

SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE
DEPARTMENT OF PUBLIC HEALTH
ETHIOPIAN FIELD EPIDEMIOLOGY AND LABORATORY TRAINING PROGRAM (EFLTP)
COMPILED BODY OF WORKS IN FIELD EPIDEMIOLOGY

BY
WOGAYEHU WORKNEH

SUBMITTED TO SAINT PAUL'S HOSPITAL MILLENIUM MEDICAL COLLEGE DEPARTMENT OF PUBLIC HEALTH, IN PARTIAL FULFILLMENT FOR THE DEGREE OF MASTER OF PUBLIC HEALTH IN FIELD EPIDEMIOLOGY

FABRUAY, 2018
ADDIS ABABA

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ADVISORS;

MISRACH AYALEW (MPH)

ELIAS SENBETO (MD MPH. PhD)

FABRUAY, 2018

ADDIS ABABA

SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE

DEPARTMENT OF PUBLIC HEALTH

APPROVAL SHEET (by advisors and program coordinator)

DECLARATION FORM

LETTER FOR DECLARATION (body of work with thesis**)**

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

Student Name: _____

Signature: _____

Date: _____

Place: _____

Date of submission: _____

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

Name of Primary advisor	Signature	Date
Name of Co-advisor	Signature	Date
Name of FETP Coordinator	Signature	Date

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List of Abbreviations and acronym

AIDS	Acquired Immuno Deficiency Virus
ANC	Antenatal Care
AOR	Adjusted Odds Ratio
ART	Antiretroviral Therapy
AR	Attack Rate
AWD	Acute Watery Diarrhea
CBN	Community Based Nutrition
CBR	Crude Birth Rate
CEO	Chief executive officer
CDR	Crude Death Rate
CFR	Case Fatality Rate
CI	Confidence Interval
CMR	Child Mortality Rate
COR	Crude Odds Ratio
CTC	Cholera Treating Center
DOT	Direct Observation Therapy
Epi	Epidemiological
E.C	Ethiopian Calendar
EDS	Enhanced Outreach Strategy
EFELTP	Ethiopian Field Epidemiology and Laboratory Training Program
EFY	Ethiopian Fiscal Year

Epi Info	Epidemiological Information
ELISA	Enzyme Linked Immuno Sorbent Assay
EPHI	Ethiopian Public Health Institute
EPI	Expanded Program on Immunization
FMoH	Federal Ministry of Health
HAV	Hepatitis A Virus
HBSAg	Hepatitis B Virus Surface Antigen
HBV	Hepatitis B Virus
HC	Health Center
HCV	Hepatitis C Virus
HEW	Health Extension Worker
HIV	Human Immuno Virus
HP	Health Post
IDSR	Integrated Disease Surveillance
IDP	Internally Displaced People
IgM	Immunoglobulin M
IMR	Infant Mortality Rate
ITN	Insecticide Treated Net
KT	Kembata Tembaro
MCV	Measles Containing Vaccine
MDG	Millennium Development Goals

MMR	Measles Mumps and Rubella
MTCT	Mother To Child Transmission
NMR	Neonatal Mortality Rate
NVS	National Vaccine Store
OPD	Outpatient Department
OPV	Oral Polio Vaccine
OR	Odds Ratio
ORS	Oral Dehydration Salt
OTP	Outpatient Therapeutic Program
PF	*Plasmodium Falciparum*
PHEM	Public Health Emergency Management
PICT	Provider Initiated Counseling and Testing
PMTCT	Prevention of Mother to Child Transmission
PNC	Postnatal Care
PNMR	Postnatal Mortality Rate
PTB	Pulmonary Tuberculosis
PV	Plasmodium Vivax
RDT	Rapid Diagnostic Test
RHB	Regional Health Bureau
Rx	Treatment
SD	Standard Deviation

SNNP	Southern Nations Nationalities and People
SOP	Standard Operating Procedure
SPHMMC	Saint Paul's Hospital Millennium Medical College
SPSS	Statistical Package for Social Science
Sr.No	Serial Number
TB	Tuberculosis
TBA	Traditional Birth Attendants
TFC	Therapeutic Feeding Center
TT	Tetanus Toxoid
V.cholerae	Vibrio Cholerae
VCT	Voluntary Counseling and Testing
WHO	World Health Organization
Wk	Week

Executive Summary

This body of works is the summary of all outputs produced and core competences accomplished during a two years and half field residency in the Field Epidemiology and Laboratory Training Program. These include outbreak investigation, surveillance data analysis, surveillance system evaluation, district health profile description, thesis development, scientific writing and communication (abstracts, manuscripts, and articles) development of laboratory standard procedures and manual.

Investigation of acute watery diarrhea outbreak in Segeg district, Nogob zone of Somali region Ethiopia, from 10th March to 15th April 2017 was done. This investigation was conducted as part of public health response for the outbreak. The outbreak was described by person, place and time characteristics, possible causes or risk factors and sources of the outbreak were identified. Public health interventions appropriate for the outbreak were recommended, and timely control and prevention measures were implemented following the investigations.

Analysis of ten years (January, 2006-Janury, 2015) routine public health surveillance data of under-five measles reported from southern nations, nationalities and peoples region was conducted. In this study the incidence of under-5 measles was assessed**.** The Proportion of epidemiologically linked, confirmed and suspected cases was identified. The proportion of confirmed measles cases was described. Vaccination status and distribution of cases by age and sex was determined. Moreover, description by place, person, and time was performed.

Evaluation of a health facilities based malaria surveillance system of Kedida Gamela woreda of kembata Tembaro zone, SNNPR was conducted with the objective of assessing the performance and operation of core and supportive functions and the system attributes, and identifying possible gaps in the system for improvement. The woreda disease surveillance officers and surveillance focal persons from selected health facilities were involved in the evaluation. Data analysis, interpretation, management, epidemic preparedness plan, timeliness of report and malaria monitoring chart were major deficiencies in the malaria surveillance system. Discussions were also conducted with woreda health officials on the identified gaps and recommendations were forwarded for all stakeholders.

District health profile description of Damboya woreda of Kembata Tembaro zone, SNNPR region was conducted. The objective of the assessment was to describe the district health system and the health status of the population, provide broad overview of the social, economic, demographic and geographic determinants of health, identify priority public health problems of the woreda and produce a baseline health profile document for possible intervention programs on the identified health problems and further studies. AFI &AURTI were the leading causes of morbidity in adults and under- five respectively in the woreda. Coverage of basic health services like immunization, ANC family planning and PNC is higher than the average for the zone as well as the region. But the coverage of skill birth attendants and Tuberculosis detection rate were low. Data management and retention needs due attention in the woreda. A copy of the health profile document was shared with district and regional health officials and other stakeholders.

Scientific manuscript for peer reviewed journals and abstracts for scientific presentations were prepared.

A research paper was developed on the prevalence and associated risk factors of Hepatitis B and hepatitis C viruses among women following antenatal care in Durame general hospital, southern Ethiopia. In the study the prevalence of hepatitis B and C viruses was determined and risk factors associated with both viruses infection were identified. Blood transfusion, family history of liver disease and multiple sexual exposures were potential factors for hepatitis B and history of previous surgery and family history of liver disease were risk factors for hepatitis C virus infection.

Laboratory quality manual of Durame general hospital was developed with the aim of improving the provision of quality of laboratory activities. Standard Operating Procedures (SOPs) for the detection of salmonella typhi and blood film for blood parasites examination were developed. Additionally the way forward was given to develop SOP for other tests being performed without SOP.

Other activities such as provision of training for public health emergency management (PHEM) officers working at different levels (regional to health facility level) on public health surveillance and response were also undertaken.

Chapter I- Outbreak Investigation

1.1 Acute Watery Diarrhea outbreak investigations in Segeg district, Nogob zone, Somali region, Ethiopia, 2017

Abstract

Introduction: Cholera is a potentially life-threatening acute diarrheal disease caused by the toxigenic bacterium *vibrio cholerae* either type 01 or O139. The infectious agent is acquired through consumption of contaminated water or food. The source of contamination is usually the feces of an infected person.

Objective: To investigate acute watery diarrhea outbreak, identify potential risk factors and provide the possible prevention and control measures in Segeg district, Somali region.

Methods: un-matched community based 1:2 case control study was conducted on 50 cases and 100 controls from 10th March to 15th April 2017 in segag district. By using outbreak investigation structured questionnaires, all the outbreak investigation team and one language translator conducted home to home visit and administering the questionnaires. The data was entered in to Epi Info Version 7 and exported to SPSS for analysis of association between possible risk factors and acute watery diarrhea occurrence. Participants of the study were informed about the study verbally to solicit their consent to participate in the study.

Result: A total of 501 suspected acute watery diarrhea cases and five RDT confirmed cases with 26 deaths were reported between March 10 and April 15, 2009. The overall attack rate and case fatality rate was 1.26% and 3.4% respectively. 53% males and 47% females were affected. Age group 5-14 was the most affected population. An adjusted unmatched analysis showed that persons who had a travel history to areas already affected with acute watery diarrhea were at greater risk of getting acute watery diarrhea [adjusted Odds ratio = 3.856 at 95% confidence interval = 1.018-9.56, p-value 0.047]. Household latrine availability was protective against acquiring acute watery diarrhoea with adjusted odds ratio 0.181 at 95% CI 0.042-0.780, p value 0.022. Treating drinking water was protective of the illness with adjusted odds ratio 0.134 at 95% CI 0.041-0.445, p value 0.001.

Conclusion and Recommendations: still acute watery diarrhea remains serious threat to public health system in Somali regional state in Segeg district. The outbreak was occurred due to Lack of safe water supply, knowledge and poor sanitation. Overall attack rate and case fatality rates were high. Hence the district health office, other concerned sectors and partners should strengthen health education on prevention and control of acute watery diarrhea. Health center should treat cases according to acute watery diarrhea case management guideline to decrease high case fatality rate.

Key words: Acute Watery Diarrhoea, V.cholerae, Segag, Ethiopia.

I. Introduction

1.1. Background

Acute Watery Diarrhea is a potentially life-threatening acute diarrheal disease caused by the toxigenic bacterium *vibrio cholerae* either type 01 or O139 (1)-(2). The infectious agent is acquired through consumption of contaminated water or food. The source of contamination is usually the feces of an infected person (3) .It is one of the key indicators of social development and remains a challenge to countries in epidemic form where access to safe drinking water and adequate sanitation cannot be guaranteed (4). AWD occurs when there is rapid urbanization without adequate sanitation and access to clean drinking water (5).
Most individuals infected with V.cholerae remain asymptomatic or show only mild diarrhoea. Symptomatic cases of human infection are characterized by acute secretory watery diarrhoea, commonly with vomiting, nausea and abdominal discomfort (6). V. cholerae O1 and O139 cause clinical disease by secreting an enterotoxin that promotes secretion of fluids and electrolytes by the small intestine (7). In the most severe cases, AWD is one of the most rapidly fatal illnesses known, due to severe dehydration or water loss. If left untreated, mortality from AWD can be 30-50% (8). The most common method of treatment is administration of oral rehydration solution (ORS); more severe cases may require intravenous rehydration and antibiotics (3).

It is estimated that approximately 3-5 million people are annually infected with AWD and it leads to 100000 to 120000 deaths worldwide. It may produce rapidly progressive epidemics or worldwide pandemics (2). It is estimated that 4.2% of the total AWD cases reported globally originate in Asian countries. The highest number of cases has been reported in India (52.9%) followed by Afghanistan (29%) and Indonesia (22%) (2).

In 2012, sub-Sahara Africa accounted for 71% of reported cases and 86% of reported deaths worldwide. The number of AWD cases is estimated to be much higher than actually reported to World Health Organization. A recent analysis from Mozambique found that 66% of cases and 90% of deaths occurred within the first 6 weeks of an outbreak (9).

In 2009, a total of 217,333 cases with a case fatality rate (CFR) of 2.25% (4,883 deaths) were reported in 30 African countries alone. Of these, eight countries, including Nigeria accounted for 191,537 cases with a CFR of 2.26% representing 88% of reported cases and deaths from the continent with the CFR in many of these countries higher than the accepted 1% threshold(10) .

In Ethiopia it was indicated that, there was acute watery diarrhea (AWD) epidemic in 1990 which persisted with recrudescence of cases till 1998. Moreover, from July 2008 to June 2009 in Ethiopia, there were a total of 9485 cases and 193 deaths (with case-fatality rate 2.0%) of acute watery diarrhea in six regions including Addis Ababa. Afar region took the country's highest share of cases, 2,988 (31.5%) and deaths 99(51.25%) of AWD with a case fatality rate of 3.3% (1).

On 01 March, 2009, the Public Health Emergency Management Team of Ethiopian Public Health Institute (EPHI), in the Federal Ministry of Health, received a report from Segag district health office, Nogob zone, Somali Regional state indicating unusual cases of watery diarrhoea from Segag district kebeles and its neighbors. Following the occurrence of unusual cases report, the Ethiopian Public Health Institute decided to deploy a team to the affected area from Ethiopian Field Epidemiology and Laboratory Training Program to investigate the outbreak.

1.2. Statement of the problem

AWD is an epidemic-prone disease of global significance that has a prominent role in the history of public health. This infectious disease has been virtually eliminated from developed countries due to improved water and sanitation infrastructure, but deadly AWD outbreaks still occur in many low-income countries including Ethiopia.

AWD is becoming endemic in Ethiopia meaning that the country experienced cases of AWD since 1990(1). Large widespread outbreaks occurred in Ethiopia from July 2008 to June 2009 in six regions including Addis Ababa with case fatality rate of 2.0%. AWD remains major public health concern in Ethiopian Somali region and in 2009 the region reported 6960 cases and 170 deaths with case fatality rate of 2.4%. Therefore this study investigated the existence of the out- break and successes and challenges of AWD outbreak control and prevention efforts in Segag district Ethiopian Somali region.

1.3. Rationale of the investigation

Currently Acute watery Diarrhea is the major public health problem in Ethiopian somale region with a high frequency of epidemic in all zones of the region. But there is a delay in outbreak investigation, reporting, control and prevention of AWD in the region. This AWD outbreak investigation described the magnitude of the outbreak, identified potential risk factors of the disease transmission and provided the possible control and prevention measures based on gaps identified. Therefore the aim of this study was to investigate AWD outbreak in Segag district of Ethiopian somale region.

2. LITERATURE REVIEW

2.1 prevalence of AWD

AWD remains a global threat to public health and a key indicator of lack of social development. It is an acute enteric infection caused by the ingestion of bacterium Vibrio cholerae present in faecally contaminated water or food. It has been classified as reemerging global threat. The disease is primarily linked to insufficient access to safe and clean water supplies, crowded living conditions and poor hygiene and sanitation (10).

The true burden of the disease is estimated world -wide to be 3–5 million cases and 100 000–120 000 deaths annually (1).

More than forty years after its resurgence in Africa in 1970, AWD remains a grave public health problem in many regions, especially in the Great Lakes of the Rift Valley and the Lake Chad basin, with large ongoing epidemics in northern Nigeria, northern Cameroun and Chad, coastal regions in West Africa, between Guinea Bissau and Ghana, and the East African coast between Tanzania and Mozambique. Cholera in Africa is characterized by large disease burden, frequent outbreaks, persistent endemicity in many countries and high case-fatality ratios (CFRs) (9).

Study conducted in Africa to investigate risk factors associated with AWD outbreak revealed that a total of 217,333 cases with a case fatality rate (CFR) of 2.25% (4,883 deaths) were reported in 30 African countries alone. Of these, eight countries, including Nigeria accounted for 191,537 cases with a CFR of 2.26% representing 88% of reported cases and deaths from the continent with the CFR in many of these countries higher than the accepted 1% threshold (10).

In Ethiopia it was indicated that, there was acute watery diarrhea (AWD) epidemic in 1990 which persisted with recrudescence of cases till 1998. Moreover, from July 2008 to June 2009 in Ethiopia, there were a total of 9485 cases and 193 deaths (with case-fatality rate 2.0%) of acute watery diarrhea in six regions including Addis Ababa. Afar region took the country's highest share of cases 2,988(31.5%) and deaths 99(51.25%) of AWD with a case fatality rate of 3.3%. During 2006-2009, 8109 cases and 194 deaths of AWD were reported from three districts of Afar with a total case fatality rate of 2.4% (1).

2.2 Risk factors associated with acute watery Diarrhea.

Study carried out in Nigeria to measure risk factors associated with AWD outbreak shown that Behaviors related to personal hygiene and food preparation contributed significantly to the occurrence and severity of outbreaks (10).

Other study conducted in Tanzania on risk factors of cholera revealed that many factors such as improper waste disposal, food handling, processing, and preservation, poor housing, improper and inadequate sewerage systems place people at a greater risk of being infected with cholera and other diarrhoeal diseases. Geographical, socio-economic and socio cultural backgrounds of people in the affected area which influence practices may also contribute to spread of cholera. These include low educational level, unhygienic food handling practices and proximity to surface water (11).

According to the results of the case control study carried out in Kenya, the risk factors of AWD outbreaks in affected areas were consumption of vegetables and fruits, consumption of food that was left out of the refrigerator (leftover), and a history of traveling to areas already affected (12).

3. Objective

3.1 General objective

To assess the existence of AWD outbreak, its magnitude and potential risk factors in Segag district of Somali region, March 04- April 15/2017.

3.2 Specific objectives

- To describe the magnitude of the outbreak by person, place and time
- To identify potential risk factors of disease transmission
- To provide the possible prevention and control measures based on identified gap

4. Methods and materials

4.1 study area

The study was conducted in Segeg district, Somali region with a total population of 60000. Administratively the woreda has 2 urban and 13 rural kebeles. In the woreda there were 1 health center and three health posts. The climate condition of the woreda is kola.

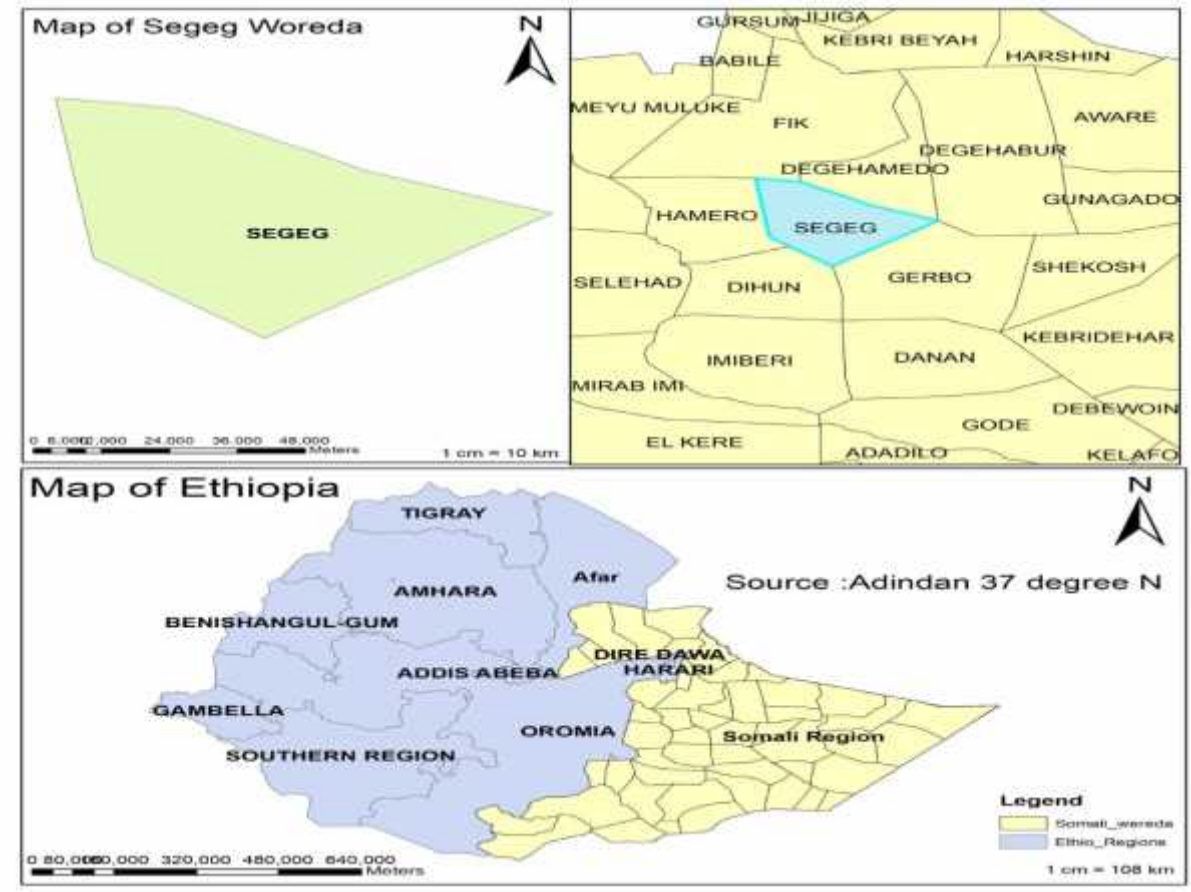


Figure 1: Map of Segag district, Nogob zone, Somali region, Ethiopia, 2017

4.2 study design and period

Un-matched community based case control study design was conducted from March 04 to April 15/2009 E.C.

4.3 Study population

The study populations were all persons living in Segeg district and confirmed with AWD and/or had epidemiological linkage with confirmed AWD cases detected during the outbreak and randomly selected community controls from the same neighborhood where the cases live.

4.4 study subjects

Cases were individuals with AWD admitted or treated in Segeg health center and who are in the line list and selected to participate in the study and their controls were persons without AWD and living in the same neighborhood as the cases.

4.5 Case definition

4.5.1 Case

For the purpose of the study, a case was defined as illness in a person living in Segeg district and its neighboring districts aged five years or more who presented at Segeg Health center with Acute Watery Diarrhoea with or without vomiting from March 04 to April 15/2009 E.C.

4.5.2 Control

A control was any person with age five years or more who lived in Segeg district from March 04 to April 15/2009 E.C and who did not present any sign and symptom of AWD.

4.6 sample size determination

The sample size was calculated using stat calc function of Epi-info version 7.1.4.0 using the confidence level of 95%, power of 80%, and assuming that a 52% prevalence of controls exposed, consumption of food left out of refrigerator an AOR 3.05 gives a total sample of 150(50 cases and 100 controls)(12) **.**

4.7 Inclusion and Exclusion Criteria

Residents of Segeg woreda who are above age of five years and able to respond were included in the study. Those who are below age of five years and unable to respond were excluded.

4.8 Sampling method

Cases were selected randomly using the lottery method where each name on the line list was allocated a number on a pieces of paper which was put in box and randomly picked and the name corresponding to their number was recruited in to the study until the sample size reached. Controls were neighbors of cases who did not suffer from AWD during the study period. Two controls for one case per household were selected from the neighbors of cases.

4.9 Study variables

4.9.1 Dependent variable

Status of acute watery diarrhea

4.9 independent variables

- Socio demographic characteristics
- Educational level
- Occupational status
- Religion
- Age
  - Sex
  - Residence
- Risk factors
  - Travel history
  - contact history
  - Family size
  - Knowledge
  - Latrine utilization
  - Water treatment
  - Hand washing

4.10 Data collection instrument

The questionnaires were developed in English and translated in to Somale language and translated back to English. The questionnaire included dependent and independent variables mentioned above.

4.11 Data collection method

By using outbreak investigation predesigned questionnaires, all the outbreak investigation team and one language translator for each assigned were conducted home to home visit and administered the questionnaires. For each case, two community controls were selected and interviewed on the same day as the cases interviewed and similarly environmental assessment of the community were carried out.

4.12 Data Analysis and interpretation

Data was cleaned manually and checked for consistency before analysis and necessary corrections were made. The data was entered in to Epi Info Version 7 and exported to SPSS statistical software package. Descriptive statistics and binary logistic regression analyses were carried out to describe the variables and to identify possible risk factors associated with AWD respectively. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated, and p-values <0.05 were considered to indicate statistical significance.

4.13 Ethical consideration

Permission to proceed with the outbreak investigation was obtained from the public health emergency management / Ethiopian Public Health Institute (EPHI) and cooperation letter was written to Ethiopian Somali regional state health bureau. Somale regional state also wrote cooperation letter to Segeg district health office.

Consent Process: participants of the study were informed about the study verbally to solicit their consent to participate in the study. Children were recruited in the study after obtaining informed consent from their parents or care-givers.

5. Results

5.1. Descriptive Epidemiology

5.1.1. Magnitude of the Outbreak

A total of 501 suspected AWD cases and five RDT confirmed cases with 26 deaths were reported between March04 and April 15, 2009 E.C. The attack rate and case fatality rates were 83 per 10,000 population and 5.1% respectively.

A. Description of the Outbreak by time

AWD cases were notified in Segeg district in WHO week number 9 (March 04 –09, 2017), the number of cases were increased and reach its peak in WHO week number 12 and gradually the outbreak was declined in week 14.

The first suspected AWD case (the index case) in the district was a 45 years old man from Ribeda kebele with a travel history to Dhun district which is the already affected area by AWD. After seven days of the occurrence of the outbreak (March 11, 2009 E.C) six stool samples were collected from patients with profuse watery diarrhoea and examined for *Vibrio cholerae* by Rapid Diagnostic Test (RDT) and five of them were positive for *Vibrio cholera* type 01. The outbreak was spread to all kebeles of Segeg district and it lasts after around one month as shown in the Epi-curve below (Figure 2).

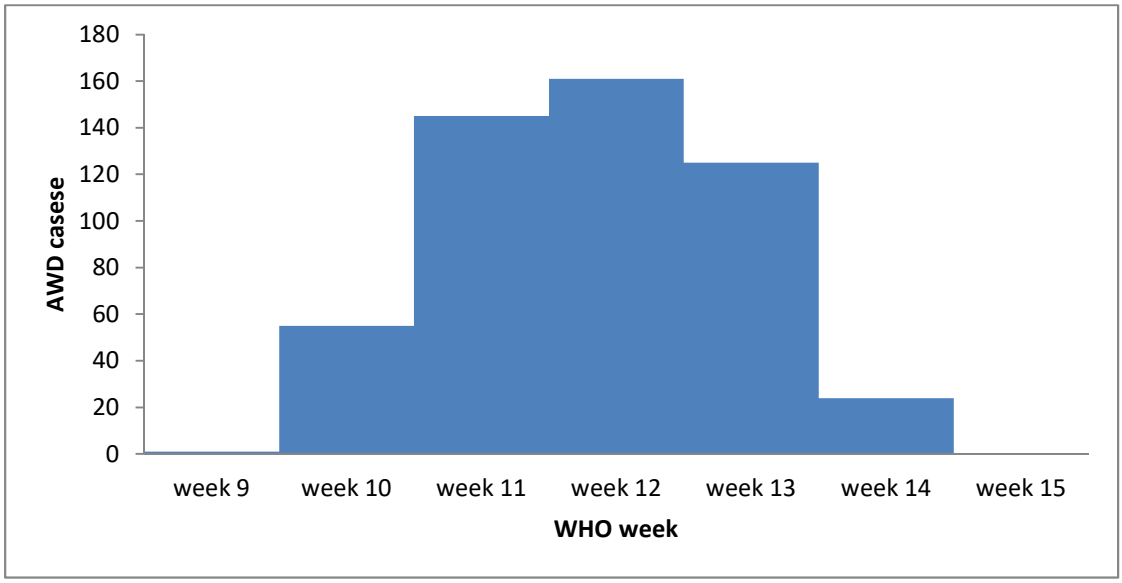


Figure 2 Epidemic Curve of AWD Outbreak by WHO week Number, Segeg district, Somali Region, Ethiopia, March-April, 2017

The outbreak is a propagated or progressive type of outbreak which the numbers of cases were increases date to date in an alarming rate for the first two weeks. The following Epi curve illustrates the situation of the outbreak depending on time of onset (figure 3

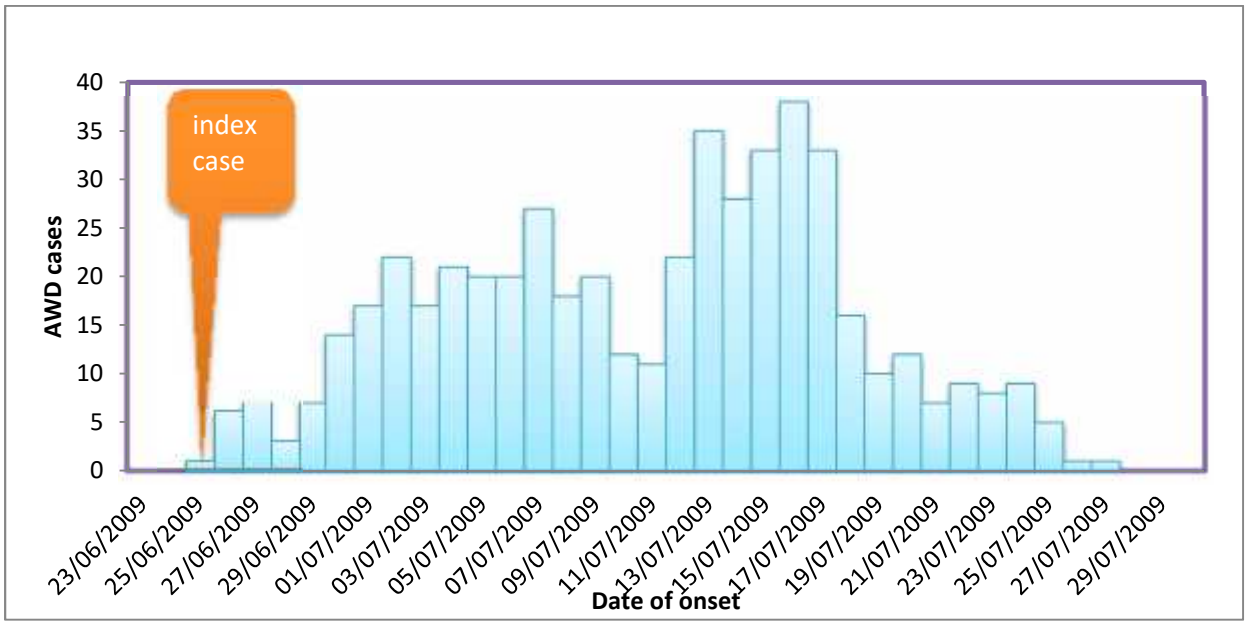


Figure 3: Distribution of AWD outbreak by Time, Segeg district, Somali Region, Ethiopia, March-April, 2009.

B. Description of the Outbreak by person

Regarding sex 53% of males were affected by AWD and 47% of females were affected by AWD.

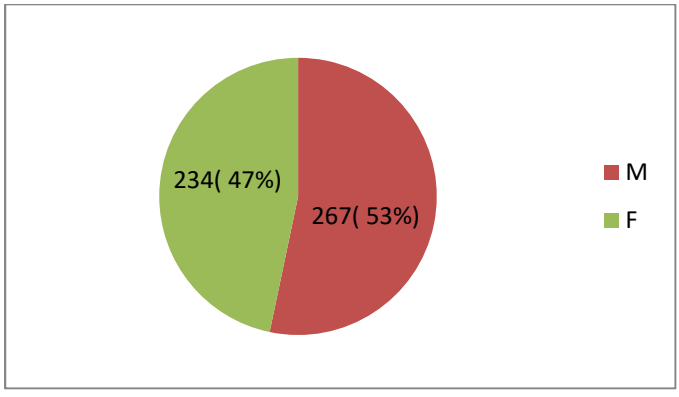


Figure 4: Distribution of AWD outbreak by sex, Segeg district, Somali Region, Ethiopia, March-April, 2009

150 (30%) of cases were in age group 0f 1-4, 173 (34.5%) of cases were 5-14 age groups, 135(27%) of cases were 15-44 age group and the rest 43 (8.5%) cases were above 45.

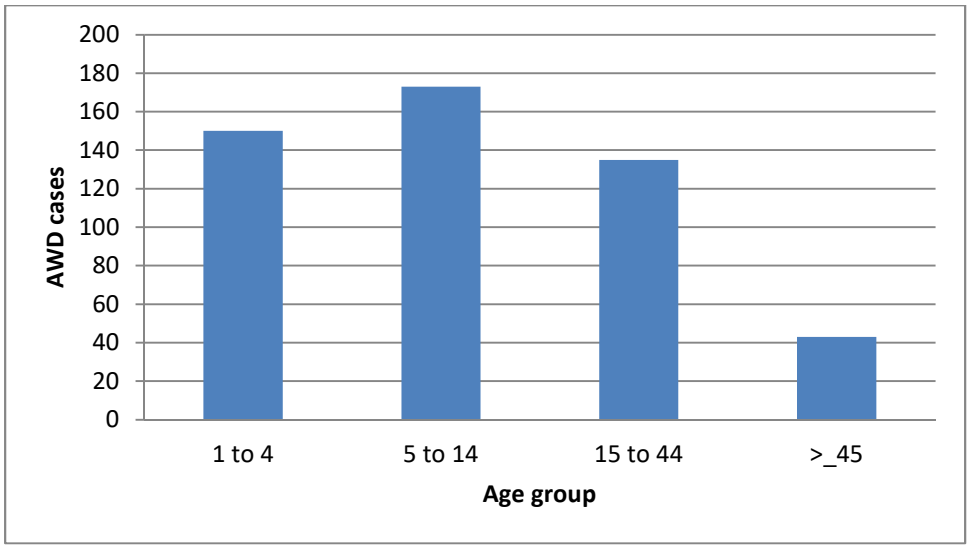


Figure 5: Distribution of AWD outbreak cases by Age, Segag district, Somali Region, Ethiopia, March-April, 2009.

C. Description of the Outbreak by Place

Regarding geographical distribution of cases, majority of cases 143(28%) were from Dudqofel kebele followed by Segeg Town and Talo kebeles.

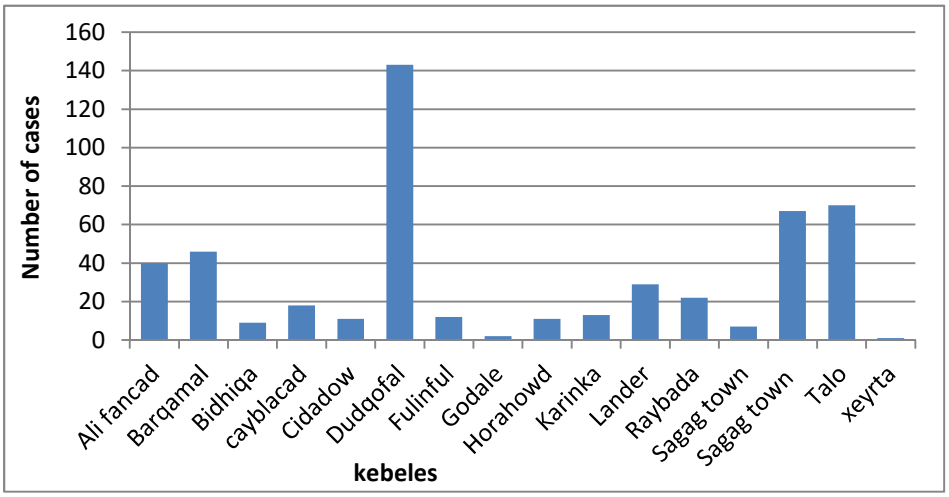


Figure 6: Distribution of AWD cases by kebele, Segeg district, Somali Region, Ethiopia, March-April, 2009:

D. Description of the Outbreak by out come

Regarding outcome of AWD case 68% (341) of them were alive, 5.1% (26) of them were died and the rest 26.7% (134) of them were unknown status.

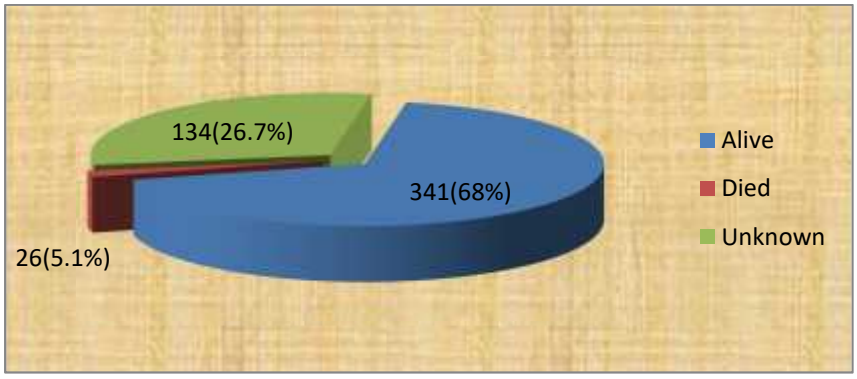


Figure7: Distribution of AWD cases by outcome, Segeg district, Somali Region, Ethiopia, March-April, 2009.

E Description of the Outbreak by Dehydration status

42.1% of AWD cases were moderately dehydrated and put on plan B whereas 57.9% of them were mildly dehydrated and put on plan

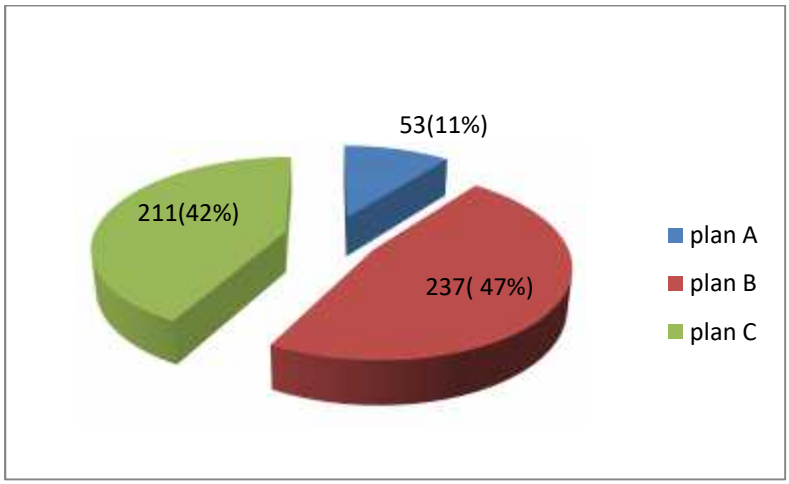


Figure 8: Distribution of AWD cases by Dehydration status, Segeg district, Somali Region, Ethiopia, March-April, 2009.

5.1.2. Laboratory test and Result

Out of six suspected AWD cases investigated by RDT (Rapid Diagnostic Test) five (83.3%) of them were confirmed positive for *Vibrio cholera* type 01. *Escherichia coli* bacteria was isolated from water samples collected from Sulul river that residents were being used for drinking and other home purposes.

5.1.3. Case Management

All suspected AWD cases were admitted and treated at Segeg health center and its catchment CTCs. Cases were treated with Ringer lactate, ORS and Doxycycline capsule according to the national guideline. Contacts were traced and given Doxycycline capsule for prophylaxis.

5.1.4. Epidemic Preparedness and Response Measures Taken

Segag district had a functional epidemic preparedness and management committee and also have preparedness plan of action. The committee had meeting in a daily basis and taken prevention and control measures to tackle the outbreak, which includes:

- Suspected AWD cases were treated in CTCS of Segeg woreda according to AWD case management guideline.

- Community mobilization and health education activities on AWD transmission and prevention were performed.
- Active case search was done to identify new cases from community.
- Contact tracing and Doxycycline capsules were given by the surveillance team to contacts'.
- Source of drinking water was treated with chlorine
- Water treating supplies were distributed to house holds

5.1.5. Environmental Assessment

There was poor environmental sanitation in the area. Source of drinking water for the study participants was Sulul River. 49.3 % of respondents treat water before drinking.58% of the study participants washes their hands before eating meal. The private latrine availability of the community was only 15%, 53(35.3%) of the respondent share common toilet with their neighbor and 82(54.7%) practice open defecation. All the latrines of the community hadn't roof at their top. Hand washing facilities were not available in all of assessed households near their toilets. There is no any solid waste disposal pit near their home in visited community and they used open area around their home. The latrine coverage and latrine utilization rate of the community was not known.

5.2. Analytic Epidemiology

5.2.1 Socieo-demographic characteristics of the study participants

A community-based unmatched 1:2 case control study was conducted between March 4 and April 15, 2009 E.C in Segeg district to identify possible risk factors and associated vehicles of transmission. 50 cases were selected from CTC and 100 neighborhood community controls were selected. The median age for both cases and controls was 28 year with a standard deviation of 13.1 year. 52.3% of the respondents were males and 47.3% were females. Regarding marital status majority 94(62.7%) was married and 37.3% were single. All of the respondents were Muslim in religion. Occupational status of most 104(69.4%) study participants was pastoralist. For both cases and controls the majority 75(50%) of the respondents level of education was read and write followed by 1-4, 31(20.7%) and the least were grade 9-10 which is 2(1.3%). Most 111(74%) of the study subjects were from rural setting and the rest 39(26%) of them were urban residents. (Table 1)

5.2.2. Epidemiological and Clinical features of study participants

Among AWD cases, age ranged from 6 to 60 years, the most affected age group was 25-29 years; 23 (15.3%). AWD cases have different symptoms; the most common symptoms include Watery diarrhoea 50 (100%), Vomiting 50 (100%), General body weakness 7 (4.6%), and fever 5(3.3%). Regarding treatment of cases, 50(100%) were treated with ORS, 36 (72%) with IV fluids and 49((98%) treated with antibiotics. 36(72%) of cases had history of close contact with individuals already diseased with AWD. 59(39.3%) of the study participants herd about AWD whereas the rest 91(60.7%) of them were not herd about AWD.

Table 1: Socieo demographic characteristics of the study subjects Segeg district, Somali Region, 2017

Parameter	Level	Frequency n=150	Percent %
Age (years)	1 – 4	1	0.66
	5 – 9	19	12.6
	10 – 14	12	8
	15 – 19	20	13.3
	20 – 24	10	6.6
	25 – 29	23	15.3
	30 – 34	19	12.6
	35 – 39	11	7.3
	40 – 44	22	14.6
	45+	13	8.6
Religion	Muslim	150	100
	Catholic	0	0
	Protestant	0	0
	Orthodox	0	0
Marital status	Married	94	62.6
	Single	56	37.4
Occupational status	Student	46	30.6
	Pastoralist	104	69.4
Educational status	Not able to read and write	19	12.6
	Read and write	75	50
	1—4	31	20.6
	5—8	23	15.3
	9—10	2	1.3
Sex	Male	79	52.6
	Female	71	47.4
Residence	Rural	111	74
	Urban	39	26

5.2.3. Associated Risk Factors of the Outbreak

An adjusted analysis showed that persons who had a travel history to areas already affected with AWD were at greater risk of getting AWD [Crude Odds ratio (COR) = 4.51 at 95% confidence interval (CI) = 2.034-10.0, p-value = 0.00] and adjusted odds ratio 3.63 at confidence interval of 0.015-0.333, p value 0.047.

Household latrine availability was protective against acquiring acute watery diarrhoea with [Odds ratio (COR) = 0.412; at 95% confidence interval (CI) = 0.246-0.62, p-value = 0.038] and adjusted odds ratio 0.189 at 95% CI 0.043-0.818, p value 0.022.

Knowledge about the mode of transmission of Acute Watery Diarrhoea of the community was found to be protective against the disease with crude odds ratio = 0.41; at confidence interval of 95% CI: 0.196-0.868, p-value = 0.02]. But it has no association in adjusted analysis.

Hand washing before eating was also protective against acquiring acute watery diarrhoea [odds ratio (OR) = 0.092; at 95% confidence interval (CI) of 0.041-0.21, p-value = 0.00] and adjusted odds ratio 0.071 at 95% CI 0.019-0.358, p value 0.001.

Treating drinking water was protective of the illness (crude OR=0.098 at confidence interval of 95% 0.041-0.232; p-value=0.00) and adjusted odds ratio 0.133 at 95% CI 0.041-0.445, p value 0.001.

Table 2 Risk Factors for AWD outbreak, Segag district, Somali Region, 2017

Sr. no	Risk factor	Cases		Controls		AOR(CI)	P value
		Yes (%)	No (%)	Yes (%)	No (%)		
1	Travel history	40(45.9)	10(15.8)	47(54)	53(84.2)	3.63(0.015-0.333)	0.047
2	Latrine utilization	6 (9.3)	44(66.6)	58 (90.7)	42(33.4)	0.189(0.043-0.818)	0.02
3	Knowledge about AWD transmission	13 (22)	37(40.6)	46 (78)	54(59.4)	0.000	0.00
4	Hand washing before eating	3 (4.4)	47(57.3)	65(95.6)	35(42.7)	0.071(0.019-0.358)	0.01
5	Water treatment	8(10.8)	42(55.2)	66(89.2)	3444.8)	0.133(0.041-0.445)	0.01
6	Close contact with AWD case	36 (36.3)	14(27.4)	63(63.7)	37(72.6)	1.62(0.422-6.21)	0.48

6. Discussion

According to this case control study the attack rate (AR) and case fatality rate (CFR) was 1.26% and 3.4% respectively. This finding is comparable to reports of study conducted in Afar regional state (4.4%) (1). However the case fatality rate (CFR) was high as compared to the WHO guide line which was supposed to be below 1% among people receiving appropriate treatment based on rehydration, and the finding of study carried out in South Africa (2.6%) (13). This might be due to less attention given to prevention and control activities, shortage of medical supplies and poor case management in case treatment centers (CTCs.) However compared with outbreaks occurred in other countries such as Kenya (7.1%) and India (8.6%) the case fatality rate become low (2)-(3).

The finding of this study revealed that males were more affected than females. This finding is similar with report of study carried out at Afar regional state in which males were more affected than females(1). However the result contradicts with the finding of study conducted in Uganda in which females were more affected than males (14). This difference might be due to males travel to areas where already affected with AWD than females.

In this study all ages of the population were exposed to AWD outbreak, but the outbreak highly affected the younger age group 5-14 and 15-44. The finding is in line with studies conducted in developing countries such as Uganda and Nigeria ((14), (10)). This might be due to high movement of younger population for different activities to areas where already affected with AWD.

The finding of this study revealed that all kebeles of the district were affected by the AWD outbreak but Dudqofal, Segag town and Talo kebeles were highly affected. The variation of disease burden in kebeles might be due to accessibility of kebeles to Sulul River, source of infection and difference in habit of treating water with available chemicals. The study is in line with studies conducted in Afar Regional state (1) and north east Nigeria(10).

The laboratory investigation of this finding has indicated that the causative agent responsible for the outbreak to occur was *V. cholerae* O1. This finding is similar with the finding of studies conducted in south and south East Asia(2) and Eastern Freetown, Sierra Leone (15).

This study revealed that history of travelling to areas where already affected with AWD has a significant association with acquiring of acute watery diarrhoea. Travelling to affected areas with AWD and coming in to contact with an infectious dose of *V. cholerae* is supposed to be one of

factors propagating the transmission of AWD (5). This finding is in line with reports of studies conducted in Cuba (6) and Ethiopia, Afar regional state(1).

