

Saint Paul's Hospital Millennium Medical College

Department of Public Health



**Ethiopian Field Epidemiology and Laboratory Training Program
(EFELTP)**

Compiled Body of Works in Field Epidemiology

By:

Lezhialem Almaw

**Submitted to St. Paul's Hospital Millennium Medical College in
Partial Fulfillment for the degree of Master of Public Health in Field
Epidemiology**

March 2018

Addis Ababa, Ethiopia

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March 2018

Addis Ababa, Ethiopia

SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE (SPHMMC)

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Approval sheet (by advisor and Programme coordinator)

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Letter for Declaration (body of work with thesis)

I, the undersigned, declared that this is my bona fide original work, has never been presented in this or any other university, and that all the resources and materials used for the body of work with thesis have been fully acknowledged.

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

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Name of Co Advisor	Signature	Date

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DEPARTMENT OF PUBLIC HEALTH GRADUATE STUDIES

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As members of the Board of Examiners of the final body of work with thesis open defense, we certify that we have read and evaluated the body of work with thesis prepared by **LEZHIALEM ALMAW** under the thesis entitled “**Seroprevalence of syphilis and associated factors among pregnant women attending antenatal clinic in Gambella hospital, Gambella, Ethiopia, 2017**” and recommendation for the degree of Master of Public Health in Field Epidemiology.

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Final approval and acceptance of the body work with thesis is contingent upon the submission of the final both hard and soft copies of the body of work with thesis in the department of public health

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List of Abbreviations and Acronyms

ACV	A cellular vaccine
AFR	Africa
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
ANRS-HB	Amhara National Regional State Health Bureau
AOR	Adjusted Odds Ratio
APHI	Amhara Public Health Institute
AR	Attack Rate
ART	Anti-Retroviral Therapy
ASAR	Age Specific Attack Rate
B.Pertussis	Bordetella Pertussis
BCG	Bacille Calmette-Guerin
BPR	Business Processing and Re-Engineering
BPR	Business Process Reengineering
CAR	Contraceptive Acceptance Rate
CASH	Clean and Safe Health Environment
CBN	Community Base Nutrition
CDC	Center for Disease Control and prevention
CHW	Community Health workers
CI	Confidence Interval
COR	Crude Odds Ratio
CPR	Contraceptive Prevalence Rate
CRF	Case-based reporting Format
CSA	Central Statistical Agency
Deg	Degree
Diag.Lab	Diagnostic Laboratory
DPH	Department of Public Health
DTaP	Diphtheria, Tetanus and Pertussis
EC	Ethiopian Calendar
EFELTP	Ethiopian Field Epidemiology and Laboratory Training Program

EFY	Ethiopian Fiscal year
EMR	Eastern Mediterranean Region
Env	Environmental
EPHI	Ethiopian Public health Institute
EPI	Expanded program on Immunization
Epi week	Epidemiological week
EQA	External Quality Assessment
FMoH	Federal Ministry of Health
FP	Family Planning
GGH	Gambella General Hospital
GOV	Government
GP	General Practitioner
HC	Health Center
HEWs	Health Extension Workers
HF	Health Facility
HH	House Hold
HIT	Health Information Technology
HIV	Human Immuno Deficiency Virus
HMIS	Health Management and Information System
HO	Health Officer
HP	Health Post
IDSR	Integrated disease surveillance and Response
IgM	Immunoglobulin M
IMR	Infant Mortality rate
IPD	In Patient Department
IRS	Indoor Residual Spray
ITNs	Insecticide threatened Nets
KTHO	Kombolcha Town Health Office
Lab	Laboratory
LLTN	Long Lasting Treated Net
MCH	Maternal and Child Health

MS	Microsoft
MUAC	Mid Upper Arm Circumference
NGO	Non-Governmental Organization
OPD	Out Patient Department
OPV	Oral Polio Vaccine
OTP	Outreach Therapeutic Program
PCR	Polymerase Chain Reaction
PHEM	Public Health Emergency and Management
PI	Principal Investigator
PICT	Provider Initiated Counseling and Testing
PLWHA	People Living With HIV/AIDS
PMTCT	Preventing Mother to child transmission
PPV	Positive Predictive Value
PTB	Pulmonary Tuberculosis
Q1	quarter 1
Q2	Quarter 2
Q3	Quarter 3
Q4	Quarter 4
RDT	Rapid Diagnostic Test
RPR	Rapid Plasma Reagin
SAM	Sever Acute Malnutrition
SIAs	Supplementary Immunization Activities
SNNPR	Southern Nation Nationalities, and Peoples Region
SOP	Standard Operating Procedure
SOP	Standard Operating Procedure
SPHMMC	St. Paul's Hospital Millennium Medical College
SPSS	Statistical Package for the Social Science
SqKm	Square Kilometer
SRS	Simple Random Sampling
SSAR	Sex Specific Attack Rate
STD	Sexually Transmitted Disease

STI	Sexually Transmitted Infections
TVET	Technical and Vocational Education Training
UNICEF	United Nations Children’s Emergency Fund
VCT	Voluntary Counseling and Testing
VDRL	Venereal Disease Research Laboratory
WCV	Whole cell pertussis vaccination
WHO	World Health Organization

Preface

Ethiopian Field Epidemiology Training Program (EFETP) is in-service training program in field epidemiology developed on the mode of the United State Center for Disease Control and Prevention (CDC) Epidemic Intelligence Service (EIS). These programs are designed to assist Ethiopian Ministry of Health in strengthening on-the-job mentorship and training.

I stayed from October 2015 to March 2018 in St. Paul's Hospital Millennium Medical College, Department of Public Health- Field Epidemiology Training Program and at Amhara Public Health Institute (APHI), Bahir Dar field base.

This compiled body of works contains many outputs which all of them were done during the residency time of the program. The body of works is categorized in to seven chapters. Each chapter is mentioned as follows: The first chapter contains outbreak investigations: outbreak investigations were conducted; the investigated outbreak was pertussis in Bahir Amba kebele Janamora district, North Gondar zone, Amhara from April, 22-May10, 2017.

The second chapter is measles surveillance data analysis of Amhara region 2003-2006 EC, Ethiopia. Five year measles data has been analyzed. The third chapter, evaluation of malaria, typhoid fever and sever acute malnutrition surveillance system in Kombolcha town, South Wollo zone of Amhara region. The third chapter is description of Health profile of Jabi tehnan district in West Gojjam zone of Amhara region.

The fourth is woreda health profile description assessment, Jabi tehnan woreda, west Gojjam zone Amhara region, Ethiopia, 2007 EC. The assessment was conducted from 15 May–June 15, 2008 EC. The fifth chapter is developing standard operating procedure for two laboratory test namely H. pylori and Hepatitis B surface antigen (HBsAg) from 01-April-15, 2017, Nefas Mewucha Hospital, south Gondar zone, Amhara, 2017. The sixth chapter is preparing laboratory quality manual from April 01.-15, 2017, Nefas Mewucha Hospital, south Gondar zone, Amhara, 2017. The seventh chapter is research thesis done on seroprevalence of syphilis and associated factors among pregnant women attending antenatal clinic in gambella hospital, gambella, Ethiopia. The study was conducted from November to December 2017.

Different trainings and conferences of public health have been conducted in different places at different times, to mention some of these, PHEM training in Bahir dar, Surveillance training in

Kombolcha and conferences like 1st Ethiopian Field Epidemiology training Programme annual scientific conference held at EPHI in Addis Ababa, I was participated as a trainer and participant in those mention above and others. Meanwhile, since the program's philosophy is learning by doing, numerous activities were carried out at the field base, which greatly contributed to strengthen the public health workforce capacity through training, conducting disease surveillance and emergency planning, preparedness and response activities.

Chapter I: Outbreak Investigation

1.1 PERTUSSIS OUTBREAK INVESTIGATIONS IN BAHIR AMBA KEBELE, NORTH GONDAR ZONE, AMHARA REGION, ETHIOPIA, 2017

Abstract

Background: Whooping cough is a highly contagious, acute respiratory illness of humans that is caused by the gram-negative bacterial *Bordetella Pertussis*. World Health Organization (WHO) estimates that in 2008 about 16 million cases of pertussis occurred worldwide, 95% of which were in developing countries, causing the death of 195 000 children. On April 17/2017 Janamora district health office reported increasing number peoples with coughing sign and symptoms.

Objective: To investigate the existence of outbreak, identify the potential risk factors of pertussis outbreak and undertake appropriate public health measures, in Bahir Amba kebele, Amhara region in April, 2017.

Method: Investigation was conducted in Bahir Amba kebele, from April, 22-May10, 2017. Unmatched 1:1 case control study design were employed and totally 120 individuals were included. Pertussis cases come to health facilities and cases those were found during door to door active case searching were the study population. Data was collected by using structured questionnaire; quality of the data was maintained and collected data was entered in to the SPSS (Statistical Package for the Social Science) software for analysis. Backward logistic regression was used to identify the possible significant variable and variable with p-value <0.05 was considered statically significant.

Result: The median age of the cases and the controls were 6.5 and 11.5 years respectively. Overall attack rate was 0.13% and the case fatality rate was 3.3 %. Of the total 120 subjects 8 cases and 10 controls were vaccinated for pertussis containing vaccine. Contact history with pertussis suspected person (AOR: 6.298; 95%CI: 2.539-15.624; p<0.000), work place contact (AOR: 3.339; 95%CI: 1.289-8.651; p=0.013), household having less than 2 windows (AOR: 3.011; 95%CI: 1.177-7.702; p=0.021), sex female (AOR: 2.919; 95%CI: 1.179-7.227; were significant predictor for pertussis disease.

Conclusion and recommendation: In this outbreak overall high attack rate with a wider age range has been observed. Contact with Pertussis suspected cases, having work place contact, living in house with less than 2 windows and being female was significantly associated with the outbreak. Health education has to be provided extensively to the community.

Key words: **Pertussis disease, Outbreak, Bahir Amba Kebele**

Introduction

Background

Pertussis, also known as “whooping cough,” is a highly contagious, acute respiratory illness of humans that is caused by the gram-negative coccobacillus bacterial *Bordetella pertussis* ^(1,2). It is a strict human pathogen with no known animal or environmental reservoir ⁽³⁾. Adolescents and adults are an important reservoir for *B. pertussis* and are often the source of infection for infants^(3,4). *Bordetella pertussis* is a fastidious, toxin-producing bacillus that causes damage to the respiratory tract. Classic pertussis, or whooping cough, is characterized by intermittent paroxysms (spasms) of severe coughing lasting from 6 to 10 weeks^(4,5). Pertussis is mainly transmitted by large droplet infection or direct contact with discharges from respiratory mucous membranes of infectious people. Indirect spread via contaminated objects occurs rarely. The incubation period of pertussis is most typically 7–10 days, with a range one to three weeks, and rarely may be as long as 42 days ^(4,6).

Pertussis typically sometimes lacks fever and classically progresses through three stages⁽⁷⁾. An initial catarrhal phase is characterized by the insidious onset of runny nose, sneezing, absent or low grade fever, and a mild occasional cough, similar to the common cold⁽⁸⁾. Infants are less likely to have the inspiratory whoop and a significant catarrhal stage and are more likely to present with gagging, gasping, cyanosis, apnea or non-specific signs such as poor feeding or seizures⁽⁴⁾. Adults and children partially protected by vaccination can present with illness ranging from a mild cough illness to classic pertussis, though this may be without the inspiratory whoop. The cough gradually becomes paroxysmal (after 1–2 weeks) ⁽⁹⁾.

It is during the paroxysmal stage that the diagnosis of pertussis is usually suspected. Characteristically, the patient has bursts, or paroxysms, of numerous, rapid coughs, apparently due to difficulty expelling thick mucus from the tracheobronchial tree. At the end of the paroxysm, a long inspiratory effort is usually accompanied by a characteristic high-pitched whoop. During such an attack, the patient may become cyanotic (turn blue). Children and young infants, especially, appear very ill and distressed. Vomiting and exhaustion commonly follow the episode ^(4,9). Convalescent stage, it begins after 4 weeks of the illness, and is manifested by a decrease in the frequency and severity of the paroxysms of coughing ⁽¹⁰⁾. The cough becomes

less paroxysmal and disappears in 2 to 3 weeks. However, paroxysms often recur with subsequent respiratory infections for many months after the onset of pertussis ⁽⁷⁾.

The most common complication, and the cause of most pertussis-related deaths, is secondary bacterial pneumonia⁽⁴⁾. Young infants are at highest risk for acquiring pertussis associated complications⁽⁴⁾. Data from 1997–2000 indicate that pneumonia occurred in 5.2% of all reported pertussis cases, and among 11.8% of infants younger than 6 months of age⁽⁴⁾. Immunization has become the most effective public health measure for the control of infectious vaccine preventable disease and one of the best tools to decrease child mortality and morbidity. Incomplete immunization can put children at greater risk of acquiring a disease and partial immunization coverage against vaccine preventable diseases is a significant public health challenge in developing countries⁽¹¹⁾. The primary series of DTaP vaccine consists of four doses, the first three doses given at 4- to 8-week intervals (minimum of 4 weeks), and beginning at 6 weeks to 2 months of age. The fourth dose is given 6–12 months after the third to maintain adequate immunity for the ensuing preschool years. DTaP should be administered simultaneously with all other indicated vaccines⁽⁴⁾.

The increase worldwide in vaccination coverage against pertussis has substantially reduced the morbidity and mortality associated with this disease (6,12,13). Managing pertussis in a setting with high rates of vaccination uptake requires knowledge of the clinical picture of pertussis according to the vaccination status and age of the patient ⁽⁶⁾.

Statement of the problem

Recent large outbreaks among infants and adults have been observed in several high-income countries⁽¹³⁾. And the infection continues to kill young children and even in countries with strong vaccination programs clinicians miss the diagnosis⁽¹⁴⁾. Long after the discovery of effective antibiotic treatments and the implementation of universal vaccination strategies, pertussis remains a disease associated with an important burden even in developed countries ⁽⁶⁾. The control of pertussis or whooping cough is of public health concern worldwide, because it is estimated that over 10 million cases and as many as 400,000 pertussis-related deaths occur annually, with 90% of the burden in infants from developing countries ⁽¹⁴⁾. The years 2010 to

2012 have seen particularly large outbreaks in Australia, the Netherlands, the United Kingdom, and the United States, with significant mortality in infant⁽¹²⁾. In United States, where the number of reported cases in 2012 was the highest since the 1950s⁽¹⁵⁾. In 2014, a total of 9,935 cases of pertussis cases were reported in America, for a statewide incidence of 26.0 cases per 100,000⁽¹⁶⁾. According to Washington state board of health 12 pertussis case has been reported in 2016⁽¹⁷⁾.

In 2008 through 2011 a total of 72 deaths from pertussis were reported to CDC. Children 3 months of age or younger accounted for 60 (83%) of these deaths. During 2008-2011, the annual mean of pertussis cases in infants was 3,132⁽⁴⁾. The World Health Organization (WHO) estimates that in 2008 about 16 million cases of pertussis occurred worldwide, 95% of which were in developing countries, causing the death of 195 000 children. A total of 27,550 pertussis cases and 27 pertussis-related deaths were reported in 2010. Case counts for 2012 have surpassed 2010, with 48,277 pertussis cases, with 13 deaths in infants⁽⁴⁾. The world health report in 2013 revealed that the number of pertussis cases in Africa WHO (World Health Organization) region was 5,816 cases; from which country's prevalence 35 (Morocco), 16 (Namibia) pertussis cases were reported. Zero case report was received from Ethiopia⁽¹⁸⁾. In Niger, notified pertussis cases are few despite the low diphtheria-tetanus-pertussis/Pentavalent vaccine coverage. With an estimated prevalence of 8.2 cases per 1000 children aged <5⁽⁴⁾.

In Ethiopia pertussis is one of the epidemic prone diseases, but it is not among the 21 diseases under surveillance system. In 1999, a national report of epidemic diseases (based on reports from regions), which included pertussis, reported 640 cases with only 3 deaths; National data in a rural survey revealed that 4.4% of all the illnesses were due to pertussis and other coughs⁽¹⁹⁾. In Bahir Amba Keble an increasing in number of individual with coughing sign and symptoms has been reported from the Janamora district health office.

Objective

General Objective

To investigate the existence of outbreak, identify the potential risk factors of pertussis outbreak and undertake appropriate public health measures, in Bahir Amba kebele, Janamora District of North Gondar zone, and Amhara region in April, 2017.

Specific Objective

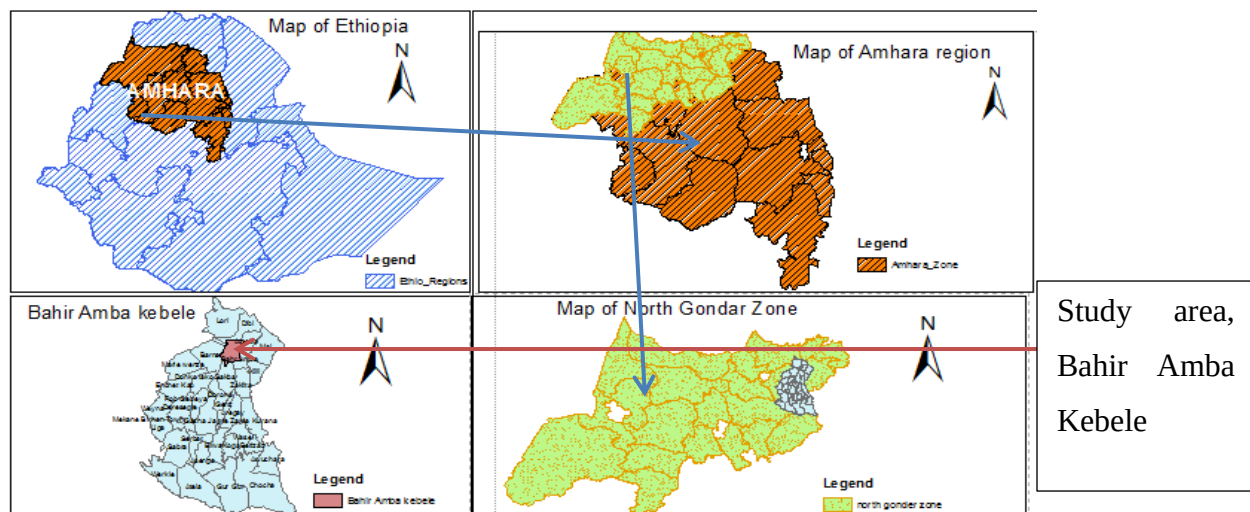
- To characterize the extent of the outbreak in terms of place, person and time variables
- To identify associated factors contributed to the occurrence of an outbreak.
- To suggest recommendations for further action.

Methods and materials

Study area

Semien Mountain one of the remarkable places in Ethiopia is found in Janamora woreda inhabiting of different endemic animals Janamora woreda is one among 167 woredas in Amhara National Regional State. It is found in North Gondar Zone which is one of the 11 zones in Amhara region. Jan Amora (Amharic: "Royal eagle") is one of the woredas in the Amhara Region of Ethiopia part of the Semien Gondar Zone, Janamora is bordered on the south by Misraq Belessa, on the southwest by Wegera, on the west by Debarq, on the north by Addi Arkay and Tselemt, on the east by Beyeda, and on the southeast by Wag Hemra Zone. The administrative center of Jan Amora is Mekane Berhan.

The woreda is 160 km away from the zonal capital, Gondar town. The woreda has a total population of 208,776 projected from 2007 national census of whom 106,478 are men and 102,302 women; 15,057 or 7.21% are urban inhabitants about 11048(14.3%) are children less than five years of age. There are about 34 kebeles in the woreda; 33 of total 34 kebeles are rural. Bahir Amba kebele is one among the 34 rural kebeles found in the woreda. It has a total population of 44,374 which accounts for 21.2% of the total population residing in the woreda. Of the total 6008 are children less than five years of age. There are one health center in the catchement area with six health professional with diferent decipline that serves for many kebeles including bahir Amba. One health post is found in Bahir Amba kebele but with out health extension worker.



Map 1: Demographic map of Bahir Amba kebele, Amhara, Ethiopia, 2017

Study design and period:

We conducted an unmatched case-control study from April 22-May 10/2017.

Source and study population

Source population of the investigation were all individuals living in Bahir Amba kebele; while the study population were all patients with pertussis cases come to health facilities and cases those were found during door to door active case searching by the investigation team and fulfills the case definition/suspected cases of pertussis in affected kebeles of Bahir Amba, Janamora woreda.

Inclusion criteria

Cases: Purposively selected individual from Bahir Amba kebele who presented with the typical case criteria of pertussis and person supposed to have contact with suspected pertussis case and had symptoms of pertussis from March 06th to 10th May 2017 and who agreed to participate in the study was included.

Control: A control was any resident of Bahir Amba kebele who was a neighbor to a case and who did not develop signs and symptoms of pertussis and agreed to participate was included.

Exclusion criteria

Cases: Those cases not conscious and family members in the same house hold were excluded.

Controls: Those who refused to participate were excluded as well as family members from same house hold.

Sample size and sampling technique:

Totally 60 cases were found, from the study area during the outbreak and all the cases were included in the case control study; likewise an equal number of controls who are the neighbors of cases were recruited and got involved in the study. Cases were selected those individual presented with sign and symptoms and sampling technique were not employed for cases; whereas controls were selected those neighbor to cases and were selected randomly. In

cumulative 120 study participants were enrolled of those 45 cases that were initially reported on line list some interviewed at the health facility and other retrospectively searched up to their residence with the guide of individuals from the kebele leader and catchment health center staffs and additional 15 cases were identified on actively searching by the investigation team.

Data collection

We assessed and reviewed surveillance reports and regular contact was maintained throughout the outbreak period in Bahir Amba kebele. Vaccination status of the woreda and the health center catchment area of the kebele were obtained.

Purposively selected key informant; Surveillance focal person and community leader interviewed at the Kebele. Cases were defined using WHO standard pertussis case definition; data for infant cases were collected by interviewing through their mother. For analytic analysis 60 pertussis cases and 60 controls (case to control ratio of 1:1) were interviewed using standard questionnaire that includes; socio-demographic, pertussis knowledge, clinical feature of the disease, exposure, treatment and possible source of infection were included. Door to door active case search was conducted. Line list was also prepared to gather information about new cases and was maintained until the end of the outbreak.

Regular communication were undertaken with woreda health office, catchment area Health Center (HC) head, HC PHEM (Public health Emergency and Management) focal and EPI(Expanded Programme of Immunization) focal personnel throughout investigation periods.

Data processing and Analysis:

Data were entered, cleaned and analyzed using SPSS version 21. Cleaning of data was done to check the consistency and completeness of the data set; if records were found out of range; it was rechecked with the corresponding questionnaire.

Frequencies and proportions were used to describe the study population in relation to relevant variables and results were presented using descriptive tables and charts; attack rate and case fatality rate were also calculated. Bivariate statistical analysis and multivariate backward conditional logistic regression analysis were done using SPSS to find association of illness with

risk factors (predictors) and exposure outcome were measured and tested using OR, 95% Confidence Interval and P-value.

During the analyses, P-value and /or 95% confidence interval (CI) for OR (odds ratio) were used in judging the significance of the associations. P-value less than 0.05 were taken as statistically significant.

Case Definitions

Suspected case: Any person with cough, fever and/or coryza and/or headache OR any person in whom a clinician suspects pertussis.

Probable case:

A. person presented with a cough illness lasting ≥ 2 weeks, with ≥ 1 of the following symptoms:

- Paroxysms of coughing or
- Inspiratory “whoop “or
- Posttussive vomiting and don’t epidemiologically linked.

B. For infants <1 year ONLY: A case with an acute cough illness of any duration with at least one case-defining symptom and apnea (with or without cyanosis).

Epidemiologically linked case:

Is a suspected case, which has contacts (possibly got the bacteria); contact with a clinical case (a case that meets the clinical case definition, but is not laboratory confirmed) and identified as a person having the disease by the health personnel in examination

Index case: Suspected pertussis case (case that met the criteria for standard pertussis case definition) that initiates the public health attention (may or may not visit health facility) and of course, the first case who possibly the source of infection for the other cases emerging.

Data quality assurance: May things has been made to maintain the quality of the data collected There were detailed discussions on the question and the collected data were checked on daily basis during the investigation. Data cleaning were done using SPSS version 21, by the principal investigator.

We used line listing for describing pertussis cases in terms of time, place and person. However, all data were checked for completeness prior to entry and cleaned before analysis.

Four people, (including Principal Investigator (PI)), one Field Epidemiology resident and two clinical nurse personnel collected the data. A single day orientation on the questionnaire was given to the data collectors and the collected data was checked daily through the investigation period. The data registered on line list and collected via structured questionnaire was cross checked to ascertain and evaluate any inconsistency of the collected data then the PI skimmed data for its completeness and any missed values before entered in to SPSS software.

Environmental Investigation:

Generally, Bahir Amba kebele environmental condition, in wide perspective including housing condition, sleeping rooms housing ventilation, and living condition of the families of both cases and controls were done. Visual inspection of dwelling of the cases and controls was also conducted; observations of the usual custom/habit they do while coughs, or sneezes has been done too, to assess the possible way of the transmission of the causative agent from infected person to the health individuals.

Operational definition:

Case: Individual presented with the sign and symptoms of pertussis.

Control: Any resident of Bahir Amba Kebele during the study who was a neighbor to a case and who did not develop signs and symptoms of pertussis irrespective of their demographic characteristics.

Educated /literate: Are individuals those who responded as they are educated /able to read and write.

Uneducated/illiterate: Are those individuals who responded as they aren't educated/don't able to read and write.

Knowledgeable about pertussis: were those individuals (respondent) who answered 3 questions and above correctly.(If mother/care taker have awareness about, mode of transmission of

pertussis diseases, sign and symptoms of pertussis diseases, prevention of pertussis diseases, considered as knowledgeable.

Don't have knowledge about pertussis: were those individual (respondents) who answered less than 3 questions correctly.

Unvaccinated: A child who does not receive any dose of pertussis vaccines and who had no record of vaccination on logbooks and failed to recall the vaccination status of their children during active case searching and during retrospectively searching the patients.

Vaccinated: Child who take at least one dose of the pertussis containing vaccines and when first single dose vaccination status was documented in their log files and/or the mother or the care taker told us as her child took vaccine that prevent pertussis disease.

Vaccination status: being vaccinated or unvaccinated with pertussis containing vaccine.

Contact History: Close contacts are defined to include immediate family members (those who spend many hours together or sleep under the same roof) and anyone who had direct contact with respiratory secretions.

Greater than/equal to two windows: Those houses supposed to be more ventilated and less confined with minimal bacterial propagation from person to person.

Less than two windows: Those houses supposed to be less ventilated and more confined with high bacterial propagation from person to person.

Ethical considerations:

We obtained Ethical clearance from St. Paul's Hospital Millennium Medical College (SPHMMC), Department of Public Health (DPH), then from Amhara Public Health Institute (APHI) and supportive letter were obtained from the Zonal Health Department to respective Woreda Health Office. Oral informed consent was obtained from all participants or from their parents to participate in the study. Confidentiality was assured and no personal details was recorded or produced on this documentation. For advanced prudence the name of respondents was not written on the questionnaire, therefore, the information study participants provide was not disclosed or demystified to others.

Result

Demographic feature

All of 120 study subjects were orthodox by religion. Similarly 39(65%) cases and 21(35%) controls were uneducated. Regarding to the educational status 74 (61.6%) were uneducated and 46(38.4) study subjects were educated. Among the study subjects suspected for pertussis cases 56(93%) of the mother/caretaker for the cases were uneducated/illiterate and 4(7%) were educated/literate. Generally, 104 (86.6%) and 16 (13.4%) of the mother/care taker were uneducated and educated population respectively.

Of the total pertussis suspected cases 24(40%) were male and 36(60%) were female population by sex .With respect to the age distribution, about 33(55%) of cases were laid from age 1- 9 years; 17(28%) were from age 1-4 and 16 (27%) of cases were within 5-9 years of age category followed by 21(35 %) of cases within age 10-19 category; thus only 3 pertussis suspected cases were found of those who yet to celebrate 1st year of birth day those of whom was less than 12 months of age. Rounding off the age category distribution of all the study subjects 58(48.3%) and 50(41.7%) of them were found within age category from 1-9 and 10-19 years of age respectively. Detail description of study subjects by age and sex is illustrated by table (1).

Table 1: Illustrating the age & sex distribution of the study subjects, Bahir Amba Kebele, Janamora, Amhara, Ethiopia, 2017.

Age Category	Case		Case +Control (all study subject)		Frequency	Percent (%)
	Male	Female	Male	Female		
<1	2	1	2	1	3	2.5
1-4	8	9	14	16	30	25
5-9	5	11	12	16	28	23.3

10-14	4	7	8	13	21	17.5
15-19	5	5	17	12	29	24.1
>=20	0	3	2	7	9	7.5
Total	24	36	55	64	120	100

Descriptive Analysis

We identified a total of 60 pertussis cases from 22th April to 10th May, 2017 from Bahir Amba kebele. There were two deaths reported. The median age of all of the subjects was 9 years (range from 9 month to 34 yrs.). The median age of the cases and the controls were 6.5 (range from 9 month to 28 yrs.) and 11.5 (range 1 year to 34 yrs.) respectively. Of total 60 cases 34(56.6%) female and 26 (43.4%) were male. And from total control 32(53.3%) male and 28(46.7%) were female. The overall attack rate (AR %) was 0.13% and with regards with age specific attack rate (ASAR) for population less than age 5 years 43.3/10,000 population. Regarding sex specific attack rate (SSAR) for female was 159/100,000 and males 110/100,000. The case fatality rate was 3.3 %.

Vaccination status

Majority of reported pertussis suspected cases 52(86.6%) had no yet received any pertussis vaccine while only 8(13.4%) of the cases have reported a history of vaccination. Of the total cases vaccinated for pertussis containing vaccine only 4 were vaccinated for the second dose penta 2 and none of them was vaccinated for the third dose penta 3. Related with low vaccination achievement in the kebele 47(78.3%) of the respondents among the cases don't know the actual time of when vaccination was provided and 19(31.6) do felt the vaccination would hurt their child. Almost all of the respondents about 55(91.6%) were complaining the health facility was too far and hard to reach and 44(73.3%) of the cases were not aware of the importance of vaccination; among those cases who was able to respond by themselves 23(38.3%) do scared of the vaccine. The overall data of the total study subjects reveled as the presumed reason for low vaccination coverage was 102(85%), 110(91.6%), 66(55%) , 42(35%) do not know the time

when vaccine for pertussis was provided, health facility was too far to reach, don't know the importance of vaccination and do scared of the vaccine respectively. From the total pertussis cases more than half 39(65%) do traveled more than 2 hours on foot to get health service and only 21(35%) of the cases had relatively short distance walked less than 2 hours to reach health facility and get the service. Overall 67(55.8%) of study subjects have walked more than 2 hours of distance on foot on a very hard to reach and up-down geographical land formation. The vaccination coverage of Bahir Amba kebele was 74%, 69% and 65% for penta1 penta2 and penta3 respectively by the year 2016/17. Similarly Janamora district has reported coverage of 83%, 82%, and 69% for penta1 penta2 and penta3 respectively (see Figure 1 for vaccination status detail).

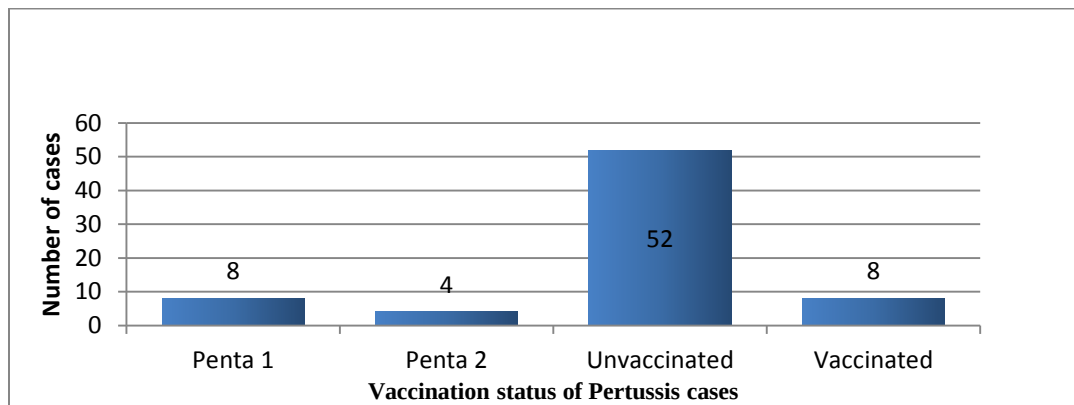


Figure 1: Previous vaccination status of cases Bahir Amba kebele, North Gondar zone, Amhara, Ethiopia, 2017

Clinical sign and symptoms criteria used to diagnosis

Of the total cases those 83.3% presented with fever and coryza and who developed cough was 60 (100%), 52(86.6%) had vomiting after paroxysmal, 44 (73.3%) were presented with Inspiratory whoop, 35(58%) had Cyanosis after cough and totally three infants were suspected with pertussis presented with sign and symptoms of the disease; of the three infants 2 were presented with apnea. Among total cases had paroxysmal cough in 39 (65%) of the cases; the paroxysmal cough was present up to the date of investigation (see table 2).

Table 2: Clinical sign and symptoms, diagnostic criteria for pertussis cases, Bahir Amba Kebele, Jana Amora District, North Gondar, Amhara, Ethiopia, 2017

Criteria	Yes	No	Percent (%)
			Yes
Fever	60	0	100
Coryza	49	11	83.3
cough	60	0	100
Vomiting After cough	52	8	86.6
Inspiratory Whoop	44	16	73.3
Cyanosis After Cough	35	11	58.3
Apnea	2	1	66.6
Paroxysmal cough still present	39	21	65

Assessment of knowledge about pertussis disease

Among all 120 study population of half 60(50%) of them have said they knew pertussis disease and 40(33.3%) of study subjects have the knowledge as the disease do transmitted through contact with suspected cases.

With respect pertussis suspected cases; 35(58.3%) didn't had the knowledge about pertussis disease. With the same speaking 16(26.6%) of them do knew vaccination as a method pertussis disease prevention and 88(73%) of respondents they didn't had the knowledge as vaccination could prevent pertussis disease those cases resembled to choose local healer as method of prevention from the disease; thence 11(18%) and 5(8%) of cases responded contact with pertussis suspected cases and through air as the possible paths of transmission of the disease from person to person respectively. On general speaking 16(26.6%) of case respondents identified contact with pertussis infected cases and air as possible transmission path (See table 3).

Table 3: Knowledge status of suspected pertussis cases Bahir Amba kebele, Janamora, Amhara, Ethiopia, 2017

Knowledge assessment criteria	Response	Frequency of respondents	%
Know pertussis disease	Yes	17	26.7%
	No	43	73.3%
Methods of prevention	Vaccination	16	27%
	Local healer	44	73%
Know ways of transmission	Air	5	8%
	Fecal/oral	28	46.6%
	food	16	26.6%
	Contact with cases	11	18%

Disease complication status of the case

Of the total 60 pertussis suspected cases 31 (51.6%) of them had developed various complication of diseases of those 8(13.3%) pneumonia, 2(3.3%) sinusitis, 10 (16.6%) viral and bacterial super infection, 11(18.3%) Nutritional deficiency and none of the cases had asthma complication. The overall disease complications of the cases are shown by figure 2.

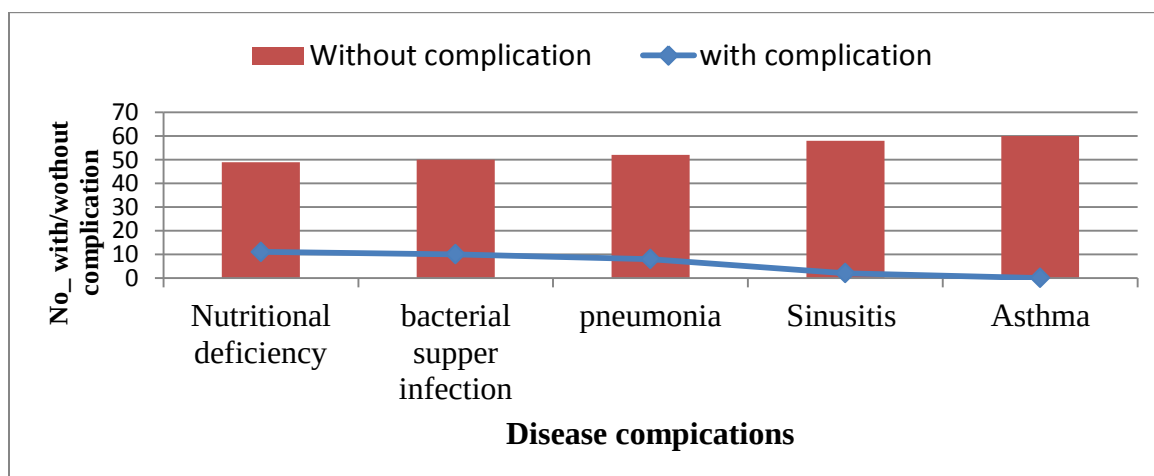


Figure 2: The disease complication status of suspected cases, Bahir Amba Kebele, Jana Amora District, Amhara, North west Ethiopia, 2017.

Date of health facility visit

Of the total 60 pertussis suspected cases the first suspected case was visited the health facility on date 04/04/2017 and the number of cases who visit the health facility (HF) increased starting from date 4/15/2017 and peak HF attendant number was seen beginning from 4/17/2017 and HF visitor with pertussis suspected cases goes in nearly steady number for a couples of weeks and cases were treated with medication. Azithromycin 500 mg p.o (per oral) in a single dose day 1; then 250 mg p.o as single daily dose on days 2–5/ Erythromycin, 1 g per day in 3 divided doses for 7 days .Children less than age 5 years was given Erythromycin suspension four times per day for 14 days/ Azithromycin 30 mg/kg for 5 days. From patients who received antibiotics treatment, 4 patients treated with antibiotic for the second time and 35(58.3%) did not respond totally and had some intermittent cough, but others 21 (35%) had improved from their illnesses (see figure 3).

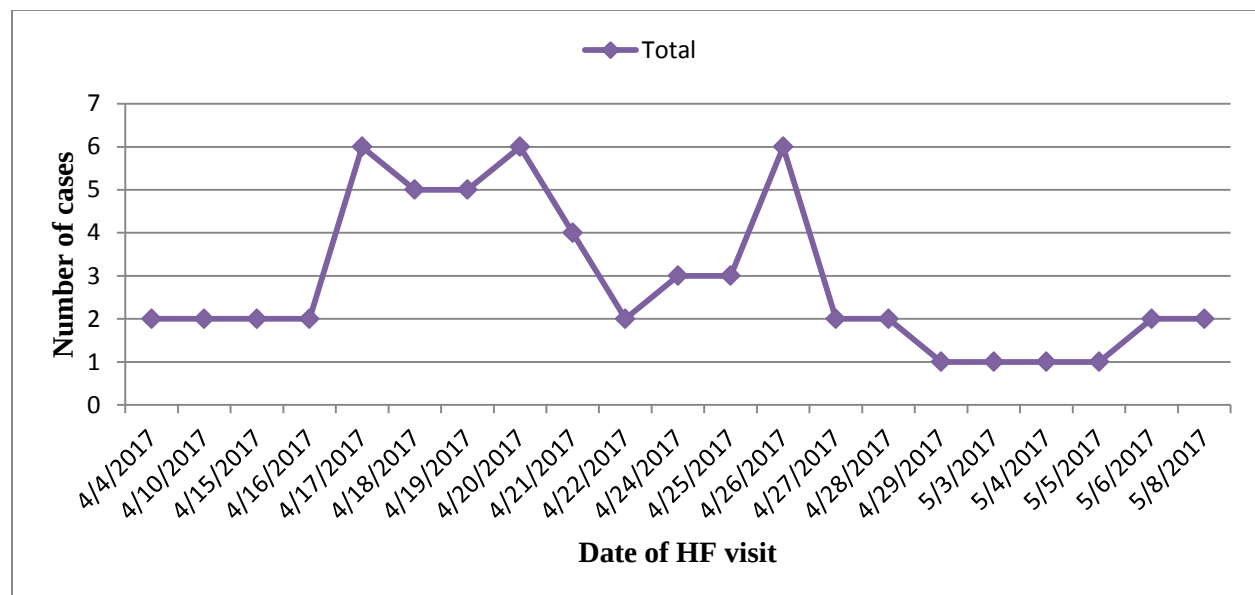


Figure 3: Date of health facility visit of cases, Bahir Amba kebele, Jana Amora, Amhara, Ethiopia, 2017.

The outbreak spanned over a period of 2 months (*from March 06, 2017 – May 10, 2017*). Majority of the cases 18(30%) occurred from March 30 up to April 2, 2017 and 12(20%) of cases were reported from March 27 to April 29, 2017. Six cases were detected on April 3 and 4, the

case incidence showed a consistence number of report on subsequent days. The possible index case was reported on March 18, 2017 and was from Bahir Amba kebele. The presumed index case was identified at *Mesha/Cheroleba* health center on 04/04/2017 and the district health department was notified on 04/17/2017, the zone notifies the regional health bureau on 04/18/2017. The subsequent cases were reported from the affected area indicating spread of disease.

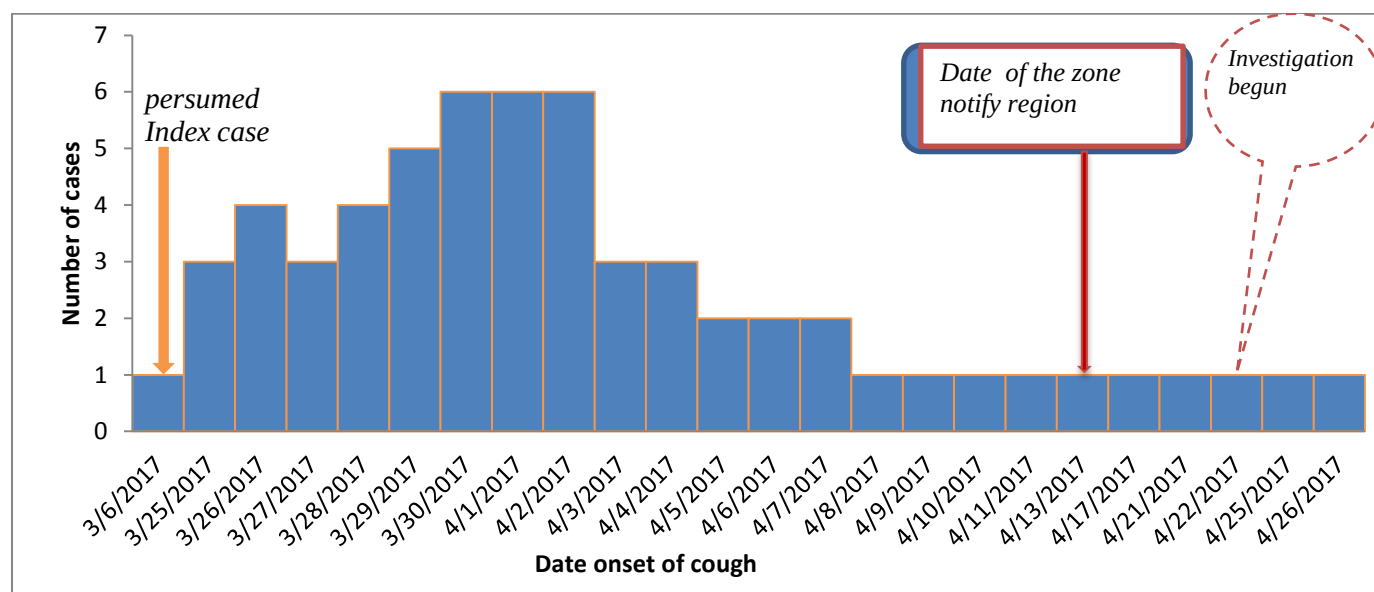


Figure 4: Distribution of Pertussis cases by date of onset of cough, Bahir Amba, Jana Amora District, Amhara Region, North west Ethiopia, 2017.

Analytical Investigation Result

A total of 120 study subjects have been included in the study; of them 60 individuals were pertussis cases and equal weight of participants of 60 controls were apparently healthy of pertussis disease were recruited.

