant. The Proportion of patients having PVL suppressed after taking ART was 72.4%. study participant contributed 94 person-year of follow up. Incident rate of plasma viral load suppression was 21.8%.

At the time or recruitment, 16.6% of female participants and 7% of male participants had BPVL less than 10,000 copies/µl. while 83.3% of female and 92.9%of male participants hade BPVL of >10,000 copies/µl. The mean and median baseline plasma viral load of study participants was 4.03×105 cells/µl and 2.03×105 cells/µl.

Bivariate analysis

Interaction between explanatory variables with the response variable was analyzed by using cross tab features of SPSS, IBM Inc. Base line PVL status of a patient did not showed significant interaction with event of interest with $\chi 2$ value 2.33(p-value .127). Other variables which did not show up includes age of the patient $\chi 2$ value of 4.44

(p-value .488), Marital status $\chi 2$ value of 6.75 (p-value .081), occupation $\chi 2$ value of .383 (p-value .826), education status $\chi 2$ value of 1.13 (p-value.770), MUAC $\chi 2$ value of .253 (p-v alue .881), BTB with $\chi 2$ value of 1.15 (p-value .283).

Significant interaction or association with Plasma viral load suppression were observed in sex $\chi 2$ value of 5.06 (p-value 0.024), BMI with 0.003, BCD4, $\chi 2$ value of 10.98

(p-value 0.004) and ART Treatment regimen with $\chi 2$ value of 14.23 (p-value .0.027)

Comparison between different categories for survival

Survival distribution for different age group reveals that there was no significant difference between different age group and other variables in the study in terms of the time to reach suppressed plasma viral load with log rank test score of $\chi 2$ value 0.860.

Table 20. Bivariate crude estimates of study participants, East Shewa Zone, Oromiya, Ethiopia, 2018

Estimated median time to PVL suppression was 181days (CI: 140.5-221.4) with the age group of 30-39years having minimum time to achieve suppression with 92 days (CI: 60.1-123.8) and the maximum time required to reach the level was age group between 50-59 years.

Significantly different survival distribution curve was observed between different categories of marriage in the study participants. The maximum median time for PVL suppression was observed in unmarried participants with 183 days (CI: 181.7-184.315). The minimum median time registered in divorced participant category with estimated median time of 92 days (CI: 91.06-92.93).

Variables	Category	Count/ percent	p-χ2 value	Sign.
BPVL	<10000 copies/µl	31(13)	2.33	.127
	>10000 copies/µl	212(87)		
Age	20 years	4(1.6)	4.44	.488
	20-29 years	109(44.9)		
	30-39 years	91(37.4)		
	40-49 years	29(11.9)		
	50-59 years	7(2.9)		
	≥60 years	3(1.2)		
sex	Male	99(40.7)	5.06	.024
	female	144(59.3)		
Marital status	Single	56(23.0)	6.75	.081
	Married	112(46.1)		
	Divorce	50(20.6)		
	widowed	25(10.3)		
occupation	Outdoor	170(70)	.383	.826
	indoor	72(30)		
Educational status	Illiterate	88(36.2)	1.13	.770
	<6 grade	65(26.7)		
	6-12 grade	81(33.3)		
	Higher education	9(3.7)		
BMI	≤18.5 kg/m^2	87(35.8)	8.98	0.003
	>18.5 kg/m^2	156(64.2)		
MUAC	≤23 cm	≥23 cm	.253	.881

	23.1-24.9 cm	23.1-24.9 cm		
	≥25 cm	≥25 cm		
BCD_4	<200 cells /µl	140(57.6)	10.98	.004
	200-350 cells /µl	77(31.7)		
	>350 cells /µl	26(10.7)		
BTB	Positive	189(77.8)	1.15	.283
	Negative	54(22.2)		
Treatment regimen	d4T, 3TC, NVP	1(0.4)	14.23	0.027
	d4t, 3TC, EFV	5(2.1)		
	AZT, 3TC, NVP	13(5.3)		
	AZT, 3TC, EFV	13(5.3)		
	TDF, 3TC, NVP	17(7.0)		
	TDF, 3TC, EFV	168(69.1)		

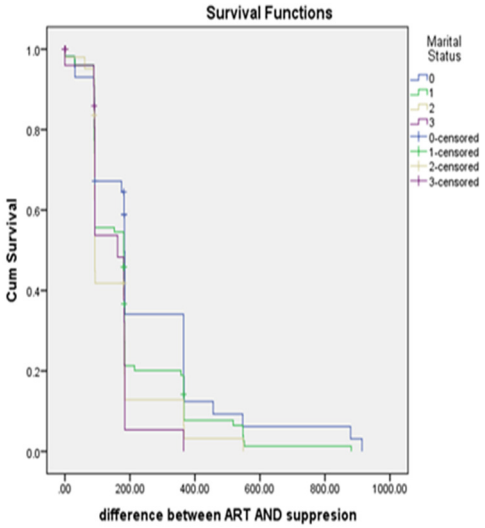


Figure 28. Survival curve for marital status of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Significant survival curve difference (log rank test: $\chi 2$ value of 8.84 and p-value of 0.012) was observed in HIV patients with different baseline CD4 count. Median survival time for patients with <200 cells/µl measured 182 days (CI: 160.80-203.19), 181 days (142.39-219.60) for BCD4 200-350 cells/µl, 174 days (CI: 133.40-214.59) and 174 days (CI: 133.40-214.59).

Multivariable analysis

Forward factor selection method (for identifying synergistic effect of variables on response variables) was used to identify factors that are significantly affect the median time. Cox-proportional hazard regression method was used to estimate the magnitude of each variable. Variables with p-value of ≤0.05 were included in the model and selected as variables to fit a model that best explain the variance in the equation. Variables identified as significant in this study was marital status with p-value 0.023 and baseline CD4 with p-value 0.023. Educational status (p-value 0.404), MUAC (p- value 0.407), BMI(p-value 0.335) and BTB(p-value 0.257).

5.4 Discussion

Median time for plasma viral load suppression in the study cohort was determined using survival regression analysis. Based on the study, median time for suppression was 181 days (CI: 140.5-221.4). This finding exactly matches with a study done by US department of health and human service in 2017, which found the median time between at about 24 weeks after initiation of ART. In another study conducted by Snippenburg W Van, Nellen FJB and Smith C, the median time to undetectable plasma viral load after initiation of treatment was found to be 60 days (12-168 days) which is lower than this study.

As of 2015, 72% of study participants achieved viral suppression, But in a study conducted in Brazil, the the percentage of HIV patients achieving viral suppression were 62%. This difference could be attributed due to the length of timing of follow up of the patients. Similar study conducted in neighboring Kenya revealed that only 39.85% of patients had virologocal suppression .In another study conducted by Shikuma CM and et al., the percentage of patients taking ART of different regimen reaching virological suppression after taking ART for 16 weeks showed 93% viral suppression. In this study, the percent of patients having virological failure was 16.5%. The same study by Shikuma CM and et al., found that 12.2% of patients have virological failure. Viral suppression rate of this study was found to be similar across different geographical spectrum. Study done in low and middle income countries of Brazil, Laos people's democratic republic, Malaysia, Mexico, Myanmar and republic of Moldova have achieved viral suppression of 80%.

Age category of 30-39 years old had minimum time to viral suppression with 92 days(CI: 60.1-123.8) and the maximum time to achieve viral suppression was found in age category of 50-59 years. Significant difference in proportion of different age group was not found by log rank test. In a study conducted in Kenya by Cherutich found significant difference between different age category in achieving viral suppression level. In this study there were significance difference between age group of 15-29 age group and 30-64 years category with the rate of 46.5% and 22.3% respectively.

significant sex difference was achieved in plasma viral load suppression among different sex category. Pearson's $\chi 2$ for sex category was 5.06 with p-value of 0.024. Significant difference between sex categories was also achieved in a study conducted by Ballesteros-zebad P. in Mexico, which found high suppression rate in male patients compared to Female patients. Other studied which found significant difference between male and female HIV patients viral suppression level was done by Pinto M. in southern Brazil, and Gray RH., in Uganda. Viral load suppression across sex category was not significant in a study done by Rangarajan S.,Colby DJ in Vietnam. In this study, which is done in Vietnam, there was no significant difference between male and female HIV patients achieving undetectable viral level. In this study, Viral suppression among

women was not significantly different with 93.7% vs 92.9% in male and female respectively.

The median baseline CD4 was similar with study conducted in Northern Province, Cameron with 204 cells/µl and 192 cells/µl respectively. Survival curve was not significantly different among different BCD4 categories which is also a result supported by the above study mentioned, But similar study in Cameron by Boelaert M. suggested significant difference in survival of patients between different BCD4 category.

Baseline Mid upper arm circumstance for evaluation of patients nutritional status does not appear to be associated with decrease in viral load suppression. Other studies suggested different association. A study by Liu E, Spiegelman D, found that base line lower MUAC was associated with lower rate of viral suppression from patient plasma.

Body Mass Index affected survival time of patient with $\chi 2$ 8.98 and p-value of 0.003. BMI category < 18.5 kg/m2 had increased risk of higher viral replication in a study by Sharma A. and Hoover DR, but association between obesity and reduced or increased viral load was not observed.

No difference in survival curve of HIV patients to reach viral load level with respective to different ART treatment regimen. Snippenburg W. Van achieved the same curve property in a study, which found no difference between protease inhibitor and non-nucleoside reverse transcriptase inhibitor based regimens.

At least one instance of viral rebound was occurred in 16.5% of cohort of HIV patients in the study period. This figure was 45.1% in the study performed by Guillemi S, Hogg R, Montaner J. equals to crude incidence of viral rebound of 12.6% compared to 16.4% crude incidence of viral rebound in this study.

Variables identified as significant in this study was marital status (p-value 0.023) and baseline CD4 (p-value 0.023). Pinto et al, found significant effect of age and ART usage on survival of patient taking ART drugs. Body mass index, sex , WHO clinical stage and hemoglobin level were cited as significant independent predictors of plasma viral load level in the patient plasma.

Educational status (p-value 0.404), MUAC(p- value 0.407) BMI(p-value 0.335) and BTB(p-value 0.257). There were no significant association found in the percentage of patients with undetectable

viremia by sex, marital status, educational level residence or wealth index(Rangarajan S, Colby DJ). Gray RH and et al, found significantly higher viral load after ART treatment in male and concurrent infection with Tuberculosis, Herpes virus,malaria and helmenthiasis. Study done by Semu H. and Hawkin C. also confirm that baseline MUAC and plasma viral load level does not have significant relation.

Limitation of the study

Sample size was not adequate to detect minimum survival difference in different study category.

Conclusion

Estimated time to achieve PVL after taking ART was found to be 181 days. Factors affecting time to suppression level was marital status and baseline CD4. Additional factors believed to be influencing survival curve were also studied, but not significant relation was found with the response variable.

Recommendation

Further study should be conducted by increasing the sample size and study area for better interpretability of the investigation.

Acknowledgements

This work was not possible without due technical assistance from Dr.Anton Reepalu, Dr. Taye Tolera Balcha, Dr. Sten Skogmar, Dr. Zelalem Habtamu Jemal, Dr. Erik Sturegård, Dr. Patrik Medstrand and Prof Per Björkman. My academic advisors Tewodros Getinet and Temesgen Geleta also gave me invaluable support to the accomplishment of this work.

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CHAPTER VI

6. Narative summary report of laboratory activity

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Affiliation: [1]Ethiopia Field Epidemiology Training Program; [2]St. Paul's Hospital Millennium Medical College Department of Public Health; [3]Oromiya Public Health Research, Capacity Building, Quality Assurance Laboratory.

6.1 Introduction

Oromia Public Health Research, Capacity Building and Quality Assurance Laboratory (OPHRCBQAL) formerly known Adama Regional Laboratory (ARL) was established by Oromia Regional Health Bureau with the help of CDC-Ethiopia in 1995 EC, in Adama town near Adama Hospital and medical college. When it started the services, there were two blocks with two laboratory professionals and five supporting staffs. Currently the laboratory has G+1 building and has 27 laboratory professionals and 24 supporting staff.

Oromia Public Health Research, Capacity Building and Quality Assurance Laboratory conducts health related and operational researches, identification of etiological agents during outbreak investigation and participate on intervention, provide advanced laboratory service and capacity building of health facility laboratories through training, monitoring and coaching of health professionals. The laboratory also mandated from Oromia Regional Health bureau to assuring the quality of laboratory services in the region by organizing and conducting regional external quality assessment scheme for health facility laboratories in the region in order to improve customer satisfaction.

Regarding to advanced diagnostic services OPHRCBQAL provides in the disciplines of HIV DNA PCR, Hematology, Clinical Chemistry, TB and clinical bacteriology serves as referral center for health facilities in Oromia and other nearby Regions. Development and implementation of quality management system in OPHRCBQAL started since 2010 GC/2003 E.C. Since then, the laboratory is working hard to improve the service and satisfy customer needs. The laboratory performs its work in the most professional and ethically way committed to good laboratory and clinical practice as well as to the requirement of ISO 15189:2012. The laboratory implements established evaluation and audit processes as well as thrives to meet its

quality objectives and reviews them to ensure quality management system is continuously improving and remains appropriate to the purpose of the organization.

Scope of the laboratory

A. Reception: Specimen collection, receiving, accession, storing, enter of test information using ILS, result collection, communication, and monitoring turnaround time.
B. Tuberculosis Laboratory: Smear microscopy (ZN/FM), Gene Xpert, TB Culture (solid and liquid), DST, Line probe assay, Phenotypic DST
C. Clinical chemistry laboratory: GPT, GOT, Urea, Creatinine, Triglycerides, ALP, Cholesterol, Glucose, Bilirubin, (total and direct)
D. Immuno Hematology: CD4 count and complete blood count (CBC)
E. Clinical Bacteriology: Gram stain, Culture and DST, fungal wet mount, KOH and urine microscopy
F. Molecular Laboratory: HIV viral Load and HIV DNA PCR
G. Operational research: conduct and participate on operational research
H. Outbreak investigation: etiological agent identification and epidemiological outbreak investigation in collaboration with other stockholders
I. Surveillance: Participate on the national HIV and meningitides sentential surveillance.
J. Public Health laboratory: conduct drinking water quality monitoring

Mission

To promote the health of the people of Oromia Region by addressing priority public health problems problem focus research advanced diagnostic services capacity building implement and maintain quality management system according to ISO 15189:2012

Vision

To see the community of the region health productive and prosperous by 2012 E.C

Responsibility, authority and interrelationship

The management has defined responsibilities and authorities of staff in their respective job descriptions. The staff read and acknowledge by signing the job descriptions witnessed by the laboratory director before they are filed in individual personnel files.

The interrelationships between management and staff are defined in the organizational chart. The management has appointed staff to be responsible for the three core processes that are deputized by sub process coordinators. Each section is headed by focal persons who report to sub process coordinators. The laboratory has appointed quality manager and deputies. The laboratory has also appointed a safety officer and deputy.

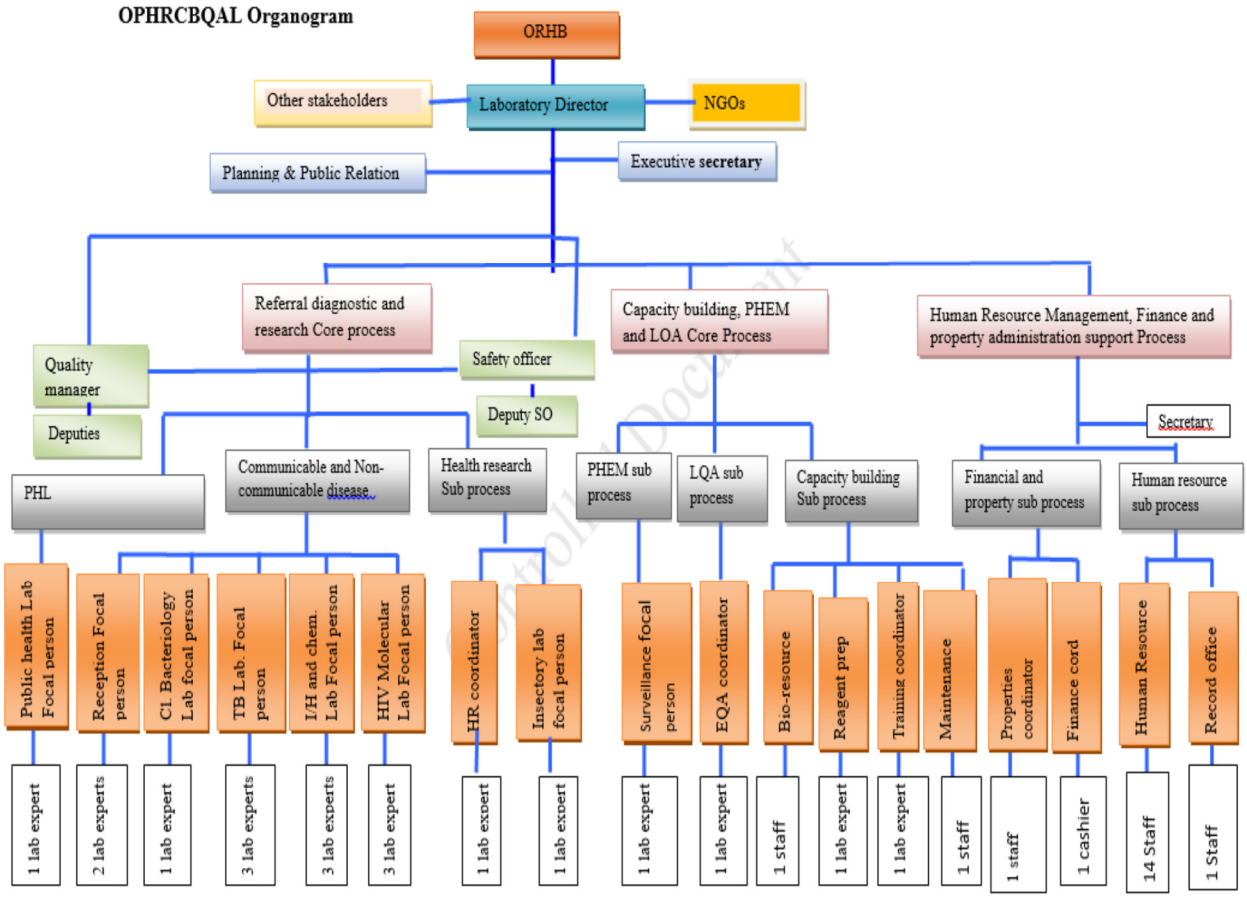


Figure 29. Organogram of Oromiya Public Health Research, Capacity Building and Quality Assurance Laboratory, Oromiya Ethiopia, 2017

Key: Solid line indicates that both chain of command and reporting

6.2 Activity report

TB Laboratory

TB laboratory is reference laboratory to Eastern Oromia health facilities and most health facilities of Afar region. TB laboratory is in the process of international accreditation program to be accredited by Ethiopian National Accreditation Organization (ENAO). The main activity of the laboratory is sputum specimen processing, capacity building (training), performing research and quality assurance of reagents prepared and distributed to other health facilities. Currently the laboratory has 4 laboratory staff, two microbiologists (MSc) and two laboratory technologists (BSc).

The laboratory activities can be categorized in to four parts: daily, weekly, monthly and as required activates. These are stated as follows

Daily activities

- Working Area cleaning
- Environmental monitoring including
    - Room temperature monitoring
    - Incubator temperature monitoring
    - Refrigerator temperature monitoring
    - Deep freezer temperature monitoring
- Daily preventive lab equipment maintenance
- Quality control
- Specimen processing
- Preparation of disinfectants
- Culture reading
- Reporting patient results
- Verification of results
- Registration of results

Weekly activities

- Culture reading
- Reagent preparation (eg. phosphate buffer)

- Weekly lab equipment preventive maintenance

Monthly activities

- Culture reading
- Monthly lab equipment preventive maintenance
- Complying laboratory reports

As required activities

These activities will be performed at any time if they are needed and may be limited by total activities of the laboratory. These activities are:

- Laboratory equipment maintenance (curative or preventive)
- Culture media preparation
- Quality assurance of ZN and FM reagents

Specimen processing

The sample required to diagnose TB is sputum. The volume may vary according to test principle generally 3 ml to 5ml of sputum needed to diagnose TB. In the laboratory TB can be diagnosed through genetic method (line probe assay and Gen-Expert), culture (liquid media or MGIT and solid media or LJ), and microscopic examination (ZN and FM). On the process identification of the bacteria, DST and genetic characteristics of the bacteria are performed. In the last 5 months a total of 656 Gene Xpert, 674 Liquid culture, 674 Solid culture, 66 Line probe assay and 1414 slides microscopically examined.