In this investigation treating water with appropriate available chemicals is preventive of acquiring AWD. Unsafe water and lack of sanitation and hygiene is a key risk factor for diarrheal and other diseases and the finding is similar with studies carried out in Eastern Freetown, Sierra Leone(15), south Africa (13), south east Asia(2) and national AWD guideline(16). In contrast the finding of this study was different from the result of studies carried out in north east Nigeria(10) and Ethiopia, Afar region(1)

In this study latrine availability was found to be protective against acquiring acute watery diarrhea. This finding is consistent with study conducted in Tanzania on knowledge, attitudes and practices regarding cholera outbreaks (11). This might be due to the fact that latrine utilization breaks the faecal-oral transmission route of AWD.

The finding of this study revealed that Hand washing before eating meal was protective of acquiring acute watery diarrhoea. The finding is consistent with the result of study conducted in Nigeria which suggested that poor hand washing habit was high predisposing factor in transmission of diarrhoea-causing agents including AWD infection through the faecal-oral route(10). This might be due to their feeding habit of cultural foods, rice and pasta. They not used spoon and fork.

7. **Challenges during intervention and Limitation of the investigation**

- Language barrier between investigators and the community and also health staffs
- Poor commitment of district health office
- Distance of the district from the center to conduct further laboratory diagnosis
- High temperature condition of the area

- It was difficult to undertake probability matched case-control study and interview more subjects during rapid epidemic investigation in a dispersed population.

8. Conclusion

AWD still remains serious threat to public health system in Somali regional state in Segeg district in recent years. Overall attack rate and case fatality rates were high. Younger age group was highly affected by the disease. All kebeles of the district were affected by AWD outbreak and the causative agent responsible for the outbreak to occur was *V.cholerae* O1. Travel history has significant statistical association with acquiring AWD. Latrine availability, treating water with appropriate chemicals and hand washing before eating meal were found to be protective against the disease.

9. Recommendations

Hence the district health office should strengthen health education on AWD transmission, prevention and control methods and restriction of population movement to affected areas with the disease. CTCs of the health center and its catchment should treat cases according to AWD case management guideline to decrease high case fatality rate. The district health office should strengthen the availability and utilization of latrine. The district health office, Education office, water office and women and children affaires offices should improve the community hand washing practice before eating meal. The district water and health office should treat drinking water sources and promote treatment of water at household level with appropriate chemicals.

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Annex 1: Questionnaire for assessment of AWD outbreak in Somali region, Segeg district, March, 2017

Part I. Socio demographic

1. Id number ____
2. Age ____ years _____months if less than 1 year
3. Sex 1. Male 2. Female
4. Address Region _____ Zone _____ Woreda _____ Kebele _____ Village __
5. Household size _____
6. Head of household 1. Male 2. Female
7. Marital status 1. Married 2. Single
8. Religion 1. Orthodox Christian 2. Muslim 3. Catholic 4. Protestant 5. Other _____
9. Education status 1. Not able to read and write 2. Read and write 3. 1-4 4. 5-8

   5. 9-10 6.11-12 7. Diploma and above
10. Occupation _____ Type of Work _____

Part II. Health/illness status for cases (circle choices or fill blanks as appropriate)

11. Have you got sick with diarrhea in the past 1 month? 1. Yes 2. No (skip to part III)
12. If yes to question 10, date of onset of diarrhea? _____(d/m/y)
13. How many episodes of diarrhea/day? _____ times/24 hrs
14. What type of diarrhea did you have? 1. Watery 2. Bloody 3. Mucoid 4. Semi-solid 5. Other _____
15. What other symptoms did you have during this time? 1. Vomiting 2. Abdominal cramps 3. Fever 4. Lethargy/unconscious 5. Generalized weakness 6. In shock 7. Other _____
16. Did you visit health facility for this illness? 1. Yes 2. No (skip to Q19)
17. Date of visit _____ (d/m/y).
18. Type of health facility 1. Government Hospital 2. Government Health Center 3. Private Hospital 4. Private Clinic 5. Bought drugs from pharmacy 6. Other _____
19. Did you get any treatment for the illness 1.Yes 2. No (Skip to Q21)
20. What type of treatment 1.ORS 2.IV fluids 3 antibiotics 4. Ant pain 5. Other _____
21. Have you recovered from your illness 1.Yes 2. No

22. Is there any person with close contact with you while you were sick?1.Yes 2.No (skip to Q26)

23. How many persons _____

24. Is there any person who got sick among those with contact to you? 1. Yes 2. No (Skip to Q26)

25. How many persons _____ **(arrange for contact tracing)**

26. Have you had any travel to other areas in the past one month? 1. Yes 2. No (to part III)

27. Where did you go? Region _____ Zone _____ Region _____ Woreda _____ Kebele _____

28. Have you had close contact with the sick person 1. Yes 2. No

Part III. Assessment of risk factors

29. What is your source of drinking water? 1. Tap water own 2. Tap water within compound communal source 3. Community tap water 4. Tap water purchased from private source 5. Other protected water source 6. River 7. Spring water 8. Rain water 9. Other----------

30. Do you store water at home in containers? 1. Yes 2. No (skip to Q34)

31. Does the container always have a cover? 1. Yes 2. No

32. How long do you store the water? _____

33. Do you use the stored water for drinking? 1. Yes 2. No

34. Do you have a tanker for storing water? 1. Yes 2. No

35. From where do you use water for drinking? 1. Directly from tap water 2. From water stored in container 3. From water stored in tanker 4. From unprotected source (river)

36. Do you treat the water with medicines to make it safe for drinking and food preparations? 1. Yes 2. No (skip to Q38)

37. Have you been using treated water in the past 2 weeks (noncase)/ prior to your illness (case)? 1. Yes 2. No

38. Do you have adequate access to water within the last 1 month 1. Yes (skip to Q40) 2. No

39. For how long did you have the water access problem in the previous month? _____ days, frequency _____1. 1-2 repeatedly

40. Have you ever eaten any food or drink outside your home within the last 7 days prior to your illness? 1. Yes 2. No (skip to Q43)

41. What did you eat? _____

42. When did you eat? _____(d/m/y)

43. Is there any person in your family who is sick with diarrhea? 1. Yes **(trace and take action)** 2. No skip to part IV)

44. What happen to this person? 1. Improved with treatment 2. Improved without treatment 3. Still sick 4. Died

Part IV. Hygiene and sanitation risks

45. Where do you use a toilet? 1. At home private/family latrine 2. Common toilet in compound 3. Public latrines 4. Open field 5. Other _____

46. Do you have a latrine at home? 1. Yes 2. No (skip to Q48)

47. Type of latrine 1. Pit latrine 2. Flash latrine 3. Other _____.

48. When do you wash your hands? 1. After visiting a toilet 2. After cleaning the bottom of children 3. Before preparing food 4. Before eating food 5. Other _____

49. How often do you wash your hands? 1. Always after _____ 2. Sometimes after _____ 3. Never after _____

50. Do you use soap or other detergents to wash hands? 1. Yes always 2. Yes sometimes 3. No

51. Where do you dispose wastes? 1. Open field 2. Waste container 3. Borehole 4. Burning 5. Damping 6. Other _____

Part V. Knowledge on AWD

52. Have you ever heard about Atet? 1. Yes 2. No (skip to part VI)

53. From where did you receive this information? 1. Family member 2. Health workers 3. Mass media 4. Social media 5. HEWs 6. Neighbor 7. Town criers 8. Other _____

54. Do you know how people acquire the disease? 1. Yes 2. No (Skip to Q57)

55. What are the methods the disease can be transmitted? 1. Drinking contaminated water 2. Eating contaminated foods 3. Eating uncooked foods 4. Eating contaminated vegetables 5. Other _____

56. How do you prevent the disease? 1. Using toilet 2. Washing hands 3. Cooking foods 4. Avoiding eating uncooked foods 5. Avoiding drinking unsafe water 6. Treating water 7. Other _____

57. If you or family members got sick with the disease what will you do? 1. Visit health facility 2. Buy drugs from pharmacy 3. Visit traditional healer 4. Take holy water 5. Do nothing 6. Other _____

58. Does the diseases curable with treatment? 1. Yes 2. No 3. Do not know

Part VI. Environmental and institutional risk factors observation

59. Households
60. Water sources
61. Tsebele areas
62. Restaurants/hotels/cafeterias
63. Slum areas
64. Sewerage areas
65. Waste disposal facilities and system
66. Schools and other major establishments
67. Populations at risk (Sanitation workers, street population, daily laborers, construction workers, etc)

Part VIII. Laboratory investigation

- Cases (RDT/Culture) Water
- Foods Environment

Chapter II- surveillance Data Analysis Report

2.1 Under Five Measles Surveillance Data Analysis, Southern, Nations, Nationalities and People (SNNP) Region, Ethiopia, 2006-2015

ABSTRACT

Background: Measles is a viral disease that spreads from person to person. It causes an estimated 2.6 million deaths each year worldwide. The objective of this study was to describe measles distribution by person, place, and time and recommend possible solutions.

Objective; To analyze under 5 measles surveillance data in southern nations nationalities and people (SNNP) region, Ethiopia, January 2006 to 2015.

Methods: measles cases were analyzed from national measles case-based surveillance system data base reported from SNNP region during January 2006 to January 2015. Epidemiologically linked, confirmed and suspected cases were included. The proportion of confirmed measles cases was computed. Vaccination status and distribution of cases by age and sex was presented. Moreover, description by place, person, and time was performed. Data was entered into a computer, edited, cleaned and analyzed using spss version 21.

Result: Cumulatively 8737 measles cases and 603 deaths with CFR 6.9% were reported from SNNP region from January 2006 to 2015.Majority of cases were from Keffa, sidama and wolyta zones. Of these 4249 cases were reported by line list while 330 cases were reported by case based. Of the total reported measles cases 1-4 year age groups were the most affected accounting 6694(76.6%) followed by under1 years age group 2043(23.4%) . Concerning sex 4680(53.5%) were males and 4055(46.5%) were females. Majority of cases 3439(24.3%) were reported in 2013 and low cases 254(2.9%) were reported in 2006. Among investigated cases 3439(83.8%) were confirmed for measles. Overall, 26.3% of cases vaccination status was unknown and 20.3% were not vaccinated. Annualized measles attack rate was 9 cases per 100,000 populations in 2015.The trend of measles showed case buildup during dry season week 45- 50/ 2015.

Conclusion and Recommendations: The analysis revealed that under- five age groups are still at risk of contracting measles in the region. The incidence rate is higher among 1-4 age groups. The immunization coverage of the region is low. Majority of zones reported outbreak during the study period. Therefore active case search should be conducted for every suspected measles cases to

assure timely reporting and contain the outbreak in the population known to be affected. Measles surveillance system should be strengthened in the region, especially zones with high measles cases. Routine immunization service delivery should be strengthened to reach all children by their first year of life.

Keywords: Surveillance, Incidence, Measles, Ethiopia

1. INTRODUCTION

1.1 BACKGROUND

Measles is an acute viral illness caused by a virus in the family paramyxovirus, genus Morbillivirus. Measles is characterized by a prodrome of fever (as high as 105°F) and malaise, cough, coryza, and conjunctivitis, followed by a maculopapular rash. The rash usually appears 14 days after exposure and spreads from head to trunk to lower extremities (1). Measles is a leading cause of childhood mortality with serious complications including pneumonia, diarrhea and blindness especially in infants and children under the age of five (17). The average incubation period for measles is 14 days, with a range of 7-21 days. Persons with measles are usually considered infectious from 4 days before until 4 days after onset of rash with the rash onset being considered as day zero (1).

In 1980, before widespread vaccination, measles caused an estimated 2.6 million deaths each year. Despite the availability of a safe and effective vaccine, measles remains one of the leading causes of death among young children globally. More than 95% of measles deaths occur in low income countries with weak health infrastructures (2).

The World Health Organization (WHO) estimates that, during 2000, measles accounted for approximately 777,000 deaths worldwide, of which 452,000 (58%) occurred in Africa(3).

There were over 200,000 measles cases and 1400 deaths reported during measles out breaks in Africa in the year 2010. It has been estimated that this figures could be 10 times higher due to under reporting. This wave of measles outbreaks pose serious threats to measles mortality reduction efforts and are due to increasing pockets of unvaccinated children and adolescents (4).

In 1999, of approximately 871,000 deaths from measles worldwide, 61% occurred in sub-Saharan Africa. In 2001, countries in the World Health Organization (WHO) African Region began an accelerated measles-control program to reduce by half by 2005 the number of deaths that were caused by measles in 1999(5).

Despite considerable improvement in measles immunization coverage in Ethiopia, measles outbreaks continue to occur in most part of the country and becoming a cause of significant number of under-five mortality and morbidity. Contributing five percent of under-five mortality, measles has been one of the major causes of death and sickness of children in Ethiopia (8). Vaccine

preventable diseases together with diarrheal diseases, acute respiratory diseases and malnutrition account for the majority of child deaths in Ethiopia. Ethiopia is also one of the eleven countries worldwide that collectively contributed to over 66% of the estimated measles related deaths that occurred in the year 2000 (6).

Unvaccinated young children are at high risk of measles and its complication, including death. Any non-immune person (who has not been vaccinated or was vaccinated but did not develop immunity) can become infected. Measles outbreak can be particularly deadly in countries experiencing or recovering from a natural disaster or conflict. Damage to health infrastructure and health services interrupts routine immunization, and overcrowding in residential camps greatly increase the risk of infection (2).

Increased measles vaccination resulted in a 74% drop in measles deaths between 2000 and 2010 worldwide. In 2010, about 85% of the world's children received one dose of measles vaccine by their first birthday through routine health services up from 72% in 2000(2). In 2010, the World Health Assembly endorsed targets to be met by 2015 as milestones toward eventual global measles eradication. These included increasing first dose coverage with MCV to ≥90% nationally and ≥80% in every district, reducing to and maintaining an annual measles incidence of <5 cases per million population, and reducing estimated measles mortality by ≥95% in comparison with 2000 estimates. WHO recommends 2 MCV doses for all children and emphasizes on-time delivery of the first dose at age 9 months in countries with ongoing measles virus transmission(7).

There is no specific treatment for measles. Most people with complicated measles will recover with rest and supportive treatment(4).

1.2 STATEMENT OF THE PROBLEM

Measles affects about 20 million people a year, primarily in the developing areas of Africa and Asia. It causes the most vaccine preventable deaths of any diseases. It resulted in about 96,000 deaths in 2013, down from 545,000 deaths in 1990. In 1980, the disease is estimated to have caused 2.6 million deaths per year. Prior to immunization, in the United States between three and four million cases occurred each year. Most of these who are infected who die are less than 5 years old. The risk of death among those infected is usually 0.2%, but may be up to 10% in those who have malnutrition. It is not believed to affect other animals.

In some developing countries case fatality rate for measles among young children may still reach 5-6%. In industrialized countries, approximately 10-30% of measles cases require hospitalization and one in thousands of those cases among children results in death from measles complications.

In Ethiopia, the number of confirmed measles cases steadily increased from 73 in 2003 to peak of 3511 in 2008 following which there was a decline to 1944 cases in 2009. Even though measles incidence rate has showed significant increase in the country since 2010 a dramatic increase is observed from 2012 to 2014. From a total of 931 measles cases registered in 2002, 42.5% of them were under five children(4).

Improving measles vaccination coverage and reducing measles related death is a global imperative, particularly as it relates to the united nations millennium development goal4(MDG4) which aims to the overall number of deaths among children by two third between 1990 and 2015.

1.3 SIGNIFICANCE OF THE STUDY

Despite the relatively high reported measles vaccination coverage, increasing number of measles cases were observed, which might raises the question of what are the risk factors for measles behind high vaccination status (16).

The finding of this analysis

- Supports primary health care providers, policy makers and planners to make better decision
- Will help planners to understand the nature and pattern of the occurrence of measles outbreaks in different zones of the region.
- Helps SNNPR health bureau and stake holders for immunizing the society.
- Will support the effort of eradicating measles in particular and improving the quality of life in general.
- Can also serve as baseline data reference and initiative to conduct further studies in the future.

As a vaccine preventable disease, measles surveillance data analysis is critical to guide intervention and vaccination activities. Therefore, this analysis was undertaken to describe proportion of confirmed measles cases, vaccination status and determine the extent, distribution, and occurrence of measles in south nations, nationalities and people region, Ethiopia.

2. LITERATURE REVIEW

Globally measles related mortality decreased from 872,000 deaths in 1990 to 556,000 in 2001 (38% reduction). Measles accounted for about 7% of deaths in this age group in 1990 and 1% in 2008 equal to 23% of the global reduction in all-cause mortality in this age group from 1990 to 2008(8).

Measles mortality in high and low burden districts showed the mortality rate of 3.3% per 1000 live birth and about 6% of all 1-59 months death in India. The measles mortality rate was nearly 70% greater in girls than in boys and 60% of the deaths were in three population states of the country (9).

In Niger from 5 year period reported cases 65% of the children were admitted in to the isolation room of the pediatric ward and the remaining 35% were seen and managed on an outpatient basis. 48% were male and 52% were female. More cases of measles 54.7% occurred during the relatively longer rainy season and 45.3% of cases occurred during the shorter dry season.18.8% of the children received measles vaccine before the illness while 81.2% had not. A case fatality rate was 3.9% (10).

Nationally measles case fatality rate was 0.2% in 2013. The age specific attack rate was 69 per 100,000 populations in less than 1 year. Half of cases were from SNNP region. Among investigated cases 44.5% were confirmed for measles. 31.2% of cases vaccination status was unknown and 22.9% were not vaccinated. Annual measles attack rate was 14 cases per 100,000 populations. The trend of measles showed case buildup during dry season week 43-50/2013(1).

Measles case fatality rate of 0.05% was reported from 2005-2014 in Addis Ababa. 27.5% were laboratory confirmed cases, 12.2% were clinically compatible cases, 52 (1.2%) were epidemiologically linked and the rest 2,485 (59.1%) cases were negative for measles IgM. Majority of the cases 92.2% were outpatient consults and 7.8% were inpatient. Measles cases were almost equally distributed between male and female. Of the total cases 10% were under one year, 35% were 1-4 year. Using the midyear population, the annual suspected measles cases incidence rate was 14.5 per 100,000 populations. The suspected measles case incidence rate was 60.0 among less than one year age, followed by 42.1 among children from1-4 per 100,000 populations (11).

3. OBJECTIVES

3.1 GENERAL OBJECTIVE:

- To analyze under 5 measles surveillance data in southern nations nationalities and people region, Ethiopia, January 2006 to 2015.

3.2 SPECIFIC OBJECTIVES:

- To assess the incidence of under- 5 measles in SNNP region
- To assess the distribution of under- 5 measles cases by person place and time.
- To describe proportion of confirmed under 5 measles cases in SNNP
- To determine the vaccination status of under 5 children in SNNP region

4. METHODS AND MATERIALS

4.1 STUDY AREA

In SNNP region, surveillance data for suspected measles cases is routinely collected at all levels of the health delivery system using the measles case based surveillance and line list form and sent to Ethiopian Public Health Institute. Data from the primary facilities is sent through the district, province onto national level where it is entered into the measles case-based surveillance system database, (EPI INFO based), where it is consolidated, cleaned, analyzed and disseminated for action. Data presented here represent measles patients from whom laboratory results were received from SNNP region during January 2005 to January 2015.

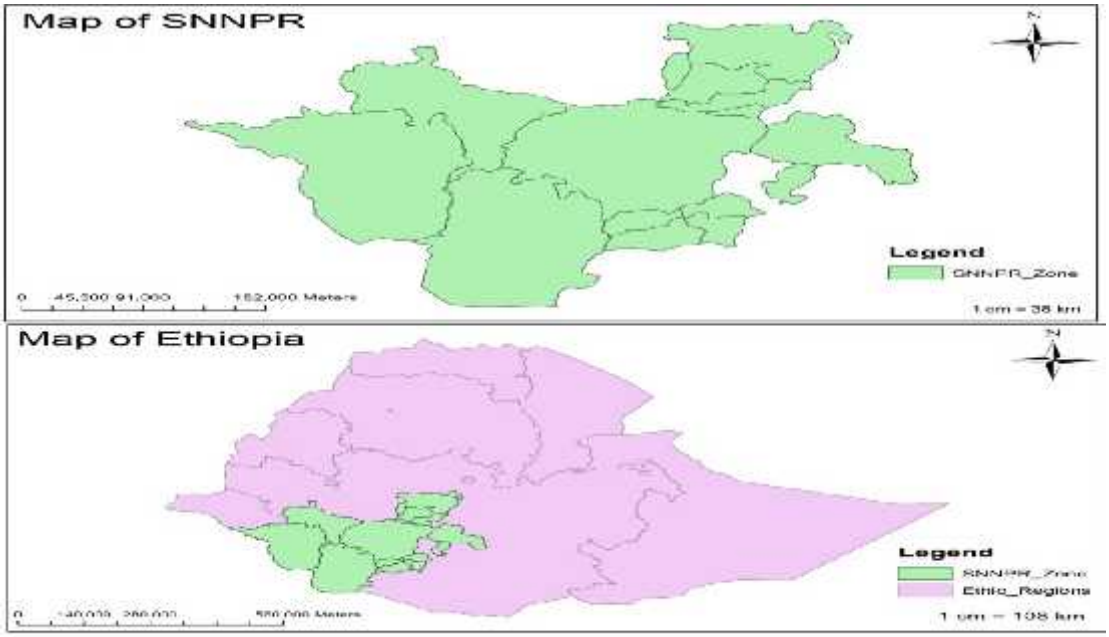


Figure 9: Map of SNNP Region, Ethiopia, 2017

4.2 STUDY PERIOD

Data presented here represent measles patients from whom laboratory results were received from SNNP region during January 2005 to January 2015

4.3 STUDY DESIGN

Retrospective descriptive surveillance data analysis was conducted.

4.4 SOURCE OF DATA

Secondary data that was reported from January 2005 to January 2015 from all districts through line list and case based format was used from EPHI/PHEM and laboratory data base.

4.5 STUDY UNIT

Secondary measles data base from EPHI sent from Zones, districts, hospitals, health centers, health posts and clinics through active case search and routine surveillance system.

4.6 INCLUSION AND EXCLUSION CRITERIA

Under- five measles cases reported from SNNP region from 2006 to 2015 were included. Under-five measles cases reported from regions other than SNNP and above five year age groups were excluded.

4.7 SAMPLE SIZE AND SAMPLING METHOD

A total of 8737 under 5 measles cases reported from January 2005 to January 2015 to EPHI/PHEM were included. All data from January 2005 to January 2015 were included.

4.8 STUDY VARIABLES

Variables captured by the dataset include; patient's age, sex, vaccination status, area of residence (by province, district), date of rash onset, date of first investigation (notification, specimen collection and specimen sending), dates of specimen arrival, specimen condition on arrival at national virology laboratory, Measles IgM test result, Rubella IgM test and final case classification.

4.9 DATA ANALYSIS

Data was cleaned and analyzed using SPSS software version 21. Finally the findings were shared with EPHI, mentors, and field supervisor.

4.10 CASE DEFINITION

- **Suspected measles case:** Is any person with fever and maculopapular (non-vesicular) generalized skin rash with cough, coryza or conjunctivitis (red eyes) and reported from SNNP region from 2006 to 2015.

- **Confirmed measles case:** A suspected case with laboratory confirmation (positive IgM antibody) or epidemiologically linked to confirmed cases in an outbreak and reported from SNNP region from 2006 to 2015.

• **epidemiologically linked case** is a suspected measles case that has not had a specimen taken for serologic confirmation and is linked (in place, person and time) to a laboratory confirmed case or another epidemiologically-confirmed case and reported from SNNP region from 2006 to 2015.

• **Compatible case** is a suspected case which has not been adequately investigated and reported from SNNP region from 2006 to 2015.

• **Discarded case** is a suspected case which, upon adequate investigation that includes a blood specimen collected in the appropriate time frame, lacks serologic evidence of a measles virus infection and reported from SNNP region from 2006 to 2015.

• **Suspected measles outbreak:** Occurrence of five or more reported suspected measles cases in one month in a defined geographic area such as a kebele, woreda or health facility catchment area and reported from SNNP region from 2006 to 2015.

• **Confirmed measles outbreak:** Occurrence of three or more laboratory confirmed measles cases in one month in a defined geographic area such as a kebele, woreda or health facility catchment area and reported from SNNP region from 2006 to 2015.

4.11 ETHICAL CONSIDERATION

Permission to proceed with the study was obtained from the public health emergency management / Ethiopian Public Health Institute (EPHI). Names of patients and addresses were omitted from the analysis. Confidentiality was assured and maintained.

4.12 DISSEMINATION OF FINDINGS

Finally the findings will be shared with Ethiopian Public Health Institute (EPHI), mentors, supervisors, and program coordinators of St Paul millennium medical college/EFETP

5. RESULT

A total of 8737 measles cases and 603 deaths with CFR 6.9% were reported from 19 zones of SNNP region from January 2006 to 2015.Majority of cases were from Keffa, sidama and wolyta zones. Of these 4249 cases were reported by line list while 330 cases were reported by case based. Of the total reported measles cases 1-4 year age groups were the most affected accounting 6694(76.6%).Concerning sex 4680(53.5%) were male and 4055(46.5%) were female.

When we see the trend of measles suspected cases by year, majority of cases 2123(24.3%) were reported in 2013 and low cases254(2.9%) were reported in 2006(figure 1).

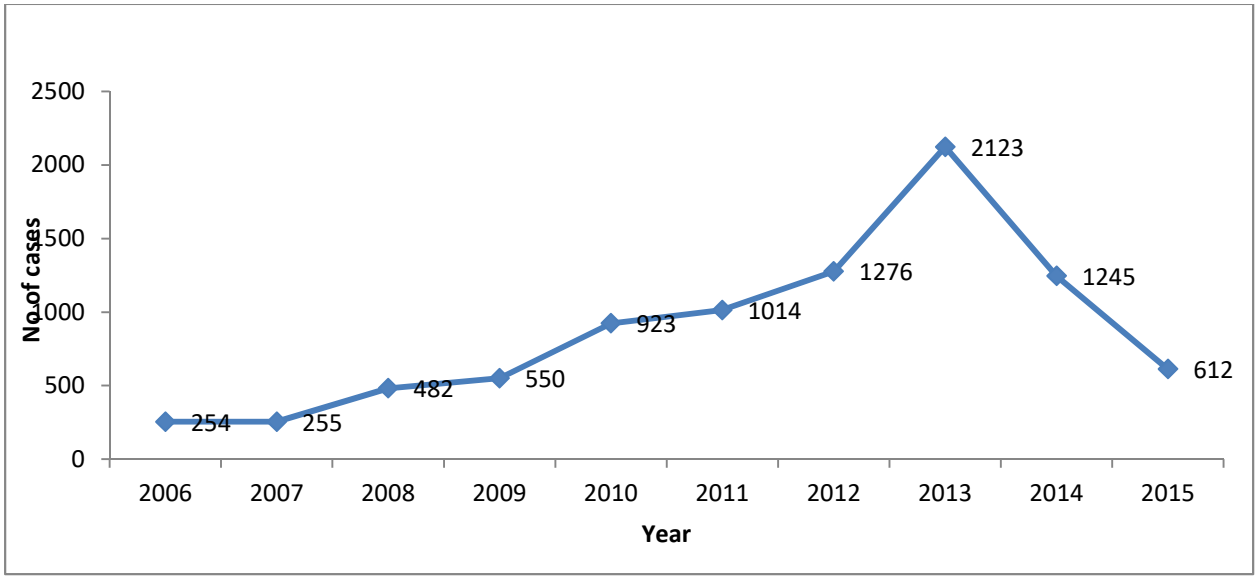


Figure 10: Trend of measles cases by year in SNNPR, Ethiopia, 2006 -2015.

The trend of measles suspect, probable and confirmed cases shows increment in number of cases respectively from 2006 to 2015 9 (Fig 3)

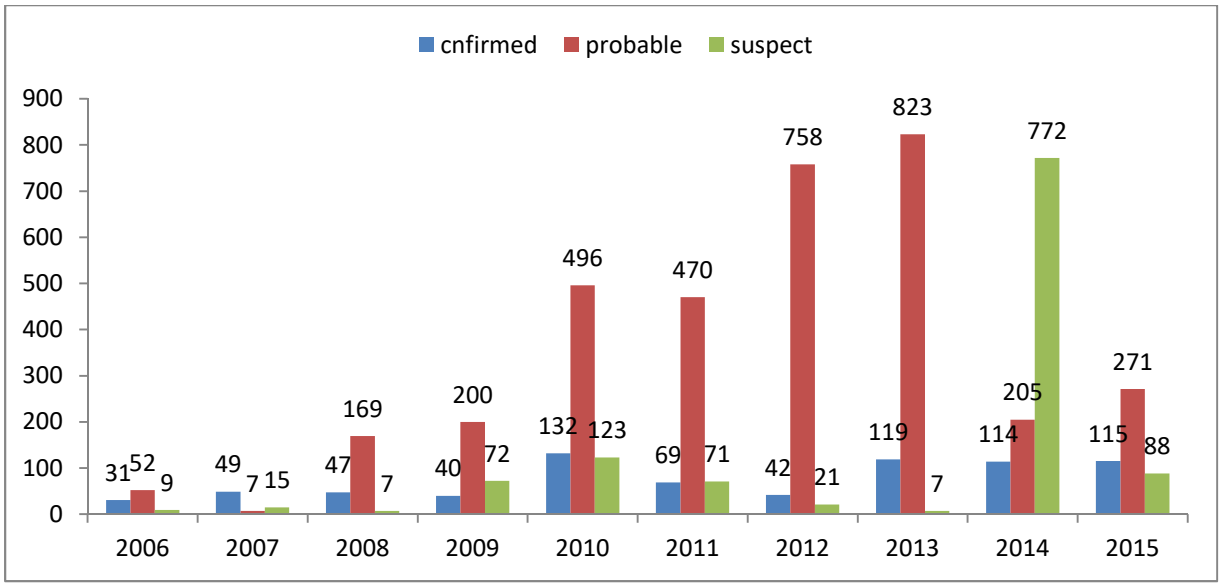


Figure 11: Trend of measeles suspect, probable and confirmed cases by yaer in SNNPR ,Ethiopia 2006-2015.

With regard to sex from a toal of 8734, 4679(46.4%) were males and the rest 4055(53.6%) were females

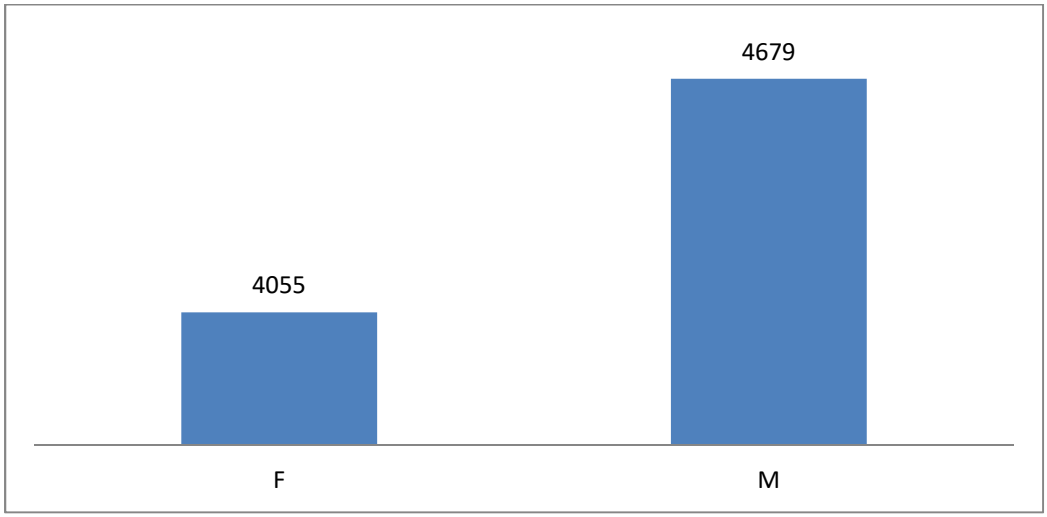


Figure 12: Sex distribution of measles cases in SNNPR, Ethiopia 2005-2015.

Of the total cases 2043 were under one year ages and 6694 cases were 1-4 years age group.

Table 3: Distribution of cases by Age groups in SNNP, Ethiopia, 2015

Age group	cases	%
‹1	2043	23.4
1-4	6694	76.6

With regard to geographical distribution majority of cases 1629(18.6%) were reported from Kefa and Low cases 124(1.4%) were reported from sheka zone.

Table 4: Trend of measles cases by Zone in SNNPR, Ethiopia 2006-2015

Zone	No of cases	population	percentage
Basketo	6	10728	0.06
Bench Maji	629	124906	0.5
Dawro	180	93044	0.1
GamoGofa	805	304127	0.2
Gedeo	467	165824	0.2
Gurage	512	245673	0.2
Hadiya	179	240170	0.07
Halaba	85	5887	1.5
Hawasa	132	41542	0.3
KEFA	1628	166315	0.97
Kembata Tembaro	151	130836	0.1
Konta	101	17365	0.58
Segen	145	109703	0.13
SHEKA	124	38504	0.32
Sidama	1521	607294	0.25
Silte	272	142988	0.19
South Omo	216	109047	0.1
Walayita	1574	287322	0.5
Yem	7	15264	0.045
Grand Total	**8734**	2,856,539	0.3

Regionally a total of 158 woredas were contributed for 8737 measles cases and majority of cases were from14 woredas, Gesha 837(9.5%),Kucha443(5%),sheybench345(3.9%), Damotsore 340(3.8%), Aroresa337(3.8%),Cheko 226(2.6%) Bolosobombe 225(2.5%), Borecha 174(2%), Damot Woyda 171(1.96%),Gedeb169(1.93), Humbo 142(1.6%), Chencha 118(1.3%) and Aleta chuko 113(1.29%).

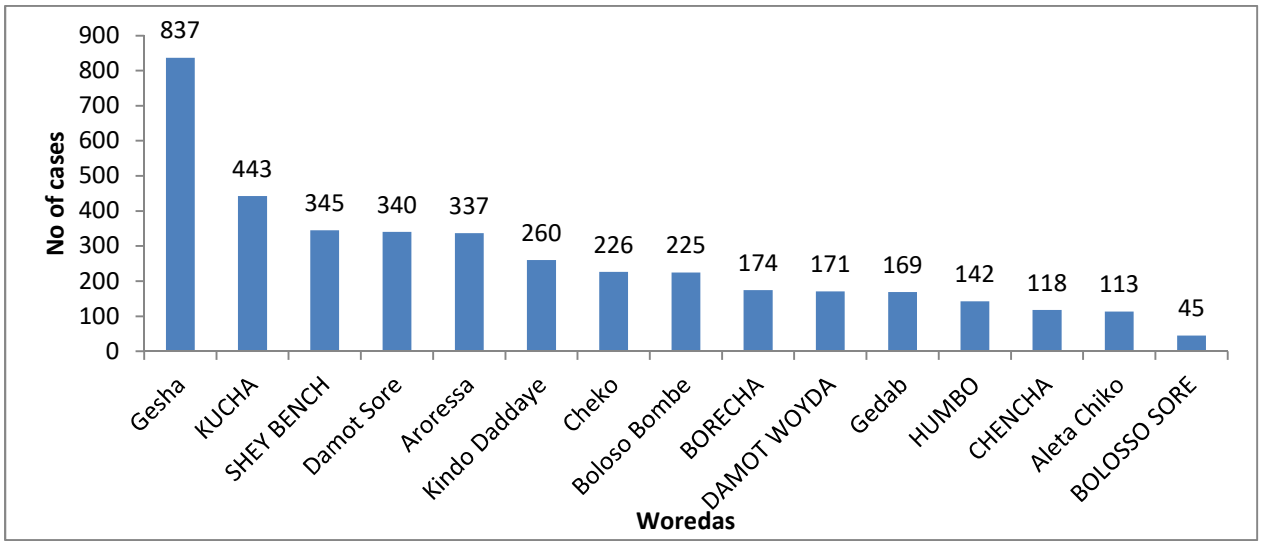


Figure 13: Distribution of Woredas with high case report SNNPR, Ethiopia 2006-2015.

Out of 4102 cumulative suspected measles cases reported with samples 3439(83.8%) of cases were confirmed for measles IgM. Of these 834 (20.3%) had not been vaccinate before and only small proportion 1041(25.3%) and 141(3.4%) had at least received a single dose and two or more doses of the measles vaccine respectively. The remaining 1080(26.3%) and 152(3.7%) had unknown and missing information on vaccination status respectively.

Zonal measles IgM positivity rate showed higher 629(18.8%) in sidama, and lower 6(0.01%) in Basketo. In 2015 annualized rate of investigation (with blood specimen) of suspected cases was 3.3 cases per 100000 populations while proportion of laboratory confirmed measles cases was 18.7%.

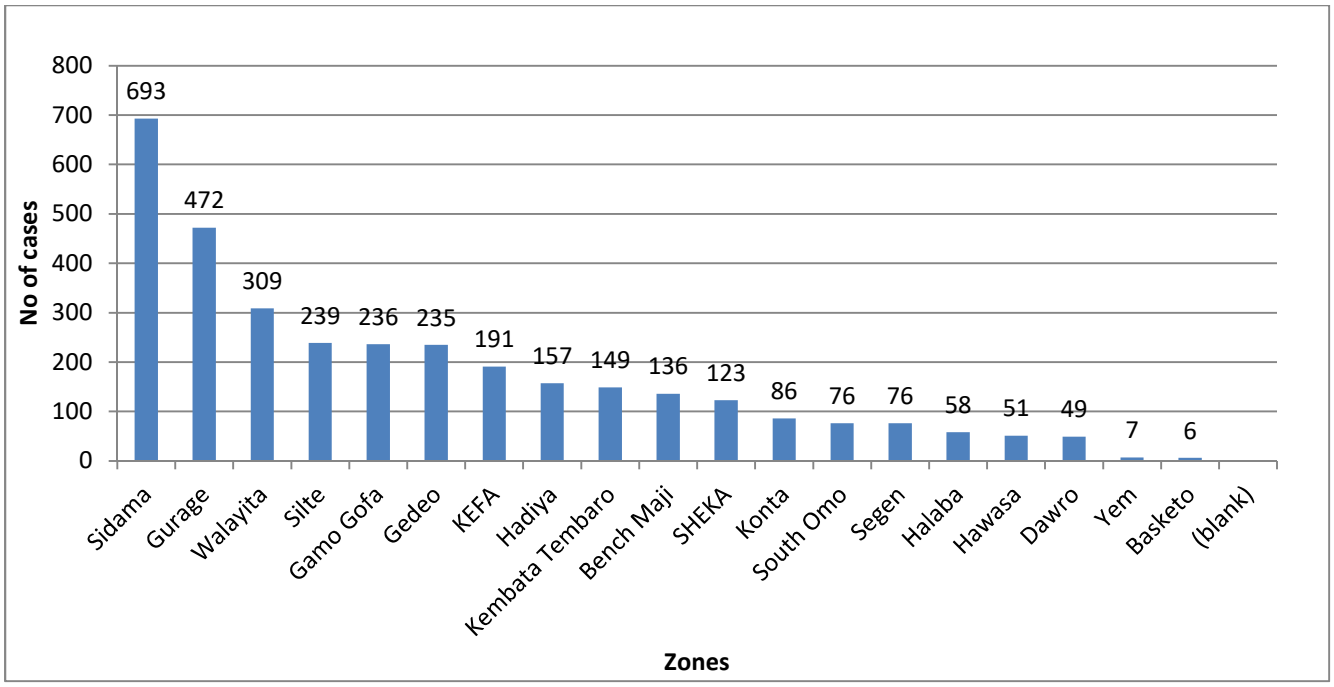


Figure 14: Trend of zones with high case reports in SNNPR, Ethiopia 2006-2015.

Overall, 1080(26.3%) of cases were their vaccination status unknown, 834(20.3%) were unvaccinated, 1042(25.3%) were received 1 dese, 141(3.4%) received greater than 2 doses of MCV and 152(3.7%) of cases had missing information on vaccination status. (Figure 7)

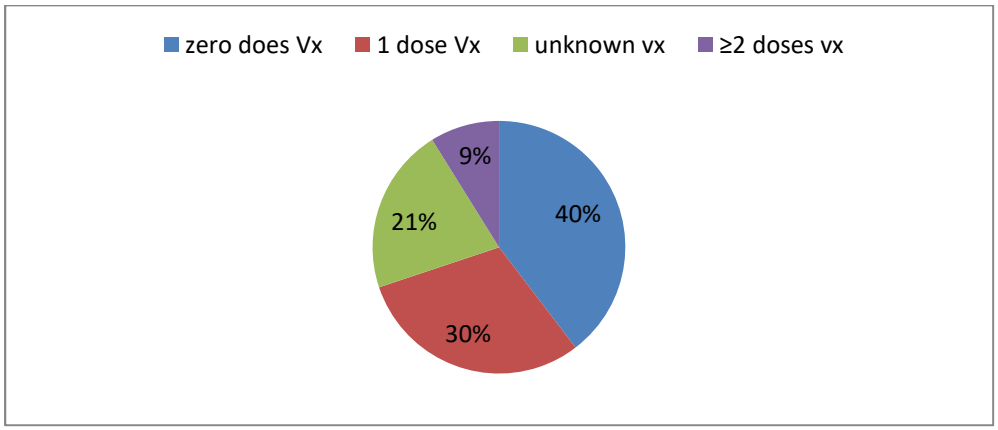


Figure 15: Vaccination status of measles cases in SNNPR, Ethiopia 2006-2015

When we see the vaccination status of reported cases by zones most of unvaccinated or their vaccination status unknown cases were from kefa, 1585(18.6%) and the least cases were from yem 5(0.05%).

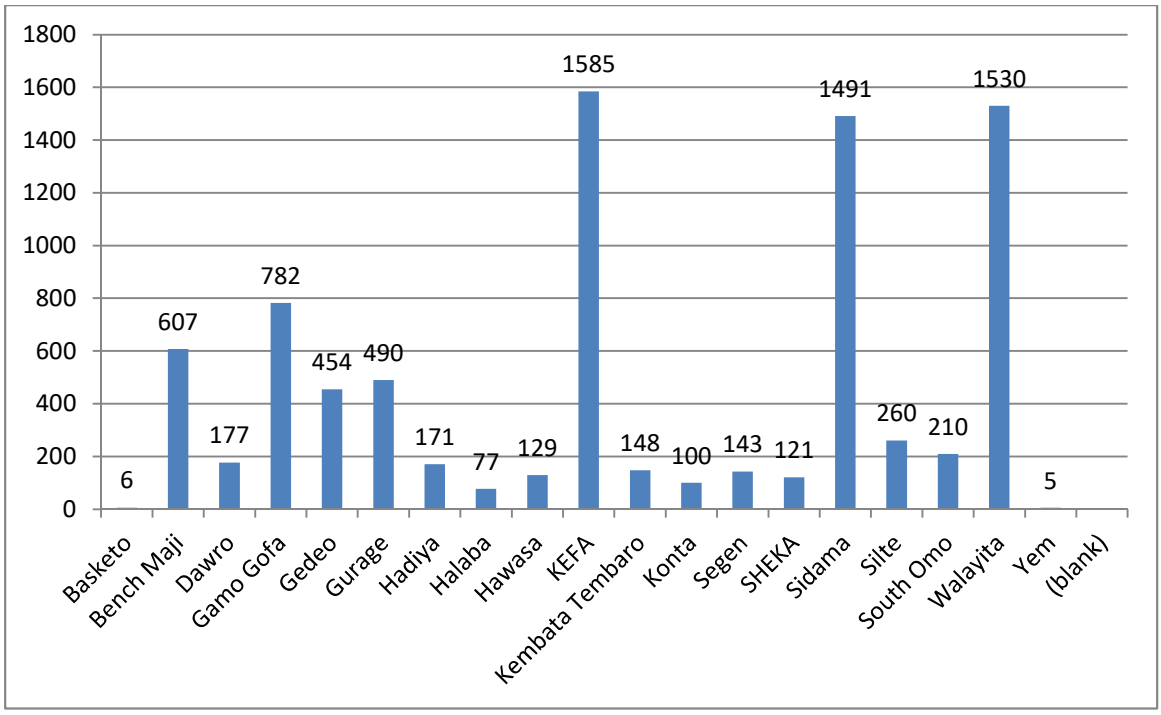


Figure 16: Distribution of unvaccinated or their vaccination status unknown measles cases by vaccination status in SNNP, Ethiopia 2015.

From a total of 8737 suspected measles cases 795(8.68%) were laboratory confirmed, 1186(13.6%) were clinically compatible cases, 3976(45.5%) were epidemiologically linked and the rest 1929(22%) were negative for measles IgM. Out of 4160 measles cases 3858(92.7%) were from inpatient and the rest 302(7.3%) cases were from outpatient. When we see the outcome status of reported cases 7535(86.2%) were alive, 630(6.2%) were died and the rest 61(0.7%) were their outcome status unknown.1083 cases were reported in the time of outbreak.

Out of 603 measles cases died during the study period, majority 406(67.3%) of them were not vaccinated, only small proportion 122(20.2%) were vaccinated,45(7.4%) of them were their vaccination status unknown and 30(4.9%) of them were missed information on vaccination.

In 2015 Measles out break was stareted to be reported since week 2 and the ternd started to increase in week 19 with peak durig week 23.

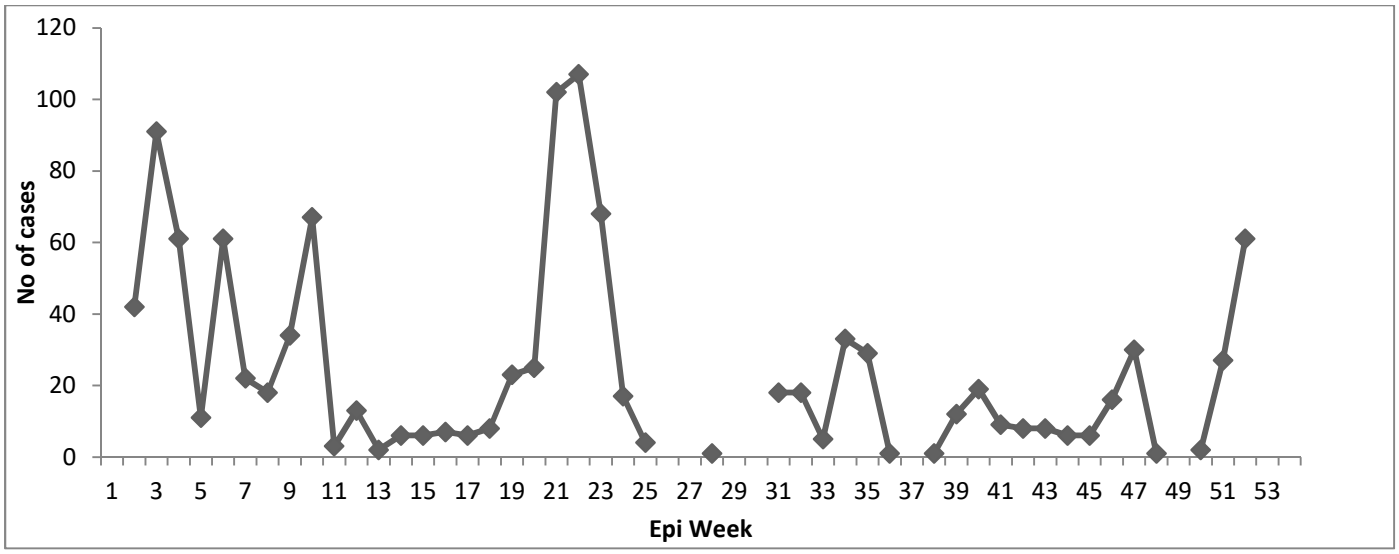


Figure 17: Measles trend by Epidemiological week SNNP, Ethiopia 2015.