On Bivariate analysis, each independent variable was tested with the dependent variable independently and those variables that had probability value (p-value) of ≤ 0.2 were included to

be tested by Multi variate logistic analysis. Here by, variables become significant in bi variant analysis were: Travel history prior 1-2 weeks before the development of cough (OR: 1.966; 95% CI:0.950-4.071; p=0.069), Age <15 years old (OR: 0.449; 95% CI: 0.193-1.046; p= 0.064), sex female (OR: 1.741; 95% CI: 0.831-3.536; p=0.144), lack of knowledge pertussis (OR:1.960; 95%CI:0.252-1.179;p=0.690), lack of knowledge on pertussis prevention (OR:0.545; 95% CI:0.84-3.963; p=0.123), house having number of window less than 2 (OR:2.875; 95% CI:1.312-6.299; p=0.008), Distance of health facility more than 2 hour from home (OR:2.122; 95%CI:1.019-4.422;p=0.044), contact history with pertussis suspected person (OR:4.929; 95%CI:2.236-10.860;p<0.000), having of contact with school (OR:2.625; 95% CI:1.211-5.691;p=0.015), having of work place contact (OR:2.667; 95% CI:1.178-6.034; p=0.19), lack of knowledge of pertussis transmission path (OR:1.833; 95% CI:0.848-3.963; p=0.123), see table 4 below.

Table 4: Identified possible risk factors for pertussis outbreak in Bahir Amba kebele, Jana Amora, Amhara, Ethiopia, 2017.

Variables		Respondent case/control	category	COR(95% CI),p-value
		Case(N=60)	Control(N=60)	
Travel history	No	23(38.3%)	33(55%)	1
	Yes	46(61.7%)	27(45%)	1.966(0.950-4.071), p=0.069
Age	>=15	11(18.4%)	20(33.4%)	1
	<15	49(81.6%)	40(66.6%)	0.449 (0.193-1.046), p=0.064
Sex	Male	24(40%)	32(53.4%)	1
	Female	36(60%)	28(46.6%)	1.741(0.831-3.536), p=0.144
Do you know pertussis	Yes	25(41.6%)	35(58.4%)	1
	No	35(58.4%)	25(41.6%)	1.960(0.948-4.050), p=0.69

Knowledge of pertussis prevention	of Vaccination		16(26.7%)	24(40%)	1
		Local healer	44(73.3%)	36(60%)	0.545(0.252-1.179), p=0.123
Number of window	of Greater than/= 2		14(23.3%)	28(46.7%)	1
		Less than 2	46(76.7%)	32(53.3%)	2.875(1.312-6.299), p=0.008
Health Facility Distance to home on foot walk	Facility to	<2hrs	21(35%)	32(53.3%)	1
		>2hrs	39(65%)	28(47.7%)	2.122(1.019-4.422), p=0.044
Contact With Suspected case	No		14(23%)	36(60%)	1
		Yes	46(77%)	24(40%)	4.929(2.236-10.86), p<0.000
School Contact	No		15(25%)	28(46.7%)	1
		Yes	44(75%)	32(53.3%)	2.625(1.211-5.691), p=0.015
Work place Contact	No		12(20%)	24(40%)	1
		Yes	48(80%)	36(60%)	2.667(1.178-6.034), p=0.19
Knowledge of pertussis transmission	of Yes		16(26.7%)	24(40%)	1
		No	44(73.3%)	36(60%)	1.833(0.848-3.963), p=0.123

Multivariate analysis

Hence, variables those significant in the bivariate analysis were also tested via multivariate logistic regression analysis, on multivariate analysis statistically significant variables and identified as having association with pertussis illness were:

Contact history with pertussis suspected person (AOR: 6.298; 95%, CI: 2.539-15.624; $p<0.000$), Pertussis cases work place contact (AOR: 3.339; 95%CI: 1.289-8.651; $p=0.013$), work place contact, household having number of window less than 2 (AOR: 3.011; 95% CI: 1.177-7.702; $p=0.021$), sex female (AOR: 2.919; 95% CI: 1.179-7.227; $p=0.021$), summarized variables significant on bivariate analysis (see table 5).

Table 5: Identified risk factors for pertussis outbreak in Bahir Amba kebele, Jana Amora, Amhara, Ethiopia, 2017.

Variables			Respondent category		AOR(95% CI), P-value
			case/control		
			Case(N=60)	Control(N=60)	
Contact with pertussis suspected person	No		14(23%)	36(60%)	1
	Yes		46(77%)	24(40%)	6.298(2.539-15.624), $p<0.000^*$
Work place contact	No		12(20%)	24(40%)	1
	Yes		48(80%)	36(60%)	3.339(1.289-8.651), $p=0.013$
House number of window	Greater than/= 2		14(23.3%)	28(46.7%)	1
	Less than		46(76.7%)	32(53.3%)	3.011(1.177-7.702), $p=0.021$

2				
Sex	Male	24(40%)	32(53.4%)	1
	Female	36(60%)	28(46.6%)	2.919(1.179-7.227), p=0.021

*Denotes the variable is more significant, which would have strong association with pertussis (p<0.000).

Environmental Investigation

We tried to observe the usual habit of the people lived in the kebele on the possible risk factor like contact with the suspected cases, housing ventilation condition, personal and environmental hygiene practice and we have seen an most of suspected cases were living housing condition a bit confined but we didn't come across to identify the maximum distance in between individuals that verify the possible potential of the bacteria to propagate; this might require additional technological input.

The health center responsible to support and supply vaccination logistics were visited for observation of vaccine cold chain. While the team arrived at the health center, the refrigerator used to store the vaccine was functional and the daily temperature reading log was posted; as a good opportunity the kebele had no electric supply but the health center was supplied with uninterrupted solar power system.

Intervention during outbreak

Onward arrival of the team on the study site; we in collaboration with individual from the kebele leader and district health office and kebele health center staffs treating of the suspected cases with antibiotic and mass health education had been provided for cases, healthy individuals and the care taker/ mother at the health center, church, at school (for the students and school community) and during our door to door active case searching on possible way of the transmission of the bacteria from suspected cases to health individuals with possible prevention ways and awareness creation has been tasked. It was irrefutable that the land scape of the area was highly cumbersome. Nevertheless, we had conducted door to door active case search to uncover more cases. Strategies like case management and enhancing the surveillance system in kebele has been done.

Discussion

Isolation of *B. pertussis* by culture and detection of *B. pertussis* by polymerase chain reaction (PCR) are the only ways to confirm the diagnosis of pertussis⁽⁵⁾. The pertussis outbreak wasn't confirmed by laboratory. The technology used to investigate the possible causative agent of the disease was not found in domestic; either in Amhara Public Health Institute (APHI) laboratory or Ethiopia Public Health Institute (EPHI) laboratory. That remains handicap to investigation the outbreak and identifies the definitive agent. The case definition in diagnosing pertussis cases has been looked thoroughly. Pertussis outbreaks occurred in Bahir Amba kebele which lasted for more than two months starting from March 06, 2017-May 10, 2017 and resulted 60 cases. This could be explained that delayed in notification of the outbreak indicates that there was poor active surveillance system at the kebele/district level that was because of the health extension worker deployed to the kebele has been off work on routine time for many months and the distance of the health facility from the community; moreover that make the health seeking habit low in the community. The sum total of these fine points enabled the outbreak to expand to neighbors' individuals household.

Only 13.4% of cases had received pertussis containing vaccine this is much smaller compared with 66.7% in South Africa⁽²⁰⁾, the possible reason might be absence health extension worker to provide routine immunization to the community. The overall pertussis containing vaccination coverage of the kebele was 69.3% which small achievement while compared with 78% of Janamora District (3rd quarter district EPI, report) and 90% as of in south Africa⁽²⁰⁾. Of the total 60 cases only 8(13.3%) and 4(6.6%) vaccinated for pertussis containing vaccine of penta 1 and penta 2 respectively; that was negligible figure of penta1 and penta 2 coverage in contrast with 80.8% and 75.2% of Amhara region respectively⁽²¹⁾. In spite of 74% and 69% vaccination coverage report of the study area, still the vaccination coverage in those cases were very low that might be reports might compiled or planed for political consumption but the fact on the ground contradict with the report.

The main reason of falsely elevated administrative immunization coverage was because of under planning of the eligible population in the kebeles as per evidence obtained from the investigation. More over the health extension who deployed on the kebele was out of routine work for more than a year despite the fact that the one health extension worker has been assigned

to work; the other reason, we got from the health worker in the catchment and the kebele leader the area was hard to reach and there was no access to road transportation at all, the land scape of the area is not comfortable to walked on

The overall attack rate of the outbreak was 0.13% (130 cases per 100,000 populations) and but had been much devastating incidence of the disease in the study area when counterweigh with only 5.7 and 1 per 100 000 population in Neuquén (Argentina) and in United States of America respectively ^(22,23). But our finding was less than by two folds as compared with 380/100, 000 populations in rural Ethiopia⁽¹⁸⁾. Possibly lack of laboratory technology in the region even in the country render of the challenge to isolate the agent and patients visit health facilities very late after getting severe illness and stay at home very long time which makes the early detection and containment of the outbreak a bit slow that paved disease to disseminate; this and other shoot out the incidence in respective kebele. The other motive might likely to be multifactorial and include improvements in diagnosis and reporting of cases in school age and adolescents. The case fatality rate among the cases were 3.3% which indicates relatively high number of human life has been lost as compared with 0.17% case fatality rate in Neuquén(Argentina)⁽²³⁾.

Highest proportion about 33(55%) of cases were laid from age 1- 9 years and the remain 45% of cases were attacked older than 9 years and this finding of the investigation goes in line with study done in Denmark where the age groups from 1 to 19 years all had an increased incidence, but the increase was particularly pronounced among the 1-9-year-olds; and analogous to the study in United States of America: proved down as: - in recent years, an increasing proportion of cases has been reported among adolescents and adults, and the number of outbreaks reported among school-age children and adolescents has been increasing ⁽²²⁾⁽²⁴⁾. In our study the clinical sign and symptoms manifestation seen was consistent with the study done in Argentina but the disease complication found in our investigation was slightly deviated in frequency with the data obtained with the study in the same study setup ⁽²³⁾.

In case-control part of our study, factors such as: mother's education, education between cases and control were not different this might be due to awareness created through health education given by health professional during active case searching and field investigation.

The most powerful relationship was observed for contact history with an AOR of 6.2 this was much lower with study conducted in urban Uganda⁽¹⁴⁾. Individuals that had exposure to a coughing individual in the home/neighborhood were 6 times more likely to have pertussis compared to individuals that had no exposure to the coughing individual in home/neighborhood; hence, those individuals who had contact with the person with the disease were more vulnerable because the disease is transmitted by large droplet infection or direct contact with discharges from respiratory mucous membranes of infectious people⁽²⁵⁾.

During our door to door visit of the communities' village we had notice that they way of live, culture of feeding together and having a coffee ceremony together mostly early before go to work place all and other as reasons had this variable to be seen in bold as a possible predictor to the response variable of pertussis disease; in addition, here knowhow of the community to segregate themselves from coughing peoples and practice patients does will coughing (don't use handkerchief).

In our study, the odds of being female was nearly 3 times much higher at risk to contract pertussis than male individuals; this study stay in inverse with that the odds of getting pertussis disease is similar for both sex in Denmark ⁽²⁴⁾. That was because females has more time to work at home and to give care to the sick child or old patients at home, that will put her to be much at risk to develop the disease.

Additional predictors we found in this study were pertussis cases work place contact (AOR: 3.339), Individuals that had exposure to work place contact were greater than 3 times more likely to have pertussis compared to individuals that had no contact to work place; the working nature of the peoples in the study area was, they works together during ploughing their farm land and those cowherd look after their sheep at same grazing land at that time they possibly share the causative agent.

The other significant variable found was household having number of window less than 2 (AOR: 3.011); Individuals who lived in house having less than 2 window(poorly ventilated) were nearly 3 times more likely to had pertussis disease as compared with individuals lived in house having greater than/equal to 2 window (well ventilated),since the study setting was done rural area, most of cases live in poorly ventilated and confined housing environment more over; unidirectional

movement of the air in house that favored the exhausted air to circulate with the house; in that case the exhaled bacteria from the patient will be inhaled by other healthy individuals in the same house. In our study few variables found significant with the illness were not fully discussed with other findings as a result of lack of literature done in other setting and those variables remain unjustified.

Limitation

- ❖ The outbreak was not confirmed by laboratory diagnosis.
- ❖ The vaccination status was determined bases on oral witness of the mother/care taker and vaccination status retrieved from the health center registration lacks complete information.
- ❖ Absence of vaccination card that was difficult to determine the vaccination status, exact date of vaccination and other relevant information.

Conclusion

This outbreak occurred in remote Bahir Amba kebele of the Janamora District with extremely low immunization coverage, weak surveillance system and delayed health service visit of the patients. In this outbreak overall high attack rate with a wider age range has been observed. More than half of the cases were affected age less than nine years. Factors contributed for the occurrence of this outbreak include; contact with pertussis suspected cases, having work place contact like shepherd and cowherd, those individuals living in poorly ventilated house was and those female population was highly affected by the outbreak. High proportion of unvaccinated pertussis cases of the outbreak most likely resulted due to the accumulation of susceptible individuals in the kebele as a result of low routine immunization coverage and weak supplementary immunization activities that aim to provide a second opportunity for pertussis immunization.

Recommendation

- ❖ The health extension worker who is committed to work in the kebele need to be hire by the placement office and district health department (District health office (DHO)).
- ❖ Routine and outreach expanded immunization programmes need to be strengthening (DHO).
- ❖ Health education has to provide extensively to the community on possible roots of transmission of the disease like contact with pertussis suspected cases and possible prevention mechanisms (Catchment health center, DHO).
- ❖ Health education needs to address risk factor areas, like work place while peoples working in mass, children and communities in school (Catchment health center, DHO).
- ❖ Awareness creation on improving house hold ventilation shall be given (Catchment health center, DHO).
- ❖ In order to improve the health seeking behavior of the community road infrastructure need constructed (regional road authority and regional health bureau (RHB)).
- ❖ Laboratory technology used to diagnoses the definitive agent need to be start as possible soon
- ❖ Preparedness needs to strengthen; as possible prudence perhaps the similar epidemic might happen on similar domain (catchment health center, DHO&RHB).
- ❖ Information related vaccination need to catch-up accordingly on the catchment health center (catchment health center & DHO).

Note: - responsible bodies are shown in bracket.

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Annex 1: Pertussis outbreak investigation questionnaire

Hello. My name is Lezhialem Almaw. I work for the Amhara public health institute and I am doing an investigation of ***pertussis outbreak*** ‘the purpose of this question to get information for public health action. The information you provide will remain confidential. Would you be willing to participate? Thank you

Respondent:

Investigators: _____

☐ Patient ☐ Family member (Mother, Father: Brother or sister or other relatives close to patient.)

Respondent’s status:

☐ Case ☐ Control

I Demography

1. Date of birth _____/_____/_____

2. Age _____Month _____year

3. Sex: Male ☐Female ☐

4. Religion: Orthodox ☐ Muslim ☐ others ☐

5. Address: woreda _____kebele_____

6. Education level of the patient/Control:

Not educated ☐ KG ☐ Primary ☐Secondary ☐Tertiary ☐Not applicable☐

7. Case/control’s education level of the mother/care giver Mother?

Illiterate/Uneducated ☐ Primary ☐Secondary ☐Tertiary☐

II Knowledge Questions

8. Did know pertussis disease? Yes ☐No ☐

If the answer to question # 8 is NO, go to Q # 12

9. How do you think pertussis is transmitted? You can pick more than one response:

Through air ☐ Fecal/oral ☐ Food ☐ Close contact with an ill person ☐

11. How do you think pertussis can be prevented? :

☐ Vaccination, ☐ local healing ☐ other _____

III Clinical presentation /for cases ONLY/

12. You have fever? Yes ☐ No ☐

13. Do you have coryza? Yes ☐ No ☐

14. Do you have headache? Yes ☐ No ☐

15. Do you have cough? Yes ☐ No ☐

16. Onset of cough: ____/____/____

17. Date of Onset of catarrhal stage: ____/____/____

17.1 Total duration of cough _____hours/days

18. Paroxysmal cough: Yes ☐ No ☐

18.1. Onset of paroxysmal cough (dd/mm/yy):/...../.....

18.2. Cough still present: Yes ☐ No ☐

18.3. Inspiratory whoop present: Yes ☐ No ☐

18.4. Vomiting after paroxysm (post cough vomiting): Yes ☐ No ☐

18.5. Apnea for < 1year children (Infants): Yes ☐ No ☐

18.7. Cyanosis after paroxysm: Yes ☐ No ☐

18.8. Pneumonia: Yes ☐ No ☐

18.9 Sneezing Yes ☐ No ☐

18.10. Hospitalized: ☐ Due to the condition ☐ No ☐ Unknown ☐

18.11. Complications: ☐ Yes – specify..... ☐ No ☐ Unknown

18.11.1 Does the patient had a history of Asthma Yes ☐ No ☐

18.11.2. Outcome: Survived ☐ Dead ☐ Unknown ☐

18.11.3. Days seen at health facility:_____/_____/_____

IV. Antibiotics given

19. Erythromycin duration _____ days

20. Bacterium duration _____ days

21. Clathriomycine duration _____ days

22. Amoxicillin _____ days

23. Other _____ days

Vaccination history (for both case and controls)

24. Have you ever vaccinated: Yes ☐ No ☐

24.1. If the answer to question# 24 is “**NO**”, got to Q# 29

25. Do you have vaccination card: Yes ☐ No ☐ Unknown ☐

Penta1 date _____/_____/_____

Penta2 date _____/_____/_____

Penta3 date _____/_____/_____

26. Date of last pertussis containing vaccine given _____/_____/_____

27. Number of doses of pertussis containing vaccine given _____

28. If numbers of doses less than 3 indicate why is the reason/s?

28.1. Religious exemption ☐

28.2. Medical contra indication ☐

28.3. You did not know the time of vaccination ☐

28.4. The vaccine will hurt me /my child ☐

28.5. Clinic was too far ☐

28.6. You are scared of vaccines ☐

V. History of exposure:

29. Did you have contact with a person with pertussis symptoms the 1-3 weeks before onset of illness/ without illness for control? Yes ☐ No ☐

30 Have you travelled outside of your village the 1-3 weeks before onset of illness/ without illness for control? Yes, ☐ No. ☐

31. How long does it take you to walk to the health center from your house?

Less than 2 hour ☐ More than 2 hour ☐

32. How many windows does the house have?

☐ Two or more windows ☐ less than two windows

33. Did you have close contact with known or suspected case?

Yes ☐ No ☐

34. Did you have contact with school? Yes ☐ No ☐

35. Did you have contact with work place? Yes ☐ No ☐

36. Did you have health facility contact? Yes ☐ No ☐

Chapter II: Surveillance Data Analysis Report

Measles surveillance Data analysis of Amhara region 2003-2006 EC, Ethiopia

Abstract

Background: Measles is an acute, highly contagious viral disease caused by measles virus and which can cause highly devastating consequence. This highly contagious virus is transmitted primarily by respiratory droplets or airborne spray to mucous membranes in the upper respiratory tract or the conjunctiva. In 2001, countries in the World Health Organization African region began accelerated measles control activities to reduce measles deaths by half by 2005.

Objective: To determine trends and burden of measles disease at Amhara region from 2003-2006 EC.

Method: Data analysis was done by using Amhara region health facilities measles surveillance data input, which was regionally compiled by regional public health emergency management (PHEM) department from 2003-2006 EC. Line list data obtained from PHEM department was skimmed for its completeness, entered and cleaned in computers via MS Excel; data was transported in to SPSS version 21 for descriptive analysis and outputs was displayed in graph, chart and tables.

Result: From 2003-2006 there were 15, 355 suspected measles cases in Amhara region with a mean annual Attack rate of 46.9 cases/100,000 people. Case ranges from 1016 in 2004 to 9501 in 2006. During the same time period, there were 97 deaths with a case fatality rate of 0.63%. The highest cases 9501 (61.8%) was reported in 2006 E.C and 3416 (22.2%) was reported in 2003 E.C. Most of the cases 5,252(34.2%) were from North Gondar zone, followed by 2,921(19.02%) from North wollo zone. Climax measles cases were reported on March 3,575(23.28%) succeeded by month February 3,453(22.43%). The case fatality rate was high (1.34%) in 2003 E.C and it was low (0.408%) in 2005 and 2006 EC.

Conclusion: Measles remains as a public health problem in the study area with relatively high prevalence rate. The highest number of measles cases was reported from North Gondar zone. The highest number of measles cases reported in 2006 and peak season occurred from January to June (winter, the main dry season in Ethiopia) .

Introduction

Background

Measles is one of the communicable diseases still causing preventable mortality and morbidity in the world and for which humans are the only reservoirs [1, 7]. Measles is also, a leading vaccine preventable childhood disease designated for elimination by world health organizations (WHO). Each year, measles is responsible for 454,000 deaths worldwide [2]. Serious complication including pneumonia diarrhea and blindness, especially in infants and children under the age of five more than 20 million peoples are affected by measles each year particularly in part of Africa [3].

In 2001, countries in the World Health Organization (WHO) African Region began accelerated measles control activities to reduce measles deaths by half by 2005 compared to the estimated number of measles deaths in 1999. Implementation of the recommended strategies led to a 75% reduction in estimated measles mortality in the African Region by 2005. Following this progress, in 2006 the African Region adopted a goal to achieve 90% measles mortality reduction by 2010 compared with the estimate for 2000. By 2008 in the African Region, reported measles cases decreased 93% and estimated measles mortality decreased 92% compared with 2000. The strategies include improving routine vaccination coverage, providing a second opportunity for measles vaccination through supplementary immunization activities (SIAs), improving measles-case management, and establishing case-based measles surveillance. Since 2002, Ethiopia adopted these regional goals and strategies and has been taking important steps to control measles. The Africa Region as well as Ethiopia is working towards measles elimination by 2020 [1].

The National Immunization Programme was established in the 1980s, and currently delivers service through static and outreach sites nationwide. The current routine immunization schedules recommend a dose of measles vaccination at 9 months of age. The WHO UNICEF coverage estimates for measles vaccination in Ethiopia also indicate an increase from 37 % in 2000 to around 80% in 2010 [1].

Measles is an acute, highly contagious viral disease caused by measles virus. This highly contagious virus is transmitted primarily by respiratory droplets or airborne spray to mucous

membranes in the upper respiratory tract or the conjunctiva. Common source outbreaks associated with airborne transmission of measles virus have been documented. The incubation period ranges from 7 to 21 days from exposure to onset of fever; rash usually appears about 14 days after exposure. Symptoms include prodromal fever that can rise as high as 105°F (40.6°C), conjunctivitis, coryza (runny nose), cough, and small spots with white or bluish-white centers on an erythematous base on the buccal mucosa (Koplik spots). A characteristic red, blotchy (maculopapular) rash appears on the third to seventh day after the prodromal symptoms appear. The rash begins on the face, becomes generalized, and lasts 4–7 days [4].

The measles virus is a member of the genus Morbillivirus of the Paramyxoviridae family. The virus appears to be antigenically stable there is no evidence that the viral antigens have significantly changed over time. The risk factors for measles virus infection include: infants who lose passive antibody before the age of routine immunization, children with vitamin A deficiency and immunodeficiency due to HIV or AIDS, leukemia, alkylating agents, or corticosteroid therapy, regardless of immunization status and children who travel to areas where measles is endemic or contact with travelers to endemic areas. Malnourished and young children are at higher risk of developing complications and mortality from measles infection.

Rationale of the study

Measles is an acute, highly contagious viral disease caused by measles virus and which can cause highly devastating consequence. So undertaking the surveillance data analysis will help to estimate magnitude of the measles disease in the regions and also early recognition of measles epidemics and it enables to follow secular (long-term) trends of measles disease in the Amhara regions.

Objectives

General objective

To determine trends and burden of measles disease in Amhara region from 2003-2006, Amhara, Ethiopia, 2008 EC

Specific objectives

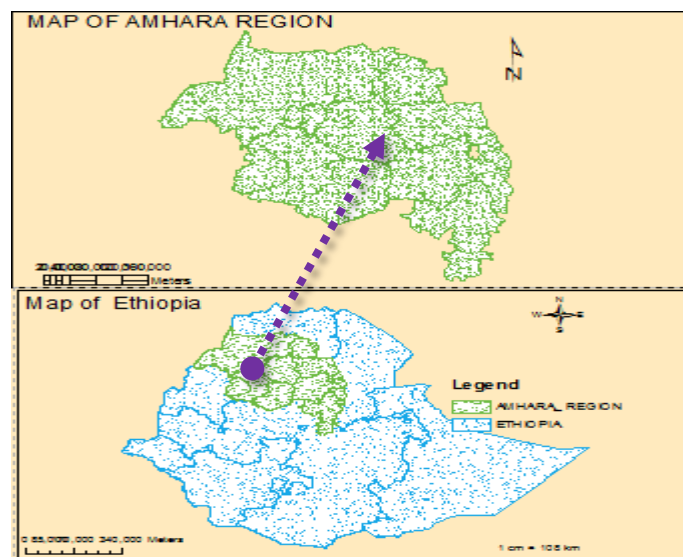
- ❖ To describe the data in terms of place, time
- ❖ To show most affected zones and town administrations in the region due to measles case
- ❖ To show the prevalence or burden of measles in Amhara region

Methods and Materials

Study area

Amhara region is located 550 Km away from the capital Addis Ababa and one of the regions among nine regions in Ethiopia. Amhara Regional State, the second most populous region in Ethiopia. The region shares common borders with Tigray, Afar, Oromia and Benshangul Gumuz regional states in North, East, South and South-West respectively and the Republic of South Sudan in the west.

The state of Amhara consist of 10 administrative zone ,one special zone,105 woreda and 78 urban centers ,the region has 17 Hospitals, 520 Health Centers and 2,941 Health Posts .Health facilities in the region which is intended to serve about 18,167,982 population.[5,6]



Map 2: Administrative map of Amhara region, Ethiopia, 2003-2006 EC

Source population

Based on 2002 (EFY) figures from the Central Statistical Agency (CSA) of Ethiopia, the Amhara Region has an estimated total population of 18,167,982 consisting of 9,110,481 male and 9,057,501 female. 87.4% of the population is estimated to be rural inhabitants, while 12.6% are urban dwellers (CSA 2007). With an estimated area of 159,173.66 square kilometers, this region has an estimated density of 108.2 people per square kilometer [5].

Study Period

The secondary data (already compiled in regional PHEM department) analysis was carried on according to the pre-defined field Programme schedules i.e. the work plan so the study was conducted beginning from Apr,15-May 1,2008 EC with that periods the study was accomplished

Study Design

A descriptive, cross sectional data analysis was employed for Amhara region's Public Health Emergency Management (PHEM) department and Measles Surveillance data was collected retrospectively from 2003-2006 EC.

Data Source

Measles surveillance secondary data was extracted from regional data base from regional Public Health Emergency Management (PHEM), line listed measles data was collected with required variables to the study objectives and data with ample evidence.

Identification of Cases

Measles surveillance is a case based surveillance in this system, each case is reported using an individual case-report form and cases are identified through the use of Ethiopian national Measles guideline which was prepared in 2012 by FMOH[7].Effective surveillance for measles entails establishing case based surveillance that includes investigation and laboratory testing of all suspected measles cases [8]

Case definition for measles:

The surveillance system must be sensitive enough to identify circulating measles virus in the community. Use of the standard case definition for 10 suspected measles cases are the primary tool in the surveillance system to ensure early detection of any suspected cases.

Measles suspected cases at community level:

A community member should report any person with **rash** and **fever** to a health worker and also advise the person to go to a health facility [1].

Suspected = Fever+ Maculopapular rash
cases

+

One of the following:

- Cough
- Coryza (runny nose)
- Conjunctivitis

Suspected measles case

Any person with fever and maculopapular (non-vesicular) generalized rash and cough, coryza or conjunctivitis (red eyes) or any person in whom a clinician suspects measles. [1, 7]

Confirmed measles case:

A suspected case with laboratory confirmation (positive IgM antibody) or epidemiologically linked to confirmed cases in an outbreak. [1]. All suspected cases of measles are finally classified based on the adequacy of the blood specimen collected, and sample taken or not in to the following categories [7].

Laboratory confirmed: A suspected measles case that is investigated, including the collection of an adequate blood specimen (5 ml), and has serological confirmation of recent measles virus infection (IgM positive) [7].

Statistical data analysis:

The line list data that obtained from PHEM department was skimmed for its completeness entered and cleaned in computers via MS Excel then the required variables were rearranged

finally, data was transported in to SPSS version 21 for descriptive analysis or statistical manipulations and outputs was displayed in graph, chart and tables.

Ethical issue:

This work was realized based on the ethical clearance of the public health emergency management, Amhara regional health bureau (ANRS-HB) and the confidentiality of the data was maintained accordingly.

Result dissemination:

The output of that four years surveillance data analysis will be presented to ANRS-HB PHEM department stuffs, stake holders and Saint Paul's hospital millennium medical college (SPHMMC), Department of public health.

Finally the finding from that study will help the decision makers to take appropriate public health action and intervention depending up on the significance of the result obtained.

Result:

Trends and magnitude of measles morbidity and mortality by year

From 2003-2006 there were 15,355 suspected measles cases in Amhara region with a mean annual Attack rate of 46.9 cases per 100,000 people. Case ranges from 1,016 on 2004 to 9,501 on 2006. During the same time period, there were 97 suspected deaths with a case fatality rate of 0.63%. The highest number of suspected cases 9,501 (61.8%) was reported in 2006 E.C and 3,416 (22.2%) was reported in 2003 E.C with annual incidence of 114.2 cases per 100,000 people and 43.29 cases per 100,000 people respectively. There have been 32,407,650 total populations at risk by data analysis period.

The lowest number of cases 1,016 (6.61%) were reported in 2004 E.C with annual incidence of 12.65 cases per 100,000 people. The highest suspected measles deaths were reported in 2003 E.C at 46 (0.248 per 100,000). The case fatality rate was high (1.34%) in 2003 E.C and it was low (0.408%) in 2005 and 2006 E.C. the population at risk for measles during the data analysis period is indicated as follows by table 1.

Table 6: population at risk for measles Amhara region, Ethiopia, 2003-2006

Year	Population at risk	No of Measles cases	No of Measles death	Total
2003	7,889,292	3,416	46	3478
2004	8,029,031	1,016	5	1021
2005	8,171,761	1,422	8	1430
2006	8,317,566	9,501	38	9583
Grand total	32,407,650	15,355	97	

Detail of morbidity and mortality of suspected measles is indicated in the fig 1 below. Among the total cases 15,355 (61.8%) occurred in 2006 EC and the highest 46(47.4%) and the lowest 5 (5.1%) measles death was occurred in 2003 and 2004 respectively, table 2 summarized below.

Table 7: Measles suspected case and death in Amhara region, Ethiopia, 2003-2006.

Year	Measles Case	Measles Death
2003	3416	46
2004	1016	5
2005	1422	8
2006	9501	38
Grand Total	15355	97

In the period of 2003-2006, the trend of case fatality (CFR) rates decreased. The higher CFR was occurred in 2003. The total case fatality rate reported the four years data analysis was 0.62%, figure 2 illustrated below.

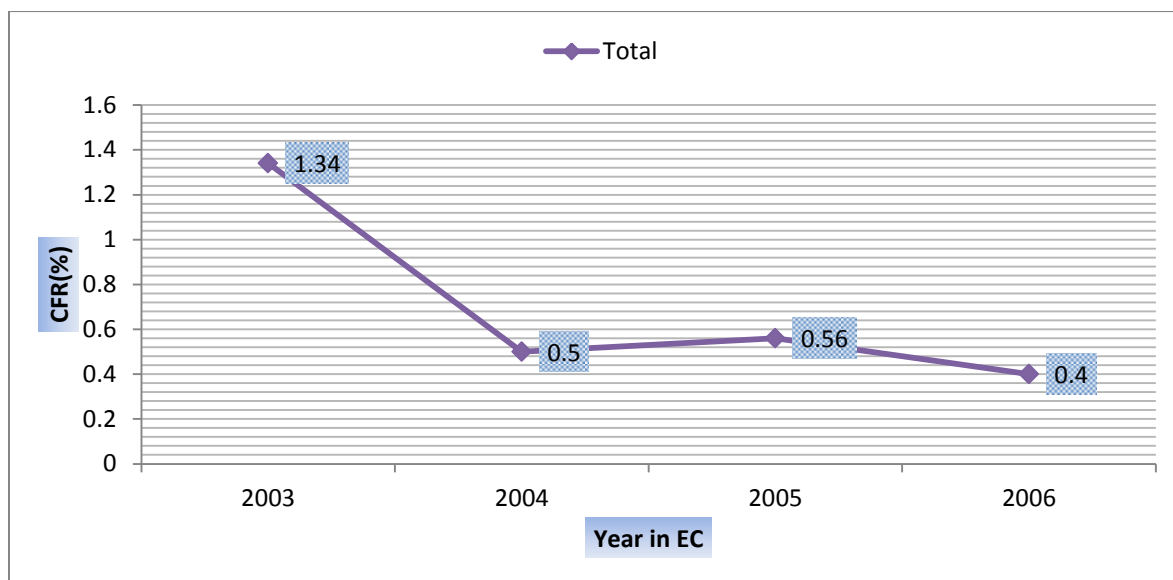


Figure 5: Measles CFR by year, Amhara, Ethiopia, 2003-2006.

During the four year surveillance data analysis periods, the incidences of measles case had a bit incremental at the beginning of the study 43.29 per 100,000 in 2003 and remain on steady number for past two data analysis years then dramatically over shoot up to 114.7 per 100,000 in 2006 .highly tremendous measles case 48.74 per 100,000 and death 0.248 per 100,000 was higher on 2006 and 2003 respectively. Trend of incidence and death rate is indicated in (Figure 3).

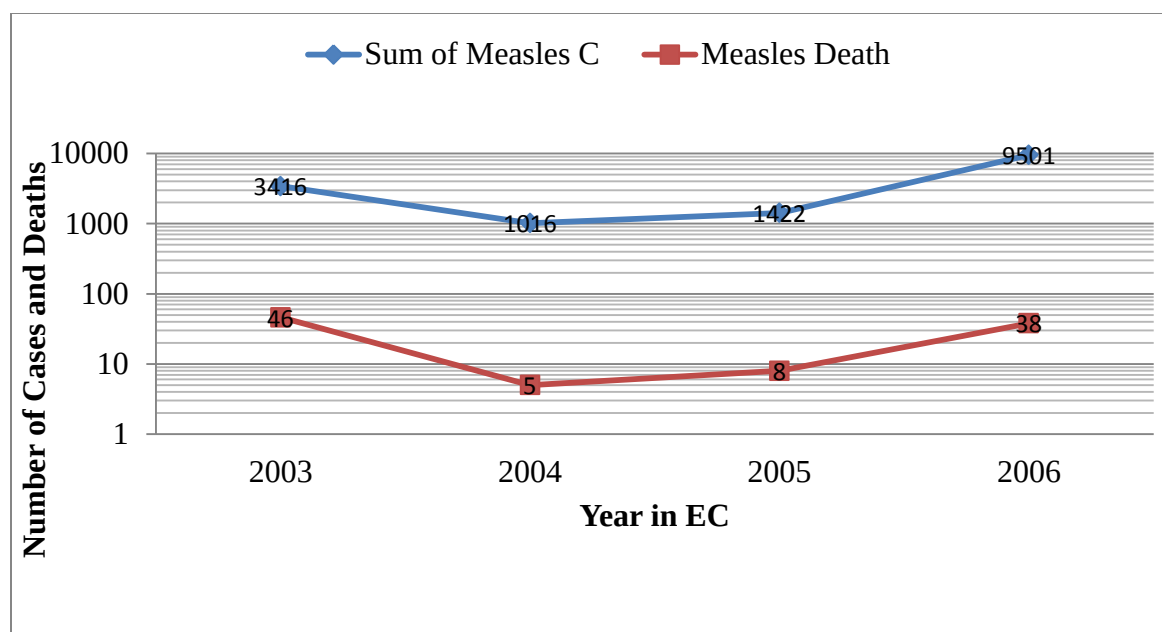


Figure 6: Measles case and death rate trend in Amhara, Ethiopia, 2003-2006.

By 2003 the peak and the least case were reported 1,440(41.9%) on third and 2,80(8.1%) on the second quarter respectively; slightly similar figure were reported 8,68(25.29%) on the first quarter 8,44(25.59) on the fourth quarter. Of the total death report on 2003 EC 18(39.1%) on the first quarter and 15(32.6%) on the third quarter, the modest measles death report were happened on 9(19.5%) on 4th quarter and 4(8.6%) on ths 2nd quarter.

Among the total 1,016 measles cases that had been occurred in 2004, 389(38.2%) cases were on 4th quarter and 245(24%) cases on 3rd quarter 230(22.6%) on the 1st quarter and 153(15%) cases report were received. here by the maximum death was occurred on the 3rd quarter surpassed half of the total cases by then. it accounts about 80%, however no case was found by the 1st & 2nd quarters.

From the total of 15,355 cases and 97 deaths, 9501 cases and 38 deaths were reporetd in 2006. On that year about 6,119(64.1%) were occurred in the third quarter followed by 3,016(31.5%) on the fourth quarter, the least case report were on the first quarter 89(0.9%) by the same year too, the highest and the least measles death were on the third quarter 31(81.5%) and 7(18.4%) on the fourth quarter. but there were null or zero death report on the fisrt two consquative quarter of 2006.

Measles case and death trend by quarter

During surveillance data analysis, a total of 15,355 cases and 97 deaths were reported, when the measles trend described in terms of quarter in the whole data analysis period

For the last four years ,when total case reported in each year quarters is considered separately the number of measles cases were reached at peak level in the third quarter 8,252(53.74%) on the four consecutive analysis years followed by the fourth quarter 4,715(30%). With similar period as that of the measles case the highest death was reported on the third quarter 53(54.6%) followed by the first and the fourth quarter 19(19.58%). The distribution of cases and deaths are summarized by table 3 below.

Table 8: Measles by quarter on each year, Amhara, Ethiopia, 2003-2006

	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
Year	Measles- D	Measle s _C	Measles- D	Measle s _C	Measles- D	Measle s _C	Measles- D	Measle s _C
2003	18	864	4	276	15	1436	9	840
2004	0	229	1	153	4	245	0	389
2005	1	180	1	294	3	463	3	485
2006	0	78	0	310	31	6108	7	3005
Total	19	1351	6	1033	53	8252	19	4719

Measles cases and death trends by month

The data analysis output from 2003-2006 E.C indicated that the climax measles were reported on March 3,575(23.28%) succeeded by month February 3,453(22.43%) cases generally speaking the seasonality of measles case has shown incremental from month 132 cases in January to 560 cases in June by how many the Epi curve shows a peak five consecutive months then on successive months the measles incidence has showed relative decrement on its impact.

Meanwhile, from the total death report ,22 (22.6%) has occurred on month February ,as that of the case the highest sum up death figure has been reported from January to June .

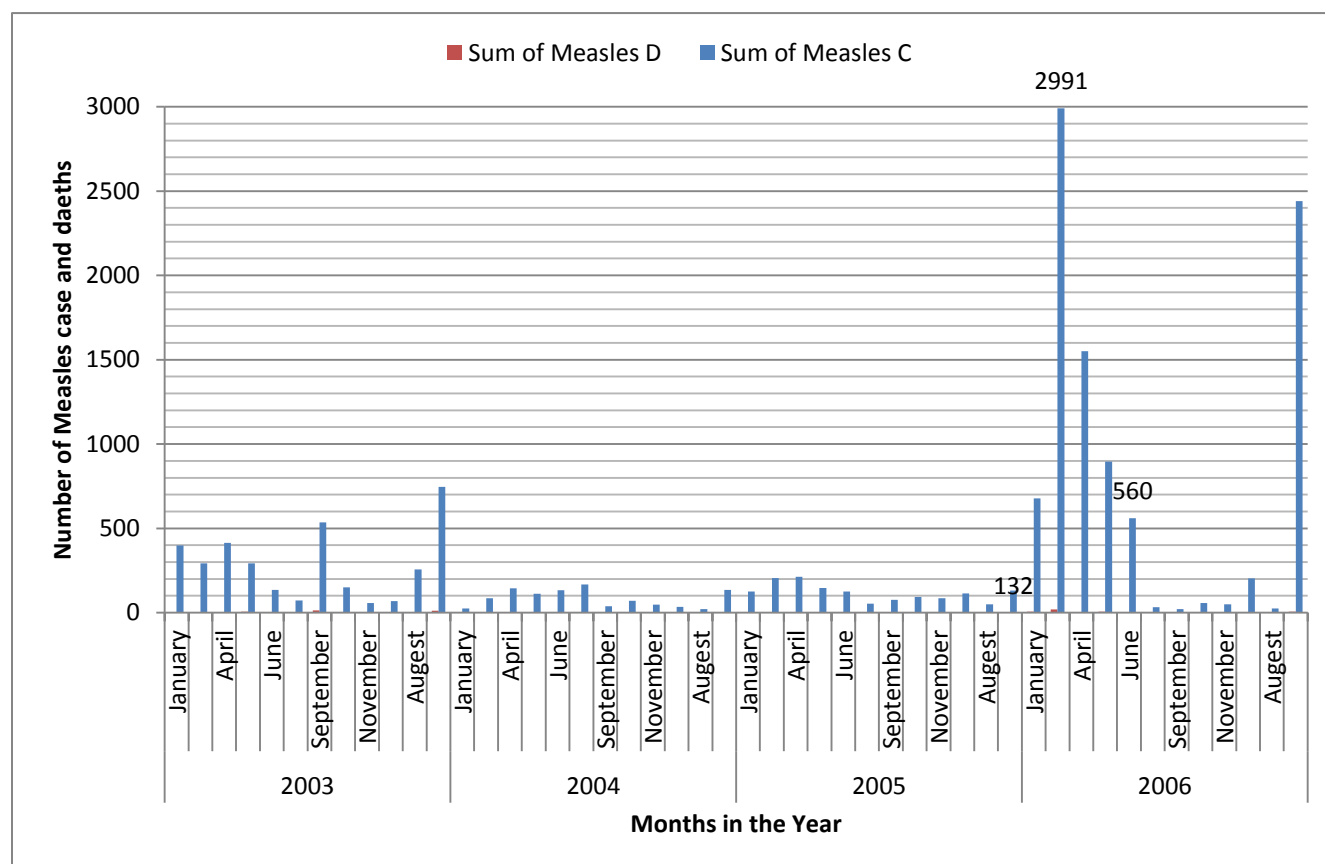


Figure 7: Trends of Measles case by month of onset of illness, Amhara, Ethiopia, 2003-2006.

Measles trend in terms of Epi-weeks

When the trend of measles case and death was described in terms of Epi week, the moderate report was seen from 2nd to 8th week and reached its highest value from 11th to 15th. The most peak case report received on week 13th 1,200 and the case shown a uniform distribution, case also has shown a bit increment on week 39th. The distribution of case and death are shown on the figure 6 below.