Total tests performed in the last 6 months by TB laboratory

Table 21. Testes performed in TB laboratory in OPHRCBQA laboratory from January to May 2017

Month	Gene Xpert	Liquid culture (MIGIT)	Solid culture (LJ)	Line prop assay	Microscopy
January	104	128	128	16	272
February	135	128	128	10	266

March	97	147	147	34	328
April	106	148	148	0	296
May	214	123	123	6	252
Total tests performed	656	674	674	66	1414

Table 22. Activities performed in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Month	Gene Xpert	Liquid culture (MGIT)	Solid culture (LJ)	Line prop assay	Microscopy
January	104	128	128	16	272
February	135	128	128	10	266
March	97	147	147	34	328
April	106	148	148	0	296
May	214	123	123	6	252
Total tests performed	656	674	674	66	1414

Bacteriology Laboratory

Bacteriology laboratory is a reference laboratory that can perform identification of bacteria and drug susceptibility test (DST). The laboratory has class II and class III biosafety level.

The laboratory activities can be categorized in to four parts: daily, weekly, monthly and as required activates. These are stated as follows

Daily activities

- Working Area cleaning

- Environmental monitoring including
    - Room temperature monitoring
    - Incubator temperature monitoring
    - Refrigerator temperature monitoring
    - Deep freezer temperature monitoring
- Daily preventive lab equipment maintenance
- Quality control
- Specimen processing
- Preparation of disinfectants
- Culture reading
- Reporting patient results
- Verification of results
- Registration of results

Weekly activities

- Weekly lab equipment preventive maintenance

Monthly activities

- Monthly lab equipment preventive maintenance
- Complying laboratory reports

As required activities

These activities will be performed at any time if they are needed and may be limited by total activities of the laboratory. These activities are:

- Laboratory equipment maintenance (curative or preventive)
- Culture media preparation

Specimen processing

The laboratory can process blood, stool, urine, ear swab, eye swab, vaginal discharge, cervical swab, CSF, sterile fluids, wound swab and through swab. In the last 5 months totally the laboratory processed 67 different samples. The list of total samples proceeded in each month and type of sample described in the tables below

Table 23. Total samples processed by culture in bacteriology laboratory January to May 2017 in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Month	Number of samples processes by culture
January	5
February	19
March	13
April	15
May	15
Total tests performed	**67**

Table 24. Type of samples processed by culture in bacteriology laboratory January to May 2017, in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Specimen type	Total specimen processed
Blood	2
CSF	6
Ear swab	11
Eye swab	1
Genital specimen	2
Sterile fluid	2
Stool	11
Urine	22
Wound	10
Total	**67**

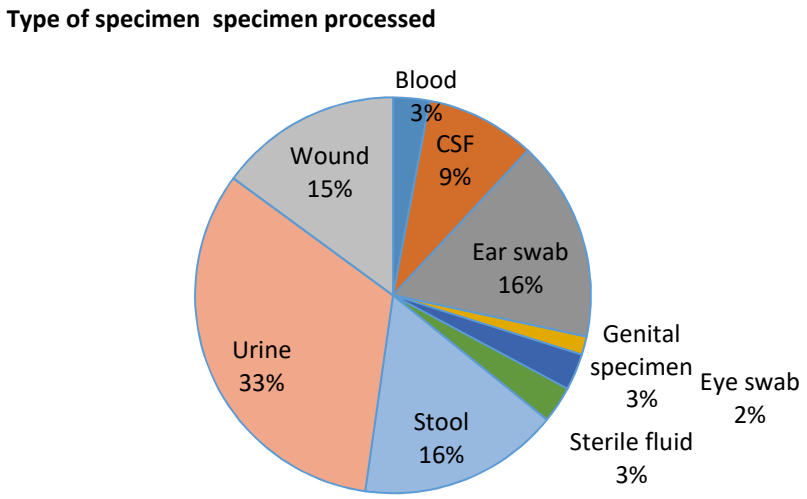


Figure 30. Type of specimen processed by Bacteriology Laboratory in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Table 25. Total culture media prepared in Microbiology department in the last 5 months in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Name of Media	Total media prepared
Blood agar	> 54
Chocolate	>22
Mac Konkey	>46
TCBS	>11
SS agar	
TSI	
Urea	
KIA	

Molecular Laboratory

In this laboratory ART monitoring and early infant diagnosis (EID) tests are performed. The laboratory has two isolated classes for Extraction and Amplification. In the extraction room, reagent preparation, sample preparation and extraction of viral genetic materials are performed. In the amplification room, amplification of viral genome and detection of viral genome are performed.

The laboratory activities can be categorized in to four parts: daily, weekly, monthly and as required activates. These are stated as follows

Daily activities

- Working Area cleaning
- Environmental monitoring including
    - Room temperature monitoring
    - Incubator temperature monitoring
    - Refrigerator temperature monitoring
    - Deep freezer temperature monitoring
- Daily preventive lab equipment maintenance
- Quality control
- Specimen processing
- Preparation of disinfectants
- Reporting patient results
- Verification of results
- Registration of results

Weekly activities

- Weekly lab equipment preventive maintenance

Monthly activities

- Monthly lab equipment preventive maintenance
- Complying laboratory reports

As required activities

These activities will be performed at any time if they are needed and may be limited by total activities of the laboratory. These activities are:

- Laboratory equipment maintenance (curative or preventive)

Specimen processing

Dried blood sample (DBS) and serum are samples needed for EID and Viral load (ART monitoring) respectively. In average, the laboratory can perform 186 samples per day.

Table 26. Activities of molecular lab in OPHRCBQA lab in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Month	DBS	Viral load
January	183	2,558
February	321	1,143
March	150	1,183
April	134	2,022
May	274	3,109
Total tests performed	**1062**	**10,015**

Quantiferon

In this section

The laboratory activities can be categorized in to four parts: daily, weekly, monthly and as required activates. These are stated as follows

Daily activities

- Working Area cleaning
- Environmental monitoring including

- Room temperature monitoring
- Incubator temperature monitoring
- Refrigerator temperature monitoring
- Deep freezer temperature monitoring

- Daily preventive lab equipment maintenance
- Specimen processing
- Preparation of disinfectants

Weekly activities

- ELISA test
- Test result reporting
- Result verification
- Registration of results
- Weekly lab equipment preventive maintenance

Monthly activities

- Monthly lab equipment preventive maintenance
- Complying laboratory reports

As required activities

These activities will be performed at any time if they are needed and may be limited by total activities of the laboratory. These activities are:

- Laboratory equipment maintenance (curative or preventive)

Specimen processing

Whole blood sample is sent to the laboratory separated to 4 test tubes than after overnight incubation plasma is separated to nunc tubes finally the plasma is ready to ELISA test. Every week ELISA is test performed.

Table 27. ELISA test performed in OPHRCBQA lab in the last five months of 2017, in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Month	Samples received	ELISA test
January	119	0
February	180	242
March	117	176
April	107	88
May	109	66
Total tests performed	**632**	**572**

Reagent preparation section

In this section reagents for TB diagnosis are prepared and distributed to hospitals and health centers. Every day one batch of ZN and FM reagents are prepared. ZN reagents are carbol fuchsin, acid alcohol and methylene blue. FM reagents prepared for FM are Auramine O, Acid alcohol and Potassium permanganate.

Daily activities

- Working Area cleaning
- Environmental monitoring including
    - Room temperature monitoring
    - Incubator temperature monitoring
    - Refrigerator temperature monitoring
    - Deep freezer temperature monitoring
- Daily preventive lab equipment maintenance
- Preparation of disinfectants
- Reagent quality control

Weekly activities

- Weekly lab equipment preventive maintenance

Monthly activities

- Monthly lab equipment preventive maintenance
- Complying laboratory reports

As required activities

These activities will be performed at any time if they are needed and may be limited by total activities of the laboratory. These activities are:

- Laboratory equipment maintenance (curative or preventive)

Table 28. Total reagents prepared in reagent preparation section of OPHRCBQA lab in the last five months of 2017, in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Month	FM reagents prepared in litter			FM reagents prepared in litter		
	Carbolfuchsin	Acid alcohol	Methylene blue	Auramine O	Acid alcohol	Potassium permanganate
January	60	60	60	-	-	-
February	40	40	40	-	-	-
March	100	100	100	-	-	-
April	100	100	100	40	40	40
May	60	60	60	80	40	40
Total Reagent prepared	**360**	**360**	**360**	**120**	**120**	**120**

Public health laboratory

Public health laboratory is class II laboratory that could perform water and food samples. Currently the laboratory only performs the bacteriological tests of water samples which sent from different factories to consumption of their employee, new constricted water pipes and from any public water sources.

The laboratory activities can be categorized in to four parts: daily, weekly, monthly and as required activates. These are stated as follows

Daily activities

- Working Area cleaning
- Environmental monitoring including
    - Room temperature monitoring
    - Incubator temperature monitoring
    - Refrigerator temperature monitoring
    - Deep freezer temperature monitoring
- Daily preventive lab equipment maintenance
- Quality control
- Specimen processing
- Preparation of disinfectants
- Culture reading
- Reporting patient results
- Verification of results
- Registration of results

Weekly activities

- Weekly lab equipment preventive maintenance

Monthly activities

- Monthly lab equipment preventive maintenance
- Complying laboratory reports

As required activities

These activities will be performed at any time if they are needed and may be limited by total activities of the laboratory. These activities are:

- Laboratory equipment maintenance (curative or preventive)
- Culture media preparation

Table 29. Total tests performed in public health laboratory, in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Specimen type	Total samples performed	
Water	37	
Food	115	Milk, research

Table 30. Culture Medias prepared in Public health laboratory, in OPHRCBQA laboratory, Oromiya, Ethiopia, 2017

Culture Media	Unit	Amount
MacKonkey broth	Litter	30
MacKonkey Agar	Plate	76
Membrane Lauryl Sulphate Broth	Litter	3
Brilliant Green Bile Broth	Litter	12
Nutrient Broth	Litter	7
Nutrient Agar	Plate	40

6.3 Gaps Identified/ Challenges

- Irregularities in implementing laboratory quality management system across the lab in similar was and consistently
- Inadequate of staff in each section and high workload in some section made us unable to share experience with them.

6.4 Recommendations

- Adhere to standards to achieve ISO accreditation all across the lab.

Employing skilled professionals especially in area where shortage is present.

CHAPTER VII

7. Time to viral load suppression and its associated factors in cohort of patients taking antiretroviral treatment in East Shewa Zone, Oromiya, Ethiopia, 2018

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Abstract

Background: Human immuno-deficiency virus (HIV) is a virus that causes Acquired Immuno-Deficiency Syndrome (AIDS). The key goal of ART is to achieve and maintain durable viral suppression. Thus, the most important use of the viral load is to monitor the effectiveness of therapy after initiation of ART. The main objective of the study was to determine the time for virological suppression and its associated factors among people living with HIV taking antiretroviral treatments in East Shewa zone, Oromiya, Ethiopia.

Methods: The study was conducted in East Shewa zone, Oromiya, Ethiopia from August 2017 to January 2018. Patients diagnosed with human immunodeficiency virus presenting to the study health centers between October 3, 2011 and March 1, 2013 were included in the study given the following criteria: age 18 years or greater, eligible to start ART. All patients with baseline viral load measurement were included in the study. Interaction between explanatory variables with the response variable was analyzed by using cross tab features of SPSS, IBM Inc. Significance group comparison was done by Kaplan Meier log rank test. Cox proportional hazard model was used to select significant factors to the variability between groups. Data was collected by using structured questionnaires and interview. A total of ETB 81,120.00 was utilized to carry out the study.

Result: plasma viral load was suppressed below detection level in 72% of individuals taking different regimen of ART. The median HIV-1 plasma viral load in the cohort was log 5.3111 copies/ml. Survival curve difference were observed in category of marital status (p-value 0.023) and baseline CD4 values (p-value 0.023) whereas no significant difference were observed in Educational status (p-value 0.404), MUAC (p- value 0.407) BMI(p-value 0.335) and BTB(p-value 0.257). Estimated median time to PVL suppression was 181days (CI: 140.5-221.4) with the age group of 30-39years having minimum time to achieve suppression with 92 days (CI:

60.1-123.8) and the maximum time required to reach the level was age group between 50-59 years.

Conclusion: Estimated time to achieve PVL after taking ART was found to be 181 days. Factors affecting time to suppression level was marital status and baseline CD_4.

7.1 Introduction

Background

Human immuno-deficiency virus (HIV) is a virus spread through different body fluids that attacks the body's immune system, specifically the CD4 cells, often called T cells (1). Acquired immunodeficiency syndrome (AIDS) is a chronic, potentially life-threatening condition caused by the human immunodeficiency virus (HIV) (2). Globally, Mycobacterium tuberculosis is the most common opportunistic infection in HIV-infected individuals (3).

The world has committed to end the AIDS epidemic by 2030 as part of the sustainable Development goals (4). Momentum is now building towards a new narrative on HIV treatment and a new, final, ambitious, but achievable target: By 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have viral suppression. When this three-part target is achieved, at least 73% of all people living with HIV worldwide will be virally suppressed – a two- to three-fold increase over current rough estimates of viral suppression. Modeling suggests that achieving these targets by 2020 will enable the world to end the AIDS epidemic by 2030, which in turn will generate profound health and economic benefits (5,6).

Viral load is a marker of response to ART. A patient's pre-ART viral load level and the magnitude of viral load decline after initiation of ART provide prognostic information about the probability of disease progression. The key goal of ART is to achieve and maintain durable viral suppression. Thus, the most important use of the viral load is to monitor the effectiveness of therapy after initiation of ART. Measurement of CD4 count is particularly useful before initiation of ART. The CD4 cell count provides information on the overall immune function of an HIV-infected patient. The measurement is critical in establishing thresholds for the initiation and discontinuation of opportunistic infection (OI) prophylaxis and in assessing the urgency to initiate ART (7).

Determinations of peripheral blood CD4+ T cell counts and measurements of the plasma levels of HIV RNA provide a powerful set of tools for determining prognosis and monitoring response

to therapy. The CD4+ T cell count is the laboratory test generally accepted as the best indicator of the immediate state of immunologic competence of the patient with HIV infection. Patients with CD4+ T cell counts <200/μL are at high risk of disease from P. jiroveci, while patients with CD4+ T cell counts <50/ μL are at high risk of disease from CMV, mycobacteria of the M. avium complex (MAC), and/or T. gondii. The measurement of serum or plasma levels of HIV RNA has become an essential component in the monitoring of patients with HIV infection. The most commonly used technique is the RT-PCR assay. This assay generates data in the form of number of copies of HIV RNA per milliliter of serum or plasma and can reliably detect as few as 40 copies of HIV RNA per milliliter of plasma. Measurements of plasma HIV RNA levels should be made at the time of HIV diagnosis and every 3–6 months thereafter in the untreated patient. Following the initiation of therapy or any change in therapy, plasma HIV RNA levels should be monitored approximately every 4 weeks until the effectiveness of the therapeutic regimen is determined by the development of a new steady-state level of HIV RNA. In most instances of effective antiretroviral therapy the plasma level of HIV RNA will drop to <50 copies/mL within 6 months of the initiation of treatment. During therapy, levels of HIV RNA should be monitored every 3–6 months to evaluate the continuing effectiveness of therapy. Weight loss and malnutrition continue to be common problems among HIV-infected patients in such settings, even in the era of ART (7).

Viral load is the most important indicator of initial and sustained response to ART and should be measured in all HIV-infected patients at entry into care, at initiation of therapy, and on a regular basis thereafter (7). Viral load (HIV-RNA copies/mL of blood plasma) as a surrogate marker for disease progression was first developed enrolling male patients and is currently considered highly predictive of the clinical course of infection (8). A number of laboratory tests are important for initial evaluation of HIV-infected patients upon entry into care, and before and after initiation or modification of antiretroviral therapy (ART) to assess the virologic and immunologic efficacy of ART and to monitor for laboratory abnormalities that may be associated with antiretroviral (ARV) drugs. Two surrogate markers are routinely used to monitor HIV-infected patients: CD4 T lymphocyte cell count to assess immune function and plasma HIV RNA (viral load) to assess level of HIV viremia. (7). Plasma viral load is the primary predictor of HIV-1 transmission (9).

Center for Disease Control and prevention guidelines recommend that PVL and CD4 cell count be monitored at baseline, at four weeks after starting antiretroviral therapy and every three months thereafter (10).

Viral load monitoring is the gold standard practice in resource-rich countries for detecting treatment failure among people receiving ART. The 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommend viral load testing as the preferred monitoring tool for diagnosing and confirming the failure of antiretroviral therapy. It recommend viral load testing six months after initiating ART and then annually for people receiving ART. Using plasma specimens for viral load testing is the preferred monitoring approach to determine viral failure at the threshold of 1000 copies/ml among people living with HIV (11).

Current WHO guidelines recommend antiretroviral therapy (ART) initiation in everyone living with HIV at any CD4 cell count (12). Because the quantity of HIV-1 in plasma is the primary predictor of HIV-1 transmission, consideration of plasma viral load in ART initiation guidelines is warranted (9).

Theoretical models and subsequent empiric data demonstrated that complete (or near complete) suppression of HIV replication is generally achieved with regimens containing three potent antiretroviral drugs and near perfect adherence. These regimen consisting of two nucleoside/nucleotide analogues plus either (1) a non-nucleoside reverse transcriptase inhibitor [NNRTI], or (2) a protease inhibitor boosted with ≤400mg/day ritonavir [boosted PI], or (3) a single protease inhibitor [non-boosted PI] (10). ART has dramatically reduced HIV-associated morbidity and mortality and has transformed HIV infection into a manageable chronic condition. It is highly effective at preventing HIV transmission (7). The primary clinical goal of ART is to inhibit viral replication and suppress plasma viral load (PVL) to undetectable levels. Studies have revealed that while a substantial proportion of individuals are able to achieve viral suppression with ART, at least one in ten patients will experience at least one episode of viral rebound (13).

Levels of virus vary greatly in most untreated patients, ranging from several thousand to a few million copies of HIV RNA per milliliter of plasma. Patients in whom viral plasma level is

suppressed to below detection by cART, (*combination antiretroviral therapy*), there is a continual low level of virus replication. Treatment with reverse transcriptase and protease inhibitors to HIV infected individuals resulted in a precipitous decline in the level of plasma viremia, which typically fell by well over 90% within 2 weeks. The number of CD4+ T cells in the blood also increased concurrently (3).

Earlier studies have shown that the total lymphocyte count (TLC), haemoglobin (HGB), body mass index (BMI), body weight and other simple laboratory and clinical markers predict mortality in HIV infected patients and thus can be used to identify patients at risk of dying (14).

The monitoring of ARV therapy using VL and genotypic resistance testing is essential to determining cases of treatment failure ; the quantification of VL serves as an indicator for whether ARV therapy leads to success or failure in HIV infected patients . To limit the emergence of resistance to ARV drugs, patients undergoing treatment for HIV should ideally undergo periodic virological monitoring, such as VL and genotypic resistance testing, to identify cases in which therapy has failed and to avoid the accumulation of drug resistance mutations(15).

Statement of the problem

According to UNAIDS 2016 report, 36.7 million people globally were living with HIV. 2.1 million people became newly infected with HIV, 1.1 million people died from AIDS-related illnesses , 78 million people have become infected with HIV since the start of the epidemic , 35 million people have died from AIDS-related illnesses since the start of the epidemic and 18.2 million people were accessing antiretroviral therapy the end of 2015. Sub-Saharan Africa remains most severely affected, with nearly 1 in every 25 adults (4.4%) living with HIV and accounting for nearly 70% of the people living with HIV worldwide. According to the 2016 HIV estimates, the national HIV prevalence in Ethiopia is 1.18 %, indicating the country has more than achieved the Millennium Development Goal 6 target of 2.5% (16).