As shown in figure11 more cases of measles 6010(68.7%) were occurred during the relatively shorter dry season (November to March) as compared with 2727(31.3%) cases reported during the longer rainy season (April to October).

5. DISCUSSION

In this study Incidence and suspected measles cases has been increased from 2006 to 2014 and slightly decreased in 2015.Similarly non -measles rash case rate also increased from 2006 to 2015.This finding is similar to the increment of both suspected measles cases and incidence from 2005 to 2014 in Addis Ababa(1). Hence the increment of cases and incidence of suspected measles cases from 2006 to 2015 mighty be attributed to the sensitivity of surveillance system. As the surveillance system more sensitive the probability of getting the cases is also increased. The increment of the incidence also might be due to unvaccinated children.

With regard to geographic distribution, most of the cases were reported from Keffa Wolyta and Sidama 18.6%, 18% and 17.4% respectively. National measles surveillance data analysis report showed the difference in magnitude of cases from region to region and zones to zones which is compatible with my finding (1). Possible reason for this difference might be due to the fact that these zones have a high density population.

In this study overall 26.3% of cases were their vaccination status unknown,20.3% of cases were unvaccinated, 25.3% were received 1 dose,3.4% were received 2 and more deses, and 3.7% of cases had missing information on vaccination status. Majority of cases 20.3% and 26.3% of cases were unvaccinated and their vaccination status unknown respectively. This finding is lower than study conducted in Nigeria in which 81.2% of children were not vaccinated but higher than 13% of unvaccinated children in Addis Ababa surveillance data analysis report(11)(10).This might be due to lack of vaccine and/or health care workers at the health facilities.

In SNNP region routine immunization is given at the age of 9 month (12). This indicates that the positivity rate is relatively low among vaccinated suspected measles cases while it is high among suspected measles cases those had no vaccination status. May be the positive measles cases among unknown vaccination status cases were not vaccinated against measles cases which makes positivity rate high among unvaccinated children. The measles vaccine efficacy is more than 85% at the age of 9 months and above (6).

The finding of this study revealed that Out of 4102 cumulative suspected measles reported cases with sample 83.8% of cases were confirmed for measles IgM. This finding is higher than national analysis of measles surveillance data during 2005-2013(1). Zonal measles IgM positivity rate

showed higher in Sidama, Gurage and Wolyta zones 18.8%, 14% and 9.2% respectively which is similar with result of national analysis of measles surveillance data(1). This difference might be due to differences in laboratory specimen taking practices and under reporting.

In this study out of 603 measles cases died during the study period, majority 406(67.3%) of them were not vaccinated, only small proportion, 122(20.2%) were vaccinated, 45(7.4%) of them were their vaccination status unknown and 30(4.9%) of them were missed information on vaccination status. This finding is consistent with the result of study conducted in Nigeria in which majority of deaths occurred in unvaccinated children (10). This might be due to the fact that measles immunization contributed for the reduction of mortality in immunized children.

6. CONCLUSION

This analysis revealed that under-five population is still at risk of contracting measles in the region. The incidence rate is higher among 1-4 age groups. Additionally it indicates that high number of zero doses and unknown vaccination status. Majority of zones reported outbreak during the study period and immunization coverage was low in most zones. Data quality of EPI is poor. Timely identification, reporting, and investigation of measles cases are important because the spread of the disease can be limited with early case identification and vaccination of susceptible contacts.

7. RECOMMENDATION

Regional PHEM structure officers should conduct active case search for every suspected measles cases to assure timely reporting and contain the outbreak in the population known to be affected as well as other segments of the community that may be at high risk of exposure or in whom vaccination coverage is known to be low.

Active surveillance should be maintained until at least two incubation periods after the last confirmed case is reported.

Measles surveillance system should be strengthened in the region, especially zones with high measles cases, those faced outbreak in 2015.

Zones with low coverage of measles vaccine should improve vaccination coverage of the targeted age group.

The stake holders and regional health bureau should increase level of immunity in children less than five years by giving measles vaccine and providing Vitamin A supplementation.

Health extension workers should strengthen routine immunization service delivery to reach all children by their first year of life.

Health professionals at all levels should improve data quality to avoid unknown vaccination status.

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Chapter III- Evaluation of Surveillance System

3.1 Malaria Surveillance System Evaluation, Kedida Gamela District, Kembata Tembaro Zone, Southern Nations Nationalities and People Region, Ethiopia, 2017

Executive summary

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.

Methods: A cross-sectional study design was applied to assess the core and supportive functions, and key attributes of the surveillance system for malaria. Health facilities were selected on a convenience bases taking into consideration time and transport accessibility. Disease under surveillance was selected based on the public health importance of the study area. Data was collected using the tools of updated Center for Disease Control questionnaires which are designed for the assessment of national communicable disease surveillance system.

Result; the woreda reported 2688 clinical malaria cases, 2593 confirmed cases and zero death from all reporting units. Standard case definition of malaria was available at district health office and health center level. The Community case definition was available at health post level. For case confirmation all health posts used Rapid Diagnostic Test and all health centers used microscope. All visited health facilities were used the same standard reporting format. The surveillance data was analyzed by person place and time at district health office level. All evaluated health facilities did not prepared epidemic preparedness plan. Supportive supervision was conducted regularly at evaluated health facilities. Report completeness of the district was 100%. All health facilities were not prepared measurement for timeliness of surveillance report. The surveillance system was helpful to detect cases early on time to permit accurate diagnosis, to estimate the magnitude of morbidity and mortality. The surveillance system did not included report of private Health facilities of the district.

Conclusion and recommendation Epidemic preparedness plan was not prepared in all surveillance units. Epidemic and rapid response team was not conducted scheduled regular meeting. The supportive supervision and its feedback were consistent and monitoring and evaluation was well established at all level. The surveillance data was complete but its timeliness was not measured. Hence all surveillance units should prepare epidemic preparedness plan to response public health

emergencies. Surveillance units should prepare and post malaria monitoring chart to track changes in malaria trend. The woreda health office should incorporate private health facilities in surveillance reporting units and prepare indicators for measuring timeliness of surveillance report.

Key words surveillance, evaluation, malaria, public health, District

1. Introduction

1.1 Background

Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health(1). Public health surveillance systems have been used for a long time for detection of abnormal disease trends which could guide the implementation of appropriate public health interventions. In particular, surveillance of infectious diseases serves the purpose of detection of early and sudden increase in disease activity(2).

Disease surveillance is essential for early detection of outbreaks, epidemics and pandemics in order to initiate timely response and also it is essential to evaluate or monitor progress of ongoing interventions targeted for disease reduction. A well-functioning disease surveillance system is critical to measures the burden of a disease, identification of populations at high risk and identification of new or emerging health concerns to the health system, provide evidence-based information for planning, implementation, monitoring trends in the burden of a disease and evaluation of public health intervention programs to prevent and control disease, injury, or adverse exposure, evaluate program performance, prioritize the allocation of health resources, describe the clinical course of disease; and stimulate for epidemiologic research(3).

Federal ministry of health (FMoH) underwent the process reengineering, identifying the integrated disease surveillance and response (IDSR) as the core process to be evaluated. By identifying the strengths and weaknesses of IDSR in 2009 E.C establishment of Public Health Emergency Management (PHEM) was recommended. 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 two health problems, Sever Acute Malnutrition (SAM) and maternal death based on their potential to cause outbreaks, became international concern and diseases on eradication/elimination and also health burden for the country(4)(5).

Malaria is one of the most severe public health problems worldwide with 300 to 500 million cases and about one million deaths reported to date, 90% of which were reported from Sub Saharan

African countries the fourth leading cause of death of children under the age of five years in developing countries(6).

About 90% of all malaria deaths in the world today occur in Africa south of the Sahara. This is because the majority of infections in Africa are caused by Plasmodium falciparum, the most dangerous of the four human malaria parasites. It is also because the most effective malaria vector – the mosquito Anopheles gambiae – is the most widespread in Africa and the most difficult to control. An estimated one million people in Africa die from malaria each year and most of these are children under 5 years old(7).

Malaria is one of the main public health problems in Ethiopia. Bimodal type of transmission: Major: September to December, following the main rainy season from June to August and Minor: April to May, following a short rainy season from February to March. Focal outbreaks are common and the distribution varies from place to place depending on climate and altitude (6).

Malaria is among the twenty communicable diseases under surveillance in Ethiopia.

1.2. Statement of the problem

Despite attaining the high coverage of the major interventions for malaria control like high distribution of LLINs, increasing of health facilities that may be facilitated on time and accurate diagnosis, in the country; malaria remains still the leading causes of morbidity and mortality in all ages particularly in children under five year and pregnant women (8).

Malaria is a killer parasitic disease and causes more than 800,000 deaths and estimated 2.7 million cases globally every year. In Africa, malaria is the leading cause of morbidity and mortality; 88% of deaths and 83% of cases occur in Sub Saharan African countries. About 75% of the Ethiopia‘s land is malarious and 68% of its population is at risk of malaria. Each year, health facilities report 5-10 million clinical cases of malaria and one million confirmed cases. According to FMOH reports, approximately 70,000 people die of malaria each year in Ethiopia. Compiling highly accurate malaria estimates is a challenge in a country with a weak health information system, the few data which are available are often unreliable and likely to overstate malaria burden, as most cases are diagnosed solely on clinical grounds and only a small percentage of those with fever will have malaria (9).

Malaria remains major public health concern in the region and the KT zone of SNNP region even though attaining high coverage of the major interventions for malaria control activities were undergoing in the place. According to national PHEM Report SNNP region reported 488885 Total malaria cases and among these 17325 cases were reported from KT zone of the region in 2016.

1.3. Rationale of the study

The evaluation of surveillance system should promote the best use of public health resources by ensuring that only important problems are under surveillance and that surveillance system operates efficiently. In so far as possible, the evaluation of surveillance system should include recommendations for improving quality and efficiency(10).

Malaria is among the major diseases of the kembata Tembaro Zone with high frequency of epidemic and public health concern. But there is a delay in detection and reporting system. For example malaria and ADW outbreaks in Tembaro districts, Kembata Tembaro Zone in 2009 were detected lately and reported about two weeks after the investigation and they didn't reported all cases in the Woredas. This disease surveillance could be used as proxy indicator of the surveillance system of the district.

Monitoring and evaluation of the surveillance system will be critical for assessing its performance by providing evidence of the validity of the data(11)

Generally, use of the collected data at the local level as evidence for public health decision making is not well known and also evaluation of surveillance system is not done in the districts of the zone and little is known about the effectiveness and efficiency of the system.

An evaluation of this district and institutions based surveillance system for malaria will make the information provided became evidence based and helps decision makers to ensure that the diseases are being monitored effectively and efficiently. Therefor an evaluation of district and health facilities based surveillance system for malaria was conducted to make recommendations that may be used to improve the current surveillance system of the disease and the preparedness and response to possible outbreaks in the future.

2. Objectives

2.1 General objective

- To evaluate the existing surveillance system of malaria in Kedida Gamela district Kembata Tembaro zone, SNNP region, 2009 E.C.

2.2 Specific objectives

- To assess the implementation of core surveillance activities.
- To assess supportive activities of surveillance system.
- To evaluate the status of surveillance system attributes.

3. Methods and Materials

3.1 Study Area

This surveillance system evaluation was conducted in Kedida Gamela district, kembata Tembaro zone of SNNP Region. The district has a total of 20 kebeles and a total population of 110971 based on the 2007 population projection. There were 4 health centers and 19 health posts in the district. All kebeles of the district are hot spot areas of malaria. The prevalence of malaria in the district was 2.3%.

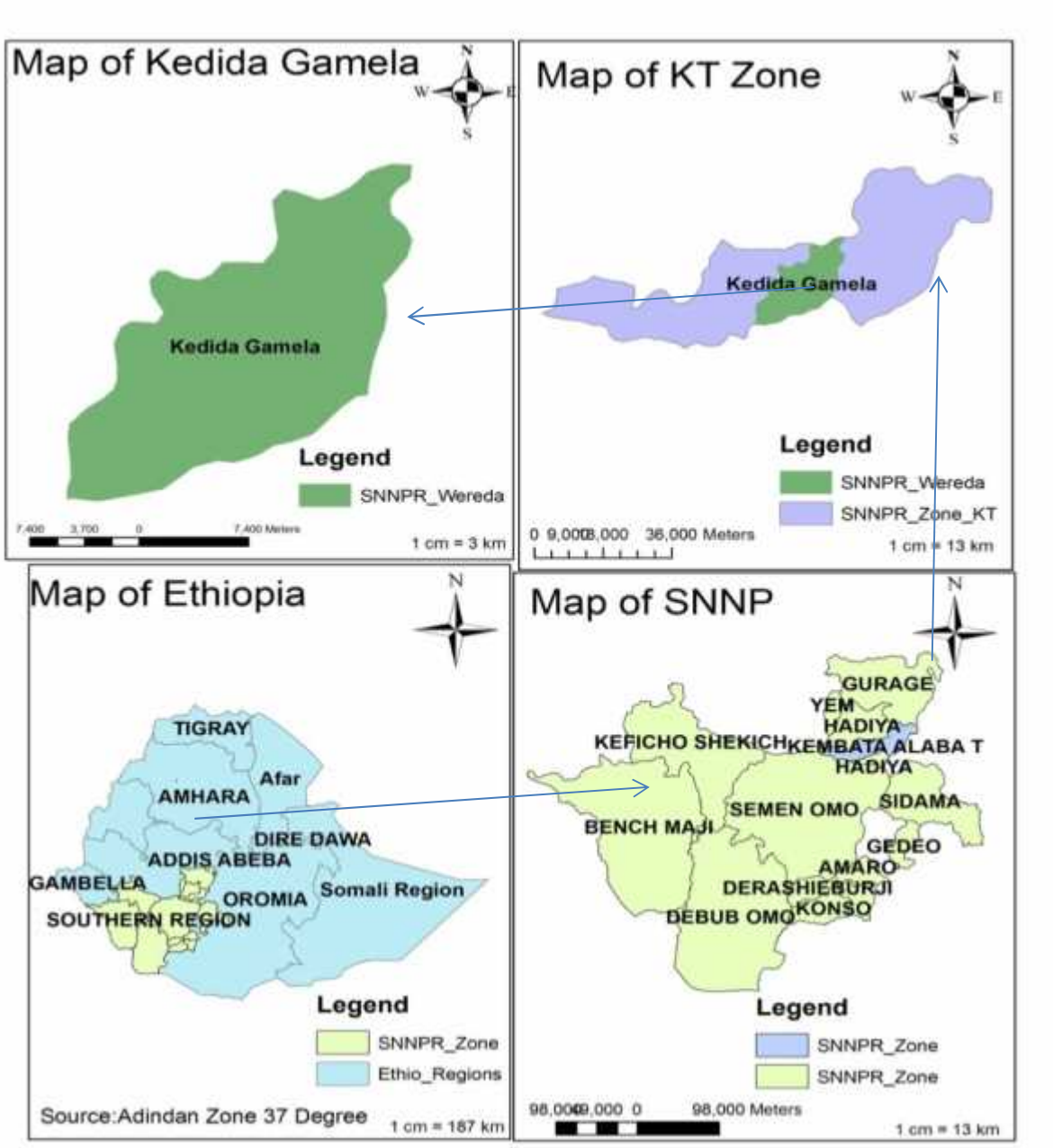


Figure 18: Map of Kedida Gamela District, SNNP region, Ethiopia, 2017

3.2 study period

The evaluation was carried out from January 18 to February 15, 2009 E.C.

3.3 study design

A cross sectional descriptive study design was employed.

3.4 study population

The study population was all health facilities and health office of Kedida Gamela district.

3.5 Sample population

The sample population was one woreda health office two health centers and six health posts.

3.6 study unit

The study unit was health workers, health post, health center and woreda health office.

3.7 Inclusion and Exclusion criteria

All surveillance system reporting health facilities of Kedida Gamela district were included in the evaluation and health posts not accessible for transportation were excluded.

3.8 study variables

3.8.1 Dependent variable

Malaria surveillance system

3.8.2 Independent variables

- Core surveillance system activities
    - Availability of case definition
    - Case confirmation
    - Availability of case registration
    - Reporting
    - Data analysis and interpretation
    - Epidemic preparedness
    - Response and control

- Supportive activities of surveillance system
    - Feed back
    - Availability of standards and guidelines
    - Training
    - Supervision
    - Communication facilities
    - Resources
    - Monitoring and evaluation
    - coordination
- Status of surveillance system attributes
    - Completeness
    - Timeliness
    - Surveillance data use
    - Simplicity
    - Acceptability
    - Flexibility
    - Sensitivity
    - Stability
    - Data quality
    - Representativeness

3.9 Sampling technique

Health facilities were selected by simple random sampling technique. Disease under surveillance was selected based on the public health importance of the study area. One weekly (malaria) reportable disease was included in the surveillance system evaluation.

3.10 Data collection methods

Data was collected using the tools updated CDC questionnaires which are designed for the assessment of national communicable disease surveillance system. Data was collected using both face to face interviews and certain observations by principal investigator were carried out as follows.

- Performance of the core activities of surveillance system of the district was assessed.
- Supportive activities of the surveillance system were assessed.
- The Status of system attributes was evaluated.

In addition posted flow charts of the surveillance system, graphs, tables, maps of the selected diseases, availability of surveillance guidelines, standard case definition, etc… were checked. Records of registration book, feedback reports of surveillance, weekly and immediately reports of surveillance in the past three months, and line lists of outbreak investigation were reviewed. Focal persons of PHEM at district and at health facility levels, health professionals, and stakeholders of districts at various levels were interviewed to get the important data of the existing surveillance system of the district.

3.10 Data Analysis

Data was entered and analyzed using the Microsoft Excel.

3.11 Data quality Assurance

Questionnaires were developed after reviewing CDC Surveillance evaluation guideline. All questionnaires were administered by principal evaluator in the presence of district PHEM officers of the district and health workers of health center who were assigned to support health posts.

3.12 Operational definitions

Standard case definition

Suspected: - Any person with fever or fever with headache, rigor, back pain, chills, sweats, myalgia, nausea, and vomiting or a person diagnosed clinically as malaria

Confirmed: - A suspected case confirmed by microscope or RDT for plasmodium species

Community case definition

Community case definition is sensitive (loose) case definition that increase case detection rate and a simplified version of standard case definition used to aware the community to notify any suspected case. It also makes community aware for early diagnosis of the priority diseases under surveillance.

Suspected: - Any person with fever**,** fever with headache, back pain, chills, sweats, muscle pain, nausea and vomiting.

Confirmed: - A suspected case confirmed by RDT

Epidemic preparedness; is the existing level of preparedness for potential epidemics and includes availability of preparedness plan, logistics, designation of isolation facilities, setting resources for outbreak response

Completeness; Completeness of reporting sites is the proportion of reporting sites that submitted the surveillance report irrespective of the time when the report was submitted.

Timeliness; refers to the proportion of reporting sites that submitted the surveillance report within expected time interval.

Simplicity; Simplicity is the structure of the system and the ease of implementation.

Flexibility; is the ability of the system to accommodate changes i.e. to add new disease/condition/ or data collection element

Sensitivity; refers to the completeness of case reporting i.e. the proportion of cases of a disease or health condition that are detected by the surveillance system and the ability to detect epidemics, including the ability to monitor changes in the number of cases over time

Stability; Stability is reliability (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.

Acceptability; Acceptability of the system is reflection of the willingness of the surveillance staffs, to implement the system, and of the end users to accept and use the data generated through the system.

Data quality; Reflects the completeness and validity of the data recorded in the public health surveillance data

Representativeness; Representativeness is the degree to which the reported cases reflect the occurrence and distribution of the cases in the population under surveillance.

3.13 Ethical Consideration

Permission to proceed with the system evaluation was obtained from the public health emergency management / Ethiopian Public Health Institute (EPHI) and cooperation letter was written to Kembata Tembaro zone health department. From KT zonal health department Cooperation letter was written to Kedida Gamela district health office and the district notified to the selected health facilities via phone calling.

3.14 Dissemination of findings

Finally the findings will be shared with Ethiopian Public Health Institute (EPHI), mentors, supervisors, Kembata Tembaro zone health department, Kedida Gamela district health office, and program coordinators of St Paul millennium medical college/EFETP

4. Result

4.1 Core Activities

4.1.1. Availability of Case definition; - standard case definition of malaria was available in the district health office and all health centers. The community case definition of malaria was available in 14(74%) health posts.

4.1.2. Availability of case registration

All evaluated reporting health facilities were using malaria registration book given by regional health bureau for registering identified cases.

4.1.3. Case confirmation

In the district all health posts were using RDT to confirm suspected malaria cases and all health centers were using microscope to confirm suspected cases. In the absence of RDT health posts were referring cases to health centers. No outbreak was detected and confirmed through evaluated reporting health facilities in the year 2008.

4.1.4. Reporting

The district reported a total of 2688 clinical malaria cases, 2593 confirmed malaria cases (examined by RDT or microscope) and zero deaths from all surveillance reporting units. There was no shortage of reporting format in the last 6 months in health centers and woreda but there was shortage of reporting formats in health posts. All the visited health facilities were used the same standard reporting format. The weekly reporting rate of the last six months for the woreda was 100%. Health facilities and woreda used telephone to send report to the next higher level. Overall completeness of reporting of the visited sites was 100%. Timeliness of reporting from HPs to HCs then to district of the priority diseases is difficult to evaluate because date of receipt was not recorded in all levels.

4.1.5. Data analysis and interpretation

Surveillance data was no analyzed at health post level. All health centers have responsible IDSR focal person to analyze and interpret the surveillance data but data was not analyzed by place, time and person at all health centers. There was responsible PHEM officer at woreda level and surveillance data was analyzed bay place, time and person.

4.1.6. Epidemic preparedness

There was no epidemic preparedness plan at all evaluated reporting facilities. All heath posts established epidemic management committee at kebele level which was led by kebele chairman. No written regular minutes were observed at health post level. All health centers and woreda health office built their rapid response team. For woreda health office epidemic management committee was built at woreda administrative office which was led by woreda chief administrator. All of the reporting health facilities had no scheduled regular meeting time. The woreda health office allocated budget for emergency response but the woreda administration office not approved the budget. All health centers and woreda health office have available motor vehicle for emergency conditions.

4.1.7. Response and control

The surveillance system is providing data for public health action. The health centers and woreda health office used surveillance data for epidemic response and control activities.

4.2 supportive functions of surveillance

4.2.1 Feed back

No written feedback was given for health development armies at village level. All health posts were giving oral feedback to health development armies. All health centers were giving written feedback monthly to health posts. The woreda health office was giving written feedback to health centers quarterly. To monitor the given feedback at health center level one health worker was assigned to each kebele.

4.2.2 Standards and guidelines

National guideline was available in woreda health office and health centers. The woreda health office and health centers were using the standard case definition for priority diseases. Health centers and woreda health office posted the standard case definition for all diseases on the wall. Case based reporting formats were available in all health centers and woreda health office. Guidelines for specimen collection handling and transportation to the next level were available in all health centers and woreda health office. The line list for reporting outbreaks were available in all health centers and woreda health office.

4.2.3 Training

Health development armies were trained by health extension workers assigned from satellite health center. 38 HEWS, 4 health center IDSR focal person and 2 woreda health office PHEM officers were trained and gave orientation for their working staffs after training. No laboratory professionals were trained on public health surveillance. Health centers IDSR focal persons have no computer skill and were analyzing surveillance data manually. Woreda health office PHEM officers have computer skill, gained by themselves and were analyzing surveillance data using computer.

4.2.4. Supervision

Health posts have no formal supervision plan for HDA. They were supporting and supervising HDAs at a time of meetings. No supervisory checklist was observed at health post level. All HPs were supervised every quarter by HCs and woreda health office. Three out of four HCs (75%) did not developed supervision plan for HPs. Four (100%) health centers conducted supervision for HPs and only one HC conducted the supervision with plan. All (100%) health centers were not notified their supervision plan prior to supervision. The woreda health office supportive supervision schedule for all health centers and health posts was posted in woreda health office. The written and phone call plan for supervision was provided prior to supervision for all health centers. The health centers and woreda health office were using standard checklist given from higher level. The supportive supervision feedback given at each level was observed at all evaluate surveillance units.

4.2.5 Communication of report

HDAs were providing the routine report from their village by means of hard copy and oral report. Monday morning was the reporting day for HDAs. The health posts were reporting by hardcopy or by using their mobile phone. The reporting day for health posts was Monday morning up to midday. All health centers were using hard copy and mobile phone. The reporting day for health centers was from Monday afternoon to Tuesday midday local time. Woreda health office was using fixed line and mobile phone. Tuesday afternoon was the reporting day for woreda health office.

4.2.6 Resource

4.2.6.1 Human resource

Nineteen HPs, 4 HCs and woreda health office were using the expected human resource based on BPR structure. But there was no specific staff assigned for surveillance activities.

4.2.6.2 Logistic resource

For surveillance activities and response the Woreda health office was used technologies that facilitate documentation, analysis, reporting and communication (computer, printer, photocopy machine and telephone). Health posts and health centers were not using any of the technologies.

4.2.6.3 Budget (financial resource)

The budget for surveillance and emergency response activities was allocated by the woreda health office but not approved by the woreda administration office. There was no ready financial resource for surveillance and emergency conditions response.

4.2.7 Monitoring and Evaluation

4.2.7.1 Monitoring

At all level (HPs, health centers and woreda health office) the health workers were assigned to monitor all planned activities. At health post level one health professional from the catchment health center was assigned to monitor all activities in the kebele and support HEWs three times per a week. At woreda health office level at least two focal persons were assigned to follow up the whole health center catchment two times per a week. The zonal health department was assigned one or two focal persons for monitoring and continuous follow up for a woreda two times per a week. Malaria monitoring chart was not used at all evaluated surveillance units.

4.2.7.2 Evaluation

All the surveillance units were evaluating their performance on a quarterly base along with other core processes and NGOs.

4.2.8 Coordination

The woreda health office was working along with rural development office, women and children affairs office, education office water office and NGOs like world vision, KMG, etc.

4.3 Description of the surveillance System Attributes

4.3.1 Completeness

Health posts were reported on average of 97.4% completeness of reporting ranging from 94.7% to 100%. All health posts were reported the surveillance report to the next level in the last six months. The average completeness of the health centers was 100%. The average completeness of reporting sites of woreda health office was 100%.

4.3.2 Timeliness

The reporting time of the health facilities in the district were not clearly registered. From the total facilities that sent report, it is difficult to identify the health facilities that report on time. Due to this calculating timelines for the district as well as for the assessed facilities found to be difficult.

4.3.4 Surveillance system and data usefulness.

All respondents were accepted as the surveillance system and its data was helpful to detect cases early on time to permit accurate diagnosis , to estimate the magnitude of morbidity and morbidity, permit assessment of the effect of prevention and control programs and estimate research intended to led to prevent and control. In all the assessed areas the surveillance system had been recognized and understood as the base for controlling the public health emergencies.

4.3.5 Simplicity of the system

At all evaluated surveillance units the case definition was easy for case detection, the surveillance formats allowed all professionals to fill data, easy to record and report data on time and allowed updating data on formats. The time to fill the format was 5-15 minutes. But confirmation of measles IgM antibody, meningococcal meningitides and polio was too long (one to two months).

4.3.6 Acceptability of the system

At all evaluated reporting sites all reporting staffs accepted the surveillance system and well engaged. Health posts, health centers and woreda health office were using the surveillance data for prevention and control. Health professionals were using the standard case definition to identify cases. All reporting units were using the given surveillance reporting formats.

4.3.7 Flexibility of the surveillance system

The interviewed respondents replied that the surveillance system was easy to add new disease or to remove an existing one. It was easy for modification of frequency of reporting time. The surveillance system can be operated with other systems. There was possibility to incorporate new variables for a disease or an event.

4.3.8 Sensitivity of surveillance case definition

The respondents said that the malaria case definition was sensitive to identify cases and to detect outbreak. Malaria cases were identified using the standard case definition in all evaluated reporting units. Malaria monitoring threshold were used to detect malaria outbreaks. Data reported by surveillance system was used for immediate public health action.

The surveillance system to detect an outbreak of malaria:

The capacity of the surveillance system to detect an outbreak is influenced by the definition of the outbreak. The sensitivity of the surveillance system is dependent on different reasons, like regular analysis of the data, definitions of the thresholds, case detection and reporting rate of the expected health facilities and so on. Unfortunately, the reporting rate of the health facilities was much lower than expected, there was no regular analysis of the collected data, and there are different definitions of thresholds and hence, the sensitivity of the cases detection and outbreak detection of the surveillance system is high likely to be lower. However, the sensitivity of the system increases once the number of cases raises high or death starts to occur, i.e. the surveillance system would be sensitive for high epidemics.

4.3.9 Stability of the surveillance system

According to this attribute the surveillance system at the district helps to collect manage and provide data properly and it was operational at any time. The continuity of the system was not interrupted due to lack of human and financial resources. But the amount of the running cost allocated for the surveillance system, especially for emergency condition has a positive effect on the functionality of the surveillance system. In the absence of budget from donors, the government was running all activities along with other integrated services.

4.3.10 data quality

The data quality was assessed on the basis of completeness of the reporting format and the timeliness of the report as set in the guideline. All health posts reported complete weekly surveillance report. All health centers sent complete weekly report for woreda health office. The woreda health office sent complete and clearly recorded weekly report to zonal health department. Hospital admission, date of admission, vaccination history, locating information, address (urban/ rural) variables were missed in case based reports. The major reasons for missed variables were language barrier, and not considering some of the variable as such an important. The reporting sites were not well trained or regularly supervised in all visited sites. There were no any regular crosschecking of the data and feedback.

4.3.11 Representativeness

Here the participants responded that even though the surveillance system enables to describe the existing and occurring health events by time and place, it has limitation in describing the health events by person (age and sex and other socio demographic characters). At health post level the surveillance report represented the population under surveillance. Nongovernmental health facilities were also included in all surveillance report. But the private health facilities found at kebele and woreda level were not included in surveillance report. Still people were using private health facilities for malaria and other diseases treatment

5. Discussion

The finding of this evaluation revealed the availability of standard case definitions in district health office and health centers and community case definition in health posts. All evaluated reporting health facilities were using malaria registration book given by regional health bureau for registering identified cases. This finding is in line with HMIS and PHEM guidelines for registering and reporting identified cases(5).

This evaluation showed that the evaluated health posts and health centers were using RDT and microscope respectively to confirm suspected malaria cases and reported to the next level by using standard reporting formats. This finding is consistent with malaria guide line of confirming suspected malaria cases at each level (5).

In this study all health centers and district health office have responsible focal person to analyze and interpret the surveillance data by place person and time but data was not analyzed by place person and time at health center level. Analyzing surveillance data by time person and place is one of public health emergency response sections and should be implemented at each surveillance unit (5). This difference might be due to lack of data analysis skill by health center professionals.

Epidemic management and rapid response team to investigate respond and control public health emergencies was established in all reporting units but there was no scheduled regular meeting of rapid response team. There was no epidemic preparedness and response plan at all evaluated surveillance units. To investigate and control public health emergencies epidemic management and response team with epidemic preparedness and response plan should be in place (5). The difference might be due to poor commitment of surveillance unit leaders.

In this evaluation written feedback given by higher level was available ay health facilities and office level. Trained professionals were working in surveillance units. Supportive supervision was conducted in reporting units regularly. The finding was in line with PHEM guideline.

In this surveillance evaluation data from private health facilities were not included in the surveillance reporting. All these surveillance activities were consistent with PHEM guide line but excluding private health facilities report contradicts the guideline (5). This might be due to lack of knowledge on type of health facilities that are expected to report for a particular level.

6. Limitations

Sensitivity, specificity and predictive values in terms of case detection were not calculated due to lack of variables to calculate sensitivity and specificity.

Timeliness of the evaluated surveillance units was not measured. Because indicators to measure timeliness of report were not available

7. Conclusion

The core surveillance activities were in place and still used consistently at all evaluated surveillance units. Epidemic preparedness plan was not prepared in all surveillance units. Epidemic and rapid response team was not conducting scheduled regular meeting. The supportive supervision and its feedback were consistent and monitoring and evaluation was well established at all level. The surveillance data was complete but its timeliness was not measured.

8. Recommendations

All surveillance units should prepare epidemic preparedness plan to response public health emergencies.

Surveillance units should prepare and post malaria monitoring chart to track changes in malaria trend.

The woreda health office should incorporate private health facilities in surveillance reporting units and prepare indicators for measuring timeliness of surveillance report.

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Annex 2: Surveillance System Evaluation District (Intermediate Level) Questionnaire

A. Communication and reporting system assessment

1. Which communication material did you have? E-mail wired phone mobile radio

fax other----------

2. Did you have address of Zonal PHEM officers? Yes No

3. How frequently are you communicating with the Zonal PHEM officers on emergencies and other daily activities? Daily weekly every 2 week monthly quarterly

every 6 month yearly others----------
---

4. Did you have address of HC/HP PHEM focal persons? Yes No

5. How frequently are you communicating with the HC/HP PHEM focal persons on emergencies and other daily activities? daily weekly every 2 week monthly quarterly

every 6 month yearly others----------

6. When are you expected to send weekly report to the Zonal PHEM unit? Monday Tuesday Wednesday Thursday Friday Saturday Sunday

7. When are you expected to receive weekly report from HCs/HPs? Monday Tuesday

Wednesday Thursday Friday Saturday Sunday

8. How is the woreda communicating the HCs/HPs PHEM officers in case of immediately reportable diseases? by e-mail by phone by fax regular weekly report others----------
----------9. Did you send summary or short report to the administrative /program leaders or other responsible organs on planning, prevention and control activities addressing Important issues at community level that have arisen through the surveillance system? Yes No

10. If answer for Q9 is yes to whom did you send? ----------

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11. If you faced any problems on communicating and reporting, list them----------

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12. Mention the alternative solutions that you take to tackle the problems you above? ----------

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B. Assessment of availability of Surveillance Documentation, Registers, and Forms

1. Did you have National Guide line for PHEM? Yes No Not Applicable

2. Did you have standard case definition for all country priority diseases? Yes No Not Applicable

3. Was the case definition posted? Yes No

4. If answer for Q2 is No, for which disease(s) did you lack the case definition?----------

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---5. Did you have case based reporting formats for out breaks? Yes No Not Applicable

6. Was there national manual for surveillance? Yes No Not Applicable

7. Was there guide line for specimen collection, handling and transportation to the next level?

Yes No Not Applicable

8. Did you have line list for reporting outbreaks? Yes No Not Applicable

9. Did you face shortage of surveillance reporting and recording formats? Yes No

10. If answer foe Q9 is yes, which form? ----------

C. Data analysis, Computer skill and training assessment

1. Had you trained on surveillance system? Yes No

2. If answer for Q1 is yes a) when----------? b) Topic----------

c) For how long----------

3. Did you give any onsite training / orientation about surveillance system for the HC and HP PHEM focal persons? Yes No

4. Was data compiled? Yes No

5. Did you have computer on your office? Yes No

6. Did you have computer on your department (PHEM unit)? Yes No

7. What is the data entry and compilation instrument? Manual Computer other----------

8. Did you have computer skill on Ms word Ms excel MS power point Epi info

9. Did you analyze data of the surveillance system? Yes No

10. If answer for Q9 is yes, did you describe data by, time place person

11. Did you have denominators for data analysis? Total population male female <5

12. Please indicate the frequency of your data analysis. weekly every two week

Monthly quarterly every 6 month annually No regular time

13. Did you notify the results of your analysis to the higher level PHEM? Yes No

14. Did you notify the results of your analysis to the lower level PHEM? Yes No

15. If answer for Q9 is No, what is the reason? lack of knowledge shortage of time do you to work load less attention given to data analysis shortage of materials analysis is not familiar activity in place negligence Other----------

D. Epidemic response and preparedness assessment

1. Did you have plan for epidemic response and preparedness? Yes No

2. Did you have emergency stocks of drugs and supplies? Yes No

3. If answer for Q2 is No, how did you control epidemics? ----------

4. Had you experienced shortage of drugs, vaccines and supplies in 2008 EFY? Yes No

5. Was an epidemic management committee built in your office? Yes No Not Applicable

6. Did the epidemic management committee have regularly scheduled meeting time? Yes No

7. Was Rapid response team built in your office? Yes No Not Applicable

8. Did the Rapid response team have regularly scheduled meeting time during epidemics?

Yes No

9. Did you have case management protocol for epidemic prone diseases? Yes No Not Applicable

10. Did your PHEM have rapid response team? Yes No Not Applicable

11. in what frequency did the Rapid response team? ----------

12. Were partners working together with your office on emergencies? Yes No

13. If answer for Q12 is yes, what type of supports did they give to your office? ----------

14. Was there a budget for epidemic response? Yes No

15. Who had the authority to mobilize the emergency finance? woreda head woreda health department experts other----------

16. Had you a car assigned for emergencies (PHEM)? Yes No Not functional

17. If answer for Q16 is NO, how did you address emergencies? ----------

18. Had you faced any Challenges on epidemic response and preparedness in 2008 EFY?

Yes No

19. If answer for Q18 is yes, a) list the challenges----------

b) what measures did you take to tackle the challenges?----------

E. Outbreak investigation and case confirmation assessment

1. Had you investigated any outbreak in 2008 EFY? Yes No

2. Did you have outbreak investigation check list? Yes No

3. If answer for Q2 is No, how did you know possible factors for the outbreak? ----------

4. Where was laboratory confirmation of cases done? Regional laboratory Hospital EPHI health center contracted private laboratory other----------

5. Who was responsible to investigate an outbreak? Rapid response team HEWs staffs of woreda health office experts organized randomly health facility staffs other----------

6. If answer for Q1 is yes how many out breaks did you investigated in 2008 EFY?

7. Had you faced any challenge in outbreak investigation in 2008 EFY? Yes No

8. If answer for Q7 is yes, a) list the challenges----------
b) list the alternatives that you take to tackle the challenges----------

F. Supervision and feedback assessment

1. Did you have supervision plan in 2008 EFY? Yes No

2. If answer for Q1 is No, how did you supervise? ----------

3. If answer for Q1 is yes, did you supervise the health centers (HCS) and health posts (HPs) according to your plan in 2003 EFY? Yes No

4. If answer for Q3 is No, what is the reason? ----------

5. If answer for Q3 is yes, how many times did you supervise each health center (HC) and health post (HP) in 2008 EFY? Health center---------- health post----------

6. Had you reviewed about surveillance practice by higher level supervision? Yes No

7. Did you have regular supervision checklist? Yes No

8. If answer for Q7 is No, how did you supervise the woredas and health facilities? ----------

9. Were you supervised by higher level officers in 2008 EFY? Yes No

10. If answer for Q9 is yes how many times in 2008 EFY? ----------

11. Did you send feedback of your supervision to the health centers (HCS) and health posts (HPs) commenting/indicating their strong and weak sides? Yes No

12. If answer for Q11 is No, why? ----------

13. If answer for Q11 is yes, for how many HCs and HPs did you send a feedback in 2008 EFY? HC---------- and health post----------

14. Had you received feedback from higher level supervisors in 2008 EFY? Yes No

15. If answer for Q14 is yes how many feedbacks did you received in 2008 EFY? ----------

16. Had you faced any challenge on supervision and feedback in 2008 EFY? Yes No

17. If answer for Q16 is yes a) list the challenges----------

b) List the measures that you take to tackle the challenges----------

QUESTIONNAIRE FOR THE HEALTH CENTER

BACKGROUND:

Woreda _____

Health center_____

Catchment population_____

Respondent(s)_____

Address: Office no _____Cellphone no _____ email_____

PART ONE:

A. Communication and reporting system assessment

1. Which communication material did you have?

E-mail wired phone mobile radio fax other----------

2. No of health posts that have access to communication facilities----------

3. Did you have address of woreda health office PHEM focal persons? Yes No

4. If No, how did you communicate? ----------

5. How frequently you communicate with the woreda Health office PHEM officers on emergencies and other daily activities? Daily weekly every 2 week monthly quarterly every 6 month yearly others----------

6. Did you have address of HP HEWs? Yes No

7. How frequently you communicate with the HP HEWs on emergencies and other daily activities? daily weekly every 2 week monthly quarterly every 6 month yearly others----------

8. When are you expected to send weekly report to the Health Bureau PHEM Unit?

Monday Tuesday Wednesday Thursday iFday Saturday Sunday

9. When are you expected to receive weekly report from HPs?

Monday Tuesday Wednesday Thursday Friday Saturday Sunday

10. How is the Health Center communicating the HPs HEWs in case of immediately reportable diseases? by e-mail by phone by fax regular weekly report others

11. Did you send summary or short report to the administrative /program leaders or other responsible organs on planning, prevention and control activities addressing Important issues at community level that have arisen through the surveillance system? Yes No

12. If answer for Q11 is yes to whom did you send? ----------

13 If No, why----------

B .Assessment of availability of Surveillance Documentation, Registers, and Forms

14. Did you have National Guide line for surveillance? Yes No Not Applicable

15. If No what did you use for priority health events----------

16. Did you have standard case definition for all country priority diseases? Yes No NA

17. Was the case definition posted? Yes No

18. If answer for Q17 is No, for which disease(s) did you lack the case definition----------

19. Did you have case based reporting formats for out breaks? Yes No NA

20. Was there guide line for specimen collection, handling and transportation to the next level? Yes No NA

21. Did you have line list for reporting outbreaks? Yes No Not Applicable

22. Did you have outbreak investigation guide line? Yes No Not Applicable

23. If No, how did you investigate, prevent and control it----------

24. Did you have a rumor logbook? Yes No Not Applicable

c. Training, computer skill and data analysis assessment

25. Did you have IDSR focal person in 2008? Yes No Not Applicable

26.If yes did he trained on surveillance system? Yes No

27. If answer for 26 is yes a) when----------? b) Topic----------? c) For how long? ----------

28. Did you give any onsite orientation about surveillance system for HC and HP PHEM focal persons? Yes No

18. If No why----------

19. Was surveillance data compiled? Yes No

20. Did you have computer? Yes No

21. Is it functional? Yes No

22. How data entry and compilation is accomplished? Manually Computer others-----

23. Did you have computer skill on Msword Ms excel MS power point Epinfo

24. Did you analyze data of the surveillance system? Yes No

25. If answer for Q24 is yes, did you describe data by time place person

26. If No, how did you used the data for action----------

27. Did you have denominators for data analysis? Total pop Male Female <5

28. Please indicate the frequency of your data analysis. Weekly every two week Monthly quarterly every 6 month annually No regular time

29. Did you notify the results of your analysis to the higher and lower level PHEM? Yes No

30. If No, why----------

D .Epidemic preparedness and response assessment

31. Did you have plan for epidemic preparedness and response? Yes No

32 If No why----------.

33. Did you have emergency stocks of drugs and supplies? Yes No

34. If answer for 33 is No, how did you control epidemics? ----------

35. Had you experienced shortage of drugs, vaccines and supplies in 2008 EFY? Yes No

36. Was Rapid response team (RRT) built in your office? Yes No Not Applicable

37. Did the RRT have regularly scheduled meeting time? Yes No

38. Did you have case management protocol for epidemic prone diseases? Yes No

39. Did partners working together with your office on emergencies? Yes No

40. Were partners working together with your office on emergencies? Yes No

41. If answer for Q40 is yes, what type of supports did they give to your office? ----------

42. Was there a budget for epidemic response? Yes No

43. Had you a vehicle assigned for emergencies (PHEM)? Yes No not applicable

44. If answer for Q43 is NO, how did you address emergencies? ----------

E. case detection, reporting case confirmation and Outbreak investigation assessment

45 Did/Do you detect any priority disease case? Yes No

46. Did/Do you register any detected cases? Yes No

47 Did you report any case to the higher level? Yes No

48. Had you investigated any outbreak in 2008 EFY? Yes No If yes list the report time-----
---

49. Did you have outbreak investigation check list? Yes No

50. If answer for Q49 is No, how did you know possible factors for the outbreak? ----------

51. Where was laboratory confirmation of cases? Regional lab Hospital EHNRI HC other----------

52. Who was responsible to investigate an outbreak? RRT HEWs staffs of Health Bureau

Experts organized randomly healthfacility staffs other----------

53. Had you faced any challenge in outbreak investigation in 2008 EFY? Yes No

54. If answer for Q53 is yes, a) List the challenges ----------
b) List the alternatives that you take to tackle the challenges ----------

F. Supervision and feedback assessment

55. Did you have supervision plan in 2008 EFY? Yes No

56. If answer for Q55 is No, how did you supported them? ----------

57 Did you notify your supervision plan prior to supervision? Yes No .

58. If No why----------

59. If answer for Q 55 is yes, did you supervised the HHS and HPs according to your plan in 2008 EFY? Yes No

60. If answer for Q60 is No, what is the reason? ----------

61. If answer for 60 is yes, how many times did you supervised each HP in 2008 EFY? _____
62.Had you reviewed about surveillance practice by higher level supervision? Yes No
63.Did you have regular supervision checklist? Yes No

64. If answer for Q63 is No, how did you supervise the HPs? ----------

65. Were you supervised by higher level officers in 2008 EFY? Yes No

66. If answer for 65 is yes how many times in 2008 EFY? ----------

67. Did you send feedback of your supervision to the health posts commenting/indicating their strong and weak sides? Yes No

68. If answer for Q67 is No, why? ----------

69. If answer for Q67 is yes, for how many HPs did you send a feedback in 2008 EFY_____

70. Had you received feedback from higher level supervisors in 2008 EFY? Yes No

71. If answer for Q70 is yes how many feedbacks did you received in 2008 EFY? ----------

72. Did you have active search plan in 2008 EFY? Yes No

73. If No how did you implemented case searching----------

74. Had you faced any challenge on supervision and feedback in 2008 EFY? Yes No

PART-TWO

IS THE SURVEILLANCE SYSTEM HELP?

