St. Paul's Hospital Millennium Medical College, Department of Public Health

Compiled Body of Works in Field Epidemiology

BY: BIRHANU LEGESE, BSc

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

March, 2018

Addis Ababa, Ethiopia

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I. Declaration

I, the undersigned, declared that this is my 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.

Name of the student: -BIRHANU LEGESE TSEGAYE

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Place _____

Date of Submission _____

Approval of Advisors

This body of work with thesis has been submitted for examination with our approval as candidate's advisors.

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ST PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE DEPARTMENT OF PUBLIC HEALTH GRADUATE STUDIES FINAL THESIS APPROVAL FORM

As member 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 in Field Epidemiology prepared by **BIRHANU LEGESE TSEGAYE** under the title "***Compiled body of work in Field Epidemiology***" and recommencement for the degree of Master of Public Health in Field Epidemiology.

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II. Acknowledgment

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Afar Regional Health bureau

III. Table of Contents

I. Declaration I
II. Acknowledgment III
III. Table of Contents IV
IV. Lists of tables V
V. Lists of figures VII
VI. Lists of Annexes VIII
VII. Abbreviations and acronyms IX
VIII. Executive summary XIII
CHAPTER 1: OUTBREAK INVESTIGATION 1
Rotavirus Outbreak Investigation in Dano Woreda, W/Shewa Zone, Oromia Regional State, 2017 1
CHAPTER 2: SURVEILLANCE DATA ANALYSIS 32
A Report on Surveillance Data Analysis of Suspected Meningitis in East Shewa Zone, Oromia Regional State; September 2004-August 2007 EFY 32
CHAPTER 3- SURVEILLANCE SYSTEM EVALUATION 56
Surveillance system evaluation of Maternal Death and Epidemic Typhus in Ada'a woreda, E/shewa zone, Oromia Regional State, 2017 56
CHAPTER 4: HEALTH PROFILE DESCRIPTION REPORT 118
Health Profile description report, Mojo Town Administration East Shewa Zone, Oromia Regional State; 2007 EFY (2014/2015) 118
CHAPTER 5: SCIENTIFIC MANUSCRIPT TO PEER REVIEWED JOURNALS 143
Rotavirus Outbreak among Young Children−Dano Woreda, Oromia Region, Ethiopia, 2017 Rotavirus Outbreak among Young Children−Dano Woreda, Oromia Region, Ethiopia, 2017 143
CHAPTER 6: ABSTRACTS TO SCIENTIFIC CONFERENCES 171
Rotavirus Outbreak among Young Children−Dano Woreda, Oromia Region, Ethiopia, 2017 171
Suspected Meningitis Cases Surveillance data analysis in Oromia Regional State, Ethiopia 173
CHAPTER 7: QUALITY MANUAL 174
BATU HOSPITAL LABORATORYORATORY QUALITY MANUAL 174
CHAPTER 8: STANDARD OPERATING PROCEDURES 216
PROCEDURE FOR VIKIA HIV ½ RAPID TEST FOR DETECTION OF HIV 1 & HIV 2 ANTIBODIES 216
PROCEDURE FOR WANTAI RAPID TEST FOR DETECTION OF HIV 1 & HIV 2 ANTIBODIES 224
CHAPTER 9: NARRATIVE SUMMARY OF LABORATORY REPORT 230
10. CHAPTER 10:THESIS 248

IV. Lists of tables

Table 1-1: Socio- demographic characteristics of cases and controls on rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 18
Table 1-2: Bivariate analysis of all variable for rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 19
Table 1-3: Multi variable logistic regression analysis of risk factor and protective factors of rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 20
Table 2-1 Incidence of suspected meningococcal meningitis in Showa zone, 2004 – 2007 EFY 43
Table 2-2 Meningitis cases by age East Shewa Zone 2004 -2007 EFY 46
Table 2-3 Incidence of meningitis in East Shewa Zone by Wereda and year, 2004-2007EFY 48
Table 3-1: Population under surveillance in Ada'a Woreda in 2016 67
Table 3-2: Reporting rates of the health facilities in Ada'a woreda Week 50, 2016 to Week 9, 2017 69
Table 4-1: Population size of Mojo by Age categories, 2007EFY 126
Table 4-2 Total number of teachers and students in Mojo Town 2007EFY 128
Table 4-3: Health institution in Mojo Town number and type, 2007 EFY 115
Table 4-4: Health professional of Mojo Town in 2007EFY 115
Table 4-5: Top ten causes of und five years morbidity in Mojo town 2007EFY 116
Table 4-6: Top ten causes of und five years morbidity in Mojo town 2006-2007EFY 117
Table 4-7: Vital statistics of mojo town 2006-2007 118
Table 4-8: Immunization coverage of Mojo town 2006-2007EFY 118
Table 4-9: MCH and family planning service performance in Mojo Town, 2006-2007 119
Table 4-10: cases of TB in Mojo Town 2005-2007 EFY 121
Table 4-11: Cases malaria in Mojo by age in200-2007EFY 122
Table 4-12: HIV positive case in Mojo by sex 2005-2007 123
Table 4-13: Some immediately and weekly reportable diseases in Mojo town 2007EFY 124
Table 5-1 Socio- demographic characteristics of cases and controls on rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 152
Table 5-2: Multi variable logistic regression analysis of risk factor and protective factors of rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 153
Table 5-3: Incidence of suspected meningococcal meningitis in Showa zone, 2011 – 2014 162
Table 5-4: Suspected meningitis cases by age East Shewa Zone 2011 -2014 164
Table 5-5 Incidence of meningitis in East Shewa Zone by Wereda and year, 2011-2014 167
Table 9-1: Testes performed in TB laboratory from January to May 2017 236
Table 9-2: Total samples processed by culture in bacteriology laboratory January to May 2017 238
Table 9-3: Type of samples processed by culture in bacteriology laboratory January to May 2017 238
Table 9-4: Total reagents prepared in reagent preparation section 245
Table 10-1: Socio-Demographic characteristic of laboratory professionals working on malaria microscopy, Afar Regional State, North East Ethiopia, 2017 271
Table 10-2 Quality assurance of malaria microscopy among laboratory professionals working in Afar Regional State, North East Ethiopia, 2017 272
Table 10-3: Overall agreement of WHO malaria expert malaria slides reading and Laboratory professionals malaria slides, Afar Region North Eat Ethiopia, 2017 273
Table 10-4: Species identification accuracy of WHO malaria expert malaria slides reading and laboratory professionals malaria slides, Afar Region North Eat Ethiopia, 2017 273

Table 10-5: Performance level of laboratory professionals on malaria microscopy, Afar Regional State, Ethiopia, 2017 275
Table 10-6 Overall Performance of laboratory professionals on Sensitivity, specificity and P.F detection, Afar Regional state, North East Ethiopia, 2017 276
Table 10-7 Bivariate analysis of associated factors to performance of laboratory professionals on malaria microscopy, Afar Region, North East Ethiopia, 2017.....277
Table 10-8 Multivariable logistic regression analysis of associated factors to performance of laboratory professionals on malaria microscopy, Afar Region, North East Ethiopia, 2017.....279

V. Lists of figures

Figure 1-1: Map of rotavirus outbreak area, Dano Woreda West shewa zone Oromia Regional State, 2017 9
Figure 1-2: The date of onset rotavirus outbreak in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017.....14
Figure 1-3: Rotavirus outbreak by age in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 .15
Figure 1-4: Kebele specific attack rate of rotavirus infection in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 16
Figure 2-1 Administrative Woreda boundary map of East Shewa Zone.....41
Figure 2-2 Total number of suspected meningitis cases by sex in East Shewa zone; 2004 to 2007EFY 44
Figure 2-3: suspected cases of meningitis by sex and age in East Shewa Zone, 2004-2007 EFY.....45
Figure 2-4: Trends of suspected meningitis cases by month in East Shewa Zone 2004-2007 EFY 46
Figure 2-5: Trends of suspected meningitis cases by month and year in East Shewa Zone 2004-2007 EFY 47
Figure 3-1: Diagram illustrating the formal and informal flow of surveillance data and information throughout a health system.....73
Figure 3-2: Immediate rumor notification/informal information flow chart.....73
Figure 4-1: Geographic location of Mojo town (Map of Mojo town).....124
Figure 4-2: Population pyramid of Mojo Town 2007EFY.....126
Figure 4-3 Distribution of population by ethnic group 2015 127
Figure 4-4: Electric Service Subscribers by Type of Functions 2006 E.C.....129
Figure 4-5: Organizational structure of Mojo Town Admin Health Office 114
Figure 4-6: Contraceptive users of Mojo town 2007EFY 119
Figure 4-7: HIV cases in mojo town by sex 2005-2007EFY 123
Figure 5-1 The date of onset rotavirus outbreak in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017.....149
Figure 5-2.: Kebele specific attack rate of rotavirus infection in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017 150
Figure 5-3: Total number of suspected meningitis cases by sex in East Shewa zone; 2011-2014.....163
Figure 5-4: suspected cases of meningitis by sex and age in East Shewa Zone, 2011-2014. 163
Figure 5-5: Trends of suspected meningitis cases by month in East Shewa Zone 2011-2014.....164
Figure 5-6: Trends of suspected meningitis cases by month and year in East Shewa Zone 2011-2014.....165
Figure 9-1: Organizational structure of OPHRCBQAL.....232
Figure 9-2: Total tests performed by specimen type in Clinical Bacteriology Laboratory.....239
Figure 9-3: Testes performed in Molecular laboratory from January to May 2017.....241
Figure 9-4: Blood specimens received ready to ELISA test and number of ELISA tests performed in Quantiferon section 243
Figure 10-1: Conceptual frame work for Performance Evaluation of Laboratory Professionals through proficiency test slides (Developed from literatures) 262
Figure 10-2: Performance of laboratory professionals on malaria parasite detection species identification, Afar Regional state, Ethiopia, 2017.....274
Figure 10-3 Performance of laboratory professionals working on malaria microscopy, Afar Regional State North East Ethiopia, 2017 276

VI. Lists of Annexes

Annex 1-I: Questionnaires for investigation 29
Annex 2-I: Data entry form 53
Annex 2-II: Data organizing tables 53
Annex 3-I: Zonal Level Questionnaire for Surveillance System Evaluation 83
Annex 3-II: Woreda Level Questionnaire for Surveillance System Evaluation 95
Annex 3-III: Health Center Level Questionnaire for Surveillance System Evaluation 104
Annex 3-IV: Health Post Level Questionnaire for Surveillance System Evaluation 112
Annex 4-I: Data collection tool of Health Profile description 130
Annex 10-I: Consent form for Blood Donors (English Version) 291
Annex 10-II: Consent form for Blood Donors (Amharic Version) 292
Annex 10-III: Consent Form for Laboratory professionals (Amharic Version) 293
Annex 10-IV: Consent Form for Laboratory professionals (English Version) 294
Annex 10-V: Questioner 295
Annex 10-VI: Performance assessment report form 299
Annex 10-VII: Dummy tables 300

VII. Abbreviations and acronyms

Admin	Administration
AFI	Acute febrile illness
AIDS	Acquire immunodeficiency syndrome
ALP	Alkaline phosphatase
ANC	Antenatal Care
ART	Anti-Retroviral Therapy
AURI	Acute Upper Respiratory Infection
AWD	Acute Watery Diarrhea
BCG	Bacilli Chalmette-Guerin
BHL	Batu Hospital Laboratory
BSL	Bio safety Level
CBC	Complete blood count
CBN	Community Base Nutrition
CD4	Cluster of differentiation
CDC	Centers for Disease Control and Prevention
CFR	Case fatality rate
CHW	Community Health Workers
CSA	Central Statistics Agency
CSF	Cerebrospinal Fluid
Deg.	Degree
Dip.	Diploma
DNA	Deoxyribonucleic Acid
DST	Drug Susceptibility Test
EDHS	Ethiopia Demographic and Health Survey
EDTA	Ethylenediaminetetraacetic acid
EFETP	Ethiopian Field Epidemiology Training Program
EFY	Ethiopian Fiscal Year
EID	Early Infant Diagnosis
EMDHS	Ethiopia Mini Demographic and Health Survey
ENAO	Ethiopian National Accreditation Office
EPHI	Ethiopian Public Health Institute
EPI	Expanded Program on Immunization
EQA	External Quality Assessment
F.P	Family planning
FM	Florescent Microscope
FMoH	Federal Ministry of Health
FMoH	Federal Ministry of Health
G.P	General practitioner
GAVI	Global Alliance for Vaccines and Immunization

GOT	Glutamic Oxaloacetic Transaminase
Gov	Government
GPT	Glutamic Pyruvic Transaminase
H.C	Health Center
H.E.W	Health Extension Workers
H.F	Health Facilities
H.O	Health Officer
H.P	Health Post
HDP	Hypertensive Diseases Related to Pregnancy
HIT	Health Information Technology
HIV	Human Immunodeficiency Virus
HIV	Human Immunodeficiency Virus
IDSR	Integrated Disease Surveillance and Response
IQC	Internal Quality Control
IQR	Inter Quartile Range
IRS	Indoor Residual Spray
ISO	International Organization for Standardization
IT	Information Technology
ITNs	Insecticide Treated Net
KOH	Potassium Hydroxide
Lab.	Laboratory
LIS	Laboratory Information System
LLINs	Long Lasting Insecticidal Nets
LOC	Loss of consciousness
LQA	Laboratory Quality Assurance
LQMS	Laboratory Quality Management System
MCH	Maternal and child health
MDSR	Maternal Death Surveillance and Response
MMR	Maternal Mortality Ratio
MRN	Medical Record Number
MSF	Me´decins Sans Frontie`res
NEQAS	National External Quality Assurance Schemes
NGO	Non-Governmental Organization
NSP	Non-structural Proteins
OPD	Out Patient Department
OPHRCBQAL	Oromia Public Health Research, Capacity Building and Quality Assurance Laboratory
OPV	Oral Polio Vaccine
OR	Odds Ratio
ORS	Oral Rehydration Salt
OTP	Outreach Therapeutic Program

P.F	*Plasmodium falciparum*
P.M	*Plasmodium malariae*
P.O	*Plasmodium ovalae*
P.V	*Plasmodium vivax*
PAB	Protected at birth
PCR	Polymerase Chain Reaction
PCV	Pneumococcal Vaccine
PFSA	Pharmaceutical fund support agency
PHEM	Public Health Emergency Management
PITC	Provider Initiated Test and counseling
PLWHA	People Living With HIV/ADS
PMTCT	Preventing Mather to Child Transmission
Pop	Population
PSNP	Productive Safety Net Program
PT	Proficiency Test
PTB	Pulmonary tuberculosis
PWTT2+	Pregnant women receiving at least two doses of tetanus-toxoid vaccine
QA	Quality Assurance
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
QSE	Quality System Essential
RBC	Red Blood Cell
RDT	Rapid Diagnostic Test
RDT	Rapid Diagnostic Tests
REQA	Regional External Quality Assessment
REQAS	Regional External Quality Assurance Schemes
RNA	Ribonucleic Acid
RTA	Road traffic accident
RV	Rotavirus
Rx	Treatment
SC	Establishing Center
SD	Standard Deviation
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SOP	Standard operating procedure
SPHMMC	Saint Paul's Hospital Millennium Medical College
SPSS	Statistical Package for the Social Sciences
SSA	Sub Saharan Africa
TAT	Turn- around Time
TB	Tuberculosis
TBA	Traditional Birth Attendant

TSF	Targeted Supplementary Food
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
UTI	Urinary Tract Infection
VCT	Voluntary Counseling Test
VP	Viral Protein
WHO	World Health Organization
ZN	Ziehl Neelsen (staining technique)

VIII. Executive summary

This body of works contains my outputs that were completed during the last two and half year residency time. This works included major outputs such as Outbreak investigation, Surveillance data analysis, surveillance system evaluation, Health profiles description, research project and other outputs expected from laboratory track like Narrative summary of laboratory report, Quality manual for selected health facility laboratory, Standard Operating procedure for selected health facility laboratory. Additionally it contains scientific manuscripts for peer revived journal and abstracts for scientific conferences.

Outbreak of rotavirus was happened among under-five children who live in Dano woreda, West shewa zone Oromia regional state from January 5 to February 10, 2017. On this outbreak 919 under-five children were affected with rotavirus that was associated with age of the children, vaccination status, and drinking water.

Surveillance data of East Shewa zone was analyzed for data of suspected meningitis cases. Health Management and Information System (HMIS) four data (2004-2007 EFY) was analyzed to characterize the cases by time, place and Person. In the four year period 882 cases were recorded with annual incidence rate of 15.6 cases per 100,000 people.

The surveillance system evaluation system was conducted in Ada'a woreda, East shewa zone Oromia regional state on two twenty two priority diseases, maternal death and epidemic typhus. The evaluation identified that there were discrepancy of reporting facilities between woreda health office and health centers. There were no national guide line, shortage of reporting formats and no cases definitions of evaluated top priority diseases.

Health profile was done for Mojo town administration, east shewa zone Oromia regional state. The assessment found that 100% health coverage, poor toilet coverage of the town, high prevalence and incidence of HIV that related to high population traffic in the town.

Regarding to laboratory quality manual and standard operating procedures, quality manual was prepared for Batu Hospital which did not have quality manual previously. Two Standard Opening procedure, for VIKIA Rapid Tests and Wantai Rapid Test for detection of HIV 1& HIV2 antibodies were prepared to Adama regional laboratory. Narrative summary was prepared for my residency place Adama regional laboratory.

My research project was concentrated on malaria, especially on performance of laboratory professionals of Afar Region who diagnose malaria microscopically. Off 119 laboratory professionals in the region in 2017, 83% of them participated on the research. The findings of this research indicated that the performance of laboratory professionals working in Afar region was poor which associated with malaria microscopy training, year of experience and their theoretical knowledge.

Other requirements of field epidemiology residents, abstract and manuscript were also prepared for scientific conferences and peer reviewed journals. Abstract of rotavirus outbreak investigation and suspected meningitis case were sent to scientific conferences and abstract of rotavirus outbreak investigation was presented on the first Ethiopian Field Epidemiology and Laboratory Training program scientific conference. The manuscript of rotavirus outbreak investigation surveillance data analysis of suspected meningitis also sent to international journals.

CHAPTER 1: OUTBREAK INVESTIGATION

Rotavirus Outbreak Investigation in Dano Woreda, W/Shewa Zone, Oromia Regional State, 2017

Summary

Introduction: Rotavirus infection is the leading cause of diarrhea among children under five years of age. Ethiopia is top ten leading countries with children death due to rotavirus infection. Outbreak of Rotavirus occurred in Dano Woreda. We investigated this outbreak to confirm the etiology, assess its scope and risk factors, and recommend control measures.

Method: We defined a probable case as a child under-five years of age with sudden onset of diarrhea or vomiting (two or more episodes within 24 hours) who resided in Dano Woreda. A confirmed case was a probable case with confirmation by rotavirus antigen stool testing or by epidemiologic linkage to a case.. We employed a case control study to identify risk factors for the outbreak, randomly selecting 180 children, 60 cases by systematic sampling and 120 unmatched, neighborhood controls by convenience sampling. We entered socio-demographic data, risk factors and other data with Epi-info 7.1 and analyzed by SPSS 21.0

Results: Of 11 stool samples sent to the reference laboratory, 7(64%) were positive for group A rotavirus; the other cases were epidemiologically linked. A total of 919 children were infected with rotavirus from January 5 to February 10, 2017 (attack rate [AR]=44/100,000 under five population). Multivariable logistic regression showed, children aged 0-12 months (aOR=7.73, 95% CI=2.10-28.46) and 13-24 months aOR=8.99 (95%CI 2.16-37.42) predominantly infected. Reported contact with a case (aOR=6.22, 95% CI= 1.89-17.34) and drinking spring water (aOR=4.59, 95% CI =1.01-20.83) were risk factors for rotavirus infection. Rotavirus vaccination (aOR=0.276, 95% CI= 0.14-.93) and drinking potable water (aOR=0.17, 95% CI= 0.05-.59) reduced the risk of infection.

Conclusion: The findings of our study confirmed a group A rotavirus outbreak among under five children in Dano woreda, predominantly affected children 0-24 months. We recommend expanding the rotavirus surveillance system beyond Addis Ababa, improving rotavirus vaccination coverage and access to potable water.

Key words: Rotavirus, Outbreak, under five children, Risk factors Dano, Ethiopia

1.1. Introduction

1.1.1. Background

Rotavirus was discovered in 1973 by Ruth Bishop, Geoffrey Davidson, Ian Holmes, and Brian Ruck. The investigators identified abundant particles of a 'new' virus (rotavirus) in the cytoplasm of mature epithelial cells lining duodenal villi and in feces, from children admitted to the Royal Children's Hospital, Melbourne. The virus was wheel-like structure in electron microscopy and the name was called Rotavirus (rota = Latin for wheel) (1).

Rotavirus belongs to the Reoviridae family of non-enveloped double stranded RNA- surrounded by a triple-layered capsid containing a core, inner, and outer capsid. Based on the antigenic and genetic features of the inner capsid protein VP6, rotaviruses are categorized into seven major groups (A–G). Most human rotaviruses belong to group A (2). Group A rotaviruses, the most important cause of severe childhood diarrhea, have an 11-segment genome encased within three icosahedral protein shells and are referred to as triple-layered viruses. The virion consists of an inner VP2 protein layer surrounding the RNA segments and several molecules of VP1 and VP3 proteins, a middle VP6 protein capsid, and an outer layer containing VP4 protein spikes embedded in a VP7 capsid (3).

The RNA gene segments encodes for six structural viral proteins (VP1–VP4, VP6, VP7) and six non-structural proteins (NSP1– NSP6). It is the gene 11, which codes for both NSP5 and NSP6. Based on the two structural proteins, VP7 (a glycoprotein—G protein) and VP4 (a protease-cleaved protein—P protein), forming the outer shell, rotavirus strains are characterized (4).

Four rotavirus genotypes are recognized as predominant: G1P [8], G2P [4], G3P [8], and G4P [8]. These genotypes represented 88% of all rotavirus strains worldwide, and genotype G1P[8] has been responsible for >70% of the rotavirus infections in North America, Europe, and Australia (5). Commonly identified genotypes in African region are G1P[6], G2P[6], G3P[6], G1P [4], G9P[4], G12P[6] and G12P[8](6).

1.1.2. Statement of the Problem

Rotavirus infection is the leading cause of diarrhea in children aged under 5 (7).Each year, rotavirus causes approximately 111 million episodes of gastroenteritis requiring only home care, 25 million clinic visits, 2 million hospitalizations and 600,000 deaths worldwide (8). Almost each child in the world is infected with rotavirus at least once by the age of five (9). Even though the incidence of rotavirus infection in developing countries is similar to that of developed countries case-fatality is higher in the developing countries due to malnutrition and barriers to accessing health services in a timely manner (10).

More than 90% of rotavirus deaths occurred in low-income and low-middle-income countries (10). Yearly death tolls are high in India (146,000), Nigeria (47,500), China (41,000), Pakistan (36,500), Congo (29,000), and Ethiopia (29,000) in 2008. Four countries (India, Nigeria, Pakistan, and Democratic Republic of Congo) accounted for approximately half (49%) of all rotavirus deaths in 2013, and 10 countries (India, Nigeria, Pakistan, Democratic Republic of Congo, Angola, Ethiopia, Afghanistan, Chad, Niger, and Kenya) accounted for almost two-thirds of all deaths (65%) in 2013(10). In contrast, in the United States of America only 20–60 deaths happened per year (9).

The severity of rotavirus infection is age dependent. Although the disease can occur at any age, the disease most commonly causes clinically significant disease in young infants and children. The first infection after 3 months of age is generally the most significant, with severe, dehydrating rotavirus gastroenteritis primarily occurring among infants and children aged 3 to 35 months (9). In developing countries, the highest infection rates occur in children aged 3-11 months, while in developed countries infection rates peak in the second year of life (7). The virus can also affects infants under 3 months but it asymptomatic in this age group(11). Additionally rotavirus can affects children above five years and adults(12).

The spectrum of rotavirus illness ranges from mild, watery diarrhea of limited duration to severe diarrhea with vomiting and fever that can result in dehydration with shock, electrolyte imbalance, and death. Following an incubation period of 1--3 days, the illness can begin abruptly, and vomiting often precedes the onset of diarrhea. Up to one third of patients have a temperature of >39°C. Gastrointestinal symptoms generally resolve in 3--7 days (13).

Rotavirus transmitted through fecal-oral rout by contaminated water (14), contaminated food (12) and though close contact person to person and through fomites (13). The viruses also nosocomial acquired gastrointestinal infection (11). It is very stable and may remain viable in the environment for weeks or months if not disinfected (15).The viral particles can survive for more than 2 months and can maintain infectivity for more than 32 months at a relatively low temperature, i.e., 10°C (16).

Rotavirus infection occurred year-round but it can be increased during the cooler and drier months (17).The infection had a distinct seasonal peak in Africa, Asia and South America and had lesser seasonal variation in Europe, North America, and Oceania(18).

An outbreak of acute diarrheal disease caused by group A rotavirus that occurred during the Autumn of 2005 in Turkey, a total of 9907 patients applied to a health center due to acute diarrheic illness. From a total of 3250 screened diarrheic stool samples 1714 (52.7%) were found to be positive for rotavirus. On this outbreak, due to contaminated water, most of the patients with severe disease were under 5 years of age and almost 70% of the patients who required hospital treatment were male infants (16).

A food-borne outbreak of gastroenteritis due to group A rotavirus genotype G1P[8] rotavirus among adolescents were attributed to salad (raw sliced cabbage) contaminated with rotavirus (12).Outbreaks of rotavirus gastroenteritis in adults are not common and infection usually occurred by food and by person to-person contact(19).

Prevalence of rotavirus in children ranges from 35% to 49% in African Rotavirus Surveillance Network countries(20). Surveillance of rotavirus in urban and rural areas of Niger, April 2010–March 2012 showed that 30.6% under five children were infected with rotavirus. On this surveillance G1P [8], G2P [4], G2P [6], G6P [6], G9P[8] and G12P[8] genotypes were identified. Genotype G12P [8] was newly emerged in the country. The study confirmed that the high morbidity rate for rotavirus in Niger, particularly among children <1 year of age and during the dry and cool season(5).

Rates of rotavirus illness among children in industrialized and less industrialized countries are similar, indicating that clean water supplies and good hygiene have little effect on virus transmission; therefore, further improvements in water or hygiene are unlikely to have a

substantial impact on disease prevention (13). The best way to prevent rotavirus infection and reduction of its severity is vaccination of children and infants(1).Rotavirus vaccination is a cost-effective intervention which could save up to 2.5 million lives over the next 20 years in Global Alliance for Vaccines and Immunization (GAVI)- eligible countries (21). After introduction of rotavirus vaccine the annual rotavirus detection rate declined slightly over time from 42.5% in 2000 to 37.3% in 2013 globally (10). Two safe and effective, oral attenuated live virus vaccines are available for children against rotavirus group A: Rotatrix (one strain: G1P8, two dose schedule) and RotaTeq (five strains, G1-4and P8 in one with three dose schedule). The treatment is non-specific and there is no anti-viral drug. Low-osmolarity oral rehydration salt (ORS) and Zink supplementation are recommended for prevention of dehydration (22).

In 2013 WHO estimated that Ethiopia ranked among the top ten leading countries with high prevalence rate of under five children death due to rotavirus infection. In this year from a total death of 195,504 in under five children 3.5% was contributed by rotavirus (23). In 2012 total cases due to rotavirus infection were estimated to be 310,000 cases of per year resulting in 13,000 deaths per year. Prevalence of rotavirus ranges from 15 % (24) to 44% (25).

Surveillance of RV was initiated at selected sentinel sites in 2007 at the Black Lion Hospital with further expansion to other two sites in Yekatit 12 and Betezata Hospitals in 2008 and 2011 respectively. Rate of confirmed cases from these rotavirus sentinel surveillance sites were 60% in 2007, 22% in 2008 15% in 2009, 19% in 2010, 19% in 2011, 31% in 2012, 32%, in 2013 and 20% in 2014. The expected rate rotavirus rate for 2020 is less than 20% (24).

To prevent child mortality and hospitalization due to rotavirus, Ethiopia initiated vaccination of rotavirus on December 2013 (24). Introduction of effective and available rotavirus vaccines could substantially decreased Ethiopian children death attributable to diarrhea (26).

Main rotavirus genotypes detected in Ethiopia are G3P [6] (48%), G1P[8] , G2P[4], G8[P6], G12[P8], G9[P8] and G12[P6] (27).

The main aim of this study was to investigate the suspected rotavirus and epidemiology of the outbreak occurred among under five children in Dano Woreda, W/shewa zone, Oromia Regional State from January 5, 2017 to February10, 2017.

1.1.3. Rationale of the study

On January 10, 2017 Dano Woreda Health Office reported to Oromia Regional State Health Bureau suspected outbreak of AWD among under five children. On January 14 W/Shewa Zone Health Department collected stool samples and sent it to EPHI. The results of these samples were negative for V.cholera, salmonella, shigella and other bacteria potentially to cause outbreak. On January 22, 2017 Oromia Regional Health Bureau deployed team of investigators to W/shewa Zone, Dano Woreda to investigate this outbreak and to identify etiological agents and to assess the magnitude of the outbreak.

1.2. Objectives

1.2.1. General Objective

To investigate the rotavirus outbreak occurred among under five children and identify possible risk factors in Dano Woreda, W/shewa zone, Oromia Regional State from Jan 5 to Feb. 10, 2017

1.2.2. Specific objectives

- To describe the magnitude of rotavirus infections among under 5 children in Dano Woreda, W/Shewa from Jan 5 to Feb. 10, 2017.
- To identify the source of rotavirus outbreak in the district
- To take possible intervention measures for containing the outbreak and preventing occurrence of further cases in the community

1.3. Methods

1.3.1. Study area and period

Dano Woreda is located in WestShewa Zone, Oromia Regional state. Administratively the woreda is divided in to 21 rural kebeles and one town. According to the national census report of 2007, the projected population of Dano woreda for the year 2016 was 127,002 (118,215 Rural and 8787Urban). It is located at a distance of 125K.m away from the Zonal town (Ambo) and 250 km away from regional town, Addis Ababa. Dano woreda shares boundaries with Chaliya and IlluGelan woreda to the north, Nono woreda to the south, Nono Benja to the west and Jibat woreda to the east. The weather condition of the woreda is 7.5 % Dega, 19.5% weynadega and 73.5% Kola. The woreda has 22 health posts with 40 health extension workers and 4 health centers with 66 heath care providers currently on service. The physical health service coverage of the woreda is one health center served for 31751 and one health post for 5773 population in 2017. The outbreak investigation conducted in this woreda January 5, 2017 to February10, 2017.

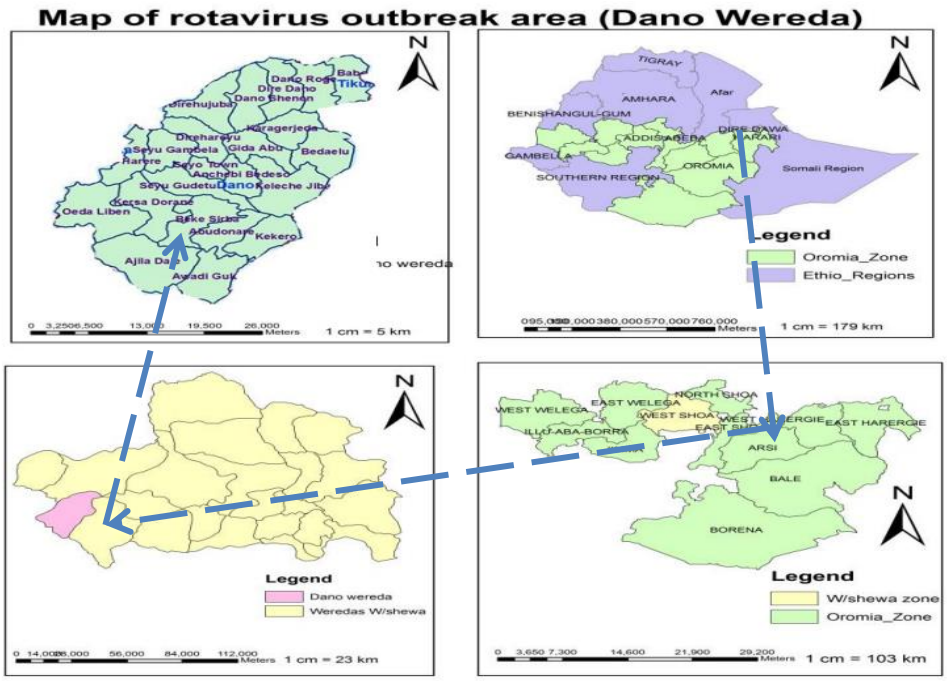


Figure 1-1: Map of rotavirus outbreak area, Dano Woreda West shewa zone Oromia Regional State, 2017

1.3.2. Study Population

Children aged under five years live in Dano woreda

1.3.3. Study population

Children aged under five years and fulfill the criteria

1.3.4. Case definitions

Cases:

- **Suspected case:** Any child under five years of age with sudden onset of diarrhea with vomiting, two or more episodes within 24 hours, from January 5, 2017 to February 10, 2017and residence of Dano Woreda.
- **Confirmed case:** Suspect case for which there is a timely stool sample and the lab results are positive for rotavirus. Outbreak is confirmed when an epidemiological link is established with a laboratory-confirmed case.
- **Controls:** Any child under five years of age without diarrhea and vomiting and resident of Dano Woreda within period of January 5, 2017 to February 10, 2017.

1.3.5. Exclusion criteria

- Prolonged diarrhea (lasting > 14 days)
- bloody diarrhea
- Admitted for another reason, although diarrhea present

1.3.6. Study design

Unmatched case-control study supported by descriptive cross sectional study was employed to conducted the outbreak

1.3.7. 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 rotavirus for control taken from previous study conducted in Jimma zone (26.6%) which is neighbors of Dano woreda (28). Based on this formula total number of cases was 60 and total number of controls was 120. With assumptions of 95% CI, 80% power, proportion of rotavirus in the community for any exposure 26.6% (from literature), estimated

proportion of rotavirus outbreak 49% (expertise judgment). In general for this unmatched case control study 180 samples were collected.

$$n_1 = \frac{r+1}{r}.\frac{\rho(1-\rho)\left(Z_\beta + \frac{Z_\alpha}{2}\right)^2}{(P_1 - P_2)^2}, n_2 = 2n_1$$

Whereas

n_1= number of cases

n_2= number of controls

r= proportion of n_2 and n_1 (n_2/n_1)

P_1= prevalence of rotavirus in a community

P_2= estimated proportion of rotavirus during outbreak (expertise judgment)

$\rho = (p_1+rp_2)/ (1+r)$

1.3.8. Data collection method

For descriptive study

We collected data from woreda health office that was collected daily during outbreak period. Woreda health office prepared standard line list format to collect relevant issues of this outbreak. The line list contained name, age, residence place, sign and symptoms and immunization status. Every day total cases were collected from each health facility by phone. On the other day hard copies collected from each facility and list of patients registered on electronic form of line list. We searched active cases home to home and gave information to the community in meetings, markets, churches and other public gathering places. The health facilities identified the cases by standard case definitions prepared by zonal health office and outbreak investigator.

For analytical study

We performed also analytical study identify risk factors of this outbreak. We interviewed parents of the children by using standard pretested questionnaire at home and at Health facilities for controls and cases respectively. We collected cases that met case definition, any child under five years of age with sudden onset of diarrhea, vomiting with two and more episodes within 24 hours. Controls were any children who do not met case definition and resident of study area. We collect cases from the line list that contains the list of all cases of rotavirus outbreak. The first case was selected randomly and then the other cases selected systematically from the line list. We selected controls from the neighborhood of the cases. If the neighbor's house had infected children, we took next neighbor's house.

Laboratory investigation

We collected stool samples from patients and sent to Ethiopian Public health Institute (EPHI) polio and measles laboratory. Samples were placed in 2-8°C till it transported to the laboratory. The maximum time samples places in refrigerator were 48 hours. Then, we transported samples to EPHI in 2-8°C and triple package.

Environmental investigation

Main water source of Seyo town (capital of Dano woreda) collected and sent to central reference laboratory (EPHI) for bacteriological indicator test. We collected samples by trained professional though sterile method. Immediately after collection we transported the water samples to EPHI in 2-8°C within triple package.

1.3.9. 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 Epi Info 7.1.4 and SPSS 21.0 version software. The risk factors were equated by using odds ratio, p-value and 95% confidence interval.

1.3.10. Variables

- **Dependent variable**
  - ✓ Rotavirus infection
- **Independent Variable**
  - ✓ Age
  - ✓ Sex
  - ✓ Travel history
  - ✓ Contact history
  - ✓ Immunization history
  - ✓ Water source
  - ✓ Using and presence of toilet
  - ✓ Exclusive breast feeding

1.3.11. Ethical consideration

Oromia Regional Health Bureau wrote a letter to Dano woreda health office to conduct the outbreak investigation in the Woreda. All parents of children were well informed about the objectives of study and we got oral consent from them.

1.3.12. Dissemination of the result

The study finding was submitted Adama Regional Laboratory/Oromia Regional Health Bureau, Dano Woreda Health Office and Dano Woreda Water and Sanitation office. It was also submitted to St. Paul's Hospital Millennium Medical College, Public Health Department. This result will also be disseminated through publication in peer reviewed local and international journals and through presenting it in related workshops and seminars.

1.4. Result

To confirm the case eleven samples sent to EPHI and 7(64%) of them were positive for group A rotavirus. The genotype of this isolate was not identified because EPHI could have ability to genotype rotavirus and the positive stool samples were sent to WHO reference laboratory for genotyping. Then other cases linked epidemiologically to rotavirus infection. To assess the environment, main water source of Seyo town we collected and sent water sample to EPHI. The water was positive for bacteriological indicator which means there was fecal contamination of water.

Since no experience of such kind of outbreak in this area and surveillance sites are only in Addis Ababa (Tikur Anbesa Specialized Hospital and Yekatit 12 Hospital), to know the background information of rotavirus in this area.

From January 5, 2017 to February10, 2017, a total of 919 under five children infected with rotavirus in Danowerada west shewa zone. The index case was seen at Seyo health center that came from Biluarere woreda.

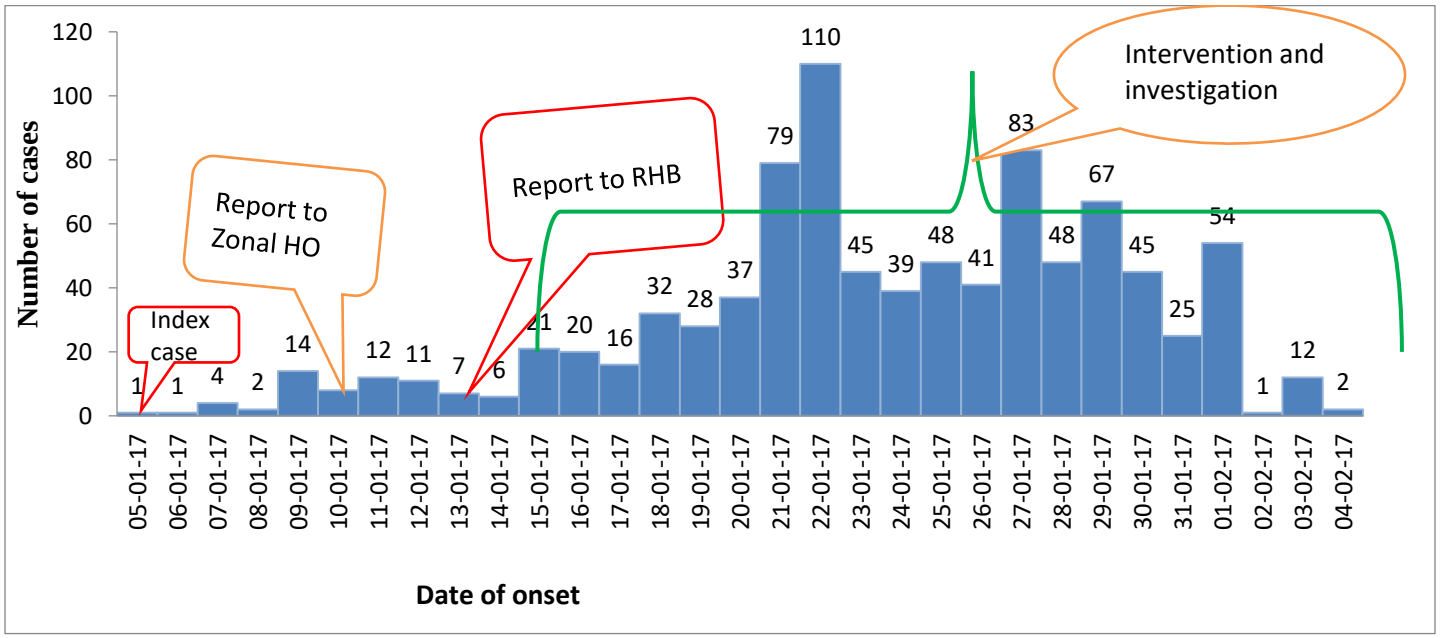


Figure 1-2: The date of onset rotavirus outbreak in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

In this outbreak 521(57%) male and 398(43%) female under five children were affected by rotavirus with median age of 12 months (IQR=8-24). In this period, the most affected population was infants aged below thirteen months 502(54.6%), followed by infants aged therein to twenty four months 260(28.3%), thirty seven to sixty months 82(8.9%) and twenty five to thirty six months 75(8.2%), with attack rate of 44 cases per 1000 under five population. No deaths were recorded during the outbreak. All children have diarrhea, vomiting fever and 619 with some dehydration, 290 with no dehydration and 10 children with severe dehydration. Before confirmation of etiologic agent patients were treated with antibiotics (corimoxazol) and supplements (ORS and Zink). Then after confirmation patients were treated only with ORS and Zink.

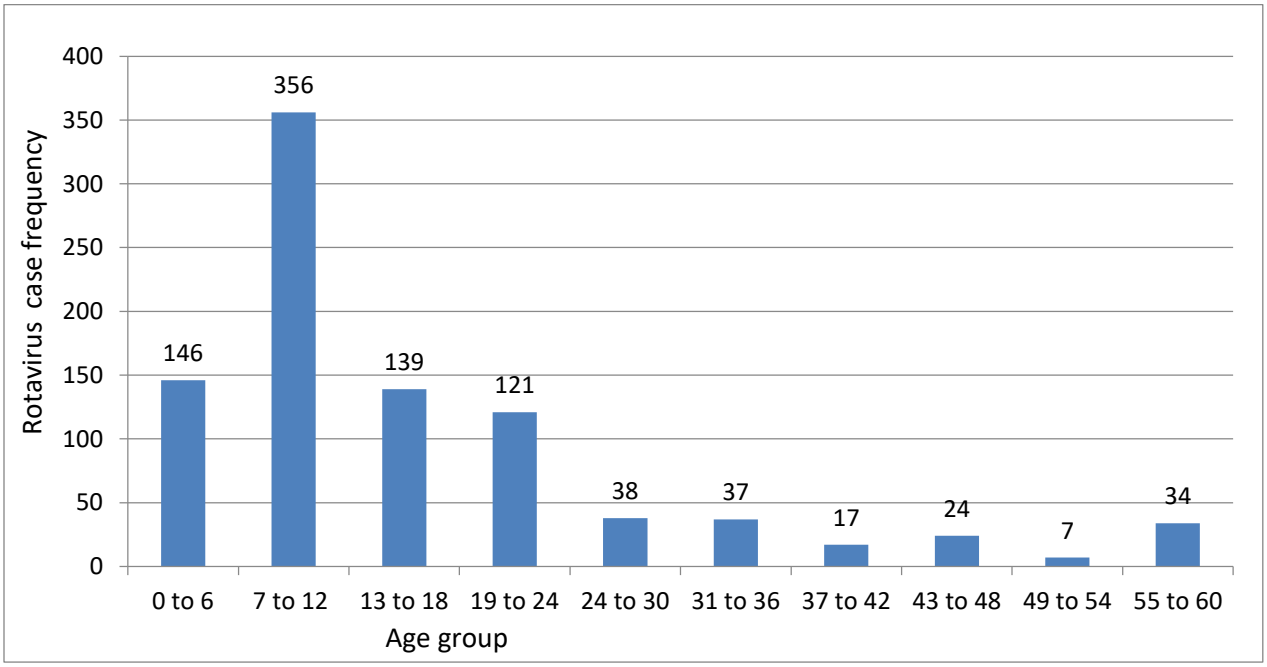
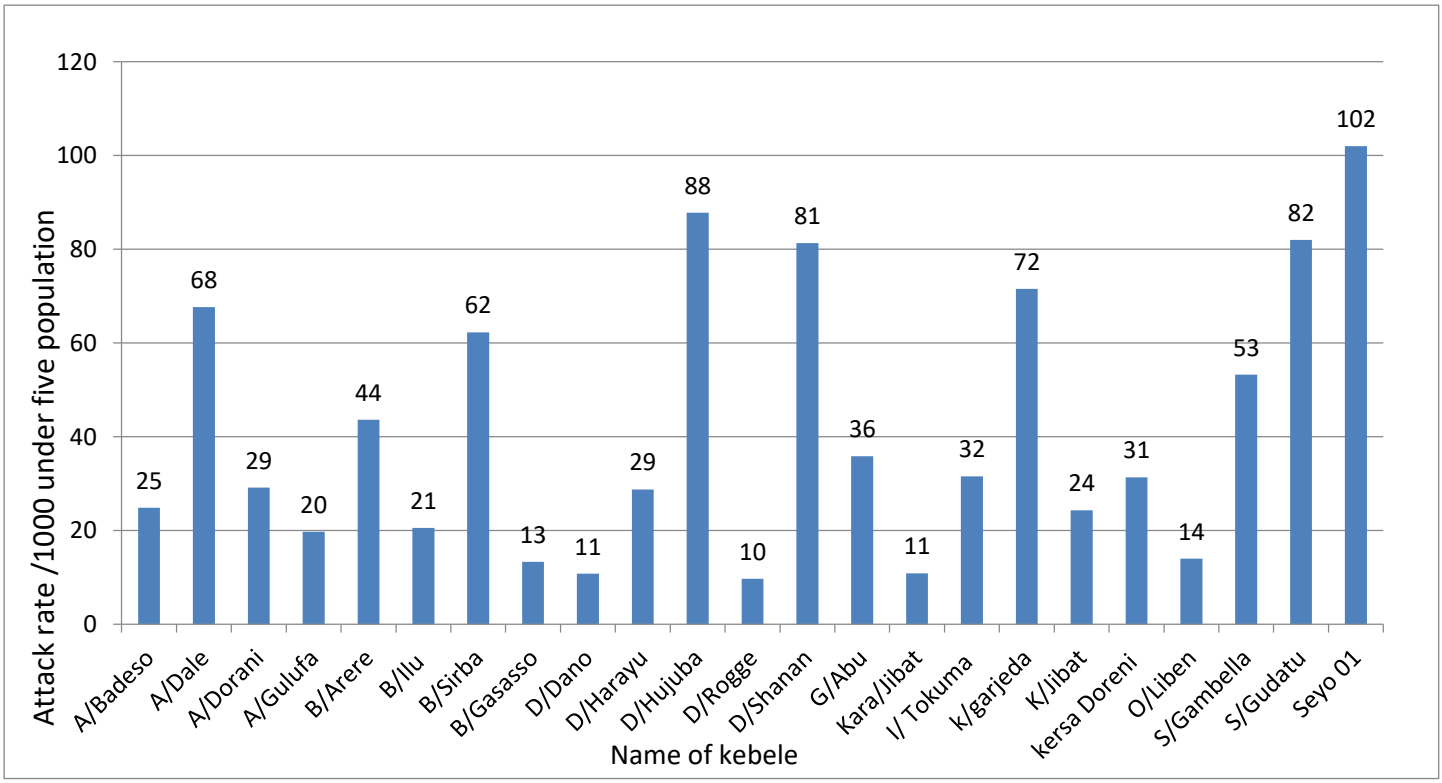


Figure 1-3: Rotavirus outbreak by age in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Distribution of rotavirus by place

The most affected district was Seyo 01 town admin (capital of Dano woreda), 102 cases per 1000 under five years population followed by Dire hujuba, Seyo gudetu, Dano shaman, Kara gerjida with attack rate of cases per 1000 under five years population 88, 82, 81, and 72 respectively



.