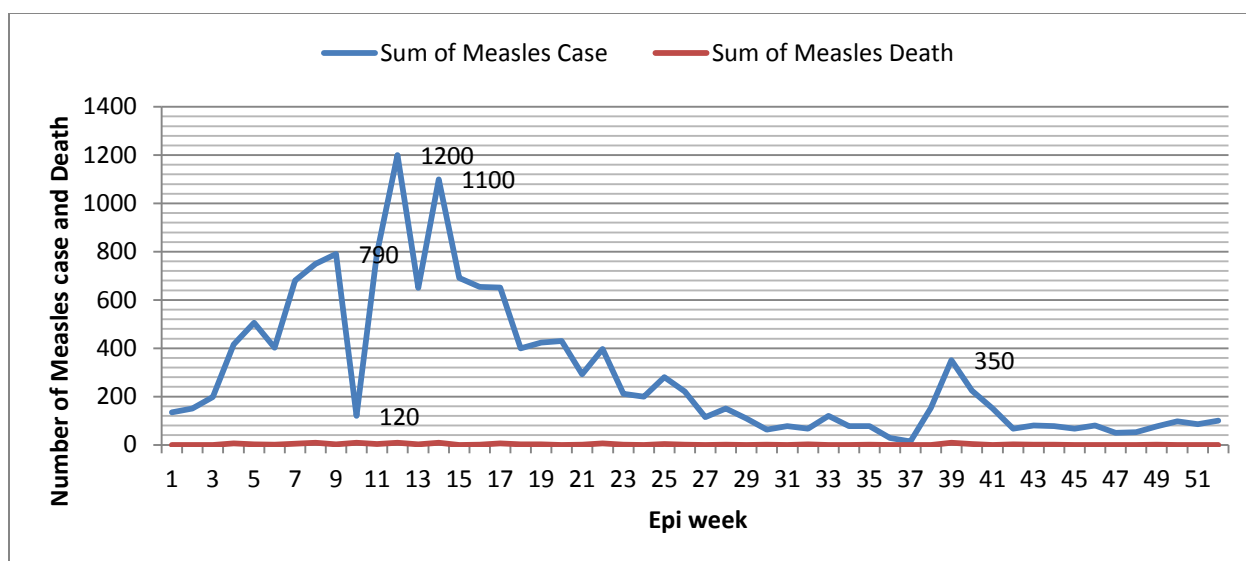


Figure 8: Trends of measles case and deaths by Epi weeks Amhara, Ethiopia, 2003-2006

Distribution by zone

From the total of 15,355 measles cases reported majority of the cases 5,252(34.2%) were from North Gondar zone, AR 92.4/100,000, Second and third largest Measles case reported 2,921(19.02%) ,AR 114.84/100,000 and 1,451 (9.45%) ,AR 36.79/100,000 was from North wollo and South Gondar respectively. Bahir dar town has reported the smallest number of measles cases, 257 (1.67%) AR 80.22/100,000 since 2003 to 2006 past four years.

From 10 zonal administration and 3 towns 97 deaths were reported, with same study periods, the highest measles mortality report was received from North Gondar 49(50.5%) with CFR 0.93% followed by West Gojjam 14(14.4%) CFR 1.1% the least or zero measles mortality rate were registered from Dessie town, Gondar town, Oromia zone and south Gondar zone. The total number of measles cases and deaths by Zone in the past four study year is shown in (Table 2)

Table 9: Distributions of Measles cases and deaths by zone, Amhara, Ethiopia, 2003-2006

Zone	2003	2004	2005	2006	total	Measles case	Measles Death	AR/100000
Awi	475,824	484,298	492,956	501,802	1,954,880	651	10	33.30128
B/Dar town	75,862	78,605	81,458	84,426	320,351	257	1	80.2245

Dessie town						52	0	
E/Gojjam	996,803	1,013,885	1,031,311	1,049,091	4,091,090	703	1	17.18368
Gondar Town						283	0	
N/Gondar	1,382,104	1,407,626	1,433,733	1,460,442	5,683,905	5,252	49	92.40126
N/Shewa	800,508	814,524	828,835	843,448	3,287,315	438	2	13.32394
N/Wollo	623,140	628,997	640,021	651,278	2,543,436	2,921	3	114.8446
Oromia	215,392	219,224	223,139	227,139	884,894	335	0	37.85764
S/Gondar	961,080	977,476	994,199	1,011,259	3,944,014	1,451	0	36.78993
S/Wollo	1,172,274	1,192,657	1,214,106	1,235,659	4,814,696	1,112	8	23.09595
W/Gojjam	987,095	1,003,767	1,020,255	1,038,100	4,049,217	1,265	14	31.24061
Wag Hemra	204,153	207,659	211,237	214,888	837,937	635	9	75.78135
TOTAL	7,894,235	8,028,718	8,171,250	8,317,532	32,411,735	15,355	97	

Discussion:

Member states of the World Health Organization (WHO) African (AFR) and Eastern Mediterranean (EMR) regions have set goals for measles elimination by 2020 and 2015, respectively. In 2010, the World Health Assembly endorsed targets to be met by 2015 as milestones toward eventual global measles eradication; the two WHO regions include AFR member states Ethiopia and Kenya, and EMR member state Somalia [9]. This would require achieving a measles incidence of less than one confirmed measles case reported per million populations per year. High measles vaccination coverage (95 % nationally and at district level), and a non-measles febrile rash (measles IgM negative or discarded case) rate of at least 2 per 100,000 population at national level indicating a high surveillance performance are two of the strategies needed to achieve this goal [10]. Measles continues to be a major public health problem in Africa, causing an estimated 28,000 deaths each year [11], and Measles has been also one of the major causes of death and sickness of children in Ethiopia [12]

Measles is still a common and often fatal disease in developing countries. The World Health Organization estimates there were 145,700 deaths globally from measles in 2013. [13, 14] .The world population was 7,086,000,000 in 2013 [12]

Analysis of the measles case-based surveillance data in Amhara region for 2003-2006 revealed that measles infections occurred widely within all zone of the regions. With that study periods there were 15355 suspected measles cases in Amhara region with a mean annual incidence of 46.9 cases per 100,000 people. This is about more than six- folds of measles incidence 7.2cases per 100000 in Ethiopia 2013[12] , about 76 fold of 0.6 cases per 100,000 population in united states of America [15,16] , and approximately three -fold 14.2/100,000 in Ethiopia [12] , but the surveillance data analysis incidence rate of 46.9/100000 annually is twice as bigger than to that of 19 cases per 100,000 population/year in Nigeria [17] the regional data analysis result also exceeds from 12/100000 peoples in Oromia region [2] .this high measles attack rate in Amhara region was because of there were an measles out breaks in different woreda of the region, especially in North Gondar zone and west Gojjam zone woredas , the mothers reluctance to vaccinate their child ,very far distance to health facility from home residence(inaccessibility of health facility) the presence high succptabile individual and low awareness about the nature of the diseases transmission [18,Un published]. Studies done on the perception of the rural

community on causes of measles revealed that both natural and supernatural forces were mentioned as a cause of measles. The number of reported suspected measles cases has increased through the years and this might be partly due to the increased sensitivity of the surveillance System, rather than a failure of the control efforts [12].

The present data analysis result revealed that cases ranging from 1016 to 9501 this was a bit higher figure to that of 500-2000 annual case the average number of measles cases reported to the Ministry of Health by the region in Ethiopia [19], and case fatality rate are 0.63%, which is very negligible as it compared with 4% case fatality in Ethiopia [19]. In Ethiopia, the expected case-fatality rate is between 3% and 6% [7] and 2.35% in Nigeria [15], 5.3% in Tigray Region, Ethiopia but very similar with 0.2% CFR report in Ethiopia [12]. This difference may be due to the type of study design used, and under report of death case.

In Amhara region a seasonal pattern of occurrence of measles has been observed over the study period. The maximum measles case reported in month March (3,575) which is smaller than 3,716 cases reported in France, and 3,800 cases in Ethiopia but this figure is much larger than 177 cases in Germany and 140 cases in Belgium. In Amhara region the second highest report is received during month February (3,453) this exceeds 2,447 in France and 340 cases in Italy.

The seasonality of measles has showed increment from month 132 cases on January to 560 cases on June this trend is analogous with 48 and 336 in January to 237 and 1303 on June in Germany and Italy respectively [20].

The highest regional measles report 9,501 in 2006 EC this year took the lion share of the total Measles case that result was very closed with findings 9,745 cases with in the same data analysis region report [21] but greater than 7,727 cases in SNNPR and 3,940 cases in Oromia regions.

An increase in the number of measles cases from 2003–2006 E.C with the peak number of measles cases 9501 being reported in 2006 there were an epidemic that could have occurred with that respective year [9] and decreased in the number of measles cases 1016 being reported in 2004 and 38 measles deaths in 2006 was less figure as it compared with 44 death reports from Oromia regions and 58 deaths in Amhara region [21]. That regional measles death report discordance happened because, the former study done by collecting data from all health facility since under report measles death was inevitable from health professional.

With respect to measles distribution by zone 5,252 cases were reported from North Gondar zone that finding was about three folds as compared to 1,724 cases from Guji zone, Oromia and 1,423 cases from west Arsi zone, Oromia. The least report were from Bahirdar town 257 cases which is much smaller 823 cases from west Hararge ,1.1% the highest CFR was from west Gojjam which is smaller as compared to 2.35% in Nigeria [15].

Conclusion

Thus measles remains as a public health problem in the study area with relatively high prevalence rate. The highest number of measles cases reported from North Gondar zone. The highest number of measles cases reported in 2006. The highest CFR was occurred in 2003.

Recommendation

The Federal Ministry of Health, Amhara regional Health bureau and other partners should collaborate and strengthen regions for the improvement of measles surveillance coverage. Since the measles surveillance data has no descriptive variable person (age, sex) this variable is the most crucial and helps to pick out the most affected age groups and sex categories. so it is good, if this variable is incorporated under the measles reporting format. Preparedness is required for prompt measles epidemic response, but more attention has to be paid during winter season, with this regard variations should be well recognized with special focus given to the annual peak seasons (month January to June), to prevent high measles transmissions and potential outbreaks. Further studies should be conducted to determine or forecast potential epidemic patterns in the study area. The supplementation of measles vaccine to the children has to be encouraged and providing health education about the nature of the disease, its transmission and sign symptoms through health extension workers, especially in those zones with high case report and to reduce the incidence of measles. It is highly recommended to improve routine immunization, and conduct a wide age group campaign. The disease occurred in all zone and town administration of the region. The death occurred as an attribute of measles was an alarming clock as it seeks due attention to March all stake holder to avert both economic and life loss. As far as measles occurred on seasonal bases the regional rapid response team has to be more conscious and get prepared with all necessary requirements.

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Annex 2: PHEM Case-based Reporting Format (CRF)

Reporting health facility			
woreda	zone	Region	
Disease type (put tick mark)			
Anthrax	cholera	Measles	Meningitis
Neonatal tetanus	Hemorrhagic fever	Yellow fever	Others/specify
Name of patient:			
Date of birth(DOB):---- ----/-----/---- ---Day month year(EC)	Age (if DOB unknown): Years-- ---month:----- If under 12 month	Sex : M=male, F=female	
Patient address:	Kebele	House number	
Woreda	zone	region	
Location information			

Location when symptoms started:		Current location:	
If applicable or If the patient is neonate or child, please write full name of mother and father of the patient:			
Fill only if specimen is collected and sent to Lab			
Date seen at the health facilities ____/____/____ Date month year (EC)	Date health facility notified Woreda/zone ____/____/____ Date month year (EC)	Date of onset ____/____/____ Date month year (EC)	
Number of vaccine/TT dose received ____/____/____ Date month year (EC)	For cases of NNT* , Measles, Yellow Fever, and Meningitis (For NNT, Measles, Yellow Fever – refer immunization card & for Meningitis - ask history) *For NNT cases please complete the additional case investigation form(NNT, Measles, Yellow Fever and Meningitis only)		
Associated with epidemics?	1=YES 2=NO		
In/out patient	1=in patient		2=out patient

Treatment given	1=yes(specify)		2=No			
Outcome of the patient at the time of report	1=Alive		2=Dead		3=unknown	
Date of specimen collection: ____/____/____ Date month year (EC)		Date of specimen sent to the lab: ____/____/____ Date month year (EC)				
Type of specimen: (put tick mark ☐)	stool	Blood	Serum	CSF	Throat swab	Other(specify)

Date form sent to woreda

____/____/____

Date month year (

Name and signature of the person completing the form:

Name

signature

telephone

For official use only

Id number Form received at National/regional level

_____/_____/_____

Date month year (EC)

Final 1=confirmed 2=probable 3=discard 4=suspect
classification of
cases

Final 1= Laboratory 2= Confirmed 3-Clinical 4=discard 5=suspect
classification of Confirmed by compatible
measles Epidemiological linkage

Name and signature of the official:

Name Signature Telephone

Chapter III: Surveillance Evaluation

AN EVALUATION OF MALARIA, TYPHOID FEVER AND SEVER ACUTE MALNUTRITION SURVEILLANCE SYSTEM IN KOMBOLCHA TOWN, AMHARA REGION, ETHIOPIA, 2016

Abstract

Background: Public health surveillance systems should be evaluated periodically to assure the effectiveness and efficiency of the systems. In Ethiopia there are 21 notifiable diseases. Malaria, Sever acute malnutrition and typhoid fever are among those notifiable diseases. In Kombolcha town administration surveillance system evaluation was not done recently and the status of public health surveillance system was not well known.

Objective: To evaluate the performance of the existing surveillance system of malaria, typhoid fever and sever acute malnutrition of Kombolcha town administration, Amhara region, 2016.

Method: The study was conducted in Kombolcha town and cross- sectional descriptive study design was employed from 18.January- 04.March, 2017. One town administration health office, four health centers and seven health posts which were the study subjects engaged in the surveillance system and was selected by simple random sampling technique. The evaluation was conducted as per CDC updated guidelines for evaluating public health surveillance systems; data cleaned and analysis was done by Microsoft office Excel 2010.

Result: In seven (58.3%) of the twelve visited health facilities there were national PHEM guideline. The cases definition for malaria, sever acute malnutrition and typhoid fever were available in eight (66.6%), nine (75%) and seven (58.3%) visited health facilities respectively. Supervision was done and feedback was provided. The completeness of the system was 92.9%, and the surveillance system is useful to determine the magnitude of morbidity and mortality and was simple to accept by all professional, they do manipulate without any difficulty. Time of report received and reported was not recorded at all levels.

Conclusion and Recommendation: The cases definition was highly valuable in detecting the health condition in the population under surveillance. The surveillance system in the study area was complete, useful, simple to manipulate, acceptable by all professional, stable and timeliness at woreda level still need great due attention throughout the system.

Introduction

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]. The idea of observing, recording, and collecting facts; analyzing them; and considering reasonable courses of action stems back from Hippocrates [2]. However, the first real public health action that can be related to surveillance probably occurred during the period of Bubonic Plague (early 1300), when public health authorities boarded ships in the port near the Republic of Venice to prevent illness with plague-like illness from disembarking [3,4].

Surveillance system includes the functional capacity for data collection, analysis, and timely dissemination of information derived from those data to persons in public health programs who can undertake effective prevention and control activities [5]. Data originated from public health surveillance system can be used for immediate public health action, program planning and evaluation, and formulating research hypotheses [6]. Those functions: 1. Guide immediate action for cases of public health importance 2. Measure the burden of a disease (or other health-related events), including changes in related factors 3. The identification of populations at high risk, and the identification of new or emerging health concerns 4. Monitor trends in the burden of a disease (or other health-related events), including the detection of epidemics (outbreaks) and pandemics 5. Guide the planning, implementation, and evaluation of programs to prevent and control disease, injury, or adverse exposure 6. Evaluate public policy 7. Detect changes in health practices and the effects of these changes 8. Prioritize the allocation of health resources 9. Describe the clinical course of disease 10. Provide a basis for epidemiologic research [7].

Ethiopia had introduced Integrated Disease Surveillance (IDS) in 1996, focusing on 17 priority communicable diseases. Two years later, in 1998, the 48th World Health Organization (WHO) Regional committee for Africa adopted a resolution on integrated disease surveillance of communicable diseases. It is aimed to assist health workers to detect and respond to diseases of epidemic potential, diseases of public health importance, and diseases targeted for eradication and/or elimination through the variable effective control and prevention interventions.

Recognizing and addressing the problem of vertical disease surveillance systems, member states adopted (Integrated Diseases Surveillance and Response (IDSR) as a regional strategy for early detection and effective response to priority communicable diseases in the African region [8]. Recently federal ministry of health (FMoH) underwent the process reengineering, identifying the IDSR to be the core process to be evaluated. The IDSR was evaluated and identifying its strength and weakness, was recommended to establish Public Health Emergency Management (PHEM) as of 2009.

One of the major activities of PHEM is to take over the diseases surveillance parallel to preparedness, response and rehabilitation in any health related emergencies and outbreaks. Based on the assignment, PHEM identified 19 communicable diseases and one health problem, Sever Acute Malnutrition (SAM) based on their potential to cause outbreaks and recently added maternal death, became international concern and diseases on eradication/elimination and also health burden for the country [9].

Typhoid fever is a systemic infection caused by the bacterium *Salmonella enterica* subspecies *enterica* serotype Typhi, which is acquired by ingestion of contaminated food and water. Each year the disease affects at least 16 million persons world-wide, most of whom reside in the developing countries of Southeast Asia and Africa [10]. In Ethiopia about 790,304 typhoid fever cases were reported with 17 deaths as a result of the disease. Typhoid fever is public health problem in Amhara regions with 92,051 cases report [11].

Malaria is one of the major health problems in sub Saharan Africa. According to the 2013 world malaria report, malaria is a cause for about 627,000 malaria deaths worldwide. The report also indicates that 3.4 billion people were at risk of malaria. Most of these malaria deaths (90 %) occurred in sub-Saharan Africa and in children under five years of age. In Ethiopia there have been an estimated 10 million clinical malaria cases annually. Since 2006, however, cases have reduced substantially. On average, 60%-70% of malaria cases have been due to *P. falciparum*, with the remainder caused by *P. vivax*. *Anopheles arabiensis* is the main malaria vector [12]. In Ethiopia 1.8 million laboratory confirmed malaria cases were reported with 662 malaria deaths [11].

Malnutrition is the underlying cause of over 50 % of child deaths in developing countries. Ethiopia has a high prevalence of malnutrition in children. Based on the 2011 Ethiopian Demographic and Health Survey (EDHS), the prevalence of stunting, being underweight and wasting among under five children are 44 %, 29 % and 10 % respectively [13].

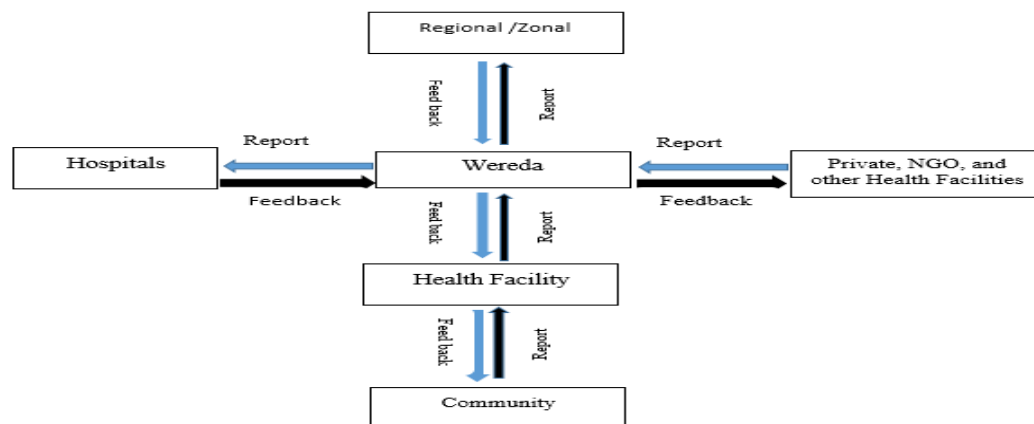


Figure 9 : Diagram illustrating the formal flow of surveillance data and information throughout the health system

The routine flow of surveillance data is usually from reporting sites to the next level up to the central level as indicated in figure 2 above. The community and health facilities especially health posts are the main source of information. The information collected from this site is compiled in standard forms, analyzed and then forwarded, to the woreda health office.

Woreda level uses standard formats to compile aggregate, and send the data to zone/region, from which the central level receives. Feedback and information sharing will follow the same route (9).

Rational of the study

Public health surveillance systems should be evaluated periodically to assure the effectiveness and efficiency of the systems. In Kombolcha town administration surveillance system evaluation was not done recently and the status of public health surveillance system was not well known. Therefore, this study was conducted to determine the status of core activities of the surveillance system, describe the specific attributes of the system and identify areas for improvements.

Objectives

General Objectives

- ❖ To evaluate the performance of the existing surveillance system of Malaria, Typhoid fever and Sever Acute Malnutrition, Kombolcha town administration, Amhara region.

Specific objectives

- ♣ To assess core activities such as case detection, registration, confirmation, reporting, epidemic preparedness and response.
- ♣ To assess supportive activities of surveillance system such as supervision, staff training, information feedback, equipment and financial support.
- ♣ To assess different attributes of surveillance system.
- ♣ To describe constraints and challenges faced in the process of implementing the surveillance system by interviewing surveillance key informants and reviewing previous registers.

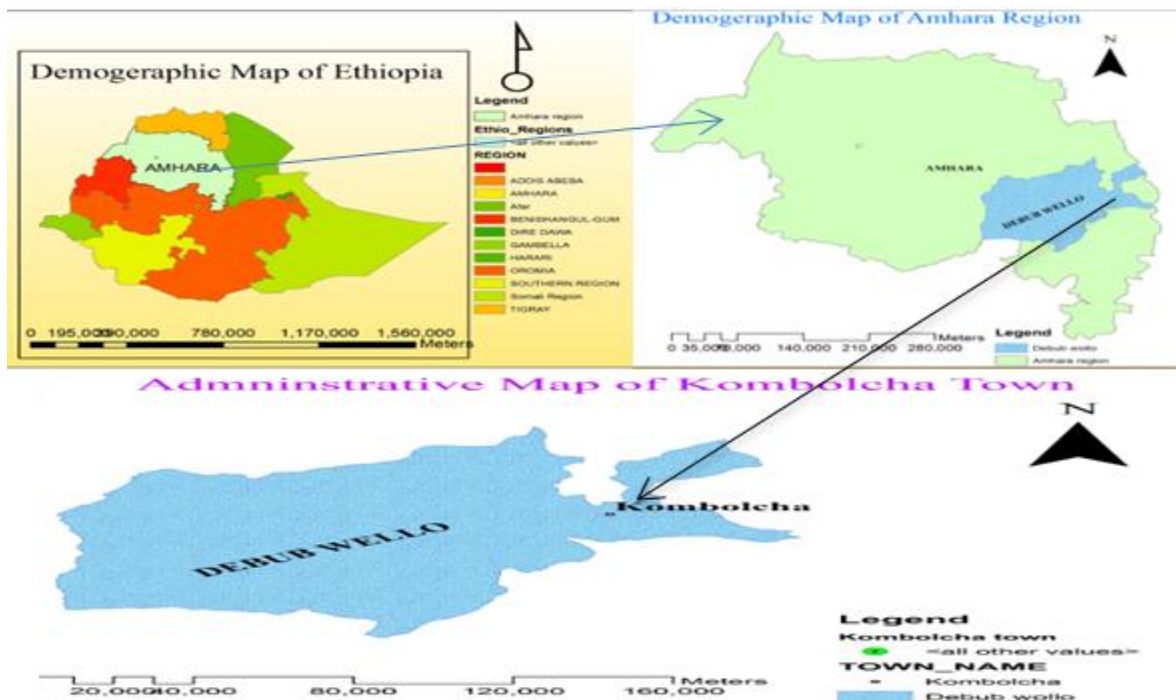
Methods

Study area:

The evaluation was carried out in Kombolcha town administration and it is located in northern Ethiopia, in Amhara National Regional State, South Wollo Zone, at a distance 377 Km from Addis Ababa, and 505 Km from Bahirdar the regional capital. Its geographical location is 11° 06' North Latitude and 39° 45' East Longitude.

According to the National Population and Housing Census carried out in 2007, the population of Kombolcha town was 58,667. Out of these 28,406 (48%) were males and 30,261 (51.58%) were females. Regarding age distribution, 18,128 (31%) were within the age group of 0-15 years, 37,349 (64%) 16-60 years, and 3,190 (5%) 61 years and above. The population growth rate at medium variant was 3.05%, while the average household size in the town was calculated to be 3.9 and the town administration has different governmental and private health facilities [15].

The woreda has 5 health centers, 9 health posts and many private clinics.



Map 3: Map of Kombolcha town administration, south wollo zone Amhara, Ethiopia, 2017.
(Source: ARC GIS)

Study design and periods: Cross- sectional descriptive study design was conducted from 18.Jan.2017-04.Mar.2017.

Study unit: The study subjects were the town administration health office and health facilities (health centers and health posts) which are engaged in the surveillance system.

Sample size and sampling technique: The selection of the zone and the woreda were based on simple random sampling (SRS); whereas town administration was selected based on the case load of the disease selected for evaluation. There were one health office, five health centers and nine health posts in the town administration considered as source population.

Thus health facilities were selected using SRS method based on the number of the health facilities available in the catchment selected study area. The town administration health office was taken conveniently as one of the sampling unit, likewise four health centers of total five were chosen by SRS and seven health posts of nine were selected as sample by SRS method.

Health care providers, PHEM focal person and health extension worker were interviewed those who were on duty during the visiting day in the visiting health facilities; the selection of health care provider and health extension worker was done by SRS as to minimize selection and information bias and the number of respondent was selected by considering the total health care staff found in each respective health facility on duty at a time and number of interviewee to be participate in the interviewing.

Data collection tools and procedures: Data was collected using Semi-structured questionnaires adopted from CDC and WHO surveillance system evaluation guideline. The tools were used to perform key informant interview of the town administration health office and facilities, PHEM focal person, Health Extension Workers (HEWs) and was interviewed by choosing randomly among those who were available at work place by the time of data collection and physical observation was made and record review (reports and log books) personal. Health facilities Selection was made on a SRS method and all health facilities (Health centers and health posts) were given equally chance to be included in the sampling and diseases under surveillance was selected purposively based on the public health importance of the disease in the study area and case load (Annex 1-3).

Data Analysis: Data was entered in to MS excel and checked for its quality then analysis was done Microsoft office Excel 2010. Data was presented by tables and graphs.

Data quality: A data collection was conducted by the principal investigator and collected data quality was monitored throughout the data collections periods.

Operational definition:

Simplicity: The simplicity of a public health surveillance system refers to both its structure and ease of operation as a surveillance system.

Acceptability: Reflects the willingness of individuals and institutions to participate in the surveillance system.

Data quality: Is the completeness and validity of the data recorded in the public health surveillance system.

Representativeness: Is the ability of the system to describe health events accurately in terms of time, place and person.

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

Timeliness: Is the ability of the system to trigger appropriate action in time.

Usefulness: Refers to the relevance of the system in terms of feeding information for action. .

Completeness: Proportion of all expected data reports that were submitted to public health surveillance.

Ethical clearance:

This work was realized based on the ethical clearance of the St. Paul's Hospital Millennium Medical College (SPHMMC); Public Health Department Ethical Review Board and Amhara Public Health Institute (APHI) and the confidentiality of the data was maintained.

Results

Socio Demographic information

The surveillance system evaluation has been undertaken in Amhara Regional state, south wollo zone Kombolcha town administration and totally one woreda health office, four health centers and seven health posts have been included in the study; but there was no hospital in the study area, it is still under construction. The total population in the town administration catchment area was 137,496 projected from 2007 national census and the number population were vary from health facilities to other health facilities within the town administration, the highest population in 03 kebele health center 52,928 and the least were registered in 07 Tulu Adami Health center with 10,326 population in catchment area and two health post namely 07 and 09 health post were found under the catchment of the 07 Tulu Adami health center.

Population under surveillance

According to the National PHEM Guideline, the total population living throughout the country is set to be under surveillance for all the twenty one priority diseases (9). Thus, the Kombolcha town administration follows the same structure, with a total population of 137,496 people to be under surveillance (projected from the 2007 national census). The number of population under the surveillance within the each health center catchments are shown below in Table 1.

Table 10: Population under surveillance of Kombolcha town administration health Centers, 2016/17

S.No	Name Health Center	Total Population (projected from 2007 census)
1	02 Kebele HC	41,801
2	03 Kebele HC	52,928
3	05 Kebele HC	32,444
4	07 Tulu Adami HC	10,326

Availability of National guidelines

In seven (58.3%) of the visited twelve health facilities there was national guideline for surveillance. But in most of the health post which specially found in very proximal to the town didn't have the national surveillance guide line except 07 kebele and 09 kebele health posts found under the catchment of Adami Tulu health center. Instead they were more stick to HEWs package guide line which contains the 16 health extension packages in town kebeles as the major activities.

Table 11: Health facilities with Public Health Emergency Management Guideline in Kombolcha Town Administration, Amhara Region, 2016/17

S.No	Name of health facility	Health facility with PHEM guideline	Health facility without manual
1	Woreda	1	0
2	Health center	4	0
3	Health post	2	5
Total		7	5

Core Activities

Case definition, Case detection and Case registration

The cases definition for malaria, SAM and typhoid fever were available in eight (66.6%), nine (75%) and seven (58.3%) visited health facilities respectively. But six (50%) of the health facilities didn't posted the case definition as the result of the recently endorsed CASH (Clean and Safe Health Environment) program. The case definitions of malaria, SAM and typhoid fever were easily understandable by the health care providers of the facilities and they were used to diagnose suspected cases of the listed diseases on their day to day diagnosing activities of the patients. The visited health facilities had standard registration but they use single registration for all priority disease which makes the data collection a bit tough. Rumor log book was found in all health centers including woreda health office; but none of the health posts had the rumor log book.

As the health supervisor and health extension worker told us the community case definition was used during community health education which helps them to induce the message easily but none of the health post had written community case definition.

Reporting

Including woreda health office 11(83.3%) of visited health facilities reported that they did not run shortage of surveillance reporting formats during the last three months. The overall completeness of the reporting health facilities was satisfactory but timeliness through the chain of reporting from health post to health center then to town administration health office of the priority disease has been hardly easy to evaluate and put figuratively; because date of received and sent was not recorded at all levels. Weekly reports were sent to woreda health office from health facilities using hard copies and cell phones. Currently, the Amhara Regional health bureau has identified 13 immediately reportable diseases and nine weekly reportable diseases; they include one additional disease known as *lishmaniasis* in weekly reportable diseases than nationally identified weekly reportable diseases because the disease is more prevalence in some areas of the region and become public health concern.

With respect to availability of some electronic material only the town administration health office used a computerized system to monitor woreda completeness and timeliness reporting, but there was no cross checking how many health facilities reported at the ground level. It has happened as a result of the woreda PHEM officer didn't have personal computer which enables him/her to manipulate the report as required.

The reporting entities that feeds report to the woreda health office were public health facilities; and reports were received from health post to health centers on Friday afternoon (some time on Monday morning) and health center compile the report received from different health post and reported to woreda health office on Monday and the woreda health surveillance officer compile the report from all reporting entities and send it to zone/ region by Tuesday up to the mid-day.

Data quality is measured by the validness of the number of cases in registration and those in reporting format, inclusion of all the necessary variables that should filled in reporting format and summary report of immediate reportable disease on weekly basis. For health facilities we counted and compared the reported malaria, SAM and Typhoid fever cases with summary report

to go to higher level and laboratory registration books for the previous one month date of report received from the next lower level, and date of report sent to next higher level, epidemic week number and inconsistency of recorded dates and the actual date of report was the missed variables, and the timeliness variable was not calculated and filled in all the report.

For malaria the total RDT (Rapid diagnostic test) and microscopic examination confirmed was 432 cases of the total annual 5628 suspected cases and but for typhoid fever there was 1520 clinical suspected and 330 widal confirmed case respectively, and for Sever acute malnutrition there was about 192 cases, the highest report received from 05 kebele health center and the least from 07 Tulu Adami health center. In spite of the high report received for all diseases and health event, there was no any death registered as an attribute of the diseases.

Table 12: The Reporting Rates under Kombolcha Town Health Office by Epi-week, Ethiopia, 2016/17

Epi week	Health Centers		Health Posts		Total	
	Expected	Reported	Expected	Reported	Expected	Reported
41	4	4	9	8	13	12
42	4	4	9	9	13	13
43	4	4	9	9	13	13
44	4	4	9	8	13	12
45	4	4	9	9	13	13
46	4	4	9	9	13	13
47	4	4	9	9	13	13
48	4	4	9	9	13	13
49	4	4	9	9	13	13
50	4	4	9	9	13	13
51	4	4	9	9	13	13
52	4	4	9	9	13	13
Average HF	12.0	12.0	9.0	8.8	13.0	12.8
Reporting Rate /Wks.		100		98.1		98.7

NB: HF=Health Facilities, Wks. = weeks

The weekly reporting rate of the woreda health office and all visited governmental health facilities in the past 12 weeks prior to assessment were 98.7% (Table 3).The overall reporting rate during 2016/17 was 92.9% for the town health office.

Data Analysis and Interpretation

Surveillance data collection either by weekly or immediately reporting system is not an end by itself; The collected data needs to be analyzed (by time place person), interpreted and used for action and decision making starting from local to the central level in order for the values of the data to be realized.

From all visited health facilities none of the staff has taken training on PHEM surveillance and most of the staffs in the health facilities they had computer skill but none of them had analysis surveillance data for either for SAM or Typhoid fever, except some performed analysis for malaria weekly to monitor its trends in all of the health centers, health office and 2(28.5%) of the health posts. They only includes total cases, deaths and activities performed and data did not described in terms of person, Place and Time which make difficult to describe and manipulate the reported data and use for intervention.

At the Woreda level, analysis of surveillance data was done quarterly, every six months and annually. This is because they were required to report for the administrative level not for real-time intervention of public health problems.

From the total visited health facilities; health office, 3(75 %) of the health centers except 07 Tulu Adami and none of the health posts had action threshold for malaria butno health facilities had for typhoid fever and SAM.

The woreda health office and all health centers had computer, but none of them used them for data entry and analysis. The woreda health office and all visited health facilities had denominators for total population, Male, Female and under five years children which are very important to calculate attack rates, geographical distribution , frequency and determine burden of disease in the study area.

Epidemic Preparedness and Response

None of the health facilities had written emergency preparedness and response plan for any of the outbreak prone diseases relevant to the area, but the health office has it as a general epidemic and response plan. The woreda health office and 90.9% of the health centers have adequate emergency stock of drugs, supplies and laboratory reagents (except in 07 Tulu Adami health center that lack laboratory reagents for Widal test). The epidemic preparedness and response

surveillance system weren't supported with pre-determined budgets line they had a trend of allocating budget after the epidemic has happened, and there wasn't Motor vehicle to support the emergency response if it occurred and in 05kebele health center the motor bicycle was non-functional because of lack repair, they lack prepositioning of the required materials prior to the event. Epidemic management committee was present in all health facilities except 09 kebele health post and Epidemic Rapid Response Team (RRT) has been formulated in all health facilities starting from the health post to the higher hierarchy health office those who had epidemic management committee, thus no one had regular meeting and there were no documents or meeting minutes found at the time of the evaluation that shows the existence and activities of the RRT at all visited health facilities; more over they only conduct meeting when there was some rumor of emergency disease. Like nationwide distributed disease acute watery diarrhea in the near past year in Ethiopia. There was no occurrence of an outbreak of either malaria or typhoid fever in the study area by the year 2016/17. The detail of emergency preparedness is shown by table below.

Table 13: Number of Health facilities and their emergency preparedness status, Kombolcha Town administration, Amhara, Ethiopia, 2016/17

Variables	Woreda health office (N=1)	Health centers (N=4)	Health posts (N=7)
Availability of Written emergency preparedness plan	1	0	0
Availability of emergency stocks of drugs and supplies	1	4	0
Experienced shortage of drugs during in the past year	0	0	0
Presence of budget line for epidemic response	0	0	0
Observed epidemic management (RRT) meetings minutes	0	0	0
Presence of epidemic management committee	1	4	6
Established Rapid Response Team (RRT)	1	4	6

Feed back

The woreda health office and health center provide feedback to the lower level in regular way without interruption in written and some time through written and orally too during their supervision down the level but there wasn't any bulletins provided from the woreda health office to health center and health post.

Supportive functions

Training

Based on the data collected from the interviewee from the health office and the health facilities no one health professional had training opportunity on PHEM surveillance system of neither malaria nor typhoid fever but some had got short term training for SAM by the year 2016/17, obviously it has impose a lot of impact on their practice, that was identified as one of the reason not to do data analysis of the surveillance report in all of the health facilities. But few professional in some health facilities had got infection prevention training in spite of there was medium attrition of trained staffs. About 48.3% of laboratory personnel have got malaria microscopic training and no any for typhoid fever.

Supervision

The woreda health office and health center PHEM focal person had supervision plan and accomplished their duties as per set plan. The woreda health office down to the level health centers and health post; likewise health centers down the level to health post conducted supervision in the year 2016/2017 and the town health office supervised all health centers, health Posts and four times during the same year. Written documents were available or used during the supervisory visits by the supervisor of health office and health center. Regional and the town health department provide feedback to their reporting units.

Communications Facility

The communication facilities available in most of the health facilities were wired and mobile phone, only the health office had E-mail access to send result to next regional level.

Resource of the Facilities and coordination

Surveillance focal persons were available in all Health Centers and health office but especially in health center the surveillance focal person wasn't assigned only for surveillance activities in addition they did their routine clinical duty. Resources like computer with printer, motor cycles, stationeries, telephone for data management, and logistics are available in the town health office. They were not fairly distributed in the rest of the health facilities. Most respondents have risen as the shortages of vehicles remain an inherent challenge which significantly affected the surveillance system and they urge the concerned bodies to pay due attention.

Table 14: Availability of resource needed for surveillance activities, Kombolcha Town Administration, Amhara, Ethiopia 2016/17.

S.no	Material	Town health Office	Health Center	Health Post
		(N=1)	(N=4)	(N=7)
1	Electricity	1(100)*	4(100)	7(100)
2	Computers	1(100)	4(100)	0(0)
3	Printer	1(100)	4(100)	0(0)
4	Stationery	1(100)	4(100)	7(100)
5	Vehicles (Ambulance)	1(100)	4(100)	NA
6	Motorcycle	1(100)	2(50)	NA
7	Bicycle	0(0)	0(0)	7(100)
8	Fax	1(100)	4(100)	0(0)
9	Wired Telephone	1(100)	4(100)	0(0)
10	Calculator	1(100)	4(100)	7(100)

* Numbers in the parenthesis indicates percentage (%).

Surveillance System Attributes

Completeness

Completeness of reporting sites refers to the proportion of reporting sites that submitted the surveillance report irrespective of the time when the report was submitted. Hence, the percentage

of completeness of reporting sites in the Town was 92.9 % in 2016/17. Low report was 81.1% from July to September 2016/17.

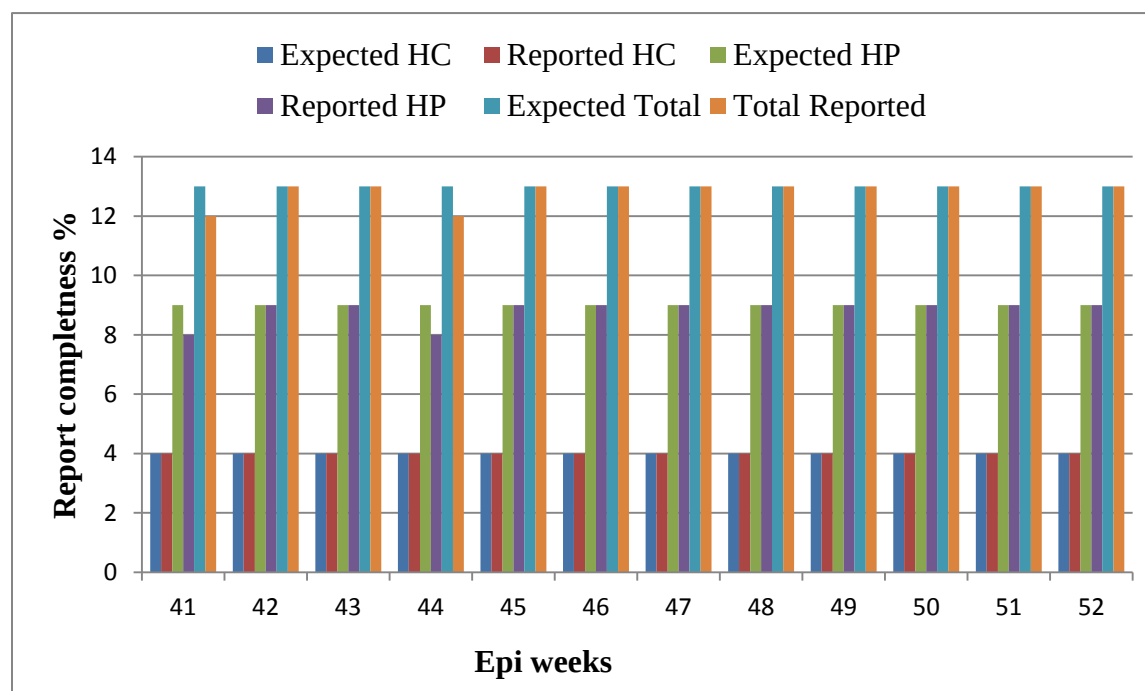


Figure 10: Completeness of weekly report (October –December) by types of health facility at Kombolcha town, Amhara, Ethiopia, 2017.

Timeliness

Timeliness reflects the speed between steps in a public health surveillance system and the single most important measure of timeliness is whether data are submitted in time to begin investigations and implement control measures. Thus, timeliness of reporting was not measured according to the National PHEM Guidelines due to absence of date of receipt and date of report. According to the findings the surveillance report Timeliness of the town was 100% in the last three months (October-December 2016/17) as per the town health office surveillance focal person because of accessibility and availability of transportations and telecommunications in the Woreda favor for the soft root of report delivery. Late reports are less important for Public health emergency management. Kombolcha town which was at moderate risk for malaria and typhoid fever, timeliness of report was very important to find out abnormal increases in the number of cases and to take immediate actions as required.

Usefulness

As the respondents from all visited facilities confirmed that the surveillance system is helpful for early case detections and based on the information initiate actions in timely manner to prevent epidemics. And claimed that the surveillance system is useful to determine the magnitude of morbidity and mortality by doing epidemiological investigation due to diseases under study in the community, in addition to that, it is important to assess the effectiveness of prevention and control programmes for the selected priority diseases. It also helps to determine that an adverse health-related event previously thought to be unimportant is actually important. The data from a surveillance system can be useful by contributing to performance measures, including health indicators of the selected priority disease that are used in needs assessments and accountability systems. Both governmental and non-governmental organizations have used the data to make decision and take action. But the surveillance system guideline was not distributed to all the health facilities especially the health posts. The continuous monitoring of the surveillance data enabled to follow the status of the priority disease in the study area.

Simplicity of the system

The simplicity of a public health surveillance system refers to both its structure and ease of operation; thus the surveillance system was examined to see how case definitions of priority diseases are simple, easy and understandable and helpful for data organizing, entry and data analysis. All respondents agreed that the case definitions for all selected priority diseases are easy to understand and allow all health professionals to fill it. In addition the system is so convenient and helps to record and report data on time but the standard case definition wasn't found in accessible place to be used by all health professional and the community based case definition was used during the provision of health education for the communities health extension workers. The time it takes to fill the data in the format is very negligible and the turnaround time it will take up to 30 minutes to perform laboratory confirmation for malaria and less than 20 minutes for typhoid fever.

Acceptability

The acceptability of a surveillance system for early outbreak detection is reflected by the willingness of participants and stakeholders to contribute to the data collection and analysis. The entire health professional along from the health office down to health post including surveillance

focal person assured the importance of the system for public health intervention. All health facilities were totally involving in the surveillance activities. Every health professional staff were contributing by their day to day endeavors to realize the surveillance system but the point that has been collected from all respondents has revealed that lack of training on PHEM surveillance system remain one the basic challenge by then. But in few health facilities the health professionals weren't using the standard case definition since it wasn't been posted as a result of the recently endorsed CASH which contradicts with the system in some ways they were not allowed to post any paper on room walls. I had reviewed the document that, all reporting agents' health post to health center and next health center to health office were sent their report using the standard and appropriate reporting formats.

Flexibilities

The flexibility of a surveillance system refers to the system's ability to change as needs change. All interviewee from visited health office and health facilities declared that the reporting formats and procedures were flexible and could be used for other newly emerging health events (diseases) without much difficulty and it can adapt to changing information needs or operating conditions with little additional time, personnel, or funds. This is due to the availability of a blank column for others which enables customize the formats for any new occurrence health event. All respondents reiterate that the surveillance systems are easy to integrate with other systems. They agree that any change in the existing procedures of case detection and reporting wouldn't be as such challenging.