1. To detect outbreaks early on time to permit accurate diagnosis? Yes No

2. To estimate the magnitude of morbidity and mortality Yes No

3. Permit assessment of the effect of prevention and control programs? Yes No

4. To estimate research intended to lead to prevention and control? Yes No

Describe Each System Attributes:

1. Simplicity:

1. Is the case definition easy for case detection by all level health professionals? Yes No

2. Does the surveillance system allow all levels of professionals to fill data? Yes No

3. Does the surveillance system help to record and report data on time? Yes No

4. Does the surveillance system have necessary information for investigation? Yes No

5. Does the surveillance system allow updating data on the cases? Yes No

6. How long does it take to fill the format? <5 min 5 to 10 min 10 to15min >15 min

7. How long does it take to have laboratory confirmation? ----------

2. Flexibility

1. Can the current reporting formats be used for other newly occurring health event (disease) without much difficulty? Yes No

2. Did you think that any change in the existing procedure of case detection and reporting formats will be difficult to implement? Yes No, Add your explanation ----------

3. Is the system easy to add new variables? Yes No

4. Is the surveillance system easy to integrate with other systems? Yes No

5. Is the surveillance system easy to add new disease on report? Yes No

6. Is the system easy to add new information technology? Yes No

3. Data quality

1. Are all reported forms Complete? Yes No

2. If answer for Q1 is No, how many unfilled spaces are in your 2008 EFY report? ----------

3. Percentage of unknown or blank responses to variables from the total reports of 2008 EFY report—

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

5. Is the recorded data clear to read and understand? Yes No

6. If answer for Q5 is No, how many records are not clear/are difficult to understand in 2008 EFY report? --------

7. Percent of records which are difficult to read/ understand. ----------

4. Acceptability

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

2. If yes, how many are active participants (of the expected)? ----------

3. If No, what is the reason for their poor participation in the surveillance activity? A) Lack of understanding of the relevance of the data to be collected B) No feedback / or recognition given by the higher bodies for their contribution C) Reporting formats are difficult to understand

D) Report formats are time consuming E) other: ----------

4. Were all participants using the standard case definition to identify cases? Yes No

5. Were all the reporting agents send their report using the current and appropriate surveillance reporting format? Yes No

6. Were all the health professionals aware about the surveillance system? Yes No

7. Was all PHEM officers send report on time? Yes No

5. Representativeness

1. was the surveillance system enabled to follow the health and health related events in the whole community? Yes No

2. If answer for Q1 is no, who do you think is well benefited by the surveillance system? the urban therural both

3. Are all the Socio demographic variables included in the surveillance reporting format? Yes No

4. If the answer for Q3 is No, which a) Sex---- b) age group---C) ethnic group----d) religion---- is less represented?

6. Timeliness

1. Are all reporting sites reporting on time? Yes No

2. Percent of reporting sites that report on time. ----------

7. Completeness

1. Are all reporting sites reporting? Yes No

2. Percent of HPs that send report of each week in 2008 EFY. ----------

8. Stability

1. Was any new restructuring affected the procedures and activities of the surveillance? Yes No

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

3. Was there any time /condition in which the surveillance is not fully operating? Yes No

If the answer for Q3 is yes, explain why? ----------

9. Sensitivity

1. Does the malaria case definition able to pick all cases? Yes No

2. What was the total malaria cases occurred in your HC catchment in 2008 EFY---------?

3. What were the total number of suspected malaria cases examined by RDT or microscopy in 2008 EFY----------

4. How many of those cases were laboratory confirmed? PF-------PV--------- Mixed-----Total--------

5. Was there malaria epidemic in your catchment are in 2008 EFY? Yes No

6. If yes, how many out breaks? ----------

QUESTIONNAIRE FOR THE HEALTH POST
BACKGROUND:

woreda_____

Health Post_____

Catchment population _____

Respondent(s) _____

Address: Office no _____ Cell phone no _____

Date of data collection----------

PART ONE:

A .Communication and reporting system assessment

1. Which communication material did you have? Wired phone mobile radio

2. Did you have address of Health center /woreda PHEM officers? Yes No

3. How frequently you communicate with the Health center PHEM officers on emergencies and other daily activities? Daily weekly every 2 week monthly quarterly ever 6 month

4. When are you expected to receive weekly report from HPs? Monday Tuesday Wednesday Thursday Friday Saturday Sunday

5. When are you expected to send weekly report to the Health center PHEM unit? Monday Tuesday Wednesday Thursday Friday Saturday Sunday

6. Did you send summery or short report to the administrative/program leaders or other responsible organs on planning, prevention and control activities addressing important issues at community level that have arisen through the surveillance system? ? Yes No

7. If yes to who did you send? ----------

B .Assessment of availability of Surveillance Documentation, Registers, and Forms

1. Did you have National Guide line for surveillance? Yes No Not Applicable

2. If No what did you used for priority health events----------

3. Did you have standard case definition for all country priority diseases? Yes No NA

4. Was the case definition posted? Yes No

5. If answer for Q3 is No, for which disease(s) did you lack the case definition----------

6. Did you have line list for reporting out break? Yes No NA

C. Training computer/calculator, data analysis assessment

1. Had you trained on surveillance system? Yes No

2. If answer for Q1 is yes a) when----------? b) Topic----------? c) For how long?

3. How the data entry and compilation is accomplished? Manually calculator/Computer others------

4. Did you analyze data of the surveillance system? Yes No

5. Did you have denominators for data analysis? Total pop Male Female <5 pregnant

6. Did you notify the result of your analysis to the health development armies? Yes No

D .case detection, reporting, confirmation assessment

1. Had you detected any case in 2008 EFY? Yes No, list if any----------

2 If yes did you reported it on time? Yes No

3. Did you have case detection check list? Yes No

4. If answer for Q3 is No, how did you know possible factors for the outbreak? ----------

5. Who was responsible to investigate an outbreak? HDA HEWs HC woreda other----------

6. Had you faced any challenge in case detection in 2008 EFY? Yes No

21. If answer for Q6 is yes, a) List the challenges ----------

b) List the alternatives that you take to tackle the challenges ----------

E. Field Supervision and feedback assessment

1. Were you supervised by higher level officers in 2008 EFY? Yes No

2. If answer for Q1 is yes how many times in 2008 EFY? ----------

3. Had you reviewed about surveillance practice by HCs, woreda or partners? Yes No

4. Had you received feedback from higher level supervisors in 2008 EFY? Yes No

5. If answer for Q4 is yes how many feedbacks did you received in 2008 EFY? ----------

6. how did you improved the weaknesses of supervision by feedbacks?----------

7. Had you faced any challenge on supervision and feedback in 2008 EFY? Yes No

8. If yes list the challenges and action taken----------

PART-TWO

IS THE SURVEILLANCE SYSTEM HELP?

1. To detect outbreaks early on time to permit accurate diagnosis? Yes No

2. To estimate the magnitude of morbidity and mortality Yes No

3. Permit assessment of the effect of prevention and control programs? Yes No

4. To estimate research intended to lead to prevention and control? Yes No

Describe Each System Attributes:

1. Simplicity:

1. Is the case definition easy for case detection by all level health professionals? Yes No

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5. Does the surveillance system allow updating data on the cases? Yes No

6. How long does it take to fill the format? <5 min 5 to 10 min 10 to15min >15 min

7. How long does it take to have laboratory confirmation? ----------

2. Flexibility

1. Can the current reporting formats be used for other newly occurring health event (disease) without much difficulty? Yes No

2. Did you think that any change in the existing procedure of case detection and reporting formats will be difficult to implement? Yes No,Add your explanation ----------

3. Is the system easy to add new variables? Yes No

4. Is the surveillance system easy to integrate with other systems? Yes No

5. Is the surveillance system easy to add new disease on report? Yes No

6. Is the system easy to add new information technology? Yes No

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

5. Is the recorded data clear to read and understand? Yes No

6. If answer for Q5 is No, how many records are not clear/are difficult to understand in 2008 EFY report? --------

7. Percent of records which are difficult to read/ understand. ----------

4. Acceptability

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

2. If yes, how many are active participants (of the expected)? ----------

3. If No, what is the reason for their poor participation in the surveillance activity? A) Lack of understanding of the relevance of the data to be collected B) No feedback / or recognition given by the higher bodies for their contribution C) Reporting formats are difficult to understand

D) Report formats are time consuming E) other: ----------

4. Were all participants using the standard case definition to identify cases? Yes No

5. Were all the reporting agents send their report using the current and appropriate surveillance reporting format? Yes No

6. Were all the health professionals aware about the surveillance system? Yes No

7. Was all PHEM officers send report on time? Yes No

5. Representativeness

1. was the surveillance system enabled to follow the health and health related events in the whole community? Yes No

2. If answer for Q1 is no, who do you think is well benefited by the surveillance system? the urban therural both

3. Are all the Socio demographic variables included in the surveillance reporting format? Yes No

4. If the answer for Q3 is No, which a) Sex---- b) age group---C) ethnic group----d) religion---- is less represented?

6. Timeliness

1. Are all reporting sites reporting on time? Yes No

2. Percent of reporting sites that report on time. ----------

7. Completeness

1. Are all reporting sites reporting? Yes No

2. Percent of HPs that send report of each week in 2008 EFY. ----------

8. Stability

1. Was any new restructuring affected the procedures and activities of the surveillance? Yes No

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

3. Was there any time /condition in which the surveillance is not fully operating? Yes No

8. If the answer for Q3 is yes, explain why? ----------

9. Sensitivity

1. Does the malaria case definition able to pick all cases? Yes No

2. What was the total malaria cases occurred in your HC catchment in 2008 EFY---------?

3. What were the total number of suspected malaria cases examined by RDT or microscopy in 2008 EFY----------

4. How many of those cases were laboratory confirmed? PF-------PV--------- Mixed------Total---

5. Was there malaria epidemic in your catchment are in 2008 EFY? Yes No

6. If yes, how many out breaks? ----------

Chapter IV-Health Profile Description Report

4.1 Health profile description of Damboya woreda, Kembata Tembaro zone, Sothern Ethiopia, March, 2017

EXECUTIVE SUMMARY

Introduction: Health profile is vital for prioritizing prominent health and health related problems of the community at any level. It is basic for planning and for appropriate intervention; and is an entry point for operational research. The purpose of this analysis is to assess and describe the health and health related issues in the district and communicate the local burden of disease and other health related information.

Methodology: From May 20-28/2015 Data necessary for the health profile description was collected from Damboya district health office, four health centers, district communication office, Rural development office ,Education office and other different sectors in the district by using check list (face to face interview or self-administered) and by document review. Finally data was compiled and analyzed manually and using Microsoft Excel.

Results: The district has 10 kebeles. In 2015 population estimate for the district was 104737 of which females constituted 50.6% (53044). 13.8 % (14509) of the district population live in urban. Out of 34 schools 12 (35%) schools have access to water. 32 schools (94%) have functional latrine. Two health centers (50%) and none of health posts have access to water supply. 3 (75%) of health centers and 9 (45%) of health posts have access to electricity. The CAR achievement of the district was 91%, the ANC4 coverage was 94%, proportion of skilled delivery was 64% and postnatal coverage was 64%. EPI coverage was 100%.The annual TB detection rate was 60% against the district target (70%). But treatment cure rate and success rate was 86% and 96% respectively. AFI and AURTI were top causes of morbidity in adults and under five outpatient departments respectively. Out of 30348 tested people for HIV 2 males and 4 females were tested reactive and linked to Damboya health center ART clinic.

Conclusion and recommendations: AFI &AURTI were the leading causes of morbidity in adults and under five outpatient departments. Proportion of delivery attended by skilled personnel was still low. TB detection and data documentation system needs due attention. Hence I recommended strengthening maternal health activities especially institutional delivery, screening people with cough of two or more week duration, well organizing data documentation system and appropriate diagnostic methods to identify diseases associated with AFI to reduce identified priority problems.

Key words: District, profile, Description, Performance

INTRODUCTION

1.1 BACKGROUND

A community health profile is a comprehensive, narrative description of the given community health status in align with historical, geographical, demographical and economical background of the area. The data in a profile reflects the health of a given community from many different angles. It is a system of collecting, organizing and summarizing health and others health related events to describe health and others health related conditions such as demographic, socio-economic, political, cultural and others aspect of a particular geographic areas of interest, and are useful for designing and preparation of development plans as well as for monitoring and evaluation of the impact of the implementation of the development plans. It is known that the health and socioeconomic well-being of the community are fundamentally connected to their natural and built environment (1).

Health systems are undergoing rapid change and the requirements for conforming to the new challenges of changing demographics, disease patterns; emerging and reemerging diseases coupled with rising costs of health care delivery have forced a comprehensive review of health systems and their functioning. As the districts examine their health systems in greater depth to adjust to new demands, the number and complexities of problems identified increases. A number of issues including governance in health, financing of health care, human resource imbalances, access and quality of health services, along with the impacts of reforms in other areas of the economies significantly affect the ability of health systems to deliver (2).

In epidemiologic point of view, it is crucial to prioritizes health and others health related condition occurred within the communities. These summarized and prioritized data is important for public health surveillance officials, as they can uses it as a baseline for planning, implementation and evaluation of public health surveillance program conducted at communities level. Therefore, the main objective of this document is to present compiled information concerning physical and socio-economic condition of the district and its health profile constraints.

1.2 STATEMENT OF THE PROBLEM

District is the most practical unit to achieve universal health coverage, while implementing a wide variety of national and international health policies like HIV preventing, Health Extension Package and Malaria prevention strategies that underpin the development of national policy and health sector reforms.

The intent of this assessment in this district is to receive a baseline health profile data and to assess the disease causing conditions and to suggest the preventive methods and incorporate the result for the interruptions in their future plan. Malnutrition, Malaria and other communicable diseases are common in the district. Moreover the health profile of the district has not yet been done in the area. Due to this I have selected the district to identify the gaps since no profile description conducted previously in the district.

1.3 SIGNIFICANCE OF THE DESCRIPTION

Health profile description helps to determine the effectiveness of policies, programs and projects to improve the health and social services of a given population by assessing the existing health service coverage, the developmental activities, social services, major health problems, risk factors and indicates areas that needs attention or focus to improve the health status of the specifically identified community or population. Moreover the health profile of the district has not yet been done in the area. So this rapid assessment was designed to describe the health profile of Damboya district.

2. LITERATURE REVIEW

Coverage of delivery attended by skilled health professionals in Mecha district was 30.4%. Annual achievement of ANC1 was 113%. PNC and CAR performance was 70% and 87.5% respectively. TB detection coverage of the district was 24%. The district`s health service coverage was 85%. Safe drinking water supply coverage was 35.8% for rural and 79.9% for urban. Latrine access coverage of the district was 100% .(3)

Safe drinking water supply coverage of Hetosa district was72%. ANC1 achievement was 89% and coverage of TT2 + pregnant and non-pregnant mothers was 63% and 47% respectively (4).

The annual coverage of fully immunized children of Achefar district was 83.8%. Malaria prevalence rate of the district was 135 per 1000. HIV prevalence of the district was 0.91. Health service coverage of the district was 85% (5).

Kedida Gamela district annual administrative coverage of CAR was 78.6%. ANC achievement was 84% and coverage of delivery attended by skilled personnel was 24.2%. TB detection, cure and success rates of the district were 32%, 95% and 98% respectively (6).

Annual administrative coverage of gross enrolment in primary and secondary schools in Kilte Awulaelo district was 97.2% and 97.9% respectively. Dropout rate from primary school was 2.83% (7).

Saktota district has educational coverage of 97%, potential health service coverage of 100%, safe drinking water coverage of 68.6% and latrine access of 85% (8).

EPI coverage of Kembata Tembaro zone in 2007 EFY was 100%. Performance of Delivery attended by skilled health personnel was 67.1%. TB detection, treatment success and cure rates were, 53%, 94% and 81% respectively(9).

Epi coverage of measles and fully immunized in SNNP Region was 97% and 94% respectively. Annual coverage of PNC was 92.8%. Achievement of delivery attended by skilled health professionals was low (61.6%). TB detection, treatment success and treatment cure rates were 62.7%, 93% and 70% respectively (10).

3. OBJECTIVE

3.1 GENERAL OBJECTIVE

To assess the health profile of Damboya district, Kembata Tembaro zone, southern nations nationalities and people region, 2007

3.2 SPECIFIC OBJECTIVES

- To describe health indicators and health related issues of the district.
- To determine the trend of primary health components in the district.
- To identify problems for priority setting.

4. METHOD

4.1 STUDY AREA

Damboya district is one of the eight districts in the Zone & found in SNNP Region Kembata Tembaro Zone of the Zonal town Durame about 50 km. It also found 125km from Hawasa in the north direction and 355 km from Addis Ababa in the south direction. In 2015 population estimate for the district was 104737 of which females constituted 50.6% (53044). 13.8 % (14509) of the district population live in urban. The district has four health centers and twenty health posts.

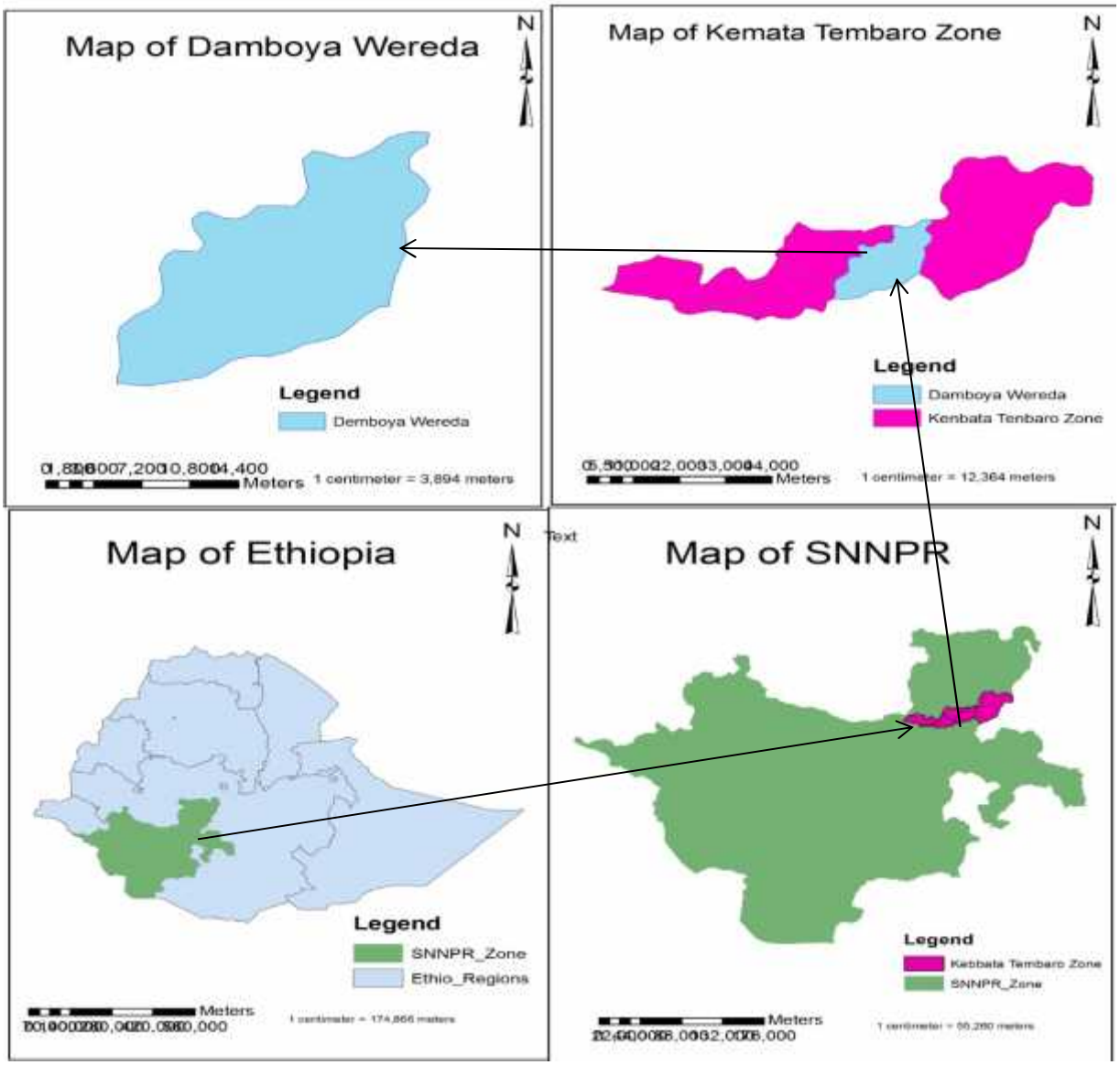


Figure 19: map of damboya district kembata tembaro zone, SNNP region, Ethiopia, 2017

4.2 STUDY DESIGN

Retrospective descriptive rapid assessment was conducted in Damboya district.

4.3 STUDY PERIOD

The rapid assessment was conducted in Damboya district from May 20-28 /2008 E.C Kembata Tembaro zone, SNNP Region.

4.4 SOURCE OF DATA

Secondary data that was reported from June1/2006 to30/2007 E.C from all district sectors/offices was used.

4.5 STUDY UNIT

Study units were district health office, rural development office, education office, water development office, finance and economy development office, public communication office, revenue authority branch and district administration offices.

4.6 SAMPLE SIZE DETERMINATION

All Damboya district public service organizations related to health were used.

4.7 SAMPLING TECHNIQUE

Because the health profile of the district has not yet been done the district damboya was purposely selected. Then all offices related to health were included in the assessment.

4.8 DATA COLLECTION

Secondary data was collected by using standard checklist from different district offices. Data available in health office, education office, rural development office, finance and economy development office, revenue authority branch and communication office was collected using standard checklist by reviewing secondary data, observation, and interview of key informants in the relevant sectors of the district with office heads and experts.

4.9 STUDY VARIABLES;

Variables captured from different district offices include; ethnicity, religion, demographic information, education, productivity and income, facilities, health service institutions ,infrastructure, maternal and child health, immunization, human resource management, disaster and outbreak occurrence, disease status , health indicators, vital statistics, district health system organization and community health service

4.10. DATA ANALYSIS AND PRESENTATION

To compile the data and to calculate frequency, ratio, proportion, and rate Microsoft Excel was used. Microsoft Excel office was also used to construct figures and tables.

4.11 ETHICAL ISSUE

Official permeation was obtained from Ethiopian public health institute /PHEM and cooperation letter was written to Kembata Tembaro zone health department. Cooperation letter was written to Damboya district health office and the district notified to the selected health facilities via phone calling.

4.12 DISSEMINATION OF FINDINGS

Findings of the assessment were shared with concerning district offices, zonal health department, mentors, supervisors and program coordinators of St Paul millennium medical college/EFELTP

5. RESULTS

5.1 GEOGRAPHY AND CLIMATE

Damboya, the district town is found on 130 kilo meters North of Hawassa, the capital of SNNP regional state. It covers 1364 square kilometers including Damboya town, with altitude range1860-2280 meters above sea level. The mean annual rain fall was 730 mm; and average monthly temperatures with the range of 24 ^{0}c to 26 ^{o}c.

5.2 ADMINISTRATIVE AND POLITICAL ORGANIZATION

Administratively the district is divided in to 17 rural and 3Urban kebeles. The district has its own council and representative in the federal parliament. All sector offices are found in the town Damboya. Megere is the furthest kebele in the district which is 20 km away from the District center. Damboya 01 is the nearest kebele in the district, which is 0.5 km from the District center. Wondo, Gonji and Kazala kebeles have no road access in the district. World vision Ethiopia, ORBIS international, Gogota care, In gender health, IFHP, USAID, UNICEF, and WHO were the main supporting organizations in the district.

BOUNDARY; The boundary of the district are Angacha in the North, Alaba special woreda in the South, Shashogo in the East, and Kedida Gamela in the West.

5.3 SOCIO-DEMOGRAPHIC CHARACTERISTICS

5.3.1 ETHNICITY AND RELIGION

The ethnic groups in the district are Kembata (70%), Hadiya (17%), Halaba (10%), and Silte (2%). Kembata is the dominant ethnic group in the area. The official language in the district is Amharic. The religious groups in the district are protestant (48%), orthodox (7%), Muslim (40%), and catholic (5%).

5.3.2 EDUCATION

There were a total of 35 governmental and one non-governmental school in the district. In 2015 a total of 25713 students were enrolled in education program. The district had 1 first cycle, 28 second cycle primary and four secondary schools. Elementary schools (grade1-8) had a total student population of 22030; with 48.6% (10727) females. In the three high schools; there were 3159 students with 54.6% (1727) females. In the district there was one preparatory school. There were a total of 420 teachers of which 34.5% (145) females elementary teachers & 94 of which 9.5% (9) females in secondary and preparatory schools. Educational coverage of the district is 96%.15(75%) kebeles each accessed with two schools, 5(25%) kebeles each accessed with one school. out of the total schools in the district 12(34.2%) schools have had access to safe water supply. whereas the rest 25(66.8%) schools have not had access to safe water supply. 32(91.4%) schools have had functional latrine, the rest 3(8.6%) schools have not latrine. All schools have had mobile telecommunication access in the district.

HIV/AIDS club, sport club, eye health care club, gender council club, Entrepreneur club, today's students tomorrows teachers and others were on educational activities in the school. The main responsibility of each club was training students in each mentioned activities based on their schedule. At time of study all clubs were functional.

5.4 DEMOGRAPHIC INFORMATION

The 2007 EFY population estimate for the district was 104737 of which females constituted 50.6% (53044) with 13.8% (14509) of the district's population live in urban.

Table 5 Population distribution by kebele for 20007 E.C with estimated population and distance in kilometers from the district town

Sr no	Name of the kebele	Population size	Distance from the district town	Remark
1	**Damboya 01**	**5726**	**0.5km**	
2	**Damboya 02**	**4702**	**1km**	
3	**Geyota grba**	**5024**	**5 km**	
4	**Hego**	**8794**	**6 km**	
5	**Yebu**	**9224**	**7 km**	
6	**Garamba**	**6960**	**5 km**	
7	**Ambaricho**	**4037**	**18.5km**	
8	**Hamancho**	**5793**	**15 km**	
9	**Kota kombola**	**4573**	**9 km**	
10	**Bonga**	**9820**	**6 km**	
11	**Hanja laloamo**	**3014**	**13 km**	
12	**Gendela**	**4441**	**17 km**	
13	**Magere**	**3337**	**20 km**	
14	**Dato**	**6303**	**15 km**	
15	**Hanja gotmaena**	**2752**	**7 km**	
16	**Heba**	**4717**	**6 km**	
17	**Gonji**	**5369**	**7 km**	
18	**Wondo**	**3759**	**6.25km**	
19	**Kazala**	**2311**	**9 km**	
20	**Funto 01**	**4081**	**5 km**	

5.5 FACILITIES

Damboya, the district town has 24 hour electric power supply, mobile and cable based telephone services, postal service and bank (commercial bank of Ethiopia). All kebeles are found within 20 kilo meters radius from the district capital town Damboya. 17 kebeles were accessible to transport in all seasons. Three kebeles were not accessible to transportation. Eighteen kebele offices had wireless telecommunication systems and all 20 kebeles accessed to mobile telephone network. However, only nine kebeles have electric power supply.

5.6 PRODUCTIVITY AND INCOME

The main base of economy for the inhabitants of Damboya district was mixed agriculture and trade. Agriculture was the major source of income in the district. The economic level in the district was classified as high, medium and low based on size of farmland. The residents who have more than four hectare farmland (1.2%) are categorized as high tax payers, those who have 1.5 to 4 hectares (18%) categorized as medium tax payers and those who have less than 1.5 hectare (80.8%) categorized as low tax payers. The average productivity of the land is 5.4 quintals per hectare during harvesting season (meher). The commonly and widely cultivated crop products are maize, teff, sorghum, wheat, bakella and others. The yearly total average GDP of the district from agriculture is 158479.041 quintals of which 131358.8 quintals are obtained during harvesting season and 27120.241 quintals from irrigation. Although the actual average income level of the inhabitants in the district is not yet estimated, most of the inhabitants especially dependents of agricultural products, maize and teff have enough product that could last them until the next harvest season.

5.7 HEALTH SERVICE INSTITUTIONS AND INFRASTRUCTURE

There were a total of 24 governmental and 10 private health facilities in the district.20 health posts, 4 health centers, 2 rural drug venders, 2 drug stores, 4 primary clinics, 1 medium clinic and 1 diagnostic laboratory. Regarding the availability of telephone service, water and electric power supply in the health facilities, three out of four health centers and eighteen out of twenty health posts have wireless telephone service. Two out of four health centers and none of the health posts have piped water supply. Three out of four health centers and 9 out of 20 health posts have 24 hour electric power supply. Even though public bus transportation is available in the three health centers, transportation to the other one health centers is possible only for small cars and motor cycles and it is seasonal. Seasonal small car and motor cycle transportation is also available for 15 of the 20 health posts. Health center to population ratio was 95% and health post to population ratio was 96%. The potential health service coverage for Damboya district is 95%. The following table shows the number of health facilities by number and type.

Table 6 Type and number of health facilities in Damboya district, Kembata Tembaro, SNNP, Ethiopia, 2007 E.C

Sr no	Type of health facility	number	Remark
1	Hospital	0	
2	Health center	4	
3	Primary clinic	4	
4	Medium clinic	1	
5	Pharmacy	0	
6	Drug store	2	
7	Rural drug vender	2	
8	Diagnostic laboratory	1	
9	Health post	20	

5.7.1 DISTRICT HEALTH SYSTEM

OREGANO-GRAM OF DISTRICT HEALTH OFFICE

The district health office implemented a new organizational structure after the business Process reengineering (BPR) concept which was endorsed by the regional sate in 2008/9. The district has five main core processes, three supportive processes within a direct command of the district health office head.

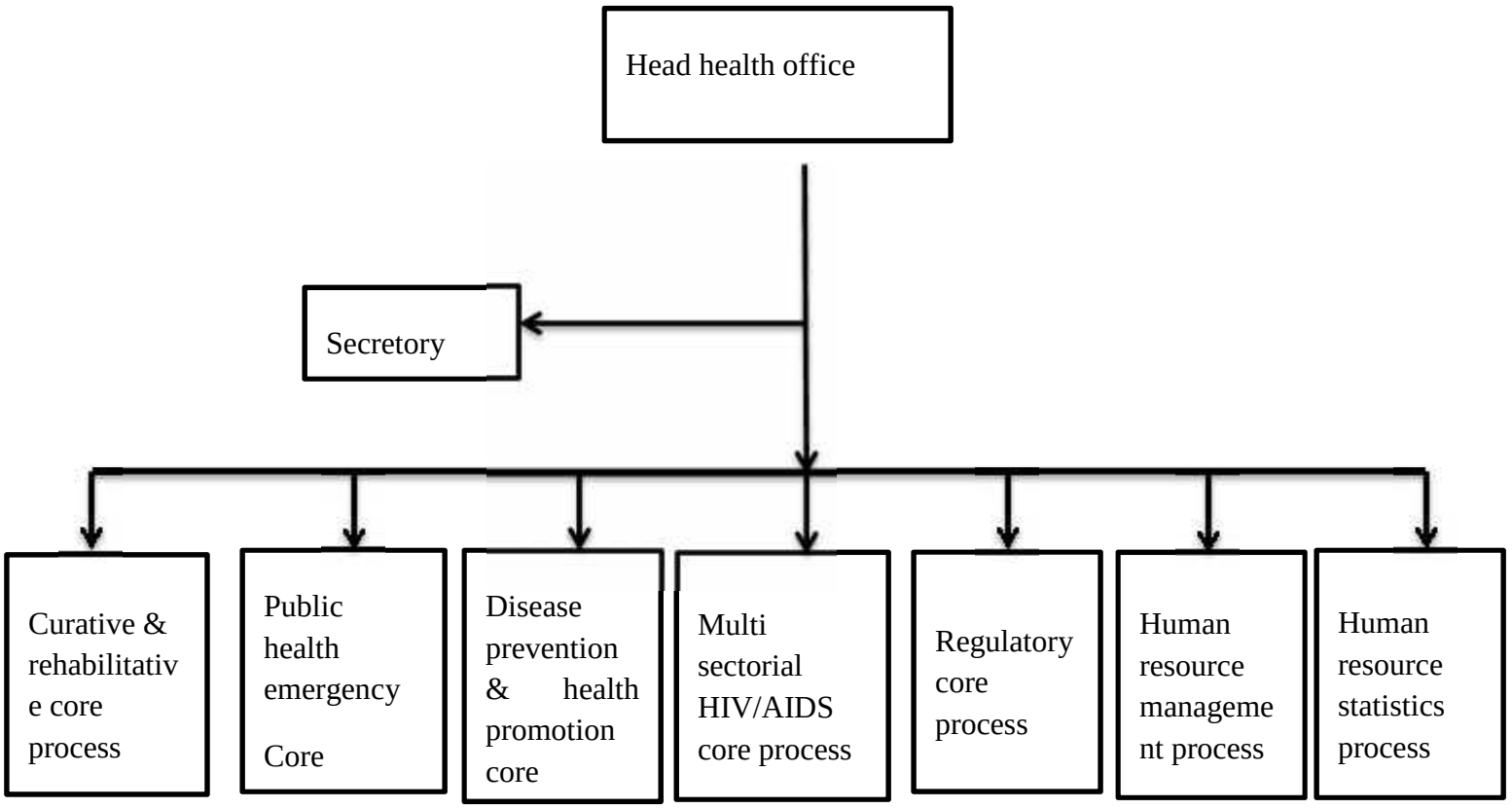


Figure 20: Organizational structure of Damboya district health office, KT, SNNPR, Ethiopia, 2007E.C

5.8 human resource and man power in health institutions and health offices

In the health facilities under Damboya district, there are 77 Nurses, 8 Laboratory professionals, 5 Pharmacy technicians, 10 health officers, and 5 Environmental health professionals. In the 20 health posts there are 45 health extension workers. The following table shows the number and type of professionals by educational level currently working in comparison with the number of professionals required.

Table 7: Distribution of health workers in Damboya district, SNNP region, 2007 EC

Sr no	Category	number	Required
1	Health officer	10	12
2	BSc clinical nurse	13	12
3	Diploma clinical nurse	42	36
4	Public health nurse	8	8
5	Midwife	14	12
6	Medical laboratory technologist	1	2
7	Pharmacist	1	1
8	Druggist	4	12
9	Medical laboratory technician	7	12
10	Environmental health officer	5	4
11	Health extension worker	45	40
12	HIT	3	4
13	Administrative staff	63	48
	Total	206	201

5.9 VITAL STATISTICS AND HEALTH INDICATORS

Vital statistics like total death, total births, Infant and under- five deaths were not recorded in the district and indices for each specific indicator mentioned in the table 4.10 were from the national estimates, projected from the 2007 national census.

Table 8, Distribution of population groups and vital statistics Damboya district, Kembata Tembaro, Ethiopia, 2007 E.C

Sr no	Parameter	Number	Remark
1	Total population	104737	
2	Male	52693	49.4%
3	Female	53044	50.6%
4	Under 1 years old	3341	3.19%
5	Under 5 years old	16349	15.63%
6	Under 15 years old	50137	47.7%
7	Urban	14509	13.8%
8	Female 14-49 years old	16789	16.03%
9	Pregnancy	3623	3.46%
10	Live birth	3623	3.46%
11	Non pregnant mothers	20779	19.84%
12	Average house hold size	5132	4.9%
13	Age dependency ratio	No data	
14	IMR/1000	1.9	
15	Under 5MR/1000	No data	
16	CBR/1000/year	0.14	
17	CDR/1000/year	No data	

5.11 MATERNAL HEALTH SERVICE COVERAGE

In 2014/15 ANC1 achievement of the district was 100% (3637), performance of ANC4 was 97% (3505). Proportion of skilled delivery attended by skilled personnel and home delivery was 64 %(2335) and 36% respectively. Achievement of family planning acceptance rate was 91 %(18882).

5.12 IMMMUNIZATION COVERAGE

Table 9: The Immunization coverage of Damboya district for children 2007 E.C

Sr no	Type	Coverage (%)	Remark
1	BCG	100	
2	Pentavalent3	100	
3	PCV3	100	
4	Polio3	100	
5	Rota2	100	
6	Measles	100	
7	Fully immunized	100	

5.13 DISEASE STATISTICS

5.13.1 TOP TEN LEADING CAUSES OF OUTPATIENT VISITS

AFI was the district's major public health problem and the top leading cause of outpatient visit followed by AURTI and typhoid fever. The following table shows top ten leading causes of outpatient visits

Table 10 Top leading causes of all outpatient visits in Damboya, Kembata Tembaro, SNNPR, Ethiopia, July 2006-June 20007.

Sr no	Disease type	male	female	total	%	Cumulative frequency (%)	Remark
1	AFI	1889	2207	4096	10.72	10.72	
2	AURTI	1879	2034	3913	10.24	20.96	
3	Typhoid fever	1717	2117	3874	10.14	31.1	
4	Pneumonia	1713	1650	3363	8.8	39.9	
5	Parasitic disease	1013	1229	2242	5.87	45.77	
6	Typhus	879	1267	2146	5.62	51.39	
7	Dyspepsia	851	1163	2014	5.27	56.66	
8	UTI	896	1112	2008	5.25	6.91	
9	Disease of musculoskeletal system & connective tissue	936	1029	1965	5.14	67.05	
10	Trauma	963	680	1643	4.3	71.35	
	Others	5284	5667	10951	28.66	100	
	Total	18020	20195	38215	100		

Table 11 Ten top leading causes of under-five outpatient visit in damboya, kembata Tembaro, SNNPR, Ethiopia, July 2006- June 2007.

Sr No	Disease type	male	Female	total	%	Cumulative frequency (%)
1	AURTI	825	742	1567	30.19	30.19
2	Pneumonia	538	450	988	19.04	49.23
3	Diarrhea(non -bloody)	292	224	516	9.94	59.17
4	AFI	258	202	460	8.86	68.03
5	Other unspecified disease of eye &adnexa	219	138	397	7.65	75.68
6	Malaria(confirmed with specious pf)	128	128	256	4.93	80.61
7	Infection of the skin and subcutaneous tissue	97	93	190	3.66	84.27
8	Other unspecified infection and parasitic disease	79	80	159	3.06	87.33
9	Otitis	49	56	105	2.02	89.35
10	Diarrhea with dehydration	40	50	90	1.73	91.08
	Others	234	228	462	8.9	100
	Total	2759	2431	5190	100	

5.13.2 MALARIA

Ten(50%) of the district kebeles (Megere, Gendela, Hanjelaloamo,Hanjegotmaena, Gonji, Yebu, Geyota gerba, Bonga, Kota kombola, and Hamancho)were known identified ten top malarias kebeles sequentially based on the incidence of malaria in the district.in previous years malaria was known epidemic disease in the district but there was no compiled data. A total of 2082 malaria cases were treated based on laboratory finding (1723 *plasmodium falciparum*, 336 *plasmodium vivax* and 23 mixed).

5.13.3TUBERCULOSIS AND LEPROSY

A total of 129 Tuberculosis cases were registered in the district in 2007 E.C. Out of these 68(52.7%) were pulmonary positive, 38(29.4%) were pulmonary negative and 23(17.8%) were extra pulmonary cases. In the district only three health centers were performing AFB smear Examination. The annual TB detection rate was 60%. The treatment cure and success rate was 86% and 97% respectively. The annual district target was 70%. In TB treatment 1 death and zero defaulter rate was reported in the district in the year. Patients suspected for MDR TB were referred to Durame general hospital.

5.13.4 HIV/AIDS

A total of 30348 people were tested for HIV/AIDS. Out of the total screened 25636(14821 males and 10815 females) people were tested in outpatient department (PIHCT).1096(571 males and 525 females) people were tested in VCT and 3616 tested were PMTCT. Among tested individuals 2 males from PIHCT, 3 females from VCT and 1 female from PMTCT were positive. The incidence rate of HIV in the district was 0.01% in 2007 E.C. There was 1 ART clinic in the district. All tested reactive clients were linked to Damboya health center ART clinic.

5.14 HEALTH EDUCATION /COMMUNITY HEALTH SERVICE

At health facility and house to house health education had been given by health care providers who have been supporting kebeles and the health extension workers (HEW).The main topics covered in the year were family planning, ANC follow up, delivery, PNC, breast feeding, immunization, harmful traditional practices, essential drug use, nutrition, HIV/AIDS, tuberculosis, diarrheal diseases, water, hygiene and sanitation.

The total community health services have implementing by the lead of health extension workers. The district has signed agreement with traditional birth attendants (TBAS) not to attend birth at home from beginning of 2007 E.C previously the community health agents/workers (CHW) or promoters, currently health development armies were assisting the health extension workers by training their village residents about health extension packages, transferring information from health extension workers to community and from community to health extension workers.

5.15 ENVIRONMENTAL HEALTH ACTIVITIES

The district has declared all the kebeles free from defecating everywhere in the field. The latrine access and utilization rate in between 2005 and 2007 were 100%. All schools and health facilities were accessed with VIP latrines. The community were using common pit latrine. To sustain these activities the district was implementing the maintenance of latrine and community sensitization in all kebeles. Prevention and control of communicable diseases such as malaria, TB, HIV control measures and health education activities were implemented in the district. The safe drinking water coverage of the district is 68.6%

5.16 DISASTERS AND OUT BREAKS OCCURED

In the time period of the health profile assessment there were no any outbreak and/or disaster occurred.

5.17 IMMEDIATELY AND WEEKLY REPORTABLE DISEASES

Thirteen diseases are targeted to be reported immediately using case based reporting format and line listing depending on the number of occurrence of cases in the district

1. Viral hemorrhagic fever (VHF),
2. Yellow fever,
3. Acute flaccid paralysis (AFP/polio),
4. Anthrax,
5. Avian human Influenza (AHI),
6. Cholera,
7. Guinea worm,
8. Measles,
9. Neonatal tetanus (NNT),
10. Human influenza (H1N1),
11. Rabies,
12. Small pox,
13. Sever acute respiratory syndrome (SARS) Seven diseases or conditions are reported on weekly bases to the next level;

1. Dysentery,
2. Malaria,

3. Meningitis,

4. Relapsing fever,

5. Typhoid fever,

6. Typhus,

7. Malnutrition

5.18 NUTRITION PROBLEMS AND ANY OTHER DISASTERS

The district is known for its good crop production and is one of the food secured areas in the zone. In the district there was one stabilizing center and 20 outpatient therapeutic programs in all health posts. There were 422 moderately malnourished and 16 severely malnourished children in the district.

5.19 HEALTH BUDGET ALLOCATION

The total budget for the district health office including health facilities was 11.4 % (7,114,052). Ethiopian Birr in 2014/15 from the district total budget 62,357,563.98 for 2014/15.

5.20 ESSENTIAL DRUGS AND OTHER SUPPLIES

The district reported that there was shortage of essential drug supply and diagnostic kits were not easily accessible in PFSA to purchase.

5.21 PRIORITIES IDENTIFIED

- Maternal and child health services were the most important parts of health service delivery system in developing countries like Ethiopia and the same is true for Damboya district. Coverage of delivery attended by skilled health professionals in the district was low (64%).
- TB detection of the district was low, which is 60%. One out of four health centers was not performing AFB examination service.
- TB cure rate of the district was low (86%).
- There was no well-organized data management system in the district.
- There was shortage of essential drug supply and diagnostic kits in the district.
- There were no appropriate diagnostic methods for disease identification.

5.22. Action plan for identified problems

Sr no	Identified problem	responsibility	time	remark
1	SBA	Medical services core process	June 1-30	
2	Low TB detection	DPHP core process	July1- August 30	
3	Low TB cure rate	DPHP core process	July1-september30	
4	Poor data management system	M & E supportive process	June 1	
5	Shortage of essential drugs	Medical services core process	May 30	
6	Lack of appropriate diagnostic methods for disease identification	Medical service core process	June 1	

6. DISCUSSION

In Damboya district one health center was providing service for 26184 populations and one health post was providing service for 5236 population making potential health service coverage of the district 95%. This finding is similar with zonal coverage of health centers to population ratio 94%, health posts to population ratio 95% and potential health service coverage 95% respectively (9). The finding was also similar with the national figure of one health center to15000-25000 population and one health post to 5000 population (pro 7). This might be due to strong commitment of government to make accessibility of health service coverage. However this finding is different from result of study carried out in Tanzania in which one health center serves 50,000 population(11).

In the district, the proportion of pregnant women who had at least one ANC visit were100% in 2007 E.C. It was encouraging and the district should work for more success in achieving MDG 5 in 2015. The percentage of delivery attended by skilled health personnel was 64%. Coverage of family planning was 91%. This finding of maternal health service was higher than the report of study conducted in republic of Uganda in which coverage of SBA 40%, ANC1 52.4% and CAR 50%(12) and national coverage (17%) (13).Family planning and postnatal care services coverage of the district is similar with the zonal coverage which is 91% and 100% respectively (9)- (10).The low coverage of skilled delivery might be due to weak implementation of skilled delivery initiatives in the district.

The analysis revealed that fully immunization coverage of the district was 100% this finding is higher than national Epi coverage of 24% (13) and the finding of study conducted in Mecha district, North West Ethiopia 56.9% PV 3, 54.5% PCV3 and 53.5% of measles coverage (14). The finding was also higher than less than 50% EPI coverage of the democratic republic of Timor-Leste (15). The status of measles immunization was 100 in under- one year`s seems well matched with absence of measles cases/outbreak in the district (9)- (10). This might be due to increased awareness of mothers on use of immunization as a result of Health Extension Program and HAD implementation by HEWS and supporting professionals from health centers.

In this descriptive study AFI and AURTI were the leading causes of morbidity in the district accounting 10.7% and 30.9% in adults and under 5 children respectively. The other diseases that are leading causes of morbidity next to AFI in adults & AURTI in children were AURTI in adults and pneumonia in under5 children. This is similar with zonal leading causes of morbidity in adults and children (9) and the finding of profile analysis of democratic republic of Timor-Leste (15). AFI being the leading cause in adults might be due to unavailability of appropriate diagnostic methods to identify diseases associated with febrile illness.

The target set nationally for TB control in EFY 2003 was to increase TB detection rate from 36% to 59%, TB treatment Success rate from 84% to 85%, and TB cure rate from 65% to 80% and increase the proportion of PLWHA screened for TB from 15% to 80% (16). In 2007 EC the district TB detection rate was 60% which is lower than the regional case detection rate 62.7% and higher than national TB detection rate 34% in 2003 but it was below 70% which is recommended by World Health Organization (WHO) (3). In 2007 a total of 129 all forms of TB cases diagnosed and reported to the Damboya District health office with an estimated TB prevalence of 123/100,000 population. This is less than national prevalence 258/100,000 population for all forms of TB (1).This might be due to strong TB prevention and control activities in the district. The TB cure rate (86%) was less than the target (95%) set for the year 2005 and treatment success rate (97.6%) which was higher than the national target (95%) set for the year 2012/13(2005 EFY) (1). The lower TB cure rate coverage might be due to weak DOT and/or community TB program implementation. There were no outbreak and/or disaster occurred in the time period of the health profile assessment. This might be due to strong communicable disease control and prevention activities and surveillance.