Figure 1-4: Kebele specific attack rate of rotavirus infection in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Intervention

We searched active cases from the community through the committee formed by the Woreda Administrator. Heath education regarding to transmission ways and prevention ways were given to the community. After the community got awareness about the disease they brought their children to health institutions immediately after they saw sign and symptoms. Before the causative agent identified antibiotics were given to the patients after the rotavirus was identified they were treated only by oral rehydration salt (ORS) and critical cases were treated by intravenous fluid (IV).

Analytical Study

A total of 60 cases and 120 controls selected from the community to identify risk factors for outbreak in affected kebeles of the Dano west shewa zone. The age range of participants was 1 to 60 months with median age of the participants of 20 months (IQR=9.25-36). All rotavirus cases

had vomiting diarrhea and fever. The socio- demographic characteristics of the study participants and risk factors for rotavirus outbreak were described in table 1.

Table 1-1: Socio- demographic characteristics of cases and controls on rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Variables		Case no. (%) n=60	Control no. (%) n=120
Sex	M	33(55)	65(54.1)
	F	27(45)	55(44.9)
Age group(in month)	0-12	29(48.3)	29(24.2)
	13-24	18(30)	23(19.2)
	25-36	7(11.7)	26(21.6)
	37-60	6(10)	42(35)
Ethnicity	Oromo	57(95)	118(98.3)
	Amhara	3(5)	2(1.7)
Religion	Orthodox	20(33.3)	27(22.5)
	Protestant	30(50)	55(30.6)
	Muslim	4(6.7)	38(31.7)
	Wakefeta	6(10)	0
Education mother	Illiterate	43(71.7)	51(42.5)
	Read and write	4(6.7)	3(2.5)
	Elementary(1-8)	12(20)	34(28.3)
	Secondary(9-12)	1(1.6)	18(15)
	Tertiary(college+++)	0	14(11.7)
Occupation of mother	Farmer	56(93.3)	87(72.5)
	Merchant	3(7.7)	11(9.2)
	Student	0	3(2.5)
	House wife	0	7(5.8)
	Gov't employee	0	10(8.3)
	Private employee	1(0.6)	0
	Daily laborer	0	2(1.7)
Education of father	Illiterate	33(55)	39(32.5)
	Read and write	6(1)	1(0.08)
	Elementary(1-8)	16(26.7)	33(27.5)
	Secondary(9-12)	5(8.3)	22(18.3)
	Tertiary(college+++)	0	25(20.8)

Table 1-2: Bivariate analysis of all variable for rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Variables		Case n=60	Control n=120	P value	OR	95% Confidence interval for OR
Age group (in month)	0-12	29	29	0.0001	7.000	2.579-18.996
	13-24	18	23	0.002	5.478	1.908-15.727
	25-35	7	26	0.299	1.885	0.570-6.226
	37-60	6	42			
Sex	Male	33	65	0.916	1.034	0.555-1.927
	Female	27	55			
Being vaccinated	Yes	31	85	0.012	0.44	0.232-0.836
	No	29	35			-
Contact with case	Yes	12	26	0.0001	6.882	3.139-15.091
	No	34	108			
Exclusive breast feeding	Yes	51	99	0.672	1.202	0.513-2.815
	No	9	21			
Family size	2-3	8	13	0.853	1.108	0.375-3.273
	4-6	37	80	0.628	0.833	0.396-1.748
	>7	15	27			
Water source	Pipe	14	91	0.0001	0.132	0.051-0.343
	Spring	27	5	0.014	4.629	1.357-15.785
	Pond	5	12	0.120	0.357	.098-1.307
	River	14	12			
Have and use toilet	Yes	38	106	0.0001	0.228	0.106-.491
	No	22	14			
Travel to other place	Yes	15	18	0.105	1.889	0.875-4.079
	No	45	102			

Bivariate analysis indicated, sex OR 1.034 (95% CI, 0.555-1.927, P= 0.916), Exclusive breast feeding OR 6.882 (95% CI, 0.513-2.815, P=0.627), using toilet OR 0.228 (95% CI, 0.106-0.491, P=0.0001) statistically not significant to rotavirus infection. Additionally travel of child to other place and family size did not statistically significant to rotavirus infection.

Having contact with cases and being between 0 and 24 months of age, and drinking spring water were risk factors for rotavirus infection. They were statistically significant with OR 7.000

(2.579-18.996, P=0.001) for age 0 to 12 months, OR 5.467 (95% CI, 1.908-15.727, P=0.0001) for age 13 to 24 months, OR 6.882 (95% CI, 3.139-15.091, P=0.0001) for contact with cases and OR 4.629 (95% CI, 1.357-15.785, P= 0.023) for drinking water from spring. In contrast, taking vaccine (at 6 week and 10 weeks) and drinking water from pipe could reduce infection OR 0.44 (95% CI, 0.232-0.836, P= 0.012) rotavirus 0.132 (95% CI, 0.051-0.343, P= 0.012) respectively.

Table 1-3: Multi variable logistic regression analysis of risk factor and protective factors of rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Variables(Risk factors)		Case (n=60)	Control (n=120)	P value	AOR	95% CI for AOR
Age group(in month)	0-12	29	29	0.002	7.736	2.102-28.468
	13-24	18	23	0.003	8.995	2.162-37.420
	25-35	7	26	0.301	2.306	.474-11.214
	37-60	6	42		1.00	
Contact with case	Yes	12	26	0.006	6.226	1.894-17.342
	No	34	108		1.00	
Water source	Pipe	14	91	0.005	0.176	0.052-.597
	Spring	27	5	0.048	4.593	1.013-20.834
	Pond	5	12	0.182	0.345	0.072-1.646
	River	14	12		1.00	
Vaccinated at 6 weeks and 10 weeks	Yes	31	85	0.036	0.372	0.148-.938
	No	29	35		1.00	
Have and use toilet	Yes	38	106	0.447	0.634	0.195-2.057
	No	22	14		1.00	

Multi variable logistic regression analysis indicated that age 0-12 months, 13-24 months, contact with cases and spring water were risk factors for rotavirus infection. Potable water (pipe water) and rotavirus vaccination had protective effect for rotavirus infection. On bivariate analysis those families had and use toilet their children were protected from rotavirus infection however on multivariable analysis indicated having and using toilet did not have any association with rotavirus infection.

1.5. Discussion

We identified group A rotavirus outbreak in Dano Woreda, west shewa zone from 05/1/2017 to 25/2/2017, in the cooler season of Ethiopia. In addition to this Oromia regional state health bureau declared that there was outbreak of RV in Nono woreda at the same period. GAVI Surveillance report of Ethiopia showed that RV cases rose up in cooler season from October through December. This outbreak began in same period with outbreak occurred in Tirana, Albania in 2000 (29).The prevalence of rotavirus infection peaked in Ghana during the cool, dry months of January and February. In Zimbabwe a seasonal peak in the prevalence of rotavirus diarrhea occurred during the winter months (6). However, a less distinct seasonal peak was observed in some low income countries (e.g., Indonesia, Vietnam, Cambodia) (18) and in equator areas (e.g., Uganda) seen year-round (6).Some studies have noted secondary seasonal peaks in rotavirus incidence associated with periods of high rainfall and flooding (30). This cooler season may increase the rotavirus infection and the season may contribute to this outbreak.

In our finding vaccinated children protected from rotavirus infection by 72.4% than unvaccinated children. In the outbreak rotavirus outbreak of Mexico among children under 36 months vaccination also prevent rotavirus and vaccinated children had odds of probability 59 % than those not vaccinated (31). Rotavirus vaccination is the primary strategy for preventing severe rotavirus disease. Incidence and hospitalization due to rotavirus successively reduced by introduction the vaccine (32). In United States of America, incidence of hospital visit and admission due to rotavirus gastroenteritis reduced by 86% and 96% respectively(13). After rotavirus vaccine introduction in Rwanda, hospital admissions for diarrhea in children younger than 5 years reduced by 29% and 17% in 2013 and 2014 respectively. In the same period the number of hospital admissions for diarrhea in children younger than 1 year decreased by 55% and by 51% (33). Some studies contradicted with this finding on vaccine efficacy had difference between high income and low income nations (21). Rotavirus vaccines are less effective in lower income settings combination of poor immunological response caused by malnutrition, other intestinal infections, and immunosuppression efficacy against other oral vaccine (OPV). The average efficacy for high, upper middle, lower middle, and low income countries are 90%, 85%, 66%, and 55%, respectively (21,34).

Disease of rotavirus attacks children aged below 2 years and more than 75 % under 12 month infants and 95% more under the age of 18 months more affected (17). On surveillance of rotavirus in Turkey, most rotavirus infections were recorded in children aged 12 to 23 months, and a second peak was observed in the 6 to 11 month age group; more than 70% of rotavirus infections occurred in children less than 2 years of age (35). In our investigation children aged between less than 24 months of age were more affected than other age groups so this was similar with outbreak occurred in Mexico (31), Solomon Island (30) and Albania (29) . However, some outbreaks of RV infection in adults have been reported (12) and even in elderly persons (36). On waterborne outbreak of two districts in Turkey due to rotavirus, the mean age of the outbreak patients was 25 years (37).

Contaminated water may be an important source of transmission in settings with poor sanitation. The waterborne transmission route may dominate during times of increased rainfall (18). A large infantile gastroenteritis outbreak in Albania caused by multiple emerging rotavirus genotypes, common source was contaminated water (29). On this outbreak spring water was risk factor and potable water could reduce the risk of rotavirus infection. In contrast, in the outbreak of rotavirus in Mexico potable water did not have any effect to the outbreak.

On this outbreak children had contact with case were more exposed to RV infection. Outbreaks of RV gastroenteritis in day-care centers and hospitals can spread rapidly among no immune children, presumably through person-to-person contacts, airborne droplets, or contact with contaminated toys (26). Nosocomial infection study on RV in Greece, 58% of RV gastroenteritis in neonates was hospital acquired (11). During the outbreak period limiting the contact children, increasing hygiene practice from normal time and limiting children from public gathering places may reduce the probability of rotavirus infection.

1.6. Limitation

Genotyping of rotavirus not performed in Ethiopia therefor genotype of this group A rotavirus was not identified. The samples were not tested for other enteric virus like Adenovirus and Norovirus which can cause gastroenteritis. Seasonality of the rotavirus infection not analyzed sine no previous data in the district. Environmental sample (water) was not collected from major areas of drinking water sources, so it was difficult to generalize the result of water sample to all drinking water sources in the woreda.

1.7. Conclusion

We confirmed group A rotavirus outbreak among under five years children in Dano woreda, west shewa zone Oromia regional state from January 5, 2017 to February 10, 2017. Children less than two years were more affected than other age groups. Risk factors of this outbreak were drinking water from springs and contact with cases. Vaccination of RV was protective for RV and drinking water from treated pipes can reduce the risk of RV infection.

1.8. Recommendations

To families/community

The family should protect their children from contacting with sick children and protect them temporarily from public gathering areas and from day cares.

Dano Woreda Health Office

- Strength vaccination of rotavirus

Dano Woreda Water and Sanitation Office

- Increase availability of portable water to the community
- Treat the water regularly to protect the community from other water borne diseases
- Check portability of drinking water on regular manner

FHoH/EPHI

- Decentralize and expand surveillance sites of RV in the country
- Since genotyping not done in Ethiopia it is vital to genotype the isolates of this outbreak in WHO regional laboratory

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Annex

Annex 1-I: Questionnaires for investigation

No.	Question	Coding Classification	Go To
	A. Socio-Demographic data		
1.	Status	1. Case 2. Control	
2.	Interviewer name	_____	
3.	Place Of Interview	1 Health Center/Hospital ___ 2 Home___ 3 Others _____specify	
4.	Date of Interview	_____/_____/_____*Date/Month/Year*	
5.	Address	Region_____ Zone_____Woreda_____ Kebele_____ Gotti_____House No_____	
6.	Child full name	_____	
7.	Mother's full name	_____	
8.	Age of the case/control	_____ Year (s) _____Month(s)	
9.	Sex of the case/control	1. Male 2. Female	
10.	How are you related to the child?	1. Mother 2. Father 3. Guardian relative 4. Other	
11.	Ethnicity	1.Oromo 2.Somale 3.Tigre 4.Gurage 5.Amhara 6.Wolayita 7. Sidama 8.Other(Specify)_____	
12.	Occupation	1. Farmer 2. Merchant 3. Student 4. House wife 5.Unemployed 6. Pastoralist 7. Gov't Employee 8.Private Employee 9. Daily Laborer 10. Not applicable 11.Other_____	
13.	Religion	1. Orthodox 2. Protestant 3. Muslim 4. Catholic 5.Wakefata 6. other_____	
14.	What is your marital status? (for mother/ father of children)	1. Single 2. Married 3.Widowed 4.Divorced 5. NA	
15.	Level of Education of Mother	1.Illiterate 2.Read and writing only 3.Elementary school (1-8) 4.Secondary School (9-12) 5.Tertiary School (college+)	
16.	Level of Education of Father	1.Illiterate 2.Read and writing only 3.Elementary school (1-8) 4.Secondary School (9-12) 5.Tertiary School (college+)	
	B. Knowledge of Rota Virus		
17.	Have you ever heard about AWD/"Rota virus"?/	1. Yes 2. No	
18.	From where did you receive this information?	1. Family member 2. Health workers 3. Mass media 4. Social media 5. HEWs 6. Neighbor 7. Town criers 8. Other	
19.	Do you know how people acquire the disease?	1. Yes 2. No	
20.	Does the disease transmittable?	1. Yes 2. No	
21.	What are the methods the disease can be transmitted? _____	1. Drinking contaminated water 2. Eating contaminated foods 3. Eating uncooked foods 4. Eating contaminated vegetables 5. Other	

No.	Question	Coding Classification	Go To
22.	How do you prevent the disease?	1. Using toilet 2. Washing hands 3. Cooking foods 4. Avoiding eating uncooked foods 5. Avoiding drinking unsafe water 6. Treating water 7. Other	
23.	Does the disease preventable?	1. Yes 2. No	
24.	If you or your family members got sick with the disease what will you do?	1. Visit health facility 2. Buy drugs from pharmacy 3. Visit traditional healer 4. Take holy water 5. Do nothing 6. Other	
	C. Risk factor Assessment		
25.	Has s/he ever been vaccinated at 6 & 10weeks?	☐Yes ☐No ☐ Don't know	If no skip to 28
26.	What is the number of Rota vaccine doses received? (refer to card if possible)	☐ NONE ☐One Age of first dose _____☐ Card validated ☐Two Age of second dose ____ ☐ Card validated ☐ More than two Age of third dose _☐ Card validated	
27.	Where did He/ She get these vaccines? Was it… (READ ANSWERS)	☐Routine vaccination at health facility ☐ Not at a health facility (HEW visit or at a site) ☐ Another way? _____ ☐Or did you forget or don't know	
28.	If child was not vaccinated, what is the reason for not vaccinating?	1 Vaccination center or clinic too far away 2 No vaccine at the vaccination site 3 Sick child at home 4 Fear of vaccine side effects 5 Shortage of money 6 Other: _____	
29.	How long does it take you to go to the health facility from your house?	1. < 10 minutes 2. 10-30 minutes 3. 30 minutes – 1 hr. 4. >1 hr. 5. >2 hrs.	
30.	Since birth, has the child been admitted to the hospital overnight for diarrhea? [Do not count current visit for cases]	☐Yes ☐No ☐ Don't know	
31.	Did your child have contact with children have vomiting and diarrhea?	☐Yes ☐No	If no skip to 33
32.	Where h/she have contact?(Kebele got)		
33.	Did your child go to other place play at many children gathered?	☐Yes ☐No	If no skip to 35
34.	If yes for Q 33 where?	_____	
35.	Did other children sick and/recovered in home/?	☐Yes ☐No	
36.	At what age the child start supplementary food?	_____	
37.	At what age did the child completely stop receiving breast milk?	_____months and_____ weeks ☐ Don't know	
38.	How many rooms in the house are used for sleeping?	_____	
39.	In total, how many people, including children, regularly sleep in the house at night?	_____	
40.	In the past month, has the child attended a daycare or school for more than 2 days per week?	☐Yes ☐No ☐ Don't know	
41.	Did the child receive any oral rehydration solution (ORS) before presenting to the Health Center?	☐Yes ☐No ☐ Don't know	
42.	Does the child have a history of premature birth?	☐Yes ☐No ☐ Don't know	
43.	What is the water source for your household for	1. Pipe water 2. Spring 3. Hand dug well 4. Deep	

No.	Question	Coding Classification	Go To
	drinking purpose?	well 5. Pond 6. River 7. Lake 8. Bottled water 9. Other(specify) _____	
44.	Do you treat the water with medicines to make it safe for drinking and food preparations?	1. Yes 2. No	
45.	Did your children take special food other than his/her routine meal?	1. Yes 2. No If yes list food items	
	D. Clinical Pictures(Current infection)		
46.	Date of on set	_____DD/MM/YY	
47.	Date visit health facility(admission)	_____ DD/MM/YY	
48.	Did the child have vomiting?	☐Yes ☐No	If no skip to 51
49.	During this illness, what was the maximum number of vomiting episodes in 24 hours?	_____☐ Don't know	
50.	How many days before admission did the vomiting begin?	_____☐ Don't know	
51.	Did the child have Diarrhea?	☐Yes ☐No	If no skip to 54
52.	During this illness, what was the maximum number of diarrhea episodes in 24 hours?	_____☐ Don't know	
53.	How many days before admission did the vomiting begin?		
54.	What antibiotics did you take?	_____ I don't know	
55.	How many days before admission did the diarrhea begin?	_____☐ Don't know	
56.	On arrival or admission (i.e., before rehydration), what was the child's general Condition?	1 Well, alert 2 Restless, irritable 3 Lethargic or unconscious 4 Don't know	
57.	On arrival, admission, or during the hospital visit, did the child have sunken Eyes?	☐Yes ☐No ☐ Don't know	
58.	On arrival or admission (i.e., before rehydration), what was the child's thirst status?	1 Drank normally, not thirsty 2 Thirsty, drank eagerly 3 Drank poorly, or not able to drink 4 Don't know	
59.	Did the child receive IV fluids for rehydration during the hospital stay?	☐Yes ☐No ☐ Don't know	
	E. WASH		
60.	Where do you discard your child's Feces?	1. Toilet 2. open field	
61.	If the answer to question number **5.1** is Open Field, can you tell me the reason?	1. No toilet 2. Culture 3.Bad odor 4. 5. Too far from my house 6.Physically damaged (toilet) 7.Other(specify)_____	
62.	When do you wash your hand (none proving)?	1.After toilet 2.Before food 3.After cleansing child 4.Before preparing food 5.Before feeding child 6.Other(specify) _____	
	F. Patient outcome		
63.	Discharge out come	1. Discharge 2. Transferred3. Unknown 4 still admitted 5 NA	
64.	Patient status	1. Alive 2. Died	

CHAPTER 2: SURVEILLANCE DATA ANALYSIS

A Report on Surveillance Data Analysis of Suspected Meningitis in East Shewa Zone, Oromia Regional State; September 2004-August 2007 EFY

Summary

Introduction: Meningitis is a devastating and deadly disease that kills patients within hours. It is caused by bacteria, viruses, fungi and parasites. Meningitis is endemic in most of African countries. Every year, bacterial meningitis epidemics affect more than 400 million people living in the 26 countries of Africa “African meningitis belt". This area extends from West Africa, Senegal to East Africa including Ethiopia.

Method: Retrospective cross-sectional study design was used for monthly collected HMIS electronic data. SPSS 21 and Epi info 7 used for the data analysis.

Result: Of the 882 suspected Meningitis cases in East Shewa zone from 2004 – 2007 EFY, 368 (41.7) were males and 514 (58.3) were females. Mean annual incidence of meningitis was 15.6 cases per 100,000 people and no death in the period. In the four years, the highest number 212(24.4%) was observed in Dugda Wereda and followed by A/T/J/kombolcha 188(21%1) cases. Moreover, there was no reported case from Awash Fentale wereda during the study period.

Conclusion: The surveillance data finding showed, incidence of meningitis in East Shewa Zone was high and it was higher in rainy season than dry season. The number of female cases was higher comparing with males. In addition, the magnitude of cases was higher among adults aged 15 and above comparing with their counterparts including infants.

2.1. Introduction

2.1.1. Background

Meningitis is a devastating and deadly disease that kills patients within hours (1).It is endemic in most of African countries(2). Every year, bacterial meningitis epidemics affect more than 400 million people living in the 26 countries of known as “African meningitis belt". This area extends from West Africa, Senegal to East Africa, Ethiopia(3). From 1995 to 2014, over 900,000 cases were reported in the last 20 years in African meningitis belt. Of these cases, 10% resulted in deaths, with another 10–20% developing neurological squeal(3).The most recent large scale epidemic in the Belt occurred in 2009 and affected mainly Nigeria and Niger, causing over 80,000 reported cases. From 2010 to 2014 cases have been steadily decreasing, with approximately 24,000 cases in 2010 to 11,500 cases in 2014(3).

Outbreaks of Meningococcal meningitis can occur in any part of the world. However, the highest burden of meningococcal disease occurs in African meningitis belt(4). Typically, outbreaks occur during hot, dry and dusty conditions in areas with high population density(2). Serogroup A and C meningococcal are the main causes of epidemic meningitis(5). Invasive disease is rare in non-outbreak areas, occurring at a rate of 0.5-10 cases per 100,000 populations per year, but can occur at a rate of up to 1,000 cases per 100,000 populations per year in outbreak prone areas (6).

Meningitis is an infection and inflammation of the meninges (the membranes that cover the brain and the spinal cord). Bacteria, viruses, fungi and parasites can cause Meningitis(6). Worldwide, approximately 75% to 80% meningitis is caused by thee pathogens, Haemophilus influenza, Neisseria meningitides and Streptococcus pneumonia(7). Neisseria meningitides is the causative agent of Meningococcal meningitis and transmitted from person to person, particularly in situations of crowding(8). At any time, 5-10% of the population may be nasopharyngeal carriers of N. meningitides (6).Rural-to-urban migration and overcrowding in poorly designed and constructed buildings in camps and slums can contribute to transmission (5). The main clinical features are fever, poor oral intake, seizure, headache, altered conscious level, neck stiffness, confusion blurred vision, hydrocephalus (1).

Meningitis can be prevented through good case management and vaccination. For serogroup A and C alone or combined vaccination against serogroups A, C, Y and W135 is used to prevent meningococcal meningitis. The vaccine is effective within 8–14 days. The group at highest risk

of meningococcal meningitis is children aged 2–10 years. Thus, WHO recommends, children in this age group this have to get the priority during period of vaccination campaigns(5).

In Ethiopia, meningitis outbreaks have been described in written reports since 1901. Outbreaks were reported in 1935, 1940, 1950, 1964, 1981 and 1989.The 1981 and 1989 outbreaks were the largest ever recorded in Ethiopia with 50,000 and 45,806 cases, and 990 and 1686 deaths, respectively (6). Between1980 and 1999, the incidence of meningitis was ranged from 0-104 cases per 100,000 populations (7). Between March and August 2000 there was an outbreak in Addis Ababa with 850 cases and 33 deaths(6).

2.1.2. Statement of the Problem

Epidemic meningitis has been recognized as serious public health problem for almost 200 years. The case-fatality in an epidemic is usually between 5% and 15% (5). Highest annual incidence of meningococcal disease in the world with superimposed frequent epidemics that constitute a major public health burden (7). In the African 'meningitis belt' alone epidemics of meningitis can cause more than 100,000 cases and 10,000 deaths in a single year nearly all of them due to serogroup A (9). Highest annual incidence of meningococcal disease in the world with superimposed frequent epidemics that constitute a major public health burden occurs in the region (7).

The most affected countries in the region are Burkina Faso, Chad, Ethiopia, and Niger. Burkina Faso, Ethiopia, and Niger were accountable for 65% of all cases in Africa. In major epidemics, the attack rate range is 100 to 800 people per 100,000. However, communities can have attack rates as high as 1000 per 100,000. During these epidemics, young children have the highest attack rates(10)

Reactive vaccination campaigns in epidemic period have an impact on countries economy. From 1999 to 2003, the hyper endemic countries (Burkina Faso, Chad, Ethiopia, Mali, Niger, the nine northern states of Nigeria, and Sudan) purchased over 109 million doses of bivalent A/C polysaccharide vaccine(11). During the same period, rest of African countries purchased only 45 million doses. On the epidemic of meningitis in Burkina Faso in 2007, 25,000 cases and 1,700 deaths were registered. From the 52 districts of Burkina Faso 41 districts were affected. In the same year, 4 million people vaccinated in less than 3 months and 9,000 health workers

mobilized. The direct cost of this campaign was US$3.5 million which accounts 5% annual heath budget (11).

Meningitis was the tenth causes of mortality in 2004 EFY (2011/2012). Of the 24,009 cases 472(2%) deaths were due to meningitis (12). In 2005 EFY, FMoH reported that meningitis was one of the 10 leading causes mortality among children under 5 years. In this year, 2005 EFY, from the total 5,084 cases 151(3%) cases children less 5 years meningitis accounted (13).

2.1.3. Rationale of the Study

In meningitis belt, the epidemics of meningococcal meningitis had been occurring previously in every 8-12 years, But recently, the epidemics began to occur annually (6). Ethiopia started robust and all-inclusive multi hazards approach surveillance system in 2012 for an early detection and management of epidemic prone diseases. Of the 21 diseases under routine surveillance of Public Health Emergency, fourteen are immediately reportable and seven are weekly reportable. Meningitis is among weekly reportable diseases (16). The main purpose of this surveillance data analysis was to assess the burden and incidence of meningitis, in East Showa Zone, Oromia Region. Therefore, East Showa Zone health department will have well compiled and analyzed data on the recent statuses of meningitis for the planning and implementations of evidence based prevention and control measures. The analyzed data can also serve as an input for future meningitis related studies and reviews.

2.2. Literature review

In USA from 1994 to 2004, of the total 395,917,007 hospitalizations 21,396 cases had a primary discharge diagnosis of pneumococcal meningitis. The median age of patients was 41 years and 53% were male. From a total of pneumococcal meningitis cases 2,684 (12.5%) were died during hospitalization(14).

Laboratory based study conducted in Kelantan, Malaysia in Hospital University Sains Malaysia on children less than 19 showed that from a total of 125 cases 43.2(54%) were aged less or equal to one, 17.3(13.6) aged 1-5 and 43.2(54) aged 5-19. From the total cases 65.6 were male. The clinical presentations of the meningitis were fever, the most common presentation, (73.6%) followed by poor oral intake (48.0%), seizure (36.0%) and headache (24.8%). It is noted here that headache was reported by those above five year olds. The incidence of postoperative nosocomial meningitis was 67% (1).

As the findings of another retrospective study that was conducted among hospital admitted meningitis cases in Malaysia Kualalumpur shown among the total 47 meningitis cases, 26 (93%) cases aged less than five. The commonest presenting complaints necessitating admission to the hospital were fever (83%), vomiting (25.5%), headaches (23%) and seizures(23%) (7).

From February 2012 to June 2013, surveillance of meningitis was conducted in tree teaching referral hospitals of Ethiopia, Gondar University Hospital, Tikur Anbessa Referral Hospital, and Hawassa Referral Hospital that represent northern, middle and southern Ethiopia, respectively. During the surveillance period, 139 cases were suspected for bacterial meningitis from these 83(59.7%) were male. From the total suspected cases, aged less than 4 were 48(34.5%), 5-12 aged 26(18.7) 13-19 aged 13(9.4%) and aged greater than 20 were 72(47.6%). The identified etiologic agents according to this study were 27 (19.4) N. meningitides, 18 (12.9%), S. pneumonia and 1 (0.7%) H.influenza. Serogroup A Neisseria meningitis was dominant in Hawassa and Serogroup W in Gondar (15).

As the retrospective study that covered five years, i.e., from Jan 1, 2006 to Dec 31, 2010, at University of Gondar Teaching Hospital shown, among the total 3085 suspected cases of meningitis, 1,589(51.5 %) were male. Of those suspected cases, 120 were true cases of bacterial meningitis. The major identified bacteria were S. pneumonia 52 (43.3%), Neisseria Meningitides

27(22. 5 %), Haemophilus influenza 12(10%), S.aureus 11(9.2%) E.coli 10(8.3%) and others 8(6.7%). Among the total 120 true cases, 63(52.5 %) were male, while 57(47.5 %) were female. Majority of the isolate (68.3%) of bacterial meningitis occurred in pediatric age groups ,i.e., 5 cases were isolated from age 1-28 days, 13 cases 1- 12 months 27 cases 1-14 years old (9).

As the findings of the surveillance data analysis of 2009 to 2013, in Oromia shown the annual incidence of Meningitis was 1.64 cases per 100,000 populations per year and CFR 2.66%. In the five years period 20498 cases of meningitis were presented in Oromia. The cases were occurred mainly in dry seasons or from December to June; and slightly higher in rainy seasons. In 2009, of the 18 Zones in Oromia , the highest incidence of suspected Meningococcal Meningitis was seen in Ilu Aba Bora (10.52 per 100,000 people), followed by East Shewa (9.07 per 100,000) and Horo Guduru Wollega (8.13 per 100,000) Zones. However, in East Shewa zone, the incidence rate of meningitis was dropped to zero in 2012. (11)

2.3. Objectives

2.3.1. General Objective

To assess the trends and distribution of suspected Meningococcal meningitis in East Showa Zone, Oromia Regional state

2.3.2. Specific Objectives

- To describe the trend of Meningitis epidemics in East Showa Zone
- To determine the morbidity and mortality rates of suspected Meningococcal meningitis by place person and time
- To assess the incidence of meningitis in the study area in the past four years.

2.4. Methods and materials

2.4.1. Study period

The surveillance data was collected from September 2003 EFY to August 2007 EFY and analyzed from April 3 to June 30, 2008 EFY (2014/2015).

2.4.2. Study area

This surveillance data analysis was focused on East Shewa Zone, Oromia Regional State, Ethiopia. East Shewa Zones has 10 Weredas and 3 city administrations. The Zone extends between $7^0$33’50”N - $9^0$08’56”N and from $38^0$24’10”E – $40^0$05’ 34”E. And 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. Towns and cities in East Shewa include Mojo, Metehara, and Batu. Based on the 2007 National Census conducted by the Central Statistical Agency, East Shewa Zone has a total population of 1,356,342; of those 696,350 are men and 659,992 women. With an area of 8,370.90 square kilometers, East Shewa has a population density of 162.03, while 340,225(25.08%) are urban inhabitants and 664 (0.05%) are pastoralists.

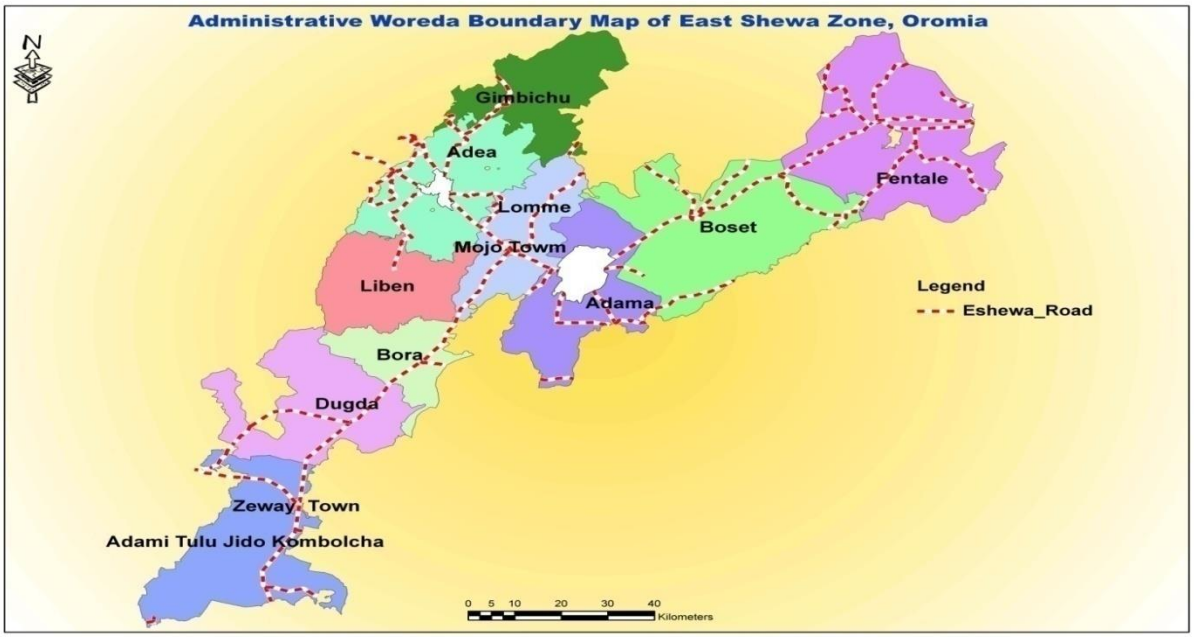


Figure 2-1 Administrative Woreda boundary map of East Shewa Zone

2.4.3. Study design and data source

Retrospective cross sectional study focused on previously collected data was used for this surveillance data analysis. The data were collected from East Shewa Zone Health Office HMIS department electronic HIMS software that comprise monthly collected data from all the 18 districts or Woredas in the Zone.

2.4.4. Source population

The total population of East Shewa Zone which is estimated 1,467,534 used as source population of this data analysis

2.4.5. Study population

All individuals suspected of meningitis in East Shewa Zone, in four years from 2004 to 2007 EFY

2.4.6. Case definition

Suspected Case

Any person with sudden onset of fever (>38.5 °C rectal or 38.0°Caxillary) and one of the following signs: neck stiffness, altered consciousness, or other meningeal signs such as bulging fontanel, convulsion (6).

Probable case:

Any suspected case with turbid or purulent CSF or with microscopic examination showing Gram-negative diplococcic (6).

Confirmed case:

A suspected or probable case confirmed by isolation of Neisseria meningitides from CSF or blood by culture, PCR or agglutination test(6).

2.4.7. Data possessing and analysis

The data was analyzed by place person and time using SPSS 21 and Epi-info7

2.4.8. Ethical consideration

The data collection was conducted after obtaining permission from all concerned offices including the Zonal Health Department.

2.4.9. Dissemination of result

The findings of this surveillance data analysis will be disseminated to all concerned, but mainly to the East Showa Zonal Health Department and SPHMMC Department of Public Health and Adama Regional Laboratory.

2.5. Result

2.5.1. Trends and magnitude of Meningitis morbidity

From 2004 – 2017 EFY there were 882 suspected Meningitis cases reported from East Shewa zone. Of the total cases 368 (41.7) were male and 514 (58.3) were female. Mean annual incidence of meningitis was 15.6 cases per 100,000 people. The highest suspected cases 263 (29.8%) was reported in 2006 EFY with annual incidence rate of 19.3 cases per 100,000 people and was followed by 263 cases reported in 2004 EFY with annual incidence rate of 19.2 cases per 100,000 People per year. The lowest cases 184(18.3%) were reported in 2007 EFY with annual incidence of 11 cases per 100,000 people. Death of meningitis was not registered from 2004 -2007 EFY.

Table 2-1 Incidence of suspected meningococcal meningitis in Showa zone, 2004 – 2007 EFY

Year(EFY)	Population at risk	Meningitis suspected cases		Incidence suspected Cases/100,000
		Number	Percent	
2004	1,367,776	263	29.8%	19.2
2005	1,408,627	184	20.8%	13.1
2006	1,416,402	274	31.1%	19.3
2007	1,467,534	161	18.3%	11.0
Total	5,660,339	882		15.6
Mean	1415085	221		15.6

In the four years, among the total 368(41.7) male suspected cases of meningitis, 25(2.8) were aged less or equal to 4 years, 125 (14.2) were 5 to 14 years old and greater than 15 years old were 218 (24.7%). From total female cases 28(3.2%) were less or equal to 4 years, 99 (11.2%) were aged 5 to 14 years and greater than 15 years old were 387(43.9%).

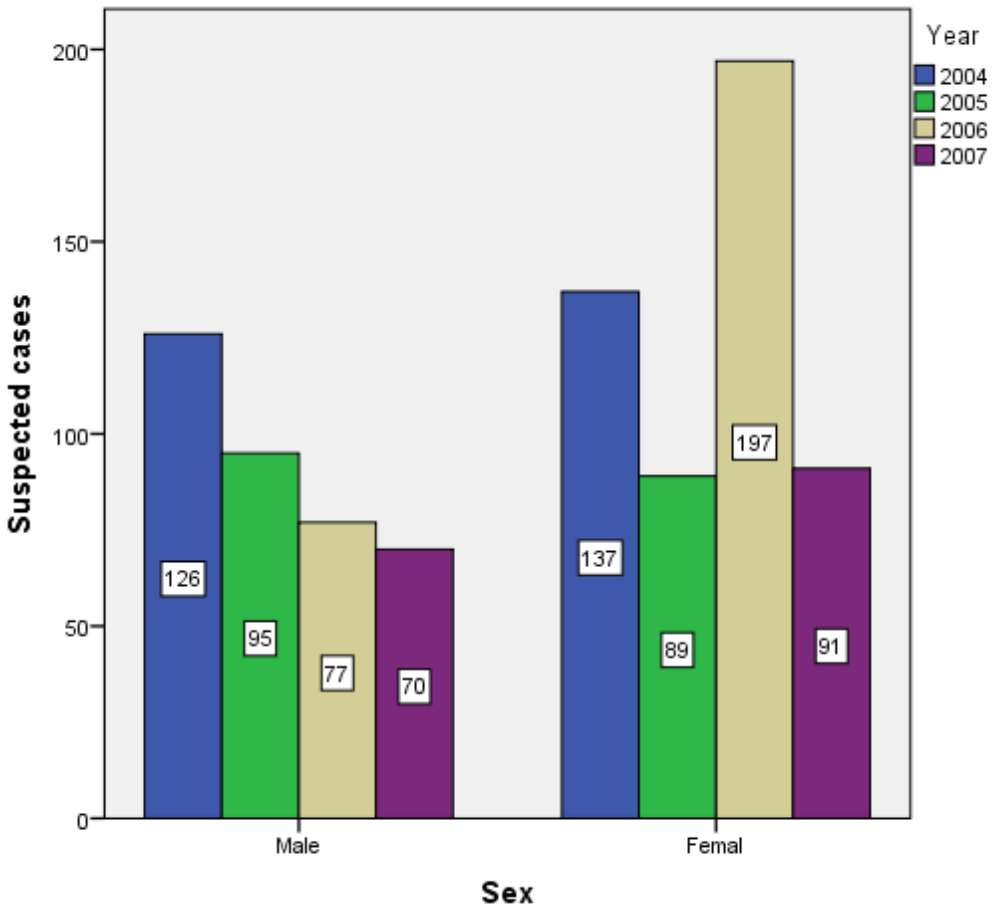


Figure 2-2 Total number of suspected meningitis cases by sex in East Shewa zone; 2004 to 2007EFY

From the total number of male suspected cases 126(14.3%) were reported in 2004 EFY and lowest number of male suspected cases were reported in 2007 were 70 cases. The highest number of female suspected cases of meningococcal meningitis 197(22.3%) were registered in 2006 and lowest number of cases 89 (10.1%) were in 2005.

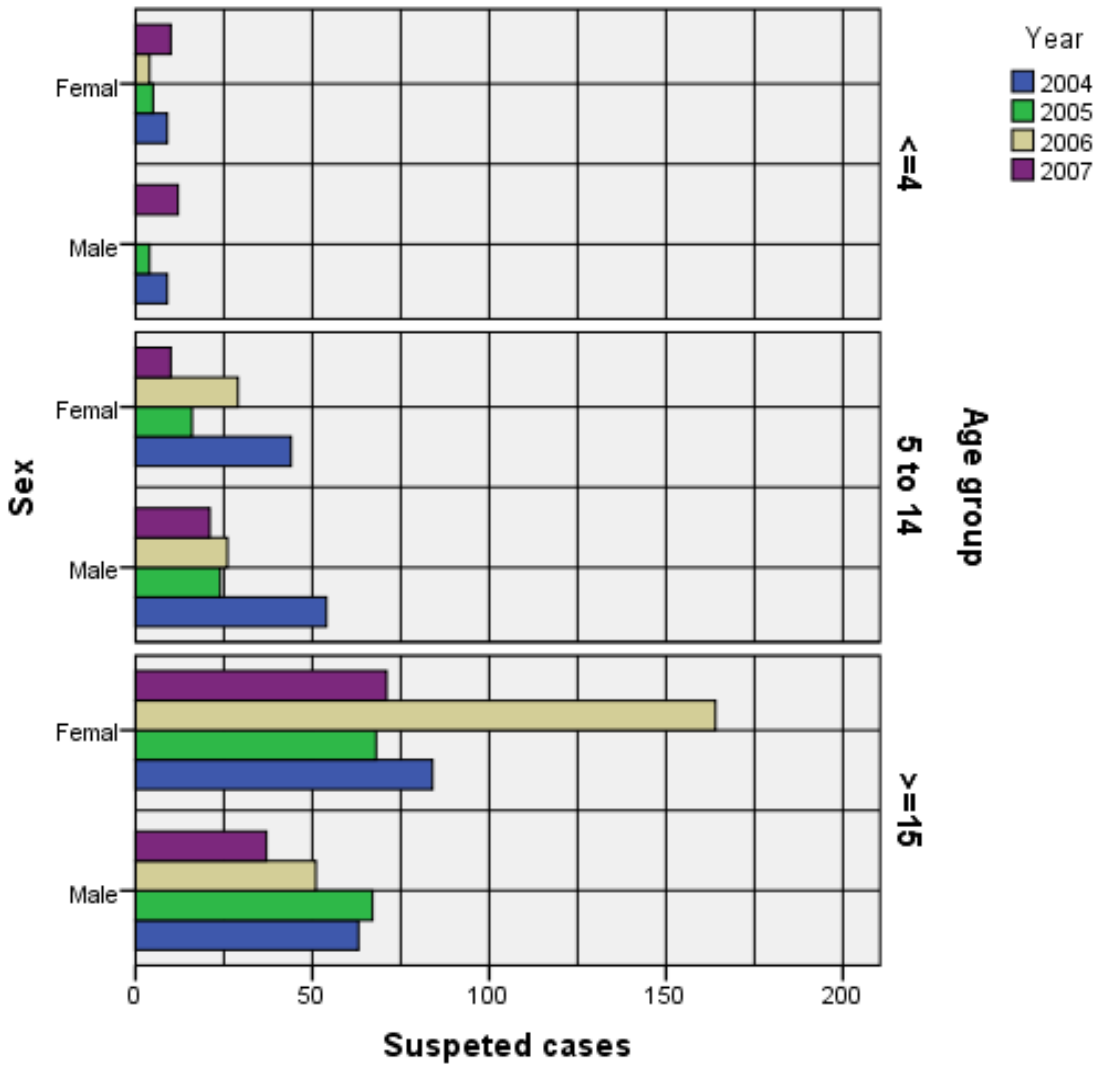


Figure 2-3: suspected cases of meningitis by sex and age in East Shewa Zone, 2004-2007 EFY.

Number of age less or equal to four were 53(6%), 5-14 age were 224(25.3%) and aged above 15 were 605(68.7%). The number of cases aged less or equal to four was the highest 22(41.5%) in 2007 and lowest in 2006EFY 4(7.5%). From the total 224 ceases, aged 5-14 the highest number 98(43.8%) was observed in 2004 and lowest in 2007 were 31(13.8%). From total 605 ceases aged above 15, the highest number 215(35.5%) was reported in 2006 and lowest 108 (17.9%) in 2007EFY.

Table 2-2 Meningitis cases by age East Shewa Zone 2004 -2007 EFY

Age group	Year				Total
	2004	2005	2006	2007	
<=4	18	9	4	22	53
5 to 14	98	40	55	31	224
>=15	147	135	215	108	605
Total	263	184	274	161	882

In four years the highest number of suspected cases 120 (13.3%) were registered in August 2006 EFY and followed by September 2005, 82(9.2%) cases. From 2004-2007 cases were high in dry December, January and February 115 (3.0%), 71(8.0%), 75 (8.5%) respectively. The numbers also increased in August 171(19.2%) and September 115 (13.0%). Figure 4 shows seasonal variation of meningitis suspected cases. Generally 31.2% cases were occurred in rainy season August and September, 29.6 % of the cases were occurred in dry season December, January and February.