Data Qualities

Data quality reflects the completeness and validity of the data recorded in the public health surveillance system. The reporting format from the visited health facilities showed that the format was complete except the fact that, timeliness variable was not calculated and filled in the entire report format. The percentage of "unknown" or "blank" responses to items on surveillance forms was small except timeliness variables. The types of reagent and instruments used to diagnosis both malaria and typhoid fever was so good quality and during supervision that was also assessed by zonal laboratory; all those have granted the system quality to be maintained. The recorded data was clear to understand and was written legible. As one of the challenge the

register book used in the outpatient department and in patients department was the same for all priority disease. But here the time of data received and reported, blank space in the reporting space was not filled with zero value and copy of report was not available in health posts and few health centers.

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. In addition representativeness shows how far the routine surveillance report is covered by the health service delivery system and how many facilities are reporting to the offices. The health service coverage of the town was 100% .In Kombolcha administrative health offices, about 71.4% of the health post were found on the near surround of the town integrated with the kebele and the rest located on the periphery among the visited sites. The typhoid fever examination for the clients found in the periphery wouldn't be accessible as that of found mid the town in that cases the HEWs were referring the suspected patients to the health facilities with better diagnostic capacity. Rapid diagnostic kit was provided to the peripheral health post health extension workers and for SAM all the health post and health centers were working with very high passion. But in general speaking the surveillance system enables to follow health and health related events in the whole communities on the meantime the data helped to accurately project the incidence of the disease in the population under surveillance and which pragmatically helps to declare the representativeness of the surveillance system.

Stability

It is the ability to collect, manages, and provides data properly without failure and the ability to be operational when it is needed for the public health surveillance system. The stability of a surveillance system is also its resilience to system changes (e.g., change in coding from International Classifications of Disease, Ninth Revision [ICD-9] to ICD-10). Stability can be demonstrated by the duration and consistent operation of the system.

According to the respondents from all facilities the new system restructuring BPR (Business Processing and Re-Engineering) didn't affect any procedure and activities, the PHEM focal persons were collecting the data from the health facilities through different means of

communication; except the fact that there was no exclusive budget allotted for the surveillance system, data collected and kept in the computer data pool available when required and computer was not stacked and get out of function, none of them had lack of the resource which forces to stop the surveillance system and it was fully operating by the year 2016/17.

. Predictive value positive

Literarily the predictive value of positive is the proportion of reported cases that actually have the health-related event under surveillance. A total of 5628 malaria suspected cases in the study period of those 199(3.5%) and 168 (2.9%) positive case of plasmodium falciparum and plasmodium vivax respectively have been confirmed either with RDT or microscopically. The highest and the least malaria suspected cases were reported from 03 kebele health center 2184(38.8%) and 260 (4.6%) from 07 Tulu Adami health center respectively.

With regard of typhoid fever a total of 1520 cases were suspected and 330 (21.7%) were confirmed positive according to data found from the report and reviewed registration

Positive Predictive Value (PPV) for malaria = Total confirmed cases by laboratory / Total suspected cases diagnosed in laboratory for confirmation

$$=367/5628*100$$

$$=6.5\%$$

PPV for typhoid fever = Total confirmed cases by laboratory/ Total suspected cases diagnosed in laboratory for confirmation

$$=330/1520*100$$

$$21.7\%$$

This report for both of the disease has been collected from four health centers and from two health post (malaria only).The PVP helped the system in monitoring the threshold level of the disease particularly malaria and was used as a best key look for any unusual increment in the priority disease.

Laboratory

All health centers have the capacity to collect and transport biological specimens such as: blood stool...to the zonal laboratory found at Dessie accompanied with reporting format for further analysis and confirmation. But the laboratory professionals have claimed that they were not involving in surveillance system although the data obtained from laboratory was very valuable. Four of (100%) health centers were involving in EQA (External Quality Assessment) for malaria and Tuberculosis. And only 3(75%) of the health centers were doing Widal test for typhoid fever laboratory confirmation except 07 Tulu Adami health center. Laboratory in all visited health centers had SOP (Standard Operating Procedures) and other manuals for malaria and Typhoid fever. Feedback from the woreda office has been received and I did a physical observation for the existence of the document.

Discussion

Surveillance system evaluation is an important tool to assess the capacity of the system to meet its intended purpose and objectives; to improve its operation and to optimize the available resources utilization (9). Since the establishment of PHEM as core process at all level of the health sectors during the restructuring of health system by Business Process Re-engineering (BPR) significant achievements were recorded on health surveillance activities (9). Moreover the starting of field epidemiology training Programme in Ethiopia at different universities has also contributed a significant role in the improvement of the surveillance by producing qualified human resource for the system and also when the residents evaluate the surveillance system in different area of the country that also remain the building block for the renaissance of the system.

The existence of the case definition for the country and regional public health priorities disease is mandatory in one health facilities which used as guiding tools to the health professionals in order to easily identify and diagnosis the disease. But in the visited health facilities the case definition for SAM and typhoid fever has been found in 75% and 58.3% of the health facilities respectively which is very significant gap that we observed and it is a must to be there in every facilities because its consequence will potentially miss leading and under investigation of cases would be prevailed. Likewise the case definition need to be posted in patient examination rooms in near distance from the sitting chair, since the physician or the health professionals should not have to rely on his/her memory for every disease case definition. Similarly the registration that are being used in the both the outpatient department(OPD) and inpatient department (IPD) were standard but they were registering all priority disease in single similar registration and it make the data retrieving a bit tough. Hereby it would be good if a separate standard registration book is used in the future. However, it is worth repeating that it is not an easy task to set up an adequate disease register and many less than successful attempts have been made to address the problem by different stakeholders to make the system more accessible.

According to the PHEM guide line a community based case definition has been used as an alternative method of diseases identification which increases the sensitivity of diagnosis which was basically used by HEWs during community health education, and it is a good experience it needs to be increasingly maintained.

The total number of cases and deaths occurred within the week (Monday to Sunday) needs to be reported; from the health facilities to district health office every Monday till midday, from the district health office to zone/region level every Tuesday till midday, from zonal health office to region every Wednesday till midday, then from the regional health bureau to national PHEM every Thursday and finally from the FMOH to stakeholders every Friday (9). Thus the health facilities in study site were founded be to following the same days to send the report to the next PHEM levels as the preset standard, it need to kept and remain accustomed since it helps for prompt intervention to any subversive tendencies. The reporting date and use of reporting format for cases from health facilities to town health office were using according to the National PHEM Guide line, even though there were some missed blank space and all health facilities reported on weekly bases with weekly reporting formats for the selected diseases.

Most of the interviewee have responded that they didn't had had any training opportunities on PHEM surveillance for any of the selected disease by the year 2016/17 and they said they are supposed to work without having an update training and they didn't had any opportunity to have personal computer even as a department division even though most of them had the know-how and skill to computer , as all knows people might have the basic knowledge about surveillance during schooling but it is good to have an update training in order to enhance the working environment and escalate the passion of the professional. Nevertheless, none of the facility staffs and office did analyzed the data by Place, Person and Time but the ultimate objective of surveillance is not to have a pack unread report rather it need to be manipulated and presented briefly in terms of descriptive variables, that was the bolded gap seen in all visited sites. Analysis of routine data provides information for predicting changes of disease rates over time and enables appropriate action, disease rates change over time; some of these changes occur regularly and can be predicted such as an increase of malaria cases following the rainy season. Analysis and use of the trends in summary data over time provides information for improving prevention activities. Moreover, during an acute epidemic of a disease or condition the information that is generated from data analysis leads to the identification of the most appropriate and timely control actions and the actions are taken immediately to limit the epidemic and prevent further cases from occurring (9). Data analysis and interpretation should be done daily and weekly at each level where data are collected starting from health facility level to national level.

Epidemic preparedness and response is existing level of preparedness for potential epidemics (emergencies) and includes availability of preparedness plans, stock keeping, designation of isolation facilities, setting aside of resources for outbreak response (9). The purpose of preparedness is to strengthen capacity in recognizing and responding to public health emergencies through conducting regular risk identification and analysis, establishing partnership and collaboration, enhancing community participation and implementing community-based interventions and strategic communication during the pre-emergency phase and ensuring their monitoring and evaluation (1).

Epidemic preparedness and response remain the back bone for the existence of surveillance system. With the same speaking pre demarked plan for the epidemic preparedness and response play a vital role for system , but except the woreda health office the rest of facilities do not have emergency plan and there were no any shortage of resource they faced by the study time. That was because of the chain of procurement of the drugs, regents and other essential materials are availed in timely manner which is the strongest side of the peoples assigned on the managerial area. Emergency management committee has been formulated in nearly all health facilities and RRT has been also ready, but the habit of conducting meeting following the occurrence some rumor need to be corrected and un interrupted regular meeting schedule has to be prepared and the meeting minute must be kept as an archive, meanwhile the woreda health office has to use their effort to fill the gap of the health facilities in preparing plan for emergency preparedness and response.

The health facilities has to visited and supervised by the immediate higher facilities as per the schedule in order to provide both technical and managerial support to the lower level which helps to identify the potential challenge and opportunities present in each respective area (15). Health office and health center had conducted four times supervision down in their catchment area by the year 2016/17 and that had given a chance to see the possible point. It provides an opportunity to the heads to have a tangible image but here lack of training on surveillance system remain the deep rooted set back.

Complete, timely, and accurate reporting is the foundation of a country's surveillance system. Completeness and timeliness are key indicators of reporting performance. These are defined as the proportion of expected reports received (completeness), and the proportion of expected

reports received on time (timeliness). Reports were considered late if they had not been received by the established deadline (due to the second day (Tuesday) of the following week at regional level, Monday from facility to district level) (9).

The frequency of unknown or blank responses to data items in the system can be used to measure the level of completeness. For systems that update data from previous transmissions, time should be factored into measurement by indicating the percentage of records that are complete (i.e., all variables are captured for a record) on initial report and within an appropriate interval (e.g., 48 hours) of submission. Sites with substantial reporting delays can be flagged for reliability concerns and targeted for improvement (1). The overall completeness of the report was 92.9% which is much more achievement as compared with the target plan 80% and more effort needs to enforce all sites to report and include all health facilities in the system to smash 100% reporting rate.

The timeliness of the surveillance report was not founded in the way possible to put it in crude figure, that was as a result of the time of report reported and received were not registered. The data quality also most in need of improvement, because many blank spaces were observed for necessary variables of the report in most of the visited sites. Even if weekly malaria trend analysis were performed by the majority of the sites.

In general speaking the surveillance system of the town administration was simple, flexible and useful. Attributes that require attention for improvement of surveillance process were data quality and timeliness.

On the recent era of health system, all health facilities laboratory starting from health center has to involve in the EQA. About 75% of health centers have been actively participating except 07 Tulu Adami. But all of the health centers need to involve in external quality assurance.

Limitation

- ❖ All the health facilities need to be included in the evaluation but two governmental health post and private health facilities has been excluded from the evaluation.
- ❖ The timeliness of the report were not addressed in the evaluation because of the time of report received and reported were not registered.
- ❖ Sensitivity and specificity was not addressed.

Conclusion

The cases definition was highly valuable in detecting the health condition in the population under surveillance; data was captured and was registered with standard registration book. Supervision was done by their immediate supervisor and communication between the respective health facilities, provision of feedback had smashed with good achievement and the availability of the most basic tool and logistic for the surveillance system was more or less available; in contrary training opportunity on PHEM surveillance system was apparently low and data analysis wasn't done across all facilities and epidemic preparedness and response plan in most of the health facilities was overlooked. The surveillance system in the study area was complete, useful, simple to manipulate, acceptable by all professional, stable but the timeliness of the reported data was not addressed throughout the visited health facilities.

Recommendation

- Written emergency preparedness and response plan should have to be prepared at all levels of surveillance system [Kombolcha town health office {KTHO}, HC & Health posts(HP)].
- Specificity and sensitivity of the system need to be addressed [KTHO]
- The time of report received and sent need to be filled in the reporting format at health office and blank report has to be corrected by writing zero(for null report),[KTHO].
- All the health facilities should have RRT and uninterrupted pre scheduled meeting should be conducted by documenting the meeting minutes too, [all health facilities].
- All Laboratories in the health facilities should be equipped with the required laboratory regents especially in 07 Tulu Adami Health centers,[KTHO].
- Continual training on PHEM surveillance has to been given to all the concerned staff,[APHI, KTHO].
- Data analysis has to make at all levels of the hierarchy for all selected public health priorities disease by Person, Place and Time and interpreted to be used for action and decision making by all levels of the system [all health facilities].
- The necessary logistic and resource has to be fulfilled and repair exhausted motor bicycles, [KTHO].
- Health facilities should have to avail standard and community case definitions of public health important diseases for health personnel and the community respectively and the standard case definition need to post in both OPD and IPD, [all health facilities].

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Annex 3: A semi-Structured questionnaire for priority disease surveillance system evaluation, 2017

Introduction: My name is Lezhialem Almaw; I have been working in Amhara public Health Institute as Field Epidemiology Resident and I would like to conducting Surveillance system evaluation of Country's priority diseases surveillance (for malaria, Sever acute malnutrition and typhoid fever) in Kombolcha town administration and I want to discuss with informant people who are being working in surveillance system in health office and health facilities .The aim of this evaluation is to evaluate objectively how the system is functioning and whether the intended objectives are being met and recommendations will be drawn to improve the overall system.

Finally I thank you prior for your cooperation.

QUESTIONNAIRE FOR WOREDA HEALTH OFFICE

1. Background Information

1.1. Region_____

1.2. Zone _____

1.3. Woreda _____

1.4. Name of Health Facility _____

1.5. Respondent Name and position _____

1.6. Catchment Population _____

1.7. Address: Office no _____ Cell phone no _____ e-mail _____

1.8. Date_____

2. Case Detection

2.1. Do you have standard case definitions for the Country's priority diseases (Malaria, Typhoid Fever and Sever Acute Malnutrition)? 1. Yes 2. No

2.2. If yes, is it posted? 1. Yes 2.No

2.3. Does all professionals are aware of it? 1. Yes 2.No

2.4. If answer for 2.1 is No, for which disease(s) did you lack the case definition?

2.5. **Personal observation** about presence of standard case definition for selected priority health problems_____

3. Case Registration

3.1. Do you have a standardized register and rumor log book to record minimal data elements on targeted diseases and conditions? 1. Yes 2.No

3.2. **Personal observation** about presence of standard registers, Rumor log book for selected priority healthproblems_____

4. Reporting

4.1. Did you have standard reporting forms recommended for the country's priority diseases (Malaria, Typhoid Fever and Sever Acute Malnutrition)?

1. Yes 2. No

4.2. What are the reporting entities for the surveillance system?

1. Public health facilities 2.NGO health facilities 3.Private health facilities

4.Military facilities 5. Others_____

4.3. Did you send surveillance data to the next level? 1. Yes 2.No

4.4. Was there any report of the immediately reportable diseases in the past one year?

1. Yes 2. No

4.5. If yes, with in what time is the report received after detection of the case/ diseases?
a. Less than 1hour b. 2-24 hour c. 1- 2 days d. 3- 7 days
e. After1 week

4.6. When are you expected to send weekly report to the next PHEM unit?

1. Monday 2.Tuesday 3.Wednesday 4. Thursday
5. Friday 6. Saturday 7.Sunday

4.7. When are you expected to receive weekly report from the lower level?

1. Monday 2.Tuesday 3.Wednesday 4. Thursday 5.Friday
6. Saturday 7.Sunday

4.8. Number of health facilities reported for the last one year compared to expected number

1. Health centers _____
2. Health Posts _____
3. Hospitals _____

5. Data analysis and interpretation

5.1. Had you trained on surveillance system? 1. Yes 2.No

5.2. Did you have computer? 1. Yes 2.No

5.3. Is it functional? 1. Yes 2.No

5.4. Did you have computer skill? 1. Yes 2.No

5.5. Did you analyze surveillance data of priority diseases? 1. Yes 2.No

5.6. For which Country's priority diseases have you analyzed the data?

5.7. Did you use computer to analyze these surveillance data? 1. Yes 2.No

5.8. If answer for 4.8 is yes, did you describe data by time, place and person? 1. Yes 2.No

5.9. How often do you analyze the collected data? 1. Daily 2.Weekly

3. Every 2 weeks 4.Monthly 5. Quarterly 6.As needed
- 5.10. Did you notify the results of your analysis to the next level? 1. Yes 2.No
- 5.11. Did you have denominator for data analysis? 1. Yes 2.No

5.12. Did you have an action threshold defined for Country's priority diseases (Malaria, Typhoid Fever and Sever Acute Malnutrition)? 1. Yes 2. No

5.13. **Personal Observation** about the presence of demographic data (E.g. population by district and hard to reach group), Data presentation and defined action threshold

6. Epidemic Preparedness

- 6.1. Was there written plan of epidemic preparedness and response? 1. Yes 2. No
- 6.2. Has the district had emergency stocks of drugs, vaccines, and supplies at all times in past 1 year? 1. Yes 2. No
- 6.3. Was there a budget line for epidemic response? 1. Yes 2.No
- 6.4. If yes, Amount in ETB_____
- 6.5. Source of Budget 1.GOV 2. NGOs 3.Othres_____
- 6.6. **Personal observation** for presence of plan of epidemic preparedness and response
-

- 6.7. Was there contingency stock for the past 3-6 months? 1. Yes 2.No
- 6.8. Was there IEC (information, education and communications) materials and activities necessary for epidemics preparedness and response? 1. Yes 2.No

7. Outbreak Response and Control

- 7.1. Was an epidemic management committee built in your office? 1 .Yes 1.No
- 7.2. If yes for Q 8.1, did the epidemic management committee have regularly scheduled meeting time? 1. Yes 2.No

7.3. Did the district have a rapid response team for epidemic? 1. Yes 2. No

7.4. **Personal observation** for presence of plan of epidemic preparedness and response

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

7.6. List the diseases: _____

7.7. Of those, number investigated: _____

7.8. Number of outbreaks in which risk factors were looked for: _____

7.9. Number of outbreaks in which findings were used for action: [observe in reports] _____

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

7.11. Did you have line list for reporting outbreaks? 1. Yes 2.No

8. Feedback

8.1. Did you provide Feedback to lower level? 1. Yes 2.No

8.2. How did you give your feedbacks? 1. Oral 2.Written 3.Others

8.3. Were there any bulletins or reports received from the next higher level? 1. Yes 2.No

8.4. **Personal Observation** about the existence of a report or bulletin that is regularly produced to disseminate surveillance data or received from next higher level:

9. Availability of a National Surveillance Standards and Guidelines

9.1 Are there national guidelines and standards for surveillance? 1. Yes 2. No

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

9.3. Did you have case management protocol for epidemic prone diseases? 1. Yes 2.No

9.4. **Personal observation** about the presence of National Guidelines and Manuals

10. Training

10.1. Did you take training on priority diseases (Malaria, Typhoid Fever and Sever Acute Malnutrition) surveillance within the last year?

1. Yes 2.No

10.2. If yes for Q 11.1, for which Country's priority diseases have you trained?

10.3. If yes for Q 11.1, how many staffs were trained? _____

10.4. What percent of your subordinate personnel have been trained in surveillance and epidemic management? _____

11. Supervision

11.1. Did you have supervision plan? 1. Yes 2.No

11.2. Did you conduct supervision based on your plan? 1. Yes 2.No

11.3. If yes for 12.1, how many times did you supervise? _____

11.4. How often you supervise? _____

11.5. Did you have supervision checklist? 1. Yes 2. No

11.6. Personal observation for presence of supervision reports_____

11.7. If not for Q 12.1, the most usual reasons for not making all required supervisory visits

12. Communication facility

12.1. Which communication material did you have? 1. E-mail 2.wired phone
3.Mobile 4. Radio fax 5.other-----

12.2. How do you send the data to the next level?

1. E-mail 2.Telephone 3.Fax or radio 4. Others _____

12.3. Did you have address of Health Centers and Hospitals PHEM officers?

1. Yes 2.No

13. Resources of the Facility

13.1. Are resources like computer with printer, motor cycles, stationeries, telephone for data management, and logistics available in the District Health Office? 1. Yes 2. No

14. Co-ordination

14.1.is there a focal unit for surveillance at the District level? 1. Yes 2. No

14.2. **Personal observation** for the presence of organogram of FMOH to confirm

Surveillance Attributes

15. Completeness

15.1. Did all selected sites report at expected time? 1. Yes 2.No

15.2. Was all surveillance data completed? 1. Yes 2.No

15.3. **Personal observation**_____

16. Timeliness

16.1. Did the surveillance data received on time? 1. Yes 2.No

16.2. Did you report the surveillance data to the next higher level on time? 1. Yes 2.No

16.3. Did you encounter any outbreaks suspected in the past year? 1. Yes 2.No

16.4. If yes for Q 17.3, within how many Hrs/Days did you notify to the next higher level?

16.5. If yes for Q 17.3, within how many Hrs/Days did you verify it? _____

16.6. **Personal observation**_____

17. Usefulness

17.1. Did the suspected outbreaks detected early by the surveillance system?

1. Yes 2.No

- 17.2. Did the response initiated in a timely manner? 1. Yes 2.No
- 17.3. Was any epidemiological investigation conducted? 1. Yes 2.No
- 17.4. For what purposes did you use the surveillance data?
-

18. Simplicity of the system

- 18.1. Was the case definition of each priority disease (Malaria, Typhoid Fever and Sever Acute Malnutrition) easy? 1. Yes 2.No
- 18.2. Did the system allow all levels of professionals to fill data? 1. Yes 2.No
- 18.3. Did the system help to record and report data on time? 1. Yes 2.No
- 18.4. How long does it take to fill the format for each disease? _____
- 18.5. How long does it take to have laboratory confirmation? _____

19. Acceptability

- 19.1. Did you believe the surveillance is important for public health intervention?
1. Yes 2. No
- 19.2. Did you think the reporting agents accept and well engaged to surveillance activities?
1. Yes 2. No
- 19.4. If yes, how many are active participants in your health office? _____
- 19.5. If No, what is the reason for their poor participation in the surveillance activity?
-

- 19.6. Were all the reporting agents send their report using the current and appropriate surveillance reporting format? 1. Yes 2.No

20. Flexibility

- 20.1. Can the current reporting formats be used for other newly occurring health event (disease) without much difficulty? 1. Yes 2.No
- 20.2. Did you think that any change in the existing procedure of case detection and reporting format will be difficult to implement? 1. Yes 2.No
- 20.3. Was the system easy to add new variables? 1. Yes 2.No

- 20.4. Was the system easy to integrate with other systems? 1. Yes 2.No
- 20.5. Was the system easy to add new disease on report? 1. Yes 2.No

21. Data quality

- 21.1. Was all reported forms Complete? 1. Yes 2.No
- 22.2. Percentage of unknown or blank responses to variables from the total reports of 2016
Sex ____ Age____ Region ____ Zone ____ Woreda ____
other_____
- 21.3. Was the recorded data clear to read and understand? 1. Yes
2.No

22. Representativeness

- 22.1. Was the surveillance system enabled to follow the health and health related events in the whole community? 1. Yes 2. No

23. Stability

- 23.1. Was any new restructuring affected the procedures and activities of the surveillance?
1. Yes 2. No
- 23.2. Was there lack of resources that interrupt the surveillance system? 1. Yes 2. No
- 23.3 Was there any time /condition in which the surveillance was not fully operating?
1. Yes 2. No

Chapter IV: Health Profile Description

Woreda Health Profile Description Assessment, Jabi Tehnan Woreda, Amhara Region, Ethiopia, 2007 EC

Abstract

Background: Health profiling is vital for prioritizing prominent health and health related problems of the community. It is basic for planning and for appropriate intervention; and is an entry point for operational research. In Jabi Tehnan Woreda, there was no organized and well documented community health profile at one place. This document presents a comprehensive health and health related information for Jabi Tehnan Woreda sectors and other health partners will clearly understand the woreda communities' health need from this document.

Objective: To assess and describe the current health profile of Jabi tehnan woreda and to compile and simplify health information, for priority setting, communicate local burden of disease in well-made and accessible document, May 2008 EC.

Method: A descriptive cross sectional study was conducted to assess and describe the current health profile of Jabi Tehnan woreda, Amhara, from 15 May–June 15, 2008 EC. Health and health related data were collected using standard check list by interviewing and reviewing medical records in the Woreda.

Result: The total population of the woreda in 2007 E.C was estimated to be about 214,763. The physical health coverage in the woreda was 100%. There were nine governmental health centers, 14 private health facility & 39 health posts. ANC visit achievement of at least one visit was 10113 (142%). Proportion of skilled delivery was 4153(58%). The leading cause of outpatient visit in the woreda for both adult and under five age group was Acute febrile illness (AFI) which account 13,029(19.96%) and 4,171(21.46%) for adult and under five age group respectively.

Conclusion and Recommendation: AFI was the leading cause of morbidity in the district both in adult and under five outpatient departments. The woreda had stepped an excellent achievement in maternal and child health.

Introduction

Back ground.

Health profile is a summarized auditing and discussion of health related data and important health related indicators to describe the health and related social, economic, political and cultural factors in the geographic area under discussion [1]. It is essential tool for change and thus must be a core element of local decision-making and strategic planning processes. The preparation of a profile provides a lively, scientifically and evidence based account of health in the woreda; it can stimulate public interest and political commitment; and it can identify targets for the future and monitor progress towards them. Data generated from health profile has very crucial role in priority setting, resource allocation, identifying gap of health event and future planning. Objective of this study is to assess health, health related events and health determinants of the woredas population and to identify health issues of public concern and the gaps to take possible interventions.

It is vital for prioritizing prominent health and health related problems of the community. It is basic for planning and for appropriate intervention; and is an entry point for operational research. Stakeholders of health and health related issues will have access to evidence-based information from well compiled health profile. Health Profiles is a Programme to improve availability and accessibility for health and health-related information. Health Profiles provide summary health information to support local authority members, officers and community partners to lead for health improvement [2]. It is common knowledge that the health and socio-economic well-being of people are fundamentally linked to their natural and built environment [1, 3].

A community health profile includes both previously identified health issues and the identification of new, emerging issues. A comprehensive community health profile includes: A narrative description of the given community, community strengths and challenges, demographic and economic data, health status data, community resources, including services, coalitions, and systems and interpretation of data presented, from both the perspective of the health council and the broader community. However, in low income countries like Ethiopia, such information especially at Woreda level is usually not complete and not comprehensive. The Woreda Health Profile will include an environmental health report that will outline environmental health

indicators such as disease and injury prevalence, health hazard types and trends, and other emergent environmental factors that impact human health.

In Jabi Tehnan Woreda, there was no organized and well documented community health profile at one place. Different health and health related data were available at different processes of the woreda in disorganized situation in such a way that no one can access and use these data at the right time and place. This document presents a comprehensive health and health related information for Jabi Tehnan Woreda sectors and other health partners will clearly understand the woreda communities' health need from this document. So, having this document, governmental and non-governmental health stakeholders working for the woreda communities' could have evidence based information for prioritizing and instituting appropriate public health interventions.

Therefore this project work hopefully create an opportunity to access of compiled health and health related issues of the woreda for planning, prioritizing health program and health related problems and in order to them in one document for users.

Rationale of the study

Health profile are designed to give an easily accessible snapshot picture of the community's health. The planning and management of health services in developing countries often proceeds within an environment of inadequate information about the health status of the population served and the occurrence of important determination of health. This is particularly the case at the woreda level where health service have traditionally underdeveloped and information system lacking. In Ethiopia, particularly at the woreda level an organized health and health related indicator which determine the health status of the community is scarce and these contribute a gap in planning and taking evidence based information for action. In Fenote selam woreda health profile was not done before and also there is no organized health and health related information.

Health profile generates data that are useful and useable at the community level

Therefore describing the health profile of the Woreda is helpful to give evidence based information for prioritizing and instituting appropriate public health interventions in the Woreda.

Objectives

General objectives

To assess and describe the current health profile of Jabi tehnan woreda and to compile and simplify health information, for priority setting, communicate local burden of disease in well-made and accessible document, May 2008 EC.

Specific objectives

- To provide a broad overview of the social, economic, demographic and geographic determinants health status of the community of Jabi Tehnan woreda
- To assess primary health care coverage of the Woreda
- To identify priority public health problems.
- To describe existing health infrastructure of the Woreda
- To assess and describe health related issues about health status and health indicators

Method:**Study area and populations**

The study was conducted at West Gojjam Zone Jabi Tehnan woreda which is situated in the Amhara National Regional state (one of the nine regional states of Ethiopia) at 376 k.m away from Addis Ababa city towards North West direction of the country, and 185 k.m away from Bahir Dar city (the Regional capital) in the south east direction. Based on the 2007 national census conducted by the central statistics agency of Ethiopia, this woreda had a total population of 179,342 of whom 89,523 were men and 89,819 women; 12,609 or 7.03% were urban inhabitants [11]

Study design and period: A descriptive cross sectional study was conducted to assess and describe the current health profile of Jabi Tehnan woreda, Amhara, from 15 May–June 15, 2008 EC.

Data analysis: Data was entered in a computer and analyzed appropriately using Microsoft Office Excel spread sheets and analyzed using Excel pivot table. Finally the result was presented with texts, tables, figures and other options.

Study population: Health and health related data were collected from the district health office while data of safe water supply coverage were collected from the woreda water resource office. Education related data were collected from the district education office. Agriculture data were collected from the district agriculture office and other data were collected from other relevant sectors. Structured questioners were developed and used to collect secondary data. Interviews were conducted with relevant officers of the above specified processes, based on the needed data. Different register books were also assessed.

Data collection and procedure:

The health data was collected from Jabi Tehnan Woreda health office and as well as health related information was collected from different woreda administrative offices (water, Culture and tourism, finance, transport, electric power offices, telecommunication) of the year 2008 EC. The main mechanism of data collection was record review, interview of woreda health workers and other concerned body. The data collection was extracted using semi structured questionnaire.

The checklist was prepared in English and accommodates all the information on Geographical location, climatic condition and socio-demographic characteristics, main health services coverage (Immunization, Maternal health service coverage, water and sanitation coverage of the woreda) and ten causes of morbidity and mortality.

Ethical clearance:

Health and Health related information of Jabi Tehnan woreda was collected after obtaining official letter from Amhara regional Health bureau Public health emergency management (PHEM) department as well as permission obtained from Jabi Tehnan woreda health office and other concerned bodies in the woreda during data collection

Dissemination of result

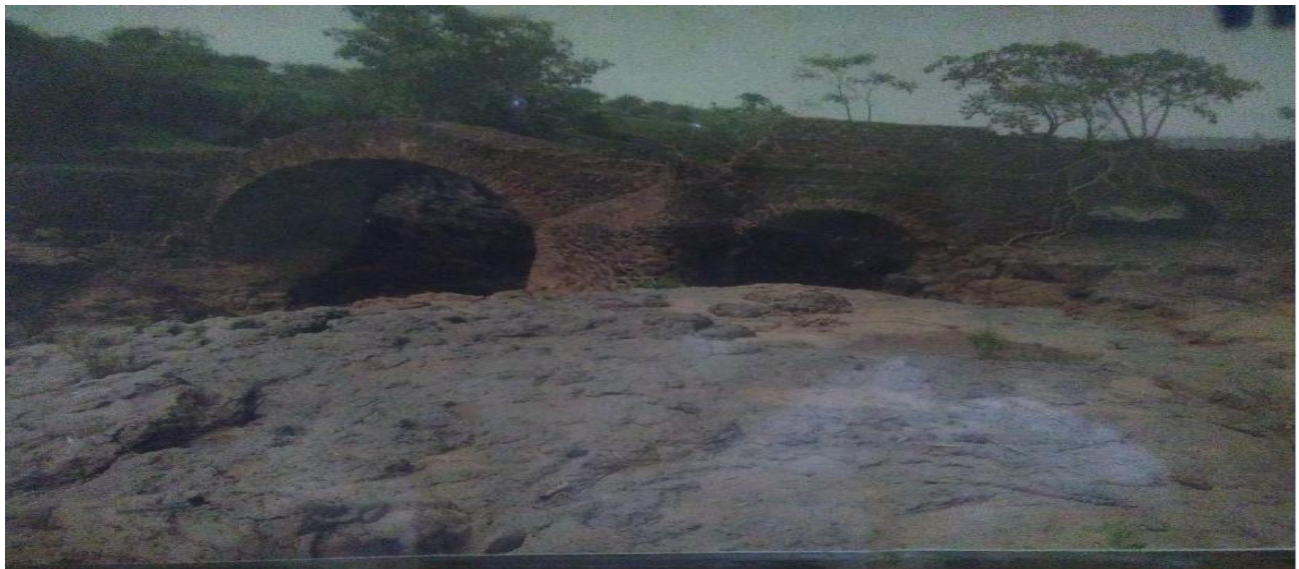
Finally finding of health profile description will be disseminated to Jabi Tehnan Woreda health office, Amhara region health bureau PHEM department and SPHMMC Department of Public Health.

Result

Historical Back ground and culture

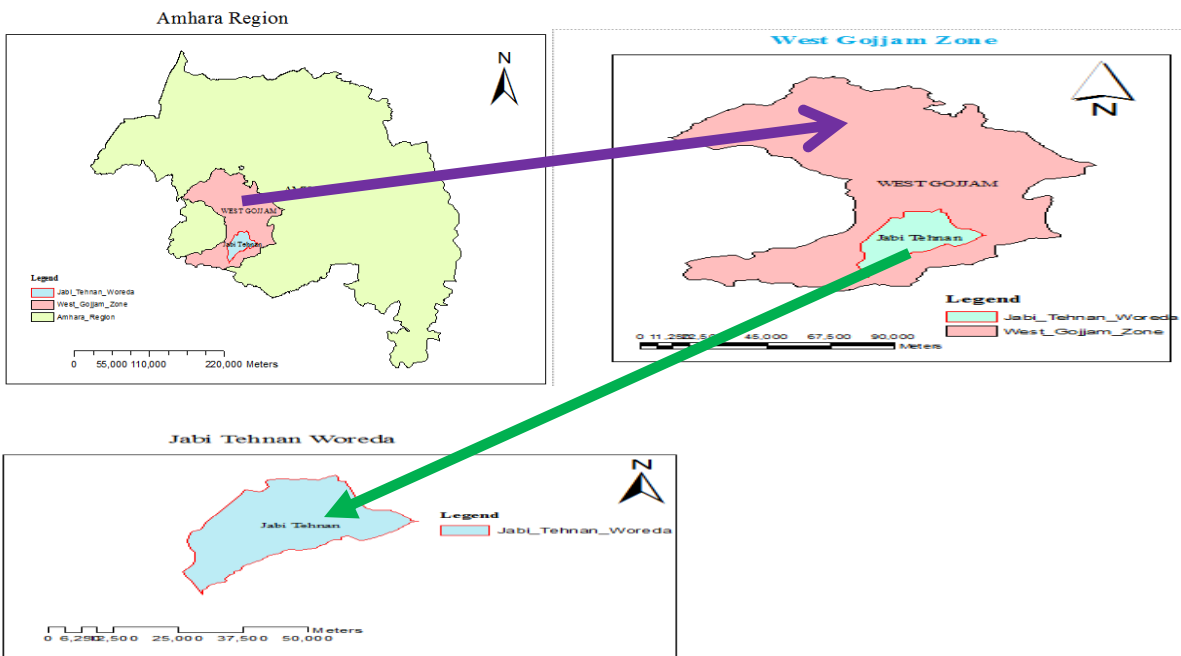
Jabi Tehnan district was believed to have been founded in around 1933. As the source from worded culture and tourism, once up on a time there were an old man called “Jabi” and southern(area below the main road) named by that an old man and the northern portion of the worded (above the main road) was name by an old man’s son called “Tehnan” finally when the father and child unit their territory the worded has got a name called “Jabi Tehnan” .this worded has many tourist attractive and historical site for instant Jorge bridge found in between Wonge and yemlidar kebeles at Birr river it thought to be was built by kegnazemach Jorge Yohannes around 1871th ,the bridge is found 14 km away from Finote selam town. other highly impressive site is ”kidaneMihret” Monastery found about 18 KMs away from the Finote selam in Arbawashdenbera kebele ,old age church called Guanssa “Medhinalem” church found 18 KMs away from finote selam at wogaguanssakebele is also the historical site the specific time when the church was built is yet not known. Many other historical sites are also there in Jabi tehnan worded (**source:** worded culture and tourism office)

Figure 11: The Historical Jorge Bridge at Jabi Tehnan worded, Amhara, Ethiopia, 2007



Geography and climate

Jabi Tehnan is one of the nine districts of the west Gojjam administration zone, bordered by six other woredas .in the north it is bordered by Quarit and Sekella woredas ,in the East by Dembecha and Dega Damot and in the west by Bure .it is located 180 km due south from the and regional capital Bahir Dar and 350 km north from the national capital Addis Ababa .the Administrative center of the woreda is Finote selam the total area of the woreda is estimated to be 1,170km²or 116,954 ha 8.7% from the zone (source; woreda office of Agriculture) .The altitude of the woreda ranges from 1,500-2,300 m above the sea level. The majority of the area is lies the higher altitude range, closer to 2,300 m .agro –ecologically, 88% the woreda is classified as “*Woyina Dega*”and the remaining 12% as “*kolla*” .The topography of the woreda is dominated by area of plain around 65% followed by 15% mountainous, 15% undulating and 10% valley. The temperature of the woreda ranges between 14°C and 32°C with an average annual temperature of 23°C. the rainfall distribution is uni-modal rainy season and the rainy season lasts for four months from mid-May to mid –September. The average annual rain fall is 1,250 mm per annual. The geographic coordinates of the woreda is 10° North latitude & 37° East longitudes.



Map 4: Administrative Map of Jabi Tehnan, woreda, west Gojjam zone, Amhara region, Ethiopia, 2007EC.

Administration and political structure

Jabi Tehnan woreda have a total of 39 kebeles of which only two are urban kebele. The woreda has its own council and representative in the regional council. There are 25 sector offices within the woreda, all sector office of the woreda is found at Finote selam town and each the sector office within the woreda has their own office head and those are member of the woreda council.

Socio-Demographic Characteristics

The total population of the woreda in 2007 E.C was estimated to be about 214,763 which account for 10.2% of the total population in the Zone .From which 105,748 (49.2%) were male and 109,014(50.8%) are females .Of the total woreda population 34089(15.8%) were living in urban which was less than 19.4% peoples live in urban in Ethiopia; whereas the remaining 180,674(84.2%) were rural inhabitants. The population density of the woreda is 183 people per square kilometer. This is greater than the zone average of 158.25 persons per square kilometer and also compared with the national and regional figure 79 people/Km², 121.9 people/km² respectively [<http://www.worldometers.info/world-population/ethiopia-population/>]. In Jabi Tehnan woreda, most of the inhabitants' ethnic groups are Amhara 99% all the other ethnic groups made up 1% of the population. Amharic is spoken as the first language by many of the inhabitants, there were no data found that indicate the actual number of followers for each respective religion in the woreda. But there were 147 orthodox Christian churches, 7Mosque and 3 protestant churches religious infrastructure in the woreda. The name of kebeles population by sex variables Jabi tehnan shown as follows by table1.

Table 15: Population distributions by kebele ,with estimated population and distance in kilometers from the woreda Town (Fenote Selam),Jabi Tehnan woreda, West Gojjam zone, Amhara region, Ethiopia, 2007 EC.

S.No	kebele name	Total population	Male	Female	Distance in KM
1	Jiga 01	11228	5558	5670	15.2
2	Jiga yilmedar	4541	2248	2293	8.4
3	Mender	5476	2711	2765	33
4	Mercha	4138	2048	2090	39.2

5	Wongi	3314	1640	1674	31
6	Berken	2613	1293	1320	23.1
7	Mankussa 01	6465	3200	3265	14.6
8	Mankussa Abdeguma	8753	4333	4420	28
9	Mana	7164	3546	3618	21
10	Woga	5447	2696	2751	17
11	Abasem	6687	3310	3377	21.3
12	Gorefe	4928	2439	2489	26
13	Woyimema	7122	3525	3597	52.4
14	Ergeb	1635	809	826	34
15	Firat	4672	2313	2359	36
16	Arba Wash	7733	3828	3905	30
17	Amestegna yefodeye gobez	5232	2590	2642	30.9
18	zengeballe	4524	2239	2285	38
19	Azimere	4005	1982	2023	11.9
20	Melanlejinit	3726	1844	1882	11.4
21	Atatiashenti	6217	3077	3140	15
22	Awenteyedefas	6639	3286	3353	16
23	Arebayitu Ensesa	5976	2958	3018	12.5
24	JimatEnkokima	3890	1926	1964	10
25	MekerechSegodit	6308	3122	3186	11.5
26	DimiriTnigefa	6337	3137	3200	13.1
27	YereberGirgi	3369	1668	1701	41.2
28	ShemedWakito	4838	2395	2443	22.3
29	Joshefide	2953	1462	1491	10
30	Radose dese	2629	1301	1325	16.5

31	Hondash	8016	3968	4048	9.3
32	Fisigem Digit	3480	1723	1757	12.4
33	YeshiretJigur	4416	2186	2230	24
34	Konisenikisita	5501	2723	2778	21.9
35	AgibiWenjila	5744	2843	2901	32.1
36	Mebeshi (Dig	2152	1065	1087	27
37	AgomamitTebelema	6777	3355	3422	36
38	zabaTsion	5293	2620	2673	52
39	Goayie	6754	3343	3411	51
	TOTAL	105,748	109,014	214,763	

Out of 214,763woreda population 5,064 (2.3%) were under 1 year, under 5 years were 28,690(13.3%) and women of child bearing age 15-49 years accounts 52,313 (24.3%), population less than 15 years old 87,171(40.5%), population greater than 64 years old 5614(2.6%) of the woreda population.121978 (56.8%) are in the productive age groups; hence the dependency ratio of the woreda was 76%. (For 100 economically active person, there are 76 economically inactive people), the (male: female) sex ratio were 0.97:1.

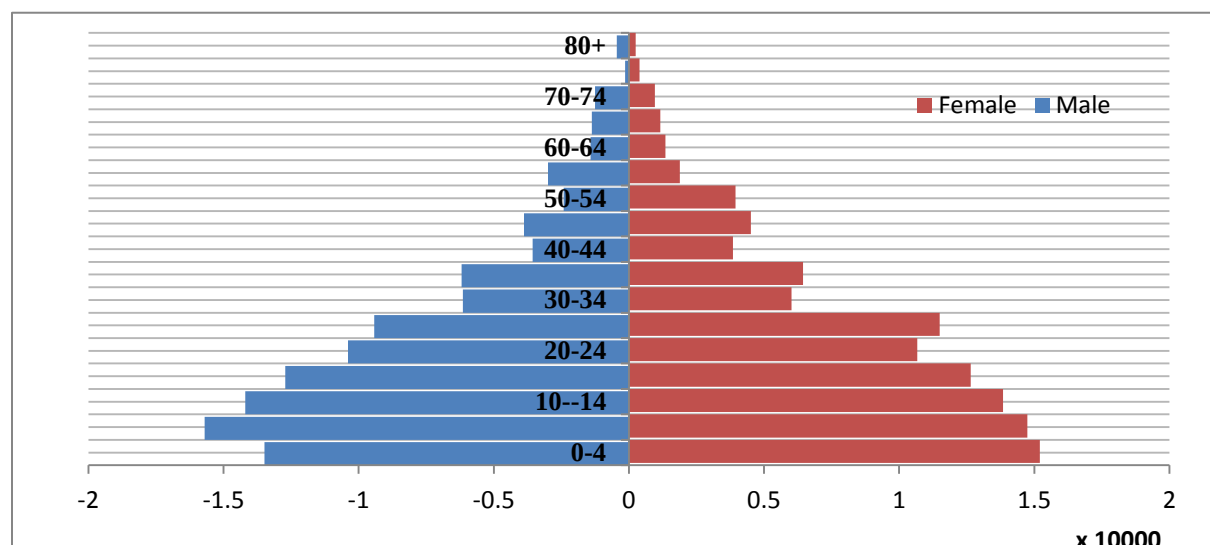


Figure 12: population of Pyramid of Jabi Tehnan woreda by Age group, West Gojjam Zone, Amhara, Ethiopia, 2007 EC.

Production and income

The woreda is very conducive for agriculture, most of the woreda population lives in rural; and the peoples led their life by practicing mixed farming, and agriculture took the lion share of the income source. The most common stable foods/crops in the woreda that are cultivated during the cropping season (May-October) using rain wet land or rain feed farming are Teff, maize, Millet, wheat, Barley, malt barley with productive land of 159,291.364(6.5%), 1,326,373.7(54.5%), 38,691(1.57%), 106,456.61(4.3%), 136,708.7(5.6%), 6,844.88(0.28%) quintals respectively. From cereals pea 3810.6 quintals, bean 29943.52 quintal and soya pea 85867 quintals.