In this district profile analysis the identified priority health problems were low coverage of delivery attended by skilled birth attendants, low TB detection and cure rate, unorganized data management system, shortage of essential drug supplies and diagnostic kits and lack of diagnostic tests for disease identification. This finding was consistent with the result of studies conducted in (2), in Rwanda (17)and Zambia(18). Unavailability/limited researches on health and heath related issues and no accessible population survey, absence of mortality records and reliability of data of 100% coverage of some activities in the district were limitations of the study.

7. CONCLUSION

AFI was the leading cause of morbidity in adults followed by AURTI and AURTI is the leading cause of morbidity in under- five outpatient department. Proportion of skilled delivery attended by health personnel was still low (64%). Health related indicators like birth and death rates and under-5 mortality rates were not recorded appropriately. There was a gap in maternal and child health services which needs attention. TB detection rate and data management and retention system issues need due attention by the district, zonal health department, regional health bureau NGOS and other stack holders in general.

8. RECOMMENDATION

The District health office should strengthen activities associated with delivery attended by skilled health professionals to increase low coverage.

Improve screening of people with cough of two or more weeks to increase low TB detection rate.

Strengthen DOT and/or community TB program to improve low TB treatment cure rate coverage. All health centers should perform AFB examination.

The district should fully supply essential drugs and diagnostic kits in order to give quality health service for the community.

There should be well organized data documentation system and appropriate diagnostic methods to identify diseases associated with AFI in the district.

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Annex 3: Data Collection Tools (Checklist) of district profile assessment

Geographic and Climatic conditions

Total Area of the District _____

Altitude _____

Latitude_____

Longitude _____

Average Annual rain fall _____

Average Annual temperature _____

Boundaries north---------- South----------

East---------- West----------

Climatic information

Socio Demographic information

Total Population _____

Male_____

Female_____

Urban_____

Rural_____

Sex ratio (Male to Female) _____

Age structure: - percentage of children < 1yrs_____. <5yrs____< 15 years

Age 15-64years--------Percentage of old people >65 years_____

Women child bearing age(15-49) years_____

Percentage of pregnant women_____

Dependency ratio_____

3. Population size by religion

Ethnic composition

4. Estimated Population size by kebele in 2008 EFY (2015/2016)

Sr.no	Name of the Kebele	Population size	Distance from the district town(km)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			

Administrative setup

Total number of kebeles: _____

Rural _____

Urban_____

District Boundaries_____

Supporting NGOs----------

Health status

Number of health facilities 2007 EFY

Sr.no	Type of Health facility	Number
1	Hospital	
2	Health center	
3	Private clinic	
4	Pharmacy	
5	Drug store/Rural drug vender	
6	Diagnostic Laboratories	
8	Health posts	

Man power of Damboya district health office and health facility in 2007 EFY

Sr. no	Type	Number	
		no	Remark
1	Physicians		
2	Health officers		
3	Laboratory technician/technologist		
4	Pharmacy technician/Pharmacist		
5	Nurses		
6	Midwife		
7	X-Ray technician		
8	ENHS		
9	HEWs		
10	TBA		
11	Others		

Top causes of morbidity and mortality 2007EFY (2015⁄2016)

A. Top ten leading causes of OPD visit (morbidity)

Sr.no	Adult	Pediatrics
1		
2		
3		

4		
5		
6		

Top ten causes of admissions

Sr. no	Adult	Pediatrics
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Top ten causes of deaths (mortality).

Sr.no	Adult	Pediatrics
1		
2		
3		
4		
5		

Vital statistics2007 EFY

CBR_____ CDR_____

NMR_____ PNMR_____

IMR_____ MMR_____

GR_____

MCH and EPI coverage of the district 2007EFY (2014/2015)

Sr.no	Description	Coverage	Remark
1	ANC 1 coverage		
2	ANC 4 coverage		
3	Institutional (skilled) delivery		
4	PNC coverage		
5	BCG coverage		
6	Measles vaccine		
7	OPV		

8	Penta1		
9	Penta3		
10	PAB		
11	Full immunization coverage%		
12	Contraceptive acceptance rate		
13	TT2 coverage for pregnant		
14	TT2 coverage for n pregnant		

Endemic Diseases

Malaria prevention and control program of 2007EFY

Sr. no	Description		Number of population (%)	
1	Number of Malarious Kebeles			
2	LLITN coverage			
3	Coverage of Insecticide chemical spray			
4	Total no. of cases/year			
5	No of malaria cases in pregnant mothers			
			<5	>5
6	Case fatality rate	PF		
		PV		
7	Case treated clinically			
8	Cases treated based on	PF		

	lab finding	PV	
		Mixed	

List of major malaria prevention and control activities----------

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Prevalence of TB/Leprosy: 2007EFY (2014⁄2015)

Sr. No	Description		Population no. (%)
	Prevalence of TB		
1	Pulmonary TB	Smear positive	
		Smear negative	
2	Extra PTB		
3	TB detection rate		
4	TB Rx completion rate		
5	TB cure rate		
6	TB Rx success rate		
7	TB defaulter rate		
8	Death on TB Rx		
9	Total TB patients screened for HIV		
10	HIV prevalence rate among TB cases		
11	Prevalence of Leprosy		

HIV/AIDS2007EFY (2014⁄2015)

S.no	Activities	Male	Female	total	Remark
1	Total people screened for HIV				
2	CT				
3	PICT				

4	PMTCT				
5	HIV Prevalence				
6	Total PLWHIV				
7	On ART				
8	No. of pregnant mothers on AR				
9	Pre ART				
10	Condom Distribution				
11	Health education coverage				
12	Number of OVC				

Topics for health education----------

Socio economic conditions 2007EFY (2014/2015)

Education and school Health

S/N	Type of School	# Schools	# teachers			# Students			Student School Drop out	Female Student School Drop out
				Female	Total	Male	Female	Total		
1	Primary									
	1-4									
	5-8									
	1-8									
2	Secondary									
	9-10									
	11-12									
	9-12									
3	Others (Take note)*									
	Total									

School health activities:

Schools with water supply_____

Schools with functional latrines _____

Schools with HIV/other Health clubs_____

Literacy ratio_____

Health education----------

Income

Main source of income _____

Productivity of the land per hectare----------

Yearly income per house hold_____

GDP (during harvesting season/ meher) = ----------

GDP from irrigation=---------- quintal

Total GDP= ---------- quintal

Average income per capita _____

Social aspects

Number of youth clubs_____

Number of public libraries_____

Others_____

Communication and Utilities

How many of the health facilities and kebeles have access to:

Transportation: kebele _____ (%)

Health facility_____ (%)

Telecommunication: Kebele _____ (%)

Health facility_____ (%)

Electric power: Kebele _____ (%)Health facility _____ (%)

Health sector expenditure and financing2003-2007 EFY (2011/2012)

	Source	2003EFY	2004 EFY	2005EFY	2006 EFY	2007 EFY
1	Total district budget (Birr)					
2	Allocated to health sector (Birr)					
3	Total per capital health expenditure(Birr)					

*Name of NGOs which Support the health Sector:_____

17.1 Health sector Budget Distribution (2003- 2007 EFY)

Sr. no	Health institution	2003 EFY		2004 EFY		2005EFY		2006 EFY		2007 EFY	
		Salary* (birr)	Recurrent (birr)	Salary (birr)	Recurrent (birr)	Salary (birr)	Recurrent (birr)	Salary (birr)	Recurrent (birr)	Salary (birr)	Recurrent (birr)
1											
2											
3											
4											
5											

17.2 Health Care financing /HCF/ (_____to_____ EFY)

No	Name of the Health HFs	HCF Started at (EFY)	Budget Allocated (birr)			Budget Utilized (birr)			Remark
			200…	200…	200..		200..	200…	
1									
2									
3									
4									
5									
6									
7									

Disaster situation in the district 2007EFY (2014/2015)

Was there any disaster (natural or manmade) in the district in the last one year?

Yes (specify) _____

No_____

Any recent disease, outbreak/other public health emergency?

Yes (specify) _____ _____

No_____

If yes cases_____ and deaths_____

What do you think the major Health problems of the district?

What do you think solutions of the addressed problems?

What are the main zoonotic diseases in the district?

A.

B.

C.

D.

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

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

Chapter V- Scientific Manuscript for Peer Reviewed Journals

5.1 Acute Watery Diarrhea Outbreak Investigation, Segeg District, Nogob Zone, Somali Region, Ethiopia, March-April, 2017

Authors: W Wogayehu[1], T. Tessema[2], S.Elias[3], A. Fana[3]

1Ethiopian Field Epidemiology and Laboratory Training Program, Addis Ababa, Ethiopia

2kembata Tembaro health department

3Saint Paul Millennium medical college, department of Public Health, Addis Ababa, Ethiopia

Abstract

Introduction: Cholera is a potentially life-threatening acute diarrheal disease caused by the toxigenic bacterium *vibrio cholerae* either type 01 or O139. The infectious agent is acquired through consumption of contaminated water or food. The source of contamination is usually the feces of an infected person. The aim of this study was to investigate acute watery diarrhea outbreak, identify potential risk factors and provide the possible prevention and control measures.

Methods: un-matched community based 1:2 case control study was conducted on 50 cases and 100 controls. By using outbreak investigation structured questionnaires, all the outbreak investigation team conducted home to home visit and administered the questionnaires. The data was entered in to Epi Info and exported to SPSS for analysis of association between possible risk factors and acute watery diarrhea occurrence.

Result: A total of 759 suspected acute watery diarrhea cases and five RDT confirmed cases with 26 deaths were reported between March 10 and April 15, 2009. The overall attack rate and case fatality rate was 1.26% and 3.4% respectively. Age group 5-14 was the most affected population. An adjusted analysis showed that persons who had a travel history to areas already affected with acute watery diarrhea were at greater risk of getting acute watery diarrhea [adjusted Odds ratio (AOR) = 3.856 at 95% confidence interval (CI) = 1.018-9.56, p-value = 0.047]. Household latrine availability was protective against acquiring acute watery diarrhoea with adjusted odds ratio 0.181 at 95% CI 0.042-0.780, p value 0.022. Treating drinking water was protective of the illness with adjusted odds ratio 0.134 at 95% CI 0.041-0.445, p value 0.001.

Conclusion: still acute watery diarrhea remains serious threat to public health system in Somali regional state in Segeg district. Overall attack rate and case fatality rates were high. Hence the district health office, other concerned sectors and partners should strengthen health education on prevention and control of acute watery diarrhea. Health center should treat cases according to acute watery diarrhea case management guideline to decrease high case fatality rate.

Key words: Acute Watery Diarrhoea, V.cholerae, Segag, Ethiopia

Introduction

Background

Acute Watery Diarrhea is a potentially life-threatening acute diarrheal disease caused by the toxigenic bacterium *vibrio cholerae* either type 01 or O139 (1)-(2). The infectious agent is acquired through consumption of contaminated water or food. The source of contamination is usually the feces of an infected person (3) .It is one of the key indicators of social development and remains a challenge to countries in epidemic form where access to safe drinking water and adequate sanitation cannot be guaranteed (4). AWD occurs when there is rapid urbanization without adequate sanitation and access to clean drinking water (5).
Most individuals infected with V.cholerae remain asymptomatic or show only mild diarrhoea. Symptomatic cases of human infection are characterized by acute secretory watery diarrhoea, commonly with vomiting, nausea and abdominal discomfort (6). V. cholerae O1 and O139 cause clinical disease by secreting an enterotoxin that promotes secretion of fluids and electrolytes by the small intestine (7). In the most severe cases, AWD is one of the most rapidly fatal illnesses known, due to severe dehydration or water loss. If left untreated, mortality from AWD can be 30-50% (8). The most common method of treatment is administration of oral rehydration solution (ORS); more severe cases may require intravenous rehydration and antibiotics (3).

It is estimated that approximately 3-5 million people are annually infected with AWD and it leads to 100000 to 120000 deaths worldwide. It may produce rapidly progressive epidemics or worldwide pandemics (2). It is estimated that 4.2% of the total AWD cases reported globally originate in Asian countries. The highest number of cases has been reported in India (52.9%) followed by Afghanistan (29%) and Indonesia (22%) (2).

In 2012, sub-Sahara Africa accounted for 71% of reported cases and 86% of reported deaths worldwide. The number of AWD cases is estimated to be much higher than actually reported to World Health Organization. A recent analysis from Mozambique found that 66% of cases and 90% of deaths occurred within the first 6 weeks of an outbreak (9).

In 2009, a total of 217,333 cases with a case fatality rate (CFR) of 2.25% (4,883 deaths) were reported in 30 African countries alone. Of these, eight countries, including Nigeria accounted for 191,537 cases with a CFR of 2.26% representing 88% of reported cases and deaths from the continent with the CFR in many of these countries higher than the accepted 1% threshold(10) .

In Ethiopia it was indicated that, there was acute watery diarrhea (AWD) epidemic in 1990 which persisted with recrudescence of cases till 1998. Moreover, from July 2008 to June 2009 in Ethiopia, there were a total of 9485 cases and 193 deaths (with case-fatality rate 2.0%) of acute watery diarrhea in six regions including Addis Ababa. Afar region took the country's highest share of cases, 2,988 (31.5%) and deaths 99(51.25%) of AWD with a case fatality rate of 3.3% (1).

AWD is an epidemic-prone disease of global significance that has a prominent role in the history of public health. This infectious disease has been virtually eliminated from developed countries due to improved water and sanitation infrastructure, but deadly AWD outbreaks still occur in many low-income countries including Ethiopia. AWD is becoming endemic in Ethiopia meaning that the country experienced cases of AWD since 1990(1). Large widespread outbreaks occurred in Ethiopia from July 2008 to June 2009 in six regions including Addis Ababa with case fatality rate of 2.0%. AWD remains major public health concern in Ethiopian Somali region and in 2009 the region reported 6960 cases and 170 deaths with case fatality rate of 2.4%. Therefore this study investigated the existence of the out- break and successes and challenges of AWD outbreak control and prevention efforts in Segag district Ethiopian Somali region.

Currently Acute watery Diarrhea is the major public health problem in Ethiopian somale region with a high frequency of epidemic in all zones of the region. But there is a delay in outbreak investigation, reporting, control and prevention of AWD in the region. This AWD outbreak investigation described the magnitude of the outbreak, identified potential risk factors of the disease transmission and provided the possible control and prevention measures based on gaps identified. Therefore the aim of this study was to investigate AWD outbreak in Segag district of Ethiopian somale region. On 01 March, 2009, the Public Health Emergency Management Team of Ethiopian Public Health Institute (EPHI), in the Federal Ministry of Health, received a report from Segag district health office, Nogob zone, Somali Regional state indicating unusual cases of watery diarrhoea from Segag district kebeles and its neighbors. Following the occurrence of unusual cases report, the Ethiopian Public Health Institute decided to deploy a team to the affected area from Ethiopian Field Epidemiology and Laboratory Training Program to investigate the outbreak.

Methods and materials

Study area

The study was conducted in Segeg district, Somali region with a total population of 60000. Administratively the woreda has 2 urban and 13 rural kebeles. In the woreda there were 1 health center and three health posts.

Study design and period

Un-matched community based **c**ase control study design was conducted from March 04 to April 15/2009 E.C.

Study population

The study populations were all persons living in Segeg district and confirmed with AWD and/or had epidemiological linkage with confirmed AWD cases detected during the outbreak and randomly selected community controls from the same neighborhood where the cases live.

Study subjects

Cases were individuals with AWD admitted or treated in Segeg health center and who are in the line list and selected to participate in the study and their controls were persons without AWD and living in the same neighborhood as the cases.

Inclusion and Exclusion Criteria

Residents of Segeg woreda who are above age of five years and able to respond were included in the study. Those who are below age of five years and unable to respond were excluded.

Sampling procedure

Cases were selected randomly using the lottery method where each name on the line list was allocated a number on a pieces of paper which was put in box and randomly picked and the name corresponding to their number was recruited in to the study until the sample size reached. Controls were neighbors of cases who did not suffer from AWD during the study period. Two controls for one case per household were selected from the neighbors of cases.

Data collection method instrument

The questionnaires were developed in English and translated in to Somale language and translated back to English. By using outbreak investigation predesigned questionnaires, all the outbreak investigation team and one language translator for each assigned were conducted home to home visit and administered the questionnaires. For each case, two community controls were selected and interviewed on the same day as the cases interviewed and similarly environmental assessment of the community were carried out.

Data Analysis and interpretation

Data was cleaned manually and checked for consistency before analysis and necessary corrections were made. The data was entered in to Epi Info Version 7 and exported to SPSS statistical software package. Descriptive statistics and binary logistic regression analyses were carried out to describe the variables and to identify possible risk factors associated with AWD respectively. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated, and p-values <0.05 were considered to indicate statistical significance.

Ethical consideration

Permission to proceed with the outbreak investigation was obtained from the public health emergency management / Ethiopian Public Health Institute (EPHI) and cooperation letter was written to Ethiopian Somali regional state health bureau. Somale regional state also wrote cooperation letter to Segeg district health office.

Consent Process: participants of the study were informed about the study verbally to solicit their consent to participate in the study. Children were recruited in the study after obtaining informed consent from their parents or care-givers.

Results

Magnitude of the Outbreak

A total of 501 suspected AWD cases and five RDT confirmed cases with 26 deaths were reported between March04 and April 15, 2009 E.C. The attack rate and case fatality rates were 83 per 10,000 population and 5.1% respectively.

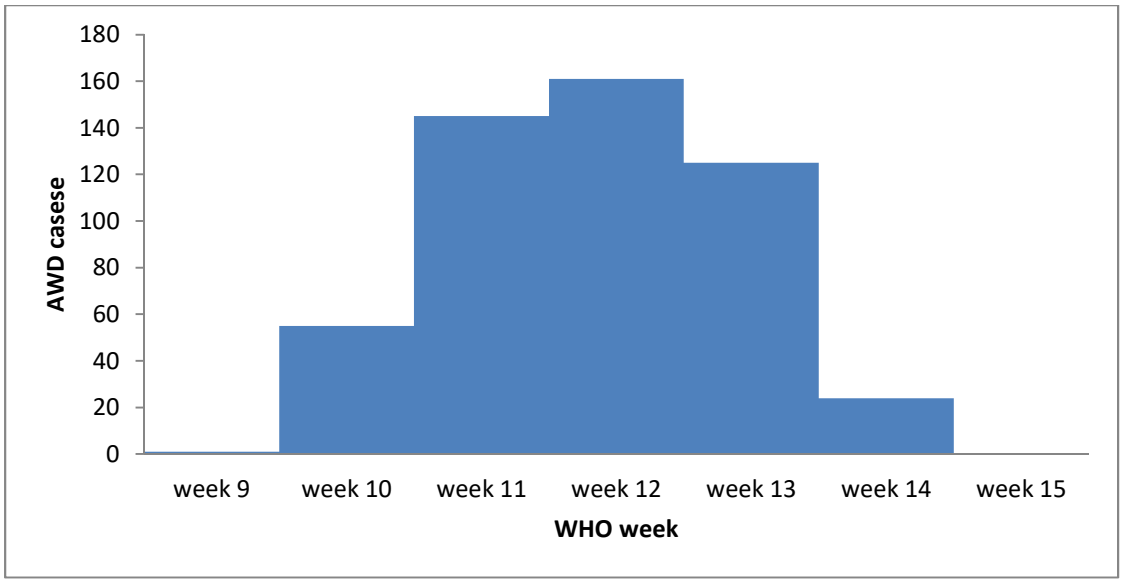


Figure: 21 Epidemic Curve of AWD Outbreak by WHO week Number, Segeg district, Somali Region, Ethiopia, March-April, 2017

The outbreak is a propagated or progressive type of outbreak which the numbers of cases were increases date to date in an alarming rate for the first two weeks. The following Epi curve illustrates the situation of the outbreak depending on time of onset (figure 3).

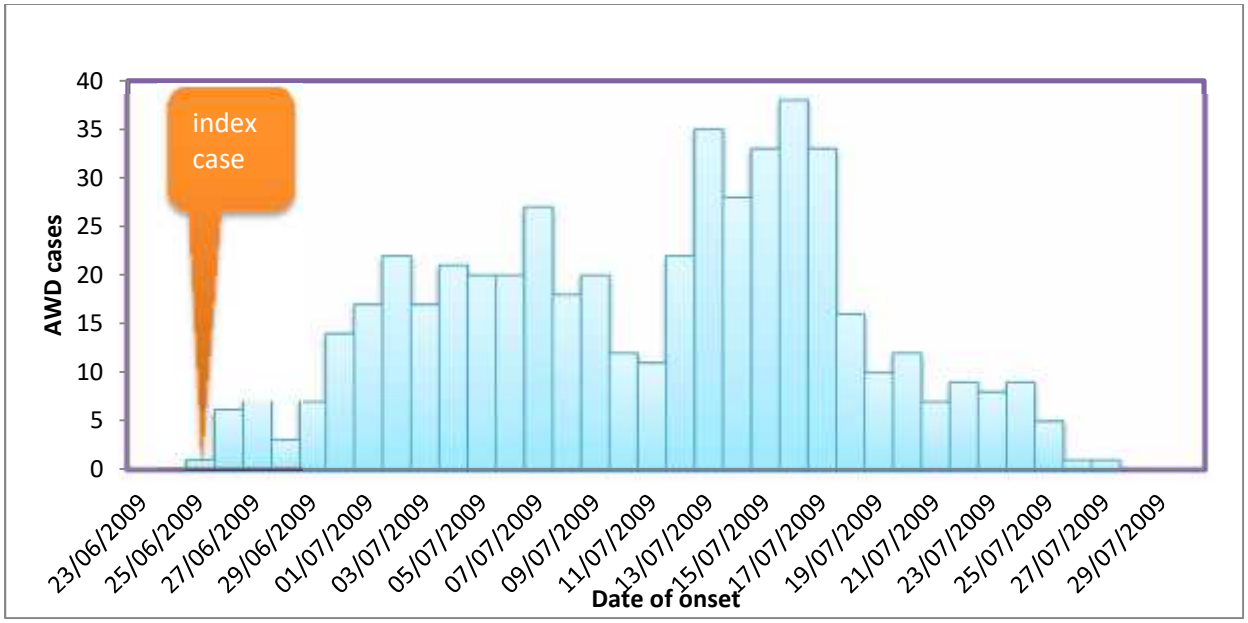


Figure:22 Distribution of AWD outbreak by Time, Segeg district, Somali Region, Ethiopia, March-April, 2009.

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Laboratory test and Result

Out of six suspected AWD cases investigated by RDT (Rapid Diagnostic Test) five (83.3%) of them were confirmed positive for *Vibrio cholera* type 01. *Escherichia coli* bacteria was isolated from water samples collected from Sulul river that residents were being used for drinking and other home purposes.

Environmental Assessment

There was poor environmental sanitation in the area. Source of drinking water for the study participants was Sulul River. 49.3 % of respondents treat water before drinking.58% of the study participants washes their hands before eating meal. The private latrine availability of the community was only 15%, 53(35.3%) of the respondent share common toilet with their neighbor and 82(54.7%) practice open defecation. All the latrines of the community hadn't roof at their top. Hand washing facilities were not available in all of assessed households near their toilets. There is no any solid waste disposal pit near their home in visited community and they used open area around their home. The latrine coverage and latrine utilization rate of the community was not known.

Socieo-demographic characteristics of the study participants

A community-based unmatched 1:2 case control study was conducted between March 4 and April 15, 2009 E.C in Segeg district to identify possible risk factors and associated vehicles of transmission. 50 cases were selected from CTC and 100 neighborhood community controls were selected. The median age for both cases and controls was 28 year with a standard deviation of 13.1 year. 52.3% of the respondents were males and 47.3% were females. Regarding marital status majority 94(62.7%) was married and 37.3% were single. All of the respondents were Muslim in religion. Occupational status of most 104(69.4%) study participants was pastoralist. For both cases and controls the majority 75(50%) of the respondents level of education was read and write followed by 1-4, 31(20.7%) and the least were grade 9-10 which is 2(1.3%). Most 111(74%) of the study subjects were from rural setting and the rest 39(26%) of them were urban residents. (Table 1)

Epidemiological and Clinical features of study participants

Among AWD cases, age ranged from 6 to 60 years, the most affected age group was 25-29 years; 23 (15.3%). AWD cases have different symptoms; the most common symptoms include Watery diarrhoea 50 (100%), Vomiting 50 (100%), General body weakness 7 (4.6%), and fever 5(3.3%).

Regarding treatment of cases, 50(100%) were treated with ORS, 36 (72%) with IV fluids and 49((98%) treated with antibiotics. 36(72%) of cases had history of close contact with individuals already diseased with AWD. 59(39.3%) of the study participants herd about AWD whereas the rest 91(60.7%) of them were not herd about AWD.

Table 12: socieo demographic characteristics of the study subjects Segeg district, Somali Region, 2017

Parameter	Level	Frequency n=150	Percent %
Age (years)	1 – 4	1	0.66
	5 – 9	19	12.6
	10 – 14	12	8
	15 – 19	20	13.3
	20 – 24	10	6.6
	25 – 29	23	15.3
	30 – 34	19	12.6
	35 – 39	11	7.3
	40 – 44	22	14.6
	45+	13	8.6
Religion	Muslim	150	100
	Catholic	0	0
	Protestant	0	0
	Orthodox	0	0
Marital status	Married	94	62.6
	Single	56	37.4
Occupational status	Student	46	30.6
	Pastoralist	104	69.4
Educational status	Not able to read and write	19	12.6
	Read and write	75	50
	1—4	31	20.6
	5—8	23	15.3
	9—10	2	1.3
Sex	Male	79	52.6
	Female	71	47.4
Residence	Rural	111	74
	Urban	39	26

Associated Risk Factors of the Outbreak

An adjusted analysis showed that persons who had a travel history to areas already affected with AWD were at greater risk of getting AWD [Crude Odds ratio (COR) = 4.51 at 95% confidence interval (CI) = 2.034-10.0, p-value = 0.00] and adjusted odds ratio 3.63 at confidence interval of 0.015-0.333, p value 0.047.

Household latrine availability was protective against acquiring acute watery diarrhoea with [Odds ratio (COR) = 0.412; at 95% confidence interval (CI) = 0.246-0.62, p-value = 0.038] and adjusted odds ratio 0.189 at 95% CI 0.043-0.818, p value 0.022.

Knowledge about the mode of transmission of Acute Watery Diarrhoea of the community was found to be protective against the disease with crude odds ratio = 0.41; at confidence interval of 95% CI: 0.196-0.868, p-value = 0.02]. But it has no association in adjusted analysis.

Hand washing before eating was also protective against acquiring acute watery diarrhoea [odds ratio (OR) = 0.092; at 95% confidence interval (CI) of 0.041-0.21, p-value = 0.00] and adjusted odds ratio 0.071 at 95% CI 0.019-0.358, p value 0.001.

Treating drinking water was protective of the illness (crude OR=0.098 at confidence interval of 95% 0.041-0.232; p-value=0.00) and adjusted odds ratio 0.133 at 95% CI 0.041-0.445, p value 0.001. It was difficult to undertake probability matched case-control study and interview more subjects during rapid epidemic investigation in a dispersed population.

Table 13: Risk Factors for AWD outbreak, Segag district, Somali Region, 2017

Sr. no	Risk factor	Cases		Controls		AOR(CI)	P value
		Yes (%)	No (%)	Yes (%)	No (%)		
1	Travel history	40(45.9)	10(15.8)	47(54)	53(84.2)	3.63(0.015-0.333)	0.047
2	Latrine utilization	6 (9.3)	44(66.6)	58 (90.7)	42(33.4)	0.189(0.043-0.818)	0.02
3	Knowledge about AWD transmission	13 (22)	37(40.6)	46 (78)	54(59.4)	0.000	0.00
4	Hand washing before eating	3 (4.4)	47(57.3)	65(95.6)	35(42.7)	0.071(0.019-0.358)	0.01
5	Water treatment	8(10.8)	42(55.2)	66(89.2)	3444.8)	0.133(0.041-0.445)	0.01
6	Close contact with AWD case	36 (36.3)	14(27.4)	63(63.7)	37(72.6)	1.62(0.422-6.21)	0.48

Conclusion

AWD still remains serious threat to public health system in Somali regional state in Segeg district in recent years. Overall attack rate and case fatality rates were high. Younger age group was highly affected by the disease. All kebeles of the district were affected by AWD outbreak and the causative agent responsible for the outbreak to occur was *V.cholerae* O1. Travel history has significant statistical association with acquiring AWD. Latrine availability, treating water with appropriate chemicals and hand washing before eating meal were found to be protective against the disease. Hence the district health office should strengthen health education on AWD transmission, prevention and control methods and restriction of population movement to affected areas with the disease. CTCs of the health center and its catchment should treat cases according to AWD case management guideline to decrease high case fatality rate. The district health office should strengthen the availability and utilization of latrine. The district health office, Education office, water office and women and children affaires offices should improve the community hand washing practice before eating meal. The district water and health office should treat drinking water sources and promote treatment of water at household level with appropriate chemicals.

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Chapter VI- Abstracts for Scientific Presentation

6.1: Acute watery diarrhea Outbreak Investigation— Segeg woreda, Nogob zone, Somali region, Ethiopia, February 2011

Authors: W Wogayehu[1], T Tesema[2,] B.Abiyot[3], S.Elias[4], A. Fana[4]

1Ethiopian Field Epidemiology and Laboratory Training Program, Addis Ababa, Ethiopia

2Kembata Tembaro zone health department

3 Ethiopian public health institutes

4Saint Paul Millennium medical college, department of Public Health, Addis Ababa, Ethiopia

Introduction: Cholera is a potentially life-threatening acute diarrheal disease caused by the toxigenic bacterium *vibrio cholerae* either type 01 or O139. The infectious agent is acquired through consumption of contaminated water or food. The source of contamination is usually the feces of an infected person. The aim of this is study was to investigate acute watery diarrhea outbreak, identify potential risk factors and provide the possible prevention and control measures.
Methods: un-matched community based 1:2 case control study was conducted from 10th March to 15th April 2017 in segag district. By using outbreak investigation structured questionnaires, all the outbreak investigation team and one language translator conducted home to home visit and administered the questionnaires. The data was entered in to Epi Info and exported to SPSS for analysis of association between possible risk factors and acute watery diarrhea occurrence.

Result: A total of 759 suspected acute watery diarrhea cases and five RDT confirmed cases with 26 deaths were reported between March 10 and April 15, 2009. The overall attack rate and case fatality rate was 1.26% and 3.4% respectively. Age group 5-14 was the most affected population. An adjusted analysis showed that persons who had a travel history to areas already affected with acute watery diarrhea were at greater risk of getting acute watery diarrhea [adjusted Odds ratio (AOR) = 3.856 at 95% confidence interval (CI) = 1.018-9.56, p-value = 0.047]. Household latrine availability was protective against acquiring acute watery diarrhoea with adjusted odds ratio 0.181 at 95% CI 0.042-0.780, p value 0.022. Treating drinking water was protective of the illness with adjusted odds ratio 0.134 at 95% CI 0.041-0.445, p value 0.001.

Conclusion: still acute watery diarrhea remains serious threat to public health system in Somali regional state in Segeg district. Overall attack rate and case fatality rates were high. Hence the district health office, other concerned sectors and partners should strengthen health education on prevention and control of acute watery diarrhea. Health center should treat cases according to acute watery diarrhea case management guideline to decrease high case fatality rate.

Key words: Acute Watery Diarrhoea, V.cholerae, Segag, Ethiopia.

6.2 seroprevalence and associated factors of hepatitis B and C viruses among pregnant women attending Antenatal care in Durame hospital, Southern Ethiopia, 2018

Authors: W Wogayehu[1], T Tesema[2,] T Habtamu[3], S.Elias[4], A Misrach[4]

1Ethiopian Field Epidemiology and Laboratory Training Program, Addis Ababa, Ethiopia

2Kembata Tembaro zone health department

3 Durame General Hospital

4Saint Paul Millennium Medical college department of Public Health, Addis Ababa, Ethiopia

Background: Hepatitis is the inflammation of liver caused by viral infections. Viral hepatitis is a leading cause of maternal complication and vertical transmission that cause fetal and neonatal hepatitis which can have serious effects on the neonate, leading to impaired mental and physical health later in life. This study was carried out to determine the seroprevalence and risk factors of hepatitis B and C viruses among pregnant women attending Antenatal care in Durame general hospital, Kembata Tembaro zone Ethiopia.

Methods; A hospital based cross sectional study design was conducted from September to October 2017. Data on socieo-demographic characteristics and potential factors was collected using pre-designed questionnaire. By using simple random sampling method blood samples were collected from 263 pregnant women. Serologic test kits were used to detect the presence of hepatitis B surface antigen and anti-hepatitis C virus antibody in serum samples. The collected data was entered in to EPI info and analyzed using SPSS software. Logistic regression analysis was conducted to assess statistically significant association between associated factors and hepatitis B Virus and hepatitis C Virus status.

Result; Sero-prevalence of hepatitis B and C virus infections was found to be 5.3% and 2.2% respectively. No pregnant women were co infected with these viruses. There was no statistically significant association between socieo-demographic variables and hepatitis B and C virus infection. Among potential risk factors blood donation (AOR=1.63, 95%CI=1.32-90.4), family history of liver disease (AOR= 2.98 95%CI=4.32-90.4) and multiple sexual exposure (AOR=3.06 95% CI=4.68-97.7) were significantly associated with hepatitis B virus infection. History of previous surgery (AOR= 2.66 95% CI=1.64-124.8) and family history of liver disease (AOR=1.14 95% CI=0.53-18.68) were significantly associated with hepatitis C virus infection.

Conclusion; This study demonstrated intermediate prevalence of hepatitis B and C viruses infection. No co infection with these viruses and statistically significant association was observed between socieo-demographic variables and hepatitis B and C virus infection. Blood transfusion, family history of liver disease and multiple sexual exposures were potential factors for hepatitis B and history of previous surgery and family history of liver disease were risk factors for hepatitis C virus infection. Hence screening pregnant women for hepatitis B and C virus infection and

provision of health education about the risk factors, mode of transmission and prevention was recommended.

Key words; Hepatitis B Virus, Hepatitis C virus, Antenatal care, Pregnancy, Seroprevalence, Risk factor

6.3 Under Five Measles Surveillance Data Analysis, South Nations Nationalities and People (SNNP) Region, Ethiopia, 2006-2015

Authors: W. Wogayehu[1], B.Abiyot[2], S.Elias (MD,MPH,PhD)[3], A. Fana[3]

1Ethiopian Field Epidemiology and Laboratory Training Program, Addis Ababa, Ethiopia

2 Ethiopian public health institutes

3Saint Paul Millennium medical college, department of Public Health, Addis Ababa, Ethiopia

Background: Measles is a viral disease that spreads from person to person. It causes an estimated 2.6 million deaths each year worldwide. The objective of this study was to describe measles distribution by person, place, and time and recommend possible solutions.

Methods: measles cases were analyzed from national measles case-based surveillance system data base reported from SNNP region during January 2006 to January 2015. Epidemiologically linked, confirmed and suspected cases were included. The proportion of confirmed measles cases was computed. Vaccination status and distribution of cases by age place and sex was presented. Data was entered into a computer, edited, cleaned and analyzed using spss version 21

Result: Cumulatively 8737 measles cases and 603 deaths with CFR 6.9% were reported from SNNP region from January 2006 to 2015.Majority of cases were from Keffa, sidama and wolyta zones. Of these 4249 cases were reported by line list while 330 cases were reported by case based. Of the total reported measles cases 1-4 year age groups were the most affected.Concerning sex 4680(53.5%) were males and 4055(46.5%) were females. Among investigated cases 3439(83.8%) were confirmed for measles. Overall, 26.3% of cases vaccination status was unknown and 20.3% were not vaccinated.

Conclusion: The analysis revealed that under- five age groups are still at risk of contracting measles in the region and the incidence rate is higher among 1-4 age groups. It indicates the high number of zero doses and unknown vaccination status. Measles surveillance system should be strengthened in the region, especially zones with high measles cases.

Keywords: Surveillance, Incidence, under five, Measles, Ethiopia

Chapter VII research paper

7.1 Sero-Prevalence and Risk Factors of Hepatitis B and C Viruses among Pregnant Women Attending Antenatal Care in Durame General Hospital Kembata Tembaro Zone, Ethiopia, 2018

Abstract

Background: Hepatitis is the inflammation of liver caused by viral infections. Viral hepatitis is a leading cause of maternal complication and vertical transmission that cause fetal and neonatal hepatitis which can have serious effects on the neonate, leading to impaired mental and physical health later in life. This study was carried out to determine the seroprevalence and risk factors of hepatitis B and C viruses among pregnant women attending Antenatal care in Durame general hospital, Kembata Tembaro zone Ethiopia.

Methods; A hospital based cross sectional study design was conducted from September to October 2017. Epi info stat calc formula was used to calculate sample size. Data on socieo-demographic characteristics and potential risk factors was collected using pre-designed questionnaire. By using simple random sampling method blood samples were collected from 263 pregnant women. Serologic test kits were used to detect the presence of hepatitis B surface antigen and anti-hepatitis C virus antibody in serum samples. The collected data was entered in to EPI info and analyzed using SPSS software. Logistic regression analysis was conducted to assess statistically significant association between socieo-demographic variables and associated factors and hepatitis B Virus and hepatitis C Virus status and p value less than 0.05 was considered as significant.

Result; Sero-prevalence of hepatitis B and C virus infections was found to be 5.3% and 2.2% respectively. No pregnant women were co infected with these viruses. There was no statistically significant association between socieo-demographic variables and hepatitis B and C virus infection. Among potential risk factors blood donation (AOR=1.63, 95%CI=1.32-90.4), family history of liver disease (AOR= 2.98 95%CI=4.32-90.4) and multiple sexual exposure (AOR=3.06 95% CI=4.68-97.7) were significantly associated with hepatitis B virus infection. History of previous surgery (AOR= 2.66 95% CI=1.64-124.8) and family history of liver disease (AOR=1.14 95% CI=0.53-18.68) were significantly associated with hepatitis C virus infection.

Conclusion and Recommendation; this study demonstrated intermediate prevalence of hepatitis B and C viruses. No co infection with these viruses and statistically significant association was

observed between socieo-demographic variables and hepatitis B and C virus infection. Blood transfusion, family history of liver disease and multiple sexual exposures were potential risk factors for hepatitis B and history of previous surgery and family history of liver disease were risk factors for hepatitis C virus infection. Hence screening pregnant women for hepatitis B and C virus infection and provision of health education about the risk factors, mode of transmission and prevention was recommended.

Key words; Hepatitis B Virus, Hepatitis C virus, Antenatal care, Pregnancy, Seroprevalence, Risk factor

1. Introduction

1.1 Background

Hepatitis is the inflammation of liver caused by viral infections. Five hepatotropic viruses (A to E) are known to cause hepatitis. Of these, hepatitis B virus (HBV) and hepatitis C virus (HCV) are of greater importance and among the most frequent viral infections in humans (1). HBV and HCV were discovered in 1963 and 1975 respectively (2). Viral hepatitis is a leading cause of maternal complication and vertical transmission that cause fetal and neonatal hepatitis which can have serious effects on the neonate, leading to impaired mental and physical health later in life (3). Viral hepatitis B and C are often discovered after several years of evolution at the stage of complications, hence the name of silent killer (4). The hepatitis B and C viruses cause chronic viral hepatitis, a major global health problem responsible for 57 % of liver cirrhosis and 75 % of primary liver cancer cases, respectively (5).

Worldwide 350 to 400 million people are infected with HBV, accounting for 1 million deaths per year. Between 130 and 170 million people are infected with HCV, causing over 350,000 deaths per year (6).

The World Health Organization (WHO) estimates the burden of HBV infection to be approximately 2 billion, >350 million chronically infected with HBV, and 500,000–700,000 patients die annually as a result of HBV-related liver disease, such as liver cirrhosis, end-stage liver disease, or hepatocellular carcinoma, with most of these deaths in developing countries. Hepatitis C virus (HCV) infection is another major worldwide public health concern. The WHO estimates that around 3% of the world's population has chronic HCV infection, with more than one million new cases annually, the majority of which occurring in Africa(7).

Hepatitis B virus (HBV) is a major blood-borne and sexually transmitted infectious agent and approximately 100 times more contagious than human immunodeficiency virus (HIV) (8). HBV account for a substantial portion of liver diseases worldwide and infected individuals can remain asymptomatic for decades. However, more than 80% of them become chronic carriers which result in an increased risk of liver cirrhosis, liver cancer and liver failure 20 - 30 years later (9).

Transmission of the hepatitis B virus from asymptomatic carrier mothers to their off springs during the perinatal period is believed to be a major mode of transmission of HBV (10). Pregnant mothers who test positive for both hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg) have 70– 90% risk of transmitting infection to their newborn infants and about 10–40% risk if they test positive for only HBsAg (11).

Hepatitis C virus (HCV) was first referred to as "non-A, non-B hepatitis," and was discovered during the late 1980s. It was uncovered when a team of doctors was studying hepatitis A and B infections (HAV and HBV respectively) in patients who had received blood transfusions (12).
Most acute and chronic HCV infections remain asymptomatic for years and, except with expensive screening tests, carriers are usually not identified. Liver cirrhosis develops in 20% of HCV infected patients after 10-20 years, while liver cancer usually appears after 20-40 years post infection. Treatment is limited, very costly, and only partly effective. No vaccine is available or expected in the near future ((2), (13)).

Therefore, the burden of hepatitis B and C viruses and possible risk factors should be known and appropriate prevention and control methods should be taken. Thus this study aims to investigate the prevalence and possible risk factors for HBV and HCV infection among pregnant women in kembata Tembaro zone.

1.2 statement of the problem

Despite the existence of a safe and effective vaccine, HBV continues to be a substantial and devastating health problem whose new cases are still being reported throughout the world(14). Globally, there are about 240 million people with chronic HBV infection and 130 to 150 million people with chronic HCV infection, reaching endemic proportions in sub Saharan Africa. HBV is estimated to result in 780,000 deaths and HCV in 350,000 to 500,000 deaths annually (1).

Although it is difficult to assess the exact burden of HBV in Africa, between 56% and 98% of the adult population show evidence of past exposure to HBV infection, and the seroprevalence of hepatitis B surface antigen (HBsAg) has been estimated to range from 6% to 20% (8). The overall prevalence of HCV in Sub-Saharan Africa is 3.0%. The central African region has the highest estimated prevalence of 6%, west Africa has an estimated prevalence of 2.4%, and southern and east Africa with the lowest estimated prevalence of 1.6% (13). As part of other sub-Saharan Africa countries, the prevalence of HIV and liver disease is high and posing a great public health problem in Ethiopia. Apart from its significant prevalence, liver disease contributes approximately 12 % of the hospital admissions and 31 % of the mortality in medical wards of Ethiopian Hospitals (3).

In Ethiopia, studies among pregnant women have shown moderate endemicity, with the prevalence of HBsAg positivity ranging from 3% to 6.1% (8) and the overall seroprevalence of hepatitis C is estimated to be around 2 %, and infection is most commonly associated with contaminated medical instruments (5).

In Ethiopia only few Hospital based cross sectional studies on seroprevalence of Hepatitis B and C have been previously done shown that hepatitis B and C are endemic in Ethiopia and the prevalence varies from region to region. However in kembata Tembaro zone institution based studies were not conducted on the prevalence of HBV and HCV among pregnant women attending ante natal care. The aim of current study was to measure the prevalence of hepatitis B and C viruses and possible associated risk factors among pregnant women attending ANC in Durame general Hospital.

1.3 Significance of the study

Preventing mother to child transmission of hepatitis B virus is fundamental for decreasing the burden of disease in sub-Saharan Africa countries including Ethiopia where it is endemic. An effective strategy for reducing the incidence of viral infections is screening pregnant mothers during ANC follow up and post exposure prophylaxis consisting of HBV vaccination immediately after delivery in infants born to HBsAg positive mothers, jointly with immunoglobulin prophylaxis. Therefore the finding of this study will have the following Significances.

- It will provide information on prevalence of HBV and HCV infection in pregnant women.
- It will give clues for means of prevention and control activities.
- It can be used as base line information to those who are interested for further study in the same area.
- It can be used by those who are responsible for planning health development activity.

2. Literature review

2.1 Prevalence of HBV and HCV

Studies on prevalence of HBV and HCV conducted in different countries have shown varied result. These differences in prevalence is due to variation in respective populations under study, and the performance of the health systems in terms of how well the control and prevention programs are implemented in the respective countries. It is estimated that worldwide 2 billion and 13 to 170 million people are infected with HBV and HCV respectively and 350 million are carriers of HBV According to the global estimates (15),(4)). Estimates indicate that globally three to four million persons are newly infected with HCV each year (16).

In Europe, estimates of antenatal HBsAg prevalence were found for 11 countries, ranging from 0.1% to 4.4%. Estimates of antenatal anti-HCV-Antibody prevalence were found for 6 countries, ranging from 0% to 1.7%. The antenatal HBsAg prevalence was on average 3 times higher than the general population prevalence. In Italy and the United Kingdom, the antenatal anti-HCV-Antibody prevalence was lower than the general population prevalence. In Germany and Greece, it was higher (6).

In sub-Saharan Africa, chronic infection with the hepatitis B virus is a profoundly important public health issue characterized by high prevalence, frequent co-infection with HIV, and sub optimally applied prevention and control strategies. Hepatitis B virus is endemic in Africa next to Asia, with a seroprevalence rate of between 8 and 20 %. West Africa is particularly affected, with 95 % of the adult population showing indicators of previous hepatitis B virus infection while the regional hepatitis C prevalence is lower than hepatitis B at 5.3 % of the general population. The world's highest prevalence is in Egypt (17.5 %), followed by Cameroon (13.8 %) and Burundi (11.3 %). Africa also has the highest hepatocellular carcinoma incidence rate in the world, partly due to a 5–25 % co-infection rate with HIV, which accelerates the progression to cirrhosis and hepatocellular carcinoma (5). The mean prevalence of Hepatitis B surface antigen is 10.3% in Sub Sahara Africa with the general carrier rate ranging from 9-20% (17).

Study conducted in Uganda on prevalence of Hepatitis B virus infection among pregnant women revealed the overall prevalence of HBsAg positivity 11.8%. HBsAg was positive in 7 of the 47 HBsAg positive women (14.9%). HBsAg-positive mothers were significantly younger than HBsAg-negative mothers (p=0.002 ;). The antibody test for HIV infection was positive among 9.3% (n=37) of participants, but there was no statistically significant association between HIV infection status and hepatitis B prevalence, OR 0.89 (CI 0.30 to 2.65, p=0.839)(11)

In Ethiopia, there is a lack of nationwide representative data on hepatitis B and hepatitis C infections. It is, therefore, difficult to present the incidence, prevalence, and mortality rates accurately. A national survey conducted and regional estimates have shown wide geographic and socioeconomic variation in hepatitis B prevalence, ranging between 5.7 and 10.8 % (5). Hospital based cross sectional study conducted on the prevalence of HBV and HCV in Felege Hiwot Referral Hospital, northwest Ethiopia shown the prevalence of 4.4 and 0.26 %, respectively. None of the pregnant women were co-infected by HBV and HCV (1). Another study conducted in Addis Ababa revealed the overall prevalence of hepatitis B virus infection of 6 % (3). In Ethiopia, Hepatitis B is endemic with an average prevalence of 10.8 %, and the prevalence of Hepatitis C is 2 % (5).