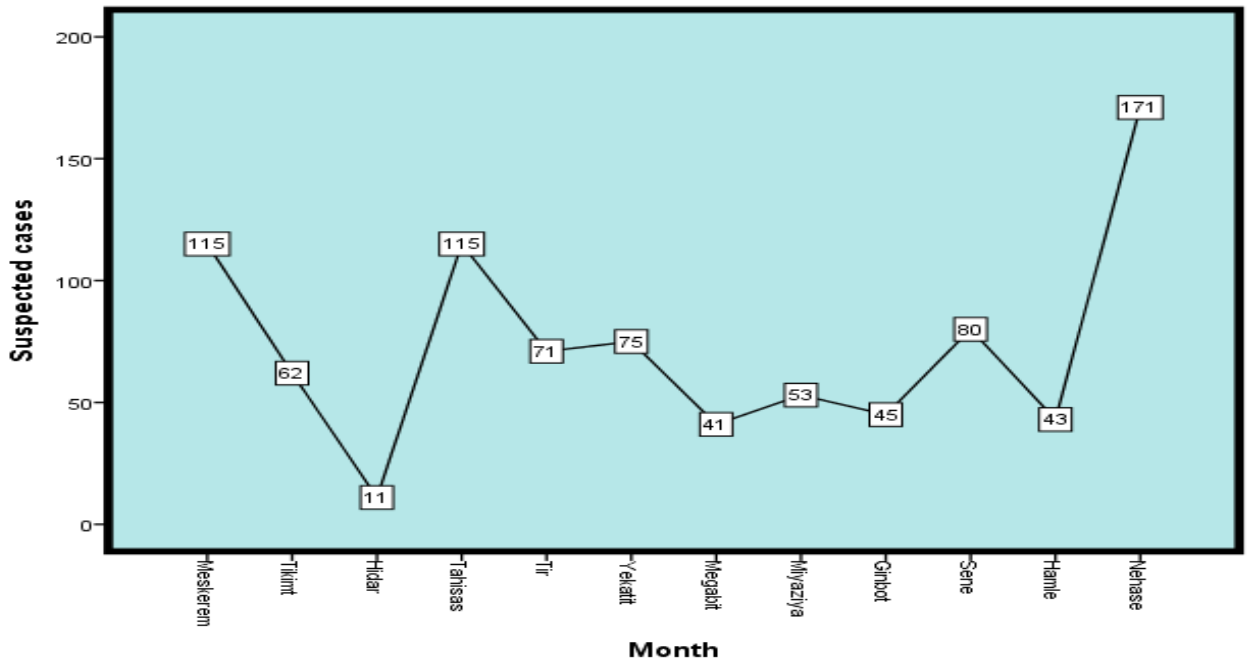


Figure 2-4: Trends of suspected meningitis cases by month in East Shewa Zone 2004-2007 EFY

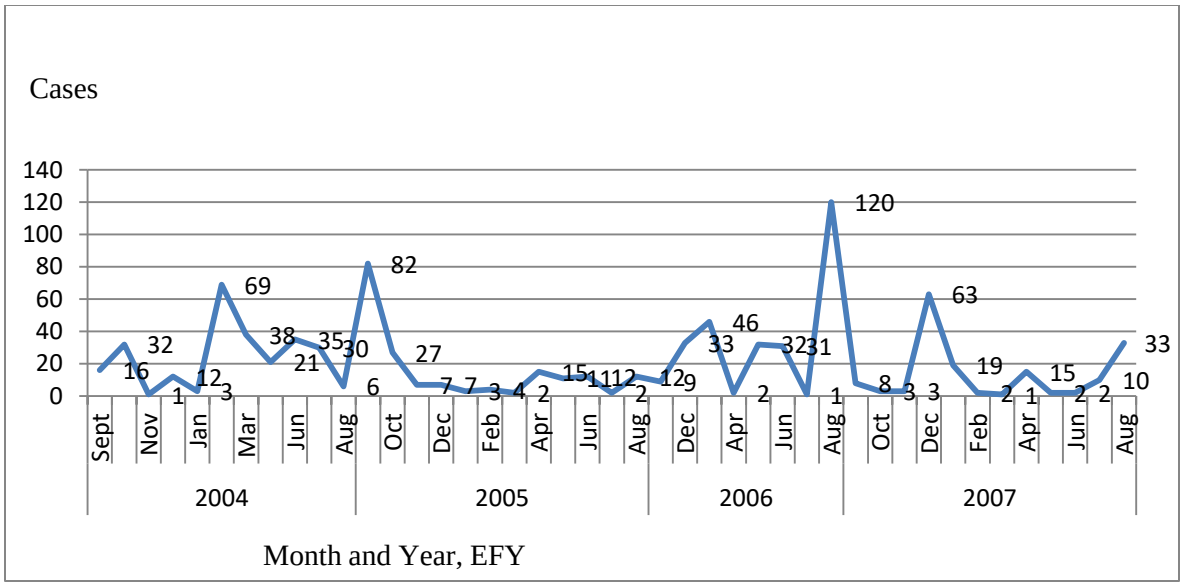


Figure 2-5: Trends of suspected meningitis cases by month and year in East Shewa Zone 2004-2007 EFY

2.5.2. Morbidity of suspected meningitis cases by Wereda

Among the 10 Weredas and 3 City Administration of East Shewa Zone only Fentale wereda were free from meningitis cases. In the four years, the highest number 212(24.4%) were seen in Dugda wereda and followed by A/T/J/kombolcha 188(21%1) cases. In Dugdawereda 96(45.3) cases were seen in August and 32(15.2%) in May and zero reports in months January, February, May and Jun. From the 188 total cases of A/T/J/Kombolcha 61(32.4%) were reported in September and 53(28.2%) in December. In this wereda there was no report in October, November, and February. In the four-year period, there were no cases in Fentale wereda and only 2 cases were reported from Bosetwered.

Table 2-3 Incidence of meningitis in East Shewa Zone by Wereda and year, 2004-2007EFY

Wereda `	Year(EFY)							
	2004		2005		2006		2007	
	Cases	Incidence /100000	Cases	Incidence /100000	Cases	Incidence /100000	Cases	Incidence /100000
Adaa	16	10.79	7	4.58	2	1.64	1	0.74
Adama	36	22.01	25	14.84	0	0.00	0	0.00
A/T/J/Kombolcha	55	30.42	80	42.96	0	0.00	53	26.90
Bora	12	17.63	2	2.85	0	0.00	0	0.00
Boset	0	0.00	1	0.59	0	0.00	1	0.56
Dugda	24	14.22	29	16.68	128	71.45	31	16.79
Fentale	0	0.00	0	0.00	0	0.00		0.00
Gimbichu	10	10.05	15	14.63	1	0.95	0	0.00
Liben	19	21.80	24	26.73	0	0.00	8	8.43
Lume	1	0.99	0	0.00	0	0.00	3	2.74
Metehara Town	12	46.91	0	0.00	0	0.00	0	0.00
Mojo Town	23	62.38	1	2.63	114	288.50	37	89.87
ZewayBatu	55	101.07	0	0.00	29	49.67	27	44.38

Table 2-3 shows that, there were high incidences of meningitis cases in different weredas of East Shewa Zone. Mojo city Administration and Batu Town Administration have 288 cases per 100,000 population and 101 cases per 100,000 populations in 2006 and 2004 respectively. In 2004 EFY, 11 weredas had the case. In this year, Batu and Mojo Town Admin were on the leading position 101 cases per 100,000 populations and 62.3 cases per 100000 populations. In 2005 EFY, 42.9 cases per 100000 populations and 26.7 cases per 100000 populations were highest cases in A/T/J/Kombolcha and Libenwereda respectively. In 2006, 8 weredas did not report cases of Meningitis. In this year next to Mojo City Admin Dugda werada had highest cases, 71.5 cases per 100000 populations and the lowest case were reported from Boset 0.59 cases per 100000 populations. In 2007 EFY, the incidence was also high in Mojo and Batu City Admin, 89.9 cases per 100000 populations and 44.4 cases per 100,000 populations.

2.6. Discussion

As the findings of this surveillance data analysis showed, the number of females affected by meningitis epidemics was higher than number of male. The number of females and males were 514 (58.3%) and (41.7%) respectively. Nevertheless, the Literature reviews done in African meningitis belt countries in 2007 shown no significant difference in numbers of cases occurred among males and females. The overall prevalence of cases was not influenced by sex. The prevalence of less than 20 years old was significantly higher in men than women. But the reverse was found in those aged 20 years and older(4). A retrospective study in Malaysia shown that number of male (62%) higher than female (38%) (24). Moreover, numbers of cases of meningitis were higher in males than females in USA 53% for male and 47% for male. Two retrospective studies in Ethiopia shown that number of male were higher than female (2,17)

Epidemic meningococcal meningitis occurred in Africa meningitis belt during the dry seasons (1). Study conducted in 6 African countries Ethiopia (Butajira), Chad, Ghana, Mali, Niger, Nigeria and Senegal on meningococcal carriages (carriers of meningitis) from 2010 -2012 showed that in Ethiopia, Ghana, Senegal and Mali meningococcal meningitis were higher in dry season than rainy season. In these four countries the prevalence of carriage was 4.2% in dry season and 3.1%. In rainy season. However, the prevalence of carriages was higher in 3 countries, Niger, Nigeria and Chad in rainy season than dray seasons(17). A retrospective study in Gonder 2006 to 2010 founded that Meningococcal meningitis and Streptococcus pneumonia were isolated in dry seasons and Hemophiles influenza was not occurred seasonally (9). In East Shewa Zone from 2004 to 2005 EFY, 31.2% cases were occurred in rainy season i.e., in August and September, and 29.6% of the cases were occurred in dry season or from December to February which is similar with the cases reported from Niger, Nigeria and Chad as described above.

As the retrospective study, results indicated the incidence of suspected meningococcal meningitides cases in Oromia region from 2009 to 2013 was 1.64 cases per 100,000 populations per year. In this period, mean annual incidence of East Shewa zone was 2.74 cases per 100,000 populations per year. In non-epidemic period incidence of meningitis was ranged from 4 to 86 cases per 100,000 populations per year in northern Togo (18). The surveillance data analysis also showed that the mean annual incidence of suspected meningitis cases was 15.6 cases per 100,000

populations per year. This incidence is much higher than the incidence of previously conducted surveillance data analysis that covered from 2009 to 2013. This may be because of difference in the data sources. In this recent surveillance data analysis the source of data were HMIS, but for the previous study conducted in the same setting PHEM data were used for analysis.

The age ranged from newborn to 19 years old, with 43.2% aged less than 1 year, 13.6% aged 1 to 5 and 43.2% aged above 5 years old (1). In this surveillance data number of cases aged less or equal to four were 53(6%), 5-14 years were 224 (25.3%) and aged above 15 years were 605(68.7%). This result shows that number of number of cases were low on age ranged from zero to four years and higher on age above 15 years.

Mortality of meningitis among children aged less than 15 years old ranged from 19.6% to 34% (1). Mortality was frequently observed among patients with pneumococcal meningitis. In Malaysia from 2004 to 2011, out of 125 cases 32.2 % were dead due to meningitis and its complication (1). However, as the findings of this recent study indicated, no death was reported from East Shewa zone in the four years period covered by the study.

2.7. Limitation

The analysis of this data was limited to clinically suspected cases of meningitis. Due to this, it was difficult to determine true cases of meningococcal meningitis. It could have been better to include laboratory results though not possible during this study because of the in availability of the required quality data in the study area during the study period. Another limitation of this study was classification of age groups; the age classification of HMIS not focuses on identifying ages less than 29 only as highly affected and more susceptible population group for meningitis.

2.8. Conclusion

This finding shows that, there was a high incidence of meningitis in East Shewa Zone (15.6 cases per 100,000 populations per year). Of the total suspected cases of meningitis, high number of cases (32.2%) were registered during the rainy seasons, August and September. The number of female was dominated the number of male and also the cases were higher in adults aged above 15 years than infants ages less than four years.

2.9. Recommendation

- There should be a system to identify suspected meningitis cases to confirm by laboratory diagnosis. This would help in the prevention, control and management of cases by knowing causative agent and its geographical distribution.
- Additional researches on meningitis are needed in East Shewa Zone to know its magnitude, seasonality and specific causative agent.
- It is better that age classification of HMIS to have age division by 5 or 10 years because it can identify highly affected and more susceptible population group for specific disease.

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Annex

Annex 2-I: Data entry form

Year

Month

Wereda name

Sex

Age

Annex 2-II: Data organizing tables

Total number of meningitis cases among Woreda's of East Showa Zone September 2004EFY – August 2007 EFY.

Name of Woreda	Total number of meningitis cases			
	2004 EFY	2005 EFY	2006 EFY	2007 EFY

Cases of suspected meningitis by sex among Woreda's of East Showa September 2004EFY – August 2007 EFY

Name of Woreda	Total number of meningitis cases							
	2004 EFY		2005 EFY		2006 EFY		2007 EFY	
	M	F	M	F	M	F	M	F

Cases of suspected meningitis by age and sex in East Showa Zone September 2003EFY – August 2007 EFY

Age group	Total number of meningitis cases							
	2004 EFY		2005 EFY		2006 EFY		2007 EFY	
	M	F	M	F	M	F	M	F

Incidence of suspected meningitis in Oromia Regional state Showa zone September 2004EFY – August 2007 EFY

Year	Total population	No. of cases	No. of deaths	Percent		Incidence	CFR (%)
				Case	death		

CHAPTER 3: SURVEILLANCE SYSTEM EVALUATION

Surveillance system evaluation of Maternal Death and Epidemic Typhus in Ada'a woreda, E/shewa zone, Oromia Regional State, 2017

Summary

Introduction: Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health. The evaluation of public health surveillance should be performed periodically, and it should include recommendations for improving quality, efficiency, and usefulness. Public health surveillance system evaluation plays significant role in identifying clearly whether the problems of public health importance are being monitored efficiently and effectively or not for sound interventions.

Objective: To evaluate the performance of the existing surveillance system of maternal death and epidemic typhus in Ada'a woreda, East Shewa zone Oromia Regional State

Methods: This surveillance system evaluation was conducted using health facility based retrospective study design. The evaluation comprises all the pertinent data collected from March 13-24 2017 regarding maternal death and epidemic typhus in the study area. Health facilities were selected by convenience sampling technique due to limited resources. One immediately reportable health event (Maternal death) and one weekly reportable disease (Typhus) were targeted for the evaluation of the surveillance system. Data was collected using the tools adopted from WHO/AFRO and updated CDC questionnaires and face to face interviews. The surveillance system related core and supportive activities as well as the collected relevant data were analyzed using Microsoft Excel 2010.The findings were presented using descriptive statistics.

Result: Thirty health facilities (23 health posts, 5 health centers, 1 NGO clinic and 1 private clinic) are expected to report all required health and health related events to Ade'a woreda health office. The total number of reported health facilities by Woreda PHEM unit to Zonal PHEM unit is greater than the number of reported health facilities actually counted during evaluation period, between week 50 of 2016 and week 9 of 2017. For the implementation of our surveillance system evaluation Ada'a woreda health office, 5 heath posts and 2 health centers visited. At zonal level case definition of all priority diseases were posted at visible place. However, in Woreda Health Office, only cases definitions of some diseases like polio, malaria and AWD were posted. At all levels except malaria the data of all top priority diseases were not described

by time, place and person and also were not interpreted. There were no national guide lines of top priority diseases at Woreda health office, health centers and health posts. From randomly selected 60 reporting formats 4(6.7%) reported through white papers due to shortage of reporting format in East Shewa Zone. The focal persons at all levels did not satisfy with training opportunities, periderm of field visit and refunding for personal mobile phone.

Conclusion and recommendation: The surveillance system was useful, flexible, simple, acceptable, and sensitive. However there should be availability of guidelines, reporting formats and communication facilities at all level. Regular supervision, monitoring and evaluation activities should be performed by zonal and woreda PHEM unit. We strongly recommend that Ada'a Woreda PHEM unit should verify number of reported facilities during the reporting period before report to next level of PHEM unit.

3.1. Introduction

3.1.1. Background

Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health (1). It is the epidemiological foundation for modern public health (2). The main purpose of surveillance to use the collected data for the formulation of policies and programmes, promoting health and preventing disease and measuring the impact of preventive efforts(2).Surveillance system also designed in order to monitor diseases with a high burden, detect outbreaks of epidemic-prone disease and monitor progress towards national or international control / eradication targets. Despite the variety of information needs, many elements of data collected in surveillance are very similar and the data source is often the same individual or facility (3).

The other objective of evaluating public health surveillance system is to ensure that problems of public health importance are being monitored efficiently and effectively or not. The evaluation should be performed periodically, and it should include recommendations for improving quality, efficiency, and usefulness. This evaluation focuses on how well the surveillance system operates to meet its purpose and objectives (1). The evaluation of public health surveillance systems should involve an assessment of system attributes, including simplicity, flexibility, data quality, acceptability, sensitivity, predictive value positive, representativeness, timeliness, and stability (4).

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 in Ethiopian Public Health Institute (EPHI), a specialized agency of the Federal Ministry of Health. The PHEM oversight cascades down to regional level through regional health bureaus, with their zonal health departments and district health offices. Through this system, 21 priority diseases and events have been identified for weekly and immediate reporting from the level of health post upwards (5). From selected priority diseases, 13 are immediately reportable whereas 7 are weekly reportable (6). The21st immediately reportable case, maternal death surveillance, was added as to PHEM implementation in 2013 (7).

Maternal death is immediately reportable top priority disease. Worldwide, there are about 200 million women become pregnant every year(8). Of these, approximately 303,000 of them were reported to die in 2013 as a result of pregnancy and childbirth related complications (9). In 2015 MMRs for high-income countries and low income countries (specially sub-Saharan Africa) was 12 deaths per 100,000 live births (11–14) and 546 deaths per 100,000 live births (511–652), respectively (10).

In 2013, thirteen thousand women died from pregnancy and its complications with MMR 420/100,000 live births in Ethiopia that contributed nearly 4% to the global maternal death burden of the year (11). Maternal death report of 2006-2007 EFY indicated that 83% of the deaths were due to direct factors and 17% were due to indirect factors. Of thedirect factors, hemorrhage, Hypertensive diseases related to pregnancy (HDP), sepsis, obstructed labor, abortion, direct others 58.0%, 12.1%, 10.1%, 7.7 %, 2.7% and 9.5% contributed respectively. The indirect contributors were anemia (51.8%), others indirect (39.6%), malaria 7 (5.0%), HIV (2.9%), and TB (0.7%) (11). Considering the high burden of maternal mortality and its impact, the FMoH launched MDRS system in 2013 and included it in to PHEM system in 2014 within the integrated disease surveillance and response (IDSR) (7).

In addition, epidemic typhus is one of the public health important problems included in the surveillance system of the country. It is an acute specific infection caused by rod-shaped, obligate intracellular bacteria called Rickettsia prowazeki. The disease is transmitted by the human body louse, which becomes infected by feeding on the blood of patients with acute typhus fever. Person infected with this disease shows symptoms of headache, chills, high fever, prostration, coughing and severe muscular pain(12).In this condition for untreated typhus cases, cases fatality rate ranges between 10%–25%(13).

Large epidemics are common in population with poor sanitary and overcrowded conditions. Typhus outbreaks has been associated with war, famine, refugee camps, cold weather, and conditions that lead to domestic crowding and reduced personal hygiene(14). During World Wars I and II, typhus spread through North Africa, the Pacific Islands, and Europe, especially in German concentration camps. Political instability made conflict in African countries were risk for typhus outbreaks in 1970s (15).

Since World War II, large outbreaks of typhus have occurred in Africa, with reported cases coming predominantly from three countries: Burundi, Ethiopia and Rwanda. In the 1970s, major epidemics occurred in Burundi and Rwanda. In 1975, 1196 and 1997 Burundi alone reported 9,000, 3,500 and 20,000 cases respectively (16).

In Ethiopia, in 1970s, the number of typhus cases reported annually had ranged between 7,000 and 17,000 (except in 1979, when a higher number was reported), although most were not confirmed in a laboratory(16). In 1983 and 1984 there were a report of typhus in Ethiopia with magnitude of 1,931 and 4,076 cases respectively and with death rate of 3.8 % (15). The outbreak reports continued from Ethiopia up to 1992 (17). FMoH design a surveillance system to monitor the progress of epidemic typhus and it included in weekly reportable priority diseases (6). The main aim of this surveillance system evaluation was to assess the performance of the existing surveillance system of maternal death and epidemic typhus in Ada'a woreda, East Shewa Zone Oromia Regional State for sound and timely actions as required.

3.1.2. Rationale of the study

The purpose of evaluating public health surveillance systems is to ensure that problems of public health importance are being monitored efficiently and effectively. Public health surveillance systems should be evaluated periodically, to assess the quality, efficiency, efficacy, usefulness and gap of the existing system for improving accordingly.

Though the maternal death rate has decreased significantly through time in Ethiopia still it is very high comparing to many other countries. Maternal Mortality Ratio(MMR) data from 2000 to 2016 indicated that steady decline from 871 deaths per 100,000 live births in the 2000 EDHS, to 673 deaths per 100,000 live births in the 2005 EDHS, and to 676 deaths in the 2011 EDHS, to reach 412 deaths per 100,000 live births in the 2016 EDHS (18). MDSR system provides essential information to stimulate and guide action to prevent future maternal deaths and improve how maternal mortality is measured. To do so,the surveillance system should be evaluated and reviewed regularly.

In addition, during 1981–97, epidemic typhus was thought to be a sporadic disease and was suspected to be prevalent only in Ethiopia (19).Though there was no report of outbreaks or epidemic of typhus in Ethiopia, health facilities are continuing to report this disease. Since the disease is becoming rare to cause epidemic, surveillance system evaluation for typhus was few in the country. However, as Ethiopia is considered as foci of epidemic typhus, regular and continuous evolution of its surveillance system will be crucial.

3.2. Objectives of the surveillance system evaluation

3.2.1. General objective

To evaluate the performance of the existing surveillance system of maternal death and epidemic typhus in Ada'a woreda, East Shewa zone Oromia Regional State.

3.2.2. Specific objectives

- To investigate the implementation of core surveillance activities focusing on the notifiable diseases reporting system, case detection, registration, confirmation, epidemic preparedness and response.
- To assess supportive activities of surveillance system such as supervision, staff training, information feedback, equipment and financial support.
- To assess the status of surveillance system attributes like sensitivity, simplicity, positive predictive value, flexibility, completeness, timeliness, acceptability, representativeness, acceptability and specificity
- To describe constraints and challenges faced in the process of implementing the surveillance system
- To draw recommendations for further improvement

3.4. Methods

3.4.1. Study area

This surveillance system evaluation was conducted in Ada'a woreda, East Shewa zone Oromia Regional State. Administratively the woreda has 16 kebeles. Ada'a is bordered in the south by Dugda Bora, inthe west by the West Shewa Zone, in the northwest by Akaki, in the northeast by Gimbichu, and in the east by Lome.The altitudes of the woreda ranges from 1500 to 2000 meters above sea level. Based on 2007 national census, the total population of this woreda for the year 2016 was projected as 142,198 with 71028 male and 71,170 female (1:1.002). The total pregnant women of Ada'a were 6747in 2016. Ada'a has 5 health centers, 23 health posts, one NGO clinic and one private clinic with health coverage of 100%.

3.4.2. Study design

The surveillance system evolution was conducted through health facility based descriptive retrospective analysis and qualitative study design.

3.4.3. Study period

The field work was carried out from March 13 to 24, 2017

3.4.4. Source Population

The total Health facilities found in East Shewa zone and expected to report to zonal PHEM unit were taken as the source population of this study

3.4.5. Study population

Selected health facilities in Ada'a Woreda, Ada'a Woreda health office and East shewa Zonal health department

3.4.6. Study unit

The surveillance system evaluation included a total of nine institutions. They were East Shewa Zone Health Department zonal health department, Ada'a woreda health office, two health centers and five health posts found in Ada'a woreda.

3.4.7. Data collection methods

Selection of health facilities was made on a convenience basis taking into consideration time and transport constraints.40% (2) health center and 20% (5) health posts which can represent the Woreda were selected. One among immediately reportable public health significant problems (Maternal death) which was recently added to surveillance system and one weekly reportable disease was selected to evaluate the surveillance system of Ade'a District. Data was collected using adopted tools from WHO/AFRO and updated CDC questionnaires which were designed for the assessment of national communicable disease surveillance system. In addition, data was collected using both face to face interviews and certain observations. Records of registration book, feedback reports of surveillance, weekly and immediately reports of surveillance in the past three months, and line lists of outbreak investigation were reviewed. Focal persons of PHEM at zonal and Wereda health office, surveillance focal persons at health facility levels were interviewed to get the important data of the existing surveillance system of the woreda.

3.4.8. Data analysis

The surveillance core activities and supportive activities were analyzed using Microsoft Excel 2010. Interviews and observations were described as narrative summary. The summary of the report was displayed by tables, graphs, charts and maps

3.4.9. Case definitions

3.4.9.1. Case Definitions of Maternal Death in Ethiopia

a. Community case definition (probable maternal deaths)

   Death of a woman of reproductive age (between 15-49 years of age)

b. Suspected maternal death:

   Community case definition plus at least one of the following:

   - Died while pregnant,
   - Died within 42 days of termination of pregnancy or
   - Missed her menses before she died

c. Standard case definition (confirmed maternal death):

   The death of a woman while pregnant or within 42 days of the end of pregnancy (irrespective of duration and site of pregnancy), from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes

3.4.9.2. Case definitions for Epidemic typhus

a. Suspected typhus cases

   Any person with an abrupt onset of headache, chills and rapidly mounting fever, malaise, prostration and rash

b. Confirmed typhus cases

   A suspected case with Weil-Felix reaction of the proteus strain OX-19 with fourfold rise in titer, or a single titer equal to or greater than 320 in the second week of illnesses**.**

3.4.10.Ethical consideration

The data collection was conducted after obtaining permission from all concerned offices including the Zonal Health Department and Ada'a woreda Health Office. Consent was asked for interviewing PHEM officers and surveillance focal persons.

3.4.11.Dissemination of result

The findings of this surveillance system evaluation was disseminated to Ada'a woreda Health Office, East Showa Zonal Health Department, Adama Regional Laboratory and Department of Public Health, SPHMMC

3.5. Result

3.5.1. Population under surveillance

Based on 2007 national census, the total population of this woreda for the year 2016 was projected as 142,198 with 71028 male and 71,170 female (1:1.002). The total pregnant women of Ada'a were 6747in 2016. Ada'a has 5 health centers, 23 health posts, one NGO clinic and one private clinic with health coverage of 100%.

Table 3-1: Population under surveillance in Ada'a Woreda in 2016

Name of institution		Population under surveillance	
		Total population	Total pregnant women
Ada'a Woreda Health Office		142,198	6,747
GodinoJitu Health Center		37,800	1,312
Under Godino Health Center	Godino health post	7,305	253
	Keteba health post	7,896	274
	Akakao health post	8,227	286
Denkaka Health Center		24,587	900
Under Denkaka Health Center	Denkaka health post	8,170	248
	Ude health post	5,379	187

3.5.2. Core functions

A. Case detection, registration and Confirmation,

At zonal level case definition of all priority diseases were posted at visible place. At Woreda health office case definitions were not posted but PHEM officer knows the case definitions. At visited health centers case definitions of malaria, neonatal tetanus, and polio were posted in under five OPD. Understanding of the available cases definitions by the health care providers was satisfactory at the time of visit. In all health posts case definitions of priority diseases except malaria was not posted. The two health centers have clinical case registration for epidemic typhus. At zonal level SAM, malaria, measles, meningitis and AWD were suspected outbreaks in 2016. From the suspected cases AWD outbreak were occurred in seven woredas. In Ada'a woreda five cases of AWD were reported from different kebeles.

The Worada health offices and health facilities have the capacity to collect and transport specimen to Regional Laboratory (Adama regional Laboratory) and national reference laboratory (Ethiopian Public Health Institute) accompanied with case based reporting form for further analysis and investigation. At woreda and health centers there were enough sample transportation package and sample containers ready for sample transportation. When they need transport medium they request from Adama regional Laboratory.

B. Reporting

Woreda health offices and health facilities used telephone and hard copies to send report to the next higher level while the zonal health office used email. There was shortage of reporting format at one health center (Denkaka HC) and 2 two health posts (Denkaka HP and Ude HP). These facilities report to next level higher level through white paper. Total number of health facilities expected to Ada'a woreda was 30 facilities between week 50 of 2016 and week 9 of 2017. Reporting data of Ada'aworeada indicated that only one health post not reported to woreda on week 8 of 2017. Completeness of health facilities of Ada'a woreda in between week 50 of 2016 and week 9 of 2017 was 99.7%. Though facility completeness report of Ada'a woreda indicated 99.7%, there was discrepancy between report of woreda health office and health center report. On week 50, 51of 2016 and week 1 of 2017, woreda health office reported that all 30 facilities expected to report were reported to the woreda health office but one health poste o week 50, 51of 2016, three health centers and two NGO/private facilities not reported. List of reporting rate of facilities of Ada'a woreda and discrepancy of reporting rate is listed in the following table. Sine time of reporting not registered it was difficult to calculate timeliness of reporting.

Table 3-2: Reporting rates of the health facilities in Ada'a woreda Week 50, 2016 to Week 9, 2017

WHO weeks	Ada'a Woreda			Denkaka health center							Godino Health center				Discrepancy b/n Woreda & facilities (Yes/No)
				Health posts			NGO/Others			Reporting rate (%)	Health posts			Reporting rate (%)	
	E	R	%	E	R	%	E	R	%		E	R	%		
*W50	30	30	100	4	3	75	2	2	100	83.33	6	6	100	100	Yes
*W51	30	30	100	4	3	75	2	2	100	83.33	6	6	100	100	Yes
*W52	30	30	100	4	4	100	2	2	100	100	6	6	100	100	No
+W1	30	30	100	4	1	25	2	0	0	16.67	6	6	100	100	Yes
+W2	30	30	100	4	3	75	2	2	100	83.33	6	6	100	100	Yes
+W3	30	30	100	4	3	75	2	2	100	83.33	6	6	100	100	Yes
+W4	30	30	100	4	3	75	2	1	50	66.67	6	6	100	100	Yes
+W5	30	30	100	4	4	100	2	2	100	100	6	6	100	100	No
+W6	30	30	100	4	4	100	2	2	100	100	6	6	100	100	No
+W7	30	30	100	4	3	75	2	2	100	83.33	6	6	100	100	Yes
+W8	30	29	96.7	4	3	75	2	2	100	83.33	6	6	100	100	Yes
+W9	30	30	100	4	3	75	2	2	100	83.33	6	6	100	100	Yes
Cumulative %			**99.7**	**77.1**			**87.5**			**80.56**			**100**	**100**	

W=WHO reporting weeks *=2016, +=2017, E= Number of facilities expected to report, R= Number of reported facilities

C. Data analysis and interpretation

There were responsible PHEM officers in both visited health offices (Zonal & Woreda) and surveillance focal persons at health centers. In health posts health extension workers had responsibility of reporting priority diseases. At all levels, except malaria, all data of top priority diseases were not analyzed by time, place and person and not interpreted.

D. Epidemic preparedness, Response and control

The zonal health department has the epidemic preparedness and response plan, Epidemic management committee and rapid response team to act during an event/s. Even though epidemic management committee and rapid response team were available they did not evaluate last year activities. There were no shortages of drugs and supplies at health facility level. However at all levels there was no budget allocated specifically to surveillance (PHEM) activities. Ada'a Woreda experienced AWD outbreak in 15/16. During the outbreak time the Woreda responded the outbreak within 48 hours and searched active cases to easily control the outbreak. In this woreda, maternal death was not registered in 2015/16.

E. Feedback

The Zonal PHEM unit gives monthly feedback to Woreda regularly. But at Woreda PHEM unit there was no any written feedback because the Woreda PHEM unit not properly document the feedbacks. Oral feedbacks also given by phone weekly from Zonal PHEM unit and the Woreda PHEM unit did the same procedure to give feedbacks to health centers. There was no any feedback of supervision and monitoring and evaluation at woreda health PHEM unit.

3.5.3. Supportive functions

A. Standards and guidelines

From the total nine institutions selected, only East Shewa Zone Zonal Health Department had all nationally published surveillance manuals. At the time of evaluation only two (maternal death and cholera) guidelines were available at Ada'a Woreda Health Office. This maternal manual was the old version which was published in 2013. From the two health centers and five health posts one health center (Godino HC) and one health post (Godino HP) had national PHEM guideline. The rest health facilities did not have any of the national guideline of priority diseases. PHEM guideline did not include MDRS as nationally priority disease because it was published in 2012 before inclusion of MDRS as priory diseases. Epidemic typhus does not have guideline while maternal death has its own guideline published in July 2016.

B. Training

In collaboration with Oromia Health Bureau and WHO, East Shewa zone health department organized training for woreda PHEM officers on selected diseases like AWD (cholera), malaria,

polio, neonatal tetanus, meningitides, measles, and maternal death in 2016/2017. However in visited health center surveillance focal persons trained on PHEM priority diseases three years ago and they need refresher training.

C. Supervision

Supervision was not performed in the last six months from Zone to the Woreda but woreda PHEM officer told that she took comments through phone weekly from zonal health office. In the last 6 months there were 3 monthly bulletins written from zonal health office to Ada'a health office. Ada'a Woreda Health Office ran supervision its health centers one time in the last six months to and written feedback was present in both visited health centers. All health posts were supervised in every 15 days and written feedbacks were present and documented at all health posts.

D. Communication facilities and Resources

From visited two health centers and five health posts one health center and 3 health posts had reporting format. In zonal health department and woreda health office there were no reporting format in their stock. The zone health department had communication material like fax and internet, office phone but these communication materials not available at woreda health office and health facilities. There was no case Zonal health department had vehicle however woreda health office did not have vehicle and sufficient budget to search active cases, conduct supportive supervision regularly.

E. Monitoring and evaluation

Health facilities were not monitored and evaluated regularly. There were no monitoring and evaluation feedbacks in each visited facility.

F. Coordination

In collaboration with WHO, Zonal PHEM unit performs active case searches and conducted training for PHEM officers. The PHEM units of each level and health center surveillance focal persons also coordinated with MNCH units. The rapid response team of zone, woreda and health center work in collaboration of each level administrative.

3.5.4. Attribute of the surveillance system/Surveillance quality

Usefulness

The surveillance system is useful to detect outbreaks, to estimate the magnitude of morbidity and mortality and to assess the effect of prevention and control programs. Collecting surveillance data through case based and weekly basis is very important but not sufficient by itself to improve the public health problems through preventing and controlling the impact of priority diseases. Data must be analyzed, interpreted, and used for taking action accordingly. In each the visited sites there was responsible person for data analysis but data was not analyzed regularly in most of the visited facilities and districts. The main reasons they reported for not analyzing data were lack of technical skills (at woreda and health posts) absence of software at woreda and zonal health department. At all levels epidemic typhus was not analyzed by place, person and time.

A. Simplicity

All visited health facilities, health office and zonal health department agreed that the case definitions of epidemic typhus and maternal deaths are easy to understand and possible to apply by all level health professional. The flow of data is clear and simple. Health posts report to health centers, health centers to woreda health department, woreda health department to zonal health department to Regional health bureau. Number of health facilities reported to woreda health office and zonal health department were known. On the 9th WHO reporting week of 2017 a total 371 health facilities expected to report to zonal health department and total of a 30 facilities reported to woreda health office. Health posts expected to report on the 9th WHO reporting week of 2017 to Denkaka health center and Godino health center were 4 and 5 respectively.

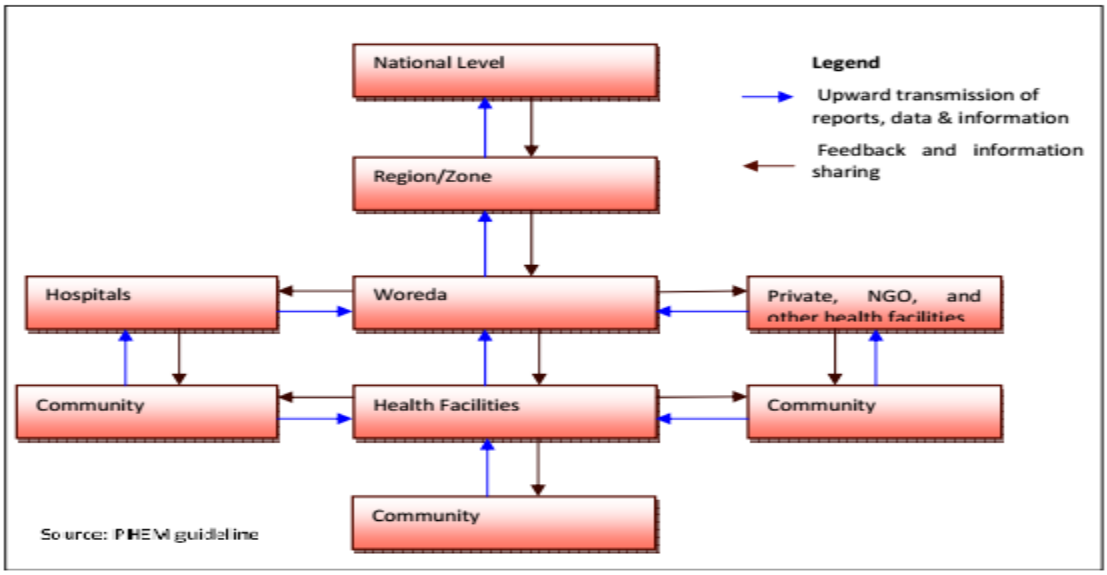


Figure 3-1: Diagram illustrating the formal and informal flow of surveillance data and information throughout a health system

Reporting line and time of reporting is clearly stated on MDSR manual and reporting of maternal death to next higher level is simple. All identified probable maternal deaths will be notified by health extension workers to their respective health center surveillance focal person. Informal information/rumor about probable maternal deaths will be reported immediately (within 30 minutes) to the next level of the PHEM structure by any channel of communication. Formal notification of probable maternal deaths are expected to be reported within 24 hours (from the time of identification) by the HEW of the health post to the respective health center surveillance focal person using maternal death identification and notification format.

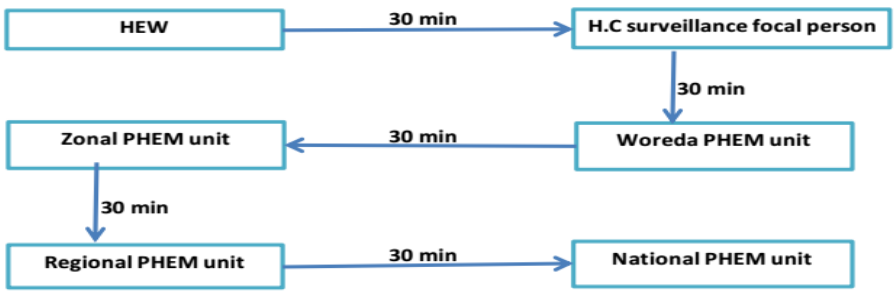


Figure 3-2: Immediate rumor notification/informal information flow chart

B. Flexibility

The surveillance system is flexible and open for new disease incorporation in the system and identification of new diseases. In 2013 maternal death was considered as MDRS and in 2015 it was included in PHEM priory diseases.

C. Data quality

The quality of data was assessed in terms of completeness and validity of the recorded data on the registry and formats. Some reports of health posts were prepared on white paper (not by provided reporting format) and their report was incomplete. From randomly selected 60 reporting formats 4(6.7%) of them did not have zero reporting and reported by white papers. This incompleteness was happened due to shortage of reporting format. From randomly selected reporting formats, 93.3% of reporting formats had zero reporting and they were complete. Since no maternal death in woreda data quality of verbal autopsy and maternal death reporting format not seen.

D. Acceptability

Acceptability reflects the willingness of persons and organizations to participate in the surveillance system. In general, health workers expressed they are satisfied with their work related to surveillance. As the focal persons at all levels self-reports revealed they were not satisfied with training opportunities, availability of the required amount of per dime for field visit and the possibilities of refunding for their used mobile expenses ..

E. Sensitivity

Sensitivity of a surveillance system can be considered in two levels: First at the level of case detection and second, the ability of the system to detect outbreaks, including the ability to monitor changes in the number of cases over time. In the detection of cases, at both health centers epidemic typhus can be identified by slide agglutination. Even though there was no maternal death in visited health facilities during the covered study period, by using case definition they can detect maternal death. In detection of outbreaks, the woreda detected AWD outbreak in 2015/16. Except malaria data, events above their thresholds were not detected because data were not analyzed regularly.

F. Predictive value positive

There was no clearly documented number of tested cases to calculate predictive positive value of epidemic typhus and also no maternal deaths registered in the woreda.

G. Representativeness

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. The surveillance system represents population live in urban and rural areas. The data can be described by time (weekly and immediately), place, and number of affected population. The surveillance also gives attention for maternal death which data has causes, contributing factors, risk factors, demographic and socio-political determinants.

H. Timeliness

In a "zero" reporting system where all reporting sites were required to report in a timely manner, irrespective of whether a health event is identified or not. All the 21 top priority diseases were reported to the next higher level on time at woreda and health facility level. Timeliness of woreda health office, health centers and health posts were not clearly known data receiving time not properly registered through mobile phone report. But woreda health office and health facilities assume that their timelines was 100%. Zonal PHEM unit focal person told that it was difficult to measure timeliness of reports because they took reports through phone and they could not register it on time properly. As the Oromia regional state feedback to East shewa zone PHEM unit indicated, timeliness of disease events reporting from East shewa zone was 84% in 2016.

3.6. Discussion

The surveillance system conducted in Ada'a Woreda was useful, flexible, simple, and acceptable. But there should be an improvement in reporting completeness, timelines, concordance of reporting facilities between woreda and health centers, distribution of guidelines and reporting formats, training of health professionals and communication facilities at health center. Supervisions not performed by zonal PHEM, but there was an integrated supervision although there was no feedback directly given to woreda PHEM units. Woreda heath office also performed an integrated supervision. However this supervision could not detect the discordance of reporting facilities between woreda PHEM unit and Denkaka health center.

Except malaria all the surveillance data were not analyzed by time place and person. As the Zonal PHEM expert respond there was "no software to analyze the bulk data of the surveillance system." The data transferred from health posts, health centers and woreda health officer were through paper based and telephone. The data changed to electronic form at Zonal Health department. Electronic systems and software can facilitate disease surveillance by reducing delays in data availability and usage. An electronic disease surveillance system can easily detect outbreaks, monitoring trends in rates of disease or effectiveness of an intervention, strengthening the local capabilities in outbreak detection and response, facilitating the generation of hypotheses by stakeholders that require further scientific investigation (20).

Cases definitions of epidemic typhus and maternal death were not posted at visible and working places in visited health centers but cases definitions were posted in Zonal and Woreda PHEM units. These case definitions should be posted at each facility to support the health professionals. Even though the case definitions are available in the national guidelines of each priority diseases, guidelines were not available in the most health facilities (one health center and four health posts). The main question here is "where the national guidelines of priority diseases are available?" Further reach needed to answer this, but they may be in the houses of someone or may not be distributed to these facilities. A research conducted in Peru to assess data quality and timelines indicated that 18.2% reporting errors were due to limited access to notification guidelines (21).

There was shortage of reporting format at visited sites. At woreda health office there was no vehicle for active case search and regular supervision. Surveillance system evolution of IDSR

conducted in Ghana also indicated that financial and material resources were inadequate for surveillance activities (22).

It was difficult to calculate the timeliness of the surveillance system. Because the time of data received from health facilities not registered properly. The timeliness seems 100% but feedback of Oromia. Health Bureau to East Shewa Zone Health Department indicated the timeliness of the zone was 84%. For this discrepancy the Zonal PHEM focal person responded that all reporting Woredas report trough phone at any time and also there was problem of network at facilities due to this they did not register time they receive the data. At health centers and health posts there was no office phone. The focal persons reported through personal mobile phone and the fee of mobile not refunded. The fee issue may delay the reporting time. The delays of reports from some facilities also delay in report to regional health bureau. Study conducted in Peru in 2009 also strengthens this idea. Findings showed that phone reporting was the main important determinant of reporting delays by surveillance personnel (21).

3.7. Limitations

Predictive positive value and sensitivity were not calculated because there was no data for total number of testes performed for Epidemic typhus. Due to budget and time constraints, private and NOG health facilities were not included in this evaluation.

3.8. Conclusion

The surveillance system was useful, flexible, simple, and acceptable. There was reporting discrepancies between woreda health office and reporting health centers. Timeliness of the reports not registered properly. There was shortage of communication facilities, no vehicle for active case searches, no guidelines, shortage of reporting formats, health worker not trained on top priority diseases and surveillance at visited health facilities. Surveillance focal persons at health center s and health extension workers usually use their personal mobile phone to report and refunding mechanism. Regular supervision monitoring and evaluation not performed by zonal and woreda PHEM units.

3.9. Recommendation

- Refresher training should be given to the surveillance focal persons, health professionals, and health extension workers by Zonal Health Department
- The Zonal health department should allocate budget for PHEM unit to conduct regular supervision, monitoring and evaluation, refunding of mobile fee and active case searches.
- There should be a replacement mechanism of personal mobile fee for surveillance focal persons and health extension workers.
- The Zonal PHEM unit should conduct regular supervision, monitoring and evaluation and giving feedbacks to woreda PHEM units.
- Health facilities should handle and use the national guidelines of priority diseases those distributed from central PHEM unit

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Annexes

Annex 3-I: 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 epidemic typhus and maternal death?

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 epidemic typhus and maternal death?

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, pregnant women 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 epidemic typhus?

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 _____

_____

_____

42. Strengths during and after training _____

_____

_____

XIV. **Resources**

Do you have;

43. **Data management equipment**

Computer_____

Printer _____

Photocopier _____

Data manager _____

Statistical package _____

Stationary _____

44. **Communications:**

Telephone service _____

Fax _____

Radio call _____

Mobile phone _____

Computers that have modems _____

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

XV. Surveillance Networking

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

a. Yes b. No c. Unknown

XVI. Budget for surveillance

47. 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?

_____(%)

48. How could surveillance be improved?

_____

_____

_____

XVII. Surveillance Co-ordination

49. 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

_____

50. 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

   Epidemic typhus_____ Total pregnant women _____

b. In 15/16, number of mothers death_____

c. The incidence / Prevalence of epidemic typhus

   incidence _____ prevalence _____Deaths _____

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

Does the surveillance system help;

d. To detect outbreaks of these selected priority diseases early? Yes/ No

e. To estimate the magnitude of morbidity and mortality of these diseases, including identification of factors associated with these diseases? Yes/ No

f. 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 epidemic typhus and maternal death 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 epidemic typhus 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 epidemic typhus_____

vii. Stability:

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

Annex 3-II: 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 in wereda HP____, HC___, Private/NGO____
6. 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)

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

Strengthening reporting

10. How can reporting be improved?

_____

_____

_____

III. ***<u>Data analysis for epidemic typhus and maternal death</u>***

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

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

If yes, Observe for each denominators _____

_____

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

a. Yes b. No c. Unknown

Observe description of data by age and sex_____

_____

_____

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

a. Yes b. No c. Unknown

Observe description of data by place _____

_____

_____

14. Do you describe of data by time?

a. Yes b. No c. Unknown

If yes, observe the description _____

_____

_____

15. Do you perform trend analysis (line graph of cases by time) for epidemic typhus and maternal daeath?

a. Yes b. No c. Unknown

If yes, Observe and list diseases_____

_____

_____

IV. Availability of threshold level for selected diseases

16. 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 _____

_____

_____

17. Who is responsible for data analysis? _____

18. 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***

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

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

_____

20. Has your district ever investigated an outbreak?

a. yes b. No c. Unknown

*VI. **Epidemic preparedness***

21. 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 _____

_____

22. 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 _____

_____

23. 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? _____

_____

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

a. Yes b. No c. Unknown

VII. Epidemic management committee

25. 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

_____

_____

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

a. Yes b. No c. Unknown

VIII. Responses

27. 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

28. 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) _____

_____

29. What were the case fatality rates during most recent outbreak mainly for typhoid fever?

_____

_____

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

30. 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. Feedback

31. 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, _____

_____

32. 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

33. 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 _____

_____

34. 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 _____

_____

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

Reason 1_____

Reason 2_____

Reason 3_____

XI. Training

36. Number of health personnel trained in disease surveillance

_____

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

XII. Resources

38. Is your district has enough logistics for surveillance activities?
    a. Electricity
    b. Bicycles
    c. Motor cycles
    d. Vehicles
39. Data management
    a. Stationery
    b. Calculator
    c. Computer
    d. Printer
    e. Statistical package
40. Communication
    a. Telephone service
    b. Fax
    c. Computers that have modems
41. **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:

42. **Hygiene and sanitation materials**
    a. Spray pump
    b. Disinfectant

XIII. Surveillance co-ordination:

43. 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

44. Are you satisfied with the surveillance system?

Yes No Unknown Not applicable

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

_____

_____

_____

XV. Opportunities for integration

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

_____

_____

_____

Annex 3-III: 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 epidemic typhus outbreak? _____
3. Is there any maternal death in the last at the last 6 months? a. yes b. no c. Unknown
4. Is there clinical register at this facility?

a. yes b. no c. Unknown

If yes, observed the existence of a clinical register _____

5. Is clinical register is filling correctly?

a. yes b. no c. unknown

Observe the last month filled clinical register if correctly done _____

_____

6. Do you have a standard case definition for epidemic typhus and maternal death?

a. Yes b. No c. Unknown

Observe the standard case definition _____

_____

7. Are you using these standardized case definitions?

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

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

_____

_____

III. Case confirmation

8. 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

9. Did the laboratory have shortage of reagents and equipment to perform epidemic typhus malaria, typhoid fever in the last 6 months? a. Yes b. No
10. Does your laboratory have adequate reagents and equipment to perform epidemic typhus malaria, typhoid fever the next 6 months?

    a. Yes b. No

    if no list reagent/equipment not available_____

    _____
11. 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 _____

_____

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

_____

_____

IV. Data reporting

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

a. Yes b. No c. Unknown

14. 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

15. 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

16. **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

17. How do you report?

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

18. **Strengthening reporting**

How can reporting be improved?