Limited data are available on HIV viral suppression rates among men and women on antiretroviral therapy (ART) and factors associated with HIV RNA viral load (VL) suppression in Ethiopia(17). Studies identified different associated factors for viral suppression. Factors includes Non-ART use, younger age, and lack of awareness of HIV status (18), not receiving a single-tablet daily regimen, and immunological failure (17).

Significance of the study

The key goal of ART is to achieve and maintain durable viral suppression. Suppression of viral load leads to improvement of quality of life and reduction of HIV related morbidity and mortality. This study determined the duration at which the PVL becomes suppressed in a study of cohort of HIV patients. The degree of suppression of the PVL count indicates the predisposition to opportunistic infections and hence shorter-term risks of morbidity and progression to AIDS. The benefit of predicting the time of suppression in HIV patients was to determine the success of ART treatment, to determine the best possible time to shift ART regimens in case of toxicity and to suspect the possibility of drug resistance in patient taking ART drugs and to determine resistance of virus to drugs the patient is currently taking. Similar study was not done in East shoa zone, Oromiya, Ethiopia. The study will help ministry of health in making treatment formulation of treatment of OI in patients on ART in this study setting. It also is useful for patients who are taking ART to have an opportunity to shift in treatment regime and avoid unnecessary drug toxicity.

7.2 Literature Review

Decreases in viral load following initiation of ART are associated with reduced risk of progression to AIDS or death. Thus, viral load testing is an established surrogate marker for treatment response. The minimal change in viral load considered to be statistically significant (2 standard deviations) is a three-fold change (equivalent to a 0.5 log10 copies/mL change). A study conducted in the United States shows that Fewer than one-third of HIV-infected individuals have suppressed viral loads, mostly resulting from undiagnosed HIV infection and failure to link or retain diagnosed patients in care (7).

After initiation of effective ART, viral load reduction to below limits of assay detection usually occurs within the first 12 to 24 weeks of therapy. Predictors of virologic success include: low baseline viremia, high potency of the ARV regimen, tolerability of the regimen, convenience of the regimen, excellent adherence to the regimen (7).

There was no evidence of association between undetectable final viral load and change of antiretroviral regimen. The analysis of the number of drugs per regimen revealed that 26% of the patients who received a double regimen had an undetectable final viral load; this percentage was 50% for patients treated with triple and quadruple regimens. patients treated with double regimen had odds of reaching an undetectable final viral load 67% lower than those receiving a triple regimen (19). In a study done in Brazil, among the patients retained in HIV care, 62% have suppressed virus (13). Of 139 HIV/AIDS patients exposed to the highly active antiretroviral therapy, virological failure was 12.2% (20).

The median HIV-1 viral loads of ART-untreated females and males were 42,200 copies/ml (8).

The percentage of subjects who achieved virological suppression to <500 copies/mL differed by antiretroviral status. At 16 weeks, 93% of the antiretroviral-naive subjects with available data had achieved virological suppression, compared with 44% of antiretroviral-experienced subjects (21).

Antiretroviral treatment led to a mean reduction of 1.8 $\log_{10}$ copies per ml with HAART, 1.2 $\log_{10}$ copies per ml with RTI(reverse transcriptase inhibitor) combination therapy, and 0.4 $\log_{10}$ copies per ml with monotherapy. The proportion of patients reaching undetectable viremia was 12% percent for monotherapy, 41% for RTI combination therapy, and 63% for HAART. The

percentage of participants reaching undetectable viremia (<400 HIV RNA copies per milliliter) during the observation period was higher for those undergoing HAART than those undergoing RTI monotherapy or combination therapy. Similarly, the proportion of participants with CD4 cell counts below 0.20x 10^9/L (200/µL) decreased more for those undergoing HAART (22).

Women with viral loads of <10,000 HIV-1 copies/mL and a CD4 T cell count >350 cells/mm3, having treatment with nelfinavir and a gestational age of >20 weeks at initiation of HAART showed a significantly shorter time to a VL of <50 copies/ml (23).

In a study conducted , 21% individuals experienced viral rebound. Median time of suppression before rebound was 2 years. the probability of virologic failure was 0.85 after being suppressed for 12 months and it was 0.08 after 72 months being suppressed (p-value <0.01) (44).

Among low- and middle-income countries, Brazil, the Laos People's Democratic Republic, Malaysia, Mexico, Myanmar and the Republic of Moldova have achieved viral suppression for more than 80% of people receiving antiretroviral therapy (4).

Overall, 61.2% (95% CI: 56.4–66.1) of HIV-infected Kenyans aged 15–64 years had not achieved virological suppression. The base 10 median and mean VL was 4,633 copies/mL and 81,750 copies/mL respectively. Among 266 persons taking ART, 26.1% (95% CI: 20.0–32.1) had detectable viremia. Non-ART use, younger age, and lack of awareness of HIV status were independently associated with significantly higher odds of detectable viral load. persons aged 15–29 years had a significantly higher percentage of detectable viremia at 79.4% (95% CI: 72.4–86.5) than persons aged 30–64 years at 53.9% (95% CI: 48.4–59.5) (p<0.0001) (18). Among 266 persons who were currently taking ART, significant differences in the proportion of detectable viremia across age groups were observed: 22.3% among persons aged 30–64 years compared with 46.5% among persons aged 15–29 years (p<0.0001)(18). Patients betw een 16 and 24 years of age had odds of undetectable final viral loads 63% lower than those of age 45 or higher, but the statistical evidence was weak after adjustment for sex, viral load prior to adherence measurement, clinical stage, current immune status, duration of treatment, group of drugs, adherence and interval between two measurements of viral loads (OR=0.36; CI 95% 0.12-1.09). There was no evidence of a difference in odds ratio of undetectable final viral loads for sex, clinical stage, current immune status and change of therapeutic regimens (19).

Regarding sex, in the ART-untreated group, females had consistently lower mean viral load than males for all groups >18 years old, although these differences were not statistically significant. For patients under ART, no sex-related differences were found except for those >55 years old where females had significantly lower mean viral loads. Female patients >55 years old showed statistically significant lower viral loads with respect to younger women. In addition, data from 31 pediatric patients (<11 years old) under ART were available for comparisons between sexes. It was observed a marked tendency to higher viral loads in girls than boys (median difference of 1.71 log10 copies/mL), although it was not statistically significant (8).

HIV load was highest in subjects (25–29 years old) with incident HIV infection but increased with age in subjects with prevalent HIV infection (24). Older age was associated with lower levels of HIV-1 replication in this sample, independent of antiretroviral therapy usage, regimen adherence, and disease stage (25).

The mean of CD4+ T cells was significantly lower in old age compared to younger (107 ± 109 cell/mm3 vs. 178 ± 189 cell/mm3; $p < 0.01$), such as the mean CD4 percentage (9% vs. 14%; $p < 0.01$). The mean of CD8+ T cells at baseline was similar in old age and younger (757 ± 380 cell/mm3 vs. 818 ± 362) (p = ns). (26).

There were no significant differences found in the percentage of persons with detectable viremia by sex, marital status, widowhood, educational level, residence, region, and wealth index. Men and women who were taking ART had similar proportions of detectable viremia at 24.1% vs. 27.2%, respectively (18). The median age was 34.5 years and the median time on ART was 46 months. HIV viral suppression below 1000 copies/mL was 93%. Viral suppression among woman was not significantly different than among men (93.7% vs 92.9%; P=0.59) (17). Higher prevalence of undetectable viral load and lower levels of viral load have been associated with age above 45, female sex, CD4 counts higher than 200 cells/mm3, and lower levels of viral load at the beginning of treatment. Female patients, duration of treatment less than 6 months and CD4 cell counts of 200 cells/mm3 or higher gave a higher prevalence of undetectable final viral load (19).

Several reports have indicated that the HIV-1 viral load of infected individuals is lower in females than in males among the antiretroviral-untreated group, females had a significantly

lower viral load than males (0.52 female/male median viral load ratio). When classified according to different ranges of CD4+T cell counts, females had consistently lower viral loads than males, although statistical significance was achieved only for the group in the range of 201-350. Patients with the lowest CD4 + T-cell counts showed similar viral loads for both sexes (8).

When classified according to CD4+ T-cell count ranges, females showed a consistent tendency to lower viral loads than males, although a statistically significant difference between sexes was found only for the group within 201-350 cells/ml. Within this group the median viral load in males was 4-fold that observed in females (8).

Some study suggested the HIV load did not differ by sex, but, among subjects with prevalent HIV infection, it was higher in males than in females (24). Association was not observed in the effect of sex, clinical status, current immune status, and changes in treatment regimen (19).

HIV loads were found to be higher in men than in women, and concurrent infections with herpes simplex virus type 2 (HSV-2), tuberculosis, malaria, and helminthes have been associated with increased HIV. A high proportion (63.7%) of sero-conversions occurred in younger persons (15–29 years old), and the majority (54.7%) of subjects who seroconverted were female. When blood samples were obtained ~5 months after infection, the mean HIV load was 4.38 log10 copies/ mL (median, 4.48 log10 copies/mL) and was slightly higher in males than in females, but this difference was not statistically significant. Sixty-nine percent of females who seroconverted were >30 years old, compared with 56.9% of males (24).

Of the 1571 participants, 740 (47.1%) were women. Women had higher mean screening CD4 cell counts (average 15 cells higher, ($p<0.001$), lower mean hemoglobin and creatinine clearance, a lower mean baseline HIV-1 viral load (4.85 log10 vs. 5.05 log10 copies/mL ($P<0.001$)) and were less likely to have a prior AIDS diagnosis than men. The sex difference in viral load difference was related to CD4 cell count, however it was independent of country and persisted within the strata with CD4 < 200 cells/mm3. Women in resource limited settings have lower levels of plasma HIV-1 RNA and appear to present for enrollment into a clinical trials at an earlier stage of disease than men (28). The unadjusted mean HIV-1 RNA level was 5.05 log10 copies/mL in men compared to 4.85 log10 copies/mL in women ($p<0.001$) (28).

Viral suppression among women (93.7%) was no different from among men (92.9%). The proportion of women and men who were married was not significantly different. Lower BMI, MUAC, and Hgb concentrations at ART initiation were strongly associated with a higher risk of death within 3 months. Among patients who survived 3 months after ART initiation, those with a decrease in weight, MUAC, or Hgb concentrations by 3 months had a higher risk of death during the first year. After 1 year, only a decrease in MUAC by 3 months after ART initiation was associated with a higher risk of death. Weight loss was associated with a higher risk of death across all levels of baseline BMI, with the highest risk observed among patients with BMI ,17 kg/m2 (relative risk, 7.9; 95% confidence interval, 4.4–14.4) (29).

Patients with lower BMI, MUAC, or Hgb concentrations when they started ART were at a significantly higher risk of early mortality. Patients with a baseline MUAC of 20.0 cm had a 4.2-fold higher risk of early mortality compared with those with a baseline MUAC of >27 cm (95% CI, 3.3–5.2). The association between baseline MUAC and early mortality was attenuated, but remained statistically significant after further adjusting for baseline BMI (relative risk, 3.5; 95% CI, 2.6–4.7; MUAC ,20 vs >27 cm). Increased mortality was noted with weight loss, MUAC decreases, and Hgb decreases after 3 months of ART (29).

The median CD4 cell count at the start of ART was 105 cells ⁄mm3 and increased significantly over 5 years of follow-up (30). The median baseline CD4 cell count for the entire cohort was 192cells/µl. Adjusted for CD4, MUAC and BMI, the HR for ART became 0.66 (0.42 to 1.03) (31). CD4+ cell count measured at last visit preceding HAART initiation (within 12 months prior) was fit both as a continuous variable and categorized (as <200 cells/mm3, 200–350, or >350); and nadir CD4+ cell count (defined as the lowest CD4+ cell count measured at any visit prior to HAART) (12). Median baseline CD4 count was 136 cells/mm3 (IQR 39–247), and was not significantly different between those with viral suppression (140 cells/mm3) and those with HIV viral load above 1000 copies/mL (112 cells/mm3) (P=0.19). Mean change in CD4 cell count while on ART was an increase of 304 cells/mm3, while 5.6% of those with both current and baseline CD4 tests available had a fall in CD4 cell count below baseline while on ART, meeting the definition for immunological treatment failure. Clinical treatment failure was experienced by 7.2% within the previous 12 months, but only 41 (3.3%) were WHO clinical stage III or IV at the time of the interview (17). Patients with initial CD4+ T cell count # 200 cells/mm3 had a

tendency to virologic failure; however, there was not any statistical significance. Studies conducted by Skowron et al demonstrated that T CD4+ cell count is a better predictor of viral suppression. However, in order to achieve viral load suppression to undetectable levels, it is necessary to have an optimal response of T CD4+ cell count in patients under antiretroviral therapy (20). A statistically significant negative correlation between viral load and CD4 + T-cell count was found in the ART-untreated group (8). CD4 count, haemoglobin, BMI, sex and clinical stage at enrolment were independent predictors of mortality (30).

Of 1428 continuous HAART users 39 (2.7%) were underweight, 521 (36.5%) normal weight, 441 (30.9%) overweight, and 427 (29.9%) obese at time of HAART initiation. being overweight or obese (vs. normal weight) was not independently associated with increased viral load level. Cumulative incidence of non-AIDS death was similar across all pre-HAART BMI categories. A report from the Women's Interagency HIV Study indicated that being overweight, obese, or morbidly obese was independently associated with higher CD4+ count, total lymphocyte count, and WBC counts compared to those of normal body mass index (BMI) (18.5–24.9 kg/m^2) obesity (BMI $\geq$ 40 kg/m^2) was associated with higher CD8+ counts. Studies of mortality risk conducted among HIV-infected populations even earlier in the HIV epidemic suggested protective associations of overweight against mortality (12).

Compared with patients with a baseline BMI between 18.5 and 22.9 kg/m2, those with a BMI between 16.0 and 16.9 kg/m2 had a 2.1-fold increased risk of early mortality (95% confidence interval, 1.7–2.5), and those with a BMI ,16.0 kg/m2 had a 2.3-fold increased risk (95% CI, 2.0–2.7). In comparison, risk were 20% or 30%lower, respectively, in patients with a BMI between 23.0 and ,25.0 kg/m2 (95% CI, .6–1.1) or between 25.0 and ,30.0 kg/m2 (95% CI, .5–1.0). However, obesity (BMI, <30 kg/m2) at ART initiation was not associated with either a reduced or an increased risk of early mortality (29). Low body mass index (BMI≤18.5 kg/m2), low mid-upper-arm-circumference (MUAC≤250 mm), low CD4 cell count (≤350 cells/µl) were independent predictors of death (31). Median BMI at inclusion was 19.7 kg/m2 (IQR 17.4–22.4, n=1057) and 256 mm (IQR 232–286, n=1064) for MUAC (31).

Significantly greater median increases in body weight (2.1 vs. 0.5 kg; p.045) occurred in subjects who achieved virological suppression (HIV-1 RNA load, <500 copies/mL) at week 16 than in subjects who did not (21).

Low body mass in adults (body mass index less than 18.5kg/m2), weight loss and wasting in children are all independent risk factors for HIV disease progression and mortality (32).

Body mass index (BMI) <= 18.5 kg/m2 at baseline was associated with death in univariate analysis. Weight loss was seen in about a third of patients who survived up to the fourth week, and it was associated with increased death. Decline in TLC, HGB and BMI was associated with death in univariate analysis only (14).

Moderate to severe malnutrition was present in 16% of patients at the time of starting ART. It was found to be a significant independent predictor of death (hazard ratio (HR) 2.19, 95% confidence interval (CI) 1.29–3.73, P<0.004 for those with BMI <17 compared with those with BMI 418.5). Also Stage of disease (HR 2.47, 95% CI 1.20–5.07, P<0.014 for those who were at stage C compared with those at stage A and the type of ART HR 0.50, 95% CI 0.27–0.93, P<0.03 for highly active antiretroviral therapy (HAART) compared with non-HAART treatment. Malnutrition did not impair the magnitude of the increase in CD4 count at 6 or 12 months (14).

Tuberculosis co-infection was associated with virologic failure demonstrated with statistical significance, P = 0.019. Patients with a previous diagnosis of tuberculosis infection had 2.9 times great risk of virologic failure. In the logistic regresion analysis the best model to explain the event of virological failure is the one that includes variables such as origin and infection by M. tuberculosis, yielding OR values of 3.2 and 3.8 respectively (20).

concurrent infections with herpes simplex virus type 2, tuberculosis, malaria, and helminthes have been associated with increased HIV viral load (24).

In bivariate analysis, younger age-group, lack of awareness of infection, no TB co-infection, not currently in HIV care, no current ART use, time in HIV care, lack of condom use at last sexual intercourse, and inconsistent condom use were significant predictors of detectable viral load at a p-value <0.1 and were included in multivariable analysis. In multivariate analysis, non-ART use, younger age, and lack of awareness of HIV infection were associated with significantly higher odds of detectable VL. Persons who were not currently taking ART had almost 12 times as high adjusted odds ratio (AOR) of having detectable VL as those who were currently taking ART (AOR 11.8, [95% CI:6.3–22.2]). Compared to persons aged 30–64 years, infected persons aged 15–29 years had more than three times the adjusted odds (AOR 3.3, [95% CI:2.1–5.3]), and

persons unaware of their infection had more than twice the adjusted odds of having detectable VL (AOR 2.2, [95% CI: 1.1–4.4]) (18).

unsuppressed HIV VL was independently associated with lower CD4 cell count, social isolation, high stigma, not receiving a single-tablet daily regimen, multiple late appointments in past year, and immunological failure (17).

The median time to undetectable VL after initiation of treatment was 60 days (12–168 days). Only baseline VL <10,000 copies/mL showed an independent association with time to viral suppression with a mean time to reach a VL <50 HIV-1 copies/mL of 49 days (95% CI 44–53). No difference in time to undetectable VL was found between protease inhibitor and non-nucleoside reverse transcriptase inhibitor-based regimens. Integrase inhibitors were not part of any treatment regimen. A multivariable Cox proportional hazards analysis using the above mentioned variables showed an independent association only of baseline VL <10,000 copies/Ml with a shorter time to viral suppression (23).

Undetectable final viral load occurred in 48% of the patients. The crude odds were lower for age 16-24 years and use of Nucleoside Analog Reverse Transcriptase Inhibitors only, but these effects were not significant in the multivariate model. There was no evidence of effect of sex, clinical status, current immune status, and changes in treatment regimen. Treatment adherence gave the largest effect. Motivational interventions directed at adherence may improve treatment effectiveness. (19).The first 4 to 6 weeks of treatment are marked by a trend of reduction in viremia of at least 1.0 log10, which represents 90% of the initial viremia and, in the next 12 to 24 weeks the viremia is expected to be undetectable or 99% lower than its initial level or from 5,000-10,000 copies/ml (19).

Patients who had a VL taken at month 3 versus at month 6 were 22% less likely to experience virological failure and 27% less likely to be switched to a second line regimen. For each additional month of delay in taking the first viral load (between 2.5 and 9 months) the risk of virological failure increased by 9% and the risk of treatment switching increased by 14% (33).

In one study the 277 participants contributed 995 person-years of follow-up with a median follow-up time of 32 months (IQR: 6 – 64) per participant. One hundred twenty-five participants

(45.1%) experienced at least one instance of viral rebound over follow-up, equal to a crude incidence of 12.6% (95% CI: 10.5–15.0) (13).

For incident HIV infection, the mean time from seroconversion to measurement of HIV load was 5 months, assuming a uniform distribution of seroconversions during the 10-month follow-up intervals (24).

Of the 1305 individuals who achieved an initial virologic response, 274 (21%) subsequently experienced viral rebound. The median time of suppression before rebound in these 274 individuals was 2.0 years (10).

7.3 Objective

General Objective

To determine the time to virological suppression and its associated factors among people living with HIV taking antiretroviral treatments in East shewa zone, Oromiya, Ethiopia, 2017.

Specific Objective

- To describe the distribution of time to PVL suppresion of HIV patients
- To determine factors affecting the time at which HIV-1 viral load level becomes suppressed below detection level
- To provide recommendation based on findings to ministry of health

7.4 Methods and Materials

Study area

The study was conducted in East Shewa zone, Oromiya region, Ethiopia. The study area covers population of approximately 600,000 residents. Location of the study includes Adama and Geda health centers from Adama town and Dhera, Wolenchiti and Modjo health centers from area surrounding Adama town in East shewa zone (1).