In South nations, nationalities and people region only one hospital based cross sectional study has been done to measure the prevalence of HBV infection and its associated risk factors. In this study the prevalence of HBV is 7.8% (8).

2.5 Risk factors of HBV and HCV

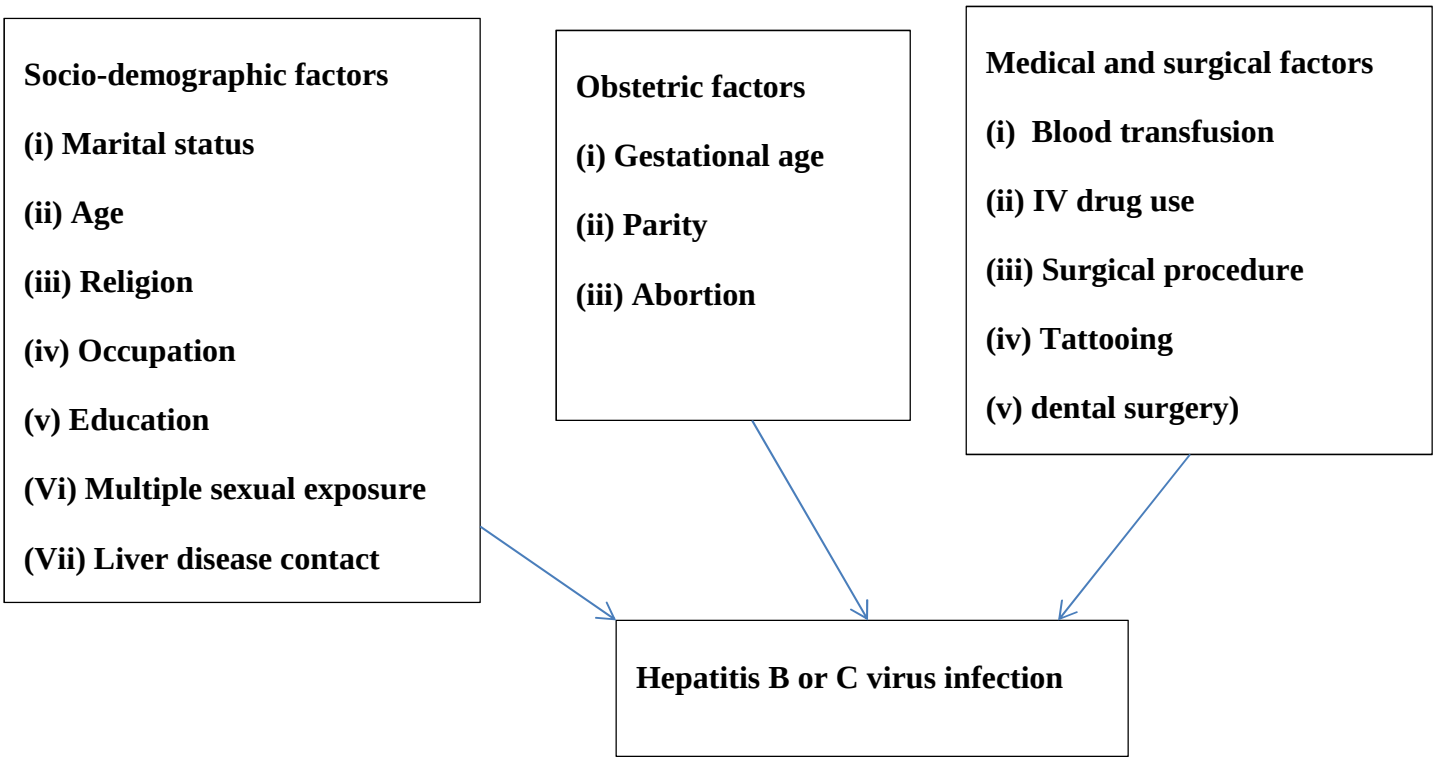
Studies conducted on assessment of risk factors of HBV shown that HBV is transmitted through parenteral or mucosal exposure to infected blood and body fluids, usually either by a vertical or horizontal route early in life in highly endemic areas, resulting in a high rate of chronic infections (8).

In study conducted in Addis Ababa multivariate analysis of different variables indicated that those having a history of abortion had a 19 times more chance of positivity for HBsAg than those without [AOR = 19 (CI 2.78–130.367); p = 0.003]. Similarly, those with a history of previous surgery had a 9.8 times more chance of positivity for HBsAg compared to their counterparts [AOR = 9.8 (CI 1.392–69.610); p = 0.022]. Moreover, the odds of having HBsAg positivity was 7.7 times more likely among those who were with experience of tattoo [OR = 7.7 (CI 1.185–50.28); p = 0.033](18)

Earlier studies have found an association between the prevalence of HCV infection and the known risk factors of this infection i.e., blood transfusion, intravenous drug abuse, multiple sexual partners, and homosexuality. In a study from northern Italy, the principal risk factors were history of intravenous drug abuse (32%) and exposure to blood products (24%).(18)

Several studies carried out on transmission channels of HCV revealed that the major channels for HCV transmission are all related to exposure to infected blood and blood products: intravenous drug use (IDU), transfusion of untested blood, unsterile medical and dental procedures, and traditional medical and cosmetic procedures like scarification and tattoos involving blood exposure. Controversy continues about whether to attribute more than a small fraction of HCV infections to sexual contact or mother-to-child transmission (MTCT). Transmission is estimated to be less than 5% for both. Other risk factors involving household exposures like eating utensils, shaving razors, and toothbrushes are felt to be minimum risk factors for HCV acquisition (13).

Figure1: Conceptual framework adapted from review of literatures on hepatitis B and C viruses and associated factors



3. Objectives

3.1 General objective

- To determine the seroprevalence and risk factors of hepatitis B and C viruses among pregnant women attending ANC in Durame general hospital, KT zone Ethiopia.

3.2 Specific Objectives

- To determine the prevalence of HBV and HCV among pregnant women
- To identify associated risk factors of HBV and HCV
- To measure the level of co infection of HBV and HCV

4. Methods and Materials

4.1 Study Area

The study was conducted in kembata Tembaro zone Durame general hospital. It is one of the 62 hospitals in Southern Nations Nationalities and Peoples region (SNNPR) in Ethiopia. In kembata tembaro zone one general hospital 31 health centers, 136 health posts, 10 medium clinics, 46 primary clinics and 12 drug stores were providing health service. The hospital is located in Durame, the capital city of the kembata Tembaro zone, 335 km south from the capital of Ethiopia, Addis Ababa, and is a secondary-level general hospital that provides health services to over 898,921 inhabitants in the zone. The hospital ANC clinic provides routine antenatal screening services, such as HIV testing, hemoglobin determination, blood group testing, rapid plasma reagin testing, and urinalysis (for glucose, proteins, and infection) for more than 15 pregnant women per day.

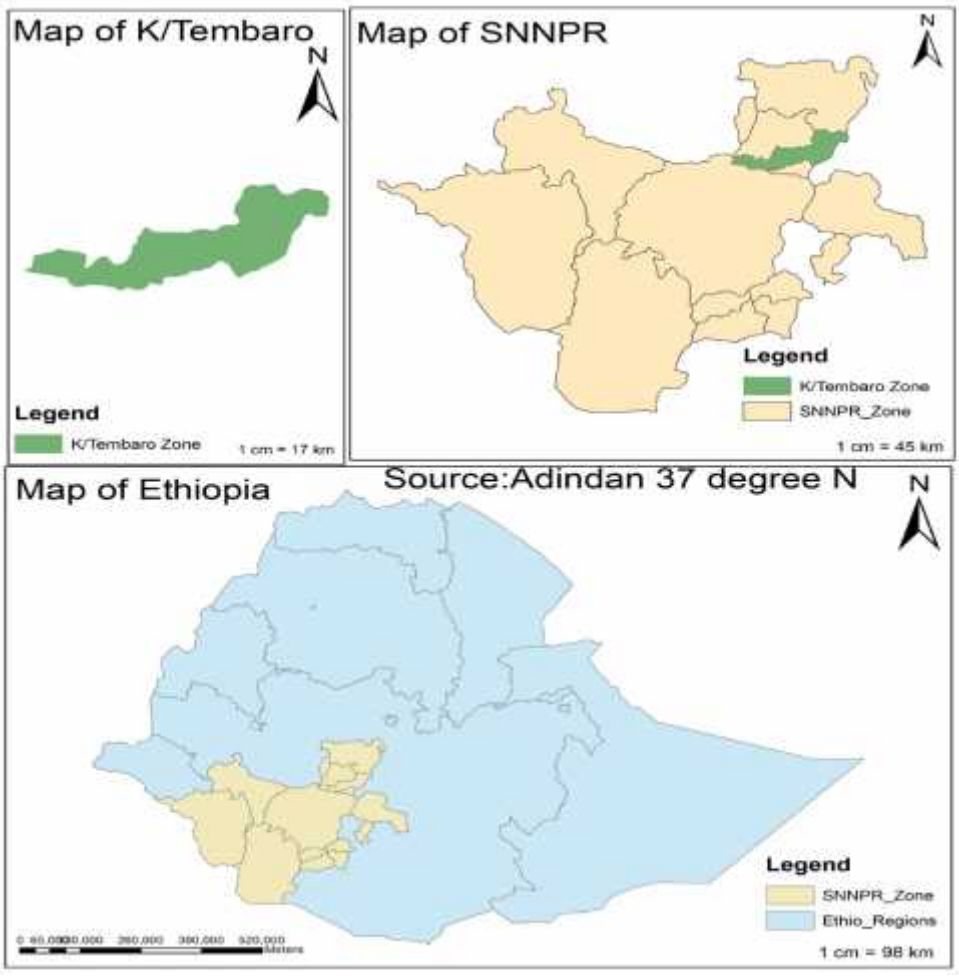


Figure 23: Map of Kembata Tembaro zone, SNNP region, 2018

4.2 Study design and period

A hospital based cross sectional study design was conducted from September to October 2017 to determine the Sero-prevalence of hepatitis B and C viruses and associated risk factors among pregnant women attending ANC in Durame general hospital.

4.3 Source population

The source population was all pregnant women in Durame general hospital catchment area.

4.4 Study population

The study population was pregnant women who followed ANC in Durame general hospital from September to October 2017.

4.5 Operational definitions

Ante natal care follow up: pregnant women who followed antenatal care at least once during the current pregnancy in Durame general hospital from September to October 2017.

Abortion: terminated pregnancy by any of surgical methods in previous pregnancies in women attending ANC in Durame general hospital.

Multiple sexual exposures: sexual exposure in which women attending antenatal care in Durame general hospital was exposed for two or more sexual partners.

Blood transfusion: the transferred blood or blood component from donor to pregnant women attending antenatal care in Durame general hospital in here previous life.

Hepatitis B virus infection: the status in which laboratory test result of pregnant women attending antenatal care in Durame general hospital is positive for hepatitis B virus surface antigen.

Hepatitis C virus infection: the status in which laboratory test result of pregnant women attending antenatal care in Durame general hospital is positive for anti-hepatitis C virus antibody.

Intravenous drug use: medication given by administration of any injectable drug through venous route in her previous life to women attending antenatal care in Durame general hospital.

Surgical procedure: a medical procedure involving an incision with instruments performed to repair damage or arrest disease in women attending ANC in Durame hospital.

Tattoo: marked skin with indelible patterns, pictures, and legends in to dermis layer of the skin in women attending ANC in Durame general hospital.

4.6 Inclusion and exclusion criteria

Pregnant women following ANC in the study period in Durame general hospital, volunteer to participate and give consent were included in the study. Pregnant women who were vaccinated against HBV and who do not give consent to participate were excluded from the study.

4.7 Study variables

4.7.1 Dependent variable

- Sero status of HBV or HCV of pregnant women

4.7.2 Independent variables

- Age
- Residence
- Educational status
- Occupational status
- Income
- marital status
- History of blood transfusion
- History of abortion
- History of households contact
- Multiple Sexual exposures
- Surgical procedures
- Dental surgery
- intravenous drug use and
- Tattooing was examined as possible associated factors for hepatitis B and C viruses.

4.8 Sampling technique

The study participants were selected by systematic sampling method. Every second woman was selected until a total of 12 women were enrolled per day. If the second woman was not consent then was replaced by the next woman.

4.9 Sample size determination

The sample size was calculated using stat calc function of Epi-info using the confidence level of 95%, power of 80%, In the study conducted in southern Ethiopia the prevalence of hepatitis B is 7.8% (8) and this prevalence was used to calculate sample size for prevalence. But for associated factors odds ratio and history of house hold contact was taken from the study conducted in Felege Hiwot hospital northern Ethiopia (1) was used to calculate sample size for associated factors.

Two sided level of significant (1−alpha):95%

Power (1−beta, % chance of detecting):80

Ratio of sample size: 1

Percent of not exposed to history of household contact with outcome: 3.3.

Percent of exposed to history of household contact with outcome: 20.

Odds ratio: 5.47.

Total population, design effect and non- response rate were considered.

$N = \frac{Z\alpha^2/2P\ Q}{d^2}$

Where:

N = sample size;

Zα/2 = standard normal distribution abscissa corresponding to 95% confidence interval (1.96);

P = proportion of HBsAg reported in similar study noted above (19.4%)

Q = (1-P); and

d = desired level of precision (5%).

$\frac{n= (1.96)^2 x\ 0.194(1-0.194)}{(0.05)2}$ = 240 for prevalence of Hepatitis B and C viruses.

Using EPI info, calculated sample size for analytic study was 204+10%= 225 and sample size for prevalence study was 246+10%= 263.

4.10 Data collection tool

Data was collected by using pre-designed questionnaire and laboratory diagnosis

4.11 Data collection and processing

4.11.1 Socieo-demographic characteristics and potential risk factors

Study participants who fulfilled eligibility criteria were interviewed by experienced midwife nurses to get relevant information using pre designed questionnaire. The questionnaires included independent variables like age, area of residence, level of education, occupational status, income, marital status, parity status, and gestational age and potential risk factors like history of dental and surgical procedures, tattooing, history of delivery at traditional birth attendants, abortion, history of house hold contacts, blood transfusion and ear piercing in jewelries were assessed.

4.11.2 Blood sample collection and processing

Five milliliters of blood was collected by medical laboratory technicians and left for 30 minutes to facilitate clotting. Then the clotted sample was centrifuged to separate serum from blood cells. The serum was divided in to two aliquots for HBsAg and HCV antibody screening.

4.12 Laboratory Diagnosis

4.12.1 Blood sample and Serological test

After written informed consent obtained, 5 ml of blood sample collected for routine ANC follow up tests using disposable EDTA tubes under aseptic condition was used. The tubes were numbered and processed at the time of Blood sample collection. The blood sample taken was centrifuged for 5 minutes at speed of 3000rpm and the serum was separated. All serum samples were tested for HBsAg and anti-HCV using rapid screening method according to the manufacturer's instruction (Zhejiang Orient Gene Biotech Co., Ltd, China). The kit has a sensitivity of 98.9% and specificity of 98.57%.

HBsAg and anti-HCV Tests:

One step tests, rapid, self-performing, qualitative, immunochromatographic techniques that detect presence of HBsAg and anti-HCV in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ ml.

Principles

a) For HBsAg: one step test that utilizes the principle of immuno-chromathography, a unique two site immunoassay on a membrane. As the test sample flows through the membrane assembly of the dipstick, the colored monoclonal anti-HBsAg colloidal gold conjugate complexes move with HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by another monoclonal anti-HBsAg antiserum coated on the membrane leading to formation of a pink-purple colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex, if any moves further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region, forming a pink/purple colored band. This control band serves to validate the test result (19).

b) For anti-HCV: one step test that utilizes the principle of immuno-chromathography, a unique two site immunoassay on a membrane. As the test sample flows through the membrane assembly of the dipstick, the colored HCV antigen colloidal gold conjugate complexes move with anti-HCV in the sample. This complex moves further on the membrane to the test region where it is immobilized by another HCV antigen coated on the membrane leading to formation of a pink-purple colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complexes, if any moves further on the membrane and are subsequently immobilized by the anti-HCV coated on the membrane at the control region, forming a pink/purple colored band. This control band serves to validate the test result(20).

4.13 Data quality control

The quality of data was controlled starting from the time of questionnaires preparation. Training was given for supervisor and data collectors on the purpose of study and procedures of data collection for 1 day prior to study. During data collection, the supervisor received questionnaires from data collectors and review for completeness, accuracy, and consistency. Standard operating procedure (SOPs) was followed during laboratory analysis and known Positive and negative sera for HBV and HCV were used to check the validity of the test kits.

4.14 Data analysis and interpretation

The collected data was entered and analyzed using SPSS software (version 21). Data was analyzed and summarized in terms of frequencies and the result of the study was presented in tables. Descriptive statistics and binary logistic regression analyses were carried out to describe the variables and to identify factors associated with HBV and HCV infection, respectively. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated, and p-values <0.05 were considered to indicate statistical significance.

4.15 Ethical consideration

Ethical clearance was obtained from ethical review board of SPHMMC. After explaining the objective of the study verbal informed consent and written consent was obtained from each of the study participants to collect blood sample and socieo-demographic data. Study participants whose laboratory result was positive for HBsAg and HCV antibody were linked to clinicians for possible follow up and treatment. Information gathered during the study period was kept confidential.

5. Result

5.1 General characteristics of the study participants

A total of 263 pregnant women were included in this study conducted from October to December 2017. The mean age of the study participants was 26.25 years (SD± 5.11) with majority of the pregnant women falling with in age group of 20-24 years This age group composed 87(33%) of the total pregnant women and age group 40-44 composed of the least number of pregnant women. Majority of the study subjects were married 246(93.2%) followed by divorced 15(5.7%) and cohabiting 3(1.1%). Of the study participants 57(21.6%) did not attended formal education, 82(31.1%) attended primary school, 69(26.1%) attended secondary school and 56(21.2%) certified with diploma and above certificate. Of the total majority 156(59.1%) were protestant religion followers followed by orthodox 39(14.8%) and catholic 35(13.3%) religion followers. Regarding occupational status majority 91(34.5%) of the study participants were housewife, 90(34.6%) were daily laborers, 57(21.6%) were government employees, 41 (15.5%) were merchants and 16(6.1%) were students. Majority 166(44.1%) of the pregnant women have monthly income of <500 Ethiopian Birr. 100(38%) of the study participants were with Primigravidea and 62.1% of them were with multigravidea parity status. Of the study participants133 (50.5%) were delivered their previous birth at health institution, 100(38%) were not delivered 23(8.7%) were delivered at home and the rest 7(2.1%) were delivered with traditional birth attendants. Among 263 pregnant women 141(53.8%) were urban residents and 122(46.2%) were from rural settings (Table 1).

Table 14: Socieo- demographic characteristics of the study participants, Durame hospital, SNNP region, Ethiopia, 2018

parameter	level	Frequency	percent
		n=263	%
Age (years)	15-18	20	7.6
	19-24	89	33.8
	25-29	80	30.4
	30-34	58	22
	35-39	14	5.3
	40-44	2	0.76
marital status	Marred	245	93.2
	Single	0	0
	Cohabiting	3	1.1
	Divorced	15	5.8
residence	Urban	141	53.6
	Rural	122	46.3
educational status	no formal education	57	21.6
	Primary	82	31.1
	Secondary	68	25.8
	Diploma & above	53	20.5
occupation	Housewife	90	34.6
	Daily labor	57	21.6
	Private employee	5	1.9
	Government employee	53	20.1
	Student	16	6
	Merchant	41	15.5
monthly income	<500	116	44.1
	500-1000	82	31.1
	>1000	65	24.7
parity status	Primigravidea	100	38
	Gravidea two	86	32.7
	Multigravidea	77	29.2
gestational age	1st trimester	69	26.2
	2nd trimester	101	38.4
	3rd trimester	93	35.4
previous delivery	Not delivered	100	38
	Home	23	8.7
	Health institute	133	50.5
	TBA	7	2.7
history of abortion	No	209	79.5
	Yes	54	20.5

5.2 HBV and HCV seroprevalence

In this study 20 pregnant women (7.5%) had serological evidence of infection with both hepatitis B and hepatitis C virus infection. Of these the seroprevalence of HBsAg and anti HCV antibody was 14(5.3%) and 6(2.2%) respectively (Table 2).

There was no serological evidence of co-infection with both HBV and HCV among pregnant women.

Table 15: Seroprevalence of hepatitis B and C infections among the study subjects, Durame hospital, SNNP region, Ethiopia, 2018.

Variables	**Status**	**Total (%)**	**Remark**
HBsAg	positive	14(5.3)	
	Negative	249(94.7	
Anti HCV Antibody	positive	6(2.2)	
	Negative	257(97.8)	
Co infection (HBV &HCV)	positive	0(0)	
	Negative	263(100)	
Total		263(100)	

5.3 Associations of HBsAg Sero-prevalence and socio-demographic characteristics

The prevalence of HBV infection in relation to residence setting showed that of the total 141 urban and 122 rural residents was 5.6% and 4.9% respectively, tested positive for HBsAg. However no statistically significant association was determined between seroprevalence of HBsAg and residence (p=0.52).HBsAg Sero-positivity was detected in most age groups except 35-39 and 40-44 years old. In the age group 25-29 the highest age specific prevalence was identified. From 81 pregnant women screened in this age group 6(7.4%) tested positive for HBsAg. There was no statistically significant association between distribution of HBsAg Sero-prevalence and age categories (p=0.351).

Majority of the study participants 246(93.1%) were married of which 14(100%) were tested positive for HBsAg. None of single or divorced pregnant women were tested positive for HBsAg. There was no statistically significant association between HBsAg Sero-positivity and the marital status of the study subjects (p=0.481). Occupation wise the highest prevalence 20% Sero-positivity of HBsAg was detected among pregnant women who are privately employed followed by daily laborers (7%). However there was no statistically significant association was observed between HBsAg and occupation of the study participants (p=0.648). The highest (7%) frequency of HBsAg Sero-positivity was detected among pregnant women who did not attended formal education followed by pregnant women who attended primary and secondary school respectively. There was no statistically significant association between HBsAg Sero-positivity and educational status of the study subjects (p=0.422). The highest Sero-prevalence (7.3%) of HBsAg was observed among pregnant women who earn monthly income of 500-1000 Ethiopian Birr. There was no statistically significant association between HBsAg Sero-positivity and monthly income of the study subjects (p=0.99). The prevalence of HBV infection among women who are pregnant for the first time was 6% whereas it was 1.1% and 7.7% among gravidea two and multigravidea respectively. However there was no statistically significant association between HBsAg Sero-positivity and parity status of the study participants (p=0.45). The highest (6.4%) frequency of HBsAg Sero-positivity was detected in women who are in third trimester followed by first and second trimesters. There was no statistically significant association between HBsAg Sero-positivity and gestational age of the study subjects (p=0.26). Regarding place of previous birth attended, 8(5.7%) of HBsAg Sero-positivity was detected among women attended birth at health institutions, while 5.2% and 1.4% Sero-positivity was detected among pregnant women not attended birth and at TBA respectively. There was no statistically significant association between HBsAg Sero-positivity and place of previous delivery attended (p=0.349).

Table 16 Sero-prevalence of HBsAg Association with socieo-demographic characteristics Durame hospital, SNNP region, Ethiopia, 2018

Parameter	Level	HBV		COR	P value
		Negative	Positive		
		Count (%)	Count (%)		
Age (years)	15-18	22(95.6)	1(4.3)	1.00	1.00
	19-24	86(98.8)	4(4.4)	0.00	0.99
	25-29	72(92.3)	6(7.6)	0.00	0.99
	30-34	56(94.9)	3(5.1)	0.00	0.99
	35-39	14(100)	0(0)	1.00	1.0
	40+	2(100)	0(0)	1	0.00
Marital status	Married	232(94.5)	14(5.5)	0.00	0.999
	Single	0(0)	0(0)		
	Cohabiting	3(100)	0(0)	1.	0.896
	Divorced	15(100)	0(0)	1	0.00
Educational status	No formal education	53(92.9)	4(7.1)	0.491	0.422
	Primary	78(95.1)	4(4.9)	0.722	0.713
	Secondary	65(95.6)	3(4.4)	0.602	0.566
	Diploma & above	54(94.7)	3(5.3)	1	0.00
Occupation	Housewife	86(94.5)	5(5.5)	0.675	0.647
	Daily labor	53(92.9)	4(7.1)	0.520	0.461
	Private employee	4(80)	1(20)	0.157	0.164
	Government employee	51(96.2)	2(3.8)	1	0.00
	Student	15(93.7)	1(6.3)	0.588	0.674
	Merchant	41(97.6)	1(2.4)	0.633	0.998
Monthly income	<500	109(93.1)	8(6.9)	0.00	0.997
	500-1000	76(92.6)	6(7.4)	0.00	0.985
	>1000	65(100)	0(0)	1	0.00
Parity status	Primigravidea	94(94)	6(6)	1.54	0.452
	Gravidea two	85(97.7)	2(2.3)	8.38	0.490
	Multigravidea	71(92.3)	6(7.7)	1	0.00
Gestational age	1st trimester	64(94.1)	4(58.9)	0.883	0.842
	2nd trimester	98(96)	4(4)	2.25	0.261
	3rd trimester	87(93.5)	6(6.5)	1	0.00
Previous delivery	Not delivered	90(94.8)	5(5.2)	3.00	0.349
	Home	23(100)	0(0)	0.269	0.998
	Health institute	131(94.3)	8(5.7)	2.73	0.378
	TBA	6(85.8)	1(14.2)	1	0.00
History of abortion	No	198(94.8)	11(5.2)	1.038	0.955
	Yes	52(94.6)	3(5.4)	1	0.00

5.4 Association of Anti HCV Antibody Sero-positivity and socio-demographic characteristics

Anti HCV antibody Sero-positivity was detected in age groups 2-24, 25-29 and 30-34. In the age group 25-29 the highest age specific prevalence was detected. There was no statistically significant association between anti HCV antibody Sero-positivity and age of the study subjects (p=0.75). The prevalence of anti HCV antibody Sero-positivity in relation to residence showed that of the 141 urban and 122 rural residents was 1.6% and 2.8% respectively, tested positive for anti HCV antibody. There was no statistically significant association between anti HCV antibody Sero-positivity and residence of the study participants (p=0.527). The highest 6.6%frequency of anti HCV antibody Sero-positivity was observed in women who are divorced followed by married. However there was no statistically significant association between anti HCV antibody Sero-positivity and marital status of the study participants (p=0.274). Occupation wise the highest (3.7%) Sero-positivity of anti HCV antibody was detected among pregnant women who are government employee followed by daily laborers (3.5%). There was no statistically significant association between anti HCV antibody Sero-positivity and occupation of the study subjects (p=0.583). The highest (3.5%) Sero-positivity of anti HCV antibody was detected among pregnant women who did not attended formal education followed by who attended primary school (2.4%). There was no statistically significant association between anti HCV antibody Sero-positivity and educational status of the study participants (p=0.699). The prevalence of anti HCV antibody Sero-positivity among pregnant women who earn monthly income of greater than 1000 Ethiopian Birr was 4.6% whereas it was 1.7% and 1.2% among women who earn less than 500 and 500-1000 Ethiopian Birr respectively. There was no statistically significant association between anti HCV antibody Sero-positivity and monthly income of the study participants (p=0.273). The prevalence of anti HCV antibody Sero-positivity among women who are pregnant for the first time was 3% whereas it was 2.3% and 1.3% among gravidea two and multigravidea respectively. However there was no statistically significant association between Sero-prevalence of anti HCV antibody and parity status of the study subjects (p=0.456). The highest serop-positivity of anti HCV antibody (2.9%) was detected among pregnant women who are in the first trimester followed by third trimester (15%). There was no statistically significant association between gestational age of the study participants and anti HCV antibody seropositive (p=0.220). Sero-positivity of anti HCV antibody among pregnant women who attended their previous birth at home was 4.3% while it was 2.1% for pregnant women who delivered birth at health institutions. There was no statistically significant association between Sero-positivity of anti HCV antibody and place of previous birth attended (p=0.991).

5.5 Potential Risk Factors of HBV and HCV among the study subjects

Potential risk factors (history of previous surgical procedure, blood transfusion, hospital admission, history of multiple sexual exposure and family history of liver disease were found to be associated with HBV infection in the univariate analysis were entered in to the multivariate logistic binary logistic regression model and risk factors family history of liver disease, history of multiple sexual exposure and blood transfusion were found to be associated with HBV infection (table 5).

In relation to family history of liver disease contact 26.9% of the study participants replied that they had family history of liver disease contact, of which 15.4% were found to be positive for HBsAg. Statistically significant association was observed between family history of liver disease contact and HBV infection (p=0.001). Pregnant women who had family history of liver disease contact were 2.98 times more likely to have infection with HBV than those without family history of liver disease contact(AOR=2.98 95% CI= 4.32-90.4). Among 263 pregnant women, 20.9% had history of blood transfusion, of these 14.5% were positive for HBsAg. Statistically significant association was observed between HBsAg Sero-positivity and blood transfusion (p=0.018). those pregnant women with history of blood transfusion were 1.63 times more likely to have HBV infection than those without history of blood transfusion(AOR=1.63 95%CI=1.322-19.03). The proportion of pregnant women who had multiple sexual partners was 25.4%, of which 16.4% were positive for HBsAg. There was statistically significant association between HBV infection and history of multiple sexual partners (p=0.001). Pregnant women who have history of multiple sexual partner were 3.06 times at increased risk of getting HBV infection than those without history of multiple sexual partners (AOR=3.06 95% CI 4.68-97.68).

In relation to previous surgical history 27.3% of the study participants had history of previous surgical procedure, of these 6.9% were positive for anti HCV antibody. Statistically significant association was observed between history of previous surgery and anti HCV antibody Sero-positivity (p=0.016). Study participants having history of previous surgery were 2.66 times more likely to have hepatitis C virus infection than those without history of previous surgery (AOR=2.66 95% CI 1.64-124.8).

Regarding family history of liver disease contact 71(26.9%) of the study subjects were exposed to family history of liver disease contact, of which 4(5.6%) were positive for anti HCV antibody. There was statistically significant association between family history of liver disease contact and anti HCV antibody Sero-positivity (p=0.005). those pregnant women who have family history of liver disease contact were 1.14 times more likely to have hepatitis C virus infection than those without family history of liver disease contact(AOR=1.14 95% CI 0.53-18.68).

Table 17 Association of potential risk factors of HBV infection among study participants Durame hospital, SNNP region, Ethiopia, 2018

		HBV status				
variables		positive	Negative	COR(CI)	AOR(CI)	P value
		Count (%)	Count (%)			
History of sharp injury						
	yes	7(4.9)	135(95.1)	0.169(0.288-2.47)	0.927(0.1-1.56)	0.758
	no	7(5.7)	114(94.3)	1	1	0.00
History of previous surgery						
	yes	8(16.3)	41(83.7)	1.349(1.28-11.53)	0.65(0.47-7.83)	0.016
	no	6(5.6)	101(94.4)	1	1	0.00
Blood transfusion						
	yes	8(14.5)	47(85.5)	1.74(1.98-17.30)	1.66(1.35-20.45)	0.002
	no	6(2.9)	201(97.1)	1	1	0.00
Hospital admission						
	yes	9(8.9)	92(91.1)	1.16(0.993-9.38)	0.37(0.28-7.44)	0.05
	no	5(3.1)	156(96.9)	1	1	0.00
Parenteral /IV drug use						
	yes	8(7)	106(93)	0.58(0.60-5.34)	0.26(0.26-6.49)	0.29
	no	6(4)	143(96)	1	1	0.00
History of dental extraction						
	yes	6(7.2)	77(92.8)	0.51(0.56-4.99)	0.40(0.18-5.40)	0.354
	no	8(4.4)	172(95.6)	1	1	0.00
Circumcision						
	yes	8(5)	149(95)	0.11(0.301-2.65)	0.29(0.29-6.06)	0.841
	no	6(5.7)	100(94.3)	1	1	0.00
scare/tattooing						
	yes	10(7.8)	117(92.2)	1.02(0.85-9.16)	1.09(0.62-12.26)	0.089
	no	4(2.9)	131(97.1)	1	1	0.00
Multiple sexual exposure						
	yes	11(16.4)	56(83.6)	2.51(3.33-45.79)	3.07(4.73-99.23)	0.001
	no	3(1.5)	192(98.5)	1	1	0.00
Family history of liver disease						
	yes	11(15.4)	60(84.6)	2.51(3.33-45.79)	2.94(4.17-86.85)	0.001
	no	3(1.5)	188(98.5)	1	1	0.00
Ear piercing						
	yes	8(5.3)	142(94.7)	0.005 (0.339-2.98)	0.65(0.40-9.28)	0.413
	no	6(5.3)	107(94.7)	1	1	0.00

Table 18 Association of potential risk factors of Hepatitis C virus among study participants, Durame hospital, SNNP region, Ethiopia, 2018

	HCV status				
Variables	positive	Negative	COR(CI)	AOR(CI)	P value
	Count (%)	Count (%)			
History of sharp injury					
Yes	5(3.5)	137(96.7)	01.47(0.505-38.01)	1.39(0.44-35.9)	0.18
No	1(0.83)	120(99.2)	1	1	0.00
History of previous surgery					
Yes	5(6.9)	67(93.1)	2.65(1.62-123.5)	2.66(1.64-124.80	0.016
No	1(0.5)	190(99.5)	1	1	0.00
Blood transfusion					
Yes	4(1.9)	53(98.1)	0.65(0.343-10.79)	0.71(0.27-15.18)	0.457
No	2(3.6)	203(96.4)	1	1	0.00
Hospital admission					
Yes	4(3.9)	97(96.1	1.16(0.993-9.38)	0.37(0.28-7.44)	0.05
No	2(1.2)	97(98.8	1	1	0.00
Parenteral /IV drug use					
Yes	4(3.5)	110(96.5)	0.58(0.60-5.34)	0.26(0.26-6.49)	0.29
No	2(1.3)	147(98.7)	1	1	0.00
History of dental extraction					
Yes	3(3.6)	80(96.4)	0.79(0.43-11.20)	0.72(0.375-11.41)	0.337
No	3(1.7)	177(98.3)	1	1	0.00
Circumcision					
Yes	2(3.5)	55(96.5	1.11(0.059-1.83)	0.55(0.08-4.10)	0.204
No	4(3.8)	102(96.2)	1	1	0.00
Scare /tattooing					
Yes	4(3.1)	123(96.9)	0.77(0.38-12.01)	0.38(0.20-10.43)	0.378
No	2(1.5)	133(98.5)	1	1	0.00
Multiple sexual exposure					
Yes	1(1.5)	66(98.5)	0.56(0.065-4.943)	0.95(0.038-3.904)	0.608
No	5(2.5)	190(97.5)	1	1	0.00
Family history of liver disease					
Yes	4(5.6)	67(94.5)	1.71(0.99-31.07)	1.14(0.53-18.68)	0.05
No	2(1)	189(99)	1	1	0.00
Ear piercing					
Yes	3(2)	147(98)	0.29(0.19-3.77)	0.95(0.38-18.04)	0.726
No	3(2.6)	110(97.4	1	1	0.00

6. Discussion

Hepatitis B and C infections are significant health problems worldwide. These infections are associated with a wide range clinical presentations ranging from acute hepatitis to chronic hepatitis and liver cirrhosis (21).

In this study the overall prevalence of HBsAg and anti HCV antibody Sero-positivity in pregnant women was 5.3% and 2.2% respectively. According to the WHO classification criteria of global epidemiology of HBV infection, the prevalence of HBV among pregnant women in this study was intermediate (2-7%) (22). The finding of this study was comparable to reports from the study conducted in Calabar, Nigeria(4.7%) (10) and Addis Ababa, Ethiopia (6%) (3). However the prevalence of HBV infection was higher than the study conducted in Benin city, Nigeria(2.2%),(23), in India(2.9%) (24), in Makurdi, Nigeria(3.3%) (4), in Bahrdar city, Ethiopia(3.8%) (25) in Abeokuta, Nigeria(4%) (9)) and in Jazan, kingdom of Saudi Arabia(4.1%) (26). In contrast the prevalence was lower than the study carried out in southern Ethiopia (7.8%) (8),In Koutiala, Mali(8%) (27), in southern Nigeria(8.3%) (28), in Yaonde, Cameroon(9.4%),(15), in northwest Ethiopia(7.9%) (1), in Hainan province, china(9.5%) (29) and in Buea health district, Cameron(9.7%) (30). Likewise in countries where regular screening and vaccination for HBV are performed low prevalence rate (<2%) have been documented in pregnant women such as 0.34% in Pakistan (2) and 0.36% in India (18). These differences might be attributable to differences in the methods used for screening, geographical variations, behavioral and cultural variations in relation to possible risk factors of HBV infection.

Comparable studies carried out in different countries have reported co infection of HBV and HCV (31) however no co infection of these viral infections were determined in this study, which is similar with studied conducted in north west Ethiopia (1), in Sana'a, Yemen (32) and in India (24).

The Sero-prevalence of anti HCV antibody in this study was found to be 2.2%. this finding was nearly comparable with the study carried out in Yaonde, Cameron(1.7%) (7) and in Nigeria(1.39%) (31). Similarly the finding of this study was much higher than studies conducted in countries like 0.13% in Slovenia (33), 0.19% in India (24), 0.26% in northwest Ethiopia (1) and 0.8% in Benin city Nigeria (23). In contrast the finding of this study was lower than anti HCV antibody seroprevalence of 8.5% observed in Sana'a (32). The lower Sero-positivity of anti HCV antibody in this study might be due to the differences in cultural and behavioral exposure to potential risk factors to HCV infection.

In current study, socieo-demographic variables such as age, occupational and educational status, monthly income, marital status, residence, gravidity, parity and history of abortion were not significantly associated with the risk of HBV and HCV infection($p>0.05$). this finding was in line with study conducted in northwest Ethiopia (1), in Bahrdar city, Ethiopia (25), in Buea health district, Cameron (30) and in Eastern region of Ghana (34). In contrast the finding of this study was different from the result of study carried out in southern Ethiopia in which socieo-demographic variables have significant association with HBV and HCV infection (18). However it is difficult to rule out the association of these socieo-demographic variables totally with HBV and HCV infection.

In this study history of blood transfusion was found to be significantly associated with HBV infection. This finding is in agreement with different studies conducted in Nigeria (35), in Arab and African countries (7), in Pakistan (2), in Rawalpindi(36) and in Sana'a, Yemen (32). Donating blood and blood products without performing screening tests for HBV might be responsible for HBV through blood transfusion.

In the current study statistically significant association was observed between history multiple sexual exposure and HBV infection (p=0.002). Pregnant women who had multiple sexual partners were three times at elevated risk of getting HBV infection than those without history of multiple sexual partners. this finding is in line with studies carried out in northwest Ethiopia (1), in Sana'a, Yemen (32), in calabar, Nigeria (10) and in Yaonde, Cameron (15). However studies conducted in northern Uganda (11) and in northern India (18)were found no association between HBV infection and multiple sexual exposure. The transmission of HBV from asymptomatic carriers to pregnant women who have practiced sexual intercourse with multiple partners might be due to the fact that HBV is one of known sexually transmitted diseases (37).

It has been reported that HBV can be transmitted among household members with in a family through sharing personal and household items contaminated with HBsAg of chronically infected persons (32). In this study statistically significant association was observed among pregnant women who had history of contact with HBV infected family member and HBV infection (p=0.001). the finding of this study is in agreement with studies conducted in northwest Ethiopia (1),in western Nigeria (9),in Jazan, kingdom of Saudi Arabia (26),In calabar, Nigeria (10) and in Hainan province, China (38). Sharing personal and household commodities contaminated with HBsAg of infected persons of family members with pregnant women might be the cause for the observed finding.

In this study history of previous surgical operation was found to be statistically associated with HCV infection (p= 0.016). this finding is in line with report of studies conducted in Sana'a, Yemen (32), in Hyderabad Sindh (31) and In northern India (18). In contrast report of studies conducted in northern Uganda (11) and in Yaonde, Cameron (15) found no association between previous surgical application and HCV infection. This difference might be due to differences in sterility of medical instruments used for surgical procedure. Repeated use of old and unsterilized instruments used during surgical procedures may account for the observation. Furthermore family history of liver disease contact was found to be a potential risk factor for HCV infection in this study. This finding is consistent with the report of study carried out in north west Ethiopia (29). The habit of sharing different personal and household commodities with in home is important mechanism for the transfer of HCV from asymptomatic carriers to other family members and this may account for the observed finding.

7. Conclusion

This study demonstrated the intermediate prevalence of HBV and HCV infections in pregnant women followed ANC in Durame general hospital. No co infection of HBV and HCV was detected. Statistically significant association was not observed in acquisition of these viruses and socieo-demographic variables. Blood transfusion, family history of liver disease contact and multiple sexual exposures were found to be potential risk factors for HBV infection. Similarly history of previous surgical procedure and family history of liver disease contact were found to be potential risk factors for HCV infection.

8. Recommendation

Durame general hospital should routinely screen pregnant women for hepatitis B and C virus infection as part of ANC service.

Zonal health department and the hospital should give health education about potential risk factors mentioned above in particular and mode of transmission and prevention of HBV and HCV in general.

Molecular detection and characterization of the other markers of HBV and HCV should be performed to determine the exact prevalence for further study.

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Annex 4: Informed Consent Form

General information of the study

Principal investigator: Mr. Wogayehu Workneh

Advisors: Misrach Ayalewu /SPHMMC/ and Dr Elias Senbeto/SPHMMC/

Study area and Period: kembata Tembaro zone SNNP region from September to December 2017

My name is Wogayehu Workneh. I am MPH candidate in field epidemiology at SPHMMC. My study is on seroprevalence of hepatitis B and C viruses and their associated risk factors in pregnant women attending ANC follow up in Durame General Hospital. Viral hepatitis is a leading cause of maternal complication and vertical transmission that cause fetal and neonatal hepatitis which can have serious effects on the neonate, leading to impaired mental and physical health later in life. The disease can affect every part of the population although the most vulnerable groups are pregnant women. Pregnant women who visit the above health facility for their regular ANC follow up will be included in the study. Thus Data will be collected by laboratory diagnosis and by using a questionnaire. Codes will be used and any information extract will not bear the identity of the participant. Therefore it is confidential. In addition to this there will be no any side effect. All the information will be used only for study purpose. If you agreed to participate in this study, your laboratory, socieo-demographic and risk factors data will be used and you are kindly requested to put your signature on the following form.

Date_____ Code_____ The objective of this study is to know the prevalence and associated risk factors of hepatitis B and C viruses in pregnant women attending ANC follow up. I have been briefed that my identity would be kept confidential and the information will be used for the intended purpose only. As my information is important to the study, I agreed to participate in the study.

Participant's signature_____ Researcher's signature _____ .

For more information, you can contact me at the following address.

Wogayehu Workneh [Mobile: +251911384918; E-mail: wogina2012@yahoo.com]

Annex 5 Informed Consent Form (Amharic version)

የጥናቱ አጠቃላይ መረጃ

ጥናቱን የሚያካሂደው፡ አቶ ወጋየሁ ወረቅነህ

የጥናቱ አማካሪ፡ ምስራች አያሌዉ (ቅ/ጳ/ሆ/ሚ/ሜ/ኮ) እና ዶ/ር ኤልያስ ሰንበቶ (ቅ/ጳ/ሆ/ሚ/ሜ/ኮ)

ጥናቱ የሚካሄድበት ቦታ እና ጊዜ፡ከምባታ ጠምባሮ ዞን ዱራሜ ሆሰፒታል ከመስከረም እስከ ጥቅምት 2010

አቶ ወጋየሁ ወርቅነህ እባላለሁ በቅ/ጳ/ሆ/ሚ/ሜ/ኮ/ጤ/ትምህርት ክፍል የሁለተኛ ዲግሪ ተማሪ ነኝ፡፡ዱራሜ አጠቃለይ ሆስፒታል ለቅድመ ወሊድ ክትትል በሚመጡ ነፍሰ ጡር እናቶች ለይ የጉበት በሽታ መጠን ምን እንደሚመስልና ተዛማች ችግሮችን ለማወቅ ምርምር ለማከሄድ አስቤያለሁ፡፡ የጉበት በሽታ ከእናት ወደ ልጅ በመተላለፍ በእናትና ከእርስዋ በሚወለደዉ ልጅ ለይ ዉስብስብ የሆኑ የጤና ችግሮችን የሚያስከትል ሲሆን በጉበት በሽታ ከተያዘችዉ እናት የሚወለዱ ጨቅላ ህጻናትን ለአካላዊና ለስነልቦናዊ ችግሮች ያጋልጣል፡፡ በሽታዉ ሁሉንም የህብረተሰብ ክፍሎችን የሚያጠቃ ቢሆንም ጫናዉ የሚበዘዉ በነፍሰጡር እናቶች ለይ ነዉ፡፡ የዚህ ጥናት ዓላማ በዱራሜ አጠቃለይ ሆስፒታል የቅድመ-ወሊድ አገልግሎት በሚከታተሉ ነፍሰጡር እናቶች ለይ የበሽታዉ ስርጭት መጠን ምን ያህል እንደሆነ ማወቅና ለበሽታዉ የሚያጋልጡ ሁኔታዎችን መለየት ይሆናል፡፡ ስለዚህ ቅድመ-ወሊድ ክትትል ምርምራ ለማድረግ ሲባል ከተወሰደው የደም ናሙና የቀረዉን ለጥናቱ የሚንጠቀም ይሆናል፡፡ በዚህ ጥናት የእናንተ ውጤት ፍጹም ሚስጥራዊነቱን በጠበቀ መልኩ ስለሚያዝ ለሌላ ወገን ተላልፎ አይሰጥም፡፡ እያንዳንዱ መረጃ በኮድ ስለሚያዝና ስማችሁ ስለማይፃፍበት ማንም ሊያውቀው አይችልም፡፡ በተጨማሪም የሚያስከትለው የጎንዮሽ ጉዳት የለም፡፡ በጥናቱ ለመሳተፍ ከተስማሙ የላብራቶሪ ውጤቶችን ለመረጃነት እጠቀምበታለሁ፡፡ በመሆኑም ከዚህ በታች ያለውን ስምምነት አንብበው በፊርማዎ ያረጋግጡልኝ፡፡

የስምምነት ቅጽ

ኮድ ---------- ቀን ----------

ይህጥናት በጉበት በሽታ ስርጭትና ለበሽታዉ በሚያጋልጡ ሁኔታዎች ላይ ያተኮረ ነው፡፡ በጥናቱ ብሳተፍ ሁሉም መረጃ ሚስጥራዊነቱን የጠበቀ እንደሚሆን ተገልጾልኛል፡፡ በመሆኑም ለጥናቱ አስፈላጊ እስከሆነ ድረስ የእኔን መረጃ ለመስጠት ተስማምቻለሁ፡፡ ፊርማ ----------

Annex 6: Questionnaire for data collection

Questionnaire for investigation of HBV and HCV viral infections and risk factors in pregnant women attending ante natal care in Durame general hospital, kembata Tembaro zone, Ethiopia

Direction: - Please circle on the answer among choices or write on the space provided

Part I. Socio demographic characteristics

Serial number: _____

Date of interview: _____/____/_____ DD MM YYYY

Identification

1. Age ____ ____

2. Marital status 1 Single 2 Co-habiting 3 Married

3. Religion 1.Orthodox Christian 2.Muslim 3.Catholic 4.Protestant 5. Other _____

4. Residence 1 rural 2 .urban

5. Education status 1.No formal education 2. Primary 3. Secondary 4. Diploma and above

6.Occupation status 1 housewife 2 daily labor 3 merchant 4 student 5 private employee 6 government employee

7. Monthly Income 1. <500 2.500-1000 3.>1000

8. Parity status 1 primigravidae 2 gravidae two 3 multigravidae

9. Gestational age 1.1st trimester 2 .2nd trimester 3. 3rd trimester

10 place of previous delivery 1 not delivered 2 home 3. Health institution

11. History of abortion 1. NO 2. Yes

Part II Risk assessment

12. History of sharp injury (cut) 1 No 2. Yes

13. If yes how many times 1. Once 2 Twice 3 Three times 4.Several times.

14. History of previous surgery 1 No 2. Yes

15. History of blood transfusion 1. No 2. Yes

16. History 0f hospital admission 1. No 2. Yes

17. parenteral/intravenous drug use 1. No 2. Yes

18. History of tooth extraction 1. No 2. Yes

19. Ear piercing 1. No 2.Yes

20. Are you circumcised 1. No 2. Yes

21. History of dental extraction 1. No 2. Yes

22. History of scare or tattooing 1. No 2.Yes

23. History of multiple sexual partner 1. No 2. Yes

24. If yes how many sexual partner 1.One 2.Two 3.Three 4.>four

25. Have you ever practiced needle recapping? 1. Never 2.Sometimes 3.Most of the time 4. All the time

26. Family history of liver disease 1. No 2. Yes

Part III Lab. Result

27. HBsAg test result 1. Reactive 2. Non-reactive 3. Invalid

28 anti HC antibody test result 1. Reactive 2.Non-reactive

Chapter VIII- Other Laboratory Outputs

8.1. Quality Policy Manual

Of

Durame General Hospital Laboratory



Complied by:	**Wogayehu Workneh**
Approved by:	**CCO**
Effective Date:	**01 June 2017**
Document No: DGHL/QPM-01	**Rev. No: 1**
	Copy No: 1

Durame general hospital laboratory is responsible for maintaining revised and up-to-date documents, however, until revision time comes; it is possible to amend the document using the template below. Any kind of changes can be initiated by the laboratory personnel. The laboratory manager will compile the changes and medical director will approve it.