_____

_____

_____

V. Data analysis

19. 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 _____

20. 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 _____

21. Do you describe data by time?

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

If yes, Observe description of data by time _____

22. Do you perform trend analysis?

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

If yes, Observe line graph of cases by time _____

23. Who is responsible for data analysis? _____

24. How often do you analyze the collected data?

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

25. 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., total number of pregnant women population by village, total population)

_____

_____

VI. Availability of threshold levels for each priority disease

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

a. Yes b. No c. Unknown

VII. <u>Epidemic preparedness</u>

27. 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. <u>Epidemic response</u>

28. 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

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

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

Observe case facility rate for most recent outbreaks _____

_____

IX. <u>Feedback</u>

30. 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

31. 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 _____

32. 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:

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

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

_____

34. 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

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

_____

36. On what topics of surveillance they trained? _____

_____

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

_____

_____

XII. Resources

Have you:

38. **Logistics**
    a. Electricity
    b. Bicycles
    c. Motor cycles
    d. Vehicles
39. **Data management**
    a. Stationery
    b. Calculator
    c. Computer
    d. Software
    e. Printer
    f. Statistical package
40. **Communications**
    a. Telephone service
    b. Fax
    c. Radio call
    d. Computers that have modems

41. **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:

42. **Hygiene and sanitation materials**

a. Spray pump
b. Disinfectant

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

_____

_____

XIII. Satisfaction with surveillance system

44. Are you satisfied with the surveillance system?

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

45. 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 3-IV: 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 clinicalregister?

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 epidemic typhus and maternal death?

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

If yes, observed the standard case definition forepidemic typhus and maternal death.

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. <u>Data reporting</u>

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. MalariaY N U N/A
b. Epidemic typhusY N U N/A
c. Measles Y N U N/A
d. Maternal death 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. <u>Data analysis</u>

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 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 4: HEALTH PROFILE DESCRIPTION

Health Profile description report, Mojo Town Administration East Shewa Zone, Oromia Regional State; 2007 EFY (2014/2015)

Summary

Introduction: Health profile is a public health report that brings together key information on health and its determinants in the defined area. It is a quantitative and qualitative description of the health of community and the factors, which influence their health.

Objective: To describe the health and health related profile of Mojo Town Administration

Methodology: Cross-sectional study focusing mainly on record review was conducted for the Health profile assessment of Mojo Town Administration East Shewa Zone, Oromia Regional State. Data were collected through structured questionnaires, interviews, record reviews, from reports of Mojo health office and other different sectors. The collected data were organized analyzed by using Microsoft excel 2010 and Arc-GIS.

Result: In 2007 EFY, health coverage of the Mojo town was 100%. Immunization coverage and first antenatal care (ANC) visit was more than 100 but mothers follow the fourth ANC was 74.17%. Neonatal mortality rate was 15 per 1000 live births but no maternal death recorded. All deliveries were assisted by skilled professionals. Contraceptive acceptance rate was 158% and injectable contraceptive method more was preferable. TB cure rate and treatment success rate was 73% and 77% respectively. HIV prevalence was 10.3% with incidence of 11new cases of HIV per 1000 inhabitance per year. Potable water coverage was 95% and toilet coverage 83.97%. The top leading causes of morbidity for under five and adults was acute febrile illness with 17.39% and 17.39% respectively. Road traffic accident was also one of the major health and social problems of the town.

Conclusion and recommendation: Health service coverage of Mojo town is in a very good status. Most indicators showed more than 100% coverage. Strengthen HIV/AIDS prevention and control, increasing TB cure and success rate, increasing toilet coverage will be expected from the town health office.

4.4. Introduction

4.4.1. Back ground

Health profile is a public health report that brings together key information on health and its determinants in the defined area and interprets and analyses of the information (1). It is a quantitative and qualitative description of the health of community and the factors which influence their health. It is made up of indicators of socio-demographic characteristics, health status and quality of life, health risk factors, and health resources that are relevant for most communities; these indicators provide basic descriptive information that can inform priority setting and interpretation of data on specific health issues (2).

The some main indicators are: distribution of the population by age and race/ethnicity, number and proportion of school aged children and adults, ratio of the number of students graduating from high school to the number of students who entered 9th grade three years previously, household income, infant mortality rate, numbers of deaths or age-adjusted death rates for motor vehicle, reported incidence of AIDS, measles, tuberculosis, and, a proportion of total live births, proportion of 2-year-old children who have received all age appropriate vaccines (3).

The main function of the health profile is to stimulate action that will improve health. Which means it is one means of identifying community health problems and their potential solutions in a specific area (1). It can also help a community maintain a broad strategic view of its population's health status and factors that influence health in the community (2).

4.4.2. Rationale of the Study

The presentation of the profile can stimulate public interest and improve general understanding of health issues(2). Mojo Town does not have recent health profile which will be used for planning health and health related issues. The purpose of this project is to assess and describe the Mojo Town Administration health profile which will be used for addressing the current gaps for program planning, priority setting and timely interventions.

4.5. Objectives

4.5.1. General Objective

To describe the health and health related profile of Mojo Town Administration.

4.5.2. Specific Objectives

- To describe the health and health related condition of the Town in time ,person and place
- To assess health status and health indicators of the Town in order to identify major health problems for priority setting
- To determine disease burden of the Town and communicate the information on main contributing factors and possible preventive measures.

4.6. Methods and materials

4.6.1. Study area and period

This health profile assessment was conducted in Mojo Town Administration, which is located in East Shewa Zone, Oromia Regional State, Ethiopia. The study or health profile assessment was done from May 25 to June 1, 2016.

4.6.2. Study design and Data collection strategy

The study design was retrospective cross sectional study. The data was collected from different sectors, Mojo town municipality, health office, education office, tourism office, Water and office, ethio-telecom, electric power, transport authority. Data was gathered from reports of the different sectors, interview and other related documents.

4.6.3. Data possessing and analysis

The data was analyzed using place person and time through Microsoft Excel 2010 and Acr GIS.

4.6.4. Source population

The total population of East Shewa zone which is 1,511,137 in 2008EFY used as the source population of this study

4.6.5. Study population

The total population of Mojo Town which is 42,692 the study population of this study

4.6.6. Study unit

Costumers those got health service in 2007 EFY in health facilities of Mojo town administration

4.6.7. Ethical consideration

The data collection was conducted after obtaining permission from all concerned offices including the Zonal Health Department and Mojo Town Health Office.

4.6.8. Dissemination of result

After final edition, the findings of the Health Profile were disseminated to Mojo Town Admin Health Office, East Showa Zonal Health Department, Adama Regional Laboratory and SPHMMC Department of Public Health

4.4. Result

4.4.1. Historical Back Ground of the area

Mojo is a town in central Ethiopia, named after the nearby Modjo River located in the East Shewa Zone of the Oromia Region. Mojo is one of towns in the country that had emerged along the Railway from Djibouti to Addis Ababa, constructed between 1894 and 1917. It is one of the Pre-Italian periods of the country that had been considered as from their early period of formation as a satellite town s along rail way lines east of the capital (4).

The name Mojo is derived from the Oromo term that refers to a person and a clan. Mojo is widely used as personal names in the surrounding areas. According to tradition of the area, there was a person who lived long in the area by the name Mojo Waqayyo. Oromo tradition elaborates that the name. Mojo and his wife Bontu had strong attachment to the river in the locality. The name of the river as well as the area came to be called Mojo. The most popular and acceptable tradition in connection to the name of the town is related to the name of Mojo Lume Mi'eecha. According to this tradition, Lume, the father of Mojo , had lived in the locality and after his death two traditional believes (4).

Mojo and its area have long history. The area had been long inherited by different branches of Tullama Oromo., mainly Gullale, Gumbuchueaka and Adae. The region also much related to historic interaction between the medieval of Fatagar, mutachaTulama common chaffe-Oda Nebe and major events of the 16th century such as the war of Imam Ahmed Ibn Ali Ghaz. The battle Shibira Qure had to be taken palace near Mojo.

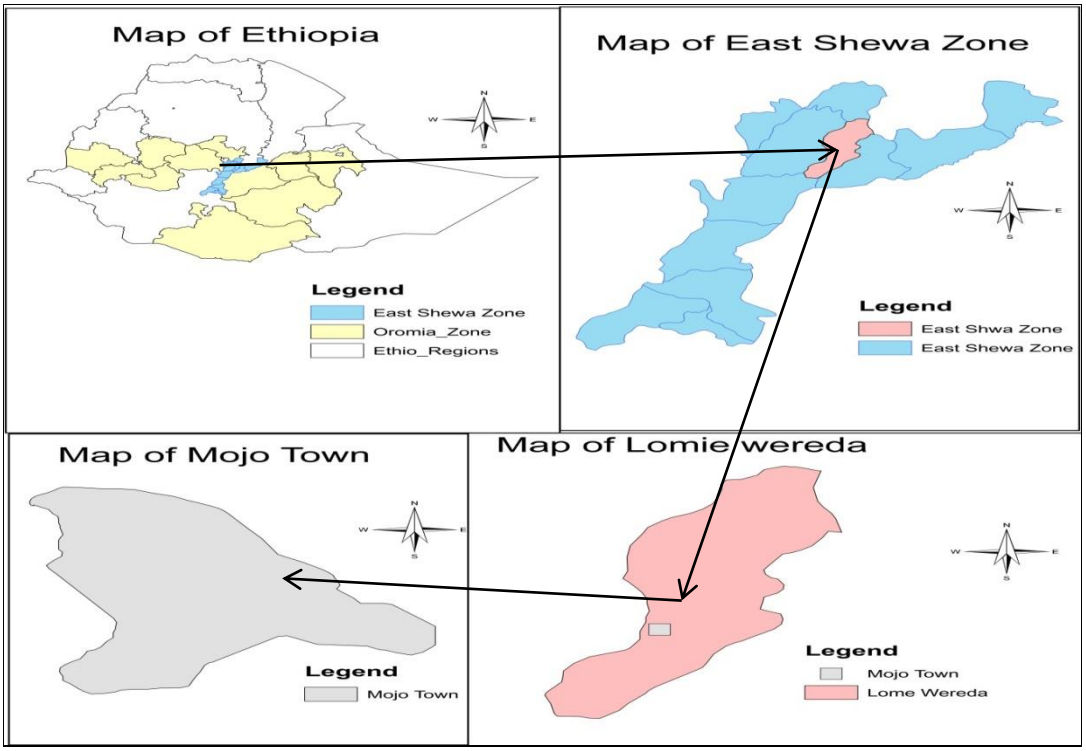
Mojo was recognized as a town since 1941 and it gained municipal status in 1944. The constriction basic infrastructures, like school, health facilities, telecommunication, electric power supply contributes for Mojo development. Mojo is one the industrial towns in the country. The establishment of industries began in 1920's and now there more than 51 in Mojo and is surrounding.

There are a number of potential tourist attractions which could have developed into important tourist attraction sites. These include the fall called Laga Finca'aaMulo, the different prides of around the town i.e. Gango, Dansa, Biyo, Dalota, Malmale etc. Furthermore, there are also cares like Malmale, Abba Ayyala and the Naturla Bridge in Buna Buta (4).

4.4.2. Geography and climate

Mojo is located in Lome Wereda, East Shewa Zone Oromia Region, southeast of Addis Ababa along highway to Adam and Djibouti at 57 Km and 28 Km from zonal capital, Adama. Mojo town extends from 8°32'44 N to 8°37'58" N latitudes 39°05'5" E to 39°10'38" longitudes. The town lies on plateau plain land scape within these landscapes there are also gullies and revers. The elevation of Mojo town ranges from 1694 to 1884 meters above sea level. Mojo's climate is influenced by altitude and latitude and general climatic condition of the town is categorized under Kola climate. Annul mean temperature and mean annual rain fall is 26.5°C and 870.6mm respectively.

Figure 4-1: Geographic location of Mojo town (Map of Mojo town)



4.4.3. Administrative and political structure

Mojo town currently have thirty one different government structures and 2 two kebeles, kebele 01 and kebele 02. Kebele 01 had total population of 16467of these 8068(49%) were male and Kebele 02 had a total population of 24701 of these 12103 were male.

4.4.4. Demographic Information

According to the national population and hosing census of 2007, the total population of Mojo town was 41168(male 20176 and female 20996) with the number of house holes 8700, population growth 2.89% and average family size was 3.4. . Out of total population 4.8% were less than 15 years of age 47.5% in intermediate age group (15-59) and 4.5 above 60 years of age. Oromia urban plan institute report on Mojo town 2007 EFY indicated that the young dependency ratio was estimated to be 57.7%, meaning of 100 person in age working group had to support the average 58 persons those age is between 0-4. And also old dependency ratio for the town was estimated to be 5.3% meaning, of 100 persons in the working age group (15-64) had to support on the average 5 persons whose age is 65 and above (4).

Five peasant associations that immediately sharing boundary with Mojo town, namely: Sharraa Dibaandibaa, KurmaaFaaxolee, Xaddee, KolbaaGoddee and AriifataaJogolaa have total population of 16165. These populations are considered as special population by Mojo health office.

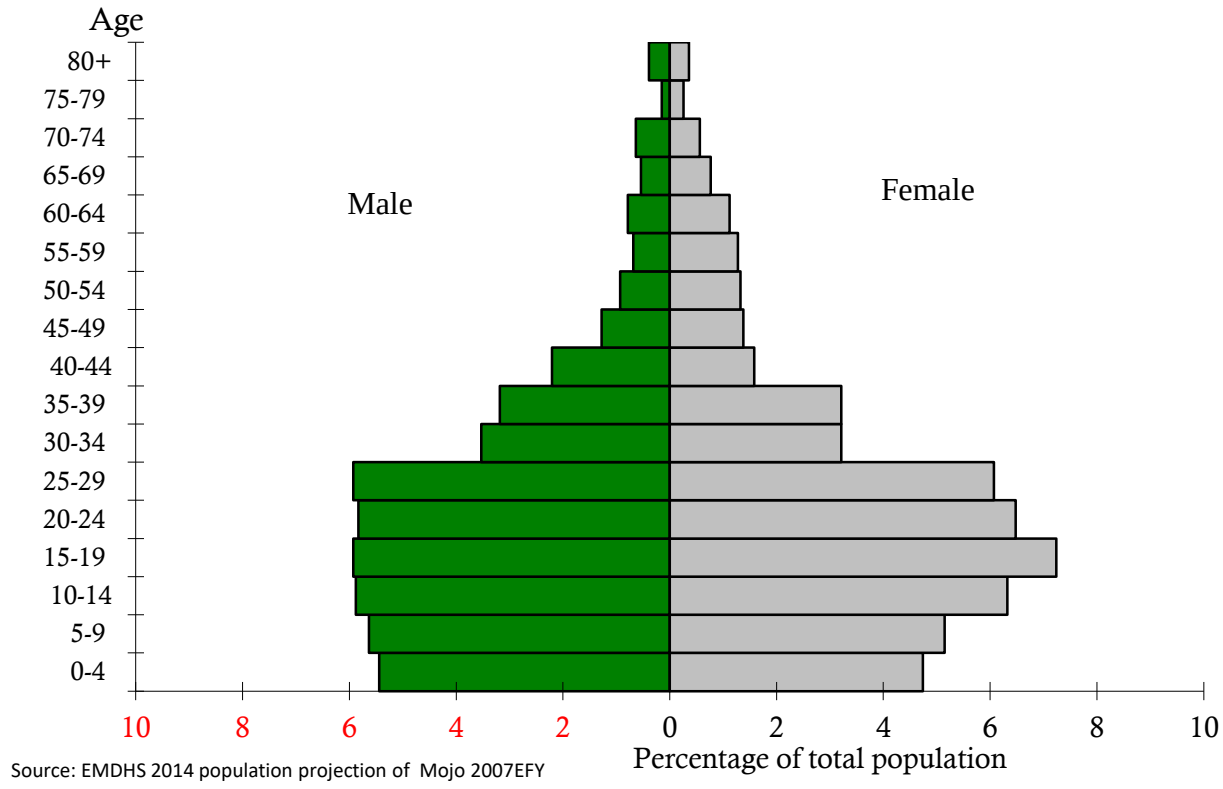


Figure 4-2: Population pyramid of Mojo Town 2007EFY

Table 4-1: Population size of Mojo by Age categories, 2007EFY

No	Population category	Numbers
1	Population under 1yrs	1276
2	Population under five yrs.	6752
3	Population < 15 yrs.	19761
	Population 15-59yrs.	19555
4	Population >60 yrs.	1852
5	Women 15_49 yrs. of age	20306
6	Average household size	4.8
7	Annual population growth rate (%)	2.89%

Mojo, as a center for trade industries, is residence of nations and nationalities. Major ethnic groups live in town are Oromo, Amhara, Siltie and Gurage. Lists of ethnic groups of Mojo list below:

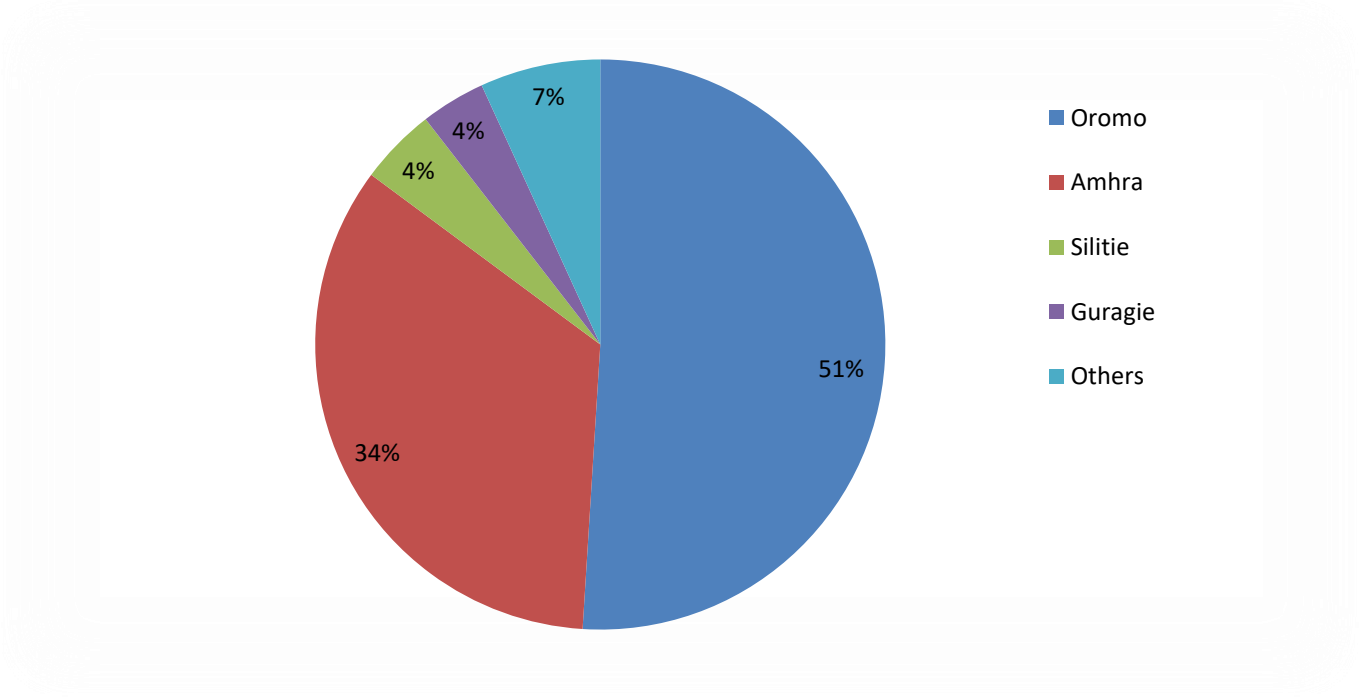


Figure 4-3 Distribution of population by ethnic group 2015

4.4.5. Productivity and income

Mojo is located on main road which takes from Addis Ababa to Djibouti (both railway and truck).its proximity to Addis Ababa and Adama gives it best advantage. Not only its proximity to AA and Adama but also its location found on junction which together from four directions, such as from AA, from Adam, from Hawassa, and fro Minjar directions. The basic economic activities of the town includes: Teff, Skin and skin products, Livestock products, fruits and vegetables, livestock, trade and commerce, construction materials agricultural products.

The major trade activities traded in the town was agricultural products such as crops, oil seed fruits and vegetables. The origins of theses goods were East Shewa zone weredas such as Bora, Dugda Adamitu Tulu ad Adaawereda.

4.4.6. Education

Mojo Town had a total of 29 schools, of these 14 kindergartens, 10 primary and 3 secondary schools and 2 preparatory schools in 2007 EFY. In this year 14505 students attended the classes, of these 2633 KG students, 8443 primary school students and 2905 and 624 students of secondary school and preparatory school. From the total students 7633 (52.3%) were female and 6972 (47.7%) were male. In 2007 EFY 444 teachers were in the process of teaching and learning. The numbers of male teachers were 216(48.6%) and the numbers of female teachers were 228(51.4%).

Table 4-2 Total number of teachers and students in Mojo Town 2007EFY

School type		**Number of students**			**Number of teaches**		
		Male	Female	Total	Male	Female	Total
KG		1327	1306	2633	3	92	95
Primary	1-4	2072	2264	4336	40	73	113
	5-8	1880	2227	4107	69	38	107
Secondary (9-10)		1338	1567	2905	75	23	98
Preparatory (11-12)		355	269	624	29	2	31
Total		6972	7633	14605	216	228	444

Source: Mojo Town education office

4.4.7. Facilities /Infrastructures

The town had one stadium, one public hall, one youth center. As to transport and communication, Mojo is accessible from the north, south, and east by road transport. Inter town roads were opened 1950/51. The railway wreakers used telegraph in Mojo railway work that means as early as foundation of the town. Telephone and postal service was introduced around the mid of 1940's. A modern postal service came to existence in Mojo in 1983. In 2007 Mojo town had a total length of 206.7km. Of these, 40 km asphalt, 13.7km cobblestone and 153km loose surface road.

The town had more than 45 hotels, 7 banks, 3 microfinance banks, 1 post office, 24 hours electric service, more than 51 industries. The town connected to hydroelectric power of national grid in 1953 EFY. In 2006 EFY there was quarter of the town do not get electric service.

Figure 4-4: Electric Service Subscribers by Type of Functions 2006 E.C

Type of function	Number of clients	No. applicants
Residential	4860	200
Commercial	1129	10
Industrial	105	10
Government	22	5
Public organizations	0	7
Total	6116	232

Source: Ethiopian Electric power service Mojo district

4.4.8. Traffic accidents

The highway that connects Addis Ababa with eastern and southern part of the country passes through Mojo town and it contributes for the movement of large number of vehicles of all types. The annual average daily traffic volume (AADT) is more than 206,776 vehicles of all types enter in to and exist through the town particularly track and trails. From 2002-2007 EFY a total of 382 accidents were occurred in Mojo under category of deaths, Sevier accidents mild accidents and property damages. By this category of accidents, 97 persons died, 61 had got sevier damage 51 51 had got mild damage.

4.4.9. Health System

Organizational structural of Mojo Town Admin Health Office shown of figure 2 indicates that the health office has five core processes and two supportive processes under head of the Office. The core processes are Family health, Communicable diseases, Environmental and Regulatory, HMIS. Plan and program, Human resource and executive secretary are supportive processes.

The health budget of Mojo town in 2007 EFY was 4, 600, 337 Birr and in 2008 the budget was increased to 7,652,651. This shows the budget increased by 60.3% from 2007 budget. Mojo Town Admin allocated 7.1% and 14% of the total budget to health sector in 2007 and 2008 respectively. This increase was for contraction of Mojo District Hospital and renovation of Health Centers.

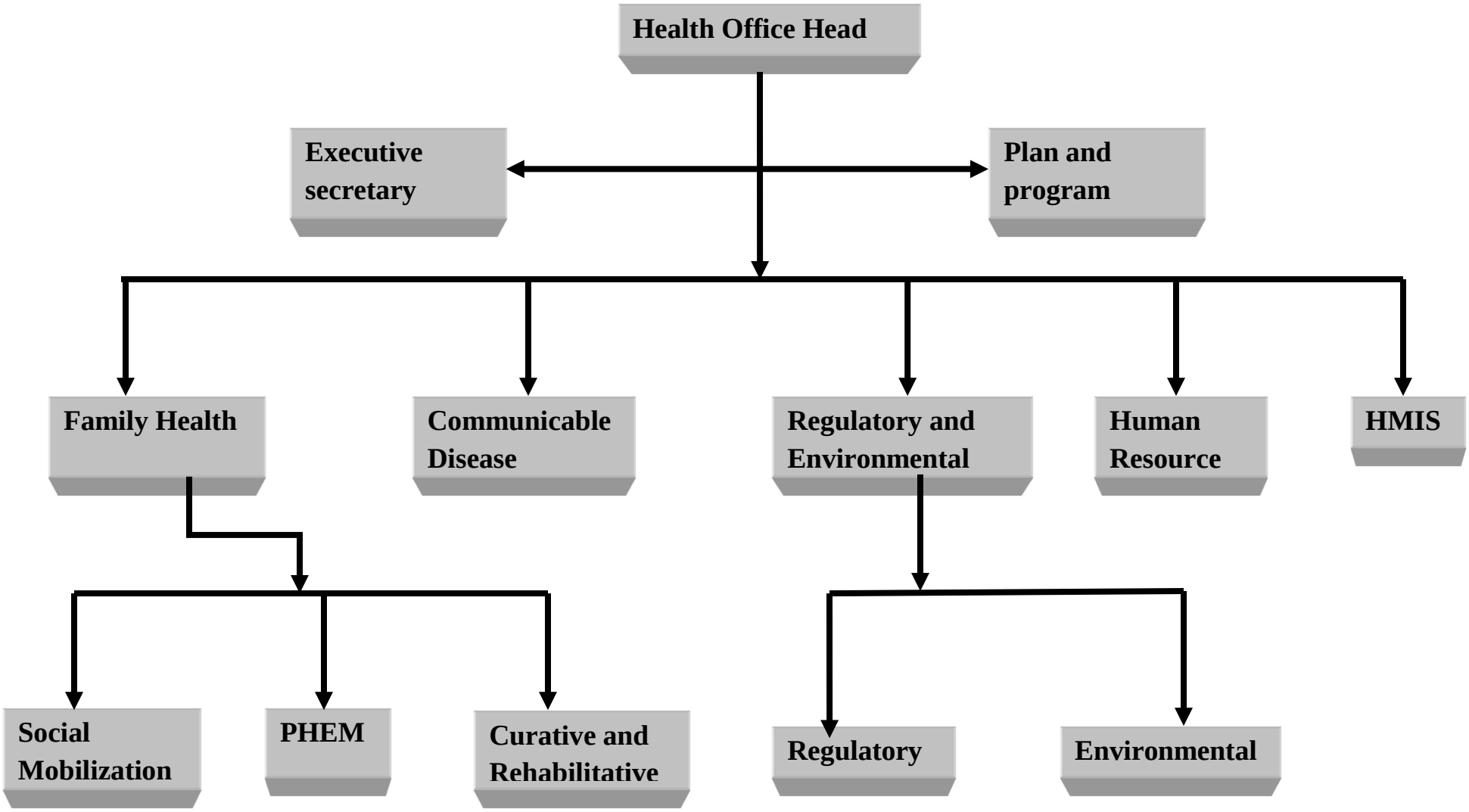


Figure 4-5: Organizational structure of Mojo Town Admin Health Office

4.4.10. Health Service

A. Health institutions

In 2007EFY, there were 2 governmental, 21private, and 1 NGO health institutions in the town. The governmental facilities were one type A and one type B health centers with 6 beds. One hospital and 2 health posts are under construction. From the 21 private institutions in the town, there were one hospital, 11drug stores and 9 clinics. Health coverage of the town is 100%.

Table 4-3: Health institution in Mojo Town number and type, 2007 EFY

Type of institution			Number	Total number of beds
Gov.	Hospital		1*	
	Health center	Type A	1	6
		Type B	1	
Private	Hospital		1	33
	Drug stores		11	
	Clinic		9	
NGO	Clinic		1	

*under construction institutions

B. Health professional

Table 4-4: Health professional of Mojo Town in 2007EFY

Profession	Number	Health Workers to Population ratio	Standard
Physician	0	0	1:10,000
HO	9	1:4574	1:10,000
Nurses (Deg. and Dip.)	14	1: 2941	1:5,000
Mid wife (Deg. and Dip.)	6	1:6861	1:5,000
Lab. (Deg. and Dip.)	5		
Pharmacy (Deg. and Dip.)	5		
Env. Health (Deg. and Dip.)	3		
X-ray technician	-		
HIT	4		
HEWs	17	1:2422	1:2,500 OR (2:1 Kebele)
Total	**63**		

C. Top causes of morbidity and mortality

In 2007 there were 101816 clients visited health institutions. Of these 14637 were in under five age groups. The top five leading causes of morbidity for under five were acute upper respiratory infections (23.18%), other or unspecified infectious and parasitic diseases (17.53%), other or unspecified diseases of respiratory system (12.58%) and Pneumonia (12.37%). The top five leading causes of morbidity for aged above five were: acute febrile illness (17.39%), acute upper respiratory infections (14.59%), Typhoid fever (14.24%), urinary tract infection (10.57%) and epidemic typhus (10.29%). Even though there were1488 admissions, no data causes of admissions.

From the total under five aged group diagnosed in 2007 there were 94 children with mild malnutrition and 8 were with sever mal nutrition.

Table 4-5: Top ten causes of und five years morbidity in Mojo town 2007EFY

Rank	Diseases	2007		Diseases	2006	
		No.	%		No.	%
1	Acute febrile illness	5600	17.39%	Acute upper respiratory infections	4368	18.18%
2	Acute upper respiratory infections	4748	14.59%	Acute febrile illness	3957	16.47%
3	Typhoid fever	4638	14.24%	Urinary tract infection	2949	12.27%
4	Urinary tract infection	3440	10.57%	Disease of musculoskeletal system and connective tissue	2310	9.61%
5	Epidemic typhus	3348	10.29%	Epidemic typhus	1819	7.57%
6	Dyspepsia	2340	7.19%	Dyspepsia	1810	7.53%
7	Pneumonia	2197	6.75%	Typhoid fever	1744	12.27%
8	Acute bronchitis	2132	6.55%	Infection of the skin and subcutaneous illness	1896	7.06%
9	Diarrhea (non- bloody)	2063	6.34%	Diarrhea (non- bloody)	1690	7.03%
10	Infection of the skin and subcutaneous illness	1982	6.09%	Acute bronchitis	1668	7.02%
Total		32548	100%		24211	100%

Table 4-6: Top ten causes of und five years morbidity in Mojo town 2006-2007EFY

Rank	Diseases	2007		Diseases	2006	
		No.	%		No.	%
1	Acute upper respiratory infections	2441	23.18%	Acute upper respiratory infections	1933	25.44%
2	Other or unspecified infectious and parasitic diseases	1846	17.53%	Other or unspecified infectious and parasitic diseases	1371	18.04%
3	Other or unspecified diseases of respiratory system	1325	12.58%	Pneumonia	996	13.11%
4	Pneumonia	1303	12.37%	Diarrhea(Non bloody)	767	10.09%
5	Diarrhea(Non bloody)	972	9.23%	Acute febrile illness	737	9.70%
6	Acute febrile illness	931	8.84%	Infection of the skin and subcutaneous tissue	481	6.33%
7	Infection of the skin and subcutaneous illness	661	6.28	Other or unspecified diseases of eye and adnexa	448	5.90
8	Acute bronchitis	466	4.42%	Other or unspecified diseases of respiratory system	408	5.37%
9	Otitis	339	3.22%	Otitis	260	3.42%
10	Acute bronchitis	248	2.35%	Acute bronchitis	198	2.61%
Total		10532	100%		7599	100%

4.4.11.Vital statistics and Health Indicators

Table 4-7: Vital statistics of mojo town 2006-2007

Indicators	2006	2007
Still birth	11	7
Neonatal death (institutional)	16	18
Infant mortality rate	No data	No data
Child mortality rate	No data	No data
Crude death rate	No data	No data
Maternal death	3	0
Total Deliveries	1071	1891

Regarding vital statistic there is no data in the health institutional level and municipal level. There is data only for maternal death and institutional neonatal deaths. There 3 maternal deaths in 2006 and no death in 2007. Institutional neonatal death in 2006 was 16 and 18 in 2007.

4.4.12.Immunization coverage for children and Women

As part of preventing and control vaccine-preventable diseases the town health system delivering vaccination activities for surviving children. In 2007EFY immunization coverage of the town was 100%. In 2007 the immunization coverage for measles 100 %, DPT3 6100% and fully immunization was 100%. The immunization coverage is generally greater than 100%.

Table 4-8: Immunization coverage of Mojo town 2006-2007EFY

Type of immunization	2007 EFY		2006 EFY	
	Performance	Coverage	Performance	Coverage
BCG	1498	>100%	1206	>100%
OPV1	1566	>100%	1212	>100%
OPV3	1576	>100%	1307	>100%
Penta1	1566	>100%	1212	>100%
Penta3	1576	>100%	1307	>100%
PCV1	1566	>100%	1053	>100%
PCV3	1575	>100%	1090	>100%
Measles	1572	>100%	1129	>100%

F/immunization	1553	>100%	1129	>100%
PWTT2^{+}	3618	>100%	3260	>100%
PAB	1544	>100%	1228	>100%

4.4.13.Maternal health Service

In Mojo there were 1647 eligible pregnant women in 2007EFY. Total number of women accesses got access of ANC1 2995 and 1221 ANC 4. All deliveries were attended by skilled birth personnel (Nurses, Midwifes, and Physician). There were no deliveries by TBA and health extension workers.

In 2006 and 2007EFY there were 1071 and 1906 institutional deliveries respectively. In 2006 from the total delivers, 1701, only 752 (70.25%) got PNC service. In this year there were 3 maternal deaths, 11 still births and 16 institutional early neonatal deaths. Where as in 2007, there were 100% PNC, no maternal death, 7 still birth and 18 institutional early neonatal deaths.

There were 20306 women in reproductive age group in 2007 EFY. From these women 15489 use different contraceptives methods; of which 1504(9.7%) use Oral contraceptives, 10642(68.7%) used injectable, 2751(17.5%) used implant, 571(3.7%) used IUCD and 57(0.4%) used other contraceptive methods. Contraceptive acceptance rate was 158% in 2007.

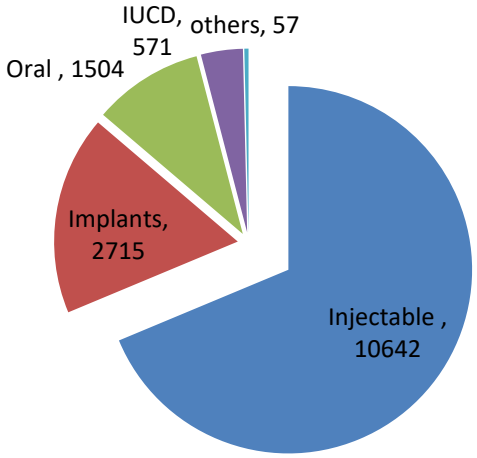


Figure 4-6: Contraceptive users of Mojo town 2007EFY

Table 4-9: MCH and family planning service performance in Mojo Town, 2006-2007

Service		Year(EFY)			
		2006		2007	
		No.	%	No.	%
ANC	ANC 1st	2502	>100%	2995	>100%
	ANC 4th			1221	74.1%
Delivery		1071		1906	
PNC	0-48 hours	752	70.25	1300	0.69
	2-3 days			335	0.18
	4-6 days			271	0.14
Family planning	Oral contraceptive	10872		1504	9.7
	Injectable			10642	68.7
	Implants			2715	17.5
	IUCD			571	3.7
	others			57	0.4
Contraceptive acceptance rate		>100%		>100%	

4.4.14. Water and sanitation

Portable water supply in Mojo began since the foundation of the town. At that time, the railway company pumped water from Mojo River to reservoir, and then distributed the water to its employee and the town. In 2007EFY the town had 95% pure water coverage and daily water consumption per day was 20 liters per person. In 2007 Mojo Town Water and Sewerage Service had 6523 customers of these 6050 were private, 402 trade, 60 governmental and 11 were religious organizations.

In mojo, only 11.77% households have improved toilets, 72.2% use non-improved toilet and 16.03% has no toilet facility which needs commitments of all stakeholders. From this result, families of these 16.03 housing units defecate on open spaces, water banks, and road sides. Generally toilet coverage of the town is 83.97% with 100% utilization. The town solid waste management is 89% and do not have liquid waste management system.

4.4.15.Endemic Diseases

TB

In 2005 EFY total cases of TB were 165, and reduced to 152 and 138 in 2006 and 2007 respectively. Pulmonary TB also reduced from 44 to 31 in 2007but extra pulmonary TB was increased from 44 in 2005 to 52 in 2007. TB cure rate and treatment success rate was 73% and 77% in 2007 repectively. In 2005 four people diagnosed for leprosy all them were negative. In 2006 two peoples diagnosed for leprosy one of them was positive and on treatment, but in 2007 leprosy cases were not registered.

Table 4-10: cases of TB in Mojo Town 2005-2007 EFY

Cases	2005	2006	2007
All forms of TB cases	165	152	138
PTB negative	96	82	55
PTB positive	25	43	31
Extra PTB	44	27	52
TB detection rate	170%	150%	150%
TB cure rate	80%	88%	73%
TB Rx success rate	80.4%	88%	77%
TB defaulter	0	3	0
Total TB patients screened for HIV	165	152	138
Death of TB positive	4	1	3
Total Leprosy case	4	2	0
Leprosy cases on Rx	0	1	0

Malaria

Mojo and its areas are endemic for malaria. In 2006 and 2007 EFY all malaria cases were 1509 and 1185 respectively. In 2007 confirmed malaria with PF was590(49.8%), of theses 48(8.1%) were children aged under five years. 22500 ITNs were distributed to the community and in average each house hold got 2.6 ITNs. There were no deaths due to malaria in all ages groups.

Table 4-11: Cases malaria in Mojo by age in200-2007EFY

Case type	All age group		Under five age group	
	2006EFY	2007 EFY	2006 EFY	2007 EFY
Clinical malaria	220(14.6%)	65(5.5%)	13(13.4%)	1(1.4%)
Confirmed PF	496(32.9%)	590(49.8%)	40(41.2%)	48(69.6%)
Malaria other than PF	793(52.6%)	530(44.7%)	44(45.4%)	20(29%)
Death by malaria	0	0	0	0

HIV/AIDS

In mojo there were 3982 peoples live with HIV in 2006 EFY. In the same year18355 clients were screened for HIV in VCT, PITC and PMTCT departments, of these 7965(%) male and 10390(%) were female, whereas 454 new HIV cases were found and these were 196 from VCT, 222 and 26 from PMTCT. HIV prevalence was 10.3% with incidence of 11new cases of HIV per 1000 inhabitance per year. In 2007 a total of 4251PLWA in Mojo and 15846 clients screened for HIV, of these 5716 (%) male 10130 (%) female. From total screened clients 344 were positive for HIV and 123 male and 221 female.

In 2006 and 2007 EFY 1668 and 2408 mothers were tested for HIV of these 26 and 44 were positive for HIV respectively.

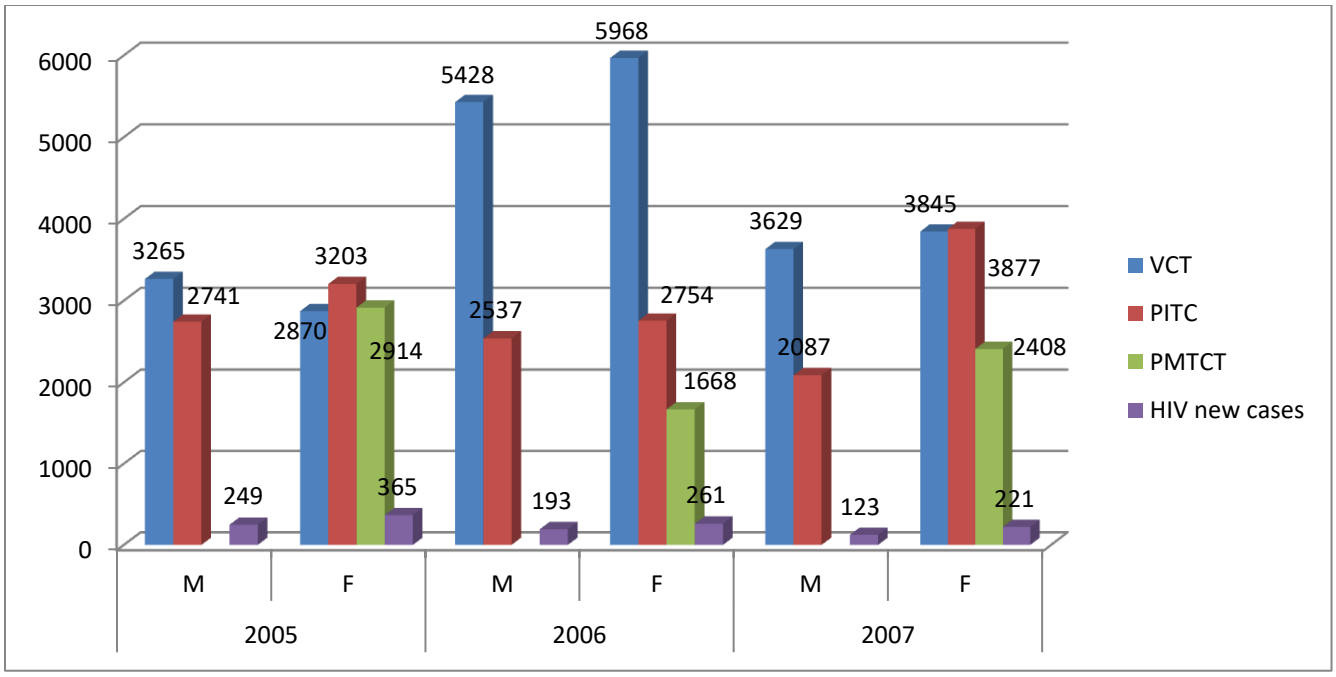


Figure 4-7: HIV cases in mojo town by sex 2005-2007EFY

Table 4-12: HIV positive case in Mojo by sex 2005-2007

Testing unit	2005		2006		2007	
	M	F	M	F	M	F
VCT	87	121	97	99	63	68
PITC	162	214	96	136	60	109
PMTCT	NA	30	NA	26	NA	44

4.4.16.IDSR

There was no any epidemic and disaster in 2007EFY in Mojo. Table 12 shows some immediately and weekly reportable diseases.

Table 4-13: Some immediately and weekly reportable diseases in Mojo town 2007EFY

Dysentery.	Typhoid fever**	Relapsing fever**	Epidemic Typhus**	Measles**	Cholera /AWD*	Pandemic Influenza*	Rabies *	AFP/ Polio*
2114	6927	2	5041	1	0	0	0	0

*Immediately reportable diseases

** Weekly reportable diseases

4.5. Discussion

Adequate sanitation facilities such as an improved toilet and disposal that separates waste are necessary at house hold level(5).In mojo, only 11.77% households have improved toilets, 72.2% use non-improved toilet and 16.03% has no toilet facility which needs commitments of all stakeholders. From this result, families of these 16.03 housing units defecate on open spaces, water banks, and road sides. Generally, toilet coverage of the town is 83.97%. This data is proportional with EMDHS 2014 (5).

In 2013, maternal mortality was estimated that 497 per 100,000 live birth 2013(). In 2006 there were 3 maternal deaths and no death in 2007EFY. Ethiopia has achieved MDG 4 three years earlier by reducing under-five mortality from 1990 estimate. In 2015 GC neonatal mortality rate was 28 per 1000 live births(6). In Mojo neonatal mortality rate was 15 per 1000 live births in the same year. This is lower than the national and regional data, and the improvement is all deliveries and post natal cares are given by health professionals. But in 2004 and 2005 EFY deliveries by skilled attendants in Oromia was 24.2% and 21.4% respectively (7,8).

In 2006, at the national level, vaccination coverage of Pentavalent 3, PCV3 Measles and fully immunization vaccine coverage reached 91.1%, 85.7%, 82.9% and 86.5%, respectively(6). In 2005 EFY vaccination coverage of Pentavalent 3, PCV3, Measles and fully immunization were 93.2%, 89.4%, 87.3% and 81.0% respectively in Oromia (8). Immunization coverage in mojo was 100% in 2006 and 2007 EFY which was greater than the national and regional repot in 2006 and 2005 EFY.

HIV prevalence was estimated at 1.2% (0.8% in males and 1.6% in females) and the adult HIV incidence at 0.03% in 2014 GC at national level (6). HIV Prevalence of Oromia was 1.0% in EDHS 2011 (9). HIV prevalence was 10.3% with incidence of 11new cases of HIV per 1000 inhabitance per year. In this year 2408 mothers were tested for HIV of these 26 and 44 were positive for HIV respectively. HIV prevalence of the town was high because the town is on junction which together from four directions, such as from AA, from Adam, from Hawassa, and from Minjar directions. With this high population traffic area like Mojo, HIV incidence and prevalence is high.

Woman without complications should have at least four antenatal visits, the first of which should take place during the first trimester Urban women are more likely than rural women to have four or more ANC visits, 65.7% in urban and 26.5% in rural(5).In Mojo there were 1647 eligible pregnant women in 2007EFY. Number of pregnant women who attended the health facility at least once for ANC service were 2995 which is greater than 100% and number of pregnant women have made at least four visit were 1221(74.17%) in 2007 EFY. This data show that number of pregnant women has made at least four visit is exceed the national data of EMDHS 2014 by 8.7%.

A large proportion of maternal and neonatal deaths occur during the 48 hours after delivery, and these first two days following delivery are critical for monitoring complications arising from the delivery. In 2014 GC, only 13% of women received postnatal care within two days of delivery. Among women who received a postnatal checkup, 8 % were examined within 4 hours of delivery, 3% within 4-23 hours, 2 % within 1-2 days, and 5 % within 3-41 days of delivery (5). In 2007, 69% have post-natal care within 0-48 hours, 18% within 2-3 day and 14% within 4-6 days. This data indicates that it is higher than national data. Nationally postnatal coverage is 13% but in Mojo it is 100%.