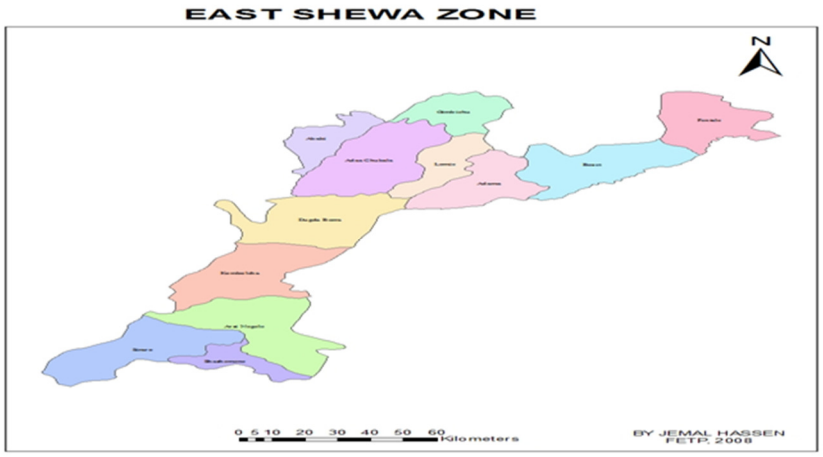


Figure 31. Administrative map of East Shewa zone, Oromiya, Ethiopia, 2017

East Shewa is one of the Zones of the Ethiopian Region of Oromia. This zone is bordered on the south by the West Arsi Zone, on the southwest by the Southern Nations, Nationalities and Peoples Region, on the west by South west Shewa and Oromia Special Zone. It Surrounds Addis Ababa, on the northwest by Gelan town, on the north by the Amhara Region, on the northeast by the Afar Region, and on the southeast by Arsi(Assela). The number of health facility in the zone includes 4 Hospitals, 59 health centers and 291 health posts. In terms of coverage, the zone has 100% coverage in Hospital, health center and health post. ART site in the zone includes 4 hospitals and 12 health centers. The number of people currently taking ART in East shewa zone is 5021 (34).

Study design and period: Retrospective cohort study was conducted from August 1, 2017 to January 30, 2018 on secondary data.

Source population: The source population were all people with confirmed HIV positive status in East Shewa Zone, Oromiya region Ethiopia.

Study population: Patients who have started ART since inclusion constitute the study population for the current study, with follow-up data collected until data abstraction on December 31, 2013.

Sample size determination and sampling

The number of study participants were 243 with base line viral load measurement value included in the study.

Study variables

Response variable: Time of viral load level to PVL suppression , PVL(<40 copies/ml)

explanatory variables: Base line Plasma Viral Load(BPVL), PVL at base line, 3rd month, 6th month, 12th month and 18th month, Age, sex, marital status, occupation, educational level, height, weight, Mid Upper Arm Circumference(MUAC), baseline CD_4(BCD_4) and baseline Tuberculosis(BTB).

Data collection tools & procedures

The study used secondary data from a long-running community-recruited prospective cohort of patients of HIV. Demographic and clinical data, including physical examination details, were collected at the start of the study by using structured questionnaires. Data was collected by structured and pretested questionnaire. Interview was also used to collect data from patients. After informed consent, data was collected and checked for completeness.

Eligibility criteria

Human immunodeficiency virus(HIV)-positive patients presenting to the study health centers between October 3, 2011 and March 1, 2013 were eligible for inclusion given the following criteria met: age 18 years or greater and residency in the catchment area of any of the study sites. Patients with current or previous ART, as well as patients on ATT for more than 2 weeks before inclusion, were excluded. This cohort has since been continuously followed. Patients who have started ART since inclusion constitute the study population for the current study, with follow-up data collected until data abstraction on December 31, 2013.

Exclusion criteria: age less than 18 years old, with current or previous ART, as well as patients on ATT for more than 2 weeks before inclusion, were excluded.

Operational definitions

Baseline VL: - the last known VL before HAART initiation.

Viral suppression: refers to a viral load below the detection threshold using viral assays.

Treatment failure: the current WHO virological criterion for treatment failure is when there are 1000 copies of virus per ml or more.

Viral rebound: the first of at least 2 consecutive viral loads >400 copies/ mL following initial viral suppression.

Duration of suppression at any month was defined as the number of prior consecutive months of viral suppression.

Virologic failure: as a confirmed viral load >200 copies/mL—a threshold that eliminates most cases of apparent viremia caused by viral load blips or assay variability.

Clinical failure:- any WHO stage III or IV illness in the past 12 months.

Immunological failure: current CD4 cell count less than CD4 cell count at time of ART initiation.

Data Quality: Training was given for two data clerks on data management of secondary data obtained from previous study. Pretest of data collection tools was done before actual data collection procedure. Double entry of data made by using EPIINFO 7 to minimize error in data management and will be analyzed by SPSS version 21.

Data Analysis

Once data is collected, it was analyzed **descriptively** to determine the demographic characteristics and distribution of time to PVL. Time to undetectable viral load level was calculated by using **Kaplan–Meier** to estimate the distribution of PVL in time, and differences between the survival curves was evaluated with the use of the **log-rank test,** which is useful for comparing potentially unequal follow up times of study participants. **Cox proportional-hazards**

regression analysis used to relate covariates with response variable with 95% confidence intervals.

Ethical considerations

Ethical approval was obtained from Saint Paul's Hospital Millennium Medical college public health department ethical review committee. Then the approval letter was forwarded to Oromiya regional health beauro. Finally, the approval letter from regional health bureau submitted to Adama regional laboratory where the actual study was done. Study participants provided written informed consent. Informed consent were received from illiterate study participants in the previous study (35).

7.5 Result

Laboratory analysis

All laboratory analyses, except TB cultures, were performed at Adama Regional Laboratory. CD4 cell counts were analyzed using BD FACSCalibur cytometer (Becton Dickinson, San Jose, CA). Sputum and FNA samples were analyzed with direct smear microscopy using Ziehl-Neelsen staining and Xpert MTB/RIF (Cepheid, Sunnyvale, CA) for polymerase chain reaction. Liquid cultures for TB were performed at International Clinical Laboratories, Addis Ababa, using a BACTEC MGIT 960 (BD Diagnostics, Franklin Lakes, NJ). Plasma HIV-RNA levels were determined using Abbott Real- Time HIV-1 assay (Abbott Molecular Inc., Des Plaines, IL) with a detection limit of 40 copies/ml. External quality assurance of the regional laboratory is regularly performed by the Center for Disease Control and Prevention (Atlanta, GA).

Study participant Characteristics

Study participants were recruited from Adama , Dhera, Geda, Modjo and Wolenchiti health centers taking ART and selected according to eligibility criteria. The minimum age included in the study was 18 years and the maximum age was 69 years old. The mean, median and mode of participant age was 34, 32 and 30 years of age respectively. Forty five percent of the participants age was between 20-29 years old and minimum category was observed in <20 years old with 1.6 percent. Sex distribution of the study participant was 41% male and 59% female participants. most of the study participants (41%) was married but widowed participant represent only 10 % of the participant. With regard to baseline viral load in which the measurement was taken when the study participants enrolled in to the study, 13% of them were with plasma viral load less than 10,000 copies/µl. plasma viral load was suppressed in 72% of individuals taking different regimen of ART treatment. The median HIV-1 plasma viral load in the untreated cohort was log 5.3111 copies/ml. Nine percent of participant complete higher education while 36% of them were illiterate. Study participants nutritional status was also assessed by the study. Six participants (2.46%) were classified as having acute malnutrition while 71(29.2%) Participants classified as having moderate malnutrition and the rest166 (68.3%) were classified as normal. Baseline CD_4 count was determined at the beginning of the study. Based on the data 140(57.6%)of the participants have BCD_4 count of <200 cells/µl, 77(31.7%) have BCD4 count 200-350 cells/µl and 26(10.7%) have BCD4 count of >350 cells/µl. Tuberculosis disease screened among

participants before enrollment and 189(77.8%) were positive for MTB by AFB light microscopy smearing and culture (MGIT and LJ). Viral rebound was seen in 16.5% of study participant. The Proportion of patients having PVL suppressed after taking ART was 72.4%. study participant contributed 94 person-year of follow up. Incident rate of plasma viral load suppression was 21.8%.

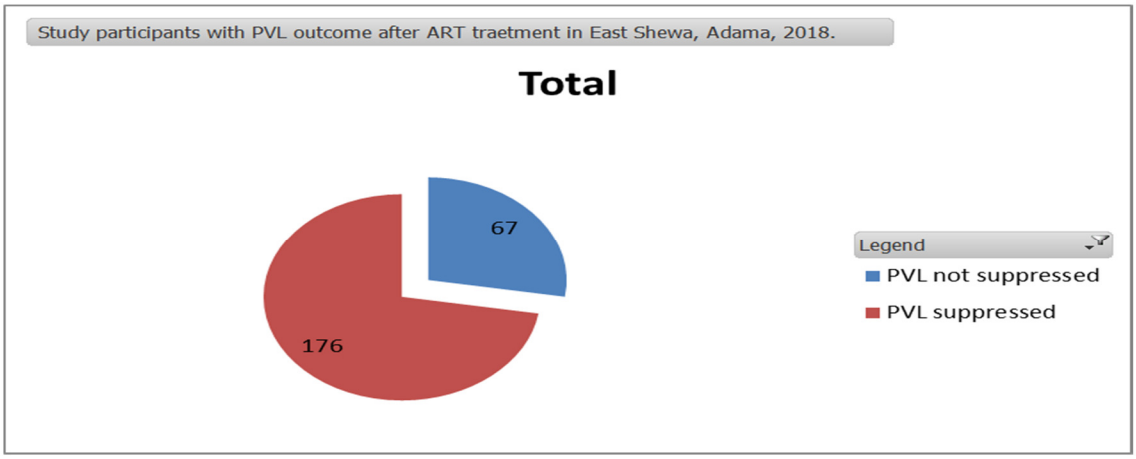


Figure 32. Proportion of HIV patients taking ART with PVL suppression level, East Shewa Zone, Oromiya , Ethiopia, 2018

Majority of the study participant age group was between 20-29 years old and age group <20 years old included in the study was only 1.6%. Female participants accounts for almost 60% of the study participant.

Table 31. Socio-demographic description of study participants, East Shewa Zone, Oromiya , Ethiopia, 2018

Variables		**Number(percent)**
Age	<20 years	4(1.6)
	20-29 years	109(44.9)
	30-39 years	91(37.4)
	40-49 years	29(11.9)

	50-59 years	7(2.9)
	≥60 years	3(1.2)
sex	Male	99(40.7)
	female	144(59.3)
residency	Adama	68(28)
	Dhera	19(7.8)
	Geda	32(13.2)
	Modjo	70(28.8)
	Wolenchiti	54(22.2)
Marital status	Single	56(23.0)
	Married	112(46.1)
	Divorse	50(20.6)
	Widowed	25(10.3)
BPVL	<10,000 copies/µl	31(13)
	≥10,000 copies/ µl	212(87)
Event occurred	Yes	176(72.4)
	No	67(27.6)
Education status	Illiterate	88(36.2)
	<6 grade	65(26.7)
	06-12 grade	81(33.3)

	Higher education	9(3.7)
BMI	<18.5 Kg/m^2	85(34.97)
	≥18.5-24.9 Kg/m^2	146(60.08)
	25-29.9 Kg/m^2	11(4.52)
	>30 Kg/m^2	1(0.41)
MUAC	<18 cm	6(2.46)
	18-21 cm	71(29.2)
	>21 cm	166(68.3)
BCD_4	<200 cells/µl	140(57.6)
	200-350 cells/µl	77(31.7)
	>350 cells/µl	26(10.7)
BTB	Positive	189(77.8)
	Negative	54(22.2)
Treatment regimen	d4T, 3TC, NVP	1(0.4)
	d4t, 3TC, EFV	5(2.1)
	AZT, 3TC, NVP	13(5.3)
	AZT, 3TC, EFV	13(5.3)
	TDF, 3TC, NVP	17(7.0)
	TDF, 3TC, EFV	168(69.1)
Occupation	Outdoor	170(70)

	Indoor)	72(30)
Viral rebound	Yes	40(16.5)
	No	203(83.5)

At the time or recruitment, 16.6% of female participants and 7% of male participants had BPVL less than 10,000 copies/µl. while 83.3% of female and 92.9%of male participants hade BPVL of >10,000 copies/µl. The mean and median baseline plasma viral load of study participants was 4.03×10^5 cells/µl and 2.03×105 cells/µl.

Table 32. base line characteristics of study participants in East shewa zone, Oromiya, Ethiopia, 2018.

Parameter	PBVL	Height	Weight	BMI	MUAC	BCD4
Mean	403554.5	1.631462	52.6936	19.78875	23.06693	204.4701
Mode	275601	1.6	52	17.57813	24	106
Median	203088.3	1.63	52	19.43209	23	178

The mean BPVL in cohort of study participants were $2.74x10^5$ cells/µl. while the median BPVL was $1.30x10^5$ cells/µl. The maximum mean change in viral load level was observed at baseline and follow up at one month. The maximum median change in viral load level was observed in follow up at 18th month.

Table 33. Central tendency measures at different follow up time with respect to BPVL in cells/µl. in East shewa zone, Oromiya, Ethiopia, 2018

	BPVL	BPVL FA1	BPVL - PVL FA1	PVL FA3	BPVL - PVL FA3	PVL FA6	BPVL - PVL FA6	PVL FA12	BPVL - PVL FA12	PVL FA18	BPVL- PVL FA18(Last)
Mean	2.74×10^5	1.90×10^4	**2.71×10^5**	2.54×10^4	2.68×10^5	1.94×10^4	2.59×10^5	3.10×10^4	2.52×10^5	**9.67×10^3**	2.68×10^5
Mode	2.75×10^5	0	2.75×10^5	0	2.75×10^5	0	2.74×10^5	0	2.74×10^5	0	2.74×10^5
Median	1.30×10^5	4.25×10^2	1.30×10^5	**69.5**	1.27×10^5	78.9	1.27×10^5	1.45×10^4	1.16×10^5	1.45×10^4	**1.28×10^5**

Bivariate analysis

Interaction between explanatory variables with the response variable was analyzed by using cross tab features of SPSS, IBM Inc. Base line PVL status of a patient did not showed significant interaction with event of interest with $\chi 2$ value 2.33(p-value .127). Other variables which did not show up includes age of the patient $\chi 2$ value of 4.44 (p-value .488), Marital status $\chi 2$ value of 6.75 (p-value .081), occupation $\chi 2$ value of .383 (p-value .826), education status $\chi 2$ value of 1.13 (p-value.770), MUAC $\chi 2$ value of .253 (p-v alue .881), BTB with $\chi 2$ value of 1.15 (p-value .283).

Significant interaction or association with Plasma viral load suppression were observed in sex $\chi 2$ value of 5.06 (p-value .0.024), BMI with 0.003, BCD_4, $\chi 2$ value of 10.98 (p-value .0.004) and ART Treatment regimen with $\chi 2$ value of 14.23 (p-value .0.027).

Table 34. Bivariate crude estimates, analysis of study participants, East Shewa Zone, Oromiya , Ethiopia, 2018.

Variables	Category	Count/ percent	p-χ2 value	Sign.
BPVL	<10000 copies/µl	31(13)	2.33	.127
	>10000 copies/µl	212(87)		
Age	20 years	4(1.6)	4.44	.488
	20-29 years	109(44.9)		
	30-39 years	91(37.4)		
	40-49 years	29(11.9)		
	50-59 years	7(2.9)		
	≥60 years	3(1.2)		
sex	Male	99(40.7)	5.06	.024
	female	144(59.3)		
Marital status	Single	56(23.0)	6.75	.081
	Married	112(46.1)		
	Divorce	50(20.6)		
	widowed	25(10.3)		
occupation	Outdoor	170(70)	.383	.826
	indoor	72(30)		
Educational status	Illiterate	88(36.2)	1.13	.770
	<6 grade	65(26.7)		
	6-12 grade	81(33.3)		
	Higher education	9(3.7)		
BMI	≤18.5 kg/m^2	87(35.8)	8.98	0.003
	>18.5 kg/m^2	156(64.2)		
MUAC	≤23 cm	≥23 cm	.253	.881
	23.1-24.9 cm	23.1-24.9 cm		
	≥25 cm	≥25 cm		
BCD_4	<200 cells /µl	140(57.6)	10.98	.004

	200-350 cells /µl	77(31.7)		
	>350 cells /µl	26(10.7)		
BTB	Positive	189(77.8)	1.15	.283
	Negative	54(22.2)		
Treatment regimen	d4T, 3TC, NVP	1(0.4)	14.23	0.027
	d4t, 3TC, EFV	5(2.1)		
	AZT, 3TC, NVP	13(5.3)		
	AZT, 3TC, EFV	13(5.3)		
	TDF, 3TC, NVP	17(7.0)		
	TDF, 3TC, EFV	168(69.1)		

Comparison between different categories for survival

Survival distribution for different age group reveals that there was no significant difference between different age group in terms of the time to reach suppressed plasma viral load with log rank test score of $\chi 2$ value 0.860. Estimated median time to PVL suppression was **181days** (CI: 140.5-221.4) with the age group of 30-39years having minimum time to achieve suppression with 92 days (CI: 60.1-123.8) and the maximum time required to reach the level was age group between 50-59 years.

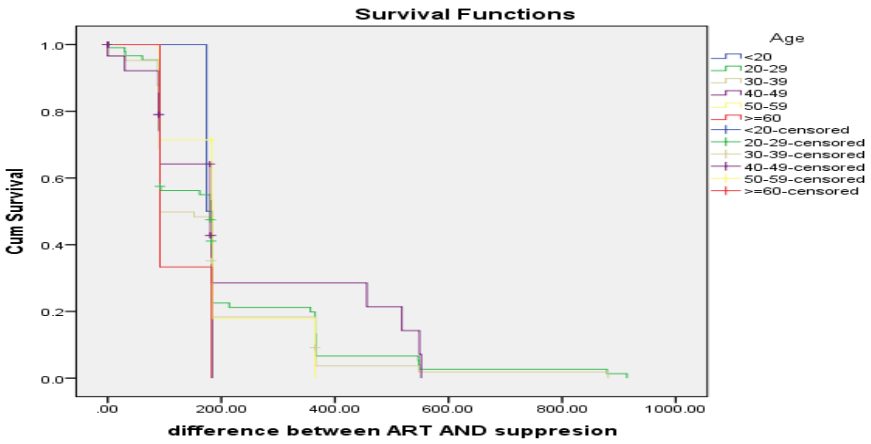


Figure 33. Survival curve between different age groups of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Survival distribution of study participant by sex category indicated that there were no significant difference between male and female in terms of time to reach viral suppression level in the plasma. In the log rank test was, $\chi 2$ value was 3.499 with p-value of 0.061.

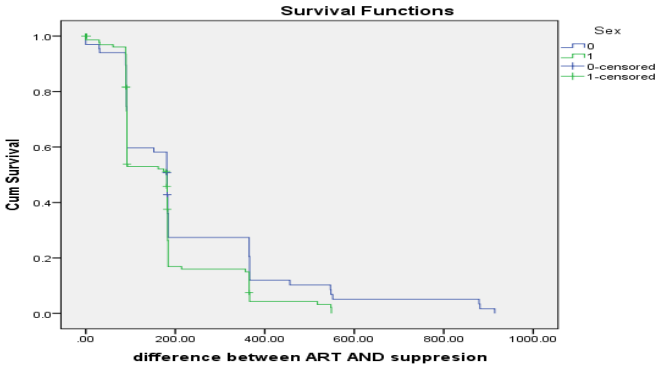


Figure 34. Survival curve between different age groups of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Significantly different survival distribution curve was observed between different categories of marriage in the study participants. The maximum median time for PVL suppression was observed in unmarried participants with 183 days (CI: 181.7-184.315). The minimum median time registered in divorced participant category with estimated median time of 92 days (CI: 91.06-92.93).