Amendment Record

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

II. Document History

Rev. No.	Document History	Effective Date	Name & Signature of approval

INTRODUCTION

This Quality Policy Manual (QPM) has been prepared to meet the requirements for laboratory accreditation of ISO 15189, Medical laboratories — Particular requirements for quality and competence. It has been formatted using the clause numbers from ISO 15189 to provide ease in review. This Quality Policy Manual shall provide an insight into the structure of Durame general hospital laboratory and of the policies and operating procedures for all the laboratory staff to carry out their job and related activities in accordance to the policies of laboratory. This will demonstrate that the Durame general hospital laboratory is competent to operate medical testing laboratories in accordance with the requirements of ISO 15189:2012 and of the accreditation body ENAO. The QPM and related quality procedures shall be reviewed and revised accordingly from time to time to reflect its status and requirements of ISO 15189: 2012, Medical laboratories-Particular requirements for quality and competence and accreditation body ENAO Requirements.

The Laboratory Manager is responsible for maintaining the official master copy of the DGHL Quality Policy Manual. General distribution of this manual is accomplished using a computer network or hardcopy. Periodically Annual review of documents is conducted as stated.

REFERENCE: This quality policy manual is solely prepared and referred ISO 15189:2012 Medical laboratories — Particular requirements for quality and competence and accreditation.

Definitions

Biological reference interval; Central 95% interval of the distribution of reference values

Chief executive officer; Authorized person responsible for overall activities of Durame general hospital service

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

Laboratory management; Persons who manage the activities of a laboratory headed by a laboratory manager

Laboratory Manager; Competent person(s) with responsibility for, and authority over, a laboratory

Logistic officer; A person who manage the stock level of laboratory reagents and supplies

Measurement; Set of operations having the object of determining a value of a quantity

Medical director; an authorized person responsible for the overall hospital services

Post-examination procedures/Post analytical phase; 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/ Pre-analytical phase; Steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the requested sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins

Quality Management system; Management system to direct and control an organization with regard to quality

Quality officer; Responsible person for the implementation and maintenance of the Quality Management System in Durame general hospital Laboratory

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

Safety officer; a person who facilitates and controls the implementation of safe laboratory safety practice

Section supervisor; a competent person who monitors and controls the day to day laboratory service in the assigned section

Traceability; Property of the result of a measurement or the value of a standard whereby it can be related to stated

References, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

Uncertainty of measurement; Parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurement

Validation; is the Process of establishing the performance characteristics and limitations of a method and the identification of the influences which may change these characteristics and to what extent.

Verification; Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

PURPOSE

This document provides a description of DGHL in terms of its legal status; its structure & function; its mission, vision and mandate and its delegation of responsibilities and authorities.

POLICY

DGHL's policy is to maintain sufficient resources in a structure which can adequately support its mandate to supply clinical services that are prompt, pro-active and reliable to the Hospital.

DESCRIPTION AND ROLE OF DGHL

DGHL is responsible for the provision of high level diagnostic laboratory testing services for patients. DGHL works to enhance laboratory quality management system.

ADDRESS:

Region: SNNP

Town: Durame

Kebele: ZERARO

P.O. Box: 17, DURAME, ETHIOPIA

Phone Number: +25146554922

Fax Number: +251465541163

DGHL provide 24 hours service: Monday through Friday**.**

24 hour Duty service: Saturday and Sunday.

VISION

To provide the highest quality of laboratory services to Clients by encouraging its laboratory personnel to continuously update their education and laboratory experience and to acquire the state of the art equipment for its personnel to use.

MISSION

To provide high quality professional medical laboratory services in the shortest time possible with emphasis on excellence, complete customer satisfaction, training and continuous quality improvement. This will be achieved through on-going development, implementation and evaluation of quality control methods appropriate to each section; testing performed efficiently and accurately; and continuous evaluation and revision of current laboratory procedures.

DGHL VALUES

Integrity - We are honest and trustworthy in everything that we do.

Compassion - We respect all people with a sense of caring and understanding.

Commitment - We work toward the greater good of the organization.

Communication - We share information in a timely and accurate manner.

Quality - We do everything with excellence.

SCOPE OF OPERATIONS AND SERVICES

DGHL consists of the following major sections providing full services:

Clinical Chemistry and serology section

Immunohematology section

Microbiology Sections

Parasitology/Urinalysis and Reception sections and other

Different specimen collection sites

The whole laboratory is sectioned to four according to type of specimen used, types of equipment used, physical location of the tests in DGHL laboratory and other scientific relations. Major activities of the sections are stated below

A. Clinical Chemistry

This section is fully automated, with chemistry analyser and performs any combination of tests up to 100 samples per work plan. The section is performing routine chemistry testing using serum or plasma for analyte present in the blood. These include a wide array of substances such as lipids, blood sugar, electrolytes, enzymes and others.

This section of laboratory operates under the management of DGHL

B. Immuno-Haematology

The Immunohematology laboratory is comprised of:

Haematological tests

Blood film

Flow Cytometry (CD4 count)

This section works with whole blood to do Complete Blood Counts (CBC), and blood films as well as many other specialized tests. It is equipped with different analysers like; Sysmex Kx-N21, FACScount, FACS calibre.

C. Microbiology

The Microbiology is specialized for the diagnosis of Bacteriology and Mycology using culture &sensitivity and microscopic examinations. And other laboratorial examinations like leshmaniasis, Onchocerciasis and other parasitological diagnosis are also performed in this section.

D. Parasitological

The Parasitological section is performing stool testing to investigate parasites. The most frequently encountered specimen here is faces. However, blood, urine, sputum, and other samples may also contain parasites and examined for confirming the presence of parasites. Urine microscopy and chemical tests for urine are also performed in this section

E. Serology

The serology section is performing routine serology tests and uses the concept of antigen-antibody interaction as a diagnostic tool.

F. Reception

The centralized specimen reception is comprised of: Phlebotomy, Specimen/Sample collection, verification, and receiving referred samples.

G. Result reporting and delivery

Tests are grouped under various sections and sample type (specimen). Based on the request the samples are transported to various laboratory sections.

Result delivery to the concerned department/doctor of the hospital after verification and signed by laboratory quality officer and/or section supervisors, it is made available to concerned doctors, nursing unit, clinic, or through runners.

Reporting Priority Laboratory Results: High priority results are reported as each test is completed to the physician's office, nursing unit, or clinic. Critical results are phoned in person by lab personnel as soon as possible.

This section of laboratory operates under the management of DGHL. Different specimen collection sites located in different clinics and specimens are collected by trained phlebotomist.

LEGAL STATUS

DGHL is found under the management of Durame General Hospital. The hospital is managed under the Kembata Tembaro zonal health department.

ETHICAL CONDUCT

All personnel shall sign the DGHL Work Ethics Agreement and confidentiality as described in the Personnel procedure. The laboratory manager protects or manages the laboratory from any activities that may affect confidentiality information, Conflict of interest and overall competency of the laboratory. Any attempts be made by clients, competitors (other lab), or other personnel to offer inducement to or to place undue pressure on personnel in terms of workload, threat or insinuation which has the objective of influencing work and by consequence would affect the quality, integrity or confidentiality of the work, such efforts shall be reported in writing by means of an IAR and will be managed accordingly.

Laboratory manager

The laboratory is directed by a person with the competence and delegated responsibility for the services provided.

The responsibilities of the laboratory manager include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory and documented in the personnel profile.

The laboratory manager may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory manager maintains the ultimate responsibility for the overall operation and administration of the laboratory.

The laboratory manager (or the designate for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard.

The laboratory director (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 staffs that are served

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

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.)* Plan and direct research and development, where necessary

Management responsibility:

Management commitment:

The laboratory manager and delegates are committed to implement and continual quality improve QMS of laboratory services through the following activities by:

Communicating to laboratory personnel the importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements?

Establishing the quality policy

Ensuring that quality objectives and planning are established

Defining responsibilities, authorities and interrelationships of all personnel

Insure competency of staff before they are involved in any activities in the laboratory

Establishing communication processes

Appointing a quality officer

Conducting management reviews

Insure management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;

There are appropriate procedures to ensure that staff treats human samples, tissues or remains according to relevant legal requirements;

Maintain confidentiality of information

Needs of users

Laboratory manager and delegates ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. And communicate to laboratory personnel the importance of meeting the needs and requirements of user, and regulatory and accreditation body.

Quality policy

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

Is appropriate to the purpose of the organization

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;

Provides a framework for establishing and reviewing quality objectives;

Is communicated and understood within the organization;

Is reviewed for continuing suitability

Quality objectives and planning

Laboratory management 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 are measurable and consistent with the quality policy.

Laboratory management ensure that planning of the quality management system is carried out to meet the requirements and the quality objectives.

Laboratory management ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Laboratory management appoint quality officer

Laboratory management conduct management review

Responsibility, authority and interrelationships

Laboratory management ensures 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 laboratory section supervisors

The Laboratory Manager is 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 are 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

Responsible to establish Quality policy manual

COMMUNICATION

The primary objective of DGHL is to satisfy client requirements by supplying fit-for-purpose services and in so doing to achieve the quality objectives of DGHL. The achievement of these objectives; the success of continual improvement of the Quality System and changes in relation to the system are communicated to all staff on a regular basis during the staff meetings, Hospital development army meetings and flow of information according to organogram which are addressed by the Laboratory manager. The laboratory manger uses different communication systems to enhance quality of the laboratory service with appropriate stockholders through written letters, meetings, email and so on.

Quality Officer

Quality officer is appointed by Laboratory manager and has delegated responsibilities and authority:

Ensuring that processes needed for the quality management system are established, implemented, and maintained; according to ISO requirement

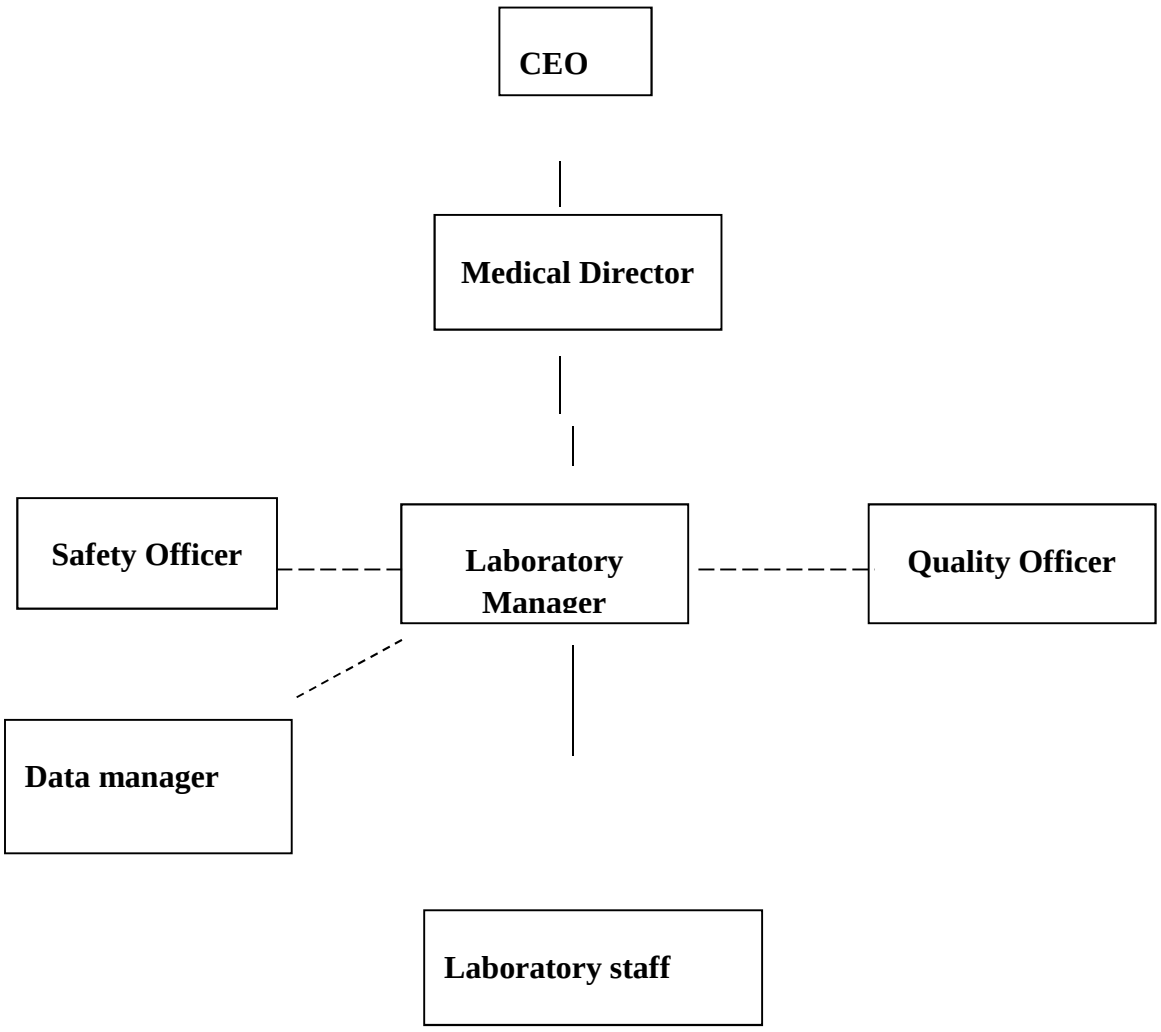
Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;

Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization

SUBSIDIARY DOCUMENTS

Document Unique ID	Document Name
DGHL/SOP4.1-01	Procedure for Communication
DGHL/SOP4.1-02	Procedure for Conducting Staff Meeting
DGHL/SOP4.1-03	Procedure for patient confidentiality
DGHL/SOP4.1-04	Procedure for disciplinary action for deviation from quality system
DGHL/F4.1-01	Communication format
DGHL/F4.1-02	Telephone call log sheet
DGHL/F4.1-03	Format for Recording of Staff Meeting
DGHL/F4.1-04.01-4	Work flow
DGHL/F4.1-05.01-10	Format for notices
DGHL/F4.1-06.01-04	Duty roaster
DGHL/F4.1-07.01	Confidentiality Agreement
DGHL/F4.1-08	Format for report
DGHL/JA4.1-01-07	Task assignment
DGHL/F4.1-09	Format for plan
DGHL/F4.1-10	Format for abbreviations

Annex-: The inter-relationship of all personnel and organizational relationship (Organogram).



PURPOSE

The purpose of this manual is to provide policy and procedure for the review of the Quality Management System to ensure its continued suitability and effectiveness, and to introduce any necessary changes or improvements.

POLICY

DGHL's policy outline its commitment to good professional practice, compliance with continuous improvement of the QMS, the scope of its service and the objectives and goal of the QMS by establishing a Quality Policy Statement, Quality Goal and Objectives

DESCRIPTION

The laboratory 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 fulfil its quality policy and objectives and meet the needs and requirements of the users.

The laboratory:

Determine the processes needed for the quality management system and ensure their application throughout the laboratory;

Determine the sequence and interaction of these processes;

Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

Ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

Monitor and evaluate these processes;

Implement actions necessary to achieve planned results and continual improvement of LQMS process

DOCUMENTATION REQUIREMENTS

Documentation

The quality management system documentation shall include:

Statements of a quality policy

A quality manual

Procedures and records required by this International Standard;

Documents, and records determined by the laboratory to ensure the effective planning, operation and control of its processes;

Copies of applicable regulations, standards and other normative documents

Quality manual

The laboratory shall establish and maintain a quality manual that includes:

The quality policy or makes reference to it;

A description of the scope of the quality management system;

A presentation of the organization and management structure of the laboratory and its place in any parent organization;

A description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard;

A description of the structure and relationships of the documentation used in the quality management system;

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.

QUALITY POLICY STATEMENT

DGHL is fully committed to the concept of third party recognition by means of accreditation to perform tests in a competent manner. The objective of the Quality Management System described in this document is to meet the requirements of the accreditation body ENAO and, in so doing, to continually satisfy our clients' requirements and to meet our organization mission and vision.

It is DGHL's policy to offer, at all times, services that comply with the requirements as specified in the standard ISO 15189, Medical Laboratories – Particular requirements for Quality and Competence. The scope of services is specified in the Organization document.

The success of any formalized system of quality management is dependent on the development of a quality culture within the laboratory that is initiated through the commitment and drive of management. It is, therefore, essential that all personnel within DGHL share this policy and the means of its implementation.

It is therefore the responsibility of all personnel to become fully familiar with this policy and the means of its implementation through the documented Quality Management System. It is also imperative that all personnel understand the importance of not only meeting client requirements but also statutory and regulatory requirements and good governance principles.

Communication of the above to staff shall begin on commencement of duty in accordance with the training requirements as specified in the Personnel procedure and on an on-going basis through our communication meetings and structured courses.

In line with our commitment that quality becomes the platform for driving our business; the quality system shall be implemented on the basis of continual improvement in the quality system and in the way that we carry out our business. All audits, corrective and preventive actions shall be approached in an opportunistic manner such that any implemented actions that are taken shall have an underlying principle of improvement in the effectiveness and efficiency of the system. Also, the Management Review (MR) process shall address improvements both in the Quality System and in the service processes.

QUALITY GOAL AND OBJECTIVES

DGH'L is determined and committed to carry out the following quality objectives and goal:

Quality Goal

To establish the implementation and maintenance of a Quality Management System

To provide medical laboratory testing services in accordance with the applicable standards to satisfy the expectation of customers and satisfy the requirements of accrediting body and authorized body

Quality objectives

Capacitate personnel to become qualified, trained and competent to perform assigned duties

Ensure that all the laboratory personnel be familiarize and comply themselves with the documented quality system and competent in performing their assigned duties.

Ensure that all equipment related to the testing activities are properly maintained and monitored.

Provide conducive and safe working environment.

Validate processes and subject them to adequate quality control and quality assurance assessments.

Ensure equipment, supplies and services are functioning properly and/or meet required specifications.

Ensure required documents and records are maintained

Quality Management System Description

The Quality Management System (QMS) is based on a series of documents that make up the Quality Manual. These documents contain the policies and procedures as required by ISO 15189 and they are directly aligned to the relevant clauses of ISO 15189 as is this document which covers the requirements for Quality Management System. The full set of documents is listed in Annex C: Quality Management System Policies. In addition, the subsidiary documents, i.e. those documents that cover operational procedures, activities and controls (Standard Operating Procedures, job aid, Job Descriptions; Forms; ; Standards, guidelines and manual) are extensive and the full set can be viewed by referring to the relevant document Master Lists. The QMS allows for the control of and common understanding of how activities, processes and systems are operated within DGHL.

Quality Management System Implementation

All personnel are trained in understanding the structure and operational requirements of the QMS only current documents shall be used and all obsolete documents shall be withdrawn from the laboratory.

SUBSIDIARY DOCUMENTS

ANNEX: QUALITY MANAGEMENT SYSTEM POLICIES AND PROCEDURES

DOC NUMBER	TITLE
4	Management Requirements
P4.1	Organization & Management
P4.2	Quality Management System
P4.3	Document Control
P4.4	Review of Contracts
P4.5	Examination by referral laboratories
P4.6	External Services & Supplies
P4.7	Advisory Services
P4.8	Resolution of complaints
P4.9	Identification and control of nonconformities
P4.10	Corrective action

P4.11	Preventive action
P4.12	Continual Improvement
P4.13	Quality and technical records
P4.14	Internal audits
P4.15	Management review
5	Technical Requirements
P5.1	Personnel
P5.2	Accommodation and environmental conditions
P5.3	Laboratory equipment
P5.4	Pre-examination procedures
P5.5	Examination procedures
P5.6	Assuring the quality of results
P5.7	Post-examination procedures
P5.8	Reporting of results
P5.9	Result releasing
P5.10	Laboratory management information system

PURPOSE

This document describes the means by which the documented quality system is controlled in DGHL.

POLICY

It is a considered policy of the DGHL to implement a system which is streamlined, effective and which is self-operational. The objective of documenting activities is for control purposes and as long as documentation of those activities maintains control, then the objective has been met. In this regard the administrative work involved in updating, and revising documents shall be minimized and, consequently, documented procedures shall not be onerous in cross referencing other documents by document or clause numbers, since the amendment trail required can be considerable. Reference can be made by title or by activity or, when absolutely necessary, by reference number.

DOCUMENT ISSUE, APPROVAL AND CONTROL

As soon as a new/revised document has been signed by both the Compiler and Approver, it is distributed for implementation on the effective date. Policies, manuals and guidelines are compiled by laboratory manager, Quality officer and other delegated personnel and approved by Medical director. Likewise, other documents (SOPs, Formats, Job Aid, etc.) will be compiled by technical personnel or section supervisor and approved by Quality Officer.

Physical distribution of documentation are controlled by the use of master register refer. All Original quality documents are controlled by manager and quality officer is responsible for control of copies of quality documents. When a new document has been prepared or an existing document has been revised the approver shall nominate the recipients of the document on the master register ensuring that the document is available at all locations where operations essential to the effective functioning of the laboratory are performed. A copy number is allocated to each recipient.

Quality Officer ensures all nominees are issued with and have signed for receipt of the relevant document.

Documents are periodically reviewed (at least annually) and revised when necessary i.e. If there is no any change and amendment within a year period, the current Rev. No and/or copy No will be used or continue as it was.

Amendment of QPM done in the “Amendment Record Format” However, other document such as SOPs can be amended by hand pending with clearly marked, initiated and dated and a revised document is formally re-issued as soon as practicable.

It is the responsibility of all personnel to indicate receipt of documents by signing the relevant master register. And immediately destroy all superseded documents.

The manager and Quality Officer shall maintain on file: the original master copy of all quality documents; the master register appropriate to the document extra copies of documents; and archive copies of obsolete MASTERS of all documents with an indication of their obsolete status

DOCUMENT IDENTIFICATION

A uniform approach to document identification, format, status and issue control, and to the procedure for document review and preparation is required for the continued integrity of the system. The laboratory has adopted the approach of aligning its documentation with the numbering of the relevant clauses of ISO 15189. The system ensures contextualization of all documentation within the quality management system that is associated with any clause of ISO 15189. Documents are identified by an alphanumeric system where the document type is identified by a descriptor as described in Clause 4.3.3.2 together with the relevant clause number from ISO 15189. The document is then pre-fixed by an abbreviation to indicate the level within the organization to which the document belongs, for example DGHL/P4.3 is a Policy document relating to clause 4.3 of ISO/IEC 15189 and it is authorized at the highest level.

The pre-fix abbreviation in use for each of the laboratories unit or section, for example Microbiology (MIC), Serology (SER), Chemistry (CHE), Immunohematology(IMH), Parasitology (PAR) and urinalysis (URI), Reception (REC); All lab section (ALS).

The suffix abbreviation shall be given for document prepared with other language, for example Amharic Version (AV). Two and more digit numbers shall be used for serial and sub-serial number respectively for identification of document.

There are several document categories that are controlled under the quality system. Computer copies of such documentation are used as active documents within a laboratory, the Lab Manager shall develop specific procedures for control, access, adherence and change to such computer files.

The structure of document ID is containing the following information:

*****Section Name

Section name shall be used for departmental specific operating procedure(s). However, as appropriate section name can be used for general laboratory or other.

****Serial number:**

The serial number shall have two digits. As appropriate extra sub-serial digit shall be used if series of documents are available under same document name or topic.

The unique identification (ID) shall be written in Capital Letter at all time.

DOCUMENT FORMAT AND CONTENT

DOCUMENT FORMAT

The format used for P-; SOP-; JD-; F-; JA-; STD-;GL-;RM-;and Man-;documents shall be in accordance with the format outlined in this document in terms of headers and outline.

DOCUMENT CONTENT

In general the P-; SOP-; JD-; F-; JA-; STD-;GL-and Man-; documents include the following content, when and where relevant. However, the content of each document does not necessarily need to include all of the prescribed headers:

P-Docs	SOP-Docs	JD-Docs	Man-Docs	F-Docs	JA-Docs	GL-Docs
Purpose; Policy; Responsibility; References; Definitions; Process/guidance (however described); Subsidiary docs;	Purpose; Procedure; Subsidiary Docs; Effective Date; Date of revision; Annexure. (For contents	Basic function Line of communication Education; Responsibilities Skills/competency; Min. Work Experience	Purpose; Policy; Responsibility References; Definitions; Process/guidance (however described); Subsidiary	Forms should be formatted so as to allow the recording of evidence or data that satisfies the requirement of a P-; SOP-; or JD-JA- as	Purpose; Instruction; Responsibility; Subsidiary Docs; Annexure.	Purpose; Policy; Responsibility; References; Definitions; Process/guidance (however described); Subsidiary docs;

Laboratory docs required; Annexure	of examination procedure refer 5.5)		docs; Laboratory docs required; Annexure	appropriate.		Laboratory docs required; Annexure

DOCUMENT STATUS AND ORIGINALITY

DGHL uses two modes of document control. The first mode is based on issuing documentation that is identifiable as an original with copy number and status and controlling the removal of that document when superseded or revised. The second mode is based on controlling the issue, removal/updating of a Document Master Register which is updated every time a document is superseded or revised. The second option is applicable, particularly in the case of an electronic document system and forms. Both modes of control provide effective regulation over status and originality.

STATUS

The current status of documentation is identified by: the Rev Number indicated in the top right hand corner of P-; SOP-; JD-; F-; JA-;GL-;RM- Man-; documents together with effective date. The original document is issued as Rev No 0 and subsequent revisions are Fixed in sequential numerical order, e.g. 1, 2, 3 etc.;

All current DGHL Laboratory documentation (P-; SOP-; JD-; F-; JA-; STD-; GL-and Man-) are identified by reference to Document Master Registers. Each register shall be formatted as a matrix which cross-references each document to its current status. The Quality Officer and Lab Manager shall maintain on the file of updated Document Master Register.

ORIGINALITY

Originality of quality documents is achieved by printing the documents (P-; SOP-; JD-; F-; JA-; ; GL- and Man) on paper with a coloured imprint and/or logo with copy number zero and the word "THIS IS A CONTROLLED COPY FOR INTERNAL USE ONLY is often used within DGHL Laboratory). Originality of other controlled documents is achieved by controlling access to the Document Master Register. Subsequent copies of documents are Fixed in sequential numerical order example 1, 2, 3 etc.

DOCUMENT CHANGES/REVISION

All personnel are responsible to identify areas where new documentation is required or revisions needed to be made or where existing documentation requires review.

Where a need for document review is identified by staff or where a need is identified through audit or management review, the relevant personnel shall initiate such review by means of memo, indicating the recommended changes to the relevant document, to the Compiler of the document. The validity of the recommendation shall be decided by the Compiler and approver.

It is advisable that the Compiler circulates a draft of the revised document to ensure that staff members to whom the matter is of concern, are given an opportunity to make comments. The Compiler must process such comments and implement feasible/valid comments in the final document.

ACCESS TO AND ADHERENCE TO QUALITY SYSTEM DOCUMENTATION

Controlled copies of standards and other documents shall be issued to or be available for reference to key laboratory personnel. Copies of documents not included within the controlled document system shall not be utilized in testing.

The documented Quality System is intended to satisfy the Quality Policy and ultimately the mission and organizational policy on quality. All personnel of DGHL shall adhere to the quality documentation. If controlled documentation requires change or modification the procedure for requesting document changes shall be followed.

UNAUTHORIZED DEVIATIONS FROM QUALITY SYSTEM

If an unauthorized deviation from documented procedures is identified, the Quality Officer/Lab Manager shall initiate an IAR. The corrective action procedure shall be followed in order to determine reason for non-compliance by the relevant staff member the consequences of deviation, and the required corrective action taking cognizance of the possible need for retraining or disciplinary action.

SUBSIDIARY DOCUMENTS

Document Unique ID	Document Name
DGHL/ISO15189	ISO 15189:Particular requirements for Medical laboratory-quality and competence
DGHL/F4.3-01.01-03	Document Master Register
DGHL/SOP4.3-01	Procedures for electronic data control and storage (back up)
DGHL/F4.3-02	Document change requesting Memo

DGHL/SOP4.3-02	Procedure for Document control
DGHL/F4.3-03	Document distribution list
DGHL/RM4.3-01-100	Books, journals and other referral materials

PURPOSE

This document provides the policy, process and indicate subsidiary document (s) for review of contracts.

POLICY

DGHL laboratory has policy to establish and maintain procedures for review of contracts when the laboratory enters into a contract to provide laboratory service. All requirements including the methods to be used, are adequately defined, documented and understood; capacity and resources of DGH laboratory has to meet the requirement. DGHL laboratory shall review its capacity and resource periodically and able to determine uncertainties of measurement, limits of detection, confidence limits, etc. Customers shall be informed of any deviation from the contract and same contract review process shall be repeated if contract needs to be amended after work has done. Records of review shall be maintained.

Establishment of service agreements

The DGHL'S laboratory has documented procedure for the establishment and review of agreements for providing medical laboratory services.

Each request accepted by the laboratory for examination(s) shall be considered as an agreement.

Agreements to provide medical laboratory services shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation.

The following conditions shall be met when the laboratory enters into an agreement to provide medical laboratory services.

The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, shall be defined, documented and understood

The laboratory shall have the capability and resources to meet the requirements.

Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations.

Examination procedures selected shall be appropriate and able to meet the customers' needs

Customers and users shall be informed of deviations from the agreement that impact upon the examination results.

Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant**.**

Review of service agreements

Reviews of agreements to provide medical laboratory services shall include all aspects of the agreement.

Records of these reviews shall include any changes to the agreement and any pertinent discussions.

When an agreement needs to be amended after laboratory services have commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties.

SUBSIDIARY DOCUMENTS

Document Unique ID	Document Name
DGHL/SOP4.4-01	Procedure for review of contract
DGHL/F4.4-01	Agreement document for contract review

PURPOSE

This document provides the policy, guidance and indicate subsidiary document (s) for examination of referral laboratories.

POLICY

DGHL laboratory ensures that an effective documented procedure for evaluating and selecting referral laboratories and consultants (i.e. monitoring the quality of referral laboratory and consultants) who provide second opinions for histopathatolgy, cytology and related disciplines. A duplicate of the laboratory report shall be retained on both patient record and in the permanent file of laboratory.

Selecting and evaluating referral laboratories and consultants

The laboratory has 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.

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.

Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met.

Records of such periodic reviews are maintained.

A register of all referral laboratories, and consultants from whom opinions are sought, is maintained.

A results of all samples referred are kept for a pre-defined period.

Provision of examination results

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

Laboratories shall adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from referring and referral laboratories, this process shall not be hindered by commercial or financial considerations.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.5-01	Procedure for selecting and monitoring referral laboratories
DGHL/F4.5-01	Format for monitoring of referral lab and consultant
DGHL/F4.5-02	Register of referral lab

PURPOSE

This document provides the policy, guidance and indicate subsidiary document (s) for external services and supplies.

POLICY

DGHL laboratory has policy and procedure for selecting and use of purchased external service, equipment and consumable supplies that affect the quality of its service. The laboratory ensures that purchased items shall consistently meet the laboratory`s quality requirement. There shall be procedures and criteria for inspection, acceptance/rejection and storage of consumable materials. Consumable and equipment items that affect the quality of service has to verified prior to use as complying with standard specifications or requirement defined for the procedures concerned.

GUIDANCE

The DGHL has 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.

DGHL laboratory have an inventory control system for supplies and reagents. The laboratory evaluates suppliers of critical reagents, supplies and service that affect the quality of examinations and shall maintain records of these evaluations and list those approved.

Appropriate quality records of external services, supplies and purchased products are established and maintained for a period of time. This system includes the recording of lot numbers of all relevant reagents, control materials and calibrators, date of receipt in the laboratory and the date the materials is placed in service. All these quality records are presented in laboratory management review.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.6-01	Procedure for Purchasing and Inventory Control System
DGHL/SOP4.6-02	Procedure for Supplier's Selecting Criteria
DGHL/SOP4.6-03	Procedure for Handling Expired or Damaged Stock
DGHL/SOP4.6-04	Procedure for Inspecting, Accepting/Rejecting and Storage of Supplies
DGHL/SOP4.6-05	Procedure for Verification of Newly Purchased Reagents and Supplies
DGHL/SOP4.6-06	Procedure for Order Tracking
DGHL/SOP4.6-07	Procedure for Recording Transactions in the Bin Card
DGHL/SOP4.6-08	Procedure for CRRF
DGHL/SOP4.6-09	Procedure for conducting visual inspection
DGHL/SOP4.6-10	Procedure for IFFRV
DGHL/SOP4.6-11	Material Management and Inventory Control
DGHL/F4.6-01	Format for Supplier's Selection Criteria
DGHL/F4.6-02	Format for Forecasting and Calculating Order Amount
DGHL/F4.6-03	Format for Requesting of Reagent or Supply Purchase
DGHL/F4.6-04	Format for Inspection of Purchased Reagent and Supplies
DGHL/F4.6-05.01-02	Format for Verification of expired Reagents and Supplies
DGHL/F4.6-06	Format/Sheet for Order Tracking
DGHL/F4.6-07	Format for Stock Card Bin
DGHL/F4.6-08	Format for CRRF
DGHL/F4.6-09.01-02	Format for Reagent Consumption
DGHL/F4.6-10.01-02	Format for Verification of newly purchased Reagents and Supplies
DGHL/F4.6-11	Format for Supply monitoring

PURPOSE

To provide policy, guidance and indicating subsidiary documents for establishment of the advisory services in DGHL Laboratory.

POLICY

DGHL laboratory professionals shall provide the clients the necessary clarification to their request including advice on choice of examinations and use of the services, repeat frequency and required type of sample and interpretation of examinations results. Meeting between representatives of the professional laboratory staff and internal hospital/clinical staff are regularly held to ensure the best possible delivery of laboratory services and minutes are documented in shared area under the control of the laboratory.

GUIDANCE

The laboratory management ensures that there is a documented procedure to advice customers on choice of examinations and use of the services, including efficiency of test, repeat frequency and required type of sample as well as interpretation of the results of examinations through Laboratory professional.

The laboratory management ensures there should be regular documented meetings of professional staff with the clinical staff regarding the use of the laboratory services and for the purpose of consultation on scientific matters.

The laboratory management ensures that the professional staff should participate in clinical rounds, enabling advice on effectiveness in general as well as in individual cases.

The laboratory shall establish arrangements for communicating with users on the following:

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;

Advising on individual clinical cases;

Professional judgments on the interpretation of the results of examinations

Promoting the effective utilization of laboratory services;

Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.7-01	Procedure for advisory service

PURPOSE

To provide the policy and procedure for the systematic investigation and resolution of complaints and other feedback obtained from clinicians, patients and other parties in order so that corrective action can be taken to prevent or minimize re-occurrence whenever possible.

POLICY

DGHL's policy on complaints is to register all concerns, queries and complaints in the Complaints Register and to investigate and resolve these complaints, concerns or queries in accordance with the Investigation, Action & Resolution (IAR) process. In addition, it is DGHL's policy to seek feedback on the quality of its service by surveying users on a regular basis.

PROCESS

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Client Satisfaction Survey	Issue the Client Satisfaction Survey Form to clients, clinicians and patients on a regular basis (twice in the year.)	Feedback from clients	Q officer	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 Register. Register all scores greater than or equal to 50% and all compliments received in the 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	Q officer	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	Q officer	Survey Results
Resolved Complaints	Notify clients of how complaint was resolved and what corrective action was taken.	Closed Complaint	Q/officer Lab manager	-

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.8-01	Procedure for compliant management
DGHL/F4.8-01.01-02	Complaints Register form
DGHL/F4.8-02	Physicians satisfaction survey form
DGHL/F4.8-03	Client satisfaction survey form
DGHL/F4.8-04.01-02	Customer satisfaction evaluation summary

PURPOSE

To provide the policy and procedure for the systematic investigation and resolution of non-conformities this may arise in the supply of testing services. The main focus of this document is to cover the production of non-conforming test work where test results have, or may be, produced which do not conform to the performance capability of the method.

POLICY

DGHL has a policy to implement a robust quality control system that makes provision for detecting non-conformities that occur in the test process that may influence or affect the quality of the test result. This system is described under assuring the Quality of test and it is based on maintaining control of the test process so that only results that comply with the performance capability of the relevant method are produced and reported to the client. Where non-conformities arise as a result of the quality control system then they are treated in accordance with this procedure.

PROCESS

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Non-conformities arising as a result of QC Breaches; Data Checks; verified non-calibration status; complaints; verified non-compliant consumables; MR outcomes; and audits.	Initiate an IAR and describe in detail together with any associated documents what the problem or non-conformity is and how it may impact or influence the quality of the test result.	Registered IAR	Q officer	-
Registered IAR	Halt the performance of the relevant examination or test work. Investigate and determine the root cause of the non-conformity and implement effective corrective action in accordance with the Corrective Action procedure. Verify the impact on the test results and associated test results (i.e. any test results that may have been affected in the same way, e.g. test results in a run or batch where the QC charts have been breached). If results have already been despatched to clients then inform the clients immediately by phone with follow up withdrawal and amendment of test reports in writing.	Implemented Actions	Lab Manager	-
Implemented Actions	Verify effectiveness of implemented actions (corrective action form is used)	Non-conformity resolved	Q officer	Effective resolution and improvement of operations
Non-conformity resolved	Sign-off the IAR form allowing the test or examination work to resume with the repeat tests or examination of the effected samples	Resumption of conforming work	Lab Manager	-

PURPOSE

This document provides the policy and procedure for the initiation and implementation of corrective actions in DGHL. This Corrective Action procedure uses the Investigation, Action & Resolution (IAR) process as the basis for determining root cause, implementing appropriate actions, and ensuring the effectiveness of the actions taken. The IAR system as described in this procedure is also used as the basis for resolution of Preventive Actions; Complaints; Non-Conforming work; and Continual Improvement.

POLICY

DGHL has a policy to implement a central corrective action system called the Investigation, Action & Resolution (IAR) process which acts as the basis for implementing corrective action for non-conformities; opportunities for improvement; preventive action; continual improvement and complaints.

GUIDANCE

Identification of corrective action sources

The need for corrective action may be identified through the following activities:

Equipment calibration and verification;

Non-conforming work;

Auditing;

Management review;

Complaints

Equipment Calibration

When corrective action is required it shall have the objective of:

a) determining the effect of the non-conformance, to the specified calibration requirements, on the test activity and, where necessary, recommending to the Laboratory Manager to notify the relevant clients of the potential effects on such test results; and

b) Investigating the cause of the non-conformance, to the specified calibration/verification requirements, and determining what action is required in order to prevent the recurrence of the situation.

Non-Conforming Work (QC Outputs)

When corrective action is required the responsible staff member shall initiate an IAR and forward it to the Quality Officer for follow-up and completion. The IAR has the objective of determining the cause of the non-conformance, taking the necessary action to prevent its recurrence and, where necessary, of notifying the relevant clients of possible effects on any data which may have been issued prior to the detection of the non-conformity.

Auditing

An IAR is only initiated to clear a finding when there is a deficiency in the system or the cause of the finding requires further investigation. The corrective action shall have the objective of determining the cause of the non-conformance, taking the necessary action to prevent its recurrence.

Management review

Corrective action shall have the objective of determining any modifications, amendments, revisions or additions to documentation to improve an identified deficiency in the system raised during the management review procedure.

Complaints

A formal corrective action shall be raised for all complaints in accordance with Complaints. The corrective action shall have the following objectives:

To determine the cause of the complaint;

To determine if other clients are affected by the cause;

recommending to the Laboratory Manager to notify other clients, where relevant, of the potential effect on the service supplied to them; and to determine why the subject of complaint was not detected by the Quality System prior to data release and correcting the system to allow for improved monitoring, where relevant.

CAUSE ANALYSIS

The following shall be used for guidance in determining the root cause of non-conformities for corrective action purposes.

Internally detected non-conformance

There are four general areas in the testing process in which errors may cause non-conformances:

a) Sample Handling and Preparations:

Improper specimen collection procedure

Mislabel

Improper preparation or conditioning of the test samples;

Cross contamination of the sample during storage;

Excessive storage prior to testing leading to deterioration of the sample

b) Sample Testing

Inadequate definition of the task;

Inadequate training and supervision of staff;

Reagent or standard contamination/preparation error;

Equipment or glassware contamination;

Sample or reagent dilution error;

Mislabelling of test portions or sub-samples

Method error (error in following method);

Misreading error (error in reading the result/measurement);

Recording and calculation error;

Poor work practise;

Use of inadequately validated methods;

Non-adherence to method; and equipment in disrepair or out of calibration

c) Data Handling:

Data transcription error and typing error

Externally detected non-conformities'

When non-conformities' are raised through complaints; second-party audits; or through external proficiency testing, the process of Assuring the quality of test results requires investigation in order to determine why the non-conformity was not identified by the Quality System.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.10-01	Cause analysis procedure
DGHL/SOP4.10-02	Procedure for corrective action

PURPOSE

This document provides the policy and procedure for the initiation and implementation of preventive actions in DGHL. Preventive actions are actions that are taken to prevent the occurrence of potential non-conformances.

POLICY

DGHL has a policy to continually review its systems and procedures and the output data for potential sources of non-conformances so that preventive action can be applied on a pro-active basis in order to prevent the occurrence of non-conformances whenever possible.

PROCESS

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
QC Charts; MR Reports; Internal & external audit reports.	Identification: Opportunities for preventive action or potential sources of non-conformances, either technical or system based, shall be identified through: trend and risk analyses; document review; proficiency testing results; QC system; Identification by individual staff members; Auditing; and Management review.	Preventive Action identified	Lab Manager	-
Identified Preventive Action	Implementation: Register each Preventive action in the Continual Improvement opportunity Register. Initiate an IAR in accordance with the Corrective Action procedure and attach any associated supporting documents.	Implemented Actions.	Q officer	Improvement of the QMS in meeting client requirements as measured by the Customer

	Cross-reference to the Continual Improvement Register. Investigate root cause; implement appropriate action and resolve in accordance with the IAR Process as described in the Corrective Action procedure.			Satisfaction Survey
Implemented Actions	Effectiveness Monitoring: All preventive actions initiatives shall be monitored for effectiveness using the IAR process. Wherever possible, the effectiveness of an improvement initiative shall be evaluated and quantified.		Q officer	-

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.11-01	Procedure for preventive action

PURPOSE

To provide the policy and procedure for the systematic improvement of the QMS in DGHL

POLICY

DGHL has a system of continual improvement in the laboratory. Laboratory management shall systematically review the quality management system practice at regular intervals to identify any potential sources of non-conformance or other opportunities for continual improvement. The laboratory management shall participate in quality improvement activities and Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care. Action plans for improvement shall be developed, documented and implemented, as appropriate and evaluated the effectiveness of the Action plans.