Currently women in urban areas are more likely than their rural counterparts to use any modern method (56% and 37 %, respectively) (5). Contraceptive acceptance rate of Oromia was 60.8 in 2004 EFY(7), which was lower than Mojo contraceptive acceptance rate. In Mojo contraceptive acceptance rate was 158% in 2007. Women use injectable contraceptive were 64.7% and women using other method were 31.3%. Women used modern contraceptive method are greater than national level which is only 42%. Injectable contraceptive methods was also preferable method for women in Oromia, which was 28.9%, in 2014 (5).

In 2005EFY top leading of morbidity in Ethiopia were AURI, Malaria (PF confirmed), AFI, pneumonia and diarrhea(non-bloody) malaria (8). The top five leading causes of morbidity of Mojo for age above five were: acute febrile illness, acute upper respiratory infections (AURI), Typhoid fever, urinary tract infection (UTI), and epidemic typhus. AFI AURI UTI dyspepsia and pneumonia are similar top ten causes of morbidity for Mojo in 2007 and for Ethiopia 2005EFY. But malaria all type, trauma and helminthiasis are not top causes of in Mojo.

Diarrhea (non-bloody, AFI, Pneumonia, AURI, malaria all type, Infections of the skin and subcutaneous tissue, diarrhea with dehydration were top ten causes of morbidity (8). In mojo top leading causes of morbidity for under five were acute upper respiratory infections, others or unspecified infectious and parasitic diseases other or unspecified diseases of respiratory system and Pneumonia. Malaria and helminthiasis not top cause of morbidity in mojo area.

Others or unspecified infectious and parasitic diseases other or unspecified diseases of respiratory system is second and third causes of morbidity for under five years. This indicates that in this aria needs hospital and skilled professionals (specialists). A doctor to population ratio is zero in 2007 EFF.

In 2005 EFY TB detection rate of all form of TB were 58% at national level and 60% in Oromia Region. TB treatment success rate and TB cure rate was 91% and 70% at national level (8). TB detection rate and cure-rates are 47.5%, 73% and 77% respectively, which are less than the data of FMoH report 2005EFY.

Road traffic injuries are leading cause of death globally that kill 1.2 million people per year. Most of these deaths are in low- and middle-income countries and these counties lose approximately 3% of their GDP due to road traffic accidents (10). Every year there are 114 deaths per 10000 vehicles per year in Ethiopia (11). In 2007 EFY a 31 road traffic accidents were occurred, of these 9 persons died, 16 were injured, 15 property damages which was approximately 844400 birr. This much money accounted 1.3% of annual budget of Mojo Town Admin for 2007 EFY budget.

4.6. Conclusion

Health service coverage of Mojo town is in a very good status. Most indicators showed are more than 100%. Even though neonatal mortality rate is less than national data still it needs more efferent to decrease it. HIV prevalence was 10.3% with incidence of 11new cases of HIV per 1000 inhabitance per year. This data shows that HIV prevention actives should be strong and continuous health education should be given for the community. 16.03% households did not have toilet facility which needs commitments of all stakeholders. From 2002-2007 EFY a total of 382 road traffic accidents which costs 11787488 birr. In 2007 EFY a 31 road traffic accidents by these accidents 9 persons died and approximately 844400 birr was lost. This was approximately 1.3% of annual budget of Mojo Town Admin in 2007 EFY.

Customers of Mojo health institutions were came from different areas like Minjar Werwda and Lome Werda and also the populations around Mojo town, 16165, which will join recently the Town Administration increased most indicators. In additionally, the nonpermanent (temporary) industry workers also increased the indicators. As discussed above most indicators were more than 100% due to these three reasons.

4.7. Recommendations

- Prevalence of HIV in the town is very high so the town health office, town HAPCO and HIV/AIDS clubs have responsibility to take immediate action on prevention and control.
- TB cure rate and treatment success rate were decreased in 2007 EFY when compared to previous years so the town health office have to take an action that increase cure rate and treatment success rate.
- Others or unspecified infectious and parasitic diseases other or unspecified diseases of respiratory system is second and third causes of morbidity for under five years. This indicates that in this aria needs hospital and skilled professionals (specialists)

- There should be a collaboration between the community transport authority, traffic police, schools and health facilities to reduce road traffic accident.

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Annex

Annex 4-I: Data collection tool of Health Profile description

1. **Historical Aspects of the area (Culture & tourism office).**
   - Woreda Name_____
   - When was the woreda established _____
   - How & why the name given_____
   - Any other historical aspect_____
2. Geography and Climate
   - Woreda map_____
   - Location(distance from AA) _____
   - Geographical coordinate
     - ✓ Latitude _____Longitude _____
     - ✓ Annual rain fall Annual temp(average)_____
     - ✓ Climatic zones_____ Lowland_____ (%) _____ (%) _____ (%)
   - Boundaries
     - North _____
     - South _____
     - East _____
     - West _____

3. **Political and Administrative Organization**
   - Total no. of kebeles: _____
     - Rural___Urban ___
4. **Population and Population structures**
   - **A. Demographic data**
     - Total Population _____ Male _____Female_____sex
     - Urban Total _____ Male___and Female_____
     - Rural Total ___ Male ____and Female____

A1 Population size by category

No	Population category	Numbers
1	Population under 1yrs	
2	Population under five yrs.	
3	Population < 15 years	
4	Population >64 years	
5	Women 15_49 years of age	
6	Average household size	
7	Annual population growth rate (%)	
8	Population pyramid by age and sex (will be analyzed after collection)	

A1Total population by kebele (each kebele pop)

S/N	Name of Kebele	Total Population

B. Ethnic/language

S/N	**Ethnic group**	**Number**	**%**
1			
2			
3			

4			

C. Religion

- Orthodox _____ (_____ %), Muslim _____ (_____ %),
- Protestant_____ (_____ %), Other _____ (_____ %)

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

- **Main income sources**
  - ✓ Agriculture_____
  - ✓ Livestock_____
  - ✓ Industry_____
  - ✓ Trade_____
  - ✓ Other business(specify) _____

6. Education and school Health

Table 3 School type, number of teachers and number of students in Mojo Town 2007 EFY

S.No	**Type of School**	**Number of students**		**Number of Teachers**	
		M	**F**	**M**	**F**
1	K.G				
2	Primarily School				
3	Secondary				
4	Preparatory				
5	College/ University				
6	TVET				
Total					

- Total School Age Children (target) _____
  - ✓ Total Enrolment _____Male_____
  - ✓ Female_____

7. **Facilities**

   A. **Transport**

   - Transport facility of Town Admin._____
   - Total road length
   - Road types _____ Asphalt _____coble stone, all weather _____

   B. **Telecommunication**

   - How many people have access to fixed telephone? _____
   - How many people have access to mobile phone? (coverage)_____
   - How many people have access to internet

   C. **Post Office**

   D. **Bank**

   E. **Power supply**

   - How many house hold get power supply_____?

   F. **Water**

   - Total safe water coverage _____
   - Safe water supply coverage by house hold_____
   - Main source of water supply _____
   - Population getting safe water_____
   - Daily water consumption per day per person _____

8. **District Health system**

   - The general health system structure of the woreda (Oregano Gram)

     _____

     _____

   - Is there health management team (HMT) at woreda level? Yes/No

     _____

     _____

   - If yes , describe the HMT in detail (composition and function)

     _____

     _____

   - Do you have NGOs working on health and health related issues? Yes/No

- List the NGOs and their work in related to health

_____

Vital Statistics and Health Indicators

Indicators	2006	2007
Infant mortality rate		
Child mortality rate		
Crude death rate		
Maternal Mortality rate		
Total Deliveries		

Immunization Coverage (for children and Women 2007E.C);

S. No	Types of immunization	2006		2007	
		No. immunized	%	No. immunized	%
	BCG				
	OPV1				
	OPV3				
	Penta1				
	Penta3				
	PCV1				
	PCV2				
	Measles				
	F/Immunization				
	PWTT2^{+}				

	PAB				

9. Health Service

A. Type and Number of Health Institution

Type		Number	Total No. of beds
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		
Facilities under constrictions	HP		
	HC		
	Hospital		

- Health institution to pop ratio: Hospital: Pop----------.HC: Pop----------
- HP: Pop----------Health service coverage----------

B. Type and Number of health professionals

Type	No.	Remark
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		
Others		

Radiologist		
Anesthesia		
Clinical pharmacy		
Ophthalmologist		
Psychiatrist		

- Doctor: pop. Ratio____Nurse: pop. Ratio____
- Mid. Wife: pop. Ratio ___HEW: pop. ratio

C. **Top causes of morbidity and mortality**

- Top ten leading causes of OPD visit (morbidity):

Adult		Pediatrics/ < 5 years		
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				99/

- **Top ten causes of admissions**

Adult		Pediatrics/ <5 year
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

- **Top ten causes of deaths (mortality) 2007 E.C.**

Adult		Pediatrics/ <5 year
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

D. Health budget allocation:

- **Government**
  - ✓ Annual budget allocated for the woreda(birr), 2006, _____ (2007)_____ 2008____

- ✓ Annual budget allocated for health or health institutions _____, _____ ,_____
- ✓ Annual budget allocation increment percent comparing to the previous year___%

- **Funds from NGO**
  - ✓ Total _____ (purpose/programs)_____

10. Community Health Services;

- Status of services provided by community health workers

  HEWs_____

  - ✓ Others_____

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

MCH

Service		Year(EFY)			
		2006		2007	
		No.	%	No.	%
ANC	ANC 1st				
	ANC 4th				
Delivery					
PNC	0- 48 hours				
	2-3 days				
	4-6 days				
Family planning	Oral contraceptive				
	Injectable				
	Implants				
	IUCD				

	others				

- Contraceptive prevalence rate, Contraceptive acceptance rate _____
- EPI(outreach service, cold chain, vaccine) _____

- Environmental Health & sanitation.
  - ✓ Latrine coverage_____ & utilization rate_____
  - ✓ Solid waste management_____
  - ✓ Liquid waste management _____
- **Endemic diseases;**
  - **Malaria:**

Cases	2006		2007	
	POD	IPD	POD	IPD
Clinical malaria				
Confirmed PF				
Malaria other than PF				
Death by malaria				

- ✓ Total malaria's kebeles_____ & Pop at risk_____
- ✓ ITNs coverage (including current dist.)_____
- ✓ Is there IRS this year(No of kebeles)_____
- ✓ Malaria supplies (Coartem, RDT, etc) shortage __NO_____
- ✓ Other issues_____

  - **TB/Leprosy**

Cases	2005	2006	2007
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 on Rx_____			

- **HIV/AIDS;**

Cases	2005	2006	2007
Total people screened for HIV			
VCT			
PITC			
PMTCT			
HIV new cases			
Total PLWHA			
ON ART			
Pre-ART			
HIV prevalence			

HIV prevention activities

_____

_____

_____

_____

- **Nutrition (malnutrition related OTPs, SC, TSF, CBN and PSNP activities)/HO & Early warning**
  - ✓ 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 _____
- ✓ General food security condition_____

- **Essential drugs (shortage):-**

_____

_____

12. 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_____

13. Discussion of the highlights and the main findings of the health profile assessment and description

_____

_____

14. Problem Identification and Priority Setting – set priority health problems based on the public health importance, magnitude, seriousness, community concern, feasibility

_____

_____

15. Conclusions made about the health status of the Woreda based on the findings

_____

17.**Action plan and recommendations- on how to address the problems identified clearly depicting responsibilities, required resource and timeline**

CHAPTER 5: SCIENTIFIC MANUSCRIPT TO PEER REVIEWED JOURNALS

Rotavirus Outbreak among Young Children−Dano Woreda, Oromia Region, Ethiopia, 2017

Rotavirus Outbreak among Young Children−Dano Woreda, Oromia Region, Ethiopia, 2017

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Introduction: Rotavirus infection is the leading cause of diarrhea among children under five years of age. Ethiopia is top ten leading countries with children death due to rotavirus infection. Outbreak of Rotavirus occurred in Dano Woreda. We investigated this outbreak to confirm the etiology, assess its scope and risk factors, and recommend control measures.

Method: We defined a probable case as a child under-five years of age with sudden onset of diarrhea or vomiting (two or more episodes within 24 hours) who resided in Dano Woreda. A confirmed case was a probable case with confirmation by rotavirus antigen stool testing or by epidemiologic linkage to a case.. We employed a case control study to identify risk factors for the outbreak, randomly selecting 180 children, 60 cases by systematic sampling and 120 unmatched, neighborhood controls by convenience sampling. We entered socio-demographic data, risk factors and other data with Epi-info 7.1 and analyzed by SPSS 21.0

Results: Of 11 stool samples sent to the reference laboratory, 7(64%) were positive for group A rotavirus; the other cases were epidemiologically linked. A total of 919 children were infected with rotavirus from January 5 to February 10, 2017 (attack rate [AR]=44/100,000 under five population). Multivariable logistic regression showed, children aged 0-12 months (aOR=7.73, 95% CI=2.10-28.46) and 13-24 months aOR=8.99 (95%CI 2.16-37.42) predominantly infected. Reported contact with a case (aOR=6.22, 95% CI= 1.89-17.34) and drinking spring water (aOR=4.59, 95% CI =1.01-20.83) were risk factors for rotavirus infection. Rotavirus vaccination (aOR=0.276, 95% CI= 0.14-.93) and drinking potable water (aOR=0.17, 95% CI= 0.05-.59) reduced the risk of infection.

Conclusion: The findings of our study confirmed a group A rotavirus outbreak among under five children in Dano woreda, predominantly affected children 0-24 months. We recommend expanding the rotavirus surveillance system beyond Addis Ababa, improving rotavirus vaccination coverage and access to potable water.

Key words: Rotavirus, Outbreak, under five children, Risk factors Dano, Ethiopia

Introduction

Rotavirus infection is the leading cause of diarrhea among children aged under five (1).Each year, rotavirus causes approximately 111 million episodes of gastroenteritis requiring only home care, 25 million clinic visits, 2 million hospitalizations and 600,000 deaths worldwide (2). Almost each child in the world is infected with rotavirus at least once by the age of five (3). More than 90% of rotavirus deaths occurred in low-income and low-middle-income countries (4). Four countries (India, Nigeria, Pakistan, and Democratic Republic of Congo) accounted for approximately half (49%) of all rotavirus deaths in 2013, and 10 countries (India, Nigeria, Pakistan, Democratic Republic of Congo, Angola, Ethiopia, Afghanistan, Chad, Niger, and Kenya) accounted for almost two-thirds of all deaths (65%) in 2013(4). In contrast, in the United States of America only 20–60 deaths happened per year (3).

The spectrum of rotavirus illness ranges from mild, watery diarrhea of limited duration to severe diarrhea with vomiting and fever that can result in dehydration with shock, electrolyte imbalance, and death. Following an incubation period of 1--3 days, the illness can begin abruptly, and vomiting often precedes the onset of diarrhea. Up to one third of patients have a temperature of >39°C. (5). Though the disease can occur at any age, dehydrating of rotavirus gastroenteritis primarily occurring among infants and children aged 3 to 35 months (3). In developing countries, the highest infection rates occur in children aged 3-11 months, while in developed countries infection rates peak in the second year of life (1). The virus can also affects infants under 3 months but it asymptomatic in this age group(6). Additionally rotavirus can affects children above five years and adults(7,8).

Rotavirus transmitted through fecal-oral rout by contaminated water (9), contaminated food (8,10) and through close contact person to person and fomites (5,10). The viruses also nosocomial acquired gastrointestinal infection (6). Rotavirus infection occurred year-round t can be increased during the cooler and drier months (11,12). It is very stable and may remain viable in the environment for weeks or months if not disinfected (13).The viral particles can survive for more than 2 months and can maintain infectivity for more than 32 months at a relatively lower than 10°C temperature (7).

In 2013 WHO estimated that Ethiopia ranked among the top ten leading countries with high prevalence rate of under five children death due to rotavirus infection. In this year from a total death of 195,504 in under five children 3.5% was contributed by rotavirus (14). In 2012 total cases due to rotavirus infection were estimated to be 310,000 cases of per year resulting in 13,000 deaths per year. Prevalence of rotavirus ranges from 15 % (15) to 44% (16)

The best way to prevent rotavirus infection and reduction of its severity is vaccination of children and infants(17). To prevent child mortality and hospitalization due to rotavirus, Ethiopia initiated vaccination of rotavirus on December 2013 (15). Though the current rotavirus surveillance system only covers Addis Ababa, vaccination coverage is 56% and 50.2% in Ethiopia and Oromia Region respectively (18). The main aim of this study was to investigate the suspected rotavirus and epidemiology of the outbreak occurred among under-five children in Dano Woreda, W/shewa zone, Oromia Regional State from January 5, 2017 to February10, 2017.

Methods

Study setting data collection

We investigated the outbreak in Dano district, Oromia Region, Ethiopia. According to the national census report of 2007, the projected population of this district in 2016 was 127,002 (118,215 Rural and 8787Urban). We collected data from woreda health office rotavirus outbreak line list which included name, age, residence place, sign and symptoms and immunization status. Every day total cases were collected from each health facility by phone. On the other day hard copies collected from each facility and list of patients registered on electronic form of line list. We searched active cases home to home and gave information to the community in meetings, markets, churches and other public gathering places. The health facilities identified the cases by standard case definitions. We performed analytical study to identify risk factors of this outbreak. We selected 60 cases and 120 controls based on case definitions. We defined a probable case as a child under five years of age with sudden onset of diarrhea or vomiting (two or more episodes within 24 hours) who resided in Dano Woreda. A confirmed case was a probable case with confirmation by rotavirus antigen stool testing or by epidemiologic linkage to a case. We collect cases from the line list that contains the list of all cases of rotavirus outbreak. The first case was selected randomly and then the other cases selected systematically from the line list. We selected controls from the neighborhood of the cases. If the neighbor's house had infected children, we took next neighbor's house.

Study design and Data analysis

We used unmatched case control study design. We analyzed the data 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 Epi Info 7.1.4 and SPSS 21.0 version software. We equated the risk factors with binary logistic regression using odds ratio, p-value and 95% confidence interval.

Laboratory investigation

We collected stool samples from patients and sent to Ethiopian Public health Institute (EPHI) polio and measles laboratory. Samples were placed in 2-8°C till it transported to the laboratory. The maximum time samples places in refrigerator were 48 hours. Then, we transported samples to EPHI in 2-8°C and triple package.

Environmental investigation

Main water source of Seyo town (capital of Dano woreda) collected and sent to central reference laboratory (EPHI) for bacteriological indicator test. We collected samples by trained professional though sterile method. Immediately after collection we transported the water samples to EPHI in 2-8°C within triple package.

Result

To confirm the case eleven samples sent to Ethiopian Public health institute (EPHI) and 7(64%) of them were positive for group A rotavirus. The genotype of this isolate was not identified because EPHI could have ability to genotype rotavirus and the positive stool samples were sent to WHO reference laboratory for genotyping. Then other cases linked epidemiologically to rotavirus infection. To assess the environment, main water source of Seyo town we collected and sent water sample to EPHI. The water was positive for bacteriological indicator which means there was fecal contamination of water.

From January 5, 2017 to February10, 2017, a total of 919 under five children infected with rotavirus in Danowerada west shewa zone. The index case was seen at Seyo health center that came from Biluarere woreda.

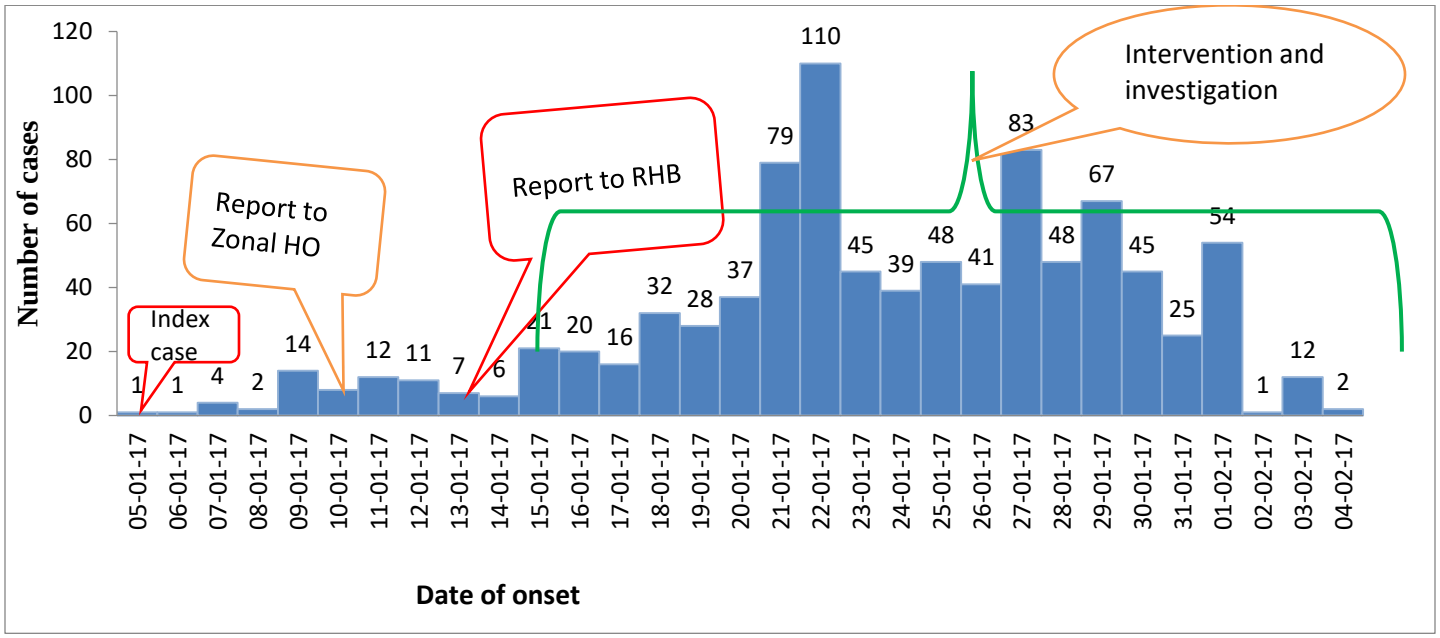


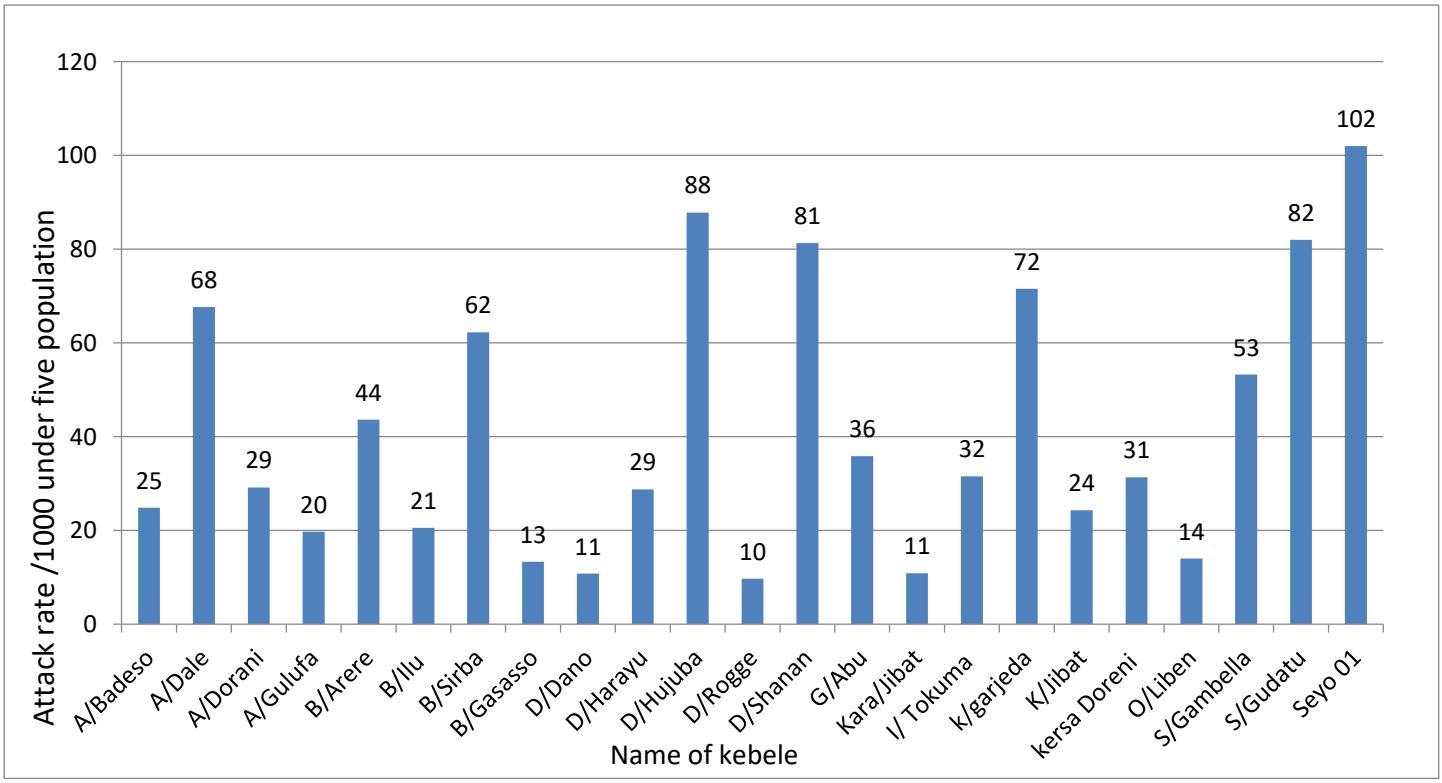
Figure 5-1 The date of onset rotavirus outbreak in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

In this outbreak 521(57%) male and 398(43%) female under five children were affected by rotavirus with median age of 12 months (IQR=8-24). In this period, the most affected population was infants aged below thirteen months 502(54.6%), followed by infants aged therein to twenty four months 260(28.3%), thirty seven to sixty months 82(8.9%) and twenty five to thirty six

months 75(8.2%), with attack rate of 44 cases per 1000 under five population. No deaths were recorded during the outbreak. All children had diarrhea, vomiting fever and 619 with some dehydration, 290 with no dehydration and 10 children with severe dehydration. Before confirmation of etiologic agent patients were treated with antibiotics (corimoxazol) and supplements (ORS and Zink). Then after confirmation patients were treated only with ORS and Zink.

Distribution of rotavirus by place

The most affected district was Seyo 01 town admin (capital of Dano woreda), 102 cases per 1000 under five years population followed by Dire hujuba, Seyo gudetu, Dano shaman, Kara gerjida



with attack rate of cases per 1000 under five years population 88, 82, 81, and 72 respectively

.

Figure 5-2.: Kebele specific attack rate of rotavirus infection in DanoWoreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Intervention

We searched active cases from the community through the committee formed by the Woreda Administrator. Heath education regarding to transmission ways and prevention ways were given to the community. After the community got awareness about the disease they brought their children to health institutions immediately after they saw sign and symptoms. Before the causative agent identified antibiotics were given to the patients after the rotavirus was identified they were treated only by oral rehydration salt (ORS) and critical cases were treated by intravenous fluid (IV).

Risk factor assessment

A total of 60 cases and 120 controls selected from the community to identify risk factors for outbreak in affected kebeles of the Dano west shewa zone. The age range of participants was 1 to 60 months with median age of the participants of 20 months (IQR=9.25-36). All rotavirus cases had vomiting diarrhea and fever. The socio- demographic characteristics of the study participants and risk factors for rotavirus outbreak were described in table 1.

Table

Table 5-1 Socio- demographic characteristics of cases and controls on rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Variables		Case no. (%) n=60	Control no. (%) n=120
Sex	M	33(55)	65(54.1)
	F	27(45)	55(44.9)
Age group(in month)	0-12	29(48.3)	29(24.2)
	13-24	18(30)	23(19.2)
	25-36	7(11.7)	26(21.6)
	37-60	6(10)	42(35)
Ethnicity	Oromo	57(95)	118(98.3)
	Amhara	3(5)	2(1.7)
Religion	Orthodox	20(33.3)	27(22.5)
	Protestant	30(50)	55(30.6)
	Muslim	4(6.7)	38(31.7)
	Wakefeta	6(10)	0
Education mother	Illiterate	43(71.7)	51(42.5)
	Read and write	4(6.7)	3(2.5)
	Elementary(1-8)	12(20)	34(28.3)
	Secondary(9-12)	1(1.6)	18(15)
	Tertiary(college+++)	0	14(11.7)
Occupation of mother	Farmer	56(93.3)	87(72.5)
	Merchant	3(7.7)	11(9.2)
	Student	0	3(2.5)
	House wife	0	7(5.8)
	Gov't employee	0	10(8.3)
	Private employee	1(0.6)	0
	Daily laborer	0	2(1.7)
Education of father	Illiterate	33(55)	39(32.5)
	Read and write	6(1)	1(0.08)
	Elementary(1-8)	16(26.7)	33(27.5)
	Secondary(9-12)	5(8.3)	22(18.3)
	Tertiary(college+++)	0	25(20.8)

Table 5-2: Multi variable logistic regression analysis of risk factor and protective factors of rotavirus outbreak in Dano Woreda, Oromia Region, Ethiopia from 05/1/2017-10/2/2017

Variables(Risk factors)		Case (n=60)	Control (n=120)	P value	AOR	95% CI for AOR
Age group(in month)	0-12	29	29	0.002	7.736	2.102-28.468
	13-24	18	23	0.003	8.995	2.162-37.420
	25-35	7	26	0.301	2.306	.474-11.214
	37-60	6	42		1.00	
Contact with case	Yes	12	26	0.006	6.226	1.894-17.342
	No	34	108		1.00	
Water source	Pipe	14	91	0.005	0.176	0.052-.597
	Spring	27	5	0.048	4.593	1.013-20.834
	Pond	5	12	0.182	0.345	0.072-1.646
	River	14	12		1.00	
Vaccinated at 6 weeks and 10 weeks	Yes	31	85	0.036	0.372	0.148-.938
	No	29	35		1.00	
Have and use toilet	Yes	38	106	0.447	0.634	0.195-2.057
	No	22	14		1.00	

Multi variable binary logistic regression analysis indicated that age 0-12 months, 13-24 months, contact with cases and spring water were risk factors for rotavirus infection. Potable water (pipe water) and rotavirus vaccination had protective effect for rotavirus infection. On bivariate analysis those families had and use toilet their children were protected from rotavirus infection however on multivariable analysis indicated having and using toilet did not have any association with rotavirus infection.

Discussion

We identified group A rotavirus outbreak in Dano Woreda, west shewa zone from 05/1/2017 to 25/2/2017, in the cooler season of Ethiopia. In addition to this Oromia regional state health bureau declared that there was outbreak of RV in Nono woreda at the same period. GAVI Surveillance report of Ethiopia showed that RV cases rose up in cooler season from October through December. This outbreak began in same period with outbreak occurred in Tirana, Albania in 2000 (20).The prevalence of rotavirus infection peaked in Ghana during the cool, dry months of January and February. In Zimbabwe a seasonal peak in the prevalence of rotavirus diarrhea occurred during the winter months (21). However, a less distinct seasonal peak was observed in some low income countries (e.g., Indonesia, Vietnam, Cambodia) (12) and in equator areas (e.g., Uganda) seen year-round (21).Some studies have noted secondary seasonal peaks in rotavirus incidence associated with periods of high rainfall and flooding (22). This cooler season may increase the rotavirus infection and the season may contribute to this outbreak.

In our finding vaccinated children protected from rotavirus infection by 72.4% than unvaccinated children. In the outbreak rotavirus outbreak of Mexico among children under 36 months vaccination also prevent rotavirus and vaccinated children had odds of probability 59 % than those not vaccinated (23). Rotavirus vaccination is the primary strategy for preventing severe rotavirus disease. Incidence and hospitalization due to rotavirus successively reduced by introduction the vaccine (24). In United States of America, incidence of hospital visit and admission due to rotavirus gastroenteritis reduced by 86% and 96% respectively(5). After rotavirus vaccine introduction in Rwanda, hospital admissions for diarrhea in children younger than 5 years reduced by 29% and 17% in 2013 and 2014 respectively. In the same period the number of hospital admissions for diarrhea in children younger than 1 year decreased by 55% and by 51% (25). Some studies contradicted with this finding on vaccine efficacy had difference between high income and low income nations (21). Rotavirus vaccines are less effective in lower income settings combination of poor immunological response caused by malnutrition, other intestinal infections, and immunosuppression efficacy against other oral vaccine (OPV). The average efficacy for high, upper middle, lower middle, and low income countries are 90%, 85%, 66%, and 55%, respectively (26,27).

Disease of rotavirus attacks children aged below 2 years and more than 75 % under 12 month infants and 95% more under the age of 18 months more affected (11). On surveillance of rotavirus in Turkey, most rotavirus infections were recorded in children aged 12 to 23 months, and a second peak was observed in the 6 to 11 month age group; more than 70% of rotavirus infections occurred in children less than 2 years of age (28). In our investigation children aged between less than 24 months of age were more affected than other age groups so this was similar with outbreak occurred in Mexico (23), Solomon Island (22) and Albania (20) . However, some outbreaks of RV infection in adults have been reported (8) and even in elderly persons (29). On waterborne outbreak of two districts in Turkey due to rotavirus, the mean age of the outbreak patients was 25 years (30).

Contaminated water may be an important source of transmission in settings with poor sanitation. The waterborne transmission route may dominate during times of increased rainfall (12). A large infantile gastroenteritis outbreak in Albania caused by multiple emerging rotavirus genotypes, common source was contaminated water (20). On this outbreak spring water was risk factor and potable water could reduce the risk of rotavirus infection. In contrast, in the outbreak of rotavirus in Mexico potable water did not have any effect to the outbreak.

On this outbreak children had contact with case were more exposed to RV infection. Outbreaks of RV gastroenteritis in day-care centers and hospitals can spread rapidly among no immune children, presumably through person-to-person contacts, airborne droplets, or contact with contaminated toys (31). Nosocomial infection study on RV in Greece, 58% of RV gastroenteritis in neonates was hospital acquired (6). During the outbreak period limiting the contact children, increasing hygiene practice from normal time and limiting children from public gathering places may reduce the probability of rotavirus infection. This outbreak had some limitations such as genotyping of rotavirus not performed; samples were not tested for other enteric virus like Adenovirus and Norovirus which can cause gastroenteritis. Seasonality of the rotavirus infection not analyzed sine no previous data in the district. We recommend that genotyping should be performed; potable water should be available to the community and children should get rotavirus vaccine. The family should protect their children from contacting with sick children and protect them temporarily from public gathering areas and day cares.

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Suspected Meningitis cases Surveillance data analysis in Oromia Regional State, Ethiopia; 2011- 2014

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Abstract

Introduction: Meningitis is a devastating and deadly disease that kills patients within hours. It is caused by bacteria, viruses, fungi and parasites. Meningitis is endemic in most of African countries. Every year, bacterial meningitis epidemics affect more than 400 million people living in the 26 countries of Africa "African meningitis belt". This area extends from West Africa, Senegal to East Africa including Ethiopia. This study aimed to assess the burden, the distribution, the trend of suspected Meningitis cases in East Showa Zone, Oromia Region, Ethiopia.

Method: We employed retrospective data analysis to assess the burden, distribution and trend of suspected Meningitis cases. We copied the data from electronic HMIS to Microsoft excel 2010 then we filtered the data of suspected meningitis alone. We entered the data to Epi Info version 7 to organize it by time place and person. We described the data trough tables, graphs, and figures by Microsoft excel 2010.

Result: Of the 882 suspected Meningitis cases in East Shewa zone from 2011 – 2014 , 368 (41.7) were males and 514 (58.3) were females. Mean annual incidence of meningitis was 15.6 cases per 100,000 people and no death in the period. In the four years, the highest number 212(24.4%) was observed in Dugda Wereda and followed by A/T/J/kombolcha 188(21%1) cases. Moreover, there was no reported case from Awash Fentale wereda during the study period.

Conclusion: The surveillance data finding showed, incidence of meningitis in East Shewa Zone was high and it was higher in rainy season than dry season. The number of female cases was higher comparing with males. In addition, the magnitude of cases was higher among adults aged 15 and above comparing with their counterparts including infants.

Introduction

Meningitis is a devastating and deadly disease that kills patients within hours (1).It is endemic in most of African countries(2). Every year, bacterial meningitis epidemics affect more than 400 million people living in the 26 countries of known as “African meningitis belt" that covers from West Africa, Senegal to East Africa, Ethiopia(3). The most affected countries in the region are Burkina Faso, Chad, Ethiopia, and Niger. Burkina Faso, Ethiopia, and Niger were accountable for 65% of all cases in Africa (4).The case-fatality in an epidemic is usually between 5% and 15% (5). Outbreaks usually occurred during hot, dry and dusty conditions in areas with high population density(2). Invasive disease is rare in non-outbreak areas, occurring at a rate of 0.5-10 cases per 100,000 populations per year, but can occur at a rate of up to 1,000 cases per 100,000 populations per year in outbreak prone areas (6). During these epidemics, young children have the highest attack rates(4). Meningitis can be prevented through good case management and vaccination. For sero-group A and C alone or combined vaccination against serogroups A, C, Y and W135 is used to prevent meningococcal meningitis. Children aged 2–10 years age have to get the priority during period of vaccination campaigns (5).

In 2009 on epidemic in the Belt, over 80,000 cases were reported from Nigeria and Niger. From 2010 to 2014 cases have been steadily decreasing, with approximately 24,000 cases in 2010 to 11,500 cases in 2014(3). In Ethiopia, meningitis outbreaks have been described in written reports since 1901. Outbreaks were reported in 1935, 1940, 1950, 1964, 1981 and 1989.The 1981 and 1989 outbreaks were the largest ever recorded in Ethiopia with 50,000 and 45,806 cases, and 990 and 1686 deaths, respectively (6). Between1980 and 1999, the incidence of meningitis was ranged from 0-104 cases per 100,000 populations (7). Between March and August 2000 there was an outbreak in Addis Ababa with 850 cases and 33 deaths(6). Meningitis was the tenth causes of mortality in Ethiopia in 2011/2012. Of the 24,009 cases 472(2%) deaths were due to meningitis (8). In 2012/2013 Ministry of Health of Ethiopia reported that meningitis was one of the 10 leading causes of mortality among children under 5 years. In this year from the total 5,084 meningitis cases 151(3%) cases were children less 5 years a (9). The aim of this study was to assess the burden, the distribution, the trend of suspected Meningitis cases in East Showa Zone, Oromia Region, Ethiopia.

Methods and materials

Study setting and period

This surveillance data analysis was focused on East Shewa Zone, Oromia Regional State, Ethiopia. It has 10 Woredas and 3 city administrations. The Zone extends between $7^0$33'50"N - $9^0$08'56"N and from $38^0$24'10"E – $40^0$05' 34"E. Based on the 2007 National Census conducted by the Central Statistical Agency, East Shewa Zone has a total population of 1,356,342; of those 696,350 are men and 659,992 women. With an area of 8,370.90 square kilometers the Zone has a population density of 162.03, while 340,225(25.08%) are urban inhabitants and 664 (0.05%) are pastoralists. We collected a five year (September 2010 to August 2014) suspected Meningitis cases data from electronic HMIS of the zonal health department in April 2016.

Study design and Data analysis

We employed retrospective data analysis to assess the burden, distribution and trend of suspected Meningitis cases. We copied the data from electronic HMIS to Microsoft excel 2010 then we filtered the data of suspected meningitis alone. We entered the data to Epi Info version 7 to organize it by time place and person. We described the data trough tables, graphs, and figures by Microsoft excel 2010.

Result

Trends and magnitude of Meningitis morbidity

From 2010 – 2014 we captured 882 suspected Meningitis cases reported from East Shewa zone. Of the total cases 368 (41.7%) were male and 514 (58.3%) were female. Mean annual incidence of meningitis was 15.6 cases per 100,000 people. The highest suspected cases 263 (29.8%) was reported in 2011 with annual incidence rate of 19.3 cases per 100,000 people and was followed by 263 cases reported in 2010 with annual incidence rate of 19.2 cases per 100,000 People per year. The lowest cases 184(18.3%) were reported in 2014 with annual incidence of 11 cases per 100,000 people. Death of meningitis was not registered from 2011 -2014

Table 5-3: Incidence of suspected meningococcal meningitis in Showa zone, 2011 – 2014

Year	Population at risk	Meningitis suspected cases		Incidence suspected Cases/100,000
		Number	Percent	
2011	1,367,776	263	29.8%	19.2
2012	1,408,627	184	20.8%	13.1
2013	1,416,402	274	31.1%	19.3
2014	1,467,534	161	18.3%	11.0
Total	5,660,339	882		15.6
Mean	1415085	221		15.6

In the four years, among the total 368(41.7) male suspected cases of meningitis, 25(2.8) were aged less or equal to 4 years, 125 (14.2) were 5 to 14 years old and greater than 15 years old were 218 (24.7%). From total female cases 28(3.2%) were less or equal to 4 years, 99 (11.2%) were aged 5 to 14 years and greater than 15 years old were 387(43.9%).

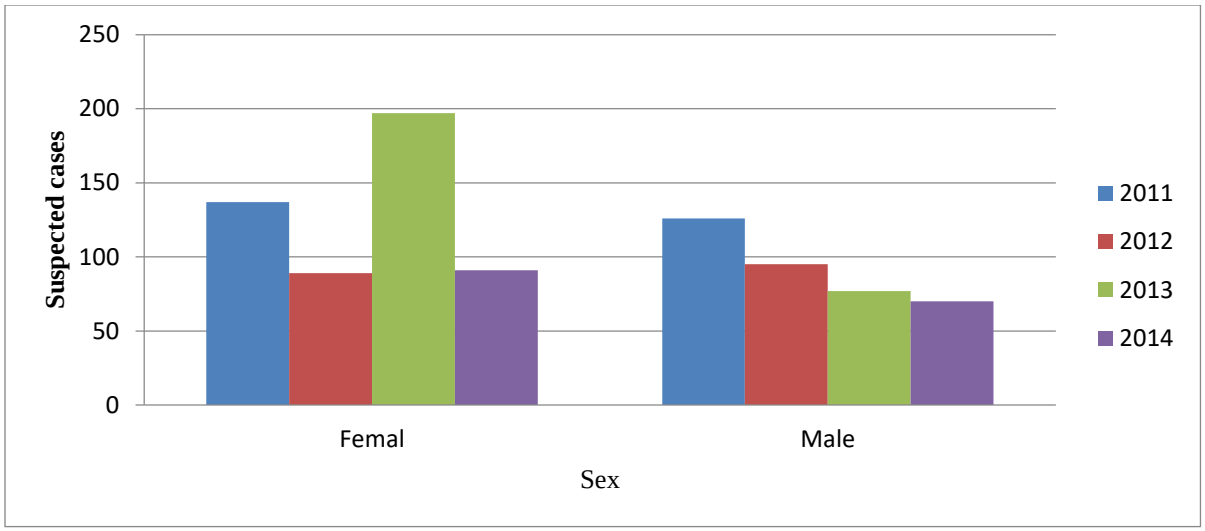


Figure 5-3: Total number of suspected meningitis cases by sex in East Shewa zone; 2011-2014

From the total number of male suspected cases 126(14.3%) were reported in 2011 and lowest number of male suspected cases were reported in 2014 were 70 cases. The highest number of female suspected cases of meningococcal meningitis 197(22.3%) were registered in 2013 and lowest number of cases 89 (10.1%) were in 2012.

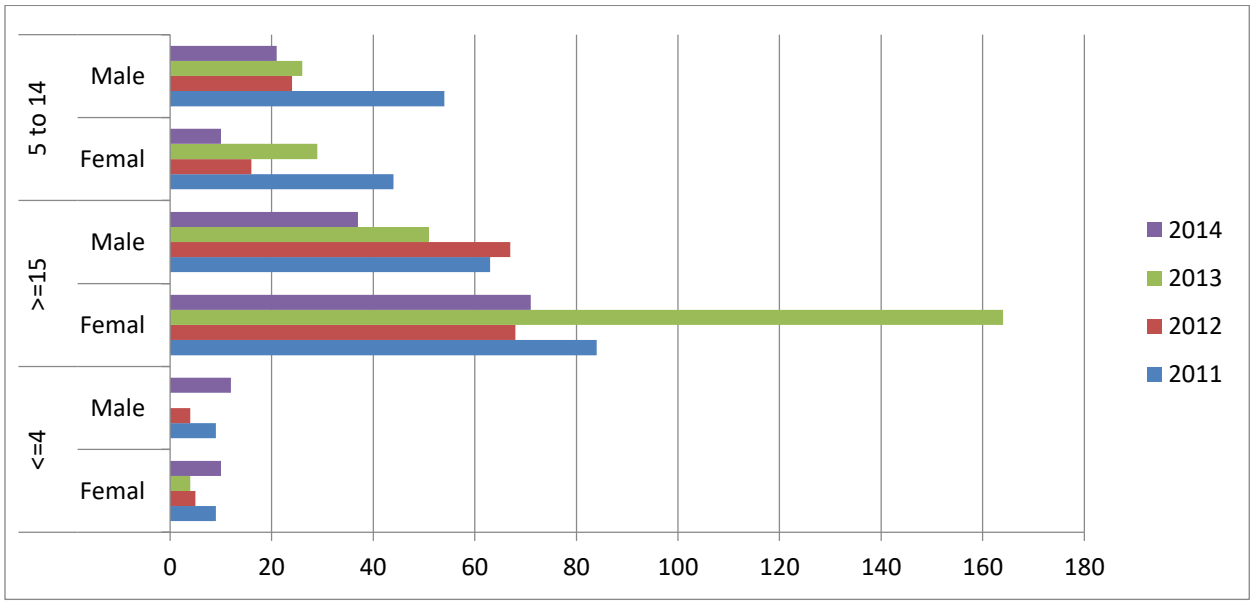


Figure 5-4: suspected cases of meningitis by sex and age in East Shewa Zone, 2011-2014.

Number of age less or equal to four were 53(6%), 5-14 age were 224(25.3%) and aged above 15 were 605(68.7%). The number of cases aged less or equal to four was the highest 22(41.5%) in 2014 and lowest in 2013 4(7.5%). From the total 224 ceases, aged 5-14 the highest number

98(43.8%) was observed in 2011 and lowest in 2014 were 31(13.8%). From total 605 ceases aged above 15, the highest number 215(35.5%) was reported in 2013 and lowest 108 (17.9%) in 2014.

Table 5-4: Suspected meningitis cases by age East Shewa Zone 2011 -2014

Age group	Year				Total
	2011	2012	2013	2014	
<=4	18	9	4	22	53
5 to 14	98	40	55	31	224
>=15	147	135	215	108	605
Total	263	184	274	161	882

In four years the highest number of suspected cases 120 (13.3%) were registered in August 2013 and followed by September 2012, 82(9.2%) cases. From 2011-2014 cases were high in dry December, January and February 115 (3.0%), 71(8.0%), 75 (8.5%) respectively. The numbers also increased in August 171(19.2%) and September 115 (13.0%). Figure 4 shows seasonal variation of meningitis suspected cases. Generally 31.2% cases were occurred in rainy season August and September, 29.6 % of the cases were occurred in dry season December, January and February.