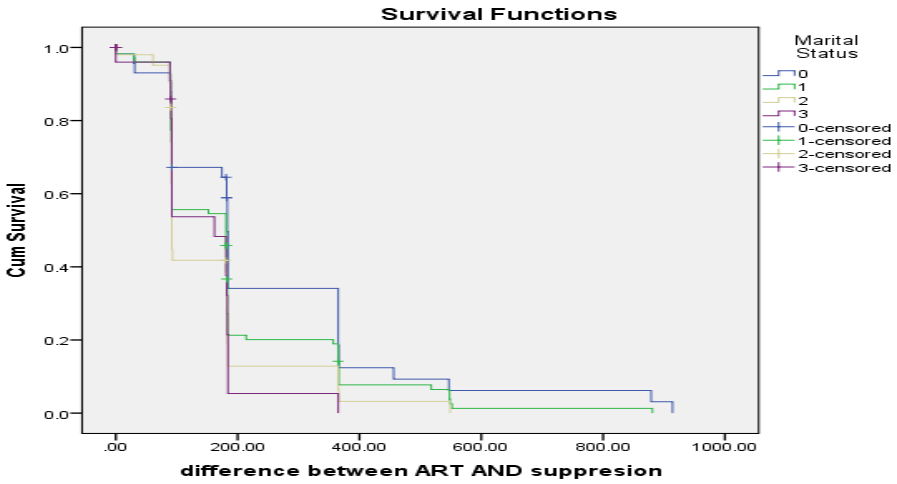


Figure 35. Survival curve for marital status of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Time to plasma viral load suppression with respect to occupation of participant showed there was no difference (log rank test $\chi 2$ value 2.26, p-value0.332) between outdoor and indoor work area. Median time to have an event was 182 days (CI: 177.2-186.7) for outdoor and 181 days (CI: 55.1-128.8) for indoor.

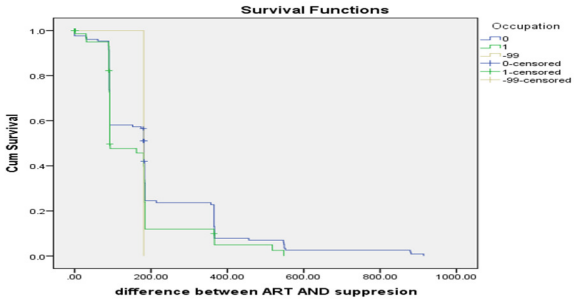


Figure 36. Survival curve between different categories of occupation for study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Survival time in terms of viral suppression from HIV patient's plasma was not significantly different with respect to educational level. Log rank test for these variable was $\chi 2$ value 3.40, p-value 0.334) and minimum median time was registered in illiterate patients with median time of 162 days (CI: 126.95-197.04) and maximum median time was observed in patients with higher education.

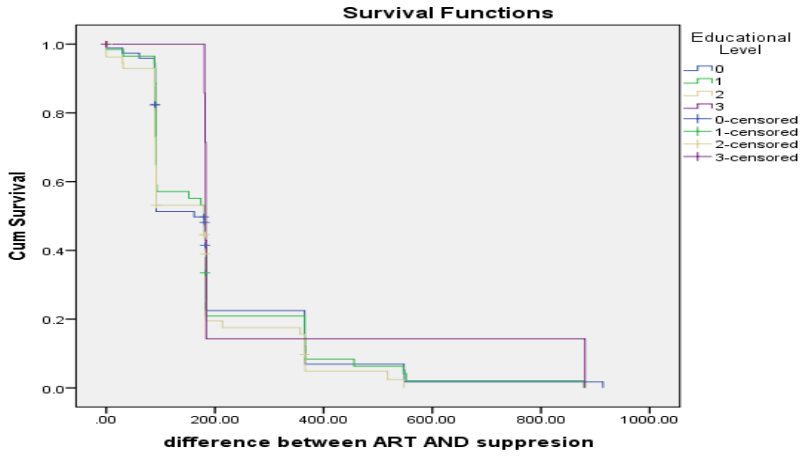


Figure 37. Survival curve between different educational levels of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Median time to viral load suppression in groups of HIV patients categorized based on their MUAC status showed no significant difference between the categories. Log rank test with $\chi 2$ value 0.206, p-value 0.902). Maximum median time observed in MUAC category of >21 cm(181 days), while the minimum median time observed in MUAC category of < 18 cm with 92 days.

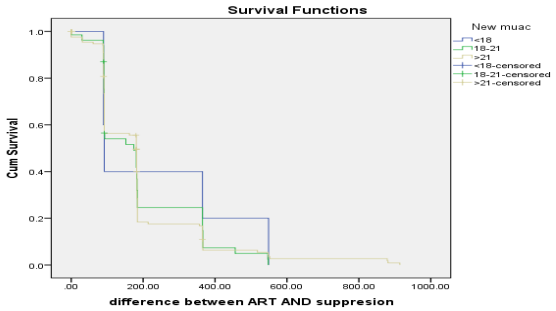


Figure 38 Survival curve between different educational levels of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

In this study, similar survival curve was observed in BMI category. The log rank test with $\chi 2$ value of 1.61 and p-value of 0.656 describes the similarity of the curves. BMI category of <18.5 kg/m^2 or underweight study participants estimated median time for suppression of 181 days (CI: 155.09-206.90), 18-24.9 kg/m^2 or normal BMI category with 181 days (CI: 155.35-206.64), BMI category of 25-29.9 kg/m^2 with median time of 90 days (CI: 0.00-186.00).

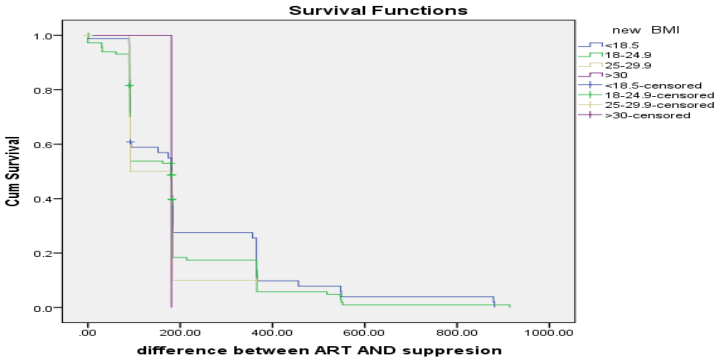


Figure 39 Survival curve between different categories of BMI of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Significant survival curve difference (log rank test: $\chi 2$ value of 8.84 and p-value of 0.012) was observed in HIV patients with different baseline CD_4 count. Median survival time for patients

with <200 cells/µl measured 182 days (CI: 160.80-203.19), 181 days (142.39-219.60) for BCD_4 200-350 cells/µl, 174 days (CI: 133.40-214.59) and 174 days (CI: 133.40-214.59).

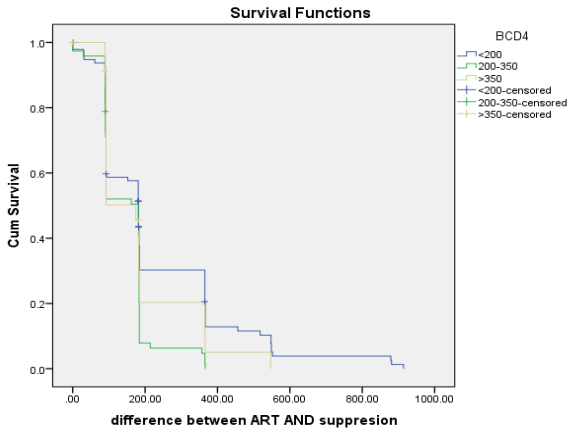


Figure 40 . Survival curve between different categories of BCD_4 of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Presence of Tuberculosis in HIV patients during enrollment of study participants showed no significant difference (log rank test: $\chi 2$ value of 0.576 and p-value of 0.448). Median survival time for baseline TB positive 92 days (CI: 91.42-92.57) compared with 182 days (CI: 177.70-186.29) for baseline TB negative patients.

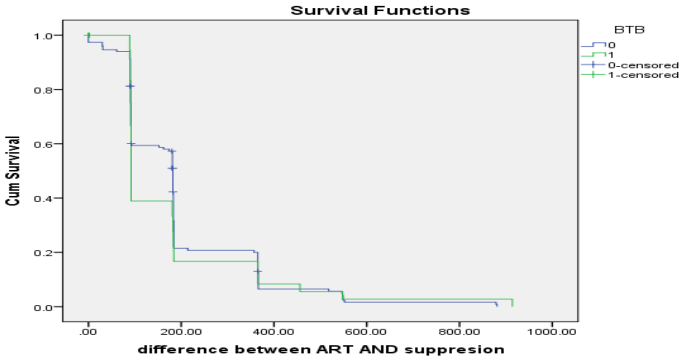


Figure 41. Survival curve between different categories of BTB of study participants in East Shewa Zone, Oromiya , Ethiopia, 2018.

Multivariable analysis

IBM Inc. SPSS V. 21 software was used to determine factors affecting the median time to plasma viral load in the patient blood. Forward factor selection method (for identifying synergistic effect of variables on response variables) was used to identify factors that are significantly affect the median time. Cox-proportional hazard regression method was used to estimate the magnitude of each variables. Variables with p-value of ≤0.05 were included in the model and selected as variables to fit a model that best explain the variance in the equation. Variables identified as significant in this study was marital status with p-value 0.023 and baseline CD_4 with p-value 0.023. Educational status (p-value 0.404), MUAC(p- value 0.407)

BMI(p-value 0.335) and BTB(p-value 0.257).

The model fit and interpretation

$h_i(t)= h_o(t)\ \exp(\beta_1 x + \beta_2 x + \beta_3 x \ldots\ldots)$

$\log h(t)=\log h_o(t)+ \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 \ldots\ldots..$

$\log h(t) = -1.16\text{Marital status} - 0.556\ BCD_4$

The log hazard ratio of single marriage status study participant having viral load suppressed below detection level will be the same as baseline log hazard ratio. But the log hazard ratio for married patient to reach viral suppression level decrease by 1.16.

7.7 Discussion

Median time for plasma viral load suppression in the study cohort was determined using survival regression analysis. Based on the study, median time for suppression was 181 days (CI: 140.5-221.4). This finding exactly matches with a study done by US department of health and human service in 2017, which found the median time between at about 24 weeks after initiation of ART. In another study conducted by Snippenburg W Van, Nellen FJB and Smith C, the median time to undetectable plasma viral load after initiation of treatment was found to be 60 days (12-168 days) which is lower than this study.

As of 2015, 72% of study participants achieved viral suppression, But in a study conducted in Brazil, the the percentage of HIV patients achieving viral suppression were 62%. This difference may be attributed due to the length of timing of follow up of the patients. Similar study conducted in neighboring Kenya revealed that only 39.85% of patients had virologocal suppression .In another study conducted by Shikuma CM and et al., the percentage of patients taking ART of different regimen reaching virological suppression after taking ART for 16 weeks showed 93% viral suppression. In this study, the percent of patients having virological failure was 16.5%. The same study by Shikuma CM and et al., found that 12.2% of patients have virological failure. Viral suppression rate of this study was found to be similar across different geographical spectrum. Study done in low and middle income countries of Brazil, Laos people's democratic republic, Malaysia, Mexico, Myanmar and republic of Moldova have achieved viral suppression of 80%.

Age category of 30-39 years old had minimum time to viral suppression with 92 days(CI: 60.1-123.8) and the maximum time to achieve viral suppression was found in age category of 50-59 years. Significant difference in proportion of different age group was not found by log rank test. In a study conducted in Kenya by Cherutich found significant difference between different age category in achieving viral suppression level. In this study there were significance difference between age group of 15-29 age group and 30-64 years category with the rate of 46.5% and 22.3% respectively.

significant sex difference was achieved in plasma viral load suppression among different sex category. Pearson's χ^2 for sex category was 5.06 with p-value of 0.024. Significant difference between sex categories was also achieved in a study conducted by Ballesteros-zebad P. in

Mexico, which found high suppression rate in male patients compared to Female patients. Other studied which found significant difference between male and female HIV patients viral suppression level was done by Pinto M. in southern Brazil, and Gray RH., in Uganda. Viral load suppression across sex category was not significant in a study done by Rangarajan S.,Colby DJ in Vietnam. In this study, which is done in Vietnam, there was no significant difference between male and female HIV patients achieving undetectable viral level. In this study, Viral suppression among women was not significantly different with 93.7% vs 92.9% in male and female respectively.

The median baseline CD_4 was similar with study conducted in Northern Province, Cameron with 204 cells/µl and 192 cells/µl respectively. Survival curve was not significantly different among different BCD_4 categories which is also a result supported by the above study mentioned, But similar study in Cameron by Boelaert M. suggested significant difference in survival of patients between different BCD_4 category.

Baseline Mid upper arm circumstance for evaluation of patients nutritional status does not appear to be associated with decrease in viral load suppression. Other studies suggested different association. A study by Liu E, Spiegelman D, found that base line lower MUAC was associated with lower rate of viral suppression from patient plasma.

Body Mass Index affected survival time of patient with $\chi 2$ 8.98 and p-value of 0.003. BMI category < 18.5 kg/m^2 had increased risk of higher viral replication in a study by Sharma A. and Hoover DR, but association between obesity and reduced or increased viral load was not observed.

No difference in survival curve of HIV patients to reach viral load level with respective to different ART treatment regimen. Snippenburg W. Van achieved the same curve property in a study, which found no difference between protease inhibitor and non-nucleoside reverse transcriptase inhibitor based regimens.

At least one instance of viral rebound was occurred in 16.5% of cohort of HIV patients in the study period. This figure was 45.1% in the study performed by Guillemi S, Hogg R, Montaner J. equals to crude incidence of viral rebound of 12.6% compared to 16.4% crude incidence of viral rebound in this study.

Variables identified as significant in this study was marital status (p-value 0.023) and baseline CD4 (p-value 0.023). Pinto et al, found significant effect of age and ART usage on survival of patient taking ART drugs. Body mass index, sex , WHO clinical stage and hemoglobin level were cited as significant independent predictors of plasma viral load level in the patient plasma.

Educational status (p-value 0.404), MUAC(p- value 0.407) BMI(p-value 0.335) and BTB(p-value 0.257). There were no significant association found in the percentage of patients with undetectable viremia by sex, marital status, educational level residence or wealth index(Rangarajan S, Colby DJ). Gray RH and et al, found significantly higher viral load after ART treatment in male and concurrent infection with Tuberculosis, Herpes virus,malaria and helmenthiasis. Study done by Semu H. and Hawkin C. also confirm that baseline MUAC and plasma viral load level does not have significant relation.

Limitation of the study

Sample size was not adequate to detect minimum survival difference in different study category.

Conclusion

Estimated time to achieve PVL after taking ART was found to be 181 days. Factors affecting time to suppression level was marital status and baseline CD4. Additional factors believed to be influencing survival curve were also studied, but not significant relation was found with the response variable.

Recommendation

Further study should be conducted by increasing the sample size and study area for better interpretability of the investigation.

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CHAPTER VIII

8. Quality manual preparation for Bekoji Hospital, Bekoji, Oromiya, Ethiopia, May 2017

Authors: Jemal Hassen Ali[1], Tizita Taegaye[2]

Affiliation: [1]Ethiopia Field Epidemiology Training Program; Oromiya Public Health Research, Capacity building and Quality Assurance Laboratory

8.1 Introduction

Bekoji hospital Laboratory was established by Oromia regional health bureau to conduct diagnostic service for patient who visit the hospital.

The provision of good laboratory service is highly dependent on the implementation of Laboratory quality management system in all level of Laboratories. Development and implementation of quality management system in BHL started since Hamle 2008 EC. Since then, the laboratory is working hard to improve the service and satisfy customer needs.

The Quality Manual outlines the policies of Bekoji Hospital Laboratory as it relates to its commitment to the implementation of the laboratory quality management system (QMS) in line with ISO 15189: 2012 in order to meet accreditation standards.

This Manual serves as a reference for laboratory personnel on all quality system matters, providing direction to general policies, processes and responsibilities that authorize and govern the creation of subsidiary quality-related documentation and activities. Many of these documents can be found within other reference materials that are indicated within different sections. All staff are trained in the use and application of the quality manual policies and be advised of any changes. It also provides comprehensive evidence to all customers, stakeholders and staff that the laboratory is committed to establishing and maintaining acceptable levels of measurable quality in its services.

Ethiopia uses Julian calendar which is seven/eight years behind the Gregorian calendar and which has 13 months in a year, the first month being September and the 13th month coming after August and before September. The 13th month has 5 to 6 days depending on the year. BHL uses Julian calendar in its quality management system. However, a calendar is available to convert to Gregorian system if needed.

8.2 Scope

Bekoji hospital laboratory quality management system covers all the activities performed in the laboratory which are:

A. **Reception:** specimen collection, receiving, accessioning, enter of test information using manual labeling method according to the sample and tests requested and , monitoring of turn-around time (TAT).
B. **Bacteriology**: Smear microscopy(ZN/FM)
C. **Clinical Chemistry tests, Serology and Hematology**: GPT, GOT, Urea, Creatinine, Triglyceride, ALP, Cholesterol, and Glucose. Billirubin (Total & direct), complete blood cell count (CBC). Blood morphology, blood grouping Widal O &H Ag tests, Weilflex tests Using OX 19 proteus Ag. syphilis test using RPR carbon test or syphilis check strip. H. pylori test, HBsAg test, ASO,HCV test ,rheumatoid factor test, HIV test
D. **Urinalysis and parasitology section**:-blood parasite ,stool wet mount microscopy, urine chemical tests ,urine microscopy ,urine HCG

Vision,Mission and Value statement

1.1. Vision statement

XXXXXXXXXXXXXX

1.2. Mission statement

To protect and promote the health of the people of surrounding by addressing priority public health problems through advanced diagnostic service, capacity building, implement and maintaining quality management system (QMS) according to ISO 15189:2012.

1.3. Values

- We value collaboration
- Excellence.
- We accept responsibility for the performance of our laboratories
- Customer satisfaction and community first
- Cost effective and efficient resource utilization
- committed to respect code of ethics
- Transparency and accountability
- Quality service

Staff Motivation and trust

8.3 Management requirements

Organization and management responsibility

Organization

General

BHLis committed to meet requirements of ISO 15189:2012 while performing work at its permanent facility.

Legal identity

BHL is legally mandated by Oromia regional health bureau to operate as investigation patient's sample of Bekoji hospital.under the license number/reference letter -------()

The permanent physical location of BHL is:

BekojiHospital Laboratoryis located

Kebele 01

Bekoji Town

Arsi Zone

Oromia Region

Ethiopia

Contact phone number +251 223 321 402

NB:-those land line phone No. is the CEO and MEDICAL DIRECTOR Bureau used

Ethical conduct

Bekoji Hospital Laboratory has put in place an ethical conduct declaration form (BHL- 4.1-F 001) to ensure that staffs do not:

fabricate or falsify laboratory results or get involved in any unethical activities that may result in clients to lose trust on the laboratory's competence, impartiality, judgment or operational integrity;

get influenced by commercial, financial, political and other pressure that may adversely affect quality of their work;

get involved in business or any activity that compete with activities the same with BHL

analyze patient samples for investigations not requested by authorized clinician;

Use patient samples to carry out research which is not cleared by ethics committee of Oromia regional health bureau.

Disclose patient confidential information to any unauthorized person for any reason.

Laboratory head

BHL is led by a competent person whose overall responsibilities includes but not limited to administrative, professional and scientific advisor to Bekoji Hospital on laboratory diagnostic issues. The detailed roles and responsibilities of the laboratory head are found in job description (JD 01).

Management responsibility

Management commitment

The management of Bekoji Hospital is committed to development, implementation, maintenance and continual improvement of the quality management system by ensuring that:

Weekly laboratory staff meetings are done where staff informed on the importance of meeting needs and requirement of patients, Clinician as well as requirements of Bekoji Hospital

quality policy statement is established;

quality objectives are established and a plan is developed to achieve them;

staff responsibilities and authorities are defined in their respective job description;

interrelationship between staff and management is defined in the organizational chart;

internal and external communication processes are established;

a quality officer is appointed by laboratory head and approved by Hospital Medical director

all staff are assessed for competency in their assigned tasks annually and bi annually for new staffs

adequate resources needed to conduct pre-examination, examination and post-examination activities are available;

All staffs are trained quality management system.

Needs of users

Bekoji Hospital laboratory ensures that services offered including advisory services continuously meet needs and requirements of patients and Clinician by addressing both negative and positive feedback received.

Quality policy

Bekoji Hospital Laboratory provides diagnostic services in the disciplines of HIV antibody screening test,Hematology, clinical chemistry, AFB (Zeil Neilson/FM)for TB diagnosis, Parasitology, Urinalysis and different serology test.BHL also participate in EQA.