About 13427.65 hectares land used for irrigation with 2,389741.65 quintals yield has been produced by using two round harvesting season first round(November –December) and second round(January –march) and irrigation farming system holds 1.2% from the total quintals production. About 26384 peoples has involved on irrigation farming. An estimated **58,262**(49.8%) hectars(ha) of land was used for cultivation of these Teff 8723(14.97%), Maize 19511(33.4%), Millet 1433(2.45%), Wheat 5917.9(10.5%), Barley 5163.25(8.8%), Malt barley 244.46(0.4%), paper 7793.35(13.3%), cereals (bean ,pea ,soya pea) 6017.35(10.3%) hectares and 5208 (4.4%) hectare of land used for grazing area.

The woreda is also enriched with different fruits like, Banana, Mango, sugarcane; side to side with crop production, animal rearing were also another source of income for the population, Cattle 187481, sheep 40931, Goat 19933, Equine 68181, poultry 201569. But data weren't found for the annual revenue from livestock. With regard to household income source there were a total of 30,069 households (HH) in the woreda those who led their life by mixed agriculture but data were not found as peoples live by farming; 1180(0.5%) are governmental employer, 5081(2.3%) were private employer, 7306 engaged in to different business, 6952 were jobless of these those who completed grade 10-12 were 1349, having diploma 1211, first degree and above 393. with sex category 872 were females and 1129 male, jobless figure was more higher in rural 3828 as compared to 171 in urban. No data were found regarding daily laborer statistic in the woreda

(Source: woreda office of Agriculture, civil service and economic and Finance annual report).The livestock population of the woreda is summarized on table 3 below.

Table 16: livestock population of Jabi Tehnan woreda, West Gojjam zone, Amhara region, Ethiopia, 2007 EC

Types of livestock	Number of animals in Woreda
Cattle	187,481
Sheep	40,931
Goat	19,933
Equine	68,181
poultry	201,569

Drink Water Supply

.A total of 132,708(61.8%) peoples has got safe water access in the woreda, of which 98,619(54.58%) in the rural and 34,089(100%) in the urban, but still there was a certain segment of the community using unsafe water for drinking and other purpose. The main source of water was hand dug well, shallow well, Rope pump well, rural pipe supply and protected spring. Although the overall actual safe water coverage of the woreda was 61.8%, and potential coverage was 87.1%, implicitly almost 38% of the woreda population does not have access to safe water.

Hence 34 kebeles 2 urban and 32 rural had safe water coverage but the coverage of safe drink water differ from kebele to kebele, some kebeles with corresponding number of water infrastructure like Awent(153), Mana(129),Jiga yelmedar(123),Hodansh(70) had relatively adequate water source infrastructure .In contrary some kebeles like Bugi 3, shigodit 5, Firat 4, Rados Dese 4, Azemireyebada 7 had low safe water coverage. Every 3-5 month frequency the woreda water office staff or kebele leader supposed to chlorinate the water used for drinking.

Table 17: Types and Numbers of water source Jabi Tehnan woreda, West Gojjam Zone, Amhara Region, Ethiopia, 2007EC

S.No	Types of Water source	Total water source	functional from total	Percentage of functional from the total
2	Deep well	3	1	33.3
3	Hand dug well	320	318	99.3
4	Shallow well	97	97	100
5	Rope pump well	627	620	98.8
6	Rural pipe system	2	1	50
Total		1049	1037	98.8

Disaster Situation both Natural and Man-Made

There was no any natural disaster but there was malaria outbreak registered in the woreda and a total of 13667 malaria case occurred but no deaths were happened. The Epidemics was occurred from month April to June the outbreak contained promptly that had contributed to save the life of the victims.

. Transportation & Communication facilities

According to the data from woreda transportation and road authority office ,the woreda has three types of roads those were 35km long first class (Asphalt) road which pass through four woreda kebeles(Mankussa,Jiga, Hodash Gatagone and Wenigeberkrgn) it connect the woreda with other nearby woredas ,zone and the region town. The second type was 86.739 Kilometers (Design class 2) DC 2 road(thickness 15 Meter and width 4 meter) and the third 42.99km long road were (thickness 15 meter& width 6 meter) DC1 (from Finote selam to Firat 24.43k.m and Jiga to Makiseignite 18.56 km). There were six accessible feeder roads to the main asphalt road which connects the woreda kebeles with the main road, a total of about 164.729 (all type) k.m long road has been built and thirty kebeles has got the all year round transportation service with an average

of 5-10 flow frequency of transportation per day from Finote selam to other woreda kebeles. The road from Jiga to Makisegnite 18.56 k.m was DC 1 type road but that road hosts more than 40 vehicles per day some structure of the road was yet to complete. From the 39 kebeles only 30 kebeles has road transportation access which about 76.9% road transportation coverage. (**Source:** Woreda transportation and Road authority)

Regarding electrification 4675 house hold of 42668 have access for electricity. which about 10.95% electric coverage .Hence, only five health center has electric power access, the remaining has been using solar power(**source:** woreda health office),the Ethiopian electric power corporation (EEPC) Finote selam district was under expansion the utility of electric power to almost all households in the woreda (**source** :EEPC Finote selam district). Concerning communication, the wireless net-work coverage was almost100% across the woreda and about 400 peoples in two woreda urban kebeles have registered and getting fixed telephone service. in addition to that two post office at (Jiga and Mankussa) kebeles and one commercial bank of Ethiopia at Jiga was found.(**source** :woreda Administration office 2007 annual report).

Education

In the woreda there are about 8 Kindergarten, 86 primary schools (85 governmental and 1 private), two high schools and two Preparatory schools that provide education for the society. The total educational coverage of the woreda is 100 %(*Educational offices annual report, 2007 EC*).

In 2007 EC, in spite the fact that the woreda had planned to enrolled 55,557 children. of the targeted children 50385(90.69%) has been enrolled 25,619(50.8%) male and 24,766(49.2%) female, of these total registry 46149 were in primary school and 4326 in the secondary school .The school dropout rate of students in 6 months of 2007 EC academic year was1.99%. Repetitive rate was 6.3%, the proportion of student sat on final year exam and passed to the next class level was 50.85% and 49.2% for male and female respectively.

Within the woreda there were a total of 1096 teachers, male589; female 507 in the first cycle (1-8) and generally, the teacher population within the woreda was 758 male and 560 female. With regard to school infrastructure facilities and services, there were 8 KG, 43 primary and 4 secondary schools with water supply and there were around 6 KGs, 25 primary and 4 high

schools having either separated sex or together latrine access, which were constructed by government funding and other both local and international NGOs .There were no data concerning HIV/AIDS and other health clubs in the woreda schools.

Health system Organization

The country health system

The recently implemented BPR (Basic Processing and Re-engineering) of the health sector has introduced a three-tier health care delivery system which is characterized by a first level of a Woreda/District health system comprising a primary hospital (with population coverage of 60,000-100,000 people), health centers (1/15,000-25,000 population) and their satellite Health Posts (1/3,000-5,000 population) that are connected to each other by a referral system. A Primary Hospital, Health center and health posts form a Primary health care unit (PHCU) with each health center having five satellite health posts. The second level in the tier is a General Hospital with population coverage of 1-1.5 million people; and the third a Specialized Hospital that covers population of 3.5-5 million. In Jabi tehnan woreda the health system were organized according to the BPR and comprised of 11 health center and 39 health post they are interlinked to each other.

Health service coverage

The physical health coverage in the woreda was 100%.There are nine governmental health centers (2 type A and 9 type B), 14 private health facility & 39 health posts that provide primary health service for the community. But there is no hospital in Jabi Tehnan woreda since, there is governmental hospital in Finote selam town administration, so this hospital has been serving for both peoples from Jabi Tehnan and Fenote selam town.

Table 18: Potential Health Service Coverage of Jabi Tehnan woreda by kebele West Gojjam, Amhara Region, Ethiopia, 2007 E.C

Cluster Name	Kebeles	Number of population	No of HFs		Total Pop. Getting service from the HC	Potential health service coverage (%)	
			HPs	H C		HC	HP
Cluster one	Jiga 01	11228	1	1	31310	79.8	44.5
	Jiga yilmedar	4541	1				110
	Mender	5476	1				91.7
	Mercha	4138	1				120
	Wongi	3314	1				150
	Berken	2613	1				191
Cluster two	Mankussa 01	6465	1	1	39444	63.3	77.3
	Mankussa Abdeguma	8753	1				57.1
	Mana	7164	1				69.7
	Woga	5447	1				91.7
	Abasem	6687	1				74.4
	Gorefe	4928	1				101.4
Cluster three	Woyimema	7122	1	1	13429	186	70
	Ergeb	1635	1				305
	Firat	4672	1				106
Cluster Four	Arba Wash	7733	1	1	21494	116.3	64.6
	Amestegnayefodeyeg obez	5232	1				95.5
	zengeballe	4524	1				110.5
	Azimere	4005	1				124
Cluster five	Melanlejinit	3726	1	1	9943	251	133.8
	Atatiashenti	6217	1				80.4
Cluster six	Awenteyedefas	6639	1	1	16505	151	75.3
	Arebayitu E	5976	1				83.6
	JimatEnkokima	3890	1				128.5
Cluster seven	MekerechSegodit	6308	1	1	12645	197.7	79.2
	DimiriTnigefa	6337	1				78.9
Cluster Eight	YereberGirgi	3369	1	1	13789	181.3	148
	ShemedWakito	4838	1				103.3
	Joshefide	2953	1				169.3
	Radose dese	2629	1				190.1
Cluster Nine	Hondashgatagon	8016	1	1	15912		62.5
	Fisigem Digit	3480	1				143.6
	YeshiretJigur	4416	1				113.2

						157	
Cluster Ten	Konisenikisita	5501	1	1	13397	186.6	90.8
	AgibiWenjila	5744	1				87
	Mebeshi (Digit Jigur)	2152	1				232
Cluster Eleven	AgomamitTebelema	6777	1		18824	132.8	73.8
	zabaTsion	5293	1				94.4
	Goayie	6754	1				74.0
	Woreda total	214763				128.0	90.7

The woredas had eleven clusters, the potential health coverage differ from cluster to cluster. Clusters those with significant high potential health coverage were cluster 3,5,7,8,10 with 186%,251%,197.7%,181%,186.6 % potential health coverage respectively. Whereas few cluster had less potential health coverage for instance cluster 1and 2 with 79.8 and 63.3 health coverage .that discrepancy in potential health coverage was occurred because of many kebeles in the woreda had fewer than 25,000in habitants.

Health service institutions and infrastructures

There were 39 health post, 11 health centers and no Hospital in Jabi Tehnan woreda. In term of electric power, telephone service and water supply :4 health center had sustainable electric power (Mankussa,Jiga, Mankussa and Woynima health centers) and 6 health center were without sustainable electric power as an alternative power source they use solar power that was provided by different supporting NGOs and both regional and federal government ,regarding telephone all health centers had mobile service access .Only two health centers had piped water supply and fixed telephone access those were Jiga and Mankussa health center , all health post lack electric power and water supply but had mobile service. The road infrastructure had joined most health centers with the main asphalt road but some health centers like Mallan ,yeraber and Assewa health center were hard to reach and transport logistic through the year ,but more worst during rainy season .

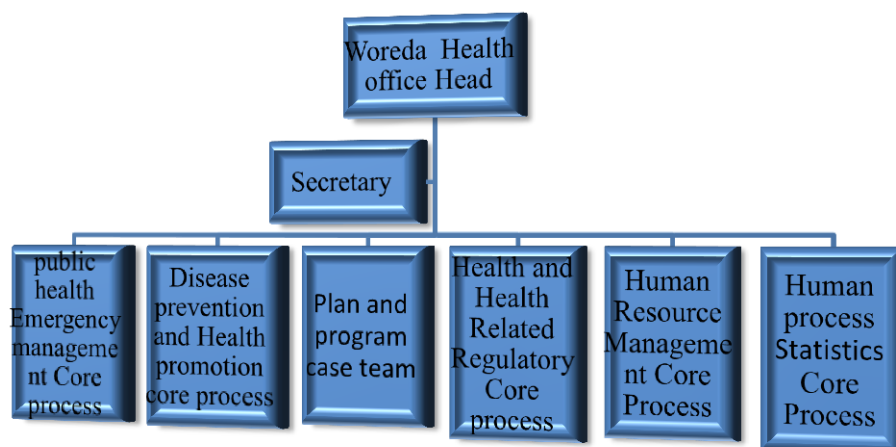
Table 19: Number of health Institution by type in Jabi Tehnan woreda, west Gojjam zone, Amhara region, Ethiopia, 2007 EC.

S.No	Type of health institution		No of institutions
1	Hospital		0
2	Number of Health Centers	with sustainable/ 24 hour /electric power	4
		without electric power/use solar power	7
		with telephone service (mobile)	11
		without telephone service (based mobile)	2
		with piped water supply	2
		Without piped water supply	9
3	Number of Health centers		11
4	Number of Health post		39
5	Number of private clinics	Lower	0
		Medium	11
		Higher	0
6	Number of Drug vendors		1
7	Number of Drug stores		0
8	Number of Pharmacies		0
9	Number of Diagnostic laboratories		2
10	Health post to population ratio		1:5507
11	Health center to population ratio		1:19,524
12	Physical health service coverage		100%

Organization Structure of Jabi Tehnan Woreda Health Office (Organ gram)

The Jabi tehnan woreda health office were organized as the basic processing and Re-engineering requirement so the office organized with woreda health office head ,secretary, curative and rehabilitative core process, public health emergency management core process ,disease prevention and health promotion core process ,Multi sectarian HIV/AIDS core process ,health and health related regulatory core process ,human resource management core process ,Human process Statistics Core Process .

Figure 13: Oregano gram of Jabi Tehnan woreda, West Gojjam zone, Amhara region, Ethiopia, 2007 EC.



Human Resource and Man Power

Human power is the central pillar of health activity, man power equipped with the required knowledge and skill is mandatory in order to meet the intended objective in the health sector. The distribution of health professional throughout the woreda health facilities are illustrated as follows by table 20.

Table 20: Number of health professional with educational level in health facilities of Jabi tehnan woreda, west Gojjam zone, Amhara region, Ethiopia, 2007 EC.

S. N	Profession type	Educational level	Number of professionals		
			Deployed		
			M	F	T
1	Nurse	Degree	6	0	6
		Diploma	37	40	77
2	Laboratory	Degree	1	0	1
		Diploma	10	7	17
3	Pharmacy	Degree	0	0	0
		Diploma	8	4	12
4	Health officer (HO)		18	4	22
5	Environmental Health	Degree	2	0	2
		Diploma	2	0	2
6	Midwife	Degree	0	1	1
		Diploma	12	14	26
8	HEW		--	73	73

9	Community councilors	1 1 2
10	HO to population ratio	1:9762
11	HEW to population ratio	1:2941
12	Doctor to population ratio	0
13	Nurse to population ratio	1:2941

Health professional found in a certain place has to be comparable with the number of inhabitants living in the area as to provide standardized health service. Peoples in Jabi Tehnan woreda to health professional ratio are displayed by table 21.

Table 21: Population to Health Professional Ratio, Jabi Tehnan, West Gojjam, Zone, Amhara Region, Ethiopia, 2007E.C.

S.No	Category	Number of Health professional	Population to Health Professional Ratio		
			WHO standard	Current Amhara Region	Jabi Tehnan Woreda
1	Health officer	22	1:10,000	1:14,817	1 :9,762
2	Nurses (Deg. and Dip.)	83	1:5,000	1:2,714	1 :2,587
3	Mid wife (Deg. and Dip.)	27	1:5,000	1:12,004	1 :7,954
4	HEWs	73	1:2,500	1:2,775	1 :2,941

Disaster situation both natural and man-made

There were no any disaster registered in the woreda for the last one year but malaria outbreak has been occurred in few kebeles and about 1,366 cases were registered but no death happened.

Vital statistics and health indicators

There were 109,014 total female populations in the woreda and females in the reproductive age group (15-49 years) are estimated to be about 52,313 (24.3%). But data on other measures of fertility like Maternal Mortality Rate(MMR), Crude Death Rate(CDR), child

Mortality(CM),Under five years age Mortality Rate(U5MR), Infant Mortality Rate(IMR),and Total Fertility Rate(TFR) were not available in the woreda.

The table 22 shown below summarizes some of the health indicators found in the woreda health office archived data.

Table 22: Vital Statistics Data of Jabi Tehnan woreda, West Gojjam zone, Amhara region, Ethiopia, 2007 EC

S. No	Indicators	Number (%)	Remarks
1	Total population	214,763(100)	
2	Male	105,748(49.2)	
3	Female	109,014(50.8)	
4	Under 1 years old	5,064(2.3)	
5	Under 5 years old	28,690(13.3)	
6	Under 15 years old	87,171(40.5)	
7	Productive age female (15-49 years)	52,313(24.3)	
8	pregnant women	10,113(4.7)	
9	Live births	-----	
10	Delivery by skilled birth attendant	4153(1.9)	
11	Total fertility rate	-----	No data
12	Crude birth rate /1000/year	-----	No data
13	Crude death rate/1000/year	-----	No data
14	maternal mortality rate	-----	No data
15	Child mortality	-----	No data
16	Under 5 mortality rate	-----	No data
17	Infant mortality rate	-----	No data
18	Dependency ratio	76%	
19	Average household size	4.2	

Maternal Health Service Coverage

Adverse pregnancy outcomes can be minimized or avoided altogether if antenatal care is received early in the pregnancy and continued through delivery. Early detection of problems in pregnancy leads to more timely referrals for women in high-risk categories or with complications; this is particularly true in Ethiopia, where three-quarters of the population live in rural areas and where physical barriers pose a challenge to providing health care.

The woreda maternal health service coverage in 2007 E.C has shown tremendous achievement. ANC achievement of at least one visit was 10113 (142%), family planning contraceptive prevalence rate (CPR) was 55,338(135.9%) with short acting contraceptive method 36674(66.2%) and long acting contraceptive method (34.8%). Data were not found on contraceptive acceptance rate (CAR).

Table 23: Family Health activities in Jabi tehnan Woreda, W/Gojjam Zone, Amhara Region, Ethiopia, 2007 EC

Activities	planned	Achieved	Percentage of Achievement (%)
ANC at least 1 visit	7111	10,113	142
ANC at least 4 visit	7111	8635	121
Skilled Delivery	7111	4153	58
HEW delivery	1067	367	34
PNC	7111	9431	132

Immunization coverage

In 2007 E.C, 5,396 children were targeted for immunization. Bacillus Calmette –Guerin (BCG) immunization coverage was 6,119(107%), data was not found for protected at birth (PAB), TT2+P.W and TT2+N.P.W the immunization of less than 1 year children shown table below

Table 24: Immunization coverage of children <1 year of age by antigen, Jabi Tehnan Woreda, West Gojjam zone, Amhara Region, Ethiopia, 2007E.C

S.No	Antigen	Annual		Coverage in percent (%)
		planned	Achieved	
1	BCG	5,396	6119	107
	Pentavalent(Penta-1)	5,396	5884	109
2	Pentavalent(Penta-3)	5,396	5775	107.2
3	Measles	5,396	5728	106
	PCV-10-1	5,396	5884	109
4	PCV-10-3	5,396	5775	107.2

Hygiene and Environmental health services

The woreda has declared all the Kebeles free from defecating everywhere in the field. The latrine access coverage was 100%. The utilization rate was 87%. Schools and health facilities were accessed with latrines, although the quality and standard was not as required and few schools were yet without latrine. The community were using common pit latrine. To sustain or maintain this activity, the woreda was implementing the maintenance of latrine and community sensitization in each and every Kebeles through health education by health extension workers. The woreda health office with in collaboration with different stakeholder has given an intensive solid and liquid waste management education and had graduated the participants.

Health Education

The health education was given at health facility, public meeting, worshipping place on topic like mothers health, and the negative impact of home delivery, Environmental and personal hygiene, prevention of communicable disease, HIV transmission and prevention. Malaria prevention activities since the woreda all kebeles are malarious.

Endemic Disease

Malaria

Jabi Tehnan woreda in the west Gojjam zone is known to be one of malarious woreda. Malaria is an endemic disease in all kebeles of the woreda but relatively malaria was more pronounced at kebeles found in the low land area. And about 214,763 peoples are thought to be at risk of the disease. More than 117,200 insecticide treated net (ITN) has been distributed throughout the woreda. However, there was any clear data about ITN utilization and the ITN coverage was estimated to be 100% including current distribution and but only 21(53.8%) kebeles has been sprayed with Insecticide Residual Spray (IRS) with that about 19,684 house hold and estimated to be 192,240 population has been addresses.

With the same year 16,559 malaria cases has been registered of that 3,444 cases has been occurred on children under five years of age and no death were registered as attribute of malaria. Malaria touches the peak level of cases from month April to June that was because the volume of rivers in woreda was decreased as a result of seasonal fluctuation. Subsequently that paved

conducive environment for malaria breed there by malaria outbreak has been occurred and about 1,366 cases were registered. There was no shortage of anti-malaria drugs to treat malaria cases.

TB/leprosy

A total of 397 new TB cases were reported in the woreda. Tuberculosis case detection rate, TB treatment completion rate (treatment success rate) and cure rate were 73%, 96.5% and 95% respectively in the woreda. (Table 25).

Table 25: Distribution of tuberculosis cases in Jabi Tehnan Woreda, West Gojjam Zone, Amhara Region, Ethiopia, 2007EC

S.No	Activity	Annual		Achievement in percent (%)
		planned	Achieved	
1	Total TB cases	544	397	73
2	Pulmonary TB Negative		126	31.7
3	Pulmonary TB Positive	211	80	4.71
4	Extra Pulmonary TB		191	48
5	TB detection rate	544	397	73
6	TB treatment completion rate	366	353	96.5
7	TB cure rate	78	74	95
8	TB treatment success rate	78	75	96
9	TB Defaulter		0	
10	Death on TB treatment		3	3.5
11	Total TB patients screened for HIV	544	397	100
12	Total Leprosy cases	5	7	140

HIV/AIDS control and prevention

In 2007 EC, 44,557 peoples has been screened for HIV male 20,534(46%) and female 24,023(54%) ,VCT 13137 ,Male 61249(46.6%) female 7013(53.4%) ,Provide Initiative treatment and counseling (PICT) 31,420 and prevention of mother to child transmission 9,834,there were a total of 66 new case (incidence) occurred . The overall HIV prevalence of the woreda was not calculated because of the denominator (population at risk is not defined) ,312 on ART and 382 on pre-ART a total of 694 peoples were living with the Virus in the woreda. Health education on transmission and prevention HIV/AIDS was given for the peoples.

Disease statistics

The major health problems of the woreda remain largely preventable communicable diseases. With this regard the top ten cause of morbidity for both adult and under five has been declared for 2007 EC.

Top ten leading cause of outpatient visits (Morbidity)

The top ten leading causes of **adult** outpatients visits in Jabi Tehnan woreda in 2007 EC were: Acute Febrile Illness (AFI), Helmenthiasis, Malaria with plasmodium falciparum(PF) confirmed , pneumonia, trauma, Disease of respiratory system, Dyspepsia, Malaria other than PF, infection of skin and other subcutaneous tissue and other unspecified infection and parasitic disease.

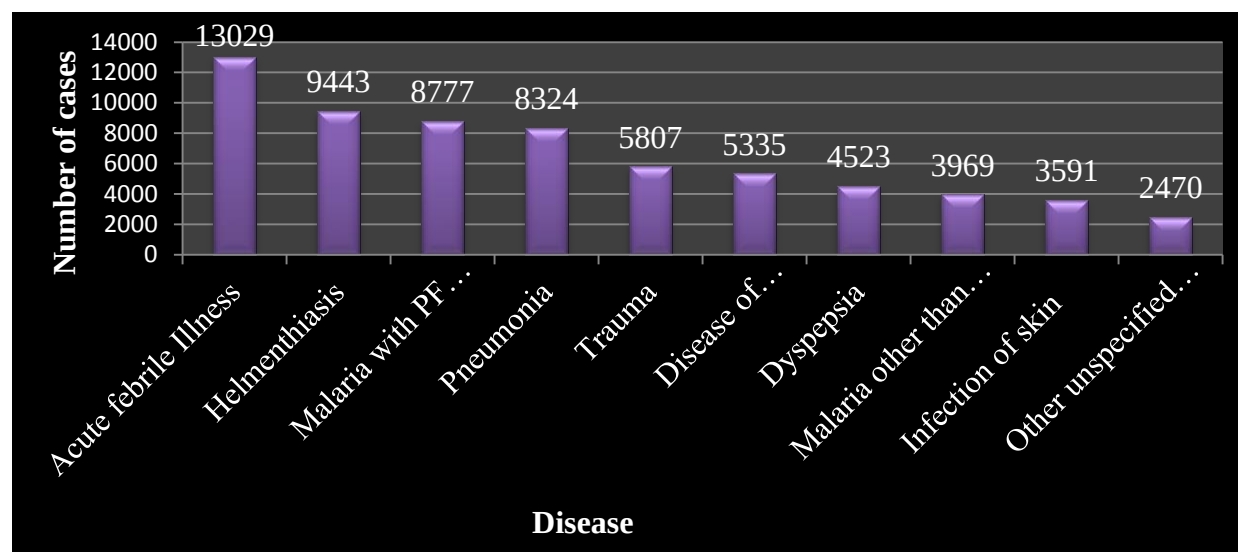


Figure 14: Top ten leading causes of adult outpatient visits in Jabi Tehnan woreda, West Gojjam zone, Amhara, Ethiopia, 2007EC.

The top ten outpatient visits **under five** was: AFI, pneumonia, diarrhea(non-bloody), malaria PF confirmed , helmenthiasis, malaria other than PF, acute upper respiratory tract infection, the and unspecified infection of eye, infection of the skin and subcutaneous tissue ,trauma(injury and fracture).There was no data on adult /under five morbidity admission and mortality at woredas level as well. The figure 3 shown down elaborates the top ten cause of OPD Visit disease and its number.

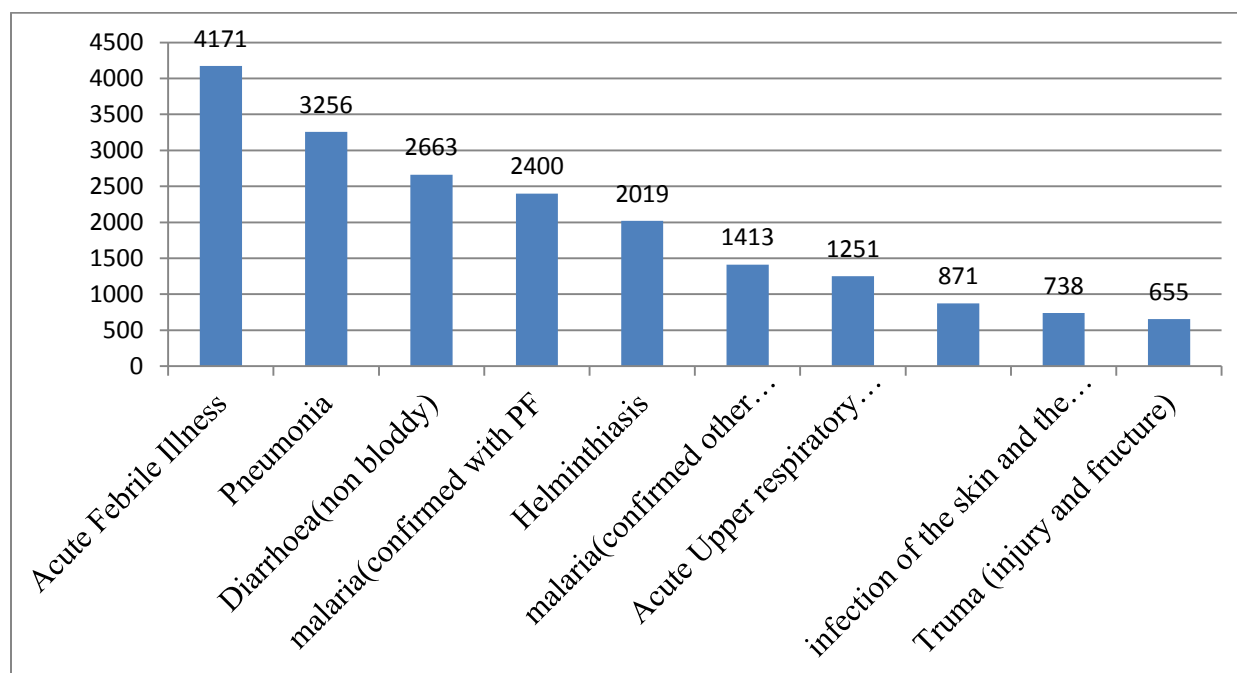


Figure 15: Top ten leading causes of < 5 outpatient visits (morbidity) in Jabi Tehnan woreda, West Gojjam zone, Amhara, Ethiopia, 2007EC.

Top ten leading cause of Morbidity

Table 26: Top ten leading causes outpatient visits (morbidity) in Jabi Tehnan woreda, West Gojjam zone, Amhara, Ethiopia, 2007EC.

Morbidity in adult OPD			Pediatrics/<5years		
Rank	Disease	No (%)	Rank	Disease	No (%)
1	AFI	13029(19.96)	1	AFI	4171(21.46)
2	Helmenthiasis	9443(14.47)	2	Pneumonia	3256(167)
3	Malaria with PF Confirmed	8777(13.45)	3	Diarrhea	2663(13.7)
4	Pneumonia	8324(12.75)	4	Malaria with PF Confirmed	2400(12.35)
5	Trauma(Injury, Fracture)	5807(8.9)	5	Helmenthiasis	2019(10.39)
6	Acute upper respiratory infection	5335(8.17)	6	Malaria (confirmed other than PF)	1413(7.27)

7	Dyspepsia	4523(6.93)	7	Acute upper respiratory infection	1251(6.44)
8	Malaria (confirmed other than PF)	3969(6.08)	8	Other or unspecified disease of the eye	871(4.48)
9	Infection of the skin and Subcutaneous tissue	3591(5.5)	9	Infection of the skin and Subcutaneous tissue	738(3.8)
10	Other or unspecified infection and parasitic infection	2470(3.78)	10	Trauma (Injury, Fracture)	655(3.37)
Total		65268(100)	Total		6563(100)

Nutrition and food shortage

The woreda is one of the food secured woreda from west Gojjam zone harvesting all the year in Amhara Region; though there was no supplementary feeding units in the woreda.

Health budget allocation

The total budget allocated for the woreda in 2007 EC was 113, 059,156. The health sector share 15,959(13.9%), ETB. Of the total budget 20,446,593.95 was fund received from Nongovernmental Organization, for the program/purpose of safe water distribution, supporting young female student on education, for constructing of public service like school, health center.

Discussion

The leading cause of outpatient (morbidity) visit in the woreda for both adult and under five age group was Acute febrile illness (AFI) which account 13,029(19.96%) and 4,171(21.46%) for Adult and under five age group respectively generally AFI holds 20.3% from the total cases reported . That finding more surpassed to three fold 3.7% of the national report [4] but smaller than 25.9% in Arsi Negele woreda, Oromia region [5]. This might be the health professional any patient presented with febrile and Blood film (BF) negative for malaria concluded as AFI. The other possible reason the woreda was hot spot area and there was no more laboratory confirmatory tests for other diseases other than Malaria and enough laboratory personnel with required lab equipment was limited, hence only 1 Bachelor graduate laboratory technologist and 17 laboratory technician were deployed it was about 1:11,932 ration lab professional to the total population.

Helmenthiasis 94439(14.43%) and Pneumonia 3256(16.7%) were the second ranked leading cause of outpatient visit for adult and under five age group respectively .Helmenthiasis was because lack of hygiene and sanitation despite the fact that the woreda health office had mobilized the health extension worker to teach the community and they tough the community but progress and behavioral change was no made in the community, since about 84.1% of the woreda population were living in rural.14.4% prevalence of Helmenthiasis ,which much more high when compared with 4.3% in Ethiopia [4].

There have been profound changes in the incidence of malaria since the beginning of the millennium – the risk of acquiring malaria has been reduced by 37% since 2000 and the risk of dying has decreased by 60%. An increasing number of countries are moving towards eliminating malaria, and zero indigenous cases were reported from the WHO European Region for the first time since record keeping began [6]. As far as all the kebeles in the woreda were malarious. Malaria (all species) accounts about 16,559 (19.55 %) of all cases for both age categories, while PF confirmed exclusively accounts 11,177(13.3%). malaria PF confirmed was higher compared with the 7.4% malaria PF confirmed national prevalence [4]

The overall malaria cases was (19.55%) in the study woreda. The prevalence rate of malaria in the woreda was 77 per 1000 populations per year. Even though the prevalence of malaria in the

woreda was high, no deaths were reported in the woreda. This could be due to early diagnosis and treatment and quality of service or deaths may not probably be recorded.

Every pregnancy is assumed to be at risk; the physiological & pathological changes that occur during pregnancy may be life threatening not only for the mother but also for the baby if the conditions are strictly followed by health professionals. It is recommended that a pregnant woman should have four ANC visits during her pregnancy period so that the likelihood of risk is identified & intervene which in turn contributes in mitigating the preventable death of mother & baby. ANC visit of pregnant mothers in the woreda. At least one visit was 10,113 (142%), and at least 4 visits were 8,635 (121%). The antenatal care coverage of the Amhara region and the National were 92.5% and 97.4% respectively [4]. So the woreda has shown a good smash in securing antenatal care. Percentage of delivery attended by skilled delivery 4153 (58%) which was much successful achievement as weigh with 19.4% in Burie woreda, Amhara region and 10% [7].

The ANC achievement of at least one visit was 10113 (142%), and at least 4 visits were 8635 (121%) that finding was indicating better number of visiting health facility as it compared with the national data 41.4% first visit and 32.1% fourth visit [8] similarly the national 57.1% for first visit and 19.1% for fourth visit [7]. Thus the highest in prevalence of ANC visit in Jabi tehnan woreda was due to under planning or the number that supposed to visit the health facility for ANC visits were under estimated by the planner but later the number of pregnant mother who seek for ANC has increased.

The percentage of delivery attended by skilled birth attendant in the woreda was 58% this was highly encouragable practice by the pregnant mother, the devotion of the health professional as it was 17.7% and 23.1% skilled birth attendant for Amhara region and national. But this also needs to scale up the percentage of delivery attended by skilled personnel. Likewise 34% of deliveries were attended by HEW in the woreda that was much high number when compared with 7.2% of the region and 11.6 of the National report [4]. The high percentage of delivery attended by the HEW in the woreda indicates low habit of mother birth at the health center where better health professionals were found. Since birth and birth related complication would be difficult to manage by HEW. Thereby the quality of antenatal care delivery can be measured by the qualifications of the provider and the kinds of service provided to the mother and the infant during delivery.

Only 2.6% of measles dropout rate and the status of measles immunization of the woreda was 5728 (106.1%) in under one year children which seems well matched with absence of measles cases/outbreak, food shortage/malnutrition cases in the district unless there was under planning.

Although both the detection rate & cure rates were greater than the target; but to reduce the incidence of TB it is apt to identify those with the disease & get them treated. These days; the issue of multidrug resistance TB is a critical challenge in fighting the disease. Those who are diagnosed positive & on treatment should be followed for not to drop & laboratory tests should be done to monitor the outcome.

In the woreda, Tuberculosis case detection rate was 73%. Which was a bit significant from the Regional achievement, National and WHO standards which was 55.6%, 58.9% & 56% respectively [4, 9] But which was less achieved as compared with Harari 95%, Dire Dawa 81% The woreda cure and treatment success rate were 95% and 96.5% which as equivalent with 92% in Afar and Gambella 89% that was because the patient those who were on direct observation therapy (DOT) followed accordingly and the health professionals were committed in providing the intended advice for the clients [10]

Vital statistics like total death, total births, under one and under five deaths, maternal mortality were not recorded in the woreda (table 10). Although the District Health Office claimed to have shortage of man power, the health professional to population ratio of the District was almost better than the Regional Health Bureau, except in HEW.

There was no strong water quality monitoring. Chlorination was not applied as per the standard i.e. every three months. This might contribute to the higher rate of diarrhea and intestinal parasites in the woreda, which was 2663 (13.7%) and 2019 (10.39%) of less than five years outpatient visits respectively. Intestinal parasite also the second outpatient visit contributor for adult 9443 (14.47%). According to the woreda Health Officials, the main problems of the woreda were limited budget, Shortage of water and power supply in the health centers and shortage of human resources according to the Business Process Reengineering (BPR).

Limitations

- ❖ The exact figure of population who receive safe water was not mentioned
- ❖ Vital statistics data was not registered like Crude birth rate, Live birth, Crude Death rate, and maternal mortality rate, infant and under five mortality rates.
- ❖ The other most important element was on immunization most of the achievements were above 100% that necessarily don't indicate the success rather under planning
- ❖ Health and other clubs on the schools were not operational similarly the 24 hours electric powered and water access in the health facility were low

Conclusion

The woreda still had shortage of health professional manpower in all disciplines. Acute febrile illness was the leading cause of morbidity in the district both in adult and under five outpatient departments. Helmentiasis and Pneumonia were the second ranked leading cause of outpatient visit for adult and under five respectively. The area is highly malarious and all forms of malaria species were found in the woreda. The ANC coverage through all visits has shown a very good achievement and pregnant mothers used to give birth both by skilled birth attendants and health extension workers. The woreda had showed satisfactory achievement in preventing and treating communicable disease like TB. More works has to be done on mother and child health related issues; since vital data mother and child has been missed.

Recommendation

Providing both onsite and offsite training for the health professional and it's good to recruit additional health extension workers in order to proportionalize the gap to the total populations. Provision of training for the woreda health office planner and enumerate the approximate estimate of the number of pregnant mothers and under five children in each kebeles via HEWs .upgrading and constructing of new road in order to connect kebeles with kebeles and kebeles with the woreda and zones. The vital statics has to be registered and any event must be catches up on time which helps to discover the burden with regarding to mother and child health. Screen those children who failed to take the antigens according to the schedule

Reference

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Annex 4: Health profile data collection tools

Data Collection Tools

1. Historical Aspects of the area (Culture and tourism office)

Woreda/ Kebele Name_____

How and why the name given_____

How and when the woreda was formed_____

Any other historical aspect_____

Geography and Climate (including map, altitudes etc...)Woreda

2.1. Map_____

2.2. Location (distance and direction) woreda from the regional capital _____

2.3. Altitude woreda _____

2.4. Geographical coordinate

2.5. Latitude _____longitude _____

2.6. Annual rainfalls (average) _____, annual temp (average) _____

2.7. Climatic zones_____ (%) _____ (%) _____ (%)

2.8. Area of woreda_____ SqKm

3. Facilities

3.1. Accessibility (main roads) _____

3.2. Type of road _____

3.3. How many kebele have access to transportation _____

3.4. Flow of transportation per day_____

3.5. How many people have access to fixed telephone? _____

3.6. How many people have access to mobile phone? (Coverage)_____

3.7. How many people get power supply_____?

4. Administrative setup

4.1. Total no. of ketenas_____

4.2. _____ Woreda _____ boundaries

North_____South_____

East_____West_____

5. Demographic information

5.1. Population: Total_____

5.2. Male _____Female _____sex ratio_____

5.3. Under 1yr_____<5yrs_____<15Yrs_____

5.4. ≥65years_____Population pyramid type _____

Age category(Year)	Sex(N ₀)		
	Male	Female	Total
<1			
1-5			
6-14			
15-24			
25-34			
35-49			
50-64			
≥ 65			

Age distribution

Women 15 - 49 years of age _____

Total population by Kebele (each Kebele pop) _____

6. Ethnic/language

Amhara _____ (____ %),

Oromo _____ (____ %),

Tigræ _____ (____ %)

Others _____ (____ %)

7. Religion

Muslim _____ (____ %),

Christian orthodox _____ (____ %),

Protestant _____ (____ %)

Other _____ (____ %)

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

Main income sources

Different business _____ (No.),

Employee _____ (No.)

Jobless _____ (No.)

Average income per HH/year _____

9. Education and school Health

Number of educational institution

College/ TVET____,

High school____,

Junior school____,

Junior and elementary school _____

Elementary _____

K.G.____

Educational status of the community

Total Educated people _____

Male _____

Female _____

School health activities:

Water supply: schools with water supply_____

Toilets: schools with functional latrines (male and female) _____

Schools with HIV/other Health clubs_____

10. Infrastructure for health Facilities (Transport, Telecommunication, Power supply, water supply...)

How many of the health centers have access to

Transportation_____ (____ %), Telecommunication_____ (____%),

Electric power_____ (____ %) Water supply _____ (____%)

11. Safe water coverage

Ketenas getting safe water_____ (_____ %)

Population getting safe water_____ (_____ %)

Main source of water_____

12. Health delivery system

12.1 Woreda (woreda)Health Structure (organography)

12.2 Health Facilities

Type		Number	Total No. of beds
Gov. Hospital			
Gov. Health center			
Private H.Fs (clinics/diag. lab/drug stores/pharmacy)	Clinics (all type)		
	Diag. Lab.		
	Drug store		
	Pharmacy		
Gov. Health posts			
NGOs	H.Ps		
	H.Cs		
	Hospitals		
	Clinics		

Health institution to population ratio:

Hospital: Pop_____

HC: Pop_____

Health service coverage_____%

12.3 Human resource for health sector

Types of Health professional	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(Applied biology)		

Nurse: pop. Ratio_____

Mid. Wife: pop. Ratio _____

UHEW: pop. ratio_____

Ho: pop. ratio_____

12.4 Top causes of morbidity and mortality

Top ten leading causes of OPD visit (morbidity):

Adult		# of cases	%	Pediatrics < 5 years	# of cases	%
1						
2						
3						
4						
5						

6						
7						
8						
9						
10						
Others						
Total						

12.5 Top ten causes of admissions

		# of cases	%	Pediatrics/<5 years	# of case	%
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Others						
Total						

12.6 Top ten causes of deaths (mortality).

S No	Adult	Pediatrics/ <5 years
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

12.7 Vital Statistics and Health Indicators

Infant Mortality Rate (IMR) _____ (total <1 yr. deaths this 2007 yr. _____)

Child Mortality Rate _____ (this year's total <15 yr. deaths _____)

Crude Birth Rate _____

Crude Death Rate _____ (total deaths 2007 yr. _____)

Maternal Mortality Rate _____ (2007 total maternal deaths _____)

Available method mix _____

Contraceptive Prevalence rate _____

Contraceptive acceptance rate _____

ANC rate (how many of the total expected pregnancies attended 1st ANC) _____

ANC rate (how many of the total expected pregnancies attended 4th ANC) _____

Percentage of deliveries attended by skilled birth attendants_____

4.12.8 Immunization Coverage (for children and Women);

Antigen	Number	Coverage
BCG		
OPV 0		
OPV 1		
OPV 2		
OPV 3		
Penta 1		
Penta 2		
Penta 3		
Rota 1		
Rota 2		
PCV 1		
PCV 2		
PCV 3		
Measles		
PAB		
Fully immunization		
TT2+ pregnant women		
TT2+ non pregnant women		

12.9 Health budget allocation:

Government

Total budget allocated for the Woreda _____

Total budget allocated for health center _____ (_____ %)

Funds from NGO

Total _____ (purpose/programs) _____

12.10 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_____

12.11 Community Health Services;

Status of services provided by community health workers namely

Responsibility of

Total number of HDA's and their responsibility

HEWs_____

Others_____

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

MCH (Delivery, ANC, PNC)

FP(Methods)

EPI (outreach service, cold chain, vaccine):

Environmental health and sanitation

Latrine coverage_____ and utilization rate_____

Water supply coverage_____

others_____

Health Education (what, when, where, how and who conducted health education)

12.13 Endemic diseases;

TB/Leprosy

Total TB cases _____ PTB negative _____ PTB positive _____ Extra PTB _____

TB detection rate _____

TB Rx completion rate _____ TB cure rate _____

TB Rx success rate _____

TB defaulter _____

Death on TB Rx _____

Total TB patients screened for HIV _____

Total Leprosy cases _____ on Rx _____

HIV/AIDS;

Total people screened for HIV (last one year) _____

VCT _____ PITC _____ PMTCT _____

HIV prevalence _____

HIV Incidence (new cases/year) _____

Total PLWHA _____

On ART _____ on Pre-ART _____

Other HIV prevention activities_____

12.14 Nutrition (malnutrition related Outpatient Therapeutic Program (OTP), Stabilization Centre (SC), Therapeutic and Supplementary feeding (TSF), Community Based Nutrition (CBN) and Productive Safe Net Program (PSNP) activities)/HO and Early warning

Total OTP sites_____, total admissions to OTP/year_____ _

Is there TSF (targeted supplementary feeding) program in the woreda _____

CBN program_____ PSNP _____ other_____

General food security condition_____

Essential drugs (shortage): - _____

12.15 What do you think the major Health problem/s of the woreda _____

12.16 Discussion of the highlights and the main findings of the health profile assessment and description-----

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

Chapter V: Standard Operating Procedures

Procedure for H. pylori rapid test

NEFAS MEWUCHA PEIMERY HOSPITAL LABORATORY STANDARED OPERATING PROCEDURE

title / description:- H. pylori Rapid Test		DOC#: NMPHL-SER-PR-03
Applies To:-Serology	Effective Date:01/APR/2017	

PROCEDURE CHANGE HISTORY:

Version #	Replaced Version		Prepared by	Revised by	Approved by
00	N/A	Name	Lezhialem Almaw	Tadesse Misganaw	Tadesse Misganaw
		Signature			
		Date	01/04/2017	01/04/2017	01/04/2017
Description of Changes:-					
Location of Mater Copy:- Master File Date of discontinuation:-					

ANNUAL REVIEW

Review Date	Name	Signature
-------------	------	-----------

Purpose

This procedure provides instruction for detection of IgG antibodies to H. Pylori in serum by visual interpretation.