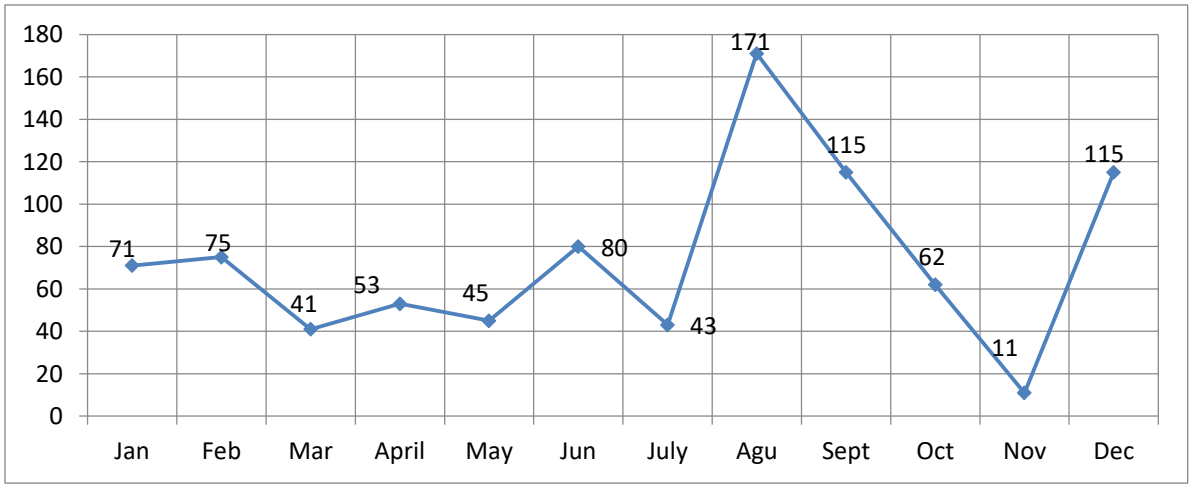


Figure 5-5: Trends of suspected meningitis cases by month in East Shewa Zone 2011-2014

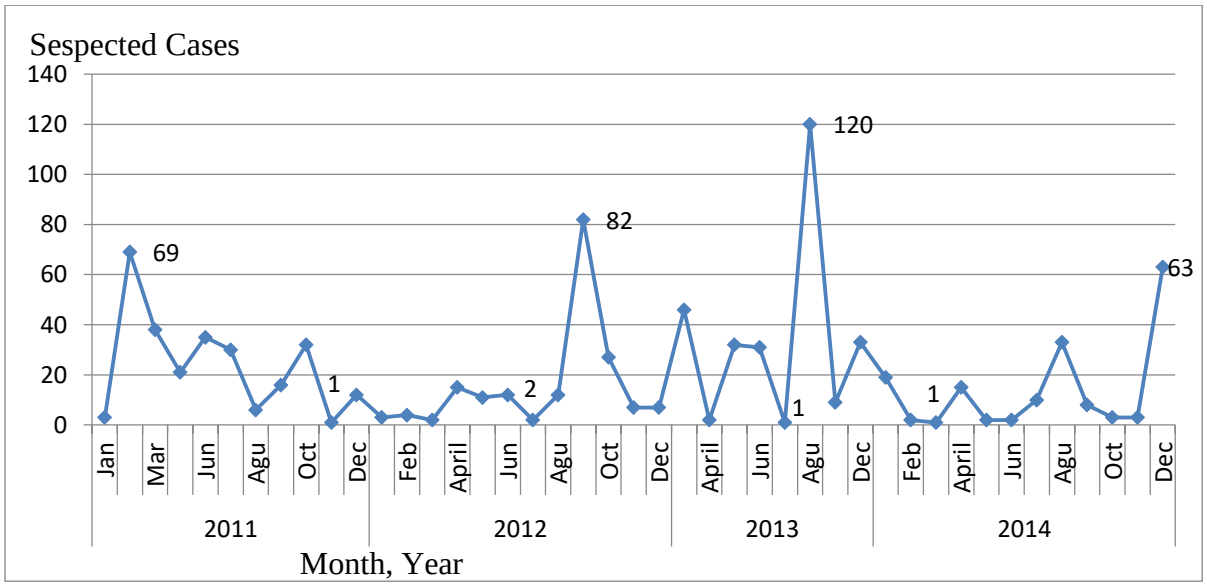


Figure 5-6: Trends of suspected meningitis cases by month and year in East Shewa Zone 2011-2014

Morbidity of suspected meningitis cases by Wereda

Among the 10 Weredas and 3 City Administration of East Shewa Zone only Fentale wereda were free from meningitis cases. In the four years, the highest number 212(24.4%) were seen in Dugda wereda and followed by A/T/J/kombolcha 188(21%1) cases. In Dugdawereda 96(45.3) cases were seen in August and 32(15.2%) in May and zero reports in months January, February, May and Jun. From the 188 total cases of A/T/J/Kombolcha 61(32.4%) were reported in September and 53(28.2%) in December. In this wereda no report in months October, November, and February. In the four-year period, there were no cases in Fentale wereda and only 2 cases were reported from Bosetwered.

Table 5-5 Incidence of meningitis in East Shewa Zone by Wereda and year, 2011-2014

Wereda `	Year							
	2011		2012		2013		2014	
	Cases	Incidence /100000	Cases	Incidence /100000	Cases	Incidence /100000	Cases	Incidence /100000
Adaa	16	10.79	7	4.58	2	1.64	1	0.74
Adama	36	22.01	25	14.84	0	0.00	0	0.00
A/T/J/Kombolcha	55	30.42	80	42.96	0	0.00	53	26.90
Bora	12	17.63	2	2.85	0	0.00	0	0.00
Boset	0	0.00	1	0.59	0	0.00	1	0.56
Dugda	24	14.22	29	16.68	128	71.45	31	16.79
Fentale	0	0.00	0	0.00	0	0.00		0.00
Gimbichu	10	10.05	15	14.63	1	0.95	0	0.00
Liben	19	21.80	24	26.73	0	0.00	8	8.43
Lume	1	0.99	0	0.00	0	0.00	3	2.74
Metehara Town	12	46.91	0	0.00	0	0.00	0	0.00
Mojo Town	23	62.38	1	2.63	114	288.50	37	89.87
ZewayBatu	55	101.07	0	0.00	29	49.67	27	44.38

Table 2 shows that, there were high incidences of meningitis cases in different weredas of East Shewa Zone. Mojo city Administration and Batu Town Administration have 288 cases per 100,000 population and 101 cases per 100,000 populations in 2013 and 2011 respectively. In 2011 , 11 weredas had the case. In this year, Batu and Mojo Town Admin were on the leading position 101 cases per 100,000 populations and 62.3 cases per 100000 populations. In 2012 , 42.9 cases per 100000 populations and 26.7 cases per 100000 populations were highest cases in A/T/J/Kombolcha and Libenwereda respectively. In 2013, 8 weredas did not report cases of Meningitis. In this year next to Mojo City Admin Dugda werada had highest cases, 71.5 cases per 100000 populations and the lowest case were reported from Boset 0.59 cases per 100000 populations. In 2014 , the incidence was also high in Mojo and Batu City Admin, 89.9 cases per 100000 populations and 44.4 cases per 100,000 populations.

Discussion

As the findings of this surveillance data analysis showed, the number of females affected by meningitis epidemics was higher than number of male. The number of females and males were 514 (58.3%) and (41.7%) respectively. Nevertheless, the Literature reviews done in African meningitis belt countries in 2014 shown no significant difference in numbers of cases occurred among males and females. The overall prevalence of cases was not influenced by sex. The prevalence of less than 20 years old was significantly higher in men than women. But the reverse was found in those aged 20 years and older(10). A retrospective study in Malaysia shown that number of male (62%) higher than female (38%) (24). Moreover, numbers of cases of meningitis were higher in males than females in USA 53% for male and 47% for male. Two retrospective studies in Ethiopia shown that number of male were higher than female (2,17)

Epidemic meningococcal meningitis occurred in Africa meningitis belt during the dry seasons (1). Study conducted in 6 African countries Ethiopia (Butajira), Chad, Ghana, Mali, Niger, Nigeria and Senegal on meningococcal carriages (carriers of meningitis) from 2010 -2012 showed that in Ethiopia, Ghana, Senegal and Mali meningococcal meningitis were higher in dry season than rainy season. In these four countries the prevalence of carriage was 4.2% in dry season and 3.1%. In rainy season. However, the prevalence of carriages was higher in 3 countries, Niger, Nigeria and Chad in rainy season than dray seasons(11). A retrospective study in Gonder 2013 to 2010 founded that Meningococcal meningitis and Streptococcus pneumonia were isolated in dry seasons and Hemophiles influenza was not occurred seasonally (12). In East Shewa Zone from 2011 to 2012 , 31.2% cases were occurred in rainy season i.e., in August and September, and 29.6% of the cases were occurred in dry season or from December to February which is similar with the cases reported from Niger, Nigeria and Chad as described above.

As the retrospective study, results indicated the incidence of suspected meningococcal meningitides cases in Oromia region from 2009 to 2013 was 1.64 cases per 100,000 populations per year. In this period, mean annual incidence of East Shewa zone was 2.74 cases per 100,000 populations per year. In non-epidemic period incidence of meningitis was ranged from 4 to 86 cases per 100,000 populations per year in northern Togo (13). The surveillance data analysis also

showed that the mean annual incidence of suspected meningitis cases was 15.6 cases per 100,000 populations per year. This incidence is much higher than the incidence of previously conducted surveillance data analysis that covered from 2009 to 2013. This may be because of difference in the data sources. In this recent surveillance data analysis the source of data were HMIS, but for the previous study conducted in the same setting PHEM data were used for analysis.

The age ranged from newborn to 19 years old, with 43.2% aged less than 1 year, 13.6% aged 1 to 5 and 43.2% aged above 5 years old (1). In this surveillance data number of cases aged less or equal to four were 53(6%), 5-14 years were 224 (25.3%) and aged above 15 years were 605(68.7%). This result shows that number of number of cases were low on age ranged from zero to four years and higher on age above 15 years.

Mortality of meningitis among children aged less than 15 years old ranged from 19.6% to 34% (1). Mortality was frequently observed among patients with pneumococcal meningitis. In Malaysia from 2011 to 2011, out of 125 cases 32.2 % were dead due to meningitis and its complication (1). However, as the findings of this recent study indicated, no death was reported from East Shewa zone in the four years period covered by the study. This study had some limitations which included; I) the cases were only clinically suspected cases of meningitis not include laboratory confirmed cases. II) The study did not find factors associated with the cases because the original data hade limited variable. III) Another limitation of this study was classification of age groups; the age classification of HMIS not focuses on identifying ages less than 29 only as highly affected and more susceptible population group for meningitis. We recommend that additional researches on meningitis are needed in East Shewa Zone to know its magnitude, seasonality and specific causative agent.

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CHAPTER 6: ABSTRACTS TO SCIENTIFIC

Rotavirus Outbreak among Young Children−Dano Woreda, Oromia Region, Ethiopia, 2017

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Introduction: Rotavirus infection is the leading cause of diarrhea among children under five years of age. Ethiopia is top ten leading countries with children death due to rotavirus infection. Outbreak of Rotavirus occurred in Dano Woreda. We investigated this outbreak to confirm the etiology, assess its scope and risk factors, and recommend control measures.

Method: We defined a probable case as a child under-five years of age with sudden onset of diarrhea or vomiting (two or more episodes within 24 hours) who resided in Dano Woreda. A confirmed case was a probable case with confirmation by rotavirus antigen stool testing or by epidemiologic linkage to a case.. We employed a case control study to identify risk factors for the outbreak, randomly selecting 180 children, 60 cases by systematic sampling and 120 unmatched, neighborhood controls by convenience sampling. We entered socio-demographic data, risk factors and other data with Epi-info 7.1 and analyzed by SPSS 21.0

Results: Of 11 stool samples sent to the reference laboratory, 7(64%) were positive for group A rotavirus; the other cases were epidemiologically linked. A total of 919 children were infected with rotavirus from January 5 to February 10, 2017 (attack rate [AR]=44/100,000 under five population). Multivariable logistic regression showed, children aged 0-12 months (aOR=7.73, 95% CI=2.10-28.46) and 13-24 months aOR=8.99 (95%CI 2.16-37.42) predominantly infected. Reported contact with a case (aOR=6.22, 95% CI= 1.89-17.34) and drinking spring water (aOR=4.59, 95% CI =1.01-20.83) were risk factors for rotavirus infection. Rotavirus vaccination (aOR=0.276, 95% CI= 0.14-.93) and drinking potable water (aOR=0.17, 95% CI= 0.05-.59) reduced the risk of infection.

Conclusion: The findings of our study confirmed a group A rotavirus outbreak among under five children in Dano woreda, predominantly affected children 0-24 months. We recommend expanding the rotavirus surveillance system beyond Addis Ababa, improving rotavirus vaccination coverage and access to potable water.

Key words: Rotavirus, Outbreak, under five children, Risk factors Dano, Ethiopia

Suspected Meningitis Cases Surveillance data analysis in Oromia Regional State, Ethiopia

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Abstract

Introduction: Meningitis is a devastating and deadly disease that kills patients within hours. It is caused by bacteria, viruses, fungi and parasites. Meningitis is endemic in most of African countries. Every year, bacterial meningitis epidemics affect more than 400 million people living in the 26 countries of Africa "African meningitis belt". This area extends from West Africa, Senegal to East Africa including Ethiopia. This study aimed to assess the burden, the distribution, the trend of suspected Meningitis cases in East Showa Zone, Oromia Region, Ethiopia.

Method: We employed retrospective data analysis to assess the burden, distribution and trend of suspected Meningitis cases. We copied the data from electronic HMIS to Microsoft excel 2010 then we filtered the data of suspected meningitis alone. We entered the data to Epi Info version 7 to organize it by time place and person. We described the data trough tables, graphs, and figures by Microsoft excel 2010.

Result: Of the 882 suspected Meningitis cases in East Shewa zone from 2011 – 2014 , 368 (41.7) were males and 514 (58.3) were females. Mean annual incidence of meningitis was 15.6 cases per 100,000 people and no death in the period. In the four years, the highest number 212(24.4%) was observed in Dugda Wereda and followed by A/T/J/kombolcha 188(21%1) cases. Moreover, there was no reported case from Awash Fentale wereda during the study period.

Conclusion: The surveillance data finding showed, incidence of meningitis in East Shewa Zone was high and it was higher in rainy season than dry season. The number of female cases was higher comparing with males. In addition, the magnitude of cases was higher among adults aged 15 and above comparing with their counterparts including infants.

CHAPTER 7: QUALITY MANUAL

BATU HOSPITAL LABORATORYORATORY QUALITY MANUAL



Version 02

Control copy number: ---

Written by	**Reviewed by**	**Approved by**
Laboratory Head	Quality Officer	Medical director
Signature:_____	Signature:_____	Signature:_____
Date:	Date:	Date:

BATU, ETHIOPIA

I. Foreword

Laboratory Medicine encompasses testing services and associated practices for screening, diagnosis, treatment and prevention of numerous deadly diseases and health related problems. It helps to detect, identify, and promptly report all diseases of public health significance. Hence, laboratories are among the key stakeholders of any health care delivery system.

Thus to provide reliable and quality assured laboratory services, a quality management system is key and has significance role in health care providing. Batu Hospital Laboratory (BHL) as a hospital laboratory and center of diagnostic service, a capacity building of health center laboratory (microscopic centers),quality management system based on ISO 15189:2012.BHL overall goal is to set international standards in laboratory diagnosis and get recognized through accreditation.

Finally, I believe that this Quality manual will help to standardize the laboratory service and improve the quality of care in the health care delivery as well as yielding greater customer satisfaction out come and it defines what BHL look likes.

Laboratory head

II. Message from Hospital Medical Director

I see and read this manual deeply, I appreciate and I will give my advice everybody to accept and apply all the policies listed in. Even the laboratory activities are vast, short and precise guide line like this manual is very important. So let all staffs in laboratory read and apply it. I am proud to approve this manual as a guide line of our laboratory (Batu Hospital laboratory).

Medical director

III. Acknowledgment

Batu Hospital laboratory would like express sincere gratitude to Oromia regional health bureau for its administrative and technical support, Batu Hospital laboratory also acknowledge Oromia Public Health Research Capacity Building and Quality Assurance Laboratory in technical and material support. We also thank the hospital management giving attention to our laboratory in its activities. The Hospital CEO and medical director also give more ideal supports to our laboratory and we appreciate them.

The Batu hospital laboratory also acknowledges all members of staffs in reading and applying this quality manual.

IV. Terms and operational definitions

Approval: An authorized person who approves documents after edition

Examination: Set of operations having the object of determining the value or characteristics of a property

Measurement: set of operations having the object of determining a value of a quantity

Post-examination procedures: Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results and storage of samples of the examinations

Pre-examination procedures: steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins

Quality officer: Responsible for the implementation and maintenance of the Quality Management System in BHL.

Referral laboratory: external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report

Safety officer: A person who facilitates and control the implementation of laboratory safety practice.

Verification: is conformation through provision of objective evidence, that the specified requirements have been fulfilled

Version number: is a number given for document when there is a change in the document

7.1. Introduction

Batu hospital Laboratory was established by Oromia regional health bureau to conduct diagnostic service for patients 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 Batu 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. mBHL uses Julian calendar in its quality management system. However a calendar is available to convert to Gregorian system if needed.

7.2. Scope

Batu 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 Haematology**: GPTGOT, 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

7.3. Vision, Mission and Value statement

7.3.1. Vision statement

7.3.2. 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.

7.3.3. 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

7.4. Management requirements

7.4.1. Organization and management responsibility

7.4.1.1. Organization

7.4.1.1.1. General

BHLis committed to meet requirements of ISO 15189:2012 while performing work at its permanent facility.

7.4.1.1.2. Legal identity

BHL is legally mandated by Oromia regional health bureau to operate as investigation patient's sample of Batu hospital.under the license number/reference letter -------()

The permanent physical location of BHL is:

Batu Hospital Laboratory is located

Kebele 01
Batu 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

7.4.1.1.3. Ethical conduct

Batu 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.

7.4.1.1.4. Laboratory head

BHL is lead by a competent person whose overall responsibilities includes but not limited to administrative, professional and scientific advisor to Batu Hospital on laboratory diagnostic

issues. The detailed roles and responsibilities of the laboratory head are found in job description (JD 01).

7.4.1.2. Management responsibility

7.4.1.2.1. Management commitment

The management of Batu 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 Batu 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.

7.4.1.2.2. Needs of users

Batu 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.

7.4.1.2.3. Quality policy

Batu 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.

Batu Hospital laboratory Staffs perform 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.

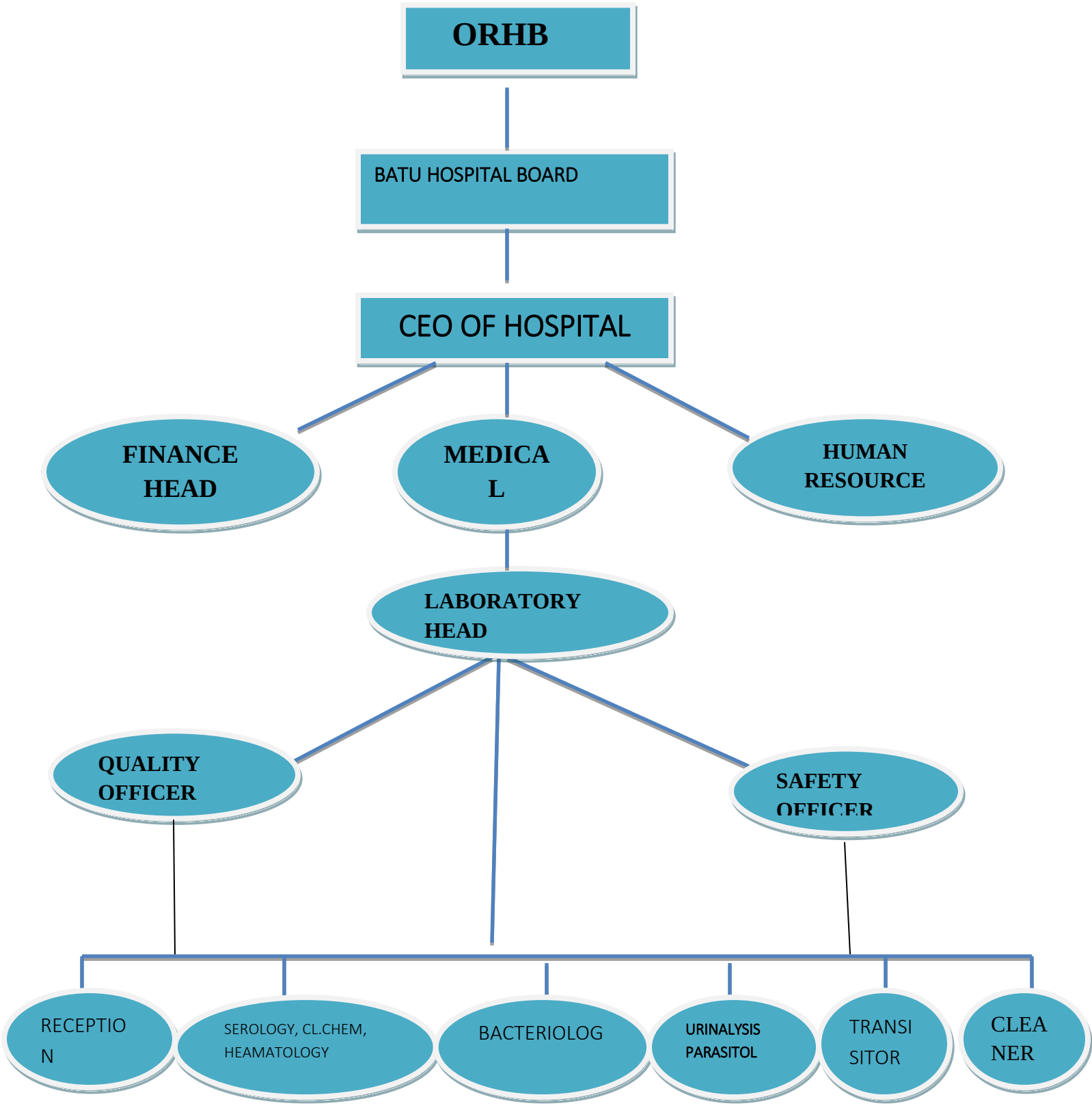
7.4.1.2.4. Quality objectives and planning

Batu 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.

7.4.1.2.5. Responsibility, authority and interrelationship

Batu 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.

Batu Hospital Laboratory Organo-Gram



7.4.1.2.6. 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. Staffs 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 captured on BHL-4.1-F-003.

7.4.1.2.7. 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).

7.4.1.2.8. Quality officer

The laboratory Head has nominate a quality Officer to Hospital Medical Director for approval. Quality officer 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).

7.4.1.2.9. Safety officer

Safety officer nominated by laboratory head and approved by Medical director. He/she report to laboratory head. He/she is well trained in infection prevention. Safety officer ensures the safety of laboratory according to ISO 15190. The detailed responsibilities of safety officer are stated in the job description (JD03)

Supporting documents

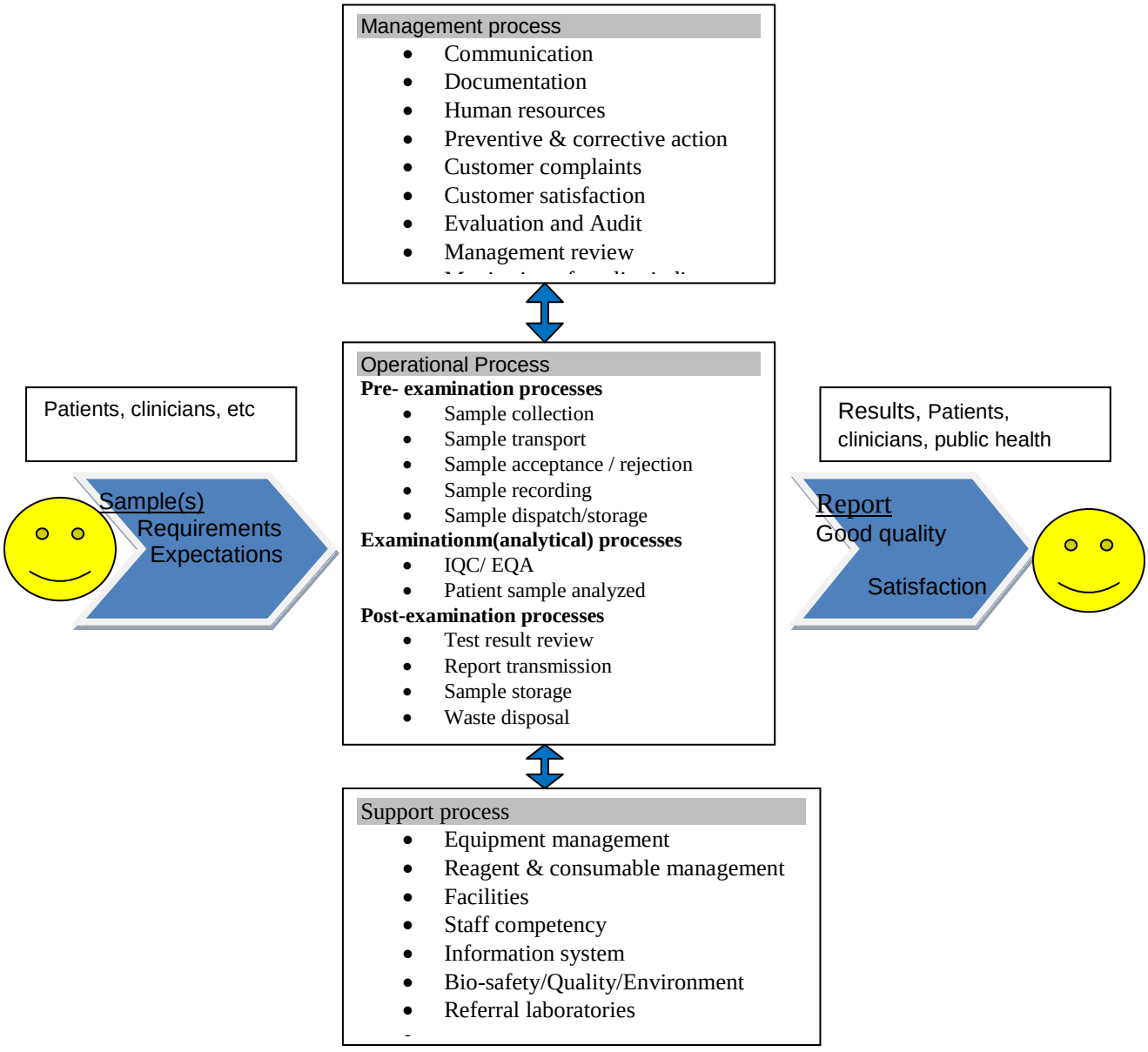
- registration license_
- ethical conduct declaration form_ BHL-4.1-F-001
- Laboratory head job description_ JD 01
- Objectives planning form_ BHL-4.1-F-002
- Staff job descriptions
- Memos template _ BHL-4.1-F-004

- Meeting minutes template _ BHL-4.1-F-003
- Quality officer job description_ JD 02
- Safety officer job description _JD 03

7.4.2. Quality management system

7.4.2.1. 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) as illustrated in diagram below:



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.

7.4.2.2. Documentation requirements

7.4.2.2.1. 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

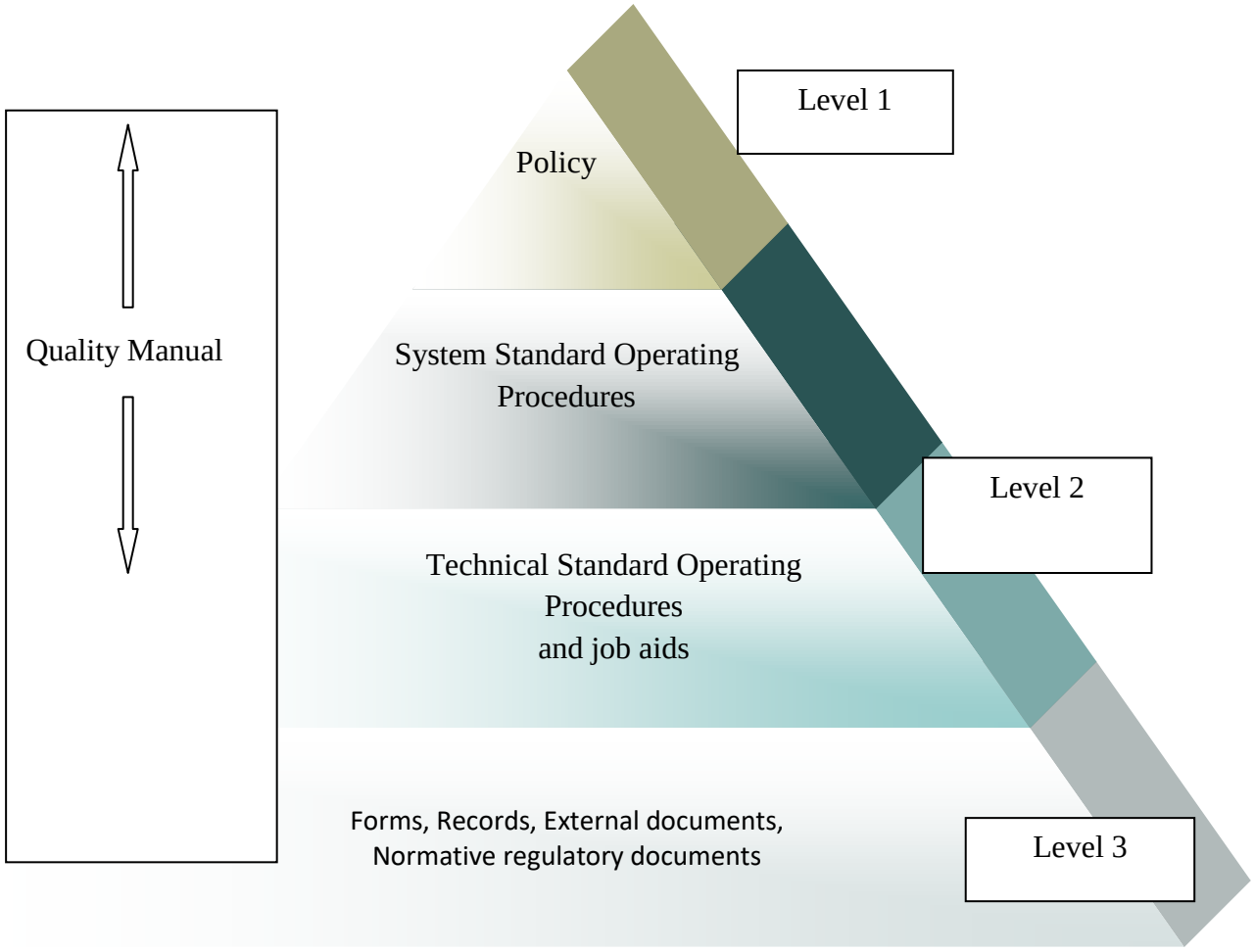
7.4.2.2.2. Quality manual

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

7.4.2.2.3. 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 level as 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.

7.4.3. 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 Laboratory Head 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

7.4.4. Service agreements

7.4.4.1. 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).

7.4.4.2. 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

7.4.5. Examination by referral laboratories

7.4.5.1. 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.

7.4.5.2. 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

7.4.6. 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

7.4.7. 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 below gives the summary of advisory services and staff who authorize to give the services.

Advisory services matrix

	Sample requirements (volume , type of container)	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						✓

7.4.8. 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

7.4.9. 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

7.4.10. 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

7.4.11. 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

7.4.12. 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

7.4.13. 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

7.4.14. Evaluation and audits

7.4.14.1. 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.

7.4.14.2. 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.

7.4.14.3. 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.

7.4.14.4. 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.

7.4.14.5. 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.

7.4.14.6. 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.

7.4.14.7. Quality indicators

Batu 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.

7.4.14.8. 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

7.4.15. Management review

7.4.15.1. General

Batu 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).

7.4.15.2. Review in put

The minimum agenda of the management reviews is as follows:

a) the periodic review of requests, and suitability of procedures and sample requirements;
b) assessment of user feedback;

c) staff suggestions;
d) internal audits;
e) risk management;
f) use of quality indicators;
g) reviews by external organizations;
h) results of participation in inter-laboratory comparison programs (PT/EQA);
i) monitoring and resolution of complaints;
j) performance of suppliers;
k) identification and control of nonconformities;
l) results of continual improvement including current status of corrective actions and preventive actions;
m) follow-up actions from previous management reviews;
n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;
o) recommendations for improvement, including technical requirements;
p) Review of quality policy and quality objectives for continued suitability.

7.4.15.3. 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.

7.4.15.4. 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

7.5. TECHNICAL REQUIREMENTS

7.5.1. Personnel

7.5.1.1.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.

7.5.1.2.Personnel qualification

Batu 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.

7.5.1.3.Job description

BHL has a job description for all positions that describe responsibility and authority for personnel.

7.5.1.4.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).

7.5.1.5.Training

BHL provide training for all personnel which include:

a) quality management system coordinated by quality Officer annually;
b) assigned work processes and procedure by laboratory head/quality officer before staff start working in the section;
c) health and safety by safety officer annually;
d) ethics by hospital human resource manager once before starting work;
e) 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.

7.5.1.6.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).

7.5.1.7.Reviews of staff performance

Batu 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.

7.5.1.8.Continuing education and professional development

Batu Hospital provides continuous education opportunities in collaboration with regional health bureau according to their performance and service year.
Batu 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.

7.5.1.9.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

7.5.2. Accommodation And Environmental Conditions

7.5.2.1.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

7.5.2.2.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.

7.5.2.3.Storage facilities

Batu Hospital laboratory has enough storage facilities for reagents, consumables, samples, equipment, records and documents. Samples and reagents are kept in different refrigerators to avoid cross contamination.

7.5.2.4.Staff facilities

Batu Hospital laboratory has enough washrooms, clean supply of drinking water and storage facilities for personal protective clothing and equipment.

7.5.2.5.Patient sample collection facilities

Batu 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.

7.5.2.6.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

7.5.3. Laboratory equipment, reagents, and consumables

7.5.3.1.Equipment

7.5.3.1.1. General

Batu 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.

7.5.3.1.2. 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.
All equipment are uniquely identified by their serial numbers and laboratory generated ID numbers.

Accept equipment by checking and record equipment acceptance criteria checklist_ BHL-5.3-F-001

7.5.3.1.3. 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 equipment to prevent its contamination or deterioration.

7.5.3.1.4. 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.

7.5.3.1.5. 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 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 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.

7.5.3.1.6. 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)

7.5.3.1.7. 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).

7.5.3.2.Reagents and consumables

7.5.3.2.1. 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.

7.5.3.2.2. 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.

7.5.3.2.3. 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.

7.5.3.2.4. 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 staffs 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.

7.5.3.2.5. 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.

7.5.3.2.6. 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.

7.5.3.2.7. 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

7.5.4. Pre examination processes

7.5.4.1.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

7.5.4.2.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

7.5.4.3.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.

7.5.4.4.Primary sample collection and handling

BHL has a procedure (BHL-MSOP-15) which gives clear instruction for sample collection and handling.

7.5.4.5.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

7.5.5. Examination Processes

7.5.5.1.Selection, verification and validation of examination procedures

7.5.5.1.1. 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.

7.5.5.1.2. Verification of examination procedures

BHL uses the examination methods and equipment 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.

7.5.5.1.3. 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.

7.5.5.1.4. 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.

7.5.5.2.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.

7.5.5.3.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

7.5.6. Ensuring Quality Of Examination Results

7.5.6.1.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.

7.5.6.2.Quality control

7.5.6.2.1. 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.

7.5.6.2.2. 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.

7.5.6.2.3. 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.

7.5.6.3.Inter-laboratory comparisons

7.5.6.3.1. 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.

7.5.6.3.2. 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.

7.5.6.3.3. 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.

7.5.6.4.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

7.5.7. Post- Examination Processes

7.5.7.1.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.

7.5.7.2.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

7.5.8. Reporting of Result

7.5.8.1.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.

7.5.8.2.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.

7.5.8.3.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

7.5.9. Release of Results

7.5.9.1.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).

7.5.9.2.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.

7.5.9.3.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

7.5.10. Laboratory information management

7.5.10.1. 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.

7.5.10.2. Authorities and responsibilities

Batu 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

7.5.10.3. Information system management

Batu 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

7.5.11. References

- ISO 15189:2012 – Medical Laboratories – Particular requirements for quality and competence
- QMS02-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

I have read, understood and agree to follow the quality manual as documented:

No	**Name**	**Signature**	**Date**
1.			
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CHAPTER 8: STANDARD OPERATING PROCEDURES

PROCEDURE FOR VIKIA HIV ½ RAPID TEST FOR DETECTION OF HIV 1 & HIV 2 ANTIBODIES

PROCEDURE CHANGE HISTORY:

	Name	Position	Signature:	Date:
Written	Birhanu Legese	Field Epidemiology Resident at SPHMMC Cohort II		10 may 2017
Reviewed	Gebeyehu Dumssa	Safety Officer		
Authorized	Daba Muleta	Capacity building, PHEM and LQA core process		

8.1.1 Purpose

This procedure provides instructions to perform rapid HIV screening test using VIKIA HIV 1 and 2 tests device

8.1.2 Scope

This procedure is used in surveillance section of OPHRCBQAL when HIV tests performed by providing appropriate techniques of test step by works.

8.1.3 Responsibility

Focal person of surveillance is responsible for ensuring effective implementation and maintenance of this procedure.

8.1.4 Principle

VIKIA HIV ½ is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2. The test consists of a plastic device containing:

1. A chromatography membrane to which are fixed: - in the test region (T), synthetic peptides specific for HIV-1 (gp41 of group M and group O), and HIV-2 (gp36), - in the control region, two color indicators.
2. A test strip impregnated with a conjugate consisting of a mixture of synthetic peptides specific for HIV-1 group M (gp41 of group M and group O), and HIV-2 (gp36), coupled to blue-dyed polystyrene microspheres. The sample is added to the sample well and migrates by capillarity along the membrane.

   If the sample contains anti-HIV antibodies they form an antigen-antibody complex with the peptides, specific to this virus, present on the blue-dyed polystyrene microspheres. The antigen-antibody complexes migrate along the membrane and bind to the synthetic peptides immobilized on the nitrocellulose membrane. This is revealed by a blue line in the test region "T". The test is validated if the color of the control line in region (C) changes from blue to pink/red. If this line does not change color the test is invalid.

8.1.5 Reagent and material (Materials)

A. Test components

- Test cassette

- Diluent buffered
- Safety lancet
- Disposable pipette
- Alcohol pad

B. Other materials required but not included provided by manufacturer

- Timer
- Tats tubes
- Needle
- Centrifuge
- Biohazard waste containers

8.1.6 Equipment

Not applicable

8.1.7 Sample and container type

The test can be performed by EDTA, Lithium Heparin or Sodium Citrate whole blood, Capillary Blood (Finger stick), serum or plasma. No need of special patient preparation

8.5.1. Capillary blood collection: Choose a puncture site on his or her fingertip. Clean the fingertip with alcohol pad. Place the safety lancet on the selected puncture site. Press the tip of the Safety Lancet against the fingertip. Wipe away the first drop of the blood with sterile gauze or cotton. Using the disposable spacemen transfer device provided within the test kit to collect blood from the puncture site.

8.5.2. Vein blood collection: collect the vein blood in collection tubes containing anticoagulants like EDTA, Heparin, or Sodium citrate by vein puncture. Do not test whole blood specimen if older than 3 days.

8.5.3. Plasma collection: Collect the whole blood in the collection tubes containing anticoagulants by vein puncture.

8.5.4. Serum: Collect the whole blood in collection tubes without any anticoagulants by vein puncture. Keep sample containing tube in standing position for 30 minutes and centrifuge it at 3000 MPR 10-15 minutes to obtain serum.

8.5.5. Whole blood specimen may be used for testing immediately or may be stored at 2-8oC for 3 days

8.5.6. If serum or plasma specimen immediately are not tested, they should be refrigerated at 2-8oC. For storage periods greater than three days, freezing at 20oC is recommended. They should be brought to room temperature prior to use.

8.5.7. Serum or plasma specimens containing precipitates may yield inconsistent test result. Such specimens much always be centrifuged prior to assaying.

8.1.8 Environmental and safety control

A. Safety

Apply universal safety precautions while handling specimens. Refer more information the safety manual (Doc number=____) for standard safety procedures.

B. Specimen storage

Specimen type	Stability
EDTA, Lithium Heparin or Sodium Citrate Whole Blood	Up to 4 hour at 15-37°C Do not freeze Whole Blood samples
Capillary Blood (Finger stick)	Should be tested immediately
Serum/plasma	5 days at 2-8°C
	4 hours at 15-37°C
	At -25±6°C for longer storage

.

C. Test device storage

- Test device can be stable at temperature of 4- 30°C
- Do not freeze
- If stored according to recommended conditions all components are stable until expire date.

8.1.9 Calibration

Not applicable

8.1.10 Procedure

8.1.10.1. Allow the test device to reach room temperature

8.1.10.2. Remove the test device from the sealed pouch and use it extemporaneously

8.1.10.3. Place the test device on clean and level surface

8.1.10.4. Using the dropper, transfer 3 drops of Plasma or serum sample, whole blood from venous or finger stick (75 µl) to the sample well (S) of the test device without trapping bubbles.

8.1.10.5. Dispense one drop of buffer (40 µl) without trapping bubbles in the sample well (S) start the timer. NB: Do not add buffer solution if the sample is plasma or serum.

8.1.10.6. Read the test result at 30 minutes. (NB: most of the positive results can be interpreted as positive before 30 minutes)

8.1.10.7. Procedural Notes

a. Do not touch the test device chromatography membrane with your figure.
b. Do not mix reagents from different batches
c. Test device should remain in the pouch until use it give
d. An invalid result should be repeated.
e. Avoid successive freezing and thawing plasma/serum.
f. Lipemia, hemolysis, bilirubinemia, has significantly influence the assay.

8.1.11 Quality Control

Control	Stability	Frequency	Preparation (Y/N)
Internal kit control	Room temperature	Each run	N

In house control	-20°C or cooler	At least weekly, new batch opened, manipulator and result suspicious	Y

8.1.12 Calculation

NA

8.1.13 Performance characteristics

Specificity of VIKIA HIV ½ for the all population is 99.77 for plasma and 99.92 for whole blood. Sensitivity of this test device for all population is 99.79 for both plasma and whole blood.

8.1.14 Uncertainty of measurement

Not applicable

8.1.15 Interferences/Limitations

a. A negative VIKIA HIV 1/2 result does not exclude the possibility of infection with HIV:
b. If the anti-HIV concentration is low in the very early stages of infection,
c. If the variant of the HIV virus is less detectable by the test format, in the case of HIV-2 infection, a “hook” effect may be observed for certain samples containing a very high concentration of specific antibodies.
d. In countries which have a high prevalence of HIV-2 infection, it is recommended to perform this test using whole blood.
e. This test has been validated for serum, plasma and whole blood. It should not be used for other biological fluids such as saliva or urine.
f. Do not use serum pools.
g. Positive specimens should be retested using another method and the results should be interpreted taking into account the overall clinical evaluation and the results of any other tests performed, before a diagnosis is made.
h. Whole blood or plasma specimens containing anticoagulants other than lithium heparin, EDTA or sodium citrate have not been validated.

i. The use of recalcified plasma has not been validated.

j. The hematocrit was not found to influence the test that was performed using whole blood, for values between 30 and 60%.

ii. Erroneous results may be obtained with serum or plasma samples which have a cloudy appearance due to bacterial contamination or several freeze/thaw cycles.

iii. Interference may be encountered with certain sera containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's history and the results of any other tests performed.

8.1.16 Critical Values

Not applicable

8.1.17 Results reporting

Reactive: the line in the control region (C) changes from blue to pink/red and a blue line appears in appears in test region (T)

Non-Reactive: the line in the control region (C) changes from blue to pink/red and no line appears in appears in test region (T)

Invalid: The line in the control region (C) does not change color

The line in the control region (C) does not change color a blue line appears in the test region (T)

8.1.18 Interpretation of Results

Result of this device can be read as "**Reactive**" or "**Non-reactive**". If the test result is "Non-reactive" report to physician as "**Negative"** for HIV1/2 antibody.

a. **Reactive result**

A line of any intensity forming in the test region (T), plus a line in the control region (C), indicates a positive result.

b. **Non-reactive**

The line in the control region (C) changes from blue to pink/red and no line appears in the test region (T).

c. **Quality control**

The line in the control region (C) changes from blue to pink/red.

d. **Invalid test**

i) The line in the control region (C) does not change color; insufficient sample volume or incorrect procedural techniques are the most likely reasons. Difficulties may be encountered with certain samples: incomplete migration, highly viscous sera, presence of fibrin. Review the procedure and repeat the test after re-centrifuging the sample.
ii) The line in the control region (C) does not change color and a blue line appears in the test region. Repeat the test after re-centrifuging the sample.

8.1.19 Biological Reference Interval

Not applicable

8.1.20 References

21.1. WHO, UNAIDS. HIV assay: operational characteristics (phase I) report 12 simple/rapid tests whole blood specimen. 2002

21.2. BIOMERIEUX. VIKIA® HIV ½ Package insert catalog number 31 112.

21.3. WHO. Consolidated guidelines on HIV testing service. July 2015. 2003.

8.1.21 Appendix

Refer document number __ and __ for detailed Sample collection procedure for vein blood and figure pique respectively.

Declaration

I have read and understand this SOP and I agree to consistently follow the procedure as described.

Print Name	Signature	Date

PROCEDURE FOR WANTAI RAPID TEST FOR DETECTION OF HIV 1 & HIV 2 ANTIBODIES

PROCEDURE CHANGE HISTORY:

	Name	**Position**	**Signature:**	**Date:**
Written	Birhanu Legese	Field Epidemiology Resident at SPHMMC Cohort II		10 may 2017
Reviewed	Gebeyehu Dumssa	Safety Officer		
Authorized	Daba Muleta	Capacity building, PHEM and LQA core process		

8.2. PROCEDURE FOR WANTAI RAPID TEST FOR DETECTION OF HIV 1 & HIV 2 ANTIBODIES

8.2.1. Purpose

This procedure provides instructions to prform rapid HIV screening test using Wantai HIV 1 a d 2 tests

8.2.2. Scope

This procedure is used in Serviellance section of OPHRCBQAL when HIV tests prformed by providing approprate techniques of test stepp by works.

8.2.3. Responsibility

Focal person of serviellance is responsible for ensuring effective implementation and maintenance of this procedure.