Bekoji Hospital laboratory Staffperform their work in the most professional and ethical way committed to good laboratory and clinical practice as well as to requirement of ISO 15189:2012. The laboratory implements established evaluation and audit processes as well as thrives to meet its quality objectives and reviews them to ensure that the developed quality management system is continuously improved and remains appropriate to the purpose of organization.

All staff of BHL understands the quality policy as well as all policies and procedures of the quality management system and is committed to implementing them while carrying out their assigned duties.

This quality policy is reviewed annually to ensure its continued suitability.

Quality objectives and planning

Bekoji Hospital laboratory sets and reviews measurable quality objectives annually during management reviews after collecting suggestions from staff. A plan which includes key activities for achieving the objectives is developed on form in the same annual management review.

The management ensures that the integrity of the quality management system is maintained when changes are being planned and implemented.

Responsibility, authority and interrelationship

Bekoji Hospital laboratory has defined responsibilities and authorities of staff in their respective job descriptions. The staff read and acknowledge by signing the job descriptions witnessed by the Human resource manager before they are filed in individual personnel files.

The interrelationships between management and staff are defined in the organizational chart.

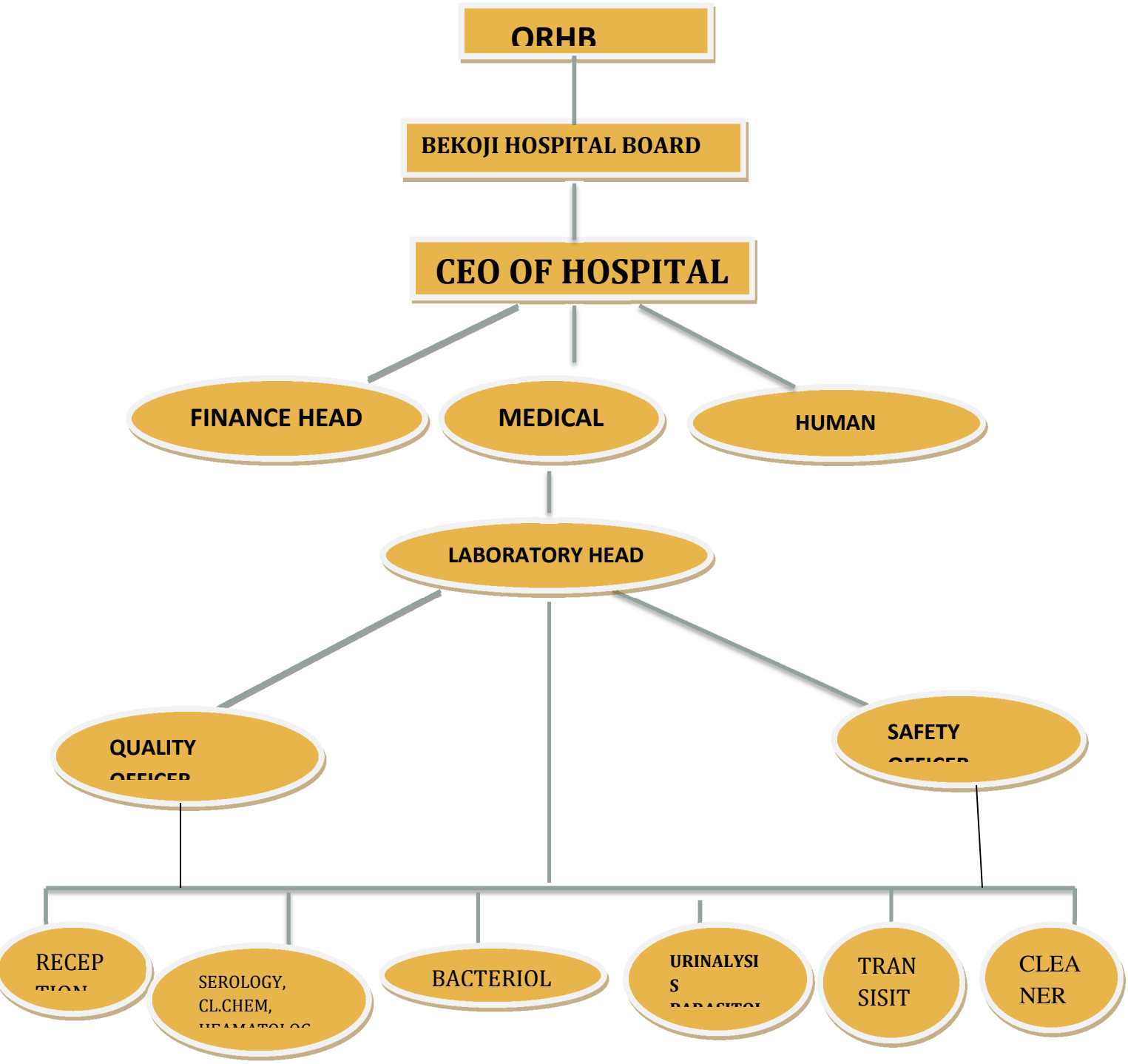


Figure 42. Bekoji Hospital Laboratory Organo-Gram, Bekoji, Oromiya, Ethiopia, May 2017

Communication

The laboratory holds weekly staff meeting where effectiveness of pre-examination, examination and post-examination processes and implementation of laboratory quality management system are discussed. Minutes of these meetings is maintained by quality Officer in BHl-4.1-F-003. The laboratory head participate on Hospital management meeting monthly about laboratory and other hospital issues. This minute capture on BHL-4.1-F-003.Staff also communicate through verbally, telephone and posting memos BHL-4.1-F-004 on notice board.

External communication with regional laboratory, Oromiya regional health bureau, zonal health department annually during review meeting.This minute capture on BHL-4.1-F-003.

Laboratory head

Laboratory head is the leader of the hospital laboratory. S/he is appointed by the hospital medical director.S/he is member of Hospital management team. S/he is report to Hospital Medical Director. S/he represents the laboratory in different team meeting and responsible for external relation with different units. The detailed responsibilities of laboratory head are stated in the job description (JD 01).

Quality officer

The laboratory Head has nominate a quality Officer to Hospital Medical Director for approval. Who reports to the laboratory head and whose overall responsibilities are to ensure that processes needed for the quality management system are established, implemented and maintained as well as to promote awareness of needs and requirements of patients and health facilities in the laboratory. The detailed responsibilities of quality officer are stated in the job description (JD 02).

Safety officer

Safety officer nominate by laboratory head and approved by Medical director. He report to laboratory head. He is well trained in infection prevention. Ensures the safety of laboratory according to ISO 15190. The detailed responsibilities of safety officer are stated in the job description (JD03)

Supporting documents

registration license_

ethical conduct declaration form_ BHL-4.1-F-001

Laboratory head job description_ JD 01

Objectives planning form_ BHL-4.1-F-002

Staff job descriptions

Memos template _ BHL-4.1-F-004

Meeting minutes template _ BHL-4.1-F-003

Quality officer job description_ JD 02

Safety officer job description _JD 03

Quality management system

General requirements

BHL has established document, implement and maintain a quality management system and continually improving its effectiveness in accordance with the requirements of ISO 15189:2012. The quality management system is composed of different processes that interact with each other to convert inputs (customer requirements) to output (customer satisfaction) .

The management processes constitute some of the monitoring and evaluation processes needed to ensure continual improvement of the quality management system while the support processes indicate the resources needed to support the quality management system.

Documentation requirements

General

BHL has established documents needed for its quality management system that include:

Statement of quality policy and quality objectives

Quality manual

Procedures and records required by ISO 15189:2012

Supporting documents of the quality manual

Copies of international, national and regional regulation documents such as ISO 15189:2012, Bio-safety regulation, ENAO documents, civil servant and good governance regulations

Quality manual

BHL quality manual is composed of:

policy statement

a description of the scope of quality management system

organizational chart

Job descriptions which define roles and responsibilities of all staffs including laboratory Head ,Quality officer, safety officer

description of the documentation structure used in quality management system

policies addressing all requirements of ISO 15189:2012 and their supporting documents

4.2.2.3 Documentation structure

BHL quality management system documents fall in to a three-tier structure which comprises of polices in first level, procedures/jab aid in second level, and forms , records, reference books , equipment manuals and other external documents in third levels illustrated in pyramid below.

Policy: describes the organization goals and intentions "what is done and why"

Procedures/Job aids: provide step by step instruction "how to do it"

Form: capture information and results generated as the process procedures

Records: result from captured information on a form

External documents: documents of external origin adopted into the system to support polices

The quality officer distributes copies of quality manual and supporting documents to each stake holders so that staff can have easy access. All staffs are trained on the use of quality manual and supporting documents.

Document control

The quality Officer of BHL ensures that all documents required by the quality management system are controlled to prevent unintended use of any obsolete documents. This is achieved by use of master list of documents(BHL-4.3-F-001) during distribution of approved current documents and retrieval and destruction of obsolete documents.

BHL has developed a procedure for document control (BHL-MSOP-01) which gives more detail on document control from creation to destruction.

All documents are uniquely identified with laboratory name & logo, document title; document ID, effective date of current version, version number, and page number to total number of pages and authority for issue.

The Hospital Medical Director approves Quality Manual, Safety manual, laboratory hand book while the LaboratoryHead Procedures. The quality officer reviews all documents to ensure that they are standardized and fulfill all requirements of ISO 15189:2012 before they are approved.

Supporting documents

Master list _ BHL-4.3-F-001

Procedure for document control _BHL-MSOP-01

Process maps/tables

Service agreements

Establishing of service agreements

BHL has developed a procedure for establishing and review of agreements (BHL-MSOP-02) for providing medical laboratory services.

BHL considers individual requests for examination brought in by patient as agreement.

The laboratory Head and the Hospital Medical Director sign agreements on behalf of BHL with

The service agreements take consideration of the following conditions:

requirements of customers such as turn-around time, reporting formats , testing algorithm;

requirements of service provider (BHL) such as sample collection requirements including sample volume and type of container; use of request form, transportation and handling of samples ;

the capability and resources available to meet the requirements;

availability of expertise to perform requested examinations;

availability of suitable examination procedures (equipment) needed to perform requested examinations;

any work that is referred to another laboratory will be identified by the name of the laboratory;

Notifying customers (health facilities and patients) any deviation from the agreement that may impact on examination results.

The Laboratory head notifies Customer through telephone of any deviation in agreement such as service interruption that may result in delayed turn-around times or temporary interruption of services. The communication with customers is recorded on communication log (BHL-4.4-F-001).

Review of service agreements

The customers initiate the review process stating the need to continue with service agreement. The conditions agreed upon in the initial agreement are reviewed and if there are any changes to any of the conditions, all parties agree before signing the new agreement.

When amendments need to be done after laboratory services already commenced, the conditions are reviewed by both parties before an agreement can be reached. The laboratory Head or Hospital Medical Director communicates all conditions and amendments to all BHL staff.

Supporting documents

Procedure for service agreement_ BHL-MSOP-02

Communication log _ BHL-4.4-F-001

Examination by referral laboratories

Selecting and evaluating referral laboratories and consultants

BHL select referral laboratories by using checklist BHL-4.5-F-001 and list selected referral laboratory on BHL-4.5-F-002.

Referral of samples may occur under any of the following temporary circumstances:

equipment breakdown;

reagents stock-out;

test not performed routinely by the laboratory;

BHL uses criteria defined in procedure for referral laboratories (BHL-MSOP-03) to select referral laboratories and maintains a list of the approved ones (BHL-4.5-F-002). The same procedure also gives guidelines on monitoring performance of referral laboratories which is done once a year, coordinated by the Quality officer.

Provision of examination result

BHL is responsible for all test results from referral laboratories to ensure they reach the customer within at agreed turn-around time. The laboratory uses referred samples log (BHL-4.5-F-003) to track samples and results from referral laboratories.

BHL does not edit or put additional remarks to reports from referral laboratories but forwards it to customer as received, keeping a copy in respective section for a period as defined in the document and record retention times (BHL-4.5-F-004).

In cases where correct interpretation or clarification of results is required, BHL collaborates with referral laboratories without any extra charge to the patient.

Supporting document

List of approved laboratories_ BHL-4.5-F-002

Procedure for referral laboratories_ BHL-MSOP-03

Referral samples log_ BHL-4.5-F-003

Documents and records retention times_ BHL-4.5-F-004

External services and supplies

BHL has procedure for selection and evaluation of external services and suppliers (BHL-MSOP-04).

BHL acquires all of its reagents and consumables and some of its equipment from PFSA and Biftu Adugna S.C the laboratory head ensures that performance of PFSA and Biftu Adugna S.C is monitored annually using checklist (BHL-4.6-F-001).

BHL receives equipment as donations from partners, OPHRCBQAL, EPHI and ORHB

BHL also acquires some of its equipment from private supplies through tendering system. The private suppliers are selected based on stated criteria and specific equipment specification. These are, not limited to the following listed criteria:

Cost

post-delivery support (training, installation & spares)

warranty period

availability (reagents and consumables)

Registration of the provider

CE marked, FMHACA registered

Validation

System interface

Capacity/test through put per day& user friendly

BHL ensures that all received reagent, consumable and equipment meet expected standards and are suitable for intended use in accordance with checklist for receiving equipment(BHL-4.6-F-002), reagent and consumable(BHL-4.6-F-003).

Supporting document

Evaluation of supplier checklist_ BHL-4.6-F-001

Procedure for selection and evaluation of external service and supplies_ BHL-MSOP-04

Checklist for receiving of equipment _BHL-4.6-F-002

Checklist for receiving reagents and consumable_ BHL-4.6-F-003

Advisory service

BHL staffs are has authorized through their job descriptions to provide advice to customers on:

sample collection, sample type and volume, type of container including preservatives , handling and transportation;

choice of examinations and effective use of laboratory;

correct interpretation of examination results;

limitations of examination procedures;

individual clinical cases;

Sample integrity and their effect on examination result.

A laboratory hand book containing the above information in more detail is distributed to all health units.

Table 35. The summary of advisory services and staff who authorize to give the services

	Sample requirements (volume , type of	**Completing request forms**	**Safe handling and Transportation of samples**	**Choice of tests**	**Interpretation of results**	**Promoting use of laboratory services**
Laboratory Head	√	√	√	√	√	√
Quality Officer	√	√	√	√	√	√
Safety officer	√	√	√			√
Laboratory staffs	√	√	√	√	√	√
Transistor						

Resolution of complaints

BHL has a procedure for resolution of complaints (BHL-MSOP-05) which is followed when resolving complaints from patients, Clinician and other customer/stakeholders as well as internal complaints from staff. The laboratory Head has overall responsibility of ensuring that all complaints are resolved while the quality Officer maintains the records thereof. Customer complaints are obtained through bi-annual customer satisfaction survey, suggestion book, Suggestion box and via telephone or directly forward to any of laboratory staff. During staff meetings, Staffs are informed to raise their complaints any time by way of filling in complaint form (BHL-4.8-F-001) anonymously and submitting it to quality officer and address in Hospital management meeting. Complaints are addressed by hospital management during their monthly meetings and feedback is given to staff during weekly meetings or to individual who raised the complain.

Supporting document

Procedure for resolution of complaint_ BHL-MSOP-05

Complaint form _ BHL-4.8-F-001

Identification and control of non-conformities

BHL has a procedure to identify and manage non-conformities (BHL-MSOP-06)raise in any aspect of its quality management system including pre-examination, examination and post-examination processes .A non-conformity form(BHL-4.9-F-001) is used to capture details of the non-conformity, the root cause as well as corrective action taken. Quality Officer has overall responsibility of ensuring that non-conformities are identified and effectively addressed. In cases of major non-conformity which has direct impact on examination results, the laboratory head is responsible for stopping work in the affected area and ensuring that effective corrective action is taken before work can be resumed. Affected result is recalled, re-analyzed and corrected results re-issued. The laboratory Head is responsible of informing affected customers of the impact of the non-conformity on the examination result. Quality officer maintains register (BHL-4.9-F-002) of all non-conformities raised and uses the information for trend analysis which is reported in annual management review.

When it is determined that non-conformities in any of the aspect of quality management system including pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory compliance with its own procedures, BHL takes action to identify, document and eliminate the root cause(s), records of all corrective action taken are documented on non-conformity form (BHL-4.9-F-001) and maintained by Quality officer.

Supporting document

Procedure of identification and manage nonconformities_ BHL-MSOP-06

Non-conformity form_ BHL-4.9-F-001

Non-conformity register_ BHL-4.9-F-002

Corrective action

BHL follows the procedure for corrective action (BHl-MSOP-07) to address all non-conformities identified in the system. Record of root cause analysis and corrective action are captured on non-conformity form (BHL-4.9-F-001). Effectiveness of corrective action taken is reviewed by internal

auditor in case of internal audits or by the quality officer before any of the same people can close the non-conformity.

Supporting documents

Procedure for corrective action_ BHL-MSOP-07

Non-conformity form_ BHL-4.9-F-001

Preventive action

BHL has established actions to be taken to prevent potential non-conformities. These pro-active actions include:

daily monitoring of environmental temperature by laboratory staffs;

daily running of internal quality controls by laboratory experts;

daily, weekly and/or monthly maintenance of equipment by laboratory staffs;

quarterly performance in external quality assurance in all sections;

Annual review of all documents of the quality management system by quality officer and laboratory head.

The laboratory staffs are responsible for reviewing data on a daily basis including trend analysis while the quality officer reviews the data on a monthly basis.

Potential non-conformities are identified through trend analysis and preventive actions are developed and implemented accordingly.

A procedure for preventive action (BHL-MSOP-08) has been developed.

Supporting document

Procedure for preventive action_ BHL-MSOP-08

Continual improvement

BHL has established mechanisms to continually improve effectiveness of its quality management system including pre-examination, examination and post-examination processes. These include but not limited to:

annual management reviews;

corrective and preventive actions;

review of quality policy and quality objectives;

implementation of quality indicators;

risk assessment;

Customer feedback.

The laboratory Head ensures that action plans for the above activities are developed, documented on respective action plan and implemented within agreed timelines. The quality officer ensures that annual internal audit is conducted with an objective to review effectiveness of continual improvement actions.

When the continual improvement activities identifying opportunities for improvement, BHL ensures that they are addressed regardless of where they occur. The laboratory head communicates any improvement plans and related goals during weekly staff meetings.

Supporting document

Action plans

Control of records

BHL has a procedure for control of records (BHL-MSOP-09) which defines how quality and technical records are identified, collected, indexed, accessed, stored, maintained, amended and safely disposed.

BHL ensures that staffs create record the same time of performing each activity that affect the quality of examination. BHL allows amendment of records by hand. This is done in blue or black ink by striking through wrong entry with one neat line and entering the correct entry next/above the

wrong entry, signing or initialing and putting the date and time of amendment. Use of correction fluid is strictly not allowed.

BHL has defined periods of retaining quality and technical records generated through implementing quality management system in the document and records retention times (BHL-4.5-F-004).

BHL facilities allow for safe storage of records to prevent their damage by fire, mites or water. The facility is also safe guarded from unauthorized persons gaining access to records.

All quality and technical records are available for discussion in management reviews.

Supporting documents

Procedure for record control_ BHL-MSOP-09

Documents and records retention times_ BHL-4.5-F-004

Evaluation and audits

General

The quality officer of BHL plans the evaluation and audit activities at the beginning of each Ethiopian physical year and documents them on a quality plan (BHL-4.14-F-001) to ensure that:

all processes including pre-examination, examination and post-examination are conducted in a manner that meets the needs and requirement of patients and Clinician;

the laboratory complies with its quality management system;

Effectiveness of the quality management system is continually improved.

All results of evaluation and audit activities are discussed in the management review.

Periodic review of requests, and suitability of procedures and sample requirements

The staffs of BHL compile annual report of all examination requests received in their respective section indicating what test were done and what was not done and stating the reasons . This information is discussed in management review with intention of either expanding scope of services according to need or considering customer need which are not cost effective to run. The staffs also

review sample volume, collection devices and preservative requirements needed for appropriate in accordance with available examination procedures.

Assessment of user feedback

BHL seeks both positive and negative feedback from its patients, Clinicians and other customers through bi-annual customer satisfaction survey, suggestion book and Suggestion box. The quality officer is responsible for summarizing the feedback into report that are shared with Hospital management and maintaining the records of all action taken. Names of patients and Clinician are not included in summary report for confidential information.