Abbreviations H. Pylori - Helicobacter Pylori

Materials

Reagents
H. Pylori Rapid Test kit

Reagent preparation:- Ready to use

Reagent stability and storage: -Stable until the expiration date when

Sample

Sample type	Amount required	Transport and Storage	Stability
Serum	50µl	Fresh serum should be used	Serum

Limitations: The test is not intended for use with asymptomatic patients. Performance characteristics for persons under the age of 18 have not been established with this test

Sample retention:

Special Safety Refer to the Laboratory Safety Manual for standard safety procedures
Precautions

-
1. All workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with human blood or other body fluids is anticipated.
 2. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited.
 3. Gloves should be worn when touching blood and body fluids, mucous membranes, or non-intact skin, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. If a glove is torn or damaged during use, it should be removed and a new glove used as promptly as safety permits. Disposable gloves should not be washed or disinfected for reuse. Washing with surfactants may enhance penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration of the glove material.
 4. Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose, and eyes.
 5. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids. Protective clothing should be removed before leaving the area.
 6. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed since no barrier is 100% effective.

Calibration N/A

Quality Control preparation:
Control

Control	Level	Stability	Frequency	Preparation (y/n)
A procedural control is built into the device				

Procedure	Step	Action
	1	Remove the H. Pylori test device from its pouch and place it on a flat surface.
	2	Label the test device with patient identification number

Calculation N/A

Result Interpretation	Negative	Two distinct blue lines in the result window, one above the letter C and one above the letter T, indicate the presence of IgG antibodies to H. Pylori	Antibodies to H. pylori are either not present or at levels undetectable by the test.
	Positive	One distinct blue line in the result window above the letter C indicates the absence of detectable IgG antibodies.	The presence of antibodies to H. Pylori, but determination of an active or inactive infection cannot be made

	Invalid		The test should be repeated. If the sample fails to flow across the test window, the test is invalid and should be repeated.
--	---------	--	--

Note: - H. Pylori Rapid test is qualitative. The intensity of the sample test line does not necessarily correlate to the concentration of the antibody in the blood.

Expected Values	Positive or negative or invalid
-----------------	---------------------------------

Limitations

Procedural Notes

Principle	The test device contains a strip of plastic – backed membrane held in a result “Window” In contact with this strip is a porous pad containing blue latex particles, which have been coated with highly purified H.Pylori antigen. The membrane has been coated with two lines in the window area (i.e., highly purified H. Pylori antigen on the test line and a control line which captures the blue latex particles. When a serum sample is introduced into the test device, it solubilizes the colored latex dried into the porous pad. The serum then moves by capillary action across the membrane. Any anti- H. Pylori present in the serum binds to the antigen on the test line. Latex particles then migrate along the test strip where they are captured by the control line.
-----------	---

The presence of two lines in the result window indicates a positive test while only a single control line is a negative test.

Clinical Utility	H. Pylori infection is common in gastric cancer patients. An accurate diagnosis of H. Pylori infection is of value in targeting antibiotic- based eradication regimens in symptomatic patients.
------------------	---

Related Procedures
and Documents

Referenc
e

Name

Signature and Date

Prepared by: - Lezhialem Almaw-----

Revised by: -Tadesse Misganaw-----

Approved by: -Tadesse Misganaw -----

Declaration

I, the undersigned laboratory personnel, certify that I am conducting every steps of the procedures incorporated in this SOP after a prior reading.

S/N	Full Name	Signature and Date	Remark
-----	-----------	--------------------	--------

1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Procedure for HBSAG Test using" *InTec* "Advanced Quality one step strip

NEFAS MEWUCHA PRIMERY HOSPITAL LABORATORY
STANDARED OPERATING PROCEDURE

TITLE / DESCRIPTION:-HBSAG Test using" <i>InTec</i> "Advanced Quality one step strip		DOC#: -NMPHL-SER-PR-06
Applies To: Serology	Effective Date:- 01/APR/2017	

Chapter VI: Laboratory Manual

NEFAS MEWUCHA PRIMARY HOSPITAL LABORATORY



QUALITY POLICY MANUAL

Compiler: Lezhialem Almaw	Signature:
Approver: Tadesse Misganaw	Signature:
Effective Date: April 01, 2017	Version No. 01
Document No: NMPHL/GEN/QPM4.2-01	Copy No. 01

Revision and Amendment

A. Annual Review of Document

Revision No.	Review Date	Reviewed by:		Approved by:	
		Name	Signature	Name	Signature

B. Version Change History/Description

Version. No.	Effective Date	Description of Version Change	Name Signature Reviewer	& of	Name Signature approval	& of

C. Amendment

Rev. No.	Page No	Description of Amendment	Amendment Date	Effective Date	Name Signature approval	& of

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 components of any health care delivery system.

Thus to provide reliable and quality assured laboratory services, a strong quality management system is a key, so based on thus facts the NMPHL develop the policy and principles with regard to the overall quality service provision through its endeavor for serving as routine diagnostic laboratory for the Lay Gaynet and the nearby other catchment areas in line with the provision of diagnostic service, External Quality Assurance and other organizational management process and procedures to meet the international and national standards with regard to quality management system based on ISO 15189:2012. NMPHL's overall goal is to set international standards in laboratory diagnosis and get recognized through accreditation.

Finally, I believe that this quality policy 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.

Mr. Ayana Gebeyehu

Chief Executive Officer of NMPH

Terms and Definitions

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

Laboratory Head: Competent person(s) with responsibility for, and authority over, a lab

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 NMPHL.

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

Revision number: is number given for document when there is no a change in the document just to indicate periodically revision of document.

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

Supportive document: It is a document that helps to accomplish tasks or policy.

Validation: is conformation through provision of objective evidence, that the requirements for specific intended use or application have been fulfilled

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 (edition)

Compiler: A person who gathers/complies information and or prepares documents.

Approver: An authorized person who is responsible for documents and records approval

Subsidiary: It is a supportive document that helps to accomplish tasks or policy.

1. Introduction

Nefas Mewucha primary hospital is responsible for the provision of diagnostic laboratory testing services for clients and who come from the area around Lay Gaynet woreda and from all its surrounding catchments.

This Quality Manual outlines and references the policies and procedure of Nefas Mewucha primary hospital Laboratory (NMPHL) as it relates to its commitment to the implementation of the laboratory quality management system. It applies to all activities and personnel within the center and conforms to relevant international standards for laboratory services. (ISO15189:2012)

The purpose of this manual is to describe the Quality Management System of NMPHL through Quality Policies to meet the regulatory requirements and accreditation standards, and to ensure that the laboratory consistently deliver quality service to its customers.

It serves as a reference for laboratory personnel on all Quality System matters, providing direction on general policies, processes and responsibilities that govern & authorize the introduction of subsidiary quality-related documentation and protocols. All staff shall be informed in the use and application of this document and be advised incase of any changes.

This document also provides comprehensive evidence to all customers, stakeholders and employees that the NMPHL's commitment to quality.

Scope of operations and Services: This quality manual describes the quality management system of the NMPHL's laboratory diagnostic services. Its scope is for:

Nefas Mewucha primary hospital laboratory consist of the following laboratory services:

- A. **Reception:** Phlebotomy, specimen accessioning, specimen collection and receiving, and result distribution through porters.
- B. **Microbiology Section:** sputum smears microscopy, gram stain, KOH, Indian ink, body fluid analysis.
- C. **Parasitology and Urinalysis section:** Direct stool examination, urine chemical and urine microscopic methods.
- D. **Serology and immunoematology section:** Blood grouping, Rh factor, Cross match, Widal, Weiflex, RPR, Rheumatoid factor, H. Pylori, HCV, HBsAg.
- E. **Participating in EQA** (Proficiency testing, blind re-checking, onsite evaluation).

NB: the PT participation are facilitated and organized by EPHI and the source of the samples should be from internationally accredited PT providers.

3. Vision, Mission and Value statement

3.1. Vision statement

“To See Healthy, Productive and Prosperous peoples in Lay Gaynet woreda & other nearby areas”

3.2. Mission statement

To protect and promote the health of the people of Lay Gaynet woreda & other nearby areas by addressing priority public health problems through diagnostic service & establishing and maintaining quality laboratory system.

3.3. Values

- a. Professionalism:
 - Application of skills and high standards
- b. Integrity:
 - Firmness in more Principles,
 - Truthfulness at all time
- c. Excellence:
 - Outstanding feature or quality obtaining reliable results,

- State of superiority or eminence.
- d. Commitment:
 - A pledge of promise or obligation
- e. Efficiency:
 - The State or quality of being competent in performance,
 - Ability to accomplish a job with a minimum expenditure of time and effort
- f. Teamwork:
 - Cooperative or coordinated efforts on the part of a group of persons acting together in the interest of a common course.

4. Management requirements

4.1. Organization and management responsibility

4.1.1. Organization

4.1.1.1 General

Nefas Mewucha primary hospital (NMPHL) is committed to meet requirements of ISO 15189:2012 while performing work at its permanent facility.

4.1.1.2 Legal identity

The NMPHL is a governmental Health institution that is located in Lay Gaynetwored and legalized by federal ministry of health. The Hospital management ensures that the laboratories are independent from any commercial, financial or other pressures, which might adversely affect the quality of tests and test reports.

ADDRESS:

Name of Lab: Nefas Mewucha Primary Hospital Laboratory

Town: Nefas Mewucha: Kebele 01

Phone No: +251-584-451-143/

+251-584-480-444

Nefas Mewucha, Ethiopia

Working Hour: NMPHL Laboratory provides service 24 hours a day & seven days a week including public holydays.

4.1.1.3 Ethical conduct

The management of NMPHL has put in place an ethical conduct 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 NMPHL activities without declaring to the management;
- Analyze patient samples for investigations not requested by authorized clinician;
- Use patient samples to carry out research which is not cleared by ethical clearance of committee of NMPHL's Ethical Review Board.
- Disclose patient confidential information to any unauthorized person for any reason.

Supporting documents

Document Unique ID	Name of the Document
NMPHL/GEN/PR4.1.1.3-001	conflict of interest sop
NMPHL/GEN/GL4.1.1.3-001	Ethical conduct declaration

4.1.1.4 Laboratory Manager

- The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided.
- The responsibilities of the Laboratory Manager shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.
- The Laboratory Manager may delegate selected duties and/or responsibilities to qualified personnel; however, the Laboratory Manager shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.
- The duties and responsibilities of the Laboratory Manager shall be documented.

- The Laboratory Manager (or the designate for delegated duties) shall have the necessary competence, authority and resources in order to fulfill the requirements of this International Standard.

The Laboratory Manager (or designate/s) shall:

- provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;
- Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;
- Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;
- Ensure the implementation of the quality policy;
- Implement a safe laboratory environment in compliance with good practice and applicable requirements;
- Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;
- Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;
- Select and monitor laboratory suppliers;
- Select referral laboratories and monitor the quality of their service (see also 4.5);
- Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;
- Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;
- Monitor all work performed in the laboratory to determine that clinically relevant information is being generated;
- Address any complaint, request or suggestion from staff and/or users of laboratory services (see 4.8, 4.14.3 and 4.14.4);

- n. Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable; (NOTE Contingency plans should be periodically tested.)
- o. Plan and direct research and development, where appropriate.

4.1.2. Management responsibility

4.1.2.1 Management commitment

The management of NMPHL is committed to develop, implement, maintain and continually improvement the quality management system by ensuring that:

- Monthly meetings are done where staff informed on the importance of meeting needs and requirement of patients, health facilities as well as requirements of Nefas Mewucha primary Hospital
- Quality policy statement is established;
- All documents in use are updated;
- 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;
- Annual management review is conducted;
- All staffs are assessed for competency in their assigned tasks.
- Adequate resources needed to conduct pre-examination, examination and post-examination activities are available;

Needs of users

The management of NMPHL shall ensure that services offered including advisory services continuously meet needs and requirements of patients and health facilities by addressing both negative and positive feedback received.

Quality policy

Laboratory management shall define the intent of its quality management system in a quality policy. Laboratory management shall ensure that the quality policy:

- a. Is appropriate to the purpose of the organization
- b. Includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services;
- c. Provides a framework for establishing and reviewing quality objectives;
- d. Is communicated and understood within the organization;
- e. Is reviewed for continuing suitability..

Quality objectives and planning

The management of NMPHL shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements and the quality objectives. Laboratory management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Responsibility, authority and interrelationship

- Laboratory management shall ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization.

This shall include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel

- The Laboratory Manager shall be responsible for ensuring the establishment/refinement of the quality system that complies with the Quality Policy Statement and for providing the resources needed to ensure the required quality of laboratory operations.
- All personnel within the laboratory shall be responsible for implementation of quality related procedures and instructions and as such are authorized to initiate an Investigation, Action & Resolution (IAR) form when a deviation from the system occurs or when a non-conformance (both technical and system based) is identified.
- Responsibilities and authorities in relation to performance outputs are detailed in the Job Descriptions. In order to place emphasis on the responsibility of all staff in relation to the quality function of test performance and in relation to fulfilment of responsibilities for establishment, maintenance and continuous improvement of the Quality System the following directives are applicable
- It is recognized that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.

The interrelationships between management and staff are defined in the organizational chart shown in appendix 1 below.

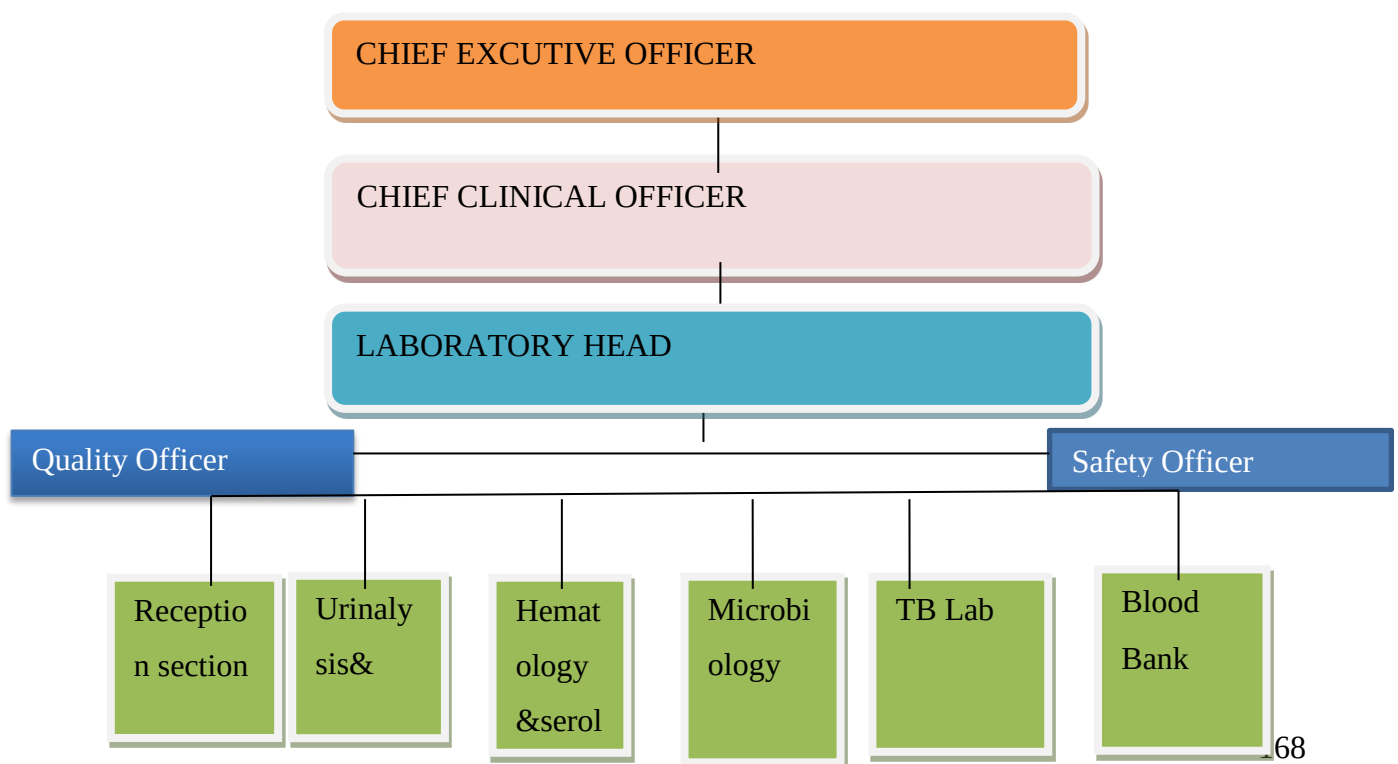


Fig: NMPHL organizational chart

Communication

Laboratory management shall have an effective means for communicating with staff. Records shall be kept of items discussed in communications and meetings. Laboratory management shall ensure that appropriate communication processes are established between the laboratory and its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system.

It is in this regard that NMPHL management has established communication mechanisms that will ensure that stake holders requirements (both internal and external) are meet. All communications (outgoing and incoming) are logged or filed whichever is appropriate.

Internal Communication

To achieve collective ownership of the system by both Management and staff, NMPHL management shall involve all staff in every aspect of the development and implementation of the QMS. For effective communication within the, NMPHL Management shall adopt channels of communication, which include but not limited to the following:

- Memos, letters, notices
- Meetings
- Oral communication
- Verbal or written instructions (e.g. through Quality Manual, Lectures).
- Periodicals (Bulletin)

External Communication:

Communication with external stakeholder is in the form of but not limited to letters, newspaper publication, electronic mail, telephone and meetings. NMPHL staffs are authorized to offer telephonic consultations on technical matters within the scope of their responsibilities to external facilities. Records of all communications shall be kept.

Supporting Documents

Document Unique ID	Documents Name
NMPHL/GEN/PR 4.1.2.6-01	Communication SOP
NMPHL/GEN/FO4.1.2.6-01	Minute Form
NMPHL/GEN/FO4.1.2.6-02	Memo Form

Quality officer

Laboratory management shall appoint a Quality Officer who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:

- i. Ensuring that processes needed for the quality management system are established, implemented, and maintained;
- ii. Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;
- iii. Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.

The Quality Officer is responsible for the implementation and maintenance of the Quality Management System in NMPHL.

The role of the Quality officer shall encompass:-

- The scheduling and performance of annual internal audits in conjunction with selected trained technical assessors;
- The scheduling of management review meetings;
- The follow-up of all corrective, remedial actions and complaints; and
- The coordination of document amendment, revision and distribution thereof

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/JD4.1.2.7-01	Quality officer job description

Quality management system

General requirements

The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The quality management system shall provide for the integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of the users.

The laboratory shall:

- a. Determine the processes needed for the quality management system and ensure their application throughout the laboratory;
- b. Determine the sequence and interaction of these processes;
- c. Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d. Ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- e. Monitor and evaluate these processes;
- f. Implement actions necessary to achieve planned results and continual improvement of these processes.

Documentation

NMPHL has established documents needed for its quality management system that include:

- Statement of quality policy and quality objectives
- Quality manual, safety manual, laboratory hand book and specimen management guideline
- 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, civil servant and good governance regulations

Type Descriptor	Document Description
M	Quality Manual
PR	Standard operating procedure
JD	Job Description
FO	Forms

JA	Job Aid
CHL	Checklist
TM	Training module
GL	Guideline
CHA	Chart
RB	Reference Books

Quality manual

The Quality Manual is maintained by the Quality Officer. The Quality officer is also responsible for ensuring that up to date versions are available both to staff and to users of the service and that any changes are communicated to all personnel concerned. All staff should understand and be governed by policies stated in this quality manual.

NMPH's laboratory shall establish and maintain a quality manual that includes:

- a) The quality policy (4.1.2.3) or makes reference to it;
 - b) A description of the scope of the quality management system;
 - c) A presentation of the organization and management structure of the laboratory and its place in any parent organization;
 - d) A description of the roles and responsibilities of laboratory management (including the Laboratory Manager and Quality Officer) for ensuring compliance with this International Standard;
 - e) A description of the structure and relationships of the documentation used in the quality management system;
 - f) The documented policies established for the quality management system and reference to the managerial and technical activities that support them.
- ❖ All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.

Documentation structure

NMPHL quality management system documents fall in to a three-tier structure which comprises of policies in first level , procedures/job aid in second level and forms , records, reference books , equipment manuals and other external documents in third level as illustrated in pyramid below.



Fig: Hierarchical structure of QMS documentation.

Policy: describes the organization goals and intentions “what is done and why”

Process: is set of interrelated or interacting activities that transforms inputs into out puts “how it happens” it will be presented as a flow chart or table that describes operations in the laboratories path of work flow or activities with-in a quality system essential.

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 policies

The quality officer distributes copies of quality manual and supporting documents to each section so that staff can have easy access. All staffs are trained on the use of quality manual and supporting documents.

Document control

The laboratory ensures that documents are managed from creation and receipt to archival and destruction, according to national laws, local regulations and international standards. The quality officer reviews and approves all requests for amendments to existing documents and the development of new procedures, processes, and policies. Staff is not permitted to make temporary amendments to documentation without the prior consent of the quality officer. When new or modified policies, processes and procedures are instituted, staff requires retraining.

All laboratory documents are reviewed on an annual basis. The responsibility for the annual review lies with the quality officer. The quality officer is responsible for the distribution of new documents, retrieval of old documents and maintenance of amendments documents. All

documents are stored in a safe environment to avoid deterioration and confidentiality. All documents are uniquely identified according to title, version number, pagenumbertotal pages, effective date, document number and authority for use. The quality officer reviews all documents to ensure that they are standardized and fulfill all requirements of ISO 15189:2012 before they are approved. NMPHL shall develop a procedure for document control SOP which gives more detail on document control from creation to destruction.

Archival of Documents

NMPHL is responsible for proper archiving of documents according to procedure NMPHL/ALS/SOP4.3-001. The laboratory retains or archives documents according to the document retention time in this manual. All documents deemed obsolete are destroyed and documented.

	Type documents	Retention time
1	Manuals, SOPs, formats and job aids	2 years after discontinue date
2	Reference books	indefinite
3	Guidelines	5 years
4	Standards	5 years

Supporting Documents

Document Unique ID	Document Name
NMPHL/GEN/SOP4.3-01	Document control SOP
NMPHL/GEN/FO4.3-01	Master index

Service agreements

Establishment of service agreements

NMPHL considers individual requests for examination brought in by patient as agreement. The Institute also makes an agreement with the health facilities that bring samples by referral system on behalf of their patients. NMPHL has developed a procedure for establishing and review of

agreements for providing medical laboratory services. The CEO signs agreements on behalf of NMPHL with respective head of health office on behalf of health facilities or organizations seeking services. The service agreement consideration states details in the service agreement SOP. If there is any deviation in agreement, there will be notification for customers.

4.4.2. Review of service agreements

The customers or service providers may initiate the review process. 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. The review is captured on service agreement review form. When there is an amendment or change on agreement, the signed parties should notify to their respective staff.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR4.4.2-001	Procedure for service agreement
NMPHL/GEN/FO4.4.2-001	Communication log
NMPHL/GEN/FO4.4.2-002	Service agreement review form
NMPHL/GEN/PR4.4.2-002	Patient notification SOP

Examination by referral laboratories

4.5.1. Selecting and evaluating referral laboratories and consultants

The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline.

The procedure shall ensure that the following conditions are met.

- I. The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the

quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.

- II. Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met.
- III. Records of such periodic reviews are maintained.
- IV. A register of all referral laboratories, and consultants from whom opinions are sought, is maintained.
- V. Requests and results of all samples referred are kept for a pre-defined period.

Provision of examination result

- Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.
- When the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report shall indicate which examinations were performed by a referral laboratory or consultant.
- The author of any additional remarks shall be clearly identified

Supporting document

Document Unique ID	Document Name
NMPHL/GEN/FO4.5.2-001	Format for list of approved laboratories
NMPHL/GEN/PR4.5.2-001	Procedure for referral laboratories
NMPHL/GEN/FO4.5.2-002	Referral samples log

External services and supplies

- The NMPHL shall have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service
- The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the

laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfil this requirement. Criteria for selection shall be established.

- A list of selected and approved suppliers of equipment, reagents and consumables shall be maintained.
- Purchasing information shall describe the requirements for the product or service to be purchased.
- The laboratory shall monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria and the supplies shall be evaluated at least annually.

NMPHL shall ensure that all received reagent, consumable and equipment meet expected standards and are suitable for intended use in accordance with checklist for receiving equipment, reagent and consumable materials. A procedure for selection and evaluation of external services and suppliers is available.

Supporting document

Document Unique ID	Document Name
NMPHL/GEN/CHL4.6-001	Evaluation of supplier checklist
NMPHL/GEN/ PR 4.6-001	Procedure for selection and evaluation of external service and supplies
NMPHL/GEN/CHL4.6-002	Checklist for receiving of equipment
NMPHL/GEN/CHL4.6-003	Checklist for receiving reagents and consumable

Advisory service

NMPH shall establish arrangements for communicating with users on the following:

- i. Advising on choice of examinations and use of the services, including required type of sample clinical indications and limitations of examination procedures and the frequency of requesting the examination;
- ii. Advising on individual clinical cases;
- iii. Professional judgments on the interpretation of the results of examinations
- iv. Promoting the effective utilization of laboratory services;
- v. Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.

Supportive Documents

Document Unique ID	Document Name
NMPHL/GEN/PR4.7-001	Procedure for Advisory Services
NMPHL/GEN/ CHL4.7-001	Supervision checklist for sample collection site
NMPHL/GEN/MAN4.7-001	Laboratory hand book

Resolution of complaints

NMPHL shall have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigation and the action taken

NMPHL shall be responsible for monitoring customer complaints obtained through bi-annual customer satisfaction survey, suggestion box and book by two weeks and via telephone or directly forward to any of laboratory management member at any time. All complaints shall be compiled by Laboratory Manager and resolved by NMPHL management. NMPHL has a procedure for resolution of complaints which is followed when resolving complaints from patients, health facilities and other customer/stakeholders as well as internal complaints from staff. During staff meetings, Staffs are informed to raise their complaints any time by way of filling in complaint form anonymously and submitting it through suggestion box which is opened weekly by laboratory Manager.

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
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Client Satisfaction Survey	Issue the Client Satisfaction Survey Form to clients, clinicians and patients on a regular basis.	Feedback from clients	All staff	Completed surveys
Proactive and reactive feedback from clients – Positive and Negative	Register all scores of less than 50% from the surveys and all reactive complaints in the Complaints& Compliments Register. Register all scores greater than or equal to 50% and all compliments received in the Complaints& Compliments Register. Initiate and register an IAR in accordance with the Investigation, Action & Resolution process and cross-reference each IAR to the respective complaint in the Complaint's Register.	Complaints/ Compliments registered. IAR initiated to investigate complaints	Quality Officer/Lab staff	Survey Results
Registered complaints and IARs	Investigate the root cause of each complaint, take corrective action and resolve in accordance with the IAR Process in the Corrective Action procedure.	Resolved Complaints	Laboratory Manager/ Quality Officer	Survey Results
Resolved Complaints	Notify clients of how complaint was resolved and what corrective action was taken.	Closed Complaint	Laboratory Manager	-

Supporting document

NMPHL/GEN/PR4.8-001	Procedure for conducting satisfaction survey
NMPHL /GEN/PR4.8-002	Procedure for Receiving and Resolution of Complaints
NMPHL /GEN/PR4.8-003	Procedure for Active Participation in the client Advice &Receiving and Resolution of Complaints
NMPHL /GEN/CHL4.8-001	Client Satisfaction Survey Check list
NMPHL/GEN/FO4.8-001	Customer Complaints Register form(Amharic version)
NMPHL/GEN/FO/FO4.8-002	Client satisfaction survey form(Amharic version)
NMPHL/GEN/FO4.8-003	Client Appointment Form

Identification and control of non-conformities

NMPHL shall be committee to the identification, documentation, correction, and prevention of nonconforming events in all aspects of the quality management system including pre-examination, examination and post-examination processes. Procedures are in placing that:

- Designate the individuals responsible and actions necessary for handling nonconformities;
- Ensures that each nonconforming event is documented, recorded, and reviewed at identified intervals, a root cause analysis performed, and that corrective action is taken and documented;
- Define when testing procedures and data reporting will be withheld due to nonconformities and when, and under what conditions, examination can resume;
- Defines the steps taken when examination data resulting from a nonconforming event has already been released.

Supporting document

Document Unique ID	Document Name
NMPHL/GEN/PR4.9-001	Procedure of identification and manage nonconformities

NMPHL/GEN/FO4.9-001	Non-conformity form
NMPHL/FO/4.9-002	Non-conformity log

Corrective action

NMPHL shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

NMPHL shall have a documented procedure for:

- a) Reviewing laboratory data and information to determine where potential nonconformities exist;
- b) Determining the root cause(s) of potential nonconformities;
- c) Evaluating the need for preventive action to prevent the occurrence of nonconformities;
- d) Determining and implementing preventive action needed;
- e) Recording the results of preventive action taken;
- f) Reviewing the effectiveness of the preventive action taken.

Action taken at the time of the nonconformity to mitigate its immediate effects is considered “immediate” action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered “corrective” action.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR4.10-001	Procedure for corrective action
NMPHL/GEN/FO4.10-001	Non-conformity form
NMPHL/GEN/FO4.10-002	Root cause analysis form

Preventive action

The NMPHL shall take action to prevent non-conformance which shall be identified from potential sources, whether technical or affecting quality management system. When a potential non-conformance is identified, the Laboratory reviews the data and implements preventive actions allowing the Laboratory to anticipate eventual nonconforming events in its activities. Preventive action includes the use of data from external assessments, internal audit results, quality records and complaints to detect, analyze and eliminate potential causes of nonconformities. A follow up of the actions implemented for improvement is ensured in the same way as described in Nonconforming Event Management. The quality officer shall be responsible for reviewing data on a monthly basis including trend analysis. Potential non-conformities are identified through trend analysis and preventive actions are developed and implemented accordingly.

Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment.

Supporting document

Document Unique ID	Document Name
NMPHL/GEN/PR4.11-001	Procedure for preventive action
NMPHL/GEN/CHL4.11-001	Preventive action checklist

Continual improvement

NMPHL management continually improves its quality management system in accordance with improvement procedure. All operational and technical procedures are reviewed annually. NMPHL shall establish mechanisms to continually improve effectiveness of its quality management system including support processes, operational processes and management 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 and Customer feedback.

The Chief Executive Officer (CEO) ensures that action plans for the above activities are developed, documented on minute's template 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. NMPHL management meets with stakeholders annually to discuss continual improvement activities that concern outcomes of patient care. When the continual improvement activities identifying opportunities for improvement, NMPHL management shall ensure that they are addressed regardless of where they occur. The Chief Executive Officer communicates any improvement plans and related goals during monthly staff meetings.

Supporting document

Document Unique ID	Document Name
NMPHL/GEN/PR4.12-001	Procedure for Continuous Quality Improvement Process
NMPHL/GEN/PR4.12-002	procedure for Continuous Quality Improvement
NMPHL/GEN/FO4.12-001	Quality Indicators Form
NMPHL/GEN/FO4.12-002	Quality Indicator Investigation Form
NMPHL/GEN/FO4.12-003	Quality Improvement Project Planning Form
NMPHL/GEN/FO4.12-004	Quality Indicator & Balanced Scorecard format

Control of records

NMPHL shall has a system for control of records which defines how quality and technical records are identified, collected, indexed, accessed, stored, maintained, amended and safely disposed. The management of NMPHL shall ensure that staffs create records at the same time of performing each activity. This is achieved through daily supervision by quality officer in each department and oversees by Quality Officer. NMPHL shall allow amendment of records by hand. This shall be 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. NMPHL has defined periods of retaining quality and technical records generated through implementing quality management system in the following table. NMPHL ensure safe storage of records to prevent their damage by fire, mites or water. The institute is also safe guarded from unauthorized persons gaining access to records. All quality and technical records are available for discussion in management reviews.

	Type records	Retention time
1	Result records (print outs & work sheets)	2 years
2	Result records (registration book)	5 years
3	Temperature records	2 years
4	Preventive maintenance (daily, weekly, monthly) records	2 years
5	Service repair (Major repairs, parts replacement and annual maintenance)	Life of instrument
6	Quality assurance, control & PT records	2 years
7	Calibration records	2 years
8	Method verification records	Life of instrument
9	Normal range change records	2 years
10	Employees continuous education, training, competency	2 years
11	Employee medical records	Indefinite

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR4.13-001	Procedure for electronic Storage Data (Back up).
NMPHL/GEN/PR4.13-002	Procedure for Document and record archival and retrieval
NMPHL/GEN/PR4.13-003	Procedure for correcting mistakes and alteration of records
NMPHL/GEN/PR4.13-004	Procedure for Identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records

Evaluation and audits

General

NMPHL shall plan and implement the evaluation and internal audit processes needed to:

- a. Demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;

b. Ensure conformity to the quality management system;

c. Continually improve the effectiveness of the quality management system.

The results of evaluation and improvement activities shall be included in the input to the management review(refer 4.15).

NMPHL performs ongoing quality assessments such as:

- Periodic review of examination requests, suitable methods and sampling requirements;
- Monitoring and evaluation of customer feedback, staff suggestions and impact of potential failures on examination results and customer expectations;
- Monitoring of determined quality indicators, corrective actions undertaken, and follow-up;
- Participation in proficiency testing program and review of the corresponding reports;
- Participation in internal and external audits.

The laboratory shall strive to continuously improve the quality of laboratory performance, the effectiveness of the quality management system and the reliability of test data. The laboratory does its best to identify and resolve any nonconformity that may affect laboratory performance and patient outcome. All results of evaluation and audit activities are discussed in the management review.

4.14.2. Periodic review of requests, and suitability of procedures and sample requirements

Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.

NMPHL shall periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.

4.14.3. Assessment of user feedback

NMPHL shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information shall include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users. Records shall be kept of information collected and actions taken.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR4.14.3-001	Resolution of complaints procedure

4.14.4. Staff suggestions

NMPHL shall encourage its staff to raise suggestions for improvement in their respective sections in staff suggestion form. Suggestions can be submitted through the suggestion box if the staff prefers anonymity or can be handed to any of the laboratory management members. The suggestions are discussed during monthly management meetings and an action agreed is implemented and communicated to staff during monthly meetings. The Quality Officer/assigned personnel maintain records of staff suggestions and action taken.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/FO4.14.4-001	1 to 5 team desiccation meeting minute

4.14.5. Internal audit

The quality officers shall schedule internal audit in the annual quality plan. 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. Internal

audit conducted by trained personnel 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 plans the audit activities which include defining objectives, scope, criteria, methods and assigning auditors to different sections and stating the actual audit dates. The planning is done at least three weeks before the audit on internal audit plan template 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 drawing conclusion on whether objectives were met and presents it in management meetings. The focal person for each section is responsible for doing corrective actions within time frame agreed with internal auditor. A procedure for internal audit has been developed which defines responsibilities and planning of audit as well as reporting results and maintain records.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR4.14.5-001	Procedure for conducting internal audit
NMPHL/GEN/FO4.14.5-001	Internal Audit report form
NMPHL/GEN/CHL4.14.5-001	Internal Audit Assessment checklist

4.14.6. Risk management

NMPHL shall evaluate 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. A procedure has been developed defining evaluation processes as well as coming up with improvement plan.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/FO4.14.6-001	Risk management form

Quality indicators

NMPHL shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

EXAMPLE Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports. The process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. The indicators shall be periodically reviewed, to ensure their continued appropriateness.

Quality indicators to monitor non-examination procedures, such as laboratory safety and environment, completeness of equipment and personnel records, and effectiveness of the document control system may provide valuable management insights.

Supporting document

Document Unique ID	Document Name
NMPHL/GEN/PR4.14.7-001	Quality indicator SOP

Review by external organizations

When reviews by external organizations indicate the institute has nonconformities or potential nonconformities, the NMPHL shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of the ISO15189. Records shall be kept of the reviews and of the corrective actions and preventive actions taken. NMPHL follows its procedure for corrective action to address all non-conformities identified by external organizations such as accreditation body, health authorities, funding program, and/or public health program. The quality officer maintains records generated thereof.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/FO4.14.8-001	Internal audit plan template
NMPHL/GEN/	Annual quality plan

AP4.14.8-001	
NMPHL/GEN/ FO4.14.8-003	Internal audit report form
NMPHL/GEN/PR4.14.8- 001	Procedure for internal audit
NMPHL/GEN/ FO4.14.8-004	Risk assessment form
NMPHL/GEN/ PR4.14.8-002	Procedure for risk management
NMPHL/GEN/ FO4.14.8-005	quality indicator planning work sheet
NMPHL/GEN/ FO4.14.8-006	Monthly sectional quality indicator form
NMPHL/GEN/ FO4.14.8-007	Quarterly quality indicator form
NMPHL/GEN/ PR4.14.8-003	Procedure for corrective action/Preventive action

Management review

The management of NMPHL shall review the effectiveness, continued suitability and adequacy of its quality management system in support of patient care annually as scheduled in the annual quality plan. The NMPHL management shall conduct an annual review, which includes at least the following agenda items, considers the following items of information.

- 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 programmes (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.

Review activities

The quality officer prepares the annual report at least two months before the management review defining reports needed for discussion and people responsible for preparing reports. As much as practical the reports are prepared showing trends over time for easy interpretation and following patterns.

Review output

The output of the management review includes minutes of discussions made and action plans for improvement of quality management system activities, definition of the quality objectives for the next year, establishment of new quality indicators in concordance with the new quality objectives, improving services to patients and health facilities and identification of resource needs and allocations. All staffs are informed of discussions made in management review including action taken in general staff meetings. The laboratory manager makes quarterly follow ups implementation of action agreed in management review.

... The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a quality management system is being established.

Supporting documents

Document Unique ID	Document Name

NMPHL/GEN/AP4.5.2-001	Annual quality plan
NMPHL/GEN/FO4.5.2-001	Annual report preparation form

Technical requirements

Personnel

NMPHL shall have a procedure for personnel management which is followed when managing personnel from the point of recruiting up to retirement. The laboratory manager shall maintain personnel files with technical record while human resource supportive process owner maintains the administrative records. The CEO informs/request the need of personnel for human resource supportive process then submits a completed staff recruitment form to the human resources department that describes the appropriate education, training, experience, and skills needed for the available position based on regional civil service rule.

Personnel qualification

NMPHL management shall document personnel qualifications for each position. The qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed.

The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience.

Professional judgments can be expressed as opinions, interpretations, predictions, simulations and models and values, and should be in accordance with national, regional and local regulations and professional guidelines.

Job description

NMPHL shall have a job description for all positions that describe responsibility and authority for personnel.

Personnel Orientation

The laboratory Manager 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.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/CHL5.1.4-001	Personnel orientation check list

Training

NMPHL shall provide training for all personnel which include:

- a) Quality management system;
- b) Assigned work processes and procedure by expertise before staff start working in the section;
- c) Laboratory information system(LIS) by super-user or IT staff once before using LIS;
- d) Health and safety annually;
- e) Ethics by human resource manager once before starting work;
- f) Confidentiality of patient information

Personnel undergoing training are supervised by the respective expertise 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.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.1.5-001	Competency Assessment SOP
NMPHL/GEN/FO5.1.5-001	Training Feedback Assessment Form

Competency assessment

Following training in their respective sections, laboratory experts are assessed for technical competency by assigned competent staff. Staff competencies cover technical and practical skills and general knowledge. Competency of each new employee (within 6 months) is assessed and verified before permitting to perform testing and report results.

The management members shall be assessed for competency in their assigned management roles. Competency assessment is done annually and anyone who fails is offered additional training then re-assessed. The criteria for competency assessment are defined in the procedure of personnel management.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.1.5-001	Competency Assessment SOP
NMPHL/GEN/FO5.1.5-001	Training Feedback Assessment Form

Reviews of staff performance

NMPHL shall use a government balanced score card system designed Regional Civil service guideline for staff performance evaluation bi-annually. Performance appraisal is planned and evaluated by Laboratory Manager. CEO with human resource supportive process owner ensures performance evaluation is done.

Staff performing reviews should receive appropriate training.

Continuing education and professional development

- A continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed.
- Personnel shall take part in regular professional development or other professional liaison activities.

Personnel records

NMPHL shall maintain the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel.

These records are readily available to relevant personnel and include but not be limited to:

- a. Educational and professional qualifications;
- b. Copy of certification or license, when applicable;
- c. Previous work experience;
- d. Job descriptions;
- e. Introduction of new staff to the laboratory environment;
- f. Training in current job tasks;
- g. Competency assessments;
- h. Records of continuing education and achievements;
- i. Reviews of staff performance (balanced score card) and appreciation letter when applicable
- j. Reports of accidents and exposure to occupational hazards;
- k. Hepatitis –B vaccine immunization, and others when relevant to assigned duties.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.1.9-001	Procedure for personnel management
NMPHL/GEN/CHL5.1.9-001	Staff orientation check list
NMPHL/GEN/FO5.1.9-001	Technical competency assessment form

5.2 Accommodation and environmental conditions

NMPHL shall provide sufficient space and reliable infrastructure to perform its work, to ensure the quality, safety and efficacy of the services provided, and to meet national safety regulations. NMPHL design shall provide an efficient and safe environment for the laboratory staff, other

health care personnel, patients, and the community. Personnel are trained in the basics of safety and bio-risk management issues.

CEO 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.

5.2.2. Laboratory and office facilities

The laboratory has several rooms, each designated for specific uses; offices, storage supplies, washrooms, patient collection area, and laboratory working areas.

All visitors entering laboratory beyond reception are identified with visitors ID card to control their access to technical sections, to patients sample and confidential information of patients and laboratory resources. All visitors authorized to gain access to the laboratory are issued with visitors ID card by the security staff and are accompanied by NMPHL staff.

Floor plan of the laboratory:

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 disposal of solid waste while designated drainage system is used for disposing liquid waste.

5.2.3. Storage facilities

- Storage space and conditions shall be provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.
- Clinical samples and materials used in examination processes shall be stored in a manner to prevent cross contamination.
- Storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified by applicable requirements.

Staff facilities

NMPHL shall have enough washrooms, clean supply of drinking water and storage facilities for personal protective clothing and equipment.

. Patient sample collection facilities

NMPHL shall have 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 and accompanying guardian. Sample collection room shall be equipped with air conditioner and temperature is monitored to prevent samples from being exposed to extreme temperatures. A first aid kit which is checked for functioning by reception staff shall be available in the sample collection room for use on staff and patient.