8.2.4. Principle

Wantai Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) Colloidal Gold device employs chromatographic lateral flow device in cassette format. Colloidal Gold conjugated recombinant antigens corresponding to HIV-1 (gp120) and HIV 2 (gp36) are dry-immobilized at the end of nitrocellulose membrane trip. HIV 1+2 antigens are bound at Test Zone (T) and antibodies are bound at Control Zone (C). When the specimen is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in specimen, HIV ½ antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by the HIV 1 or 2 antibodies in specimen, no red line formed in the test Zone (T). The gold conjugate will continue to migrate alone until it is captured the Control Zone (C) by the antibodies aggregating in a red line, which indicates validity of the test.

8.2.5. Reagent and material (Materials)

A. Test componenets

- Test cassette
- dilunnbuffure
- weighing boats
- Spatula
- Flask
- Beaker
- sterile screw-cap tubes.
- Distilled or deionized water

8.2.6. Equipment

Not applicable

8.2.7. Sample and container type

The test can be performed by whole blood, serum or plasma. No need of special petient preparation

8.2.8. Environmental and safety control

Using several precautions (gloves, lab coats, washing hand, when handling infectious materials are needed. Refer for the safety manual (Doc number=____) for standard safety procedures

8.2.9. Calibration

Not applicable

8.2.10. Procedure

A. Open the pouch and remove the test device and the sample pipette from the foil pouch and place it on a flat dry surface
B. Add 50 µl (one drop using the provided pipette) of the whole blood in to the specimen window(S) or add 80 µl (two drop of the provided pipette) serum or plasma in to the specimen window(S)
C. Immediately add one drop of diluent buffer in to the in to the specimen window(S) if you use whole blood. Do not add diluent for serum or plasma specimen.
D. Read the result from 10 minutes after specimen and buffer loading, to maximum of 30 minutes. Do not read results after 30 minutes.

Procedural Notes

Avoid the use of hemolytic turbid and microorganism contaminated specimens.

8.2.11. Quality Control

Control	Stability	frequency	Preparation (Y/N)
Internal kit control	Room temperature	Each run	N
In house control	-20°C or cooler	At least weekly, new batch opened, manipulator and result suspicious	Y

Storage

Test device can be stable at 2- 30 Sto°C for up to 6 months; Make sure caps are tightly closed to prevent evaporation.

8.2.12. Calculation

See manufacturer insert

8.2.13. Performance characteristics

Not applicable

8.2.14. Uncertainty of measurement

Not applicable

8.2.15. Interferences/Limitations

a. Hemolytic sample give reddish background even after end of test time. Non-reactive results do not exclude the possibility of HIV exposure or infection. Infection through resent exposure (seroconverting) to HIV, or late AIDS may not be detectable. For reactive results, line intensity cannot be used to evaluate the ant-HIV antibody levels. A test giving an invalid result should be repeated. Rapid test for antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) does not differentiate between recognition of HIV-1 antibodies and HIV-2 antibodies.
b. Rapid test for antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) has not been sufficiently validated for HIV-1 serotype O.
c. If after retesting of the initially reactive specimen, the test result are non-reactive, these specimens should be considered as non-repeatable (false reactive) and interpreted as non-reactive. As with many very sensitive rapid diagnostic tests, false reactive results can occur due to several reasons, most of which are related but not limited to the quality of spacemen, operator error, explosion of the test devise to humidity.
d. Rapid test for antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) is intended only for testing of individual specimen. Do not use it for testing of cadaver specimen, saliva, urine or other body fluids or pooled (mixed) blood.
e. Rapid test for antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) is qualitative assay and the result cannot be used to measure antibodies concentration.

8.2.16. **Critical Values**

Not applicable

8.2.17. Results reporting

Not applicable

8.2.18. Interpretation of Results

a. Reactive result

One red line appears within 10 to 30 minutes next to the Test Zone (T) which indicates that antibodies to HIV 1+2 have been detected through using this test.

b. Non-reactive

No red line appears within 30 minutes next to the Test Zone (T) which indicates that no antibodies to HIV 1+2 have been detected with this device. However, this does not exclude the possibility from infection with HIV.

c. Quality control

One red line will always appear next to the Control Zone (C) indicating the validity of the test.

d. Invalid test

If no red line appears in the control Zone, the test is invalid- discard the test and repeat with new specimen and new cassette.

8.2.19. Biological Refference Interval

Not applicable

8.2.20. **Supporting document**

8.2.21. References

20.1. WHO,UNAIDS. HIV assay: operational characteristics (phase I) report 12 simple/rapid tests whole blood specimen. 2002

20.2. Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. Wantai rapd HIV test, Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colodial Gold Device) Catalog no. WJ- 1810, WJ 1850, WJ 1810E, WJ1850E

20.3. WHO. Consolidated guidelines on HIV testing service. July 2015. 2003.

Media Quality Control Form: Selenite Broth

Declaration

I have read and understand this SOP and I agree to consistently follow the procedure as described.

Print Name	Signature	Date

CHAPTER 9: NARRATIVE SUMMARY OF LABORATORY REPORT

9.1. 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 E.C in Adama town near Adama Hospital. At the time it started the service within two blocks by 2 laboratory professionals and 5 administrative staffs. In 2000 E.C, the number of laboratory professionals was increased to 5 and immediately after the inauguration of the new building (G+1) the number of laboratory personnel and administrative staff raised up to 21 and 23 respectively. Currently the laboratory has 27 laboratory professional, 2 biologist and 22 administrative staff.

Oromia Public Health Research, Capacity Building and Quality Assurance Laboratory has been mandated to conduct health related 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 served as referral laboratory in the disciplines of HIV DNA PCR, Hematology, Clinical Chemistry, TB and clinical bacteriology for health facilities in Oromia and other nearly Regions (Amhara, Afar and Somali). This document contains the 6 month activity OPHCBQAL and the contribution of Field Epidemiology Lab Track residents in this laboratory.

9.2. Objective

The main objective of this document is to describe the activity of Oromia Public Health Research, Capacity Building and Quality Assurance Laboratory and contribution of the Field Epidemiology Lab Track resident in this laboratory.

9.3. Methods

I wrote this report by reviewing different documents and records of OPHCBQAL like Quality manual, job descriptions, formats, reports and laboratory records. I also interviewed the laboratory director, processor owners, section focal persons, quality manager and laboratory experts to get additional important points. Additionally I also included my activities and observations of each laboratory section (departments). The data gather from documents and records described through graphs and tables by Microsoft Excel Office 10.

9.4. Organizational Stricture

Oromia Public Health Research, Capacity Building and Quality Assurance Laboratory is technical wing of Omomia Regional State Health Bureau to perform issues regarding to laboratories in Eastern, Southern and Central zones of the region. The laboratory has a laboratory director and 3 deputy laboratory directors. The laboratory director is directly responsible to Omomia Regional State Health Bureau while deputy directors are responsible to the laboratory director. The laboratory has 2 core processes, 1 support process and 8 sub processes.

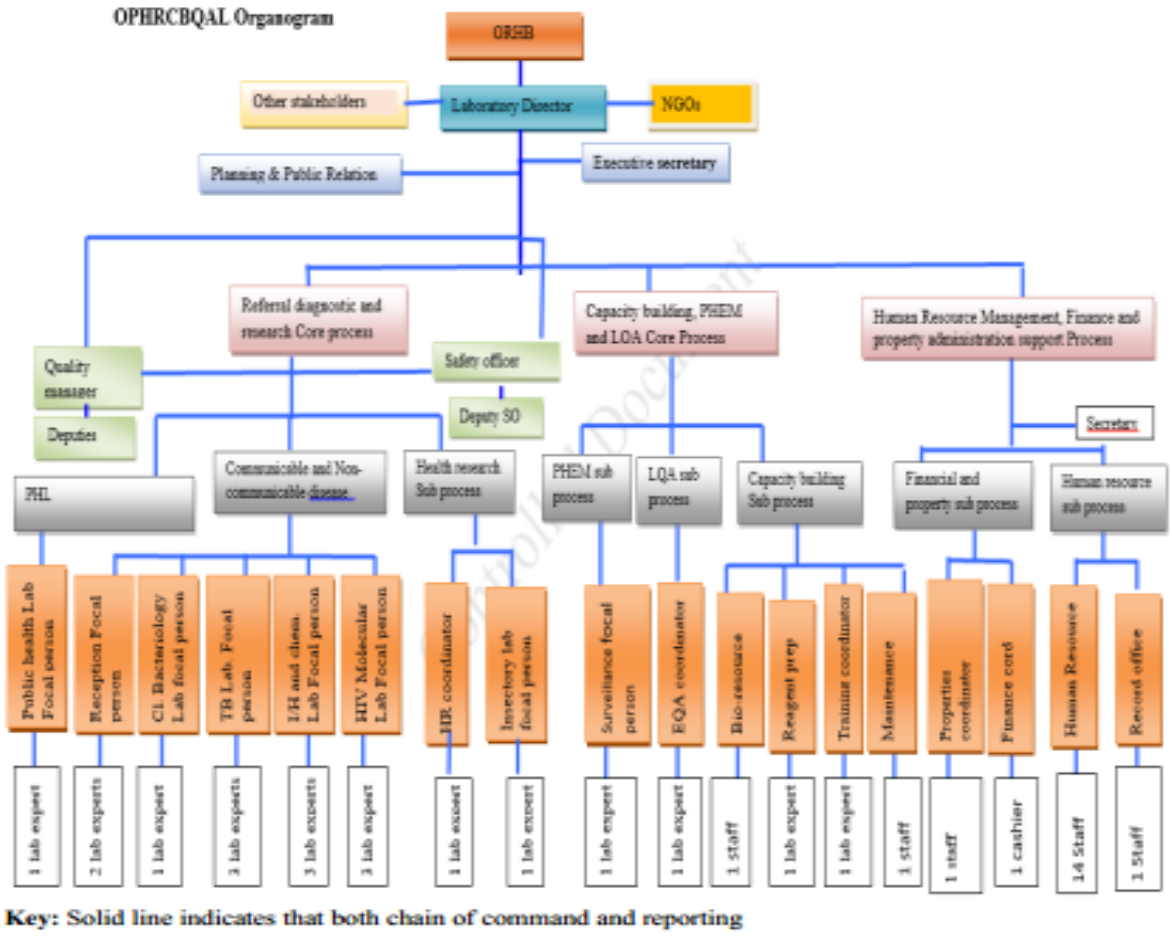


Figure 9-1: Organizational structure of OPHRCBQAL

9.4.1. Referral diagnostics and Research Core process

This core process has 3 sub processes, Public laboratory sub process, communicable and non-communicable diseases sub process and Health research sub process. This core process controls the activities of public health surveillance, operational researches, and referral tests (ART monitoring, culture and DST).

9.4.2. Capacity building, PHEM and LQA core process

This core process has 3 sub processes, PHEM sub process, LQA sub process and Capacity building sub process. This core process controls the activities of In- service training, EQA (REQAS), Reagent preparation, LQMS/SLIPTA implementation, Mentoring/coaching, Document development & customization and Strengthen referral.

9.4.3. Human resource management, Finance and Resource administration support Process

It has two sub processes, Finance and Resource administration and Human resource management. This support process controls daily attendance, hiring, purchasing, and finance issues.

9.5. Scope of the laboratory

A. Reception: Specimen collection, receiving, accession, storing, enter of test information using LIS, 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.

9.5.1. Mission

To protect and promote the health of 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

9.5.2. Vision

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

9.6. Laboratory Activities

9.6.1. TB Laboratory

TB laboratory is reference laboratory to Eastern Oromia health facilities and most health facilities of Afar region. By WHO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) program it scored……. points. Now the laboratory is in the process of international accreditation program to be accredited by Ethiopian Accreditation Organization (ENO). 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 aria 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

- 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 5 ml of sputum needed to diagnose TB. In the laboratory TB can be diagnosed through genetic method (line probe assay and Gen-Xpert), culture (liquid media or MIGIT 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 Gen Xpert, 674 Liquid culture, 674 Solid culture, 66 Line prop assay and 1414 slides microscopically examined.

Table 9-1: Testes performed in TB 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

9.6.2. Bacteriology Laboratory

Bacteriology laboratory is a reference laboratory that can perform identification of bacteria and drug susceptibility test (DST). The laboratory also participated on outbreak investigation by identification of the etiological agent. The laboratory has been working in class II and class III biosafety level laboratory. The laboratory has one microbiologists and one laboratory technologist.

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 aria 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 9-2: Total samples processed by culture in bacteriology laboratory January to May 2017

Month	Number of samples processes by culture
January	5
February	19
March	13
April	15
May	15
Total tests performed	

Table 9-3: Type of samples processed by culture in bacteriology laboratory January to May 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

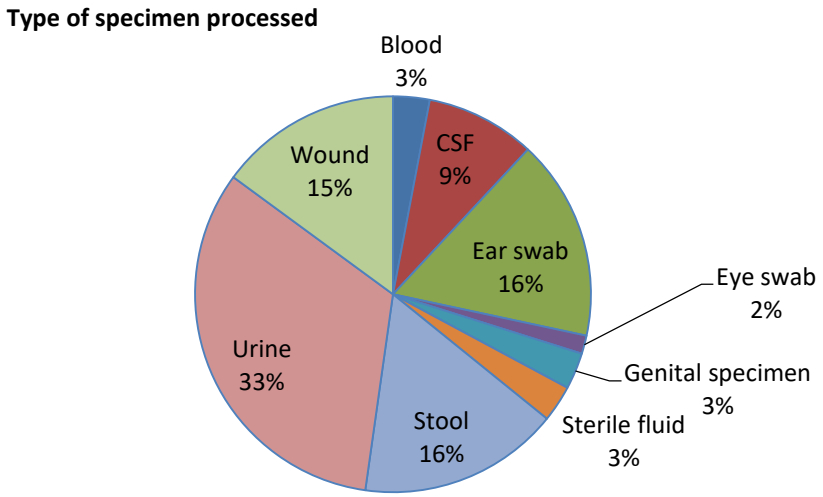


Figure 9-2: Total tests performed by specimen type in Clinical Bacteriology Laboratory

9.6.3. 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 aria 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. In the last

5 months the laboratory performed 1061 DBS and 10015 viral load samples in molecular laboratory.

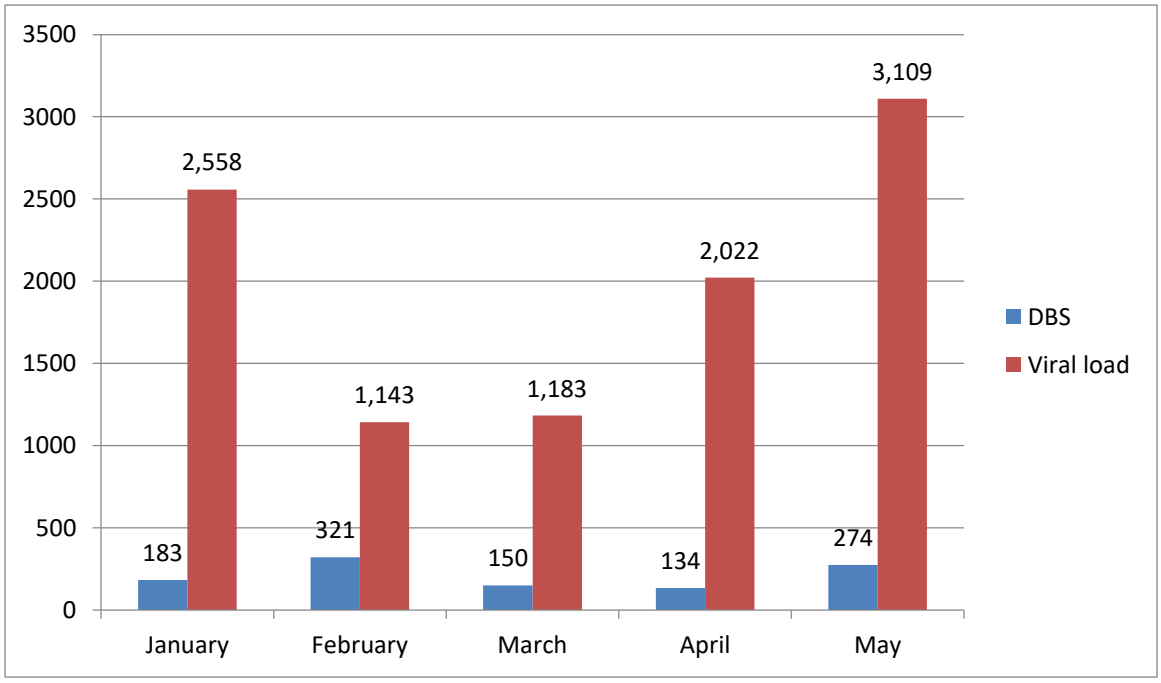


Figure 9-3: Testes performed in Molecular laboratory from January to May 2017

9.6.4. HIV and Surveillance Laboratory

In this section HIV sentinel surveillance, meningitides surveillance and different research projects like quantiferon, trachoma are perform in this laboratory. From the listed above I participated on Quantiferon test and I'm going to describe what was done in this section.

Quantiferon

This is a research project that aimed to detect latent TB and further characterize it. 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 aria 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 nunk tubes finally the plasma is ready to ELISA test. Every week ELISA is test performed. From January to June 2017, 632 samples received and ready to ELISA test and 572 ELISA tests performed.

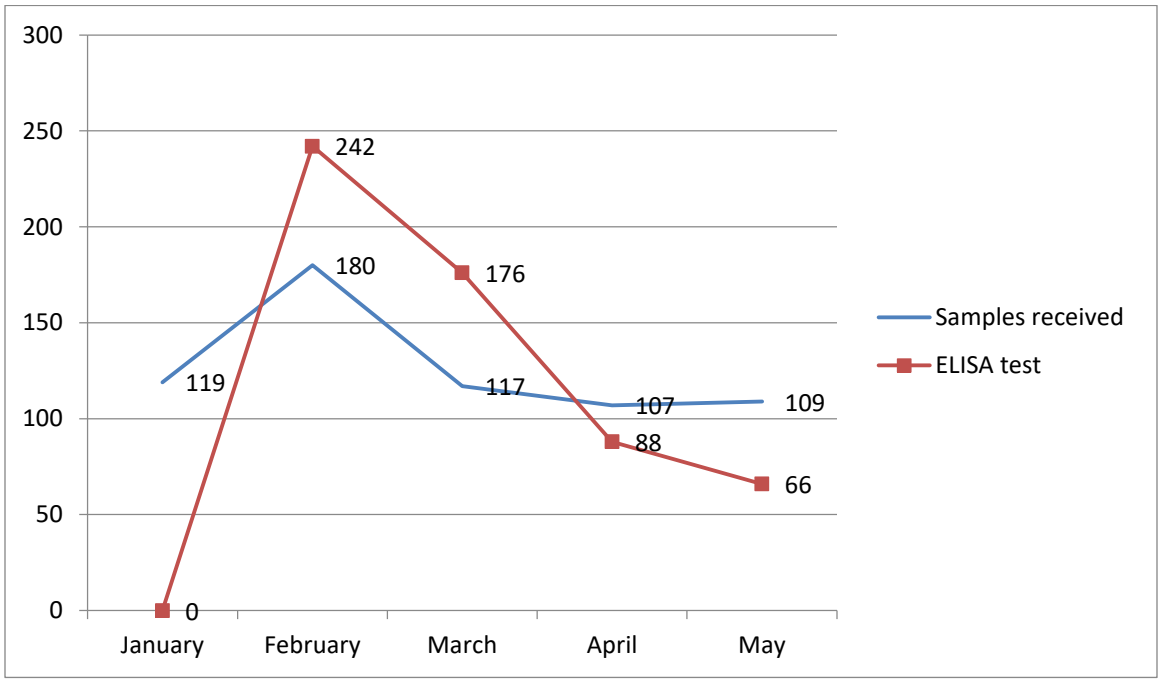


Figure 9-4: Blood specimens received ready to ELISA test and number of ELISA tests performed in Quantiferon section

9.6.5. 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 aria cleaning
- Environmental monitoring included
    - 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

In public health laboratory total of 17 water samples and 115 food samples were processed

9.6.6. 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 carbolfuchsin, acid alcohol and methylene blue. FM reagents prepared for FM are Auramine O, Acid alcohol and Potassium permanganate.

Daily activities

- Working aria 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

- Laboratory equipment maintenance (curative or preventive)

Table 9-4: Total reagents prepared in reagent preparation section

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	80	80
Total reagents prepared	360	360	360	120	120	120

9.7. Activities of the Field epidemiology resident in the laboratory

The laboratory supervisor oriented I was about the general information of the laboratory and introduced me to each laboratory section. Then each section focal persons also oriented me on daily, weekly and monthly activities of the section, laboratory safety and internal laboratory guides. With the consultation of my field supervisor and laboratory supervisors I planned the laboratory practical schedule and then according to the schedule I started activities in each section. We perform the laboratory activities under the supervision of the section focal persons and laboratory experts.

In each section listed above except reception I worked at least 3 weeks with in the residency period (six months). In TB laboratory I prepared more than 450 media, examined more than 150 AFB slides, more than 40 Gene Xpert test and participate in TB culture. In clinical bacteriology laboratory I prepared more than 50 different culture media, 11speciemn processing, bacteria identification and DST. In Molecular laboratory I was participated on DBS sample preparation and viral load preparation. In HIV and surveillance laboratory I only participated on Quantiferon and I processed more than 150 blood samples. In each section laboratories I performed daily and weekly laboratory activities such as room temperature monitoring, refrigerator temperature monitoring, documentation and work areas cleaning.

I also prepared two standard operating procedure, Wintai HIV ½ test and VIKIA HIV ½ test, to OPHRCBQAL and quality manual to Batu Hospital.

9.8. Identified Gaps

In general the laboratory did not have a major gap in my point of view. But I identified some issues that may compromise the quality of the laboratory.

- In reagent preparation section, person who prepare reagents break the phenol bottle with stone. The broken bottle may harm the laboratory personnel who prepare the reagent.
- In some sections refrigerators preventive maintains not done due to this the refrigerators door were difficult to close or open.
- There was shortage of glove in the laboratory for the last 3 or 4 months, if the problem continued like this it may limit activity of the laboratory.

- HIV and surveillance laboratory and public health laboratory was not regularly inspected as other laboratory section by quality manger and safety officer.

9.9. Recommendations

- Use water bath or incubator to dissolve/melt Phenol. Additionally perform risk assessment in reagent preparation section.
- Perform regular preventive maintenance for each refrigerator according to manufacture instructions and policy of the laboratory.
- Purchase gloves from legal venders
- Please pay attention for all laboratory sections.

9.10. Summary

OPHCBQAL is reference laboratory for advances diagnostic tests for eastern, southern and central Oromia zones and other neighboring regions. The laboratory is also served as a training center, research center and strengthens LQMS among health facility laboratories. I was happy in my laboratory practical attachment in this laboratory. I increased my knowledge, practical skill and inter personal relationships. I would like to acknowledge the management and all of staff the laboratory.

CHAPTER 10: THESIS



SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE

DEPARTMENT OF PUBLIC HEALTH

PERFORMANCE EVALUATION OF MEDICAL LABORATORY PROFESSIONALS' ON MALARIA MICROSCOPY, AFAR REGIONAL STATE, NORTH-EAST ETHIOPIA, 2017

BY: BIRHANU LEGESE, BSc

A THESIS SUBMITTED TO THE DEPARTMENT OF PUBLIC HEALTH, IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF PUBLIC HEALTH IN FIELD EPIDEMIOLOGY

January 2018

Addis Ababa, Ethiopia

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ADVISORS:

YOSEPH WORKU, MD, MPH

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GETACHEW TILAHUN, BSc, MSc

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January, 2018

Addis Ababa, Ethiopia

Declaration

I, the undersigned student, declare that this research project is my original work in partial fulfillment of the requirement for the Master of Public Health in Field Epidemiology training program. I also declare that it has never been presented in this or any other higher institution and that all resources and materials used in the research work have been duly acknowledged.

Name of the student: _____

Signature: _____

Date: _____

.....

Approval of Advisors

This research work has been submitted for examination with my approval.

Name of Primary Advisor: _____

Signature: _____

Date: _____

Name of Secondary Advisor: _____

Signature: _____

Date: _____

Acknowledgement

I would like to thank St. Paul's Hospital Millennium Medical College for financial support & Afar Regional State Health Bureau for its financial support and allowing me to conduct this study. I would like to express my sincere thanks to advisors Dr. Yoseph Worku, Mr. Tewodros Getinet and Mr. Getachew Tilahun for their valuable comments from the beginning of the research proposal to write-up of the thesis. I would like to acknowledge Mrs. Tsehaynesh and Mrs. Tewabech from Adama Malaria Control Center for preparing and validating the proficiency testing slides. I would like also to express my heartfelt gratitude to Afar Regional Laboratory staffs for their support on data collection, supervision and availing necessary materials. I would like to thank Mr. Gemechu Leta and Mr. Abinet Abebe from Ethiopian Public Health Institute for their technical support while I standardize the questionnaires.

Abstract

Introduction: Light microscopy is a gold standard method to malaria diagnosis. The effectiveness of malaria microscopy depends on maintaining a high level of staff performance. The aim of this study is to evaluate performance of laboratory professionals working in Health Facility Laboratories of Afar Region on malaria microscopy through proficiency slides and factors influencing their performance.

Method: We implemented institution based cross sectional study. We measured the performance of each laboratory professionals with 23 panel malaria slides. Microscopists achieving ≥90% sensitivity and ≥80% specificity and 95% Plasmodium falciparum detection (if present) were good performer otherwise poor performer. We collected data from November 13 to December 26, 2017 and entered to Epi Info version 7 and analyzed by SPSS version 21. We equated associated factor with performance through binary logistic regression. Odds ratio, p-value and 95% confidence interval was used to test association.

Result: Of the total 119 laboratory professionals working in Afar Region 99 (83.2%) professionals participated on this research. Of the total participants only 48(48.5%) not fulfilled the criteria to diagnose malaria at periphery level. Of total 2277 distributed slides, 1683(73.9%) correctly read and of 99 low load Plasmodium Vivax species 22(22.2%) slides correctly read. The overall Sensitivity and specificity was 86.7% (Kappa=0.73). Laboratory professionals trained malaria microscopy had better performance than not trained [AOR]=3.894, CI=1.329-11.410. Laboratory professionals with good theoretical knowledge had good performance than had poor theoretical knowledge. (AOR=4.067, CI=1.327-12.469, P=0.014). Laboratory professionals with less than 2 year experience had poor performance than those have more than 5 year experience (AOR=0.124, CI=0.030-0.51 1.943).

Conclusion and recommendation: Performance of laboratory professionals working in Afar region on malaria diagnosis under light microscopy was poor and not sufficiently skilled to detect the low density parasitaemia that help to malaria elimination program. Providing training and regular competence evaluation may improve their performance.

10.1. Introduction

10.1.1.Back ground

Malaria is a disease caused by a protozoan parasite belonging to the genus Plasmodium, and is spread from one person to another through bite of female Anopheles mosquitoes. There are more than 400 different species of Anopheles mosquito, but only 30 are malaria vectors of major importance. Five species of Plasmodium can infect human beings; two of these – P. falciparum and P. vivax – pose the greatest threat. Although P. vivax can cause severe illness and death, P. falciparum is the most dangerous malaria parasite, the most prevalent on the African continent and responsible for most malaria related deaths. P. vivax has a wider distribution than P. falciparum, and predominates in many countries outside of Africa. Although P. vivax can occur in Africa, the high frequency of a genetic trait known as Duffy negativity among African populations makes many individuals resistant to infection with P. vivax (1).

Laboratories play a significant role in the diagnosis, monitoring and treatment of malaria. As multi-drug resistant falciparum malaria continues to emerge and new regimens are developed for differential treatment of malaria species, accurate species detection becomes critical (2).

Malaria can be diagnosed by clinical sign and symptom, light microscopy, Polymerase chain reaction and other methods (3). The detection of malaria parasites by light microscopy thick/thin blood film remains the reference method (Gold standard) for diagnosis of malaria. Microscopy requires trained staff, well-maintained equipment, a regular supply of reliable reagents, clean water and electricity, and a well-executed quality management system. Where the training of microscopists, equipment and reagents are substandard, the microscopy services are almost always of poor quality (4).

To minimize errors and to produce reliable patient results WHO recommended Quality Assurance program for every laboratory. External Quality assessment is one part of QA program which can be applied in three main ways, each with advantages and disadvantages: i) Proficiency test (PT), where an external provider sends samples of undisclosed results to laboratories or individual testers and provides feedback on results. It is usually measure performance individual laboratory professionals; ii) Rechecking or retesting samples in higher level or peer laboratories (inter-laboratory comparison); iii) On-site assessment by approved evaluators. On this study we

implemented PT to evaluate the performance of laboratory professionals working at peripheral level.

10.1.2.Statement of the Problem

Nearly half of the world's population, 3.3 billion, are at risk of malaria, and 1.2 billion are leaving at high risk areas (5). Within fifteen years, 2001 and 2015, 1.3 billion malaria cases and 6.8 million malaria deaths occurred globally. Of all deaths about 6.6 million (97%) were children aged under 5 years (1). Each year, 212 million cases and 429,000 deaths of malaria occurred globally and most deaths (92%) estimated to have occurred in African (6). About 292,00 under 5 children died (6) and 1.5 million pregnant women suffered from malaria and its adverse consequences in Sub-Saharan Africa (SSA) (7). Nigeria and the Democratic Republic of the Congo contribute 35% for deaths from malaria (8).

Malaria is a major public health problem in Ethiopia and approximately 60% of Ethiopians live in malaria risk areas, and 75% of the country's landmass is favorable for malaria transmission, with malaria primarily associated with altitude and rainfall (9). The transmission peaks bi-annually from September to December and April to May following rains of the season (10). Federal Ministry of Health reported malaria was the tenth causes of outpatient morbidity and admission accounting 3.37% and 1.38% respectively in 2016. In the same year 5.17% outpatient visits, 3.71% admission and 1.16% of deaths among under five children were due to malaria (11).

Malaria is also the leading cause of morbidity and mortality in Afar Region. The transmission in the region is generally unstable, with perennial transmission in areas along the Awash River Valley specially (12). Federal ministry of health reported that total malaria case of Afar Regional State was 119,053 which contributed 5.5% to national malaria cases in 2015. In this year the incidence of malaria was 6,387 cases per 100,000 populations at risk with CFR of 0.01% (13).

To prevent complicated malaria, treatment must begin as soon as possible, generally within 24 hours after symptom onset. Effective malaria treatment requires improved diagnosis of malaria (3,18). Malaria can be diagnosed though Giemsa-stained light microscopy, Antigen detection (RDT), Molecular methods (DNA PCR), Quantitative Buffy Coat, Dark-field microscopy, Automated blood cell analyzers (15,16).

Reliable laboratory testing remains challenging issue in many resource-limited countries (17,18). The main source of unreliability of results includes; limited resource of laboratories, inadequate infrastructure, poorly-trained professionals and lack of standardization (19). Other obstacles that contributed to low quality are low access to financial service (20), the cultural beliefs of the patients, attrition of healthcare workers, physicians' attitudes and high work load of microscopists (4). These challenges faced in laboratories of developing countries are the main obstacles for early detection, diagnosis treatment, control and prevention of malaria (21).

Human error is inevitable however it can be minimized thorough designing safer systems. A study on British Medical Journal (BMJ) indicated that in the United States of America medical error was the third leading causes of death in 2013 (22). The common causes of medical errors listed on other BMJ were diagnosis error 26%, improper performance (14%), failure to supervise or monitor case (11%), failure to recognize a complication of treatment (3%) and medication error (3%) (23). In laboratory errors can be occurred in the Pre- analytical, Analytical or Post-analytical stages. The distribution of errors estimated that 46%-68.2 in the pre-analytic phase, 7-13% in the analytic phase, and 18.5-47% in the post-analytic phase (24). Overall, it is estimated that laboratory results are misleadingly wrong in 2–4% of cases (23) and had an of effect 24.4%–30% on patient care (25). From the whole laboratory estimated errors about 8% (26) with range 2.7 % to 12 % (25) of them had the potential for serious harm. Most of the errors that occur in the analytical stage are caused by laboratory personnel (27).

The trust of microscopy in diagnosing also depends on the knowledge, level of skill, judgment and motivated staff. WHO recommended that an acceptable microscopic service which expected to produce cost effective, accurate, and timely result requires a comprehensive and active quality assurance (QA) programs. Without an efficient QA program, resources spent on diagnostic services are likely to be wasted and clinicians will lose confidence in the results provided by malaria microscopy (28). However most developing countries did not know the quality service of their diagnostic laboratories (29).

In Ethiopia, of 2.18 million malaria cases, 1.88 million (85.9 %) were confirmed by either microscopy or rapid diagnostic tests (RDTs) (13). However, the actual number of malaria cases in the country is estimated more than 5 million per year (9,30).

On this elimination era of malaria(31), highly competent laboratory professionals, regular external assessment, ensuring good-quality reagents and equipment are important issues (28). Performance of laboratory professionals working in Afar region is not well known even though performance of laboratory professionals done in different parts of Ethiopia (32–34). These literatures summarized that the performance of laboratory professionals in the study areas were poor. At malaria rechecking sites of Ethiopia (34) there was no malaria expert and most laboratory professionals could not have skill of malaria species identification and parasite counting. The aim of this study is to assess performance of laboratory professionals on malaria smear microscopy and factors influencing the performance of the professionals to diagnosis of malaria under light microscopy.

10.1.3.Significance of the study

This study provided information about the performance of laboratory professionals on malaria diagnosis under light microscope who are working in Afar region. Thereby concerned Health authorities at Federal and Regional level will have a complied data about the current performance of laboratory professionals on diagnosing malaria, able to identify identified gaps and will take appropriate actions to improve gaps. Additionally the findings of this research will provide information for policy developers at national regional organizations. Moreover, this study will also serve as an input for future performance evaluation of malaria diagnosis and other related studies and reviews.

10.2. Literature Review

10.2.1.Performance of Laboratory professionals

A comprehensive assessment of the malaria microscopy system in Indonesia, 547 microscopists participated in proficiency testing. Nearly all microscopists (413 or 95.6 %) scored at basic or in-training level, while 10 (2.3 %) were advanced, 9 (2.1 %) were reference microscopists and no microscopists achieved expert level (35).

External quality assessment of Giemsa-stained blood film microscopy for the diagnosis of malaria and sleeping sickness in the Democratic Republic of the Congo showed that Plasmodium falciparum gametocytes was read without errors by 44.8% of participants, whereas 37.7% made a minor error and 17.5% made a major error. Additionally on parasite negative slide 81 % participants scored as negative while the rest (19%) reported as positive (36).

On cross sectional study conducted in clinical laboratories of Hawassa town to evaluate the performance of laboratory professionals 10 slides were distributed to each 72 laboratory professionals. Of 72 participants, 14(19.4%) correctly interpreted all ten distributed slides, and 58(80.6%) missed at least one slide. 18 (25%) of the participants reported correct results of all positive samples and 67(93.3%) of participants correctly reported all four negative slides. Based on the WHO grading system, 17(23.6%) of the participants were rated as ‘in training”, 23(31.9%) as “competent”, 14(19.4%) as “reference”, and 18(25%) as “expert” level. The overall agreement between reference WHO readers and participants in the detection of malaria parasites was 88% and in the identification of different species of malaria was 74.3%. Overall agreement between participants and the experts malaria microscopists on detection and identification was 74.3% (Kappa = 0.63) and 88% (Kappa =0.76) respectively. This study found that gender, work experience, number of slides examined per day, in-service training and supervision did not had any association for poor performance of laboratory professionals (32).

Another cross sectional study to evaluate performance of laboratory professionals in Defense health facilities of Ethiopia around Addis Ababa area a total of 12 slides six stained and six unstained slides distributed to 60 study participants. From the total participants only 5 (8.3%) interpreted all the distributed slides correctly in terms of parasite detection & species identification; and the rest 55 (91.6%), each of which, interpreted at least two slides incorrectly.

Based on WHO grading system, 40 (66.7%) of participants were at “In-training”, five (8.3%) at “Advanced”, 10 (16.7%) at “Reference”, and five (8.3%) at an “Expert level” in malaria parasite detection. On this study the overall sensitivity and specificity of the professionals in detecting malaria parasites were 65.7% and 100%, respectively. The overall agreement of malaria parasite between the study subjects and expert reader was 71.4% (Kappa: 0.4) which is ’fair agreement’. The overall agreement on identification of malaria species was 51.1% (kappa: 0.04) which is ’slight agreement’. This research founded that laboratory professionals had difficulties in the identification of low density parasite and mixed infections. The low performance of laboratory professionals did not have association with educational level, work experience and malaria microscopy/QA training (33).

Another cross sectional study conducted in 2015 to evaluate performance of laboratory professionals working at rechecking sites had participant of 107. The investigator distributed 12 slides to each laboratory. On this finding the mean age of participants was 30 ± 5 yrs and 90 (84.1%) were men. From a total of 1070 blood film slides that were distributed for detection, 1036 (96.8%) were correctly reported for the presence or absence of malaria parasites and from a total of 856 positive blood film slides only 486 (56.8%) were reported correctly in terms of species identification. From the total participants 72.9% (78) were ‘in training’ with respect to species identification. The overall agreement on detection of malaria parasites was 96.8% (Kappa = 0.9), which is ‘perfect agreement’ while on identification of malaria species it was 64.8% (Kappa = 0.33) which is a ‘fair agreement’. Out of 107 participants, 97 (90.7%) scored <80% overall and the least accurately identified malaria parasite species was P. malariae (3/107; 2.8%) followed by P. ovale (35/107; 32.7%) (34). On this study laboratory professionals who had malaria microscopy and QA training had high performance than not training and work experience did not had any association with performance of the participants (34).

10.2.2. Associated factors with Performance of Laboratory Professionals

A. Training

Laboratory errors are common and that they are facilitated by defects in the equipment and mistakes by the laboratory staffs. Many of the errors are as a result of adequate training and shortage of laboratory staff members. A comparison of literature shows that training of laboratory staffs has a direct bearing on the reduction of errors in the laboratories (27)

Refresher malaria training in four districts of Uganda indicated that pre-training test scores of participants were generally low, with an average score of 41% and post training test was improved significantly with an average of 75% score with p- value of (P<0.0001) (37).

A seven day malaria microscopy training of laboratory professionals in Nigeria additionally indicated that the trainee knowledge and microscopic skills significantly increased. The mean slide reading detection, species and counting agreements in pre-training assessment were 48.9%, 27.9% and 0%, respectively, and in post-training 56.8%, 39.2% and 25%, respectively (P<0.001) (38).

On research conducted among laboratory professionals working in rechecking sites of Ethiopia to evaluate their performance indicated that laboratory professionals who had malaria microscopy and QA training had high performance than not trained (Chi-Square 24.0 and P<001) and work experience did not had any association with performance of the participants (Chi-Square 0.4 and P<0.823) (34).

B. Low density parasitimia

A research conducted in Cambodia and Indonesia found that malaria reference readers (experts) had difficulty in identifying low density parasitimia. On this study only 85% of slides correctly read with densities <100 parasites/µl and those slides with densities >350 parasites/µl 100% correctly read (2). Researches done in Ethiopia, Hawassa town (32), Addis Ababa (33) and Malaria rechecking sites of Ethiopia (34) , also agreed that laboratory professionals were challenged by slides with low parasitimia.

C. Work experience

On cross sectional study conducted in the Peruvian Amazon 68 microscopists without experience (< 1 year experience) and 76 microscopists with experience (>1 year experience) recruited in the study. Microscopists with expertise (68.6%) had more agreement than those without expertise (48.2%). The study found that 80.2% of microscopists without experience were “in training” while 47.7% microscopists with experience were “in training”. In the study only 1 (1.5%) microscopists were categorized in “experts” while 9 (11.8%) were categorized in “experts”. The competency assessment was acceptable (competent, referent, or experts levels) in 11.8% of the microscopists without expertise and in 52.6% from those with expertise (39).

A retrospective data review of existing PT in USA laboratory professionals with 2 years or less of experience had almost twice the odds (adjusted odds ratio, 1.849, P=0.043) of producing an error compared with personnel with more than 20 years of experience (40). However different researches conducted in Hawassa town (32), Addis Ababa (33) and Malaria rechecking sites of Ethiopia (34) reported that work experience did not have significant association with microscopists performance.

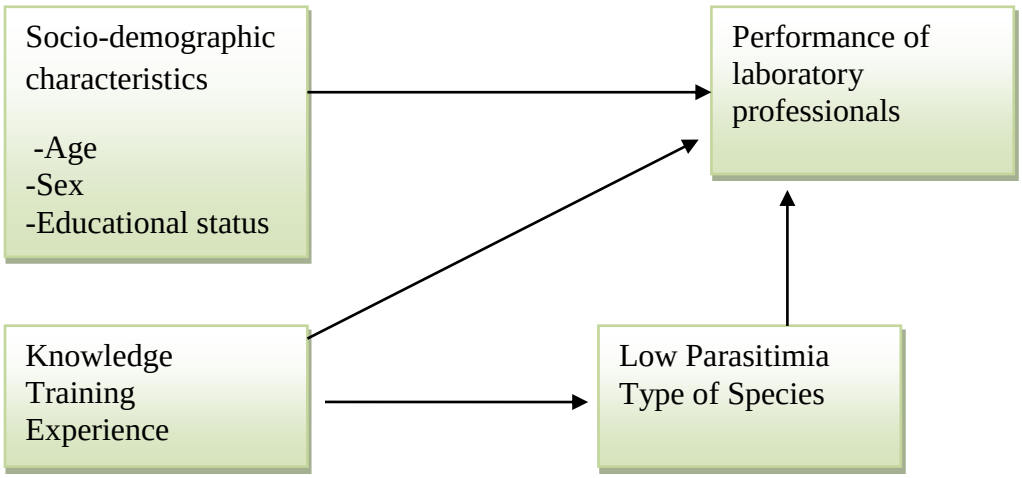
Participation of External Quality Assessment

A cohort study by Me´decins Sans Frontie`res (MSF) Operational Center Amsterdam indicated that QC program played a significant role by providing key information to conduct supervision and training for laboratory professionals. The study was conducted in 2005 with two cohorts and 2008 also two cohorts. Marked progressive improvement in the overall malaria microscopy QC performance was seen over the period (2005 and 2008). At the commencement of the QC program for the period May– December 2005 32.3% (10/31), 17.4% (4/23), and 58.1% (18/ 31) of laboratories complied with the percent agreement, FP, and FN targets, respectively. By 2008, for the period January–August there were significant improvements (P<0.001) in the proportion of laboratories meeting each QC target, with the results of 95.7% (45/ 47), 86.7% (13/15), and 91.3% (42/46), respectively (41).

10.2.3.Conceptual Framework

The performance of laboratory professionals may vary with socio-demographic characteristics like age and sex. Low knowledge of characteristics of malaria parasite at analytical stages, lack of training, inexperienced laboratory professionals decrease the performance. Increasing level of knowledge trough training and experience will increase performance of laboratory professionals. Low parasitimia and species identification are difficult to Laboratory Professionals with low knowledge, less experience and without training.

Figure 10-1: Conceptual frame work for Performance Evaluation of Laboratory Professionals through proficiency test slides (Developed from literatures)



10.3. Objective

10.3.1. General objective

- To evaluate performance of laboratory professionals working in Health Facility Laboratories of Afar Regional State through proficiency test slides to diagnose malaria under light microscope and associated factors with performance laboratory professionals to diagnose malaria in 2017

10.3.2. Specific objectives

- To determine the performance of laboratory professionals in detecting malaria parasite on under light microscope.
- To determine the performance of laboratory professionals in identifying negative blood films as negative under light microscope.
- To identify associated factors influencing the performance laboratory professionals to detect and identify malaria parasite.

10.4. Method and Materials

10.4.1.Study area

The study was conducted in Afar region, North-East Ethiopia. The total geographical area is about 270,000km^2 located between 39^0 34'and 42^{0}28' east longitude and 8^{0}49'and 14^0 30' north latitude. It is generally low land having an altitude ranging from 200 meters below sea level to 1500 meters above sea level. Malaria transmission of the Afar depends on seasonal rivers in the area which is called "Aridity". Some areas of the region also affected by malaria through seasonal rain(10).

According to the regional administration office, the region has 5 zones; 32 woredas, 2 administrative towns and 404 kebeles. The mainstay of the economy is livestock husbandry. Around 70% engaged in animal rearing, 27% are agro-pastoralist and only 0.4% in farming. Based on the figures from the Central Statistical Agency projection of 2007, the region had an estimated total population of 1.89 million of whom 86.6 % are rural dwellers in 2016.

Based on the region health office report there are six public hospitals and one private maternal hospital, 77 health centres, 1 regional laboratory, 314 health posts and 29 private lower and medium clinics delivering health services for the people living in the region. Afar Regional Heath Research and Laboratory Service (Afar Regional Laboratory) supports health facilities to increase quality of malaria diagnosis and other tests. In 2016/17 the laboratory collected and rechecked 3740 malaria slides (Blood Films) from 45 health facilities to check quality of laboratories.

10.4.2.Study Design

Institution based cross sectional study was conducted

10.4.3.Study Period

The data of this study was collected from November 13, 2017 to December 26, 2017.

10.4.4.Source Population and Study Population

All laboratory professionals working in Afar Region were source and study population of this study.

Inclusion and exclusion criteria

Inclusion criteria: Laboratory professionals working in Afar Regional State health facilities and participate on diagnosing malaria with light microscope

Exclusion criteria: Laboratory Professionals Laboratory Professionals with sick and unable to diagnose and color blinded microscopists were excluded from the study.

10.4.5.Sample Size

Calculation of samples size is based on single population proportion

$$n = \frac{\left(\frac{Z_\alpha}{2}\right)^2}{d^2}.\rho q$$

Where

Z_α =level of confidence (Z score) (95%)

n= number of laboratory professionals to be participated in the study

p= proportion of laboratory professionals score greater than 80% performance (performance of laboratory professionals in Hawassa was 44% (32))

q= 1-*p*

d= margin of error (0.05)

$$n = \frac{(1.96)^2}{0.05^2} x0.44x.56 = 378$$

Since total number of laboratory in the region is only 1 all laboratory professionals working in the region included in the study.

10.4.6.Sampling technique

Since all laboratory professionals working in Afar Region used as study population no need of special sampling technique.

10.4.7.Data collection

The data was collected through proficiency test (PT) malaria slides and questionnaires

10.4.7.1. Preparation of blood films for PT

Two expert microscopists who have been pre-qualified and certified by WHO as Level I Expert Microscopists (28) prepare and validate the PT slides at Adama Malaria Control Laboratory. 3-5 milliliters of EDTA anti coagulated whole blood sample was collected from patients who have typical malaria sign and symptom attend the Adama Malaria Control Laboratory after obtaining informed consent and the negative sample was collected from a person who never had history of malaria. Totally 6 different samples were collected to obtain high load P.F, medium load P.F, low load PF, high load P.V, mixed infection of P.F/P.V and negative slides. All samples were processed within one hour of collection to preserve leukocyte and parasite morphology.