Staff suggestions

BHL encourages its staff to raise suggestions for improvement in their respective responsibilities in staff suggestion form (BHL-4.14-F-002). Suggestions can be submitted to Quality officer or hospital management member. The suggestions are discussed during monthly Hospital management meetings and an action agreed is implemented and communicated to staff during weekly meetings. The quality Officer maintains records of staff suggestions and action taken.

Internal audit

The quality Officer schedules internal audit in the annual quality plan (BHL-4.14-F-001).All activities including pre-examination, examination and post-examination are audited once a year to ensure that they conform to requirement of ISO 15189:2012 and to the laboratory quality management system as well as to ensure effective implementation and maintenance of the system.

Trained personnel conduct audit of both management and technical requirements at the same time maintaining objectivity by ensuring that they do not audit their own activities.

The quality Officer in collaboration with internal auditors plan the audit activities which includes defining objectives, scope, criteria, methods and assigning auditors to different sections and stating the actual audit dates. The planning is done at least two weeks before the audit on internal audit plan template (BHL-4.14-F-003) and distributed to all staff concerned. Internal auditors verify effectiveness of corrective action for previous audit before undertaking the new one.

The team leader of the internal auditors compiles final audit report (BHL-4.14-F-004) drawing conclusion on whether objectives were met and presents it in Hospital meetings.Every staff is responsible for doing corrective actions within time frame agreed with internal auditor.

A procedure for internal audit (BHL-MSOP-10) has been developed which defines responsibilities and planning of audit as well as reporting results and maintain records.

Risk management

BHL evaluates impact of work processes and potential failures on examination results as they affect patient safety and come up with the action plans to prevent, reduce or eliminate the identified risks. The evaluation and action plans are documented on the risk assessment form (BHL-4.14-F-00). A procedure (BHL-MSOP-11) has been developed defining evaluation processes as well as coming up with improvement plan.

Quality indicators

Bekoji Hospital management establishes and reviews quality indicators during annual management review to monitor and evaluate performance of its activities of QMS including pre-examination, examination and post-examination process. The management agrees on the objectives, methodology, interpretations, target limits, action plan and duration of measurement of quality indicators during the management review. The quality Officer ensures that process of monthly monitoring of quality indicators are planned on work sheet (BHL-4.14-F006). Quality officer monitor monthly quality indicator data on form (BHL-4.14-F-007) and present in management review.

BHL establishes turn-around time for each of examination in consultation with Clinicians. Turn-around time is monitored monthly by Quality Officer.

Review by external organizations

BHL follows its procedure for corrective action to address all non-conformities identified by external organizations such as OPHRCBQAL, ORHB and partners. The Quality Officer maintains records generated thereof.

Supporting documents

Annual quality plan_ BHL-4.14-F-001

Staff suggestions from _ BHL-4.14-F-002

Internal audit plan template_ BHL-4.14-F-003

Internal audit report form _ BHL-4.14-F-004

Procedure for internal audit _ BHL-MSOP-10

Risk assessment form_ BHL-4.14-F-005

Procedure for risk management _ BHL-MSOP-11

quality indicator planning work sheet_ BHL-4.14-F-006

Monthly sectional quality indicatory form _BHL-4.14-F-007

Procedure for corrective action _ BHL-MSOP-07

Management review

General

Bekoji Hospital management reviews the effectiveness, continued suitability and adequacy of its quality management system in support of patient care annually as scheduled in the annual quality plan (BHL-4.14-F-001).

Review in put

The minimum agenda of the management reviews is as follows:

the periodic review of requests, and suitability of procedures and sample requirements;

assessment of user feedback;

staff suggestions;

internal audits;

risk management;

use of quality indicators;

reviews by external organizations;

results of participation in inter-laboratory comparison programs (PT/EQA);

monitoring and resolution of complaints;

performance of suppliers;

identification and control of nonconformities;

results of continual improvement including current status of corrective actions and preventive actions;

follow-up actions from previous management reviews;

changes in the volume and scope of work, personnel, and premises that could affect the quality management system;

recommendations for improvement, including technical requirements;

Review of quality policy and quality objectives for continued suitability.

Review Annual activities

The quality Officer prepares the annual report preparation form (BHL-4.15-F-001) at least two weeks before the management review defining reports needed for discussion and people responsible for preparing reports. As much as practical the reports are prepared showing trends over time for easy interpretation and following patterns.

Review output

The output of the management review includes minutes of discussions made and action plans for improvement of quality management system activities, improving services to Customer and identification of resource needs and allocations. All staffs are informed of discussions made in management review including action taken in weekly staff meetings. The laboratory head makes quarterly follow ups implementation of action agreed in management review.

Supporting documents

Annual quality plan_ BHL-4.14-F-001

Annual report preparation form _ BHL-4.15-F-001

8.4 TECHNICAL REQUIREMENTS

Personnel

General

BHL has a procedure for personnel management (BHL-MSOP-12) which is followed when managing personnel from the point of recruiting up to retirement. The laboratory head maintains personnel files with technical record while hospital human resource manager maintains the administrative records.

Personnel qualification

Bekoji Hospital management has documented personnel qualifications for each position which also reflect the education, training, experience, and skills needed for the position.

All technical staff performing examination procedures and releasing patient result have diploma in laboratory technology at a minimum.

Job description

BHL has a job description for all positions that describe responsibility and authority for personnel.

Personnel introduction to the organizational environment

Medical director ensures that all new staffs joining the laboratory are introduced to the different sections, staff facilities, health and safety requirement, terms and conditions of employment and occupational health services during the first month of employment using orientation check list (BHL-5.1-F-001).

Training

BHL provide training for all personnel which include:

quality management system coordinated by quality Officer annually;

assigned work processes and procedure by laboratory head/quality officer before staff start working in the section;

health and safety by safety officer annually;

ethics by hospital human resource manager once before starting work;

Confidentiality of patient information by laboratory Head/ Hospital human resource manager.

Personnel undergoing training are supervised by laboratory head/quality Officer until competency assessment is done.

The effectiveness of the training program is reviewed by use of training feedback from the trained staff, competency assessment and/or practical evaluation implementation of the training conducted.

Competency assessment

Following training in their respective sections, laboratory professional are assessed for technical competency by their assigned competent certified staff. Competency assessment is done annually for senior staffs and bi annually for newly hired staffs. Anyone who fails is offered more internal (on job) and external training. The criteria for competency assessment are defined in the procedure of personnel management (BHL-MSOP-12).Records for technical competency assessment is captured on form (BHL-5.1-F-002).

Reviews of staff performance

Bekoji Hospital uses a government compressive 360^0evaluation tool (ED-01) for staff performance evaluation bi-annually by Evaluation committee. The medical director and human resource approves the evaluation process.

Continuing education and professional development

Bekoji Hospital provides continuous education opportunities in collaboration with regional health bureau according to their performance and service year.

Bekoji Hospital laboratory head plan training for staff (BHL-5.1-F-003) and participate in service trainings as part of continuous professional development organized by OPHRCBQAL and EPHI and all staff are required to participate.

Personnel records

Records of the relevant educational, professional qualifications, training, experience and competence of all personnel are maintained by laboratory Head.

Supporting documents

Procedure for personnel management _ BHL-MSOP-12

Staff orientation check list _ BHL-5.1-F-001

Technical competency assessment form _ BHL-5.1-F-002

Comprehensive 360° evaluation tool_ ED-01

Staff training plan _ BHL-5.1-F-003

Accommodation And Environmental Conditions

General

BHL has space to perform its work without compromising quality, safety and efficacy of the services provided to patients and health facilities as well as ensuring health and safety of laboratory staff, patients. Laboratory Head evaluates and determines the sufficiency and adequacy of the space whenever there is need to expand scope of services and/or new equipment is to be brought in. Similar provision made for sample when sample collected at ward and when we perform POC testing like random blood sugar testing, HIV testing

Laboratory and office facility

Technical sections are equipped with enough electricity, light, ventilation and water supply to allow for the correct performance of examination procedure.

Waste disposal bins and sharps containers are also available for safe disposable of solid waste while designated drainage system is used for disposing liquid waste (refer to safety manual and health and safety guideline for public health laboratories in Ethiopia_(ED-02).

The laboratory is safe environment for staff by having firefighting equipment which is serviced annually by external contractors, first aid kit, and spill kit in common which is checked for functioning monthly by Safety Officer.

Storage facilities

Bekoji Hospital laboratory has enough storage facilities for reagents, consumables, samples, equipments, records and documents. Samples and reagents are kept in different refrigerators to avoid cross contamination.

Staff facilities

Bekoji Hospital laboratory has enough washrooms, clean supply of drinking water and storage facilities for personal protective clothing and equipment.

Patient sample collection facilities

Bekoji Hospital laboratory has a separate patient waiting area and sample collection room where patients are served one at a time for privacy and confidentiality. Toilets are also available for patients. Sample collection room is equipped with sample collection materials. A first aid kit which is checked for functioning by Safety Officer is available in the sample collection room for use on staff and patient.

Facility maintenance and environmental conditions

Environmental temperatures are monitored daily and benches are decontaminated daily by laboratory staffs in respective sections. Floors are cleaned once daily by janitors. Additional cleaning is done between run if it is necessary.

Different examination procedures are done in separate rooms to avoid cross contamination.

Supporting document

Safety manual_ BHL-SM-03

health and safety guideline for public health laboratories in Ethiopia_ ED-O2

Temperature monitoring charts_ BHL-5.2-F-001

Eye wash station maintenance chart_ BHL-5.2-F-002

Emergency shower maintenance chart_ BHL-5.2-F-003

First aid kit monitoring chart_ BHL-5.2-F-004

Spill kit monitoring chart_ BHL-5.2-F-005

Laboratory equipment, reagents, and consumables

Equipment

5.3.1.1 General

Bekoji Hospital laboratory has a procedure (BHL-MSOP-13) for equipment management, which gives details on the selection, purchasing and management of equipment. BHL furnished with all equipment needed for the provision of services in its scope including for sample collection, sample preparation and sample processing. BHL does not use equipment outside its permanent control.

Equipment acceptance testing

Bio-medical engineers from the supplying company perform installation of new equipment and generate all necessary records proving that installation passed. After successful installation, staffs are trained on operating and maintaining the equipment.

Trained staff analyzes known samples on the equipment to ensure proper functioning of equipment. Laboratory head is responsible for ensuring operator qualification is done

Studies to verify that the equipment performs as intended by the manufacturer and as expected by BHL are done. Quality officer is responsible for ensuring performance qualification is done.

Their serial numbers uniquely identify all equipment's and laboratory generated ID numbers.

Accept equipment by checking and record equipment acceptance criteria checklist_ BHL-5.3-F-001

5.3.1.3 Equipment instructions for use

BHL has authorized its trained staff to perform examination procedures including use of equipment. Equipment manuals are readily accessible to staff. Procedure for equipment management (BHL-MSOP-13) gives guidelines and makes reference to equipment manuals on safe handling, transportation and storage of equipments to prevent its contamination or deterioration.

5.3.1.4 Equipment calibration and metrological traceability

BHL outsource calibration service of its ancillary equipment such as thermometers, micropipettes, centrifuges from National metrology institute of Ethiopia.

Assay calibration of analyzers is done as per operator manual.

5.3.1.5 Equipment maintenance and repair

BHL has preventive maintenance program for its equipment which is developed based on manufacturer recommendations as given in equipment manual. Annual and/or bi-annual service of equipment by engineers is organized by EPHI who enter in to service agreement with the vendors.

Defective equipment's are decontaminated and clearly labeled as "**do not use**" and date when equipment broke down. The engineer is shown record of equipment decontamination (BHL-5.3-F-002) and provided with personnel protective equipment's before performing any repairs or service. After service or repair, equipment is checked for proper function by analyzing calibration and control materials and obtaining expected results.

Laboratory head is responsible for assessing results released from the equipment before it broke down and any affected samples are reanalyzed, affected results recalled and corrected result reissued.

When any equipment is taken out of the laboratory for services /repairs, laboratory head /quality officer ensure its proper function by calibrating and running controls upon its return.

Equipment adverse incident reporting

Any adverse incidents and accidents that can be attributed directly to equipment are investigated by laboratory personnel and reported to laboratory head and the laboratory head report to Medical director who in turn reports in writing to , ORHB or directly to the vendors. And record on equipment adverse incidence report (BHL-5.3-F-003)

5.3.1.7 Equipment records

Laboratory head maintain equipment records on equipment inventory form (BHL-5.3-F-004) and in book of life. Equipment records are retained for periods defined in documents and record retention time (BHl-4.5-F-004).

Reagents and consumables

General

BHL has a procedure (BHL-MSOP-14) for reagents and consumables management which defines how reagents and consumables are received, accepted, stored and inventory controlled.

Reagents and consumables – Reception and storage

A laboratory head is responsible for receiving and ensuring proper storage of reagents and consumables according to manufacturer recommendations. Reagents are received according to criteria in checklist BHL-5.3-F-005.

Reagents and consumables – Acceptance testing

Quality control is done for each shipment of reagents received and records are maintained by laboratory staffs. Where quality control cannot be done immediately after receipt, the reagents are clearly labeled as “waiting for QC”. The label is removed after QC performed.

Reagents and consumables – Inventory management

The mini store room of BHL has bin card (ED-03) for monitoring consumption of reagents and consumables that includes stock level, expire date, lot number and balance. Laboratory staff update the reagent daily consumption log (BHL-5.3-F-006). Physical inventory of reagents and consumables is done quarterly by Store man on form number BHL-5.3-F-007.

Reagents and consumables – Instructions for use

Laboratory staff maintain leaflet for reagents and consumables in their respective sections for making reference when required. A file of Material Safety Data Sheet (MSDS) ED-07 is kept in mini store room.

Reagents and consumables – Adverse incident reporting

Any adverse incidents and accidents that can be attributed directly to reagents and consumables are investigated by staffs and reported to laboratory head and the laboratory head report to Pharmacy unit who in turn reports in writing to OPHRCBQAL, Zonal health department , and PFSA or directly to the vendors.

Reagents and consumables – Records

Reagent receiving checklist, bin card, quarterly physical Inventory and reagent daily consumption log are used together to ensure records for reagents and consumables are maintained.

Supporting documents

Procedure for equipment management _ BHL-MSOP- 13

Procedure for reagent and consumable management _ BHL-MSOP- 14

Check list for receiving reagents and consumables _ BHL-5.3-F-005

Bin Card _ ED-03

Equipment decontamination form _ BHL-5.3-F-002

Equipment inventory form _ BHL-5.3-F-004

Document and record retention time form _BHL-4.5-F-004

Reagents daily consumption log _ BHL-5.3-F-006

Physical inventory count form _ BHL-5.3-F-007

Checklist for receiving equipment_BHL-5.3-F-001

Pre examination processes

General

BHL has procedure for collection, handling, packaging and transportation of specimen (BHL-MSOP-15) to ensure the validity of the test result of examination

Information for patient and users

BHL has a developed a laboratory hand book (BHL-LHB-02) giving details on information for pre-examination processes to be used by patient, clinician and customer.

The laboratory hand book (BHL-LHB-02) includes:-

The location of the laboratory

Type of clinical service offered by the laboratory

Opening hours of the laboratory

Primary sample volume, special precautions

Turnaround time

Instruction for completion of request form

Instruction of preparation of patient

Instruction for patient collected samples

Instruction for transportation sample

Accepting and rejection criteria

Preservative used

Patient information confidentiality

Laboratory complaint procedure

Request form information

BHL uses ministry of health request form for ART monitoring (ED-04), for HIV DNA-PCR (ED-05), for TB request form (ED-06), and for other tests use internally developed request form.

Request forms used in BHL contain the listed information but not limited

Patient identification include sex, date of birth/age, location, contact details of the patient and MRN

Name and signature of requesting clinician

Type of primary sample

Examination requested

Clinical relevant information

Date and time of primary sample collection

BHL accept verbal request on sample already submitted to the laboratory however, the requesting clinician is required to send the signed request form before the result can be released. Procedure for verbal request (BHL-MSOP-16) is available to be followed by staff.

BHL has enough, secure storage facilities for samples to ensure they do not deteriorate during pre-examination activities, handling and preparation. Time limits for additional request are defined in the Laboratory hand book.

Primary sample collection and handling

BHL has a procedure (BHL-MSOP-15) which gives clear instruction for sample collection and handling.

Sample transportation

BHL has a procedure (BHL-MSOP-15) which gives clear instruction for sample transportation

Supporting document

laboratory hand book_ BHL-LHB-02

HIV1 DNA-PCR request form _ED-05

ART monitoring request form _ED-04

TB request form_ ED-06

Procedure for verbal request _ BHL-MSOP-16

Examination Processes

Selection, verification and validation of examination procedures

General

BHL uses well known examination methods which are well referenced from literature and equipment that is validated by their manufacturers for intended use. Laboratory experts performing examination activities are identified by their initials in request paper.

Verification of examination procedures

BHL uses the examination methods and equipment's as acquired from manufactures without any modifications. Studies to verify that these methods perform as intended are done before they are put into use or when major parts like mother board of equipment are replaced. Verification studies take into account performance claims by manufactures as well as expectations of laboratory as acceptability criteria for approving method for use. A procedure for verification of examination method (BHL-MSOP-17) has been developed which defines the different studies to be considered when verifying both quantitative and qualitative methods. A verification protocol is developed by Quality officer, reviewed and approved by Laboratory head. The protocol defines objective, method and materials, result analysis, interpretation, acceptability criteria and responsibilities of performing study. Review and approval of verification result is done by quality officer and laboratory head.

Validation of examination procedure

BHL does not use any non standard methods, nor does not design, developed or modify any methods. Therefore BHL dos not perform any validation of methods.

Measurement uncertainty of measured quantity values

BHL has determined uncertainty of measurement values (BHL-5.5-F-001) of its quantitative methods to be used when helping clinicians to interpret patient results, and to determine the inherent error in the system. BHL has defined expected values of measurement uncertainty of each quantitative method and these are compared with values obtained from annual estimates. A procedure for uncertainty of measurement (BHL-MSOP-18) has been developed to guide staff in estimating uncertainty of values. When clinicians or other stake holders request uncertainty of measurement of values BHL cooperates.

Biological reference intervals or clinical decision values

BHL has adopted biological references from kit inserts and this has been communicated to health facilities through the Laboratory hand book. Critical values have been established in consultation with local clinicians and are also communicated to patient and clinician though Laboratory hand book. Whenever examination procedures are changed such that reference ranges and critical values are different, the laboratory hand book is updated and clinicians are informed by laboratory.

Documentation of examination procedures

BHL has documented all examination procedures used in its different sections and available at each work station. Job aids used for quick reference at some work stations have ID numbers which correspond to a documented procedure. All examination procedures and job aids are controlled according to document control procedure (BHL-MSOP-01).

All examination procedures are written in standard format as defined in document control procedure which complies with the requirements of ISO 15189:2012.

If BHL intends to change any examination procedures such that results or their interpretations could be significantly different, the implications are explained to clinicians and patient before putting new procedure in service.

Supporting documents

procedure for verification of methods _ BHL-MSOP-17

uncertainty of measurement values form _ BHL-5.5-F-001

procedure for uncertainty of measurement _ BHL-MSOP-18

procedure for document control _ BHL-MSOP-01

Ensuring Quality Of Examination Results

General

BHL is implementing quality management system to ensure that examinations performed are standardized. All staffs have declared in the ethical conduct form (BHL-4.1-F-001) that they will not fabricate any results.

Quality control

General

BHL has defined frequency and type of internal quality control procedures in each technical standard operating procedure that verify the attainment of the intended quality of results.

Quality control materials

BHL uses commercial and/or in-house internal quality control materials that react to the examining system in a manner as close as possible to clinical sample. The frequency of examining quality control materials is defined in each technical standard operating procedure and is based on stability of the procedure and risk of harm to the patients from erroneous results.

Quality control data

Procedure for review of quality control data (BHL-MSOP-19) has been developed to guide staff on reviewing and interpretation of quality control results which prevents release of patient results in event of quality control fail. When quality control chart and multi rule systems detect any random or systematic errors, preventive actions are put in place. Laboratory staffs review quality control data on a daily bases while Quality Officer review the data monthly.