Facility maintenance and environmental conditions

Environmental temperatures shall be monitored twice daily and benches are decontaminated twice daily by laboratory experts in respective sections. Floors are cleaned once daily and ceilings and walls quarterly by janitors. Different examination procedures are done in separate rooms to avoid cross contamination. NMPHL environment is quiet and no interruptions are there to disturb staff from doing their work.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/REG5.2.6-001	FMHACA waste management and disposal regulation
NMPHL/GEN/GL5.2.6-001	Health and safety guideline for public health laboratories in Ethiopia
NMPHL/GEN/CHA5.2.6-001	Temperature monitoring charts
NMPHL/GEN/CHA5.2.6.-002	First aid kit monitoring chart
NMPHL/GEN/CHA 5.2.6-003	Spill kit monitoring chart
NMPHL/GEN/FO5.2.6-001	Bench and floor decontamination form

5.3. Laboratory equipment, reagents, and consumables

5.3.1. Equipment

The management of NMPHL shall be furnished with all equipment needed for the provision of laboratory services and ensures proper equipment selection, purchasing installation, calibration, validation, and disposal according to established procedures and manufacturer's instructions to

meet the needs of the laboratory to perform quality diagnostic testing. The laboratory shall replace equipment as needed to ensure the quality of examination results. The management gets advice from bio-medical engineers when to replace equipment.

5.3.1.2 Equipment acceptance testing

5.3.1.2.1 Installation qualification

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 shall be trained on operating and maintaining the equipment.

5.3.1.2.2 Operator qualification

Trained staff analyzes known samples on the equipment to ensure proper functioning of equipment. Section laboratory persons are responsible for ensuring operator qualification is done.

5.3.1.2.3 Performance qualification

Inspection shall be done to verify that the equipment performs as intended by the manufacturer and as expected by NMPHL are done. Section focal persons are responsible for ensuring performance qualification is done. All equipment shall be uniquely identified by their serial numbers and laboratory generated ID numbers.

5.3.1.3 Equipment instructions for use

NMPHL has authorized its trained staff to perform examination procedures and manage the equipment. Equipment manuals shall be readily accessible to staff in each section. NMPHL shall have a procedure for equipment management which gives guidelines and reference to equipment manuals for safe handling, transportation and storage of equipment to prevent its contamination or deterioration.

5.3.1.4 Equipment calibration and metrological traceability

NMPHL shall calibrate its equipment by using Ethiopian metrological agencies. When this is not possible or relevant; the laboratory uses certified material for calibrating the equipment or calibration by another procedure.

5.3.1.5 Equipment maintenance and repair

Each section of NMPHL shall have preventive maintenance program for its equipment which is developed based on manufacturer recommendations as given in equipment user manual. Annual and/or biannual service of equipment by engineers shall be organized by APHI which enter in to service agreement with the vendors for some equipment. NMPHL makes service agreement for equipment which have no service agreement by APHI.

Defective equipment shall be decontaminated and clearly labeled as “do not use” and date when equipment broke down and expected date of repair. The equipment decontamination takes place before performing any repairs or service and provides necessary space and personnel protective equipment.

After onsite service/repair or any equipment is taken out of the laboratory for services /repairs, section laboratory persons ensure its proper function by calibrating and running controls upon its return.

5.3.1.6 Equipment adverse incident reporting

Any adverse incidents and accidents that can be attributed directly to equipment shall be investigated by section focal person then reported to NMPHLCEO who in turn reports in writing to APhi or directly to the vendors.

5.3.1.7 Equipment records

NMPHL shall maintain equipment records on equipment inventory form. Equipment records are retained for periods defined in documents and record retention time. All equipment shall be uniquely identified by quality officer. Updating of the equipment inventory records shall be ensured by quality officer. The equipment records include but not limited to:

- Name of the equipment, model and serial number
- Identity of the equipment
- brand (manufacturer)
- contact information
- Location
- Date of purchase
- Date of receiving and date of entering into service
- Condition when received (New, used or reconditioned)
- Maintenance records
- Acceptance records
- Equipment performance records
- Equipment repair, modification or malfunction

Supporting documents

Document Unique ID	Document Name
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NMPHL/GEN/PR5.3.1.7-001	Equipment management SOP
NMPHL/GEN/FO5.3.1.7-001	Equipment maintenance form
NMPHL/GEN/M5.3.1.7-001	Equipment user manuals
NMPHL/GEN/FO5.3.1.7-002	Equipment acceptance criteria form

5.3.2 Reagents and consumables

NMPHL shall ensure that the procedures for the receipt, storage, and inventory management of all reagents guarantee the quality of testing is not compromised.

5.3.2.2 Reagents and consumables – Reception and storage

A laboratory personnel assigned to the store shall be responsible for receiving and ensuring proper storage of reagents and consumables according to manufacturer recommendations. Reagents are received according to criteria in checklist.

5.3.2.3 Reagents and consumables – Acceptance testing

Quality control shall be done for each shipment or new lot of reagents received and records are maintained by respective laboratory personnel.

5.3.2.4 Reagents and consumables – Inventory management

NMPHL store room ensures monitoring consumption of reagents and consumables. Stock level, expire date, lot number and balance are monitored using bin card. Section laboratory professionals update the reagent consumption every two weeks using Intra Facility Request and Reporting (IFRR). Requesting and Reporting Format (RRF) is used to order reagents and consumables from Pharmaceutical and Fund Supply Agency (PFSA) every other month. Physical inventory of reagents and consumables is done once a year by designated inventory committee.

5.3.2.5 Reagents and consumables – Instructions for use

NMPHL personnel shall maintain leaflet for reagents and consumables in their respective sections for making reference when required. A file of Material Safety Data Sheet (MSDS) is kept in store room and in each laboratory section.

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 section focal person or safety officer and reported to laboratory process owner who in turn reports in writing to NMPHL CEO and PFSA or directly to the vendors.

5.3.2.7 Reagents and consumables – Records

Reagent receiving checklist, bin card and reagent two weeks consumption log shall be used together to ensure records for reagents and consumables are maintained. In-house prepared reagents are identified by name of reagent, initial of person who prepared the reagent, date of preparation, expiry date and assigned lot number.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.3.2.7-001	Procedure for equipment management
NMPHL/GEN/PR5.3.2.7-002	Procedure for reagent and consumable management
NMPHL/GEN/CHL5.3.2.7-001	Check list for receiving reagents and consumables
NMPHL/GEN/FO5.3.2.7-002	Bin Card
NMPHL/GEN/FO5.3.2.7-003	Equipment decontamination form
NMPHL/GEN/FO5.3.2.7-004	Equipment inventory form
NMPHL/GEN/FO5.3.2.7-005	Document and record retention time form
NMPHL/GEN/CHL5.3.2.7-002	Reagents daily consumption log
NMPHL/GEN/FO5.3.2.7-006	Physical inventory count form
NMPHL/GEN/PR5.3.2.7-001	Purchasing and inventory SOP

5.4. Pre examination processes

5.4.1. General

NMPHL shall be develops written documents related to information for patients and users, information's included on request form, and specimen management guideline.

5.4.2 Information for patients and users

NMPHL shall have information available for patients and users of the laboratory services. The information shall include as appropriate:

- a. The location of the laboratory;
- b. Types of clinical services offered by the laboratory including examinations referred to other laboratories;
- c. Opening hours of the laboratory;
- d. The examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, and turnaround time (TAT)
- e. instructions for completion of the request form;
- f. instruction for preparation of the patient;
- g. Instructions for patient-collected samples;
- h. Instructions for transportation of samples, including any special handling needs;
- i. Any requirements for patient consent (e.g. Consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);
- j. The laboratory's criteria for accepting and rejecting samples;
- k. A list of factors known to significantly affect the performance of the examination or the interpretation of the results
- l. Availability of clinical advice on ordering of examinations and on interpretation of examination results;
- m. The laboratory's policy on protection of personal information;
- n. The laboratory's complaint procedure.

5.4.3 Request form information

NMPHL shall have the request form that contains information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical data according to local requirement. All the request forms developed and accepted as external annexed in specimen management guideline.

5.4.4 Primary sample collection and handling

NMPHL laboratory shall provide written instructions for specimen management (collection, transport and handling).

5.4.4.2 Instructions for pre-collection activities

NMPHL's instructions for pre-collection activities shall include the following:

- completion of request form;
- preparation of the patient
- type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;
- special timing of collection, where needed;
- Clinical information relevant to or affecting sample collection, examination performance or result interpretation.

5.4.4.3 Instructions for collection activities

NMPHL shall develop instructions for collection activities of samples, labeling needs, storage conditions and disposal of materials used for collection.

5.4.5 Sample transportation

NMPHL specimen transport shall follow national and international transport guidelines and regulations.

5.4.6 Sample reception

NMPHL shall establish written specimen/sample acceptance and rejection criteria for each test offered and provide this information to its customers, as applicable. All specimens/samples are inspected according to these acceptance/rejection criteria. Specimens/samples that are not suitable for processing are rejected and notified for requester with reason for rejection.

If the specimen/sample is critical and cannot be rejected, the examination is performed and a notation is made on the report. In the case of critical specimens/samples, such as one of limited volume, the laboratory receptionist consults with the requestor to prioritize testing.

A unique registration number is assigned to each specimen/sample to be analyzed. All patients' data is recorded.

5.4.7 Pre-examination handling, preparation and storage

If the specimen needs to be shared for different tests throughout the laboratory and/or storage purposes, each aliquot (sample) is labeled individually with the unique registration number. Samples are stored under proper temperature and safety conditions.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/M5.4.7-001	Clinician hand book
NMPHL/GEN/PR5.4.7-001	Procedure for verbal request
NMPHL/GEN/GL5.4.7-001	Specimen management guideline
NMPHL/GEN/PR5.4.7-002	Sample transportation SOP

5.5. Examination processes

5.5.1. Selection, verification and validation of examination procedures

5.5.1.1 Policy

NMPHL shall ensure to implement an approved examination procedure and use only validated and verified methods to produce accurate and reliable results. Latest version of examination procedure must be available and use at all time. All procedures must be documented and be available at the workstation for relevant staff. Performance characteristics for each examination have in place.

5.5.1.2 Verification of examination procedures

The procedures developed in the laboratory have been through a documented verification process. The procedures used in the laboratory, that have been published in scientific reviews or transmitted by national or international reference centers, have been verified and documented under the laboratory's conditions and adapted when needed.

The methods and techniques used in the laboratory are described in the standard operating procedures (SOPs) and associated documents

5.5.1.3 Validation of examination procedure

NMPHL shall validate examination procedures derived from the following sources:

- a. Non-standard methods;
- b. Laboratory designed or developed methods;
- c. Standard methods used outside their intended scope;
- d. Validated methods subsequently modified.

5.5.1.4 Measurement uncertainty of measured quantity values

NMPHL shall determine uncertainty of measurement values of its quantitative methods to be used when helping clinicians to interpret patient results, and to determine the inherent error in the system. The management defines expected values of measurement uncertainty of each quantitative method and these are compared with values obtained from annual estimates. NMPHL develops a procedure for uncertainty of measurement to guide staff in estimating uncertainty of values. When clinicians or other stake holders request uncertainty of measurement of values NMPHL cooperates.

5.5.2 Biological reference intervals or clinical decision values

NMPHL shall adopt biological references from kit inserts/country studies on reference intervals and this has been communicated to health facilities through the clinicians hand book. Critical values have been established in consultation with local clinicians and are also communicated to health facilities through clinicians hand book. Whenever examination procedures are changed such that reference ranges and critical values are different, the clinician hand book is updated and clinicians are informed by laboratory management.

5.5.3 Documentation of examination procedures

NMPHL shall document all examination procedures used in its different sections that are available at each work station and kept centrally at the general quality officer's office. All examination procedures and job aids are controlled according to document control procedure. All examination procedures are written in standard format as defined in document control procedure which complies with the requirements of ISO 15189:2012. If NMPHL intends to change any

examination procedures such that results or their interpretations could be significantly different, the implications are explained to clinicians and health facilities before putting new procedure in service.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.5.3-001	procedure for verification of methods
NMPHL/GEN/FO5.5.3-001	uncertainty of measurement values form
NMPHL/GEN/PR5.5.3-002	procedure for uncertainty of measurement

5.6 Ensuring quality of examination results

5.6.1 Policy

NMPHL shall implements quality management system to ensure that examinations performed are standardized. All staffs have declared in the ethical conduct form that they will strictly understand and follow the standardized methods and procedures.

5.6.2 Quality control

5.6.2.1 Policy

NMPHL shall be defines frequency and type of internal quality control procedures in each technical standard operating procedure that verify the attainment of the intended quality of results.

5.6.2.2 Quality control materials

NMPHL shall be 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.

5.6.2.3 Quality control data

NMPHL shall develop a procedure for review of quality control data to guide staff on reviewing and interpretation of quality control results which prevents release of patient results in the event of quality control failure. When quality control chart and multi rule systems detect any random or

systematic errors, preventive actions are put in place. Laboratory experts review quality control data on a daily bases while quality officer review the data monthly.

5.6.3 Inter-laboratory comparisons

5.6.3.1 Participation

NMPHL shall participate in inter laboratory comparisons program such as external quality assessment program or proficiency testing for all its examination procedures while schedules are provided by EQA bodies. EQA samples are performed in the same way of patient samples. If results are unacceptable or do not fulfill the requirement, corrective actions will be taken and documented. Procedure for participation in EQA which defines instructions for participation and review of the performance has been developed. 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.

5.6.3.2 Analysis of inter-laboratory comparison samples

NMPHL shall ensure that EQA samples are integrated into routine work flow in a manner that resembles handling of patient samples. The EQA samples shall be analyzed by laboratory experts who analysis routine patient samples using the same examination procedures. Laboratory experts are not allowed to communicate with other participating laboratories about EQA sample data until results are submitted. EQA samples are not referred to other laboratory for confirmatory tests nor are expert advice sought. Staffs are bound by ethical conduct declaration to abide by this regulation.

5.6.3.3 Evaluation of laboratory performance

NMPHL's Quality Officer, section focal person and laboratory expert of respective sections involved in analyzing EQA samples shall be responsible for review of performance and implementing corrective actions when results are not acceptable. Quality officer and section focal persons monitor the effectiveness of corrective action taken through daily internal quality control and subsequent EQA. The section focal persons compile annual report on performance in EQA which is used as a preventive action to detect trends. The reports are presented and discussed in management reviews.

5.6.4 Comparability of examination results

NMPHL shall have a means of comparing 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 stake

holders meetings. Section focal persons maintain comparability records and any actions taken as a result of problem identified.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.6.4-001	procedure for review of internal quality control results
NMPHL/GEN/PR5.6.4-002	Procedure for participation in EQA
NMPHL/GEN/FO5.6.4-001	ethical conduct declaration form
NMPHL/GEN/PR5.6.4-003	Procedure for comparison of equipment or methods

5.7 Post- examination processes

5.7.1 Review of results

NMPHL shall have procedures to ensure results are reviewed and released by authorized laboratory personnel. The review process takes into account results of internal quality control. NMPHL information system does not automatically select and report results unless approved and released by authorized laboratory personnel.

5.7.2 Storage, retention and disposal of clinical samples

NMPHL shall have a procedure 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. Samples are safely disposed in accordance with health and safety guideline for public health laboratories in Ethiopia.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.7.2-001	procedure for reporting and releasing result
NMPHL/GEN/GL5.7.2-001	sample management guideline
NMPHL/GEN/FO5.7.2-001	sample retention schedule
NMPHL/GEN/GL5.7.2-002	Health and safety guideline for public laboratory

	in Ethiopia
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5.8 Reporting of result

NMPHL shall report results through the laboratory information system (LIS) which ensures accuracy, clarity, unambiguously in accordance to procedure for reporting and releasing of results and as per examination procedures. Hard copies of result are printed from the laboratory information system by reception staff and send to health facilities. Result review process ensures checking of transcription or transmitting errors before results are released by authorized laboratory expert. Reports are released with reference ranges in SI unit where applicable, and accompanied by any relevant comments on integrity of sample. Reception staff notifies health facilities and patients of any delay in processing sample that could compromise patient care.

5.8.2 Report attribute

NMPHL ensures laboratory results shall effectively communicated and meet the users need 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 timely communicated through telephone and flagged/highlighted on the report:
- Interpretative comments are made.

5.8.3 Report content

NMPHL report shall include, but not be limited to, the following:

- a) A clear, unambiguous identification of the examination including, where appropriate, the examination procedure;
- b) The identification of the laboratory that issued the report;
- c) Identification of all examinations that have been performed by a referral laboratory;
- d) Patient identification and patient location on each page;
- e) Name or other unique identifier of the requester and the requester's contact details;
- f) Date of primary sample collection (and time, when available and relevant to patient care);
- g) Type of primary sample;

- h) Measurement procedure, where appropriate;
- i) Examination results reported in SI units, units traceable to SI units, or other applicable units;
- j) Biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable;

Under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.8.3-001	Procedure for reporting and releasing result
NMPHL/GEN/PR5.8.3-002	Procedures for acceptance and rejection criteria

5.9 Release of results

5.9.1 Policy

A procedure for reporting and releasing of results has been developed which guide authorized laboratory personnel on how to release results and to whom. Results of patients with serious implications are not communicated directly to the patients. Such results are communicated to referring health facility for opportunity to better patient management. Staffs ensure that when suitability of primary sample is compromised, it should be indicated in the report. Laboratory experts are responsible for communicating critical results to health facilities by telephone and ensuring that the hard copy report gets to the facility in the shortest possible time. When results are communicated through telephone, the laboratory experts ask the identity of the received person to ensure that results reach only authorized personnel. Such communications are captured in communication log.

5.9.2 Automated selection and reporting of results

NMPHL shall be operate a system which automatically selects and report results. All results are verified in the laboratory information system by authorized laboratory personnel before released.

5.9.3 Revised report

NMPHL shall be establishes a procedure how to revise original reports for reporting and releasing of results. Laboratory personnel authorized to revise reports shall 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 focal person 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 section focal person maintains records of revised reports.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.9.3-001	Procedure for reporting and releasing of results
NMPHL/GEN/FO5.9.3-001	Communication log Form

5.10 Laboratory information management

5.10.1 Policy

NMPHL staffs shall have access to data and information needed to provide service which meets the needs and requirements of customers. Procedure for ensuring confidentiality of patient information is available and staff has also signed ethical conduct declaration preventing them from disclosing patient confidential information from unauthorized persons.

5.10.2 Authorities and responsibilities

The management of NMPHL has authorized some of its staff 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

5.10.3 Information system management

NMPHL shall be operates a laboratory information system for collection, recording, reporting, storing and retrieval of examination data. The laboratory information system in use has been validated by the vendor and verified by the laboratory that it's suitability for its intended use. A procedure for the operation and maintenance of Laboratory information system is available giving instructions on the day to day activities use. All staffs are issued with password which has access levels to use the laboratory information system. This ensures the Laboratory information system is protected from unauthorized persons as well as from tempering or loss. NMPHL shall be maintains records of changes/updates. NMPHL customers are not connected automatically to the laboratory information system; results are printed and issued as hard copy. NMPHL shall has backup generator and uninterrupted power supply (UPS) connected to all computers to ensure service is not interrupted during power cuts. The IT officer of NMPHL shall be responsible for doing data backup as per a procedure for the operation and maintenance of Laboratory information system. When the LIS system fails the laboratory will revert back to the manual system of recording patient data in work sheet and releasing manual report, and the patient's results in hardcopy are protected by locking in lock board.

Supporting documents

Document Unique ID	Document Name
NMPHL/GEN/PR5.10.3-001	Procedure for ensuring confidentiality of patient information
NMPHL/GEN/PR5.10.3-002	procedure for the operation and maintenance of Laboratory information system
NMPHL/GEN/PR5.10.3-003	Procedure for corrected amended result

References

1. ISO 15189:2012 – Medical Laboratories – Particular requirements for quality and competence

2. QMS02-A6, Quality management system: development and management of laboratory documents; approved guideline- six edition. February 2013
3. CAN/CSA-Z15189 Medical laboratories –particular requirement for quality and competency;4.8-4.9.

DECLARATION

I have read and understand this quality manual and I agree to consistently follow the guide as described.

S/N	Full Name	Signature and Date	Remark

Chapter VII: Research

7.1 seroprevalence of syphilis and associated factors among pregnant women attending antenatal clinic in gambella hospital, gambella, Ethiopia, 2017

Abstract

Background: Syphilis is one of the sexually transmitted infections caused by bacteria and it is transmitted through sexual contact, via blood transfusion, or transplacentally. In 2008 there were 1,360,485 pregnant women with probable active syphilis infections. In Ethiopia the prevalence of syphilis among antenatal care attenders has been quantified and survey every two year has been undertaken and showed that 9% prevalence of syphilis was highest in gambella hospital.

Objective: To assess seroprevalence and associated factors of syphilis infections among pregnant women attending antenatal care at Gambella General Hospital, Gambella , Ethiopia, 2017.

Methods: The study was conducted at Gambella General Hospital from November to December. Pregnant women attending antenatal clinics were study population. Cross sectional study design was employed. The sample size calculated was 385 pregnant women. Data was entered and analysed using Stata Statistical Software for Social Science (STATA). Variables in multivariate analysis with p-value < 0.05 were considered statistically significant. Ethical clearance was obtained and confidentiality maintained.

Result: The overall sero prevalence of syphilis was 11.9%. About 45.6% of the sero positive mothers were found in 26-30 age categories. Six (8.5%) of respondents with genitourinary symptoms were reactive for VDRL test. The prevalence of syphilis was 24.0% for mothers who had abortion. Mother history of sexually transmitted disease; adjusted odds ratio (AOR) : 8.488; 95%CI: 3.289-21.906), Mother who had extra sexual partner (AOR: 7.510; (95%CI: 2.839-19.863), husband, who had extra sexual partner (AOR: 6.005; 95% CI: 2.487-14.495), history of abortion (AOR: 5.082; 95%CI: 2.043-12.646) and husband travel history (AOR: 3.191; (95%CI: 1.402-7.262) were significantly associated with syphilis infections.

Conclusion and Recommendation: Syphilis infection among pregnant women in Gambella hospital was high-intermediate. Mother history of abortion, mother extra sexual partner relationship, travel history of husband, multi sexual partnership of husband and mother history of sexual transmitted disease associated with syphilis infection. Health education needs to be provided to mothers and husband about possible risk factors.

Key words: Syphilis, Gambella, prevalence

Introduction

Background

Syphilis is one of the sexually transmitted infections (STI) caused by the bacteria known as *Treponema pallidum* that results in substantial morbidity and mortality which is a fragile spiral bacterium with 6-15 micrometer long by 0.25 micrometer in diameter; the bacteria can survive only briefly outside of the body (1). Syphilis is transmitted through sexual contact with infectious lesions of the mucous membranes or abraded skin, via blood transfusion, or in utero by transplacental passage of the *Treponema* from a pregnant woman to her fetus. The risk of transmission is related to the maternal *Treponema* load; hence early maternal infection carries a much greater risk of transmission than late infection. Congenital syphilis is due to hematogenous dissemination of *Treponema pallidum* from untreated or inadequately treated pregnant women to their fetus, via the placenta untreated, the disease lasts many years and is divided into stages (2,3).

Early syphilis consists of primary syphilis, secondary syphilis and early latent syphilis, while late syphilis consist of late latent syphilis and tertiary syphilis (3). Syphilis may go clinically unnoticed, especially in women, in whom even the primary stage may not have visible symptoms. It is paramount that pregnant women be examined many times during antenatal care (ANC) in order to detect any suggestive finding on physical examination; however, both the detection and diagnosis of syphilis are based chiefly on routine serological tests. Syphilis more than any other bacterial and curable sexually transmitted infection, has greater potential to cause adverse birth outcomes when the diagnosis is missed (4).

Syphilis is estimated to cause over 500,000 adverse pregnancy outcomes per year, like spontaneous abortion, stillbirth, prematurity, clinical manifestations of congenital syphilis, infant death, and late sequelae; seventeen percent of all adverse pregnancy outcomes in unscreened women were attributable to maternal syphilis(4).

Statement of the problem

Syphilis is still serious public health issue in the modern world both in developed and developing country. Approximately 12 million new cases of syphilis detected each year and more than 2

million occur in pregnant women (5). The risk of contracting syphilis through a sexual contact with a person that has primary or secondary syphilis is 30–50% (5).

Worldwide, a million pregnancies are adversely affected each year by syphilis because of maternal infection. About 270 000 babies are born with congenital syphilis, 460 000 pregnancies end with abortion or perinatal death. Furtherly, vertical transmission can occur at any time during pregnancy and at any stage of syphilis but it is more common in primary (50%) and secondary syphilis (50%), compared with early latent (40%), late latent (10%) and tertiary syphilis (10%) (6,7).

World Health Organization (WHO) estimates that in 2012 there were approximately 950 000 maternal syphilis infections; that resulted in 360 000 adverse outcomes, including 150 000 early fetal deaths or stillbirths, 110 000 infants with congenital infection, 60 000 neonatal deaths, and 50 000 preterm or low-birth-weight infants (8). In 2008 there were 1,360,485 pregnant women with probable active syphilis infections; the estimated number of infected pregnant women by region was (44.3%) in Asia, (39.3%) in Africa (7.8%) in the Americas, (4.0%) in the Pacific (3.0%) in the Mediterranean and (1.6%) in Europe (9).

In Brazil, more than 100,000 cases were reported during pregnancy between 2005 and 2014 (10). The burden of syphilis in pregnancy was greatest in Africa, representing 63.1% of global maternal infections and 64.0% of adverse outcomes and the lowest was in Europe, representing 2.0% of maternal infections and 1.2% of adverse outcomes (10).

In Africa, its prevalence among pregnant women has been found to vary from 1.2 % in Nigeria (11), to 9.3% in Zambia (12) and 22.1% in south Sudan (13). Ethiopia is a country where maternal syphilis is highly prevalent; The prevalence of syphilis among ANC attendants has been quantified and survey every two year has been undertaken since 1989 (14).

Syphilis infections have been causing a serious pregnancy related problems with high morbidity and mortality effect. As a result; Understanding the burden of these infections in pregnant women is an integral part to develop strategy for prevention and to emphasis on providing integrated service. In Ethiopia the prevalence of syphilis was high in the past three consecutive survey periods. National ANC survey conducted in Ethiopia showed that 9% prevalence of syphilis was highest in Gambella General hospital compared to other regions and even more

than the national 1.2% prevalence(15). Hence, there was a recommendation placed that further research need to undertake in Gambella region aiming to determine the possible determinant factors for high syphilis prevalence in the region. Therefore; this study will provide a data on the current burden and determinant factors of this infection at Gambella General Hospital.

Significance of the study

Syphilis infections are the major causes for the development of different complications during pregnancy worldwide. The result of this study will be used by Programme managers, health planners or policy makers and other concerned bodies to initiate the relevant intervention measures and screening packages in pregnant women.

Generally, this study will used to:

- Find out the current burden of syphilis among pregnant women in the study area.
- Identify the possible determinant factors for acquisition of this infection among pregnant women in the area.
- Identify gaps that help to design a strategy for prevention of syphilis infection transmission among pregnant women in the area.
- Draw the attention of stake holders to focus on such life threatening but preventable infection.
- It may also serve as a baseline data for the coming researchers who are interested in related topics.

Conceptual frame work

The study used this conceptual framework, which was developed after referring different literatures. The detail of conceptual framework displayed as follow and the arrows in the diagram show the relationship between dependent and independent variables.

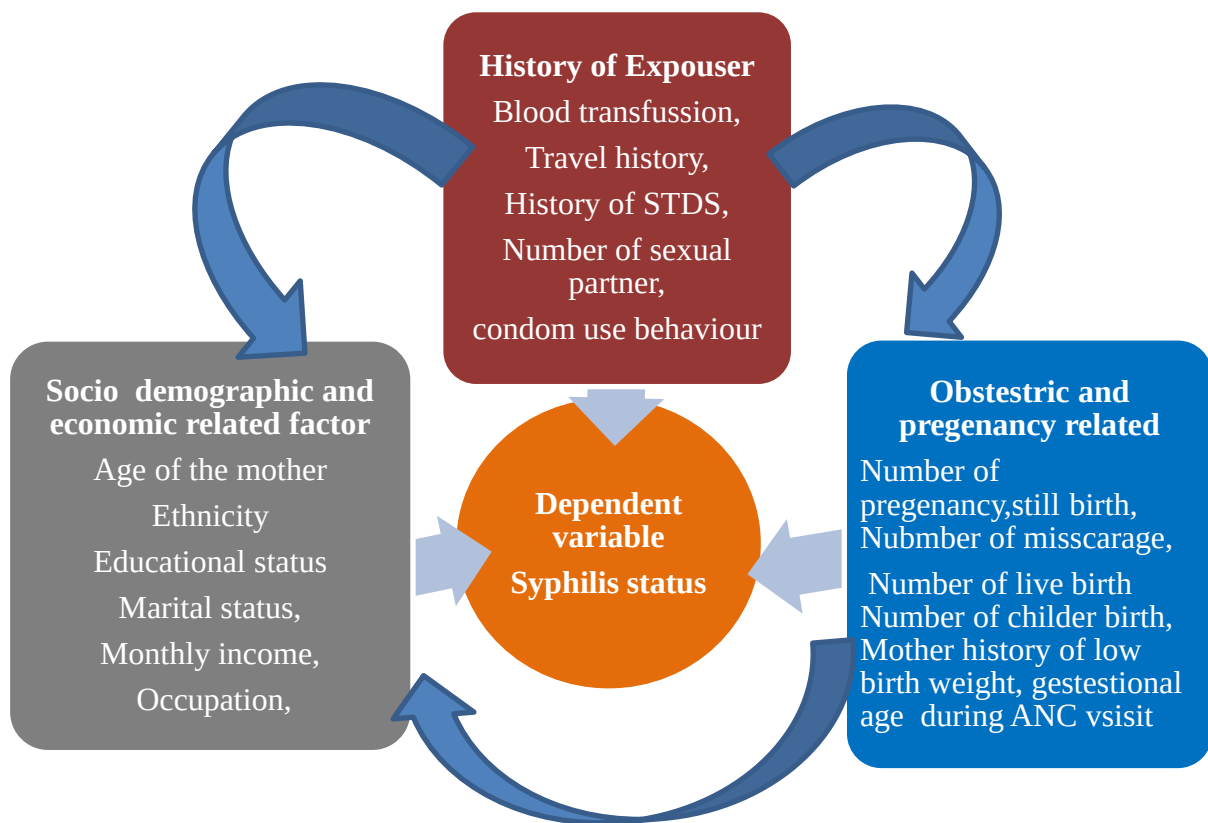


Figure 16: Conceptual framework showing the factors associated with syphilis among pregnant women ANC attendant.

Literature review

Prevalence of syphilis

A syphilis infection is well recognized worldwide but has been reported to be more common in developing countries especially in Africa and Asia. Perhaps it's wide spread all over the world; different epidemiological studies suggest that the prevalence of such common sexually transmitted infections has been shown to vary from one country to other among different groups k(5).

A study conducted by Gabriela T et al, from 2010 to 2013 on seroprevalence of syphilis among pregnant women in the Varna region (Bulgaria), the prevalence of syphilis was in range 0.43% in 2010 and 0.74% by 2013 (16).

A cross-sectional prevalence study done on women attending ANC in Karachi, Pakistan on 2007, with Prevalence of syphilis among antenatal clinic attendees, the prevalence of syphilis found to be less than 1 percent (0.9%) (17).

A study conducted on Sero prevalence of syphilis infection among patients attending antenatal Care & Sexually transmitted disease (STD) clinics among 17440 pregnant women in Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, India by Nazish Fatima, et al, 2014 showed that 23 (0.15%) were found to be positive by Venereal Disease Research Laboratory (VDRL) (2).

Baseline report on global sexually transmitted infection surveillance 2012, indicated the prevalence of syphilis among ANC attendee: Argentina (1.1%), Brazil (1.2%), Chile (0.2%) Algeria (1.9%) and Togo (1.2%) (18).

Cross sectional study done in Tanzania in 2011, shown syphilis seroprevalence of 2.5% and (27) likewise study conducted by Jacob Sakala, et al., on 2015 in Zambia ,reveled the overall prevalence of syphilis was 9.3% (12).

Survey done in South Africa on the year 2010, national prevalence of syphilis shows a 0.4% decrement where the prevalence was 1.8% in 2009 to 1.5% in 2010 (28).

A study done in Nigeria in 2011, on *Treponema pallidum* Infection among a Cohort of Pregnant Women with 185 consenting women, with prevalence of syphilis 0.5% (6). Similarly a study conducted in Maiduguri, Nigeria on prevalence of syphilis among pregnant women of 108 serum samples syphilis prevalence was 1.9% (24).

Study in Tanzania done by Sia E Msuya, et al on 2009 to determine Prevalence of sexually transmitted infections among 2654 pregnant women, 0.9% of syphilis prevalence was found (19).

In a cross-sectional study conducted among 7069 pregnant women attending antenatal clinics in Cameroon to assess the Hepatitis B, HIV, and Syphilis Seroprevalence in Pregnant Women by Jodie Dionne-Odom et al, 2014 shows with an overall prevalence of 4% for syphilis (20).

On the other study to correlates syphilis sero-reactivity on pregnant women among a total of 2270 women with HIV-infected and 366 with HIV-uninfected in countries, Malawi, Tanzania, and Zambia antenatal syphilis prevalence rates were 2.7% ,7.2% and 8.2% respectively (21).

Similar cross-sectional study conducted in Ikot Ekpene, Nigeria by Etim Inyang E et al, in 2011 to determine prevalence of sexually transmitted diseases among pregnant women in a total of 562 pregnant shows with overall seroprevalence syphilis was found to be 1.2%. In this study 1.9% highest prevalence syphilis was seen among 73/108 those women who visited on first trimester (1-13Weeks) most of them were civil servant and 1.4% were married by marital status women (11).

In Kenya, a study done among 13,478 pregnant women attending care of age ranging 15-49 ,the prevalence of syphilis was 0.2% (22).

In Namibia, the 2014 national syphilis sentinel surveillance done among ANC attendant showed as the over prevalence of syphilis be 1.9% (23).

In south Sudan, a cross-sectional study conducted to determine prevalence and associated factors for syphilis in pregnant women attending selected antenatal clinics showed with syphilis prevalence of 22.1% within the study (13). Similarly ANC survey done on assessing the magnitude of HIV and Syphilis at 35 sentinel surveillance site among ANC attendee, South Sudan for the year 2012 shows with a seroprevalence 8.3% (25).

In Sudan, a study done on seroprevalence of syphilis among pregnant women in Khartoum, Sudan on 100 pregnant ANC attendant women by Abdel-bagi et al., 2008 maternal syphilis prevalence found to be 9% (26).

Study done by Elizabeth D, et al, on prevalence and significance of sexually transmitted diseases, among 342 pregnant women attending ANC in Addis Ababa two teaching hospitals shown seroprevalence of syphilis be 28% (29).

In a cross sectional study conducted by E. Kebede and B.Chamiso in Addis Ababa, on 1997 with prevalence of syphilis in pregnant women were carried out among 410 antenatal attendants, with the study 2.9% prevalence of syphilis was found (30).

Prospective cross sectional study done in 2005, by Andargachew M. et al, on Seroprevalence of syphilis and HIV-1 during pregnancy in a teaching hospital in northwest Ethiopia among 480 pregnant women, the syphilis prevalence was 1% and (31).

Similarly, a study done by Mengistu E et al, 2011 in Gondar teaching Hospital, Northwest Ethiopia, the overall prevalence of syphilis among pregnant women was 2.9%. (32).

In north east Ethiopia, a study done by Mulugeta M.et al in 2012, on magnitude of HIV and syphilis seroprevalence among 300 ANC attendant pregnant women was 3.7% (33).

Similarly, national ANC sentinel survey of Ethiopia, in 2014, among 53,431 pregnant women the overall national syphilis prevalence was 1.2% and syphilis prevalence was 0.7% in urban and 1.3% in rural sites respectively; likewise the syphilis prevalence in 2012 round were 0.7% in urban and 1% in rural sites, but the syphilis prevalence was 0.7% in urban and 1.3% in rural sites in 2014 round. (15).

In national ANC sentinel survey of Ethiopia in 2009, the highest and lowest syphilis prevalence was reported from Gambella (4.7%) and Dire Dawa (0.1%); moreover 4.7% and 6.7% syphilis prevalence was reported from urban and rural setting of Ethiopia respectively (34).

According to, report on the 2014 round antenatal care based sentinel HIV surveillance in Ethiopia the prevalence of syphilis in Gambella region with 390 pregnant mothers was 5.0 %; the high syphilis figure were reported from Gambella General Hospital with a magnitude of 9% syphilis prevalence (15).

2.2. Determinant factors

A study conducted by Gabriela T et al, from 2010 to 2013 on seroprevalence of syphilis among pregnant women in the Varna region (Bulgaria), mother's place of residence has association with syphilis (16).

A cross-sectional prevalence study done on women attending ANC in Karachi, Pakistan on 2007, with prevalence of syphilis among antenatal clinic attendees; on this study women married to men with a lower educational background ,history of still birth and abortion was associated with contracting syphilis (17).

A study done in Nigeria in 2011, on *Treponema pallidum* infection among a cohort of pregnant women with 185 consenting women age group 31-40 were the risk factor for syphilis (6).

On the other study to correlates syphilis sero-reactivity on pregnant women among a total of 2270 women with HIV-infected and 366 with HIV-uninfected in countries, Malawi, Tanzania, and Zambia thus HIV infection (OR = 3.3), maternal age 20 to 24 years (OR = 2.5, being divorced/widowed/ separated (OR = 2.9, having had treatment for genital ulcers in the last year (OR = 2.9), history of stillbirth (OR = 2.8 for one stillbirth; OR = 4.3 for 2–5 stillbirths), or having had a preterm delivery (OR = 2.7 for one preterm delivery) were identified risk factors for the prevalence of syphilis (21).

In Kenya, a study done among 13,478 pregnant women attending antenatal care of age ranging 15-49 within this study age 35-49 and living in rural area were identified as a determinant factors (22).

A study conducted in Maiduguri, Nigeria on prevalence of syphilis among pregnant women of 108 serum sampled women with in this social demographic variable such as age, gravidity, trimester and history of blood transfusion were not statically significant with contracting syphilis (24).

In south Sudan, a cross-sectional study conducted to determine prevalence and associated factors for syphilis in pregnant women attending selected antenatal clinics being a housewife, history of abortion, attending ANC for previous pregnancy and history of partner travel were determinant factors associated with syphilis (13).

Similarly ANC survey done on assessing the magnitude of HIV and Syphilis at 35 sentinel surveillance site among ANC attendee, South Sudan for the year 2012 shows Pregnant women with no formal education, age group of 30 – 34 years, women with a history of two pregnancies, widowed women, and married women in polygamous relationships, married women in monogamous relationships were risk factor for syphilis (25).

In Sudan, a study done on seroprevalence of syphilis among pregnant women in Khartoum, Sudan on 100 pregnant ANC attendant women by Abdel-bagi et al., 2008 here the past history of genital ulcers was found to be significant with positive cases of syphilis (26).

Study done in Tanzania in 2011, among ANC attendant women having more than three previous pregnancies and attending semi-urban and rural ANC clinics were significant to syphilis(27).

A study conducted by Jacob Sakala, et al., on 2015 in Zambia revealed; abortion history, still birth, multiple sexual partners, previous maternal syphilis infection, partner history of sexually transmitted infection and maternal co-morbid conditions of HIV and genital ulcer disease were significantly associated to maternal syphilis (12).

In a cross-sectional study conducted by E. Kebede and B.Chamiso in Addis Ababa, on 1997 with prevalence of syphilis in pregnant women were carried out among 410 antenatal attendants, Meanwhile monthly income less than 600 birr/month was identified as the risk factor for syphilis (30).

Prospective cross-sectional study done in 2005, by Andargachew M. et al, on Seroprevalence of syphilis and HIV-1 during pregnancy in a teaching hospital in northwest Ethiopia among 480 pregnant women, on this study age had no association with syphilis seroprevalence (31).

Similarly, a study done by Mengistu E et al, 2011 in Gondar teaching Hospital, Northwest Ethiopia, in this study, women with a history of miscarriage and stillbirth had statistically significant association with syphilis sero-positivity (32).

In North East Ethiopia, a study done by Mulugeta M.et al in 2012, on magnitude of HIV and syphilis seroprevalence among 300 ANC attendant pregnant women on this study husband illiteracy was a determinant factor for syphilis (33).

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Objective:**General Objective**

To assess seroprevalence and associated factors of syphilis infections among pregnant women attending antenatal care at Gambella General Hospital, Gambella , Ethiopia, 2017.

3.2. Specific objectives:

To determine seroprevalence of syphilis infection among pregnant women.

To identify socio-demographic factors associated with syphilis

To assess sexual behavior and obstetrics related factors associated with syphilis.

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Method and Materials

Study Design and Settings:

Institution based, cross-sectional study design was employed at the Gambella General Hospital (GGH), from 01 November –December 2017.

The study was conducted at Gambella General Hospital located in Gambella Town administration, Gambella Regional State, which is about 777 km from the capital city of Ethiopia, Addis Ababa.

Based on the 2007 Census conducted in Ethiopia, CSA total population projection documents that the total population of Gambella was 435,999 (consisting of 227,000 men and 208,999 women). Of those female populations 100,280 and 13,079 are child bearing female population and pregnant mothers respectively (35)(36).

It serves as a referral for more than 250 thousand people coming from various districts of the region. It has 95 beds for inpatient and outpatient health care services including ANC for pregnant women. Many pregnant women visit the ANC clinic in a year for routine pregnancy check-up services that include the assessment of pre-existing health conditions (screening for anemia, syphilis, HIV), vaccination, nutrition counseling, micronutrient supplementation and early detection of pregnancy related complications. The ANC clinic serves pregnant women five days in a week and mostly they are attended by midwives and nurses and the clinic serves on average 20 pregnant women visit the hospital for ANC utilization each day from Monday to Friday.

The laboratory department in the hospital provides routine screening services for pregnant women with trained laboratory professionals; a quality syphilis diagnosis is done in the hospital laboratory using non Treponema specific testing kits. The study was conducted between November 01, 2017 and last week of December, 2017.

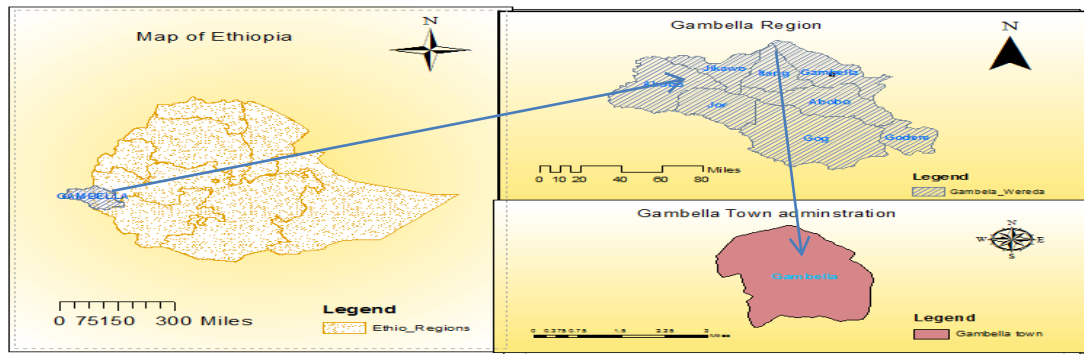


Figure 17: Map showing study area, Gambella region.

Study population with eligibility criteria:

The source populations were all consecutive pregnant women who were attend Antenatal care (ANC) clinic for check-up services at Gambella General Hospital during the study period. Study populations were pregnant women attending antenatal care clinics in Gambella general Hospital and provide consent and referred for serological test to the laboratory between November-December, 2017.

Inclusion Criteria: Any pregnant woman attending antenatal care clinics in Gambella General Hospital between November-December, 2017 was recruited for the study

Exclusion criteria: pregnant woman who was mentally sick and unable to respond by her own self was excluded from the study.

Pregnant mothers who attended the clinic for more than one visit were excluded.