High-quality microscope slides were used for staining the blood films. These slides were frosted end for labeling, free from grease, moisture or fungus. The slides were cleaned and stored before use which prevent most of the artifacts, avoid detachment and washing away of thick blood films during staining (28). From the collected blood samples, multiple set of high quality blood film PT were prepared containing both thin (with 2µl of blood) and thick (with 6µl of blood) on a single slide. After blood collection, ten negative, five P.F slides with density of 62,000 parasites parasites/µL, five P.F slides with density of 1350 parasites parasites/ µL, one P.V slide with a with density of 46,000 parasites parasites/ µL parasites/µL, one P.V slide with a with density of 760 parasites/µL and one mixed slide with density of 88,000 parasites parasites/ µL. Totally 23 blood films were prepared to each laboratory professional to obtain high load P.F, high load P.V, medium load PF, lo lad P.V and mixed infection of P.F/P.V and negative slides.

Determining of parasite density/µl is performed from thick film by counting asexual parasites per 200 leukocytes by assuming a standard WBC count of 8,000 leukocytes/µl. The true counts were determined by the two malaria expert readers. Parasite counts were scored as acceptable if they were within 25% of the true count.

$$Parasite/\mu l = \frac{Number\ of\ asexual\ parasites\ \times\ 8000\ leukocytes}{200\ leukocytes}$$

10.4.7.2. Questionnaire

The questionnaires were developed from WHO and national malaria guide lines which contain general information of the laboratory on malaria, QA activity of the laboratory on malaria, socio-demographic information of the respondents and knowledge questions. The knowledge of laboratory professionals was collected through standardized pre tested questionnaire that would assess a practical skill to perform, interpret or prepare, stain and examine malaria parasite. The malaria identification performance of laboratory professionals were measured by standardized PT slides. The result of PT slides were registered on pre tested format and collected immediately after its completion. The data was collected by four laboratory professionals who first trained on the collection method of this research.

10.4.7.3. Data Quality Assurance

The questionnaires were prepared as clear and understandable way and these questionnaires were pre tested before actual data collection. The pretest was conducted among 10 laboratory professionals work in Adam town. The data collectors were trained for 2 days on how they would collect the data. They made role play practice on the training section. The supervisor and data collectors were selected from Afar Regional Health Research and Laboratory Service who have experience of supervision and data collection. Supervision was done during data collection and data was double entered. The quality of the blood film slides were properly checked against WHO standard before providing to laboratory professionals for reading and the results was critically seen for completeness. The decrease influence of equipment to performance the data collectors checked the functionality of microscope though control slide.

10.4.8.List of Variables

Dependent Variable: Performance of laboratory professionals on malaria microscopy

Independent Variables: Age, Gender, Educational Level, Work Experience, Training, and Knowledge

10.4.9.Operational definitions

Agreement: It is a combination of sensitivity and specificity that describes the number of correct answers given or the amount of covenant between expert readers and the participant's answers, so both true negatives and true positives are counted toward this measurement

Diagnostic accuracy: The proportion of both negative and positive slides correctly read. (Calculated by dividing the number of slides with correct diagnosis by the total slides examined)

Error rate: The proportion of slides incorrectly diagnosed

Knowledge: On this contexts knowledge is defined as; theoretical knowledge of laboratory professionals to examine malaria parasite, interpret and report through thin/thick blood film Gaimsa stain. Laboratory professionals score 15(75%) out of 20 question are knowledgeable and called "have good knowledge" otherwise "poor knowledge". The cut point was decided by malaria experts in EPHI.

External quality assessment: Set of activities organized outside a laboratory or health facility (by external supervisors or an external quality provider) to effectively and systematically monitors work carried out, including not only proficiency testing but also validation of the results of routine blood slide and on-site supervision.

Performance: The skill of a Malaria Microscopists for performing an accurate examination and reporting of a malaria blood film.

Performance of laboratory professionals at Periphery level

WHO recommended that malaria microscopists achieving ≥90% sensitivity, ≥80% specificity and 95% *plasmodium falciparum* detection if present is achievable and satisfactory for a peripheral-level microscopists during performance evaluation or training (28).

Good Performer Laboratory Professional: Laboratory professional has "sensitivity ≥90% and "specificity ≥80%" and "≥95% detection *Plasmodium falciparum* if present" is " Good performer" or fulfill minimum WHO criteria at periphery level to diagnose malaria microscopically.

Poor Performer Laboratory Professional: Laboratory professional has "sensitivity <90%" or "specificity <80%" or "< 95% detection *Plasmodium falciparum* if present" is "Poor Performer" or not fulfill minimum WHO criteria at periphery level to diagnose malaria microscopically.

Performance of laboratory professionals (malaria microscopists) at international level

In training : Laboratory professionals considered as in training when they score less than 70% on parasite detection, species identification and with 25% true count;

Advanced: Laboratory professionals considered as Advanced when they score greater than or equal to 70% but less than 80; on parasite detection, species identification and with 25% true count the agreement was

Reference: Laboratory professionals considered as reference when they score greater than or equal to 80% but less 90% on parasite detection, species identification and with 25% true count

Expert: Laboratory professionals considered as Expert when they greater than or equal to 90% on parasite detection, species identification and with 25% true (28). Sensitivity: Proportion of positive slides correctly read as positive

Species accuracy: The proportion of positive slides correctly identified with their species

Specificity: Proportion of negative slides correctly read as negative.

Training: On job malaria microscopy and quality assurance training of laboratory professionals for at least one week.

True count: In this context true count expressed as, average parasite density/µl calculated by WHO malaria experts by counting asexual parasites per 200 leukocytes, by assuming a standard WBC count of 8,000 leukocytes/µl.

10.4.10. Data Analysis

The data was checked for its completeness, inconsistencies and missing values and entered in Epi Info 7 then was analyzed using SPSS 21. Diagnostic performance indicators such as; Sensitivity, specificity, diagnosis accuracy (agreement), species accuracy, error rate and parasitaemia counting were calculated and compared with independent variables. Associated factors were equated binary

logistic regression and odds ratio with 95% confidence interval, p-value and was used to test association.

10.4.11. Ethical issues

This study was conducted after approval of Institutional Review Board of SPHMMC and official letter written to Afar Regional Health Bureau. Afar Regional Health Bureau also wrote support letter to the participating facilities. Consents also asked from participating facilities and participating laboratory professionals thorough formats and signed if agreed. Information obtained about the laboratory professionals from the questionnaires, data capturing formats and the slides were kept totally anonymous. Participants had the right not to participate or to withdraw from the study at any time and also have the right to jump a question not willing to answer. The consent of those gave blood were asked to prepare blood films. The blood was tested for any other tests except malaria and those gave people gave blood had the right not to participate in the study and they have the right to withdraw at any time from the study.

10.4.12. Dissemination of findings

The study will be submitted to St. Paul's Hospital Millennium Medical College, Public Health Department and will serve as a reference in the library. Copy of this material will be given to Afar Regional State Health Bureau, FMoH, and other concerning bodies. This result will also be disseminated through publication in peer reviewed local and international journals and through presenting it in related workshops and seminars.

10.5. Results

10.5.1.Socio-demographic characteristics of the participants

Of the total 119 medical laboratory professionals working in Afar Region 99 (83.2%) professionals participated on this research. The rest 18 were not present during data collection and 2 professionals were not volunteer to participate on the study. They were from 21 Woredas and 2 city administrations. They were also from 5 public hospital, 33 public health centers, 4 Tendaho sugar factory health centers and 13 private clinics. The median age of the participants was of 27 years (IQR=25-30) and 67(67.7%) male.

Table 10-1: Socio-Demographic characteristic of laboratory professionals working on malaria microscopy, Afar Regional State, North East Ethiopia, 2017

Variables		Frequency (Number of participants) (N=99)	Percent
Sex	M	67	67.7
	F	32	32.3
Age	20-24	21	21.2
	25-30	59	59.6
	31-35	8	8.1
	>=35	11	11.1
Educational status	Diploma	79	79.8
	First Degree and above	20	20.2
Working facility of participant	Private clinic	13	13.1
	Public Hospital	29	29.3
	Health center	57	57.6
Work experience (year)	<2	24	24.2
	2-4	28	28.3
	≥5	47	47.5
Malaria Training	yes	66	66.7
	No	33	33.3

10.5.2.Assessment of Malaria Quality assurance

Laboratory professionals done malaria IQC regularly were 84(84.8). No laboratory professional perform only thin blood film. However 14(14.1) of them perform only thick blood film. All participants, except one professional, participated on Regional External Quality Assurance Schemes. Two microscopes were excluded from the study because they were not functional or not pass by the control slides.

Table 10-2 Quality assurance of malaria microscopy among laboratory professionals working in Afar Regional State, North East Ethiopia, 2017

Variables		Frequency (Number of participants)	Percent
Perform Malaria IQC	yes	84	84.8
	No	15	15.2
Blood films they routinely perform	Only thin BF	0	0
	Only thick	14	14.1
	Both thin and thick BF	85	82.9
Participate REQAS/ IEQAS	Yes	98	99
	No	1	1

10.5.3.Performance of laboratory professionals on Malaria microscopy

Nearly half 48(48.5%) participants did not fulfill WHO minimum criteria (had poor performance) to diagnose malaria at periphery level. Of the total 2277 distributed slides, 1683 (73.9%) slides were correctly read, 132 false positive out of 990 (13.3%), 172 (13.4%) false negative out of 1287 and 290 (22.5%) spices miss identification (SMI) out of 1287 slides. From 495 high load Plasmodium Falciparum 377(76.2%) slides correctly read, 44(8.9%) false negative and 74(14.9%) incorrectly read as another species (SMI). Of 99 distributed low load Plasmodium Vivax species 22(22.2%) slides correctly read, 61(61.6%) false negative and 16(16.2%) incorrectly read as other species (SMI). The overall agreement between WHO malaria experts Participants was 86.44%. The agreement of species identification accuracy was 64.1%. 86.44%, agreement in species identification accuracy was 64.1% (described on table 3 and 4). The error rate of the participants was 26.1%.

Table 10-3: Overall agreement of WHO malaria expert malaria slides reading and Laboratory professionals malaria slides, Afar Region North Eat Ethiopia, 2017

Parasite detection		WHO malaria expert's reading		Sensitivity	Specificity	Agreement	Kappa
		Positive	Negative				
Participant's reading	Positive	1115	132	86.66%	86.67%	86.44%	0.73
	Negative	172	858				
	Total	1287	990				

Table 10-4: Species identification accuracy of WHO malaria expert malaria slides reading and laboratory professionals malaria slides, Afar Region North Eat Ethiopia, 2017

Species identification		WHO malaria expert's reading			Sensitivity	Specificity	Agreement	Kappa
		P.F	P.V	Mixed	86.66%	NA	61.44%	0.30
Participant's reading	P.F	695	23	41				
	P.V	76	95	17				
	Mixed	127	5	35				
	Negative	91	75	6				
	P.O	1	0	0				
Total		990	198	99				

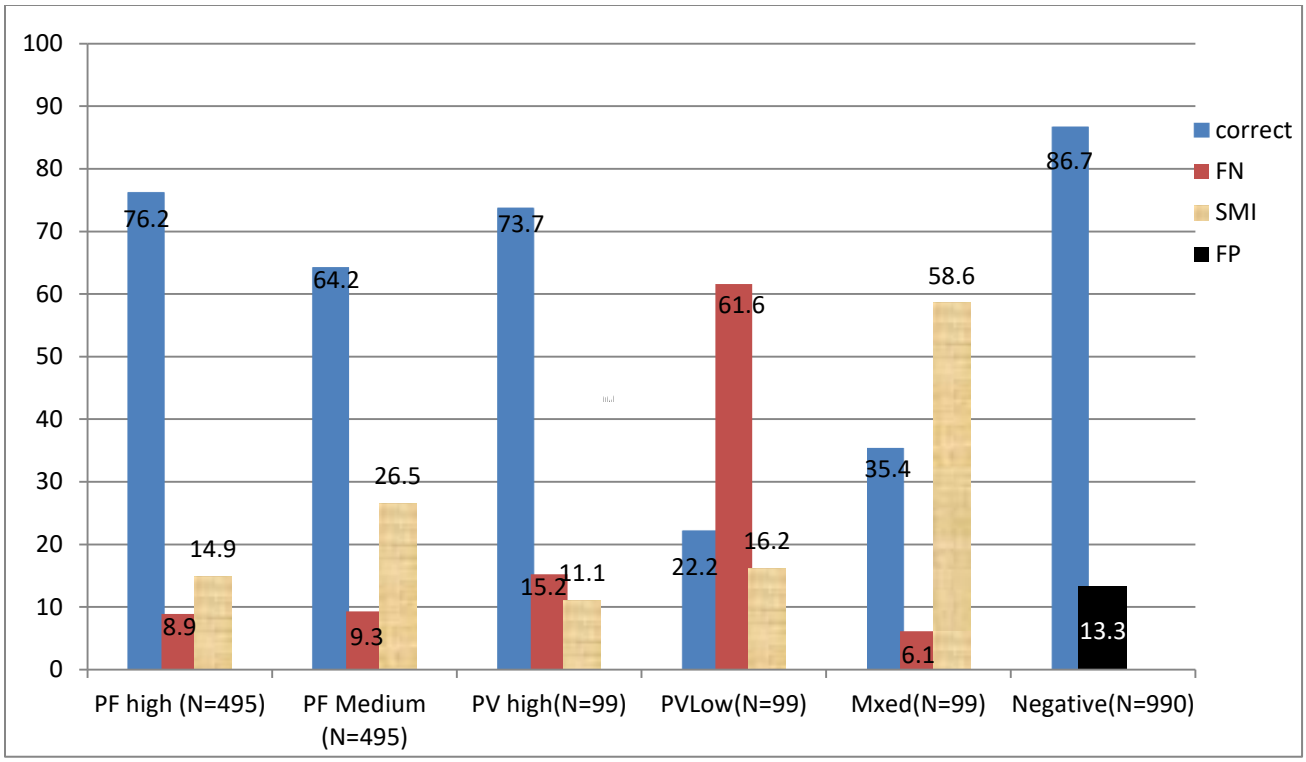


Figure 10-2: Performance of laboratory professionals on malaria parasite detection species identification, Afar Regional state, Ethiopia, 2017

According to WHO competence level of malaria microscopists, on parasite detection, 18(18.2%) level-I (Expert) and 16 (16.2%) level-IV (In training). The competence level (performance) of laboratory professionals on species identification showed only 14(14.1%) of them were categorized in level-I (Expert) and 16(16.2%) of them were in level-IV (In training). However, with regard to parasite quantification, no laboratory professional was categorized in level-I (Expert) because all of them did not quantify the positive slides correctly according to the standard. Therefore, all laboratory professionals participated to this research were categorized under level-IV (In training).

Table 10-5: Performance level of laboratory professionals on malaria microscopy, Afar Regional State, Ethiopia, 2017

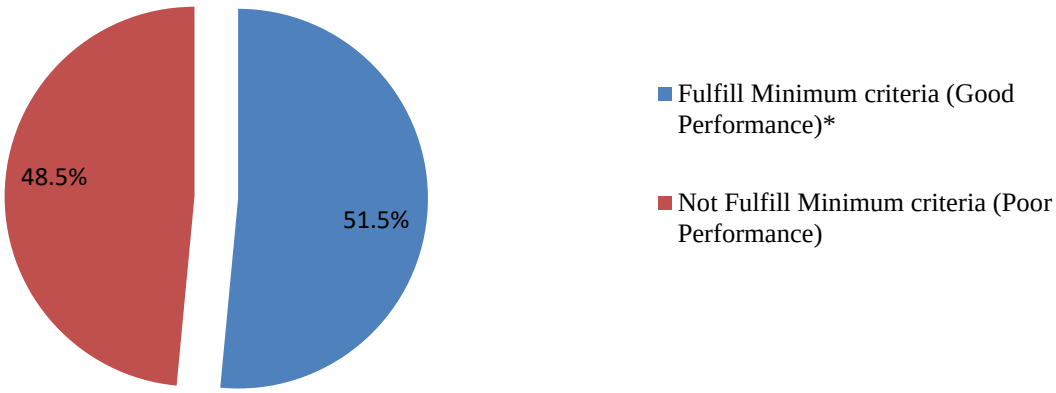
WHO competence level (Performance)		Frequency	Percent	Cumulative Percent
WHO parasite detection level (%)	90-100 (Level-I)	69	69.7	69.7
	80-89 (Level-II)	10	10.1	79.8
	70-79 (Level-III)	4	4.0	83.8
	0-69 (Level-IV)	16	16.2	100.0
WHO Species Identification level (%)	90-100 (Level-I)	14	14.1	14.1
	80-89 (Level-II)	22	22.2	36.4
	70-79 (Level-III)	14	14.1	50.5
	0-69 (Level-IV)	49	49.5	100.0
WHO Parasite Quantification level (%)	90-100 (Level-I)	0	0	0
	80-89 (Level-II)	0	0	0
	70-79 (Level-III)	0	0	0
	0-69 (Level-IV)	99	100	100

Based on WHO recommendation professionals working at periphery level, 51(51.5%) fulfilled minimum competence level (had good performance) to diagnose malaria microscopy at periphery-level. Of the total participants 72(72.7%) good on parasite detection, 81 (81.6%) parasite species identification and 51(51.6%) of them detected 95% Plasmodium Falciparum. From 99 participants only 3(3.00%) of them correctly read all slides without any errors, 16(16.2%) missed only one slide and the other participants (80, 80.8%) missed at least 2 slides and above.

Table 10-6 Overall Performance of laboratory professionals on Sensitivity, specificity and P.F detection, Afar Regional state, North East Ethiopia, 2017

Performance indicators		Frequency (N=99)	Percent
Sensitivity (Parasite detection)	≥90	72	72.7
	<90	27	27.3
Specificity (Negative slides correctly read	≥80	81	81.8
	<80	18	18.2
Plasmodium Falciparum detection	≥95	51	51.5
	<95	48	48.5

Of the total participants 51(51.5%) fulfilled World Health Organization minimum criteria of good performer in the diagnosis of malaria microscopically at periphery level.



*Fulfill Minimum criteria (Good Performance) sensitivity ≥90, specificity ≥80 and 95% PF detetection

Figure 10-3 Performance of laboratory professionals working on malaria microscopy, Afar Regional State North East Ethiopia, 2017

10.5.4.Associated factors of Performance

Bivariate analysis indicated that educational status, work experience, malaria microscopy training, performing malaria IQC regularly and theoretical knowledge had an association with performance of laboratory professionals to diagnose malaria microscopically. Other variable like age sex and place of did not have any association. Diploma holder laboratory professionals had poor performance than degree holder laboratory professionals Crude Odds Ratio (COR) =0.307 (Confidence Interval [CI] =0.101-0.934, P=0.038 Laboratory professionals had malaria microscopy training had better performance than not have malaria microscopy training. COR 4.845 (CI=1.981-11.853, P=0.001). The detail of bivariate analysis is described on table 9.

Table 10-7 Bivariate analysis of associated factors to performance of laboratory professionals on malaria microscopy, Afar Region, North East Ethiopia, 2017

Variables		Total Participants (N=99)		P value	COR	95% CI for OR
		Good performer(%)	Poor performer(%)			
Age group (Year)	20-24	8(8.1)	13(13.1)	0.117	0.359	0.100-1.249
	25-30	31(31.3)	28(28.3)	0.420	0.646	0.535-4.483
	≥31	12(12.1)	7(7.1)			
Sex	M	38(38.4)	29(29.3)	0.136	1.915	0.814-4.504
	F	13(13.1)	19(19.2)			
Educational status*	Diploma	37(37.4)	43(43.4)	0.038	0.307	0.101-0.934
	First degree and above	14(14.1)	5(51.1)			
Work experience (Year)*	less than 2 years	4(4.0)	20(24.2	0.001	0.113	0.033-0.387
	2-4 years	17(17.2)	11(11.1)	0.787	0.876	0.334-2.296
	≥5 years	30(30.3)	17(17.2)			
Malaria microscopy training*	Yes	41(41.4)	22(22.2)	0.001	4.845	1.981-11.853
	No	10(10.1)	26(26.3)			
Perform malaria IQC regular*	Yes	47(47.5)	37(37.4)	0.045	3.493	1.028-11.865
	No	4(4.0)	11(11.1)			
Theoretical knowledge*	Good	24(24.2)	7(7.1)	0.001	5.206	1.970-13.762
	Poor	27(27.73)	41(41.4)			
Place of work	Private clinic	5(5.1)	8(8.1)	0.859	0.885	0.232-3.380
	Health centers	34(34.3)	23(23.2)	0.111	2.094	0.844-5.197
	Hospitals	12(12.1)	17(17.2)			

*=there is an association, CI= confidence interval, COR= Crude Odds Ratio

Multivariable logistic regression analysis showed that malaria microscopy on job training, work experience and theoretical knowledge had association with performance of laboratory professionals to diagnose malaria. Laboratory professionals had malaria microscopy training had better performance than not have malaria microscopy training (Adjusted Odds Ratio [AOR]= 3.894 CI=1.329-11.410). This means laboratory professional trained malaria microscopy had 3.89 times performance than not trained malaria microscopy. Laboratory professionals answered provided theoretical knowledge 75% and more had good performance than those not answered less than 75% of provided questions. (AOR=4.067, 1.327-12.469 CI=P=0.014). Laboratory professional answered 75% or more provided questions had 4.07 times performance than those answered less than 75%. Additionally those participants worked less than 2 year had poor performance than those have more than 5 year experience (AOR=0.124, CI= 0.030-0.51 1.943). Laboratory professionals with less than 2 year experience had 8.073 times probability to be poor performer than professionals those have more than 5 year experience.

Other variable which had an association on bivariate analysis such as educational status and performing malaria IQC regularly did not have any association on multivariable logistic regression. Table 10 shows the detail of multivariable logistic regression.

Table 10-8 Multivariable logistic regression analysis of associated factors to performance of laboratory professionals on malaria microscopy, Afar Region, North East Ethiopia, 2017

Variables		Total participants (N=99)		P value	AOR	95% CI for OR
		Good performance (%)	Poor performance (%)			
Educational status	Diploma	37(37.4)	43(43.4)	0.091	0.305	0.077-1.210
	First degree and above	14(14.1)	5(5.1)			
Work experience (Year)*	less than 2 years	4(4.0)	20(24.2)	0.004	0.124	0.030-0.515
	2-4 years	17(17.2)	11(11.1)	0.703	1.250	0.397-3.940
	≥5 years	30(30.3)	17(17.2)			
Malaria on job training*	Yes	41(41.4)	22(22.2)	0.013	3.894	1.329-11.410
	No	10(10.1)	26(26.3)			
Perform malaria IQC regular	Yes	47(47.5)	37(37.4)	0.3	2.184	0.498-9.586
	No	4(4.0)	11(11.1)			
Theoretical knowledge*	Good	24(24.2)	7(7.1)	0.014	4.067	1.327-12.469
	Poor	27(27.73)	41(41.4)			

*=there is an association, CI= confidence interval, AOR= Adjusted Odds Ratio

10.6. Discussion

The FMOH national malaria strategic plan (NMSP) 2014-2020 aimed that microscopy is the primary means of malaria diagnosis at hospitals and health centers, and malaria RDTs at rural health posts which helps for malaria elimination program (42). The detection of malaria parasites by light microscopy thick/thin blood film remains Gold standard for diagnosis of malaria which is needs competent laboratory professionals or malaria microscopists (4). This research is conducted to support the elimination of malaria in Ethiopia especially, Afar Region by assessing the performance of laboratory professionals. Literatures indicated that most laboratory professionals or malaria microscopists in diagnosing malaria have poor performance (32–35).

On this study, 48.5% of laboratory professionals had poor performance on diagnosing malaria microscopically. No laboratory professional categorized under Expert, Reference and Advanced Level. The overall sensitivity, specificity and species accuracy were 86.7%, 86.1% and 64.1% respectively. Their performance was associated with experience, training and theoretical knowledge.

WHO recommended that malaria microscopists achieving ≥90% sensitivity, ≥80% specificity and 95% plasmodium falciparum detection if present is achievable and satisfactory for a peripheral-level microscopists during training or performance evaluation (28). We also analyzed this study based on this recommendation to identify factors associated with performance of laboratory professionals. Of the total study participants 48(48.5%) of them score < 90 Sensitivity, < 80 specificity and unable to detect 95% PF. On this study all participants (99 or 100%) were categorized under “in training” level. On research conducted in Indonesia nearly all malaria microscopists (413 or 95.6 %) categorized under “in training” level (35). Laboratory professionals working at malaria rechecking site of Ethiopia (34) majority of them (78 or 72.9%) were ‘in training’, and laboratory professionals working at Addis Ababa showed (40 or 66.6%) were ‘in training’(33). However on researches in Indonesia and Malaria rechecking sites there were reference and advanced level and no Expert level (34,35). Absence of malaria microscopy training or lack of experience (exposure) in diagnosing malaria may lid to poor performance. Poor performance of laboratory professionals in diagnosing malaria may challenge malaria elimination agenda in Ethiopia, the community may not trusts the diagnosis and clinicians not use microscopic results.

On this research the participants were categorized under “in training” level due to quantification error. None of the participant did not quantify parasite density on each of malaria positive slides using parasite per microliter against white blood cells on thick blood film. Almost all (95.6%), microscopists in Indonesia (35) and 100% in Hawasa (32) could not quantify. In routine malaria diagnosis and reporting system laboratory professionals did not quantify parasite density and they may forget how to quantify even though we told them the quantification procedure. Not quantifying the parasite may be due to lack of training, or lack of awareness of the advantage of the quantification, or it may be due to lack of commitment to adhere to specified time for counting parasite with the recommended quantification system. Quantification is used to monitor patient response to treatment

Sensitivity of the participant on this study was 86.7%. It was almost equivalent (82%) with laboratory professionals in Hawassa (32), higher (65.7. %) than laboratory professionals worked in Addis Ababa(33) and lower (96.8%) than laboratory professionals of malaria rechecking site of Ethiopia(34). Addis Ababa is low malaria risk area (10) and the professionals in the area may not have daily exposure to diagnose malaria; Afar and Hawassa is malarious area (10). So professionals in the area may easily detect malaria parasite. Professionals at reckecking site expected to have better detection than professionals at periphery level. Difficultly in detection may be due to lack of training, or may be lack of experience in diagnosing malaria, or may not scan 100 fields or may not take insufficient time for scanning. Miss identification of malaria species, specially missing of PF may cause malaria related cases.. If sensitivity of malaria diagnosis increased, communities at risk for malaria have greater confidence in their services and clinicians use the microscopy services more effectively. Additionally the patients get malaria treatment and malaria related deaths may decrease.

Specificity of laboratory professionals on this study was 86.1%. It is higher sensitivity (68.6%) than laboratory professionals in Democratic republic of Congo (43). For laboratory professionals in Democratic republic of Congo only one negative slide distributed may decrease the sensitivity. It was lower than laboratory professionals in Hawassa (96.5%) (32), than laboratory professionals worked in Addis Ababa (100%) (33) and laboratory professionals of malaria rechecking site of Ethiopia (96.7%) (34). Difficultly in sensitivity may be due to lack of training, or may be lack of experience in diagnosing malaria, not take insufficient time for scanning, or they may not able to

differentiate artifact from malaria parasite. If true malaria negative slides read as malaria positive, community at risk may not trust the service, clinicians may not trust microscopy service, and the patients may take unnecessary treatments which may lid to drug resistant.

On this Species accuracy of laboratory professionals working in Afar was 64.1% (Kappa=0.298). Only 48.5% of the participants detected P.F correctly. It was lower than laboratory professionals in Hawassa 74.3% (Kappa=0.63) (32) and higher than laboratory professionals worked in Addis Ababa 51.1% (Kappa 0.04) (33) and laboratory professionals of malaria rechecking site of Ethiopia 64.8 % (Kappa= 0.33) (34). Laboratory professionals in Addis Ababa may not have exposure to different species. On malaria rechecking site of Ethiopia the four species were distributed and they couldn't identify PO and PM. Difficultly in identification may be due to lack of training, or may be lack of experience in diagnosing malaria, or may be not scanning thin blood film. Miss identification of malaria species, specially missing of PF may cause malaria related deaths.

On this study those professionals get malaria training had better performance than untrained laboratory professionals. In Indonesia the sensitivity of trained professionals better than not trained (69.1 vs 57 %, $p < 0.001$). Additionally, species accuracy of trained professionals was better than not trained (37.2 % vs 27.7 %, $p < 0.001$). Similarly, trained professionals at rechecking site of Ethiopia had better performance than not trained malaria microscopy ($P < 001$) (34). Researches done in Uganda(37) and Nigeria(38) also that training has a power to increase performance of laboratory professionals to diagnose malaria microscopically. However among the laboratory professionals Addis Ababa surrounding area (33) and Hawasa town (32), having malaria training not associated with their performance.

Our findings also showed that those participants worked less than 2 years had poor performance than those have more than 5 year experience (AOR=8.073, P=0.004). In USA laboratory professionals with 2 years or less of experience had almost twice the odds (AOR, 1.849, P=0.043) of producing an error compared with personnel with more than 20 years of experience (40). On a study conducted in the Peruvian Amazon 68 microscopists without experience (< 1 year experience) and 76 microscopists with experience (>1 year experience) recruited in the study. Microscopists with more than 1year experience (68.6%) had more agreement than those with less than 1 year (48.2%) (39).. However on researches done in Ethiopia specially Hawassa (32), Addis

Ababa (33) and malaria rechecking site (34) work experience and performance of laboratory professionals not associated. The variation with experience may be due exposure to diagnose malaria, or may be lack of basic malaria microscopy training. Working in laboratory needs experience and exposure to minimize analytical stage errors. Unless with support of senior microscopists and training inexperienced (fresh) laboratory professionals may produce false results that affects the patients, decrease trust of clinics and the community on the microscopy.

On current study laboratory professionals with good theoretical knowledge had better performance than laboratory professionals with good theoretical knowledge. The theoretical knowledge questions were pictorial and they did not contain other theoretical questions about transmission, mosquito, geographical distribution, staining and reagents. Laboratory professionals with good performance detecting and identifying malaria simply answered the questions because they can describe what they saw under microscope.

The most incorrectly slides read by the participants were low load plasmodium vivax and mixed (plasmodium falciparum and plasmodium vivax). Only 22.2% low load plasmodium vivax slides and 35.4% mixed slides correctly read. Not only professionals at periphery level but also malaria experts had difficulty in identifying low density parasitimia (2). On Researches done in rEthiopia , Hawassa town (32), Addis Ababa (33) and Malaria rechecking sites of Ethiopia (34) showed laboratory professionals missed low density parasitimia slides. This indicates the need of training with special emphasis for detection at a low level of Parasitemia and species identification. Unable to detect malaria at low density may lead to treatment error and also difficult to malaria illumination strategies which needs accurate laboratory diagnosis. The assessment identified that the laboratory professionals in Afar region microscopists are not sufficiently skilled to detect the low density parasitaemia associated with malaria elimination program.

10.7. Limitations

This study come with some limitations, Performance of Malaria Microscopists could not include all malaria microscopists in the study sites; only those who were available during the time of data collection were recruited. The species of malaria parasites used for malaria blood film slide panel preparation were not characterized or molecularly typed by polymerase chain reaction, only identified by certified malaria expert (WHO level-I). Only the two species, Plasmodium falciparum and Plasmodium vivax, used for this study: since the National Malaria Slide Bank not functional this avails other plasmodium species not common in Ethiopia.

10.8. Conclusion

On the current study the performance of laboratory professionals on detection and identification malaria diagnosis under light microscopy was poor. The most microscopists missed low density parasitimia and mixed infections which may lead to under treatment to antimalarial drugs. Almost half of the laboratory professionals missed plasmodium falciparum which is the most prevalent species and leading malaria related deaths. Associated factors for the poor performance of laboratory professionals were lack of training, experience and their theoretical knowledge. Processionals trained on malaria, more than 2 year experience of malaria diagnosis and those good with theoretical knowledge had good performance in diagnosing malaria microscopically. The assessment identified that the laboratory professionals in Afar region microscopists are not sufficiently skilled to detect the low density parasitaemia associated with malaria elimination program.

10.9. Recommendations

- To fill those gaps Afar regional health bureau and other concerned stakeholders have to give malaria training
- Afar Regional health bureau should perform regular malaria competency assessment for laboratory professionals
- Laboratories should practice on positive blood film slides regularly to improve their skill on detection & species identification.
- Laboratory professionals should increase their knowledge by reading reference books malaria job aids
- Afar Regional health bureau should give malaria training for new employees before deployment to working area

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Annexes

Annex 10-I: Consent form for Blood Donors (English Version)

My name is Birhanu Legese and I am MPH student in Field Epidemiology at St. Paul's Hospital Millennium Medical College. I am doing a research entitled "Performance Evaluation of Medical Laboratory Professionals on Malaria Microscopy in Afar Region". The objective of the study is to assess the Performance of Malaria Microscopists Working at Hospitals, Health Centers and Clinics.

To assess the performance I have to collect sample from different donors and I have to produce many blood film slides. So to get this I have to collect sufficient volume of blood from volunteers. If you are agree to participate in the study, about 3-5 ml of blood will be collected from you or you will allow us to use the sample that you will give for your medical examination and you will be interviewed. During collection of blood, you may feel some discomfort, but this does not produce serious pain. All the data obtained will be kept strictly confidential by using only code numbers and locking the data, only study personnel will have access to the files. The sample will be coded and the result will not be identified by names. There will be no costs to you as a result of taking part in this study and you are not asked to pay for the laboratory examination. Participating and not participating has no influence on the service you seek to get.

Participant's response: I am free to decline to be in this study, or to withdraw from it at any point and also to stop blood donation if I will feel discomfort. My decision as to whether or not to participate in this study will have no influence on my present or future medical service. My signature below indicates that I agree to participate in this study.

Signature of Person Obtaining Consent _____date of signature_____

Annex 10-II: **Consent form for Blood Donors (Amharic Version)**

ብርሀኑ ለገሰ እባላለሁ በቅዱስ ጳዉሎስ ሆስፒታል ሚሊኒየም ሜዲካል ኮሌጅ በማስትርስ ዲግሪ የፊልድ ኢፒደዲሞሎጂ ተማሪ ስሆን የመመረቂያ ጥናቴን **"Performance Evaluation of Medical Laboratory Professionals on Malaria Microscopy in Afar Region"** በሚል ርዕስ በመስራ ላይ እገኛለሁ። የጥናቱ አላማ በአፋር ክልለለ በሚገኙ ሆሰፒታሎች፣ ጤና ጣቢያዎች እና ክሊኒኮች የሚሰሩትን የህክምና ላቦራቶሪ ባለሙያዎችን ወባ የመመርመር ብቃታቸውን ለመለካት ነው።

የእነዚህን የላቦራቶሪ ባላሙያዎች ብቃት ለላመለካት ከተለያዩ በጎ ፈቃደኛ ሰዎች የደም ናሙናዎችን በመሰብሰብ የወባ መመርመሪያ ስላይዶችን በማዘጋጀት ላይ እገኛላሁ። እርስዎ ደም ለመስጠት ፈቃደኛ ከሆኑ ከ 3-5 ሲሲ ደም ይወሰድና በደምዎ ውስጥ የወባ አምጪ ተዋህሲያን መኖራቸውና አለመኖራቸው ይምረመራል። በጨማሪም አንዳንድ ጥያቄዎችን እንጠይቆታለን። ደሙ ከእጅዎ ላይ በሚወሰድበት ጊዜ ትንሽ ህመም ከሚወሰድበት ቦታ ላይ ህመም ሊሰማዎት ቢችልም ቶሎ ይተዎታል። ከእርስዎ የተወሰደው ደም ከወባ ምርመራ ውጪ ሌላ ምንም ምርመራ አይደረግለትም። ከእርስዎ የሚወሰዱት መረጃዎች እና የደም ናሙና ላይ የእርስዎ ስም የማይጻፍ ሲሆን መረጃዎቹ የሚያዙት በሚስጢር ቁጥሮች ይሆናል። ሁሉም መረጃዎች በሚስጢር የሚያዙ ሲሆን ለሌላ ሥስተኛ ወገንም ተላልፈው አይሰጡም። የወባ ምርመራ ውጤትዎን ለመዉሰድ ምንም አይነት ክፍያ የማይከፍሉ ሲሆን በጥናቱ በመሳተፍዎ ወይም ባለመሳተፍዎ በምርመራ ውጤትዎ ላይ ምንም ለውጥ የለዉም።

የተሳተፊዉ መልስ፡- እኔም በጥናቱ ላይ የተሳተፍኩት የጥናቱ አላማ ገብቶኝ ያለማንም አስገዳጅነት በፈቃዴ ነው። የደም ናሙናዉን በምሰጥበት ጊዜ ያመኛል ብየ ከሰጋሁ ደም አለመስጠት እችላላሁ። ጥናቱን በማንኛውም ጊዜ የማቋረጥና መልስ መስጠት ለማልፈልጋቸው ጥያቄዎችን አለመመመለስ እችላላሁ። እንዲሁም በዚህ ጥናት ተሳታፊ ብሆንም በልሆንም አሁን ለሰጠሁት ደም የምርመራ ውጤትና ለወደፊት በመገኛገቸው የህክምና አገልግሎቶች ላይ ምንም ተፅእኖ እንደሌለው ተገንዚቢያለሁ።

የፈቃደኛ ተሳታፊው ፊርማ _____ የፊርማ ቀን _____

Annex 10-III: **Consent Form for Laboratory professionals (Amharic Version)**

ብርሀኑ ለገሰ እባላለሁ በቅዱስ ጳዉሎስ ሆስፒታል ሚሊኒየም ሜዲካል ኮሌጅ በማስትርስ ዲግሪ የፊልድ ኢፒደዲሞሎጂ ተማሪ ስሆን የመመረቂያ ጥናቴን **"Performance Evaluation of Medical Laboratory Professionals on Malaria Microscopy in Afar Region"** በሚል ርዕስ በመስራ ላይ እገኛለሁ። የጥናቱ አላማ በአፋር ክልል በሚገኙ ሆሰፒታሎች፣ ጤና ጣቢያዎች እና ክሊኒኮች የሚሰሩትን የህክምና ላቦራቶሪ ባለሙያዎችን ወባ የመመርመር ብቃታቸውን ለመለካት ነው።

የላቦራቶሪ ባላሙያዎች ወባ የመመረመር ብቃት ለመለካት ጥራታቸው የተረጋገጡ በፈቃደኛ ላቦራቶሪ ባለሙያዎች የሚሰሩ 23 የወባ ስላይዶችን ይዣለሁ። እርስዎም የጥናቱ ተሳታፊ እንዲሆኑ የተመርጡ ሲሆን ስላይዶቹን እንዲሰሩልኝና ጥያቄዎችን እንዲሞሉልኝ የእረስዎን ፈቃድ እጠይቃሁ። በጥናቱ ለመሳተፍ አይገደዱም፣ እንዲሁም ጥናቱን በፈለጉት ጊዜ ማቋረጥ ይችላሉ። በጥናቱ መበሳተፍዎ ወይም ባለመሳተፍዎ በስራዎ ላይ፣ በወደፊት እድገትዎ ላይ ምንም ተፅዕኖ አይኖረውም። የእርዎ መረጃ የሚያዘው በሚስጥር ሆኖ የእርስዎ ስም ሳይጻፍ በሚስጥር ቁጥር ይሆናል። መረጃዎቹም ከእርዎ ፈቃድ ውጪ ለሌላ ሶሰስትኛ ወገን አይሰጡም። በመሆኑም ለመሳተፍ ፍቃደኛ ከሆኑ በመጀመሪያ በመጠየቂያው ላይ ያሉትን ጥያቆዎች ይሞላሉ ከዚያም ስላይዶቹን ይሰራሉ። አንድ ስላይድ ለመስራት 10 ደቂቃ የተሰጠ ሲሆን በአጠቃላይ ሃያ ሦስቱን ስላይዶች ሰርቶ ለማጠናቀቅ ሦስት ሰዓት ከሃምሳ ደቂቃ ተሰጥቷል።

የተሳተፊዉ መልስ:- እኔም በጥናቱ ላይ የተሳተፍኩት የጥናቱ አላማ ገብቶኝ ያለማንም አስገዳጅነት በፈቃዴ ነው። ጥናቱን በማንኛውም ጊዜ የማቋረጥና መልስ መስጠት ለማልፈልጋቸው ጥያቄዎችን አለመመመለስ እችላላሁ። እንዲሁም በዚህ ጥናት ተሳታፊ ብሆንም በልሆንም በስራዬና ወደፊት በሚኖረኝ እድገቴ ላይ ምንም ተፅእኖ እንደሌለው ተገንዚቢያለሁ።

የፈቃደኛ ተሳታፊው ፊርማ _____ የፊርማ ቀን _____

Annex 10-IV: **Consent Form for Laboratory professionals (English Version)**

My name is Birhanu Legese and I am MPH student in Field Epidemiology at St. Paul's Hospital Millennium Medical College. I am doing a research entitled "Performance Evaluation of Medical Laboratory Professionals on Malaria Microscopy in Afar Region". The objective of the study is to assess the performance of malaria microscopists working at Hospitals, Health Centers and Clinics.

To assess the performance of medical laboratory professionals I have 23 validated blood film slides which will be examined by volunteer participants. So you are selected to participate on this study to do malaria examination and to answer some questions related to your profession. All the data obtained will be kept strictly confidential by using only code numbers and locking the data. Only study personnel will have access to the files. The result will not be identified by names, it will be coded. If you are agreeing to participate in the study you will have 10 for each slide and totally three hours and fifty minutes allocated to examine all slides.

Participant's response: I am free to decline to be in this study, or to withdraw from it at any point and also to jump a question that feels me discomfort. My decision as to whether or not to participate in this study will have no influence on my present or future Carrier. My signature below indicates that I agree to participate in this study.

Signature of Person Obtaining Consent_____ date of signature_____

Annex 10-V: Questioner

Name of Data Collector _____ Date of data collection _____ _____

Participant code, _____Zone, _____Woreda, _____ Facility type HC / Hosp. /Private

Section I: Scio-demographic information

1. Age _____

2. Sex 0. Male 1. Female

3. Educational Status 0. Diploma 1.First degree 2. Second degree and above

4. Work experience 0. < 2 years 1. 2-4 years 2. >5 years

5. Did you have on job malaria training 0. No 1. Yes

6. **If yes for question 5,** when did you take the training?

0. Within the last 12 months 1. 1 or 2 years ago 3. 3 years ago

Section II: Laboratory assessment For Malaria QC

7. Does your laboratory participate on malaria REQAS? (Observe documents and feedbacks)

0. Yes 1. No

8. Does your laboratory participate on malaria NEQAS or IEQAS? (Observe documents and feedbacks)

0. Yes 1. No

9. Does your laboratory perform malaria IQC? (Observe documents and feedbacks)

0. Yes 1. No

10. Which blood film do you prepare when you routinely diagnose malaria?

0. Only thin blood film 1. Only thick blood film 2. Both thin and thick blood films

Section III: Knowledge assessment

These questions asses the knowledge of laboratory professionals at analytical stage of malaria diagnosis especially when they are working on microscopy and post analytical stages. The questioner do not has per analytical stage and general malaria knowledge.

11. Which objective do you use to diagnose and report malaria parasite?

0. 10X 1. 40X 2. 100X oil immersion

12. Which type of blood film is more sensitive to detect malaria parasite?

0. Thin blood film 1. Thick blood film

13. Which type of blood film is more specific to confirm malaria species?

0. Thin blood film 1. Thick blood film

14. More than one parasites in a single red cell is common characteristics of _____ species

0. Plasmodium Falciparum
1. Plasmodium Vivax
2. Plasmodium Ovale
3. Plasmodium Malariae

15. Red stippling (Schuffner's dots) seen with _____ species

0. Plasmodium Falciparum only
1. Plasmodium Vivax and Plasmodium Ovale
2. Plasmodium Ovale only
3. Plasmodium Malariae only

16. Maurer's clefts seen with _____ species

0. Plasmodium Falciparum only
1. Plasmodium Vivax only
2. Plasmodium Ovale only
3. Plasmodium Malariae and Plasmodium Ovale

17. Which species characterize with presence of marginal or appliqué form

0. Plasmodium Falciparum
1. Plasmodium Vivax
2. Plasmodium Ovale
3. Plasmodium Malariae

18. Banana/crescent shape gametocyte is for _____ species

0. Plasmodium Falciparum
1. Plasmodium Vivax
2. Plasmodium Ovale
3. Plasmodium Malariae

19. For which species RBCs not enlarged?

0. Plasmodium Falciparum only
1. Plasmodium Vivax only
2. Plasmodium Ovale Plasmodium Vivax
3. Plasmodium Falciparum and Plasmodium Malariae
4. Plasmodium Malariae only

20. Which species usually has double chromatin dots?

0. Plasmodium Falciparum
1. Plasmodium Vivax
2. Plasmodium Ovale
3. Plasmodium Malariae

21. What is the color of chromatin dot (Parasite nucleus) by Geimsa stain?

0. Red 1. Blue 2. Yellow-gold 3. Pink

22. What is the color of the malaria parasite cytoplasm by Geimsa stain?

0. Red 1. Blue 2. Yellow-gold 3. Pink

23. What is the color of the malaria pigment by Geimsa stain?

0. Red 1. Blue 2. Yellow-gold, Brown-black 3. Pink

24. Enlargement of infected RBC is characterstics of _____ parasite

0. P/Vivax only 1. P/ falciparum only 2. P/Vivax and P/ovale 3. P/ falciparum and P/malariae

25. Which spices has large, ring and amoeboid shape trophozoite?

0. P/Vivax 1. P/ falciparum 2. P/ovale 3. P/malariae

26. How many fields do you scan a blood film to report as negative on thick blood film?

0. 10 fields 1. 20 fields 2. 70 fields 3. 100 fields

27. How many fields do you scan a blood film to report as negative on thin blood film?

0. 10 fields 1. 20 fields 2. 100 fields 3. 200 fields

28. Parasite quantification can be performed against _____ WBCs

0. 50 WBCs 1. 100 WBCs 2. 150 WBCs 3. 200 WBCs

29. What is the purpose of malaria parasite quantification/ counting?

0. To monitor the evolution of the disease
1. To see the efficacy of the therapy
2. To know type of species

3. 0 and 1

30. What do you do if you see schizons of plasmodium falciparum?_____

0. Schizons never found on blood film
1. Report as routine reporting condition
2. Immediately report to the physician
3. Schizons are not reportable

Annex 10-VI: Performance assessment report form

(Answer sheet for malaria slides)

Questionnaire Number:_____ Code of Health Facility: _____

Interviewee Code:_____ Date of Report:_____

NB: Give √ sign for detection (for negative and positive) but write the detail for stage and parasite density.

S/ Number	Slide ID	Negative	Positive					Parasite load (Semi-quantitative)	Parasite Density(Only for requested) (quantitative)	Remark
			P.F	P.V	P.O	P.M	Mixed			
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
Total score										

Signature ---------- date ----------

Annex 10-VII: **Dummy tables**

performance classification	**percent agreement on Detection of malaria parasite**	**Frequency (n=___)**	**Present%**
Expert	≥ 90%		
Reference	≥ 80%		
Advanced	≥ 70%		
In-training	<70%		
Total			

performance classification	**percent agreement on identification malaria species**	**Frequency (n=___)**	**Present%**
Expert	≥ 90%		
Reference	≥ 80%		
Advanced	≥ 70%		
In-training	<70%		
Total			

Participant reading		WHO expert reading		Sensitivity	Specificity	Agreement
		Positive	Negative			
(Malaria detection)	Positive					
	Negative					