Inter-laboratory comparisons

Participation

BHL participates in external quality assessment (EQA) for all its examination methods on a quarterly and biannual provided by OPHRCBQAL and Three times a year provided by one world accuracy. The Quality Officer and laboratory staffs performing EQA samples monitor results and implement corrective actions when results are unacceptable. Procedure for participation in EQA (BHL-MSOP-20) has been developed which defines instructions for participation and review of the performance. The EQA programs are adequate to check the entire examination process including pre-examination and post-examination process in a manner that resembles as close as possible to patient samples.

Analysis of inter-laboratory comparison samples

BHL ensures that EQA samples are integrated into routine work flow in a manner that resembles handling of patient samples. The EQA samples are analyzed by laboratory staffs who analysis routine patient samples using the same examination procedures. Laboratory staffs are not allowed to communicate with other participating laboratories about EQA sample data until after results are submitted. EQA samples are not referred to other laboratory for confirmatory tests nor are staffs advice sought. Staffs are bound by ethical conduct declaration (BHL-4.1-F-001) to abide by this regulation.

Evaluation of laboratory performance

Quality Officer and laboratory staffs of involved in analyzing EQA samples are responsible for review of performance and implementing corrective actions when results are not acceptable. Laboratory staff monitors the effectiveness of corrective action taken through daily internal quality control and subsequent EQA. Quality officer compile annual report on performance in EQA which is used as preventive actions to detect trends. The reports are presented and discussed in management reviews.

Comparability of examination results

BHL conduct annual comparison studies on equipment or examination methods performing the same tests in order to have confidence in using methods parallel to each other. Any differences in comparability and their effect to patient samples are discussed with clinicians during annual review meetings. Laboratory staff persons maintain comparability records and any actions taken as a result of problem identified.

Supporting documents

procedure for review of internal quality control results _ BHL-MSOP-19

Procedure for participation in EQA _ BHL-MSOP-20

ethical conduct declaration form_ BHL-4.1-F-001

Post- Examination Processes

Review of results

BHL has procedures (BHL-MSOP-21) to ensure results are reviewed and released by authorized laboratory personnel. The review process takes into account results of internal quality control and clinical history of the patient.

Storage, retention and disposal of clinical samples

BHL has a procedure (BHL-MSOP-22) for sample management which defines identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.

The period of sample retention is defined in sample retention schedule (BHL-5.7-F-001).

Samples are safely disposed in accordance with health and safety guideline for public health laboratories in Ethiopia (ED-02).

Supporting document

procedure for reporting and releasing result _BHL-MSOP-21

procedure for sample management_ BHL-MSOP-22

sample retention schedule_ BHL-5.7-F-001

Health and safety guideline for public laboratory in Ethiopia_ED-02

Reporting of Result

General

BHL report results by writing on request paper manually which ensures accuracy, clarity, unambiguously in accordance to procedure for reporting and releasing of results (BHL-MSOP-21) and as per examination procedures. Result review process ensures checking of transcription or transmitting errors before results are released by authorized laboratory personnel. Reports are released with reference ranges, in SI unit, with clinic history of patient and accompanied by any relevant comments on integrity of sample. This ensures correct interpretation of laboratory results. Transistor of BHL will give OPD results to respective units.

Report attribute

Laboratory personnel authorized to report results ensure that where relevant:

Comments on sample quality that might compromise examination results are made;

Comments on regarding sample suitability with respect to acceptance/rejection criteria are made;

Critical results are timorously communicated through as fast as possible verbally or telephone on the report:

Interpretive comments are made.

Report content

BHL report content Include but not limited

identification of the examination

the identification of the laboratory that issued the report;

identification of all examinations that have been performed by a referral laboratory;

patient identification and patient location

name and signature of the requester

date of primary sample collection (and time, when available and relevant to patient care);

type of primary sample;

examination results reported in SI units, units traceable to SI units, or other applicable units;

biological reference intervals, clinical decision values

interpretation of results

comments which may have compromised the result

identification of the person(s) reviewing the results and authorizing the release of the report

date of the report, and time of release (if not contained in the report, readily available when needed);

page number to total number of pages

Supporting document

Procedure reporting and releasing result_ BHL-MSOP-21

Acceptance and rejection criteria_ laboratory. Hand book

Release Of Results

General

BHL has a procedure for reporting and releasing of results (BHL-MSOP-21) which guide authorized laboratory personnel on how to release results and to whom. BHL does not issue results of infectious diseases (HIV screening test) directly to patients. Such results are communicated to requesting clinicians

Staffs ensure that when suitability of primary sample was compromised, it is indicated in the report. Laboratory personnel are responsible for communicating critical results to clinicians through laboratory transistor or by verbally with the clinicians or nurses and ensuring that the report gets to the units in the shortest possible time. When interim reports are issued pending confirmatory test, laboratory personnel ensure the final report is issued in the shortest possible time. When results are communicated through telephone, the laboratory personnel ask the identity of the received person to ensure that results reach only authorized personnel. Such communications are captured in communication log (BHL-4.4-F-001).

Automated selection and reporting of results

BHL does not operate a system which automatically selects and report results. All results are verified manually by authorized personnel before releasing.

Revised report

Procedure for reporting and releasing of results (BHL-MSOP-21) gives instructions on how to revise original reports. Laboratory staffs authorized to revise reports ensure that:

the revised report is clearly identified as revised and makes reference to the date and patients identity in the original report;

the requesting clinician is made aware of the revision and original report is recalled by laboratory head and revised report is re-issued;

the revised report shows date and time of the change and name of person responsible for the change;

the original report entries remain in the records when revisions are made;

The responsible person maintains records of revised reports.

Supporting documents

Procedure for reporting and releasing of results_ BHL-MSOP-21

communication log _BHL-4.4-F-001

Laboratory information management

General

BHL staffs have access to data and information needed to provide service which meets the needs and requirement of patients. Procedure for ensuring confidentiality of patient information (BHL-MSOP-23) is available and staff have also signed ethical conduct declaration (BHL-4.1-F-001) preventing them from disclosing patient confidential information from unauthorized persons.

Authorities and responsibilities

Bekoji Hospital laboratory staffs are authorized through their job descriptions to perform one or all of the following:

access patient data and information;

enter patient data and examination results;

change patient data or examination result;

release examination result and report

Information system management

Bekoji hospital has 24 hour security. All staffs are issued with ID card to enter in to the compound and to the laboratory. This ensures the Laboratory information system is protected from unauthorized persons as well as from tempering or loss.

Supporting documents

Procedure for ensuring confidentiality of patient information_ BHL-MSOP-23

procedure for the operation and maintenance of Laboratory information system_ BHL-MSOP-24

7.5 References

ISO 15189:2012 – Medical Laboratories – Particular requirements for quality and competence

QMS 02-A6, Quality management system: development and management of laboratory documents; approved guideline- six edition. February 2013

AMMENDMENT SHEET

Proposed by	Section	Summary of Changes	Date of amendments
Quality officer	Quality officer office	Align to ISO 15189:2012	xxx

I have read, understood and agree to follow the quality manual as documented:

No	**Name**	**Signature**	**Date**

CHAPTER IX

9. Standard Operating Procedure for Tuberculosis Acid Fast Bacilli Microscopy, External Quality Assessment

Authors: Jemal Hassen[1], Daba Muleta[2]

Affiliations: [1]Ethiopia Field Epidemiology Training Program; [2]Oromiya Public Health Research, Capacity Building, Quality Assurance Laboratory

Purpose

This procedure provides instructions for Tuberculosis Acid Fast Bacilli (TB AFB) Microscopy External Quality Assessment.

Scope

This Standard Operating Procedure (SOP) describes external quality assessment of acid-fast bacilli smears stained by the Ziehl–Neelsen or fluorescent dye technique by rechecking of a random and representative sample of the routine work. This method is considered to be the most efficient since it allows monitoring of daily performance and, if well performed, is motivating for staff. Through continuous screening for substandard performance followed by identification and solving of problems, it aims to achieve optimal results in all laboratories of a network performing AFB smear microscopy.

2.1 Responsibility

External Quality Assessment (EQA) sub-process coordinator and EQA experts are responsible for ensuring effective implementation and updating of this procedure based on the national EQA guide line.

2.2 Principle

To guarantee representativeness, all examined smears are kept by each laboratory. Regardless of results, a sample of smears is periodically selected at random by a visiting supervisor. The samples are given to a first-level controller, for blinded re-reading; the list of results stays with the

supervisor. The supervisor compares the results obtained by the laboratory and by the first-level controller, and makes a list of smears for which results are discordant.

The list and the discordant smears are given to a second-level controller for more careful examination and correct results. The EQA coordinator then uses the correct results to identify errors and determine whether they were made by the original laboratory or by the first-level controller. Routine feedback is given as frequently as possible during this process by returning results and any slides with serious errors. Final analysis must wait until a full year's sample have been processed. Except in extreme cases, only then is it possible to identify the laboratories that have failed this screening process.

Further investigation of failing laboratories is needed for confirmation and to identify and solve the underlying problems. In the worst cases this will be done during a supervisory visit by a laboratory expert. The performance of second-level controllers must also be evaluated to ensure that the system works reliably.

Reagent and supplies (Materials)

Slides

Slide box

Immersion Oil

Pen

Pencil /Diamond pencil

Equipment

Bright filed and /or Flourcent Microscopy

Specimens

Blood, Cerebrospinal fluid (CSF) and other boy fluids, discharges from the eyes and ears, genital, stool, respiratory specimens (e.g., sputum, tracheal aspirates, bronchoalveolar lavage), throat swabs, urine, wound swabs or pus and tissue, and other specimens as appropriate.

Environmental and Safety Precautions

5.1.1 Use appropriate personal protective equipment (PPE) (e.g., gloves, gowns) when collecting specimens.

Use leak proof specimen containers and transport the containers within a sealable leak proof plastic bag with a separate compartment for paper work. Bags should be marked with biohazard labels.

Never transport syringes with needles attached to the laboratory. Instead transfer contents to a sterile screw-cap tube and place tube in a sealable leak proof plastic bag.

Do not transport leaking specimen containers to the laboratory or process them. If a new specimen is submitted, autoclave and discard the leaking one. If another specimen cannot be obtained, e.g., needle aspirates, body fluids, use appropriate PPE and process the specimen in a biological safety cabinet.

Monitor room temperature and record on System Form(SF) 26.

Decontaminate and clean work area twice daily and record on SF 50.

Calibration

Not applicable

Quality control

Not applicable

Procedure

Selection and Collection of Specimens. *Refer to Appendix A*

The following instructions are applicable for specimen selection and collection from all sites. Collect samples before starting antibiotics.

Select the proper anatomic site from which to collect the specimen.

Avoid contamination with indigenous flora as this may overgrow and obscure the growth of true pathogens in cultures.

Observe careful skin preparation before procedures such as blood cultures and spinal taps to decrease the chance that organisms normally present on the skin will contaminate the specimen.

Collect by proper technique.

Use appropriate collection material.

Collect in appropriate containers.

Collect sufficient volume of material to enable all test requests to be performed satisfactorily. Insufficient material may yield false negative results.

Specimen Labeling

Each specimen must be clearly labeled with the following;

patient identifiers, usually patient name and hospital or clinic number

Type of specimen – indicate specific body site

Date and time collected

These information must be present on the specimen container so that the specimen can be matched up with the requisition when it is received in the laboratory.

Note: labels shoul be placed on the specimen container, not on the lid.

Specimen Requisition

Each specimen must be accompanied by a requisition form. The requisition should contain appropriate clinical information that will help the microbiologist working up the specimen to determine the significance of organisms obtained on culture.

A completed requisition should include all the following.

Patient's name and identification number (patien'ts unique identifier)

Patients adress or location (Hôpital Ward, clinc, etc.)

Patient's age and sex

Description of and source of specimen

Date and time of specimen collection

Name of collector

Test requested

Name of requestor/ordering physician

Indicate if test is urgent or routine

Any antibiotics patient may be on

Any other pertinent medical information

Specimen Transport and Storage

Ideally specimens should be sent to the laboratory as soon after collection as possible and processed immediately on receipt in the laboratory. This is not always possible in a busy hospital or laboratory. The following are general guidelines for transport and storage of specimens for culture:

Specimens must be delivered to the laboratory immediately on collection. This is essential in the case of CSF's and other body fluids and all tissue specimens.

All other specimens (routine specimens) should be submitted within 2 hours of collection.

If there is a delay in transport the specimens should be refrigerated- except for blood, body fluids, tissue, genital, eye and inner ear specimens. Exposure to temperature extremes must be avoided.

Specimens stored for > 24 hours are not suitable for culture.

Transportation of clinical specimens and transportation of infectious substances from one health care facility or laboratory to another, regardless of the distance, requires strict attention to specimen packaging and labeling instructions.

Specimen Rejection Criteria

Culturing an improperly collected specimen, unlabeled specimen or inappropriately handled specimen seldom leads to clinically useful information. It is important to remember that the results forms for specimen culture are used to make critical decisions about patient care. If those results cannot be relied upon, patient care suffers. Rejection of a specimen is not a punitive measure but is essential for quality patient care. Individuals submitting specimens to the laboratory must know what criteria are being used to assess the acceptability of specimens.

General criteria for specimen rejection are divided into categories:

Clerical error

Unlabeled specimen container

No test requisition form

Test or patient information not indicated on requisition form

No collection date on requisition form

Specimen source not noted

Container and requisition form information does not match, often clerical errors can be rectified by notifying the individual who collected the specimen. For example, if a specimen is unlabeled and the nurse is notified, he/she may come down and identify the specimen and label it. In this scenario, it is important to document what occurred.

General Microbiology rejection criteria

Specimen received in fixatives

Improper or non-sterile container

Quantity of specimen not sufficient

Leaking container or outside of container contaminated with specimen

Requisition form soiled by specimen

Dry swab

Specimens received in non sterile containers (stool cultures may be in “clean” containers)

More than one specimen submitted on the same day from the same source (urine, stool, sputum, throat)

Specimen collected from inappropriate site

Specimen specific criteria

Urines

Foley Catheters

Urine from catheter bag

Urine greater than 24 hours from collection

Sputum

Sputum with squamous epithelial cells (SEC) >10/low power field (LPF)

Sputum standing for more than 24 hours from collection

CSF

CSF specimens not delivered immediately on collection-may be processed once the ward has been notified-see below under corrective action.

Refrigerated

Anaerobic cultures

Specimen received in improper transport media

Inappropriate source – urine, sputum, throat, stool, vaginal secretions, decubitus ulcer and other specimens likely to be contaminated with normal flora anaerobic organisms

Corrective action to be instituted as soon as possible when a specimen is rejected:

Contact physician or nurse in-charge and request another sample, if possible. If the cause of the rejection is a clerical error, it may be possible to resolve the problem.

If the specimen cannot be recollected (surgical specimen, biopsy or CSF for example), the issue is discussed with the physician. It may be possible to culture the specimen with a disclaimer indicating on the report the problem, it is important to include the name of the physician taking responsibility for accepting the specimen.

Specimen-related problems and corrective action taken must be properly documented.

Data on rejection of specimens are used for quality improvement.

Collected and received sample should be recorded on specimen accession log TF 001.

If the sample is rejected it should be recorded on sample rejected log SF 54.

Calculation

Not applicable

Performance characteristics

Not applicable

Uncertainty of measurement

Not applicable

Interferences/limitation

inappropriate sample collection

Inappropriate way of sample transportation and storage

Critical values

Not applicable

Result reporting

Not applicable

Result Interpretation

Not applicable

Biological reference interval

Not applicable

Supporting documents

Room temperature monitoring record _SF 26

Decontamination and cleaning of work area record _ SF 50

Specimen accession log_ Technical Form(TF) 001

Sample rejection log_SF 54

References

Manual of Clinical Microbiology. American Society for Microbiology (ASM), Washington D.C., USA. 9th edition, 2007.

The African Field Epidemiology Network: Outbreak Investigation Laboratory Guidelines.CDC, USAID, AFENET.

Guide for National Public Health Laboratory Networking to Strengthen Integrated Disease Surveillance and Response. WHO, CDC, USAID. Brazzaville, Republic of Congo. 2008

Appendices

Appendix A: Collection and Transport Requirement for Specific Specimens

Appendix B: Microbiology Test Requisition Form

Appendix A: The following table summarizes the collection and transport requirements for specific specimens.

SPECIMEN	COLLECTION	TRANSPORT CONTAINER	TRANSPORT TIME	COMMENTS
Blood	Cleanse venipuncture site with 70% alcohol followed by Iodine. .	Inoculate the blood into the Blood culture bottle immediately.	Immediately on collection. **Do not refrigerate**	Volume**-Adults** 8-10 ml/bottle 2- 3 cultures per septic episode. **Infants** 1-2 ml
Body Fluid	Cleanse skin as above-collected by physician	Sterile screw cap tube	Immediately on collection **Do not refrigerate**	Volume-5 ml (minimum-1ml)
CSF	Cleanse skin as above-collected by physician	Sterile screw cap tube	Immediately on collection **Do not refrigerate**	Volume-5 ml (minimum-1ml)
Conjunctiva/ Eye	Cleanse skin around the eye with a mild antiseptic and swab infected area	Swab in Transport Media	Within 2 hours of collection	Submit a swab from the uninfected eye for comparison

Ear (Otiits Externa)	Remove debris; collect specimen by rotating the swab in the ear canal.	Swab in Transport Media	Refrigerate if >2hour delay in transport	Inner ear specimens are collected by a physician
Genital Females	Cervix and vagina-use a non-lubricated speculum and swab affected site.	Swab in Transport Media	For diagnosis of ***N.gonorrhoeae*** transport immediately Vaginal swabs - refrigerate if >2 hour delay in transport	For diagnosis of ***N.gonorrhoeae*** submit swab in charcoal Transport Media. **Do not refrigerate**
Genital Males & females	Swab urethra, collect discharge	Swab in charcoal Transport Media	For diagnosis of ***N.gonorrhoeae*** transport immediately	As above
Sputum	Freshly expectorated sputum	Sterile wide-mouthed container	Refrigerate if > 2 hour delay in transport	Delay of > 2hours compromises the ability to isolate fastidious organisms
Stool	Freshly passed stool	Sterile/ clean container	Refrigerate if > 2 hour delay in transport	Rectal swabs in Transport Media are acceptable
Throat	Swab of pharynx and tonsils	Swab in Transport Media		Avoid touching mouth or gums

				with the swab
Urine	Mid-stream, clean catch, catheter, cystoscopy	Sterile wide-mouthed container	Refrigerate if > 2 hour delay in transport	24 hour urines and those from catheter bags are unacceptable
Wound	Aspirate, swab of pus, tissue	Swab in Transport Media Aspirate , tissue in sterile container	Aspirates and tissues to be delivered immediately Refrigerate swab if delay in transport media	

NOTE: TM = Transport Media.

Specimens must be delivered to the laboratory immediately on collection. This is essential in the case of CSF's and other body fluids and all tissue specimens.

All other specimens- routine specimens- should be submitted within 2 hours of collection.

If there is a delay in transport the specimens should be refrigerated- except for blood, body fluids, tissue, genital, eye and inner ear specimens.

Specimens stored for > 24 hours are not suitable for culture

AMMENDMENT SHEET			
Proposed by	***Section***	***Summary of amendment***	***Date of amendments***

Declartion

I have read and understand this SOP and I agree to consistently follow the procedure as described.

Print Name	Signature	Date

DEACLARATION

I, the under signed, declared that this is my Bona Fide original work, has never been presented in this or any other University, and that all the resources and materials used for the body of work with thesis, have been fully acknowledged. Student

Name: _____

Signature: _____

Date: _____

Place: _____

Date of submission: _____

This body of work with thesis has been submitted for examination with our approval as Candidate's advisors.

Name of Primary advisor_____

Signature _____

Date _____

Name of Co-advisor _____

Signature _____

Date _____

Name of FETP Coordinator_____

Signature _____

Date _____

DEACLARATION

As members of the Board of Examiners of the final body of work with thesis open defense, we certify that we have read and evaluated the body of work with thesis prepared by _____ under the title "_____" and recommencement for the degree of Master of Public Health in Field Epidemiology.

Name of the Chairperson _____

Signature _____

Date _____ _____

Name of Primary Advisor _____

Signature _____

Date _____ _____

Name of Co-advisor_____

Signature _____

Date _____ _____

Name of Internal Examiner Signature _____