Sample size determination:

Sample size was statistically calculated based on single population proportion formula by taking 9.0% prevalence of syphilis infection from previous study (15), desired precision of 3%, a 95% confidence level and 10% non- response rate was considered. In addition sample size was also calculated for the predictors'; then sample size was calculated by considering its prevalence and determinant factors. Finally, the calculated sample size indicated below:

$$n = \frac{(Z_{\alpha/2})^2 * p(1-p)}{d^2}, \quad n = \frac{(1.96)^2 * 0.09(1-0.09)}{(0.03)^2} = 350; \quad 350 * 10/100 = 385$$

Where: n= sample size

$Z_{\alpha/2}$ = Z value at 95% CI [1.96]

p = prevalence of syphilis is = 9%

d = precision or degree of error (d = 0.03)

With the above inputs the sample size required including 10% non-response was 385.

Variables	CI (%)	Power (%)	Ratio (Exposed: Unexposed)	% of outcome in unexposed	AOR	% of outcome in exposed	Sample size	Reference
Husband Educational status (Illiterate)	95	80	2	1.3	7.2	8.4	285	15
Occupation (house wife)	95	80	4.2	1.5	7.19	9.6	312	15

After computing the sample size using syphilis prevalence and based on its predictors the highest sample size was 385. It was considered in for the final study sample size

Sampling Technique and Procedures:

As a routine service delivery procedure of the ANC clinic, pregnant women were triaged and assigned to the ANC clinic. According to the sequence of their registration, they were allowed to enter into the ANC room for routine follow-up care one by one. Meanwhile, after the purpose of the study was explained to the subjects, they were asked to participate voluntarily in the study. All pregnant women with confirmed pregnancy and willing to involve were enrolled in this study. Pregnant mothers who attended the clinic for more than one visit during the study period were excluded. To avoid this, a unique mark was putted on cards of all enrolled mothers. Accordingly, pregnant women who attended the ANC clinic were on consecutive systematically enrolled until the desired sample size was attained. Information on socio-demographic and other pertinent data was collected by trained data collectors using a pre-tested structured questionnaire.

Study Variables:

Dependent variable: Seroprevalence of syphilis among pregnant women

Independent variables: Age, educational status, monthly income, history of blood transfusion, history of sexually transmitted diseases, number of pregnancy, number of child, miscarriage/abortion.

Data collection tools and procedures:

Before starting data collection for the actual study; the questionnaire was pre tested on 10% of the study population at nearby health institution. Finally, Information regarding socio-demographic exposure history and obstetric characteristics of the study participants was collected using pretested questionnaires. In the questionnaire, data like marital status, residence, self-reported history of prior still birth and/or miscarriage, occupation and education levels was included.

Laboratory method:

Five ml of venous blood was obtained in vacutainer tubes from each study participants as part of a routine ANC and used for sera preparation. Syphilis sero reactivity was tested using the Venereal Disease Research Laboratory (VDRL) as per the manufacturer's instructions and recommendations; the left over serum sample was used for performing the test.

Operational definition:

High Income: Those mothers who get greater than or equal 3000 ETB per month.

Low income: Those mothers who get less than 3,000 ETB per month.

Syphilis positive: pregnant woman who tested positive by VDRL test kit.

Syphilis Negative: pregnant woman who tested negative by VDRL test kit.

Husband extra marital relationship: husband/sexual partner who had more than one wife and/or had sexual contact other than his wife.

Travel history of the mother: Mother who had traveled from her residence area/village irrespective to the frequency of journey

Travel history of the husband: Husband/pregnant mother's sexual partner who had traveled from his residence area/village irrespective to the frequency of journey.

Data Quality:

Before the start of the actual research data collection work, a two days training was given for all data collectors on overall objective, data collection tools and method of data collection, similarly pilot study was done in adjacent health facility on 10% of the sample size in order to evaluate for the data collection tools of the questionnaire.

Likewise, to maintain the quality of laboratory results, standard operating procedures (SOPs) of the test kit's manufacturer was followed strictly. Positive and negative controls were run along with each batch of VDRL test kit

Data Analysis:

Data was entered and analysed using SPSS version 21. A descriptive statistical test such as proportion, frequency and median was carried out to compute the socio demographic, behavioral and the outcome variable of the study population. Binary logistic regression analysis was used to determine the association between predictor (explanatory) variables and the outcome variable with odds ratio at 95% confidence interval (CI). All explanatory variables with P-value ≤ 0.2 in the bivariate analysis were included in multivariate logistic regression model. P-value < 0.05 in multivariate analysis was considered as statistically significance.

Ethical considerations:

The study obtained ethical clearance from Institutional Review Board (IRB) of the St. Paul's Hospital Millennium Medical College, Department of Public Health. Letter to perform the study was obtained from the department of public health to Gambella regional health bureau. Regional health bureau in turn wrote supportive letter to Gambella General Hospital; then the hospital administrator wrote permission letter to the ANC clinics as to start the study. All study participants were informed about the study and assured about the confidentiality, protection and

anonymity of data. Written consent was obtained from each study participant prior to data collection and they participated voluntarily in the study. Laboratory results of Syphilis were reported to the ANC clinic with the consent of the mother for further management of infected pregnant women and they were also advised not to have sexual contact unless their sexual partner gets tested of syphilis and treated.

Result

A total of 385 pregnant women were enrolled in the study. All women approached for participation were consented, interviewed and provided clinical samples (participation rate=100%)

Socio-demographic Characteristics of the Study Participants

Regarding to the age group distribution of the respondents; median age of the study population was 26 years (IQR of 5). One hundred sixty eight women (43.6%) were in the age group of 26-30 years. Of all the study participants, 326 (84.7%) were living in urban settings. Within the ethnicity category; 96(24.9%) of them were Anywaa, followed by Nuer 75(19.5%), Oromo 49(15.3%) other ethnic group holds the rest of the percent. With respect to the marital status of the mothers majority 371(96.4%) of the pregnant mothers were married and the other (single, divorced and widowed) holds less than five percent of the respondents (See table 1).

Table 27 Socio-demographic characteristics of pregnant women attending at Gambella General Hospital, September to November 2017, Gambella, Ethiopia

Variables	Frequency	Percentage (%)
Age		
≤20	38	9.9
21-25	121	31.4
25-30	168	43.6
31-35	43	11.2
≥36	15	3.9
Residence of the mother		
Urban	59	15.3
Rural	326	84.7
Mother educational level		
Uneducated	72	18.7
Read and write	77	20.0
1-8	57	14.8
9-12	94	24.4
Higher Institution	85	22.1
Mother occupation		
Employed	113	29.4
House wife	157	40.8
Daily laborer	43	11.2
Merchant	57	14.8
Commercial sex worker	3	8.0

Others	12	3.1
Ethnicity		
Anywaa	96	24.9
Nuer	75	19.5
Majang	5	1.3
Kembata	53	13.8
Amhara	49	12.7
Oromo	59	15.3
Tigre	32	8.3
Wolayita	9	2.3
Others	7	1.8
Marital status		
Single	7	1.8
Married	371	96.4
Divorced	5	1.3
Widowed	2	0.5
Husband educational level		
Uneducated	84	21.8
Read and write	60	15.6
1-8	59	15.3
9-12	40	10.4
Higher Institution	142	36.9
Mother monthly income		
≤2000	277	72.0
2001-4000	79	20.5
≥4001	29	7.5

Knowledge status of the pregnant women

Of the total pregnant mothers who participated in the study less than half 170(44.2%) of the respondents didn't hear about syphilis but 14(3.6%) of them don't know any clue about the syphilis. Similarly 153(76.1 of them don't know as the disease can transmit to unborn child through the placenta (table 2).

Table 28: Knowledge status of pregnant women attending ANC clinic at Gambella General Hospital, Gambella, Ethiopia, 2017

Variables		Frequency	percentage
Heard about Syphilis	Yes	201	52.2
	No	170	44.2
	I don't know	14	3.6
Knows ways of disease transmission	Yes	106	52.3
	No	95	47.7
Knows mother-child transmission	Yes	48	23.9
	No	153	76.1
Attending ANC reduce the risk to unborn child	Yes	82	40.7
	No	119	59.3

Seroprevalence of syphilis and associated risk factors

The overall seroprevalence of syphilis was 46/385(11.9%). About 45.6% of the sero-positive mothers were found in 26-30 age categories. The prevalence of syphilis was 18.6% and 10.7% in rural and urban respectively. Similarly of total reactive for VDRL test, more than three fourth (76%) of syphilis sero-positive were from urban setup. The prevalence of syphilis was 28.6% among single and 11.6% among married women. With regard to the educational level of the mothers the prevalence of syphilis was higher among those women who able to read and write13 (28.2%) and those have attended higher education 12(26%).

From the total syphilis sero positive pregnant mothers, 15(32.6%) were Nuer and 9(19.5%) of them were Anywaa by ethnicity. Of the total syphilis sero-reactive pregnant mothers 43(93.45%) of them were married. High proportion, 65% of reactive pregnant mothers had monthly income of less than or equal to 2000 Ethiopian birr (ETB). Among 201 respondents who ever heard about syphilis 28(13.9%) of them were positive for syphilis

Only 5(15%) of the pregnant women were reactive for syphilis among those who had had blood transfusion previously. One hundred fifty two (39.4%) of ANC attendants had previous history of sexual transmitted disease; of them 30(20%) were infected with syphilis. Among those mothers who had previous history of genitourinary symptoms 6(8.5%) of them were reactive for VDRL test. Whereas, 83(21.5%) of husbands had had history of genitourinary symptoms of which 8(9.6%) of their sexual partner (Wives) were reactive for syphilis.

Fifty (12.9%) pregnant women and 121(31.4%) husband had extra sexual partner. Similarly prevalence of syphilis was slightly higher among those women who had more than one extra sexual partners 36% and 25.6% mothers were reactive among those whose partners have extra sexual partner relationship. The prevalence of syphilis was 19.5% among women who get pregnant for the fourth times and more followed by 19.3% for women on their third pregnancy number.

Nearly three fourth (73.3%) of the pregnant women were multigravida; 14% of them were positive for syphilis. likewise 127(48.4%) of the respondents had only single delivery. Of the 385 respondents, 104(27%) had had history of abortion; hereby the prevalence of syphilis was 24.0% among those who had abortion before.

Socio-Demographic and knowledge Data related to Syphilis infection

From socio demographic variables those were significant in bivariate analysis here each predictor tested with the dependent variables: Living in rural setup (OR: 1.905; 95% CI: 0.906-4.006; $p=0.089$), Mothers who don't know how syphilis transmits (OR:0.465; 95% CI: 0.193-1.119; $p=0.087$), Mothers who don't know as syphilis transmit to newborn child (OR:0.465; 95% CI: 0.193-1.119; $P=0.087$) (see table 3).

Table 29: Association of possible risk factors related to syphilis infection in pregnant women attending ANC at Gambella General Hospital, Gambella, Ethiopia, 2017

Variables	Categories	Non-Reactive N (%)	Reactive N (%)	COR at 95%CI	P-value
Mother educational level	No formal education	114(87.4%)	15(11.6%)	0.8(0.355-1.806)	0.592
	Primary	87(92.5%)	6(6.5%)	0.42(0.150-1.173)	0.098
	secondary	65(82.3%)	13(16.7%)	1.217(0.519-2.855)	0.652
	Higher education	73(86%)	12(14%)	1	
Residency	Urban	291(89.3%)	35(10.7%)	1	
	Rural	48(81.4%)	11(18.6%)	1.905(0.903-4.006)	0.089
Husband educational level	No formal education	127(88.2%)	17(11.8%)	0.867(0.430-1.745)	0.688
	Primary	54(91.5%)	5(8.5%)	0.599(0.213-1.689)	0.333
	Secondary	35(87.5%)	5(12.5%)	0.925(0.322-2.65)	0.884
	Higher institution	123(86.6%)	19(13.4%)	1	

Sexual behavior and risk factors for acquiring syphilis

Sexual behavior related risk factor those were significant in bivariate analysis: mothers having previous history of STD (OR: 3.335; 95% CI: 1.748-6.363; P= 0.000), Husband who had travel history (OR:2.633; 95% CI: 1.383-5.014; P=0.003), Mother who had extra sexual partner before (OR:5.117; (95% CI: 2.522-10.382; P=0.000) were more likely to be positive for syphilis infection (Table 4).

Table 30: Association of sexual behavior and risk factors related to syphilis infection in pregnant women attending ANC at Gambella General Hospital, Gambella, Ethiopia, 2017.

Variables	Categories	Non-Reactive N (%)	Reactive N (%)	COR at 95%CI	P-value
Mother history of STD	Yes	122(80.3)	30(19.7)	3.335(1.748-6.363	0.000
	No	217(93.1)	16(6.9)	1	
Types of STDs mother infected	Syphilis	61(80.3%)	15(19.7)		
	Other than syphilis	47(81.1)	11(18.9)		
	Undetermined	14(77.8)	4(22.2)		
Mother travel history	Yes	113(88.3)	15(11.7)	0.968(0.502-1.860	0.922
	No	226(88)	31(12)	1	
Husband travel history	Yes	141(87.5)	20(12.5)	2.633(1.383-5.014)	0.003
	No	198(88.4)	26(11.6)	1	
Mother extra sexual partner relationship	Yes	32(64)	18(36)	5.117(2.522-10.382)	0.000
	No	307(91.6)	28(8.4)	1	
Husband extra sexual relationship	Yes	90(74)	31(26)	6.167 (3.078-12.359)	0.000
	No	249(94.3)	15(5.7)	1	
	≤ 2	218(92.8)	17(7.2)	1	

Number of pregnancy	pregnancies				
	>2pregnancies	121(79.7)	29(19.3%)	3.073(1.60-5.80)	0.001
Number of delivery	One	114(89.7)	13(10.3)	1.54(0.700-3.424)	0.281
	Two	85(82.5)	18(17.5)	2.192(0.800-6.005)	0.127
	≥ Three	28(80)	7(20)	0.861(0.370-2.003)	0.729
	No delivery	112(90.)	11(10)	1	
History of abortion	Yes	79(75.9)	25(24.1)	3.918(2.08-7.375)	0.000
	No	260(92.1)	21(7.9)	1	
Transfusion	Yes	28(84.8)	5(15.2)	1.355(0.495-3.703)	0.554
	No	311(88.4)	41(11.6)	1	
Partner history of STD	Yes	101(82.3%)	21(17.2%)	1.979(1.059-3.698)	0.032
	No	238(90.5%)	25(9.5%)	1	
Mother Genitourinary Symptoms	Present	64(91.4)	6(8.5)	0.645(0.262-1.586)	0.339
	Absent	275(87.3)	40(12.7)	1	
Parent Genitourinary Symptoms	Yes	75(90.4)	8(9.6)	0.74(0.322-1.66)	0.465
	No	264(87.4)	38(12.6)	1	
Mother condom use	Yes	121(90.3%)	13(9.7%)	1	
	No	218(87%)	33(13%)	1.409(0.714-2.779)	0.322
Mother past history of low birth weight	Yes	80(85.1%)	14(14.9%)	1.325()	
	No	259(89%)	32(11%)	1	

Gestational age	First trimester	166(92.3%)	12(6.7%)	1	
	Second trimester	153(81.4%)	22(12.6%)	1.899(0.952-4.156)	0.067
	Third trimester	20(61.5%)	12(37.5%)	8.300(3.292-20.93)	0.000
Age at first sexual contact	<18 years	143(82.2%)	31(17.8%)	1	
	>=18 years	148(89.8%)	15(9.2%)	2.139(1.108-4.130)	0.024

Multivariate Analysis

Results of multivariate logistic regression analysis indicated that few predictor variables showed statistically significant association with syphilis infection. Pregnant women who had history of abortion (AOR: 5.082; 95% CI: 2.043-12.646; P=0.000) , Pregnant women who had history of STD previously (AOR: 8.488; 95% CI: 3.289-21.906; P=0.000), Mother who had extra sexual partner (AOR: 7.510; (95% CI: 2.839-19.863; P=0.000), Husband or sexual partners who had extra sexual partner (AOR:6.005; 95% CI: 2.487-14.495; P=0.000), Husband/sexual partner who had traveled away from his residency area (AOR: 3.191; (95% CI: 1.402-7.262; p=0.006) (table 5).

Table 31: Multivariate analysis of possible predictors of syphilis among pregnant women attending Gambella General Hospital ANC, Gambella, Ethiopia, 2017

Variables	Category	Non-Reactive N (%)	Reactive N(%)	COR(CI)	AOR	p-value
Number of Pregnancy	≤ 2 pregnancies	218(92.8%)	17(7.2%)	1	1	
	>2pregnancies	121(79.7%)	29(19.3%)	3.073(1.60-5.80)	1.199(0.450-3.193)	0.717
Gestational Age	First trimester	166(92.3%)	12(6.7%)	1	1	

	Second trimester	153(81.4%)	22(12.6%)	1.899(0.952-4.156)	0.894(0.368-2.172)	0.804
	Third trimester	20(61.5%)	12(37.5%)	8.300(3.292-20.93)	3.664(1.130-11.875)	0.300
Mother history of STD	Yes	122(80.3)	30(19.7)	3.335(1.748-6.363)	8.488(3.289-21.906)	0.000**
	No	217(93.1)	16(6.9)	1	1	
Travel history of Husband	Yes	141(87.5)	20(12.5)	2.633(1.383-5.014)	3.19(1.402-7.262)	0.006**
	No	198(88.4)	26(11.6)	1	1	
Mother extra sexual partner relationship	Yes	32(64)	18(36)	5.117(2.522-10.382)	7.51(2.839-19.863)	0.000**
	No	307(91.6)	28(8.4)	1	1	
Husband extra sexual partner	Yes	90(74)	31(26)	5.72(2.95-11.08)	6.005(2.487-14.495)	0.000**
	No	249(94.3)	15(5.7)	1	1	
History of abortion	Yes	79	25	3.918(2.08-7.375)	5.082(2.043-12.646)	0.000**
	No	260	21	1	1	
Parent history of STD	Yes	101(82.3%)	21(17.2%)	1.979(1.059-3.698)	1.15(0.97-1.97)	0.360
	No	238(90.5%)	25(9.5%)	1	1	
Age at first sexual contact	<18 years	143(82.2%)	31(17.8%)	2.139(1.108-4.130)	1.645(1.707-3.826)	0.248
	>=18 years	148(89.8%)	15(9.2%)	1	1	
Residency	Urban	291(89.3%)	35(10.7%)	1	1	
	Rural	48(81.4%)	11(18.6%)	1.905(0.903-4.006)	0.383(0.357-1.257)	0.212

** indicate variables significantly associated with syphilis infection.

Discussion

This study sought the seroprevalence of syphilis infections and identifying the possible risk factors among pregnant women attending at Gambella General Hospital and we found that the prevalence of syphilis among study participants was 11.9%. This finding is similar with a prevalence of 8.3% reported in south Sudan (25), 9% in Sudan (26), 9.3% in Zambia(12).But, relatively it is higher than 4.7%, 2.9%, and 0.1 % of prevalence which were reported from Gambella(34), Gondar (32) and Diredawa (34) respectively. Here our finding less than by two fold from the study reported 22.1% from south Sudan (13) and 28% from Addis Ababa (29). Likewise the finding still greater than the study reported from Malawi, Tanzania and Zambia with 2.7% 7.2% and 8.2% respectively (21). As far as the prevalence of syphilis concerned much smaller prevalence was reported from 1.1% Argentina, 1.2% brazil and 0.2% from Chile (18).This variation might be due to differences geographical variation, differences in cultural practices, sexual behavior and practices, and differences in the test methods employed to detect syphilis infection. This also attributed to the decreased in efficient syphilis screening at the ANC and effective treatment with antibiotics in the last few years.

In the present study, the prevalence of syphilis higher among the pregnant women whose age category lies from 26-30 years this finding was consistent with finding in Gondar(32) and India(2). The possible explanation for this finding could be that women in these age groups are more sexually active and they may have higher chance of multiple sexual partners. Syphilis prevalence was higher among age 30-35 thus as the age increase the prevalence of the disease increases. This goes in line with 2014 ANC survey done in Ethiopia(37). That was more likely because most of the women in this age category has gave more birth and they were multigravida.

The prevalence of syphilis among married women was 11.6%. This much figures of syphilis prevalence was quite higher as weigh with 1.4% of prevalence in Nigeria (11). It could be the higher number of the respondent in the study was married that showed the highest prevalence it might be as a fact of numerical advantage among married women (high proportion of married women in the study). Moreover they are less likely to use protective methods like condom and mostly uncommon among married couples.

The prevalence of syphilis was 6.7% and 37.5% for pregnant women who visited the hospital ANC on their first and third trimester gestational age respectively. In contrary with this finding, syphilis prevalence was high among pregnant women who visited ANC on first trimester (11). That might be less habit of the pregnant women to visit ANC in their earlier pregnancy periods and late detection of the disease; hence mothers who visit ANC lately could have high syphilis prevalence. With the same speaking, it could also highlight low awareness of the pregnant mothers about the importance of visiting ANC in earlier pregnancy period.

The prevalence of syphilis was 18.6% and 10.7% in rural and urban respectively, where a bit higher in urban. This was much higher as compared with the national ANC sentinel report 0.7% in urban and 1.3% in rural sites in Ethiopia(37). It could be low educational level and poor knowledge on adequate prevention of sexually transmitted diseases in rural communities. Rural resident's differ from urban residents in terms of cultural and social behavior: rural communities are generally closed communities with limited access to medical information. Since syphilis is a treatable and curable disease and urban residents might have better health seeking behavior to get tested and treated earlier which could alter the status of syphilis.

In fact our study demonstrated that history of abortion; mother history of STDs, travel history of husband or sexual partners, history extra sexual partner of the mother and history of husband multiple sexual partners were significant predictors of syphilis infection. Pregnant women with history of abortion had five times (AOR: 5.082; 95% CI: 2.043-12.646) to develop syphilis infection compared to their counterpart. Similar results were reported from Gondar(32). Similarly study from other countries, they have shown similar findings in Pakistan(17), south Sudan(13) and Zambia(12). This high incidence of infection could be attributed to poor practices of infection prevention and control during abortion and related activities. It could be also less habit of the pregnant mothers to visit health facilities as soon as they get conceived.

Pregnant women who had history of STD previously (AOR: 8.488; 95%CI: 3.289-21.906; P=0.000) were eight times more likely of being infected by syphilis than those pregnant women who had no history of STD. Here our study, was compatible with study done in Zambia(12); where pregnant women having previous history of STDs were found to be at increased risk for syphilis. That could be as a result of the causative agent (bacteria) might remain for many years and failed to attain adequate diagnosis and treatment.

Husband or sexual partners who had multiple sexual relationship (AOR: 6.005; 95%CI: 2.487-14.495) were six times more likely to be infected with the disease compared with those with single partner. Similar finding was reported from Zambia with those husbands with multiple sexual partner were much at risk to be infected(12). This finding may be explained as, since syphilis is one sexually transmitted disease, sexual contact exposes to the bacteria hence semen and other body fluids are common source of infection that sexual contacts serve as a mode of transmission. Moreover, as a result of cultural influence (permit) husband tends to have more than one wife.

Pregnant women, whose husband had travel history (AOR: 3.191; 95% CI: 1.402-7.262; $p=0.006$) were three times more likely to be infected with syphilis than those mothers whose husbands didn't had traveled away from their living area. This displayed agreement with study done in south Sudan where husband or partners travel history had association with syphilis (13). It was attributed as a result of husband travel away from their area for different jobs and commitments and they would have sexual contact with other than their wife, though husband sexual practice to use protective method like condom might be very negligible.

The other significant predictor showed association with syphilis contracting was mother extra sexual relationship or pregnant women with multiple sexual relationship (AOR: 7.510; 95% CI: 2.839-19.863); pregnant women who had multiple sexual partner were more than seven times more likely to be infected with syphilis than those mothers who didn't had multiple sexual partners. Thus, sexually active women have a higher chance of getting the infection especially those who have the history of multiple sexual partners. Moreover, pregnant women with multiple sexual relations, the vulnerability to acquire syphilis increase as the time in relation elapsed and they tend to neglect to care solely even forget the disease risk without proving syphilis status as a result of adaptation and staying for long time together.

Limitation

- The study was conducted in hospital, so this study includes only those clients who have get access to the hospital during the data collection period. It doesn't include those who didn't have come to the hospital during the study period that may affect findings (estimation).
- The syphilis status of pregnant mothers' husband/ sexual partners was not detected.
- As the study design was cross-sectional; it is difficult to verify whether syphilis preceded the predisposing factors or the vice versa in this study.

Conclusion

The overall prevalence of syphilis infection among pregnant women in Gambella general hospital was high-intermediate (11.9%). Prevalence of syphilis increased as the age of the mother increase. Similarly as number of pregnancy increase prevalence of syphilis increase indeed mothers who visited ANC lately could have high syphilis prevalence. Syphilis more strikes those mothers who get married. Factors such as mother history of abortion, mother history of extra sexual partner relationship, travel history of husband, husbands' history of multi sexual partnership and mother history of sexual transmitted disease associated with syphilis infection.

Recommendation

Thus, to decrease the prevalence of this bacterial infection, we recommend that health education programs on the mode of syphilis transmission, pregnant mothers to visit ANC during their earlier pregnancy period, high-risk behaviors and methods of preventions should be instituted at antenatal care clinics to raise the awareness of mothers. Behavioral changes on both husbands and pregnant mothers to keep calm from having sexual contact with multi partners. Treat pregnant women who were reactive for VDRL test. Moreover further studies on syphilis that includes different study sites are recommended and all condition needs to be suited to address all those husbands/sexual partners to get tested for syphilis and know their status.

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Annex 5: English version of participant information sheet, consent and questionnaire:

Participant information sheet

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

Title: Sero prevalence of syphilis and associated factors amongst pregnant women attending antenatal clinics in Gambella hospital, Gambella, Ethiopia.

First of all, I would like to say thanks in advance to your cooperation and consent in participating in this study. More over; I were request you politely to read or listen attentively in order to provide relevant information about the study and if there is any confusable information or question which isn't clear regarding the study please don't hesitate to ask freely.

Objective: The aim of the study will be to determine the sero-prevalence of syphilis and Associated factors amongst pregnant women attending antenatal clinics in Gambella hospital, Gambella, Ethiopia.

Benefits for participants

Study participants will not having any financial incentives or other inducements being participated in this study. However, those positives for syphilis will contact with the physician in the hospital for treatment and follow up. Furthermore, this study will provide a base line information or data for nationwide to develop health programmes for health policy and pave a strategic means of prevention for such sexually transmitted infection.

Risks and complication: Other than minor bleeding from the site of venipuncture when they give sample, there will no considerable risks to the study subjects being they are participated in the study. Venipuncture is a routine clinical practice for blood sample collection and can stop by pressing cotton on the site of puncture within a short period of time. Additionally the amounts of blood collected will be too little which is 5 ml (1 to 2 tea spoon) blood only.

Confidentiality: In order to maintain the confidentiality of participants' information, their name will not be given and the samples will be coded. Participants will not prohibit stopping or withdrawing at any time from the study. Only interested participants can retrieve their own

laboratory results using their code number and the information can only be accessed through the physician/clinical nurse. The physician/ clinical nurse will be responsible for the interpretation of the results and providing treatment. No personnel information will have disclosed to third party or will not appear in any report from this study.

Assurance of Principal Investigator

I will put my signature below to confirm you that I take over the responsibility for the scientific ethical and technical conduct of the research project and for provision of progress reports for all stakeholders of the research project.

Lezhialem Almaw (PI)

Signature: _____ Date: _____

Note: If you have any questions about this study, you should feel free to ask now or at any time throughout the study by contacting:

PI Address: Lezhialem Almaw, St. Paul's Hospital Millennium Medical College, School of Public Health, Addis Ababa, Ethiopia.

Email:Lezhailem10@gmail.com, Tel: +251913349861

Informed consent:

I, (Full Name)

Here by voluntarily authorize the researcher to interview me and consent to him in order to obtain information that is relevant to his research topic on “sero-prevalence of syphilis and associated factors amongst pregnant women attending antenatal clinics in Gambella hospital, Gambella, Ethiopia, 2017”. I understand that as a participant, my privacy was maintained and the information obtained in this research was used in a manner that protects with guaranteed confidentiality, respect and personal rights.

I am aware that participating in this study is voluntary and I haven't obligated to answer every question asked for me and that I may withdraw my consent at any time without disadvantage to

myself or others. I am informed that information collected in this study was strictly confidential and for this study only.

Signature of Participant Date.....

Signature of data collector..... Date.....

Questionnaire

“Determine sero prevalence of syphilis and associated factors amongst pregnant women attending antenatal clinics in Gambella hospital, Gambella, Ethiopia, 2017”

PART I: Socio-demographic characteristics Direction: fill the answer by encircling the corresponding choice

1 Address:

S · N O	Questions	Response of categories	
1	Address:	Region_____ Zone_____	
		Woreda_____	
		Kebele_____	
2	Age (in years)	_____	
3	Where are you living?	1. Urban 2. Rural	
4	What is your educational status?	1. Illiterate 2.read and write 3. 1-8	
		4. 9-12 5. Diploma 6. Higher institution	
5	What is your occupation status?	1. Employed 2. House wife	
		3. Daily laborer 4. Merchant	

		5. Commercial sex worker 6. Other [specify] _____	
6	Ethnicity	1. Anywaa 2.Nuer 3.Mezenger 4. Kembata 5. Oromo 6. Tigre 7. Amhara 8.Wolayita 9. other [specify]	
7	Marital Status	1. Single 2.Married 3. Divorced 4. Widowed	
8	If mother is married, husbands education status	1. Illiterate 2. Read and write 3. 1-8 4. 9-12 5. Diploma 6. Higher institution	
9	Mothers monthly income in birr?	_____	
Part II. Knowledge			
10	Have you heard about syphilis?	1. Yes 2. No 3. I don't know	
11	Do you know how these diseases can be transmitted?	1. Yes 2. No	
12	Do you know that these diseases can be transmitted to unborn child?	1. Yes 2.No	
13	Do you think by attending ANC that reduces the chances of risk to your unborn	1.Yes 2.No	

	child?		
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Annex 6: Amharic version of participant information sheet, consent and questionnaire

2.1. የጥናቱ መረጃና መግለጫ ቅጽ

የጥናቱ አላማ

የዚህ ጥናት አላማ መሰረት ያደረገው ቁጥኝ ተብሎ የሚጠራውን የአባላዘር በሽታ አምጪ ባክተሪያ ከሱ ጋር የተያያዙ ተጋላጪ መንስኤዎችን በነፍሱ-ጡር እናቶች ላይ ለማጥናት ነው። የእርሶ በዚህ ጥናት ውስጥ መሳተፍ ነፍሱ-ጡር እናቶች በቁጥኝ በሽታ እንዳይጠቁ ለመከላከል ይረዳል።

በጥናቱ ስለመሳተፍ

በዚህ ጥናት መሳተፍ በሙሉ ፈቃደኝነት ላይ የተመሠረተ ነው። ስለሆነም በመጀመሪያ በጥናቱ እንዲሳተፉ ፈቃደኝነትዎን በትህትና እንጠይቃለን። በዚህ ጥናት ለመሳተፍ ከፈቀዱ ለግማሽ ሰዓት ያህል ለጥያቄዎች ምላሽ ይሰጡናል።

በጥናቱ በመሳተፍ የሚገኝ ጥቅም

የደመዎ ናሙና በላብራቶሪ ሲመረመር የቁጥኝ በሽታ አምጪ ባክተሪያ ቴሪፖንማ ፓሊድም ከተገኘ የሀኪም ክትትልና አስፈላጊውን ምክር ይሰጠዎታል። ደሙም ነፃ ከሆነ ደግሞ ለወደፊቱ ማድረግ ስለሚገባዎት ጥንቃቄ በሀኪም በኩል ምክር ይሰጠዎታል።

ምስጢርን ስለመጠበቅ

በጥናቱ ውስጥ የተሰበሰቡ ማናቸውም ግላዊ መረጃዎች ሚስጥራዊነታቸው የተጠበቀ ይሆናል። ከማንነትዎ ጋር በቀጥታ ተያያዥነት ያላቸው መረጃዎች በሙሉ በዋና ተመራማሪው ሚስጥራዊ በሆነ የመረጃ ጥንቅር ዘዴ ከተቀየሩ በኋላ ብቻ ለምርምር ሂደቱ የሚውል ይሆናል።

ከጥናቱ ስለመውጣትና ስለማቋረጥ

ይህ ጥናት በፈቃደኝነት ላይ የተመሰረተ እንደመሆኑ መጠን በማናቸውም ወቅት በፈቃደዎ ከጥናቱ መውጣት ይችላሉ። ከጥናቱ ቢወጡም እንኳ በስራዎት ላይ ምንም አይነት ችግር አያመጣም። ከጥናቱ ጋር በተያያዘ ማናቸውም ጥያቄ ቢኖርዎ በሚከተለው አድራሻ ጥያቄዎን ማቅረብ ይችላሉ።

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ዋና ተመራማሪ:- ለዚህዓለም አልማው

አድራሻ: ቅዱስ ጳውሎስ ሆስፒታል ሚኒንጃም ህክምና ኮሌጅ ህብረተሰብ ጤና ትምህርት ክፍል

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አዲስ አበባ ኢትዮጵያ

2.2. ስለ ስምምነቱ ማረጋገጫ ቅፅ

እኔ ስሜ ከታች የተገለፀው የጥናቱ ተሳታፊ ለመሆን ስወስን የጥናቱን አላማዎች አሰራሮችና ቅድመ ሁኔታዎች በግልጽ በመረዳትና ከጥናቱ ተሳታፊነት ፈቃደኝነቴን በማንኛውም ደረጃ የማንሳት መብቴን በማረጋገጥ ነው፡፡

እኔ----- በጥናቱ ተሳታፊ መሆኔን በፊርማዬ እያረጋገጥሁ ይህንን ስወስን በጥናቱ ሳቢያ ሊከሰቱ የሚችሉ አደጋዎች በሚገባ የተረዳሁና ከጥናቱ በማንኛውም ደረጃ እራሴን ለመሰረዝ ብወስን ቅጣት እንደሌለው ወይም ተገቢ የሆነ ጥቅም እንደማይካፈልኝ በማመን መሆኔን በፊርማዬ አረጋግጣለሁ፡፡

የተሳታፊው መለያ ቁጥር ----- ፊርማ-----

የተመራማሪው ሙሉ ስም፣ አቶ ለዚህዓለም አልማው እውነቱ ፊርማ -----

የምስክር ሙሉ ስም አቶ/ወ/ሮ/ወ/ረት/ሲ/ር-----ፊርማ-----

አሁን ጥያቄዎችን መጠየቅ እችላለሁ?

አዎ----- ወደ ጥያቄ አይቻልም -----ያበቃል

የጠያቂ ስም _____

መጠይቁ የተጀመረበት ሰአት _____ ደቂቃ ____

የጠያቂው ቃል :-ይህንን መጠየቂያ በላዩ ላይ በተጻፈው መመሪያና ጥያቄ እንድሁም በተሰጠኝ ስልጠና መሰረት ሞልቻለሁ፡፡

በላዩም ላይ የሰፈረው ሀሳብ ትክክለኛ መሆኑን እቀበላለሁ፡፡

ፊርማ _____ ቀን _____

2.3. የጥናቱ መጠይቅ ቅፅ:

ተ.ቁ ጥያቄዎችምላሾች ምርምራ

1. አድራሻ ክልል----- ዞን ----- ወርዳ ----- ቀበሌ -----

2. ዕድሜ -----

3. የመኖሪያ ስፍራዎ የት ነው 1. ከተማ 2. ገጠር

4. የትምህርት ደርጃዎ 1. ያልተማር 2. ማንበብ እና መፃፍ 3. 1-8ኛ ክፍል 4. 9-12ኛ ክፍል 5. ዲፕሎማ

6. የመጀመሪያ ድግሪ እና ከዚያ በላይ

5. ስራዎ 1. የመንግስት ሰራተኛ 2. የቤት እመቤት 3. የቀን ሰራተኛ 4. ነጋዴ 5. ሌተኛ አዳሪ 6. ሌላ.....

6. ብሔርዎ 1. አኝዋክ 2. ኝወር 3. መኻኩንግር 4. ከምባታ 5. ኦሮሞ 6. አማራ

7. ትግሬ 8. ወላይታ 9 ሌላ.....

7. የጋብቻ ሁኔታ 1. ያላገባች 2. ያገባች 3. አግብታ የፈታች 4. ባሏ የሞተባት

8. የትዳር አጋርዎ የትምህርት ሁኔታ (ያገባች ከሆነ) 1. ያልተማር 2. ማንበብ እና መፃፍ 3. 1-8ኛ ክፍል 4. 9-12ኛ ክፍል 5. ዲፕሎማ 6. የመጀመሪያ ድግሪ እና ከዚያ በላይ

9. ወርሃዊ ገቢ በብር ፡፡፡.....

ስለ ቂጢኝ ያላቸው ግንዛቤ የተመለከቱ ጥያቄዎች

10. ስለ ቂጢኝ ሰምተው ያውቃሉ 1. አዎ 2. አልሰማሁም 3. ምንም አላውቅም

11. የቂጢኝ በሽታ እንዴት እንደሚተላለፍ ያውቃሉ 1. አዎ 2. አልሰማሁም

12. የቂጢኝ በሽታ በማህፀንዎ ወዳለው ህፃን እንደሚተላለፍ ያውቃሉ 1. አዎ 2. አልሰማሁም 13. የእርግዝና ከትትል በማድርግ ህፃንዎን ከበሽታው መከላከል እንደሚቻል ያውቃሉ 1. አዎ 2. አልሰማሁም

ክፍል 3 ለቂጢኝ አጋልጭ የሆኑ ምክንያቶች

14. ከሌላ ሰው ደም ተለግሰው ያውቃሉ 1. አዎ 2. አይደለም

15. የአባላዘር በሽታ ይዞት ያውቃሉ 1. አዎ 2. አይደለም መልሱ’’አይደለም’’ ከሆነ ወደ ጥያቄ

17 ሂድ

16 ለጥያቄ ተ.ቁ 15 መልስዎ አዎ ከሆነ፤ ምን አይነት 1. ቁጥኝ 2. ሌላ አይነት አባላዘር በሽታ 3.
አልታወቀም

17 የትዳር አጋርዎ በአባላዘር በሽታ ከዚህ ቀደም ታመው ያውቃሉ (ያገባች ከሆነ) 1. አዎ 2.
አይደለም

3. አልታወቀም መልሱ 'አይደለም' ከሆነ ወደ ጥያቄ 19 ሂድ

18 ለጥያቄ ተ.ቁ 17 መልስዎ አዎ ከሆነ፤ ምን አይነት 1. ቁጥኝ 2. ሌላ አይነት አባላዘር በሽታ 3.
አልታወቀም

19 አሁን በብልትዎ አከባቢ ህመም ስሜት አለበዎት 1. አዎ 2. የለም

20 የትዳር አጋርዎ በብልታቸው አከባቢ ህመም ስሜት አለባቸው 1. አዎ 2. የለም

3 አልታወቀም

21 እናት ላለፉት አንድ ዓመት ወደ ሌላ ቦታ ጉዞ ተጉዘው ያውቃሉ 1. አዎ 2. የለም

22 ባለቤትዎ ስራቸውን ለመስራት ወደ ሌላ ቦታ ይሄዳሉ እንዴ 1. አዎ 2. የለም

23 ላለፉት አንድ ዓመት ግብር ስጋ ግንኙነት ወቅት ኮንዶም ተጠቅመዋል 1. አዎ 2. የለም

24 እርስዎ ከአንድ ሰው በላይ ጋር የግብርስጋ ግንኙነት አድርገው ያውቃሉ

1. አዎ 2. የለም

መልሱ 'አይደለም' ከሆነ ወደ ጥያቄ 26 ሂድ

25 ለጥያቄ ተ.ቁ 24 መልስዎ አዎ ከሆነ፤ ከስንት ሰዎች ጋር 1.ሁለት 2. ሦስት 3. አራት እና ከዚያ
በላይ

- 26 ባለቤትዎ ከእርስዎ ውጭ ከሌላ ሴት ጋር ግንኙነት አድረገው ያውቃሉ 1. አዎ 2. የለም
- 27 የአሁኑ ስንተኛ እርግዝናዎ ነው 1. የመጀመሪያ እርግዝና 2. ሁለተኛ እርግዝና 3. ሶስተኛ እርግዝና 4. አራተኛ እና ከዚያ በላይ እርግዝና
- 28 የእርግዝና ሁኔታ 1. አንድ ጊዜ ብቻ አርግዘዋል
2. ከአንድ ጊዜ በላይ አርግዘዋል
- 29 ስንት ጊዜ አርግዘዋል 1. አንድ 2. ሁለት 3. ሶስት እና ከዚያ በላይ
- 30 ስንት ልጅ አለዎት 1. አንድ
2. ከሁለት- አራት
3. አምስት እና ከዚያ በላይ
- 31 ከዚህ ቀደም ነፍሰጡር ሳሉ አስወርድዎት ያውቃል 1. አዎ 2. የለም መልሱ
''አይደለም'' ከሆነ ወደ ጥያቄ 34 ሂድ
- 32 ለጥያቄ ተ.ቁ 31 መልስዎ አዎ ከሆነ፤ ስንት ጊዜ 1. አንድ 2. ሁለት
- 33 ትክክለኛ የመወለጃ ጊዜአቸው ሳይደርስ የተወለዱ ልጆች ብዛት 1. ዜሮ 2. አንድ እና ከዚያ በላይ
- 34 ከዚህ ቀደም ዝቅተኛ ክብደት ያለው ልጅ ወልደው ያውቃሉ 1. አዎ 2. አልወለድኩም
- 35 የእርግዝና ክትትል ሲጀምሩ የስንት ሳምንት ነፍሰጡር ነበሩ 1. 1-13 ሳምንት
2. 14-27 ሳምንት
3. 28-39 ሳምንት
- 36 ለመጀመሪያ ጊዜ የግብር ስጋ ግንኙነት ሲያደርጉ ዕድሜዎ ስንት ዓመት ይሆኖት ነበር

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37 የእናትዬዋ የቂጥኝ በሽታ ሁኔታ 1. በሽታው አለ (ፖዘቲቭ)

2. በሽታው የለም (ኔገቲቭ)

Annex 7: Syphilis Standard operating procedures (SOP)

Procedures (standard operating procedure) and principles for syphilis

Test Principle

The Syphilis Rapid Test Strip (Quick Test™ Syphilis Serum/ Plasma/Whole Blood Strip) will be used to determine the presence of syphilis antibodies. This is a qualitative membrane strip based immunoassay for the detection of *Treponema pallidum* antibodies (IgG and IgM) in whole blood serum or plasma. In this test procedure, recombinant syphilis antigen was immobilized in the test line region of the strip. After a specimen (serum) was added to the specimen pad; it reacted with syphilis antigen coated particles that had been applied to the specimen pad. The mixture migrated chromatographically along the length of the test strip and interacted with the immobilized syphilis antigen. This double antigen test format can detect both IgG and IgM in the specimens. For specimens containing antibodies to *Treponema pallidum* a red line appeared in the test line region indicating a positive result; those without *Treponema pallidum* did not have a red line appearing in this region indicating a negative result. To serve as a procedural control, a colored band at control region always appears in the test area.

Procedure

- 1) Bring all reagents and specimen to room temperature
- 2) Remove the test strip from the foil pouch and place on a clean dry surface
- 3) Identify the test strip for each specimen or control
- 4) Apply 60ul of specimen on the sample pad
- 5) Interpret test result at 15 minutes
- 6) Do not interpret test result after 20 minute

Result Interpretation

Negative: One pink line appears in control line but no line in the test region

Positive: when there is pink color in the control line and testing region.

Invalid: when there is a total absence of color in both regions, in such case the test should be repeated using a new strip.

Annex 8: Bibliography of principal investor (resident)

I am Lezhialem Almaw Ewunete, was born on June 1987 GC in Godere woreda Gambella region. I have attended my primary education and high school at Tiliku Metti Elementary School and Tinishu Metti Secondary and preparatory school respectively. Then I joined Arba Minch University and graduated with BSc in Medical Laboratory Science in 2010 GC.

Soon after graduation, I have been working as junior laboratory technologist in Gambella region, Gambella general hospital since January 2011 to the time I join St.Paul's Hospital Millennium Medical College for post-graduation study in Field Epidemiology and laboratory training program on October 2015.