PROCESS

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Management Review; Internal Audit; Complaint & Compliments; Personnel & client training; Corrective Action; Preventive Action; External assessment	Identification: Continual improvement shall be identified by: Reviewing and updating the Quality Policy and Procedures. Reviewing internal and external audit results for improvement opportunities. Analysing quality data and customer survey results and using this data to set new quality objectives or modify existing ones. Evaluating the quality indicators of the laboratory's contribution to patient care Ensuring corrective and preventive actions are implemented and effective. Performing periodic management reviews to evaluate the system per Management Review document. Training opportunities for personnel & users of the laboratories	Improvement Opportunities identified.	Lab Manager	-
Improvement Opportunities	Implementation: Register each improvement opportunity in the Improvement Opportunity Register. Initiate an IAR form for each new improvement opportunity and cross reference to the Improvement Opportunity Register. Investigate root cause; implement appropriate action and resolve in accordance with the IAR Process as described in the Corrective Action procedure.	Implemented Actions.	Q officer	Improvement of the QMS in meeting client requirements as measured by the Customer Satisfaction Survey
Implemented Actions	Improvement Monitoring: All improvement initiatives shall be monitored for effectiveness using the IAR process. Wherever possible, the effectiveness of an improvement initiative shall be evaluated and quantified.		Q officer	-

Subsidiary Documents

Document Unique ID	Document Name
DGHL/F4.12-01	Format for Quality Indicators

PURPOSE

To provide policy, guidance and indicating subsidiary documents for establishment and implementation of Quality and technical records system for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records in DGHL

POLICY

DGHL shall ensure that all quality records and technical records are effectively identified, indexed, accessible, filled and stored appropriately, maintained and disposed where necessary. Procedures are established to ensure the above requirements are carried out effectively and all records shall be legible, stored securely, in confidence and easily retrievable by authorized personnel, and each type of record allocate specific retention time according to local requirements.

QUALITY AND TECHNICAL RECORDS

The laboratory shall ensure that all quality and technical records are retained in archive for a defined period so as to enable audit trail. This is done by ensuring that records maintained in the laboratory information system; Back up of data is made to protect against loss or deterioration, Passwords are used according to level of security determined by the laboratory management to maintain confidentiality and prevent unauthorized access to an amendment of data.

The laboratory shall have procedure for back up of all records including computerized records and specific procedure for correcting mistakes and alterations. No erasure or white out are made on the original data. Corrections are made to the data by drawing a single line through the entry and initial the change.

Promptly and systematically document all technical records (including all records electronically stored) and to ensure that any corrections or alterations to any part of the records are legibly undertaken by authorized personnel. A copy of each report issued by the subcontracting laboratory is reproduced and kept in the laboratory.

Quality and Technical Records Retention Time

The laboratory defines the length of time various records pertaining to the quality management system and examination results are to be retained and the retention time is defined by the nature of the examination or specifically for each record**.**

S.N	Name of Quality and Technical Records	Retention Time
1	Request forms (including the patient chart or medical record only if used as the request form)	2 years
2	Hard copy of examination results and reports	2 years
3	Soft copy of examination results	5 years
4	Instrument printouts;	2 years
5	Examination procedures;	2 years
6	Laboratory work-books or sheets;	2 years
7	Accession records;	2 years
8	Calibration functions and conversion factors;	2 years
9	Quality control records;	2 years
10	Complaints and action taken;	2 years
11	Records of internal and external audits	2 years
12	External quality assessment records/inter-laboratory comparisons	5 years
13	Quality improvement records	2 years
14	Instrument maintenance records, including internal and external calibration records;	5 years
15	Lot documentation, certificates of supplies, package inserts;	2 years
16	Incident/accident records and action taken;	2 years
17	Staff training and competency records.	10 years
18	Supplier selection and performance records	

19	Instrument print out	2 years
20	Non conformities	2 years
21	Preventive actions	2 years
22	Corrective actions	2 years
23	Complaints	2 years
24	Risk management records	1 year

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.13-01	Procedure for Identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records
DGHL/F4.13-01	Format for back up of electronic data storage

PURPOSE

To provide policy, guidance and indicating subsidiary documents for establishment, planning and implementation of internal audit in DGHL

POLICY

Evaluation and Internal audits are conducted at the request of management and at predetermined scheduled (twice a year) to ensure that the laboratory's activities comply with the requirements of ISO 15189:2012. The internal audit committee shall establish and maintain documented procedures for planning and implementing internal quality audits in order to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. The Quality Officer is responsible for planning and organizing the audits and audits are conducted by personnel who are qualified and preferably independent of the activity being audited.

General

The laboratory plans and implements 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 included in the input to the management review

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

Assigned personnel review the examinations provided annually to ensure that they are clinically appropriate for the requests received. The laboratory annually 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 measured.

Assessment of user feedback

The laboratory seeks information relating to user perception as to whether the service has met the needs and requirements of users. The method for obtaining and using this information includes 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.

Staff suggestions

Laboratory management encourages staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management are maintained.

Internal audit

The laboratory conducts internal audits at annually to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:

a) Conform to the requirements of this International Standard and to requirements established by the laboratory, and

b) Are implemented, effective, and maintained.

NOTE 1 *the cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth, all elements of the quality management system. The laboratory may decide to focus on a particular activity without completely neglecting the others.*

Audits are conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit criteria, scope, frequency and methods are defined and documented. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors are selected wherever resources permit, independent of the activity to be audited.

The laboratory has a documented procedure to define the responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records. Personnel responsible for the area being audited ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective actions are taken without undue delay to eliminate the causes of the detected nonconformities.

Risk management

The laboratory evaluates the impact of work processes and potential failures on examination results as they affect patient safety, and modify processes to reduce or eliminate the identified risks and document.

Quality indicators

The laboratory establishes 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 is planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. The indicators are annually reviewed, to ensure their continued appropriateness.

DGHL, in consultation with the users, establishes turnaround times for each of its examinations that reflect clinical needs. The laboratory shall periodically evaluate whether or not it is meeting the established turnaround times.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP4.14-01	Procedure for Internal Audit
DGHL/F4.14-01	Internal Audit Report Form
DGHL/F14-02	Internal Audit Assessment check list
DGHL/SOP4.14-02	Procedure for establishing Turnaround time
DGHL/ F14-03	TAT Data Collection Sheet

PURPOSE

To provide the policy and procedure for the review of the Quality Management System to ensure its continued suitability and effectiveness and to introduce any necessary changes or improvements

POLICY

Lab Manager shall evaluate and analyse practices for introducing necessary changes or improvements to the QMS. The review shall cover all of its medical services including examination and advisory services. All documented policies and relevant records shall be reviewed and a list of action plans for improvements will be produced and documented. The laboratory conduct management review at least annually.

PROCESS

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
User feedbacks, Internal audits, risk management, IAR, Quality indicators, EQA result, periodic review of results, stakeholders, supply management, continual improvement and other relevant findings for Quality laboratory services	Issue notification of Management Review meeting together with Agenda (Annex 4.15); minutes of last review meeting (if applicable) & Summery Reports	MR Meeting arranged. Agenda & minutes distributed to participants.	Q officer	MR Meeting occurs.
Agenda; Minute format is used ;	Conduct & facilitate MR Meeting in accordance with the Agenda	MR Plan: Goals, Objectives and Actions	Lab Manager	_
IARs raised as a result of the MR meeting	Investigate; perform root cause analysis; implement relevant actions and verify effectiveness in accordance with the IAR procedure	IAR objectives achieved	RPs assigned during MR meeting	Improved activities
MR Plan	Facilitate fulfilment of MR Plan by expediting IARs and ensuring that objectives & goals are achieved.	Updated & Completed MR Plan	QM	Objectives Achieved

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP5-01	Procedure for Management Review

PURPOSE

This document provides the policy and procedure for implementation of laboratory's human resources management in DGHL.

POLICY

Human Resource Management of DGHL ensures the hiring of qualified personnel and the provision of well-defined job descriptions, Personnel qualifications, and laboratory management coordinates and/or provides orientation, training and competency assessment programs including continuing education and professional development and staff performance appraisal every six month.

General

The laboratory has a documented procedure for personnel management and maintains records for all personnel to indicate compliance with requirements.

Personnel qualifications

Laboratory management documents personnel qualifications for each position. The qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and are appropriate to the tasks performed.

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

Job descriptions

The laboratory has job descriptions that describe responsibilities, authorities and tasks for all personnel.

Personnel introduction to the organizational environment

The laboratory has a programme to introduce/orient new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services

Training

The laboratory provides training for all personnel which include the following areas:

The quality management system;

Assigned work processes and procedures;

The applicable laboratory information system;

Health and safety, including the prevention or containment of the effects of adverse incidents;

Ethics;

Confidentiality of patient information

Personnel that are undergoing training are supervised at all times. And the effectiveness of the training programme is reviewed by section supervisor and quality officer.

Competence assessment

The laboratory assesses the competence of each person to perform assigned managerial or technical tasks according to established criteria and the competence assessment is conducted following training.

Reassessment is in place annually and accordingly retraining will occur when necessary.

The Competence of laboratory staff will be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:

Direct observation of routine work processes and procedures, including all applicable safety practices;

Direct observation of equipment maintenance and function checks;

Monitoring the recording and reporting of examination results;

Review of work records;

Assessment of problem solving skills;

Examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples

Written examination for assessing theoretical knowledge on the assigned tasks

The competency assessments for professional judgment should be designed as specific and fit for purpose.

Reviews of staff performance

In addition to the assessment of technical competence, the laboratory shall ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.

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

Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel shall be maintained.

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

Educational and professional qualifications;

Copy of certification or license, when applicable;

Previous work experience;

Job descriptions;

Introduction of new staff to the laboratory environment;

Training in current job tasks;

Competency assessments;

Records of continuing education and achievements;

Reviews of staff performance;

Reports of accidents and exposure to occupational hazards;

Immunisation status, when relevant to assigned duties

The records listed above are not required to be stored in the laboratory, but can be maintained in other specified locations, providing they remain accessible as needed

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP5.1-01	Competency Assessment Procedure
DGHL/F5.1-01.01-06	Competency Assessment Checklist/form
DGHL/SOP5.1-02	Procedure for identifying training needs
DGHL/SOP5.1-03	Procedure for providing training
DGHL/SOP5.1-04	Procedure for Continuing Education
DGHL/SOP5.1-05	Performance Appraisals Procedure
DGHL/F5.1-02	Performance Appraisals Form
DGHL/F5.1-03	Job Description format
DGHL/SOP5.1-06	Laboratory work ethics agreement and confidentiality
DGHL/SOP5.1-06	Procedure for use of computer system
DGHL/F5.1-04	Format for Laboratory work ethics agreement and confidentiality
DGHL/F5.1-05	Format new staff orientation
DGHL/F5.1-06	Format for identifying training needs
DGHL/F5.1-07.1-50	Training check list
DGHL/F5.1-08	Onsite evaluation check list for point of care rapid HIV testing
DGHL/SOP5.1-07	Procedure for personnel management

PURPOSE

To provide policy, guidance and indicating subsidiary documents for establishment of the convenient accommodation and environmental conditions for laboratory work and personnel.

POLICY

DGHL management ensures that accommodation and environmental conditions of laboratory is safe for quality work practices, promotes personal wellness, and safety to the staff, client and environment. The laboratory shall have adequate space to fit for its intended use and to optimize the comfort of its occupants and there shall have separate reception/waiting and collection areas. As well as the laboratory and storage area are monitored, controlled and recorded environmental conditions in addition the laboratory management ensures that a communication system is established within the laboratory. Storage and disposal of dangerous materials is performed in compliance with statutory regulations and provisions.

GENERAL

The laboratory has space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory evaluates and determines the sufficiency and adequacy of the space allocated for the performance of the work.

Where applicable, similar provisions are made for primary sample collection and examinations at sites other than the main laboratory premises, under the management of the laboratory

Laboratory and office facilities

The laboratory management provides an environment suitable for the tasks to be undertaken, to ensure the following conditions are met.

Access to areas affecting the quality of examinations is controlled. The access control takes into consideration safety, confidentiality, quality and prevailing practices.

Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.

Facilities for examination allow for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.

Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.

Safety facilities and devices are provided and their functioning regularly verified. Such as Operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers; accessibility of emergency showers and eyewash, etc (only when applicable)

Storage facilities

Storage space and conditions are 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 are stored in a manner to prevent cross contamination.

Storage and disposal facilities for dangerous materials are appropriate to the hazards of the materials and as specified by applicable requirements.

Staff facilities

The laboratory management ensures that there shall be adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing. When possible, the laboratory should provide space for staff activities such as meetings and quiet study and a rest area.

Patient sample collection facilities

The laboratory management ensures that:

Patient sample collection facilities are separate reception/waiting and collection areas. Consideration are given to the accommodation of patient privacy, comfort and needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection (we use different expertise from the staff).

Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) are enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination.

Sample collection facilities are maintained appropriate first aid materials for both patient and staff needs.

Facility maintenance and environmental conditions

The laboratory management ensures that:

Laboratory premises are maintained in a functional and reliable condition. Work areas shall be clean and well maintained.

The laboratory monitors, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff. Attentions are paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.

There are effective separations between laboratory sections in which there are incompatible activities. Procedures are in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.

The laboratory provides a quiet and uninterrupted work environment where it is needed

Subsidiary Documents

Document Unique Id	Document Name
DGHL/5.2-01	Laboratory Safety Guideline
DGHL/SOP5.2-01	Procedure for Segregation and disposal of waste materials
DGHL/SOP5.2-02	procedure for hazardous chemical storage and inventory
DGHL/SOP5.2-03	procedure for cross-contamination
DGHL/F-5.2-01	Safety instructions format
DGHL/F-5.2-02	Form for environmental room temperature monitoring records
DGHL/F-5.2-03	Form for Waste Disposal
DGHL/F-5.2-04	Work station cleaning check list
DGHL/F-5.2-05	Format for Refusal Vaccination
DGHL/F-5.2-06	Format for vaccination status
DGHL/F-5.2-07	Form for Eye Wash & Emergency Shower Preventive Maintenance
DGHL/F-5.2-08	Log book for Fire Extinguisher
DGHL/F-5.2-09	Material Safety Data Sheet (MSDS)

PURPOSE

To provide policy, guidance and indicating subsidiary documents of laboratory equipment's management for implementation of preventive maintenance program requirement, processes and procedures related to receiving equipment management, and retire/old/out-dated equipment of laboratory equipment, reagents and supplies.

Policy

DGHL ensures that all laboratory equipment are installed, calibrated, maintained and used in accordance with the manufacturer's instructions and accreditation requirements. DGHL have system equipment acceptance testing, equipment calibration and metrological traceability, equipment adverse incident reporting and equipment records. In addition there shall be a system for reagents and consumables reception, storage, acceptance testing, inventory management, and instructions for use adverse incident reporting records

Equipment

General

Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems. Reagents include reference materials, calibrators and quality control materials; consumables include culture media, pipette tips, glass slides, etc.

The laboratory has a documented procedure for the selection, purchasing and management of equipment.

The laboratory is furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control (microscopes and other portable equipment), laboratory management shall ensure that the requirements of this International Standard are met

The laboratory replaces equipment as needed to ensure the quality of examination results.

Equipment acceptance testing

The laboratory management ensures that:

The laboratory verifies upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned. This requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory (when is applicable in any time the laboratory functions).

Each item of equipment are uniquely labelled, marked or otherwise identified.

Equipment instructions for use

The laboratory management ensures that:

Equipment shall be operated at all times by trained and authorized personnel. Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, shall be readily available.

The laboratory shall have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

Equipment calibration and metrological traceability

The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:

Taking into account conditions of use and the manufacturer's instructions;

Recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;

Verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;

Recording the calibration status and date of recalibration;

Ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;

Safeguards to prevent adjustments or tampering that might invalidate examination results.

Metrological traceability is to a reference material or reference procedure of the higher metrological order available

Documentation of calibration traceability to a higher order reference material or reference procedure is provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.

Where this is not possible or relevant, other means for providing confidence in the results are applied, including to the following:

Use of certified reference materials;

Examination or calibration by another procedure;

Mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

Comparing in equipment' in metrological institutions

Equipment maintenance and repair

The laboratory has a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions.

Equipment has maintained in a safe working condition and in working order. This shall include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used.

Whenever equipment is found to be defective, it shall be taken out of service and clearly labelled. The laboratory ensures that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The laboratory shall examine the effect of any defects on previous examinations and institute immediate action or corrective action

The laboratory takes reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.

When equipment is removed from the direct control of the laboratory, the laboratory ensures that its performance is verified before being returned to laboratory use.

Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment are investigated and reported to the manufacturer and appropriate authorities, as required.

Equipment records

Records are maintained for each item of equipment that contributes to the performance of examinations.

These equipment records include, but not are limited to, the following:

Identity of the equipment;

Manufacturer's name, model and serial number or other unique identification;

Contact information for the supplier or the manufacturer;

Date of receiving and date of entering into service;

Location;

Condition when received (e.g. new, used or reconditioned);

Manufacturer's instructions;

Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;

Maintenance carried out and the schedule for preventive maintenance;

Equipment performance records that confirm the equipment's on going acceptability for use;

Damage to, or malfunction, modification, or repair of the equipment

The performance records referred to in j) includes copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or this entire requirement.

These records are maintained and are readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure

Reagents and consumables

General

The laboratory has a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.

Reagents and consumables — Reception and storage

Where the laboratory is not the receiving facility, it verifies that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.

The laboratory stores received reagents and consumables according to manufacturer's specifications.

Reagents and consumables — Acceptance testing

Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, are verified for performance before use in examinations.

Consumables that can affect the quality of examinations are verified for performance before use in examinations.

Reagents and consumables — Inventory management

The laboratory establishes an inventory control system for reagents and consumables.

The system for inventory control segregates uninspected and unacceptable reagents and consumables from those that have been accepted for use.

Reagents and consumables — Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers, are readily available.

Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables are investigated and reported to the manufacturer and appropriate authorities, as required

Reagents and consumables — Records

Records are maintained for each reagent and consumable that contributes to the performance of examinations. These records shall include but not be limited to the following:

Identity of the reagent or consumable;

Manufacturer's name and batch code or lot number;

Contact information for the supplier or the manufacturer;

Date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service;

Condition when received (e.g. acceptable or damaged);

Manufacturer's instructions;

Records that confirmed the reagent's or consumable's initial acceptance for use;

Performance records that confirm the reagents or consumables on going acceptance for use

Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP5.3-01	Procedure for Acquiring, storage and Retiring Equipment
DGHL/SOP5.3-02	Procedure for equipment inventory
DGHL/SOP5.3-03	Procedure for Equipment Failure Cause analysis and Corrective Action
DGHL//F5.3-01	Format for Equipment Information
DGHL/F5.3-02	Format Equipment maintenance and Service Information
DGHL/F5.3-03	Form for equipment master list
DGHLF5.3-04	Form for equipment calibration record
DGHL/F5.3-05.01-16	Form for preventive maintenance record
DGHL/JA5.3-01	Job aid for backup microscopy

PURPOSE

To provide policy, guidance and indicating subsidiary documents for pre-examination procedures implementation in the laboratory.

POLICY

DGHL has a policy to ensure that the pre examination procedures are properly implemented in the laboratory in accordance with accreditation and customer requirements. The laboratory has sample collection manual for execution of consistent processes on sample collection, processing, transportation and storage and laboratory management establish a system for recording and tracking of sample, monitoring sample transportation and storage, samples acceptance or rejection criteria, periodically reviewing of sample volume requirements, and systematically reviewing of requests and samples. The laboratory also ensures that sample portions are traceable to the original primary by sample, and the laboratory has a policy for verbal requests for examinations.

General

The laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.

Information for patients and users

The laboratory has information available for patients and users of the laboratory services. The information shall include as appropriate:

The location of the laboratory;

Types of services offered by the laboratory including examinations referred to other laboratories;

Opening hours of the laboratory;

the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values;

Instructions for completion of the request form;

Instruction for preparation of the patient;

Instructions for patient-collected samples;

Instructions for transportation of samples, including any special handling needs;

Any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);

The laboratory's criteria for accepting and rejecting samples;

A list of factors known to significantly affect the performance of the examination or the interpretation of the results

Availability of clinical advice on ordering of examinations and on interpretation of examination results;

The laboratory's policy on protection of personal information;

The laboratory's complaint procedure

The laboratory has information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant are explained to the patient and user.

Request form information

The request form or an electronic equivalent allows space for the inclusion of, but not be limited to, the following:

Patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier. The laboratory uses hospital number and full name as unique identification

Name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;

Type of primary sample and, where relevant, the anatomic site of origin;

Examinations requested;

Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;

Information needed for examination performance and results interpretation may include the patient's ancestry, family history, travel and exposure history, communicable diseases and other clinically relevant information.

Financial information for billing purposes, financial audit, resource management and utilization reviews may also be collected. The patient should be aware of the information collected and the purpose for which it is collected.

Date and, where relevant, time of primary sample collection;

Date and time of sample receipt.

The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory are determined in discussion with the users of laboratory services.

The laboratory has a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time.

The laboratory is willing to cooperate with users or their representatives in clarifying the user's request.

Primary sample collection and handling

General

The laboratory has documented procedures for the proper collection and handling of primary samples.

The documented procedures are available to those responsible for primary sample collection whether or not the collectors are laboratory staff.

Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these are recorded and included in all documents containing examination results and shall be communicated to the appropriate personnel.

All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, vein puncture. Patients in a hospital bed should normally be given the opportunity to refuse.

Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.

In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

Adequate privacy during reception and sampling are available and appropriate to the type of information being requested and primary sample being collected.

Instructions for pre-collection activities

The laboratory's instructions for pre-collection activities include the following:

Completion of request form or electronic request;

Preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);

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 (e.g. history of administration of drugs)

Instructions for collection activities

The laboratory's instructions for collection activities include the following:

Determination of the identity of the patient from whom a primary sample is collected;

Verification that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.];

Instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;

in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff;

Instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;

Recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;

Instructions for proper storage conditions before collected samples are delivered to the laboratory;

Safe disposal of materials used in the collection.

Sample transportation

The laboratory's instructions for post-collection activities include packaging of samples for transportation.

The laboratory has a documented procedure for monitoring the transportations of samples to ensure they are transported:

Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;

Within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;

In a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

Sample reception

The laboratory's procedure for sample reception ensures that the following conditions are met.

Samples are unequivocally traceable, by request and labelling, to an identified patient or site.

Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.

Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.

All samples received are recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt and/or registration of samples shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded.

Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).

Where relevant, there shall be instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.

All portions of the primary sample shall be unequivocally traceable to the original primary sample.

Pre-examination handling, preparation and storage

The laboratory has procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

A laboratory procedure includes time limits for requesting additional examinations or further examinations on the same primary sample

Subsidiary Documents

Document Unique Id	Document Name
DGHL/MAN5.4-01	Sample Collection manual
DGHLMAN5.4-02	Laboratory handbook
DGHL/SOP5.4-01	Procedure for verbal requests
DGHL/SOP5.4-02	Urgent Order management
DGHL/F5.4-01	Accession book for records of received samples,
DGHL/F5.4-02	Record formats for specimen collection
DGHL/F5.4-03	Laboratory Requesting Format
DGHL/F5.4-04	Specimen referral tracking log
DGHL/F5.4-05.01-02	Blood transfusion registration format
DGHL/F5.4-06	Specimen rejection/acceptance criteria
DGHL/F5.4-07	Specimen IAR log sheet
DGHL/F5.4-08	Sample rejection log
DGHL/JA5.4-01	Job aid for sample shipment
DGHL/JA5.4-02	Job aid for capillary sample collection

PURPOSE

This document provides the policy, guidance and indicate subsidiary document (s) for examination of procedure.

POLICY

DGHL has a policy to implement an approved examination procedure and used only verified and validated method to produce accurate and reliable results. Latest version of examination procedure shall be available and use at all time. All procedures shall be documented and be available at the workstation for relevant staff. Performance specification for each examination shall have in place. Examination procedure shall have unique identifiable and shall be part of document control.

Selection, verification and validation of examination procedures

General

The laboratory selects examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes is recorded.

The specified requirements (performance specifications) for each examination procedure relates to the intended use of that examination.

Preferred procedures are those specified in the instructions for use of in vitro medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines, or national or regional regulations.

Verification of examination procedures

Validated examination procedures used without modification are subject to independent verification by the laboratory before being introduced into routine use.

The laboratory obtains information from the manufacturer/method developer for confirming the performance characteristics of the procedure.

The independent verification by the laboratory confirms, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met.

The performance claims for the examination procedure confirmed during the verification process are those relevant to the intended use of the examination results.

The laboratory documents the procedure used for the verification and records the results obtained. Staff with the appropriate authority reviews the verification results and record the review.

Validation of examination procedures

DGHL validates examination procedures when it derives from the following sources:

Non-standard methods;

Laboratory designed or developed methods;

Standard methods used outside their intended scope;

Validated methods subsequently modified.

The validations are as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.

Performance characteristics of an examination procedure include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantization limit, measuring interval, diagnostic specificity and diagnostic sensitivity according to manufacturer claims.

The laboratory documents the procedure used for the validation and record the results obtained. Staff with the authority shall review the validation results and record the review.

When changes are made to a validated examination procedure, the influences of such changes are documented and, when appropriate, a new validation will be carried out.

Measurement uncertainty of measured quantity values

The laboratory determines measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory defines the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty. However; if the method used in the laboratory is with similar performance conditions approved by EQA, IQC, and service maintenance information, and calibration, no need to determine measure of uncertainty.

The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of the measured value.

Measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions that include as many routine changes as reasonably possible in the standard operation of a measurement procedure

Examples of the practical utility of measurement uncertainty estimates might include confirmation that patients' values meet quality goals set by the laboratory and meaningful comparison of a patient value with a previous value of the same type or with a clinical decision value

The laboratory considers measurement uncertainty when interpreting measured quantity values. Upon request, or written letter or posts the laboratory make its estimates of measurement uncertainty available to laboratory users.

Where examinations include a measurement step but do not report a measured quantity value, the laboratory calculates the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.

Biological reference intervals or clinical decision values

The laboratory defines the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users.

When a particular biological reference interval or decision value is no longer relevant for the population served, appropriate changes are made and communicated to the users.

When the laboratory changes an examination procedure or pre-examination procedure, the laboratory shall review associated reference intervals and clinical decision values, as applicable.

Documentation of examination procedures

Examination procedures are written in language commonly understood by the staff, available in the appropriate location and

Any condensed document format (e.g. card files or similarly used systems) corresponds to the documented procedure.

Working instructions, card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a full documented procedure is available for reference.

Information from product instructions for use may be incorporated into examination procedures by reference.

All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, shall be subject to document control.

In addition to document control identifiers, documentation shall include, when applicable to the examination procedure, the following:

Purpose of the examination;

Principle and method of the procedure used for examinations;

Performance characteristics

Type of sample (e.g. plasma, serum, urine);

Patient preparation;

Type of container and additives;

Required equipment and reagents;

Environmental and safety controls;

Calibration procedures (metrological traceability);

Procedural steps;

Quality control procedures;

Interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions;

Principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values

Biological reference intervals or clinical decision values;

Reportable interval of examination results;

Instructions for determining quantitative results when a result is not within the measurement interval;

Alert/critical values, where appropriate;

Laboratory clinical interpretation;

Potential sources of variation;

References

If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure.

This requirement can be accomplished in different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters or part of the examination report itself.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/MIC/SOP5.5-01.01-50	Procedure for Microbiology test (s)
DGHL/CHE/SOP5.5-02.01-15	Procedure for Chemistry test (s)
DGHL/IMH/SOP5.5-03.01-16	Procedure for Immuno-Haematology test (s)
DGHL/PAR/SOP5.5-04.01-05	Procedure for Parasitological test (s)
DGHL/URI/SOP5.5-05.01-03	Procedure for Urinalysis test (s)
DGHL/SER/SOP5.5-06.01-05	Procedure for Serology test (s)
DGHL/TB/SOP5.5-07.01-14	Procedure for TB laboratory
DGHL/MIC/JA5.5-01.01-10	Job Aid on test method for Microbiology test (s)
DGHL/CHE/JA5.5-02.01-05	Job Aid on test method for chemistry test (s)
DGHL/IMH/JA5.5-03.01-07	Job Aid on test method for Immunohematology
DGHL/PAR/JA5.5-04.01-02	Job Aid on test method for Parasitology
DGHL/URI/JA5.5-05.01-02	Job Aid on test method Urinalysis
DGHL/SER/JA/5.5-06.01-02	Job Aid on test method Serology
DGHL/TB/JA/5.5-07.01-07	Job Aid on test method TB laboratory
DGHL/JA5.5-08	Job Aid on blood Collection
DGHL/SOP5.5-08	Quantitative verification procedure
DGHL/SOP5.5-09	Qualitative verification procedure
DGHL/SOP5.5-10	Specimen Carryover verification
DGHL/SOP5.5-11	Procedure for linearity
DGHL/F5.5-01.01	Format for Assay Calibration
DGHL/F5.5-01.02	Format for FACS calibre calibration

PURPOSE

This document provides the policy, guidance and indicates subsidiary documents for assuring the quality of test results.

POLICY

DGHL has a policy to design, implement, maintain and improve quality assurance (Internal and external quality controls) procedures to monitor the validity of tests. The laboratory shall participate in inter-laboratory comparisons and/or external quality assessment (EQA) scheme such as proficiency test (PT) or Laboratory shall set mechanism to exchange of samples with other laboratories and monitoring of result accordingly. There shall be defined system for verifying results throughout examination procedures. Quality records shall be retrievable and documented.

General

The laboratory ensures the quality of examinations by performing them under defined conditions. Appropriate pre and post-examination processes shall be implemented. The laboratory shall not fabricate any results.

Quality control

The laboratory designs quality control procedures that verify the attainment of the intended quality of results.

General

The laboratory design quality control procedures that verify the attainment of the intended quality of results for all tests available in the laboratory

Quality control materials

The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples. Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer. And in the absence of certified quality control material the laboratory can use in house prepared quality control that can show the accuracy and precision of laboratory system.

Quality control data

The laboratory has a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results will be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory evaluates the results from patient samples that were examined after the last successful quality control event.

Quality control data are reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded.

NOTE Statistical and non-statistical techniques for process control are used wherever possible to continuously monitor examination system performance.

Inter-laboratory comparisons

Participation

The laboratory participates in an inter-laboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory monitors the results of the inter-laboratory comparison programme(s) and participates in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

The laboratory participates in inter-laboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043. The laboratory establishes a documented procedure for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison programme.

Alternative approaches

Whenever an inter-laboratory comparison is not available, the laboratory develops other approaches and provides objective evidence for determining the acceptability of examination results.

NOTE Examples of such materials used may include:

Certified reference materials;

Samples previously examined;

Material from cell or tissue repositories;

Exchange of samples with other laboratories;

Control materials that are tested daily in inter laboratory comparison programmes.

Analysis of inter laboratory comparison samples

The laboratory integrates inter laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. Inter-laboratory comparison samples shall be examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.

The laboratory doesn't communicate with other participants in the inter-laboratory comparison programme about sample data until after the date for submission of the data. The laboratory doesn't refer inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples

Evaluation of laboratory performance

The performance in inter-laboratory comparisons are reviewed and discussed with relevant staff. When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff participates in the implementation and recording of corrective action. The effectiveness of corrective action is monitored. The returned results are evaluated for trends that indicate potential nonconformities and preventive action shall be taken.

Comparability of examination results

There are a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.

In the particular case of measurement results that are metrological traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable. The laboratories notifies users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed.

The laboratory documents record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be acted

PURPOSE

This document provides the policy, guidance and indicates subsidiary documents for post examination procedures.

POLICY

This is the laboratory policy to systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results and storage of samples of the examinations.

Review of results

The laboratory has procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results. When the procedure for reviewing results involves automatic selection and reporting, review criteria shall be established, approved and documented.

Storage, retention and disposal of clinical samples

The laboratory shall have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. The laboratory shall define the length of time clinical samples are to be retained. Retention time shall be defined by the nature of the sample, the examination and any applicable requirements.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/JA5.7-01	procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples
DGHL/JA5.7-01	Job aid for result verification
DGHL/F5.7-01	Sputum storage format
DGHL/F5.7-02	Blood specimen storage format

PURPOSE

This document provides the policy, guidance and indicates subsidiary documents for reporting of result.

POLICY

It is the policy of DGHL to standardize report formatting and to designate authorized personnel for reporting results. Reported results shall be retrievable for defined period on document retention policy. All important information has to be included in result reporting format and as necessary comments has to accompany.

General

The results of each examination are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures. The laboratory defines the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory. The laboratory has a procedure to ensure the correctness of transcription of laboratory results. Reports include the information necessary for the interpretation of the examination results. The laboratory has a process for notifying the requester when an examination is delayed that could compromise patient care.

Report attributes

The laboratory ensures that the following report attributes effectively communicate laboratory results and meet the users' needs:

a) Comments on sample quality that might compromise examination results;

b) Comments regarding sample suitability with respect to acceptance/rejection criteria;

c) Critical results, where applicable;

d) Interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.1) in the final report.

Report content

The report shall include, but not be limited to, the following:

A clear, unambiguous identification of the examination including, where appropriate, the examination procedure;

The identification of the laboratory that issued the report;

Identification of all examinations that have been performed by a referral laboratory;

Patient identification and patient location on each page;

Name or other unique identifier of the requester and the requester's contact details;

Date of primary sample collection (and time, when available and relevant to patient care);

Type of primary sample;

Measurement procedure, where appropriate;

Examination results reported in SI units, units traceable to SI units, or other applicable units;

Biological reference intervals, clinical decision values, or diagrams/monograms supporting clinical decision values, where applicable;

NOTE 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.

Interpretation of results, where appropriate;

NOTE Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.

Other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);

Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;

Identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);

Date of the report, and time of release (if not contained in the report, readily available when needed);

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP5.8-02	Procedure for transcribed referral lab results
DGHL/JA5.8-01	Job aid for urinalysis/ Parasitology result interpretation
DGHL/JA5.8-02	Job aid for managing Clerical errors

Purpose

This document provides the policy, guidance and indicates subsidiary documents for release of result.

Policy

DGHL shall have documented procedures for the release of examination results and identify who may release the results and to whom. The laboratory shall have procedure and/or process or system for automated selection and reporting of results and revision of report.

General

The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.

a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.

b) When examination results fall within established “alert” or “critical” intervals:

— A physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination];

— Records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.

c) Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.

d) When results are transmitted as an interim report, the final report is always forwarded to the requester.

e) There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally shall be followed by a written report. There shall be a record of all oral results provided.

NOTE 1 for the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

NOTE 2 Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

Automated selection and reporting of results

There are procedures for automated selection and reporting of results which ensures

The criteria for automated selection and reporting are defined, approved, readily available and understood by the staff;

The criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning;

There is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination;

There is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate;

Results selected for automated reporting are identifiable at the time of review before release and include date and time of selection.

There is a process for rapid suspension of automated selection and reporting.

Revised reports

When an original report is revised there shall be written instructions regarding the revision so that:

The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;

The user is made aware of the revision;

The revised record shows the time and date of the change and the name of the person responsible for the change;

The original report entries remain in the record when revisions are made.

Results that have been made available for clinical decision making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised. When the reporting system cannot capture amendments, changes or alterations, a record

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP5.9-01	Notification procedure on “Alert” or “Critical intervals”
DGHL/SOP5.9-02	Electronic records editing procedure
DGHL/SOP5.9-03	Procedure for automated selection, report ,review, verify and release of results
DGHL/SOP5.9-04	Corrected or Amended Result
DGHL/SOP5.9-05	Procedure for release of results through telephone
DGHL/F5.9-01	Format for interim report
DGHL/F5.9-02	Format for “Alert” or Critical intervals”
DGHL/F5.9-03.01-07	Format for result verification
DGHL//JA5.9-01	Results revision job aid
DGHL/JA5.9-02	Job aid for “Alert” or “Critical intervals”

Purpose

This document provides the policy, guidance and indicates subsidiary documents for laboratory information management.

Policy

DGHL has a policy to standardize and access to laboratory data and information management. The laboratory defines responsibilities and authorities for handling LIM. The laboratory uses validated and verified Information system management prior to introduction of LMS.

General

The laboratory has access to the data and information needed to provide a service which meets the needs and requirements of the user. The laboratory has a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

Authorities and responsibilities

The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.

The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:

Access patient data and information;

Enter patient data and examination results;

Change patient data or examination results;

Authorize the release of examination results and reports.

Information system management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

A) Validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation.

NOTE Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation, hospital patient administration systems and systems in primary care.

B) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;

C) protected from unauthorized access;

D) safeguarded against tampering or loss;

E) Operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription

F) Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;

g) In compliance with national or international requirements regarding data protection.

The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service. When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.

Subsidiary Documents

Document Unique ID	Document Name
DGHL/SOP5.10-01	Procedure for collection, processing, recording, reporting, storage or retrieval, validation, verifying, handling, of laboratory data and information
DGHL/SOP5.10-02	Procedure for confidentiality, integrity and backup system of data for electronic systems
DGHL/SOP5.10-03	Procedure for use of computers automated LIM

Name Signature

Compiled by: _____ _____

Approved by---------- ----------

Declaration:

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

Name	**Signature & Date**
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8.2. Standard Operational Procedure of Typhoid Fever

DURAME GENERAL HOSPITAL LABORATORY

DURAME, ETHIOPIA

TITLE: SOP for the detection of Salmonella typhi (ST), (H & O) Ags in Human serum or plasma.	**Origin Date:** May, 2017
	Revised Date: August, 2018
Document Number: DHL-Sero-01	**Version No. :**02
Section: Lab Head Office/Serology Workstation	**Effective Date: June**, 2017
	Page: 277 of 301

Procedure change history

Version #	Replaced version		Prepared by	Reviewed by	Approved by
01	01	**Name**	Wogayehu W	**Quality officer**	Lab head
		Sign			
		Date	May, 2017	May, 2017	May, 2017

Annual Review Table for unchanged documents

Date Reviewed	Reviewed By	Revision Date	Initials
Distribution/location	**Lab head office shelf number-**		
	Serology Workstation Folder #:		

Date of Discontinuation		
Abbreviations	QC = Quality Control S.typhi=Salmonella typhi	Ag= antigen Ab=antibody

Purpose	This procedure provides instruction on rapid self-performing Immuno agglutination assay for the detection of antibodies to Salmonella typhi in Human serum or plasma

Materials	**Reagents**			
	Device: contains ready to use concentrated smooth Ag suspension of the bacilli;S.typhi'O',S.typhi'H'and poly specific positive control reactive with this Ags			
	Reagents stability and storage			
	1. Store the reagent at 2-8°c.DO NOT FREEZ **2.** The shelf life of reagents is as per the expiry date mentioned on the reagent vial labels. Do not use beyond expiry date.			
	Supplies			
	• Ag (O, H) Suspension • Control +ve & -ve • Disposable sample dropper • Slide		• Stop watch, high intensity light source • Package insert • Mixing sticks ladder • Rubber teat	
Sample	**Sample type**	**Amount required**	**Transport and Storage**	**Stability**
	Serum or plasma	1drop (dropper used is sent by the manufacturer)	Sample must be stored at 2-8 ^{0}C, if not tested immediately up to 72 hrs	Sample should be refrigerated, if it is not tested immediately
	Limitations: Do not read result after one minute. **Sample retention:** Specimens are discarded in accordance with durame General Hospital Laboratory Specimen Retention Policy.			
Special Safety Precautions	• Use Universal safety precaution(wearing gloves lab coat and washing hands) when handling infectious materials • Refer to the SRHL Safety Manual for standard safety procedures			

Quality Control	**Control**	**Level**	**Stability**	**Frequency**	**Preparation (y/n)**
	Internal kit control	-	4 - 30 ^{0}C	Each run	No
	In house control	-			

Procedure	1. Bring the Reagent at room Temperature 2. Place one drop of positive control on to reaction circle of the slide 3. place 50 µl of physical saline on to the next reaction circle of the slide 4. Place one drop of patient's serum to be tested on to each of the required number of reaction circles. 5. Add one drop of appropriate TIDAL Ag suspension to the reaction circles containing positive control and physical saline 6. Add one drop of appropriate TYDAL Ag Suspensions to the reaction circles

	containing the patient serum 7. Mix contents of each circle uniformly over the entire circle with separate mixing sticks **8.** Rock the slide gently back and forth, and observe for agglutination macroscopically at one minute.

Result Interpretation	**Step**	**Action**
	1	Agglutination is a positive test result and indicates presence of the corresponding Ab in the patient's serum.
	2	*No agglutination is a negative test result and indicates absence of the corresponding Ab in the patient serum.*

Principle	When the colored ,smooth attenuated TYDAL Ag suspension are mixed/incubated with patient serum, anti-salmonella Ab present in the patient serum react with the Ag suspension to give agglutination .Agglutination is a positive test result ,indicating presence of anti-salmonella antibodies in the patient serum .No agglutination is a negative test result indicting absence of anti-salmonella antibodies.
Reference	• Widal test kit insert

Name	**Date**	**Signature**
Prepared by:- Wogayehu Workneh	May, 2017	…….
Reviewed by: - Lab quality officer	May, 2017	…….....
Approved by: laboratory head	May, 2017	**……**

Declaration

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

Name	**Signature and Date**
……..	**…….....**
……..	**…….....**
……..	**…….....**

8.3. Standard Operating Procedure of Blood Film

Durame General Hospital Laboratory

TITLE: **SOP for Blood Parasite Examination (BP)**	Origin Date: **May, 2017**
	Revised Date: **June, 2018**
Document Number: **PARA-BP-01**	Version: **02**
Section: **Lab Head Office, Microscopy, Parasitology & Urinalysis workstation**	Effective Date: **June, 2017**
	Page: **280 of 301**

Procedure change history

Version #	Replaced version		Prepared by	Reviewed by	Approved by
01	**01**	**Name**	**Wogayehu W**	**Quality officer**	**Laboratory head**
		Sign			
		Date	May, 2017	May, 2017	May, 2017

Annual Review Table for unchanged documents

Date Reviewed	Reviewed By	Revision Date	Initials
Distribution/location	**Lab head office shelf number-**		
	Parasitology Workstation		
Date of Discontinuation			

Purpose	This procedure provides instruction for the detections of blood parasites in patients with clinical sign and symptoms of suggestive malarial infection.

Materials	**Reagents**: Giemsa/wright stain, Deionized water, 70% alcohol, Buffer Tablet **Supplies**: Lancet/syring; slide; guaze/cotton; slide rack; staining jar/rack; biohazard bag/waste bin; Microscope; Disposable gloves; Filter paper; Tourniquet **Reagents preparation:** • 156 ml working Giemsa buffer • 4ml Giemsa stain stock • 8 drops of 5%Triton X-100
Special Safety Precautions	• Wear personal protective equipment such as gloves, laboratory coats. • If you have cuts or abrasions on the skin of your hands, cover them with adhesive dressing. • Use needles and lancets only once, and dispose of them in a "sharps" container for decontamination. • Remove gloves and wash your hands after completing any task involving the handling of biological material.
Specimen collection & storage: **1. Capillary blood collection**	• Label pre-cleaned slides (preferably frosted-end) with the patient's name (or other identifier) and date and time of collection. • Clean the site well with alcohol (70%); allow drying. • Prick the side of the pulp of the 3rd or 4th finger (alternate sites include ear lobe, or in infants large toe or heel). • Wipe away the first drop of blood with clean gauze. • Prepare at least two thick smear and two thin smear

<table>
<tr><td>Materials</td><td>
<table>
<tr><th>Reagents</th><th>Supplies</th></tr>
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Deionized water,
70% alcohol,
Buffer Tablet</td><td>• Lancet/syring
• slide
• guaze/cotton
• slide rack
• staining jar/rack
• biohazard bag/waste bin
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• Use needles and lancets only once, and dispose of them in a “sharps” container for decontamination.
• Remove gloves and wash your hands after completing any task involving the handling of biological material.</td></tr>
<tr><td>Specimen collection & storage:
2. Capillary blood collection</td><td>• Label pre-cleaned slides (preferably frosted-end) with the patient’s name (or other identifier) and date and time of collection.
• Clean the site well with alcohol (70%); allow drying.
• Prick the side of the pulp of the 3rd or 4th finger (alternate sites include ear lobe, or in infants large toe or heel).
• Wipe away the first drop of blood with clean gauze.
• Prepare at least two thick smear and two thin smear</td></tr>
<tr><td>3. Venous blood collection</td><td>• Label collection tubes and pre-cleaned slides (preferably frosted-end) with the patient’s name (or other identifier) and date and time of collection.
• Place a tourniquet above the Venipuncture site.
• Palpate and locate the vein.
• Clean the site well with alcohol (70%); allow to dry.
• Collect the venous blood in a vacuum tube containing anticoagulant (preferably EDTA); alternatively, collect the blood in a syringe and transfer it to a tube with anticoagulant; mix well.
• Prepare at least two thick smear and two thin smear as soon as possible after collection (delay can result in changes in parasite morphology and staining characteristics).</td></tr>
</table>

Preparation & staining of Thick smears*:*	• Place a small drop of blood in the center of the pre-cleaned, labeled slide. • Using the corner of another slide or an applicator stick spread the drop in a circular pattern until it is the size of a dime. • Lay the slides flat and allow the smears to dry thoroughly, protect from dust and insects. • Air dry at room temperature, need minimum of 30 minutes. Do not fix thick smears with methanol or heat. If there will be a delay in staining smears, dip the thick smear briefly in water to hemolyse the RBCs. • Place the unfixed thick film in to the working Giemsa stain • At the end of the staining time remove & drain briefly on to absorbent paper • Wash by placing in PH 7.0 to 7.2 buffered water for five minutes • Allow to dry in vertical position(fan may be used to shorten drying time)
Preparation& staining of Thin smears:	• Place a small drop of blood on the pre-cleaned, labeled slide, near its frosted end. • Bring another slide at a 30-45° angle up to the drop, allowing the drop to spread along the contact line of the 2 slides. • Quickly push the upper (spreader) slide toward the unfrosted end of the lower slide. • Make sure that the smears have a good feathered edge. • Allow the thin smears to dry & Fix film in absolute methanol • Air dry & place in to the working Giemsa stain • At the end of the staining time remove & drain briefly on to absorbent paper • Rinse by dipping slide in & out the jar containing 7.0 to 7.2 PH buffered water • Allow to air dry in vertical position(fan may be used to shorten drying time)

Quality Control	Select a patient specimen with at least one parasite per oil immersion field (p.vivax preferred, since well-stained smears will demonstrate schifners stippling) • Prepare as many thin smears as possible • Allow them to dry quickly • Fix them in absolute alcohol • Pack them front to back, tightly in the same box to which the slides are supplied • Label the outside of the box Giemsa +control + species & date • Store at -70 degree centigrade or colder indefinitely • When need remove one slide from box, label it & allow it to come to room T^0 & stain

Procedure-examination of thick smear	• First screen the entire smear at a low magnification (10× objective lens), to detect large parasites such as microfilaria. • Add one drop of immersion oil. • Then examine the smear using the 100× oil immersion objective lens. Select an area that is well-stained, free of stain precipitate and well-populated with white blood cells (10-20 WBCs/field). • If you see parasites, make a tentative species determination on the thick smear and then examine the thin smear to determine the species present. • Screen at least 100 fields each contain 10-20 WBCs using 100x oil immersion objective, to report, No blood parasites seen(NBPS)
Procedure-examination thin smear	• Screen at low magnification (10× objective lens). • Add one drop of immersion oil. • Carefully examine the smear using the 100× oil immersion objective lens. • Examine 200-300 fields using the 100× oil immersion objective lens for the determination of No blood parasite seen (NBPS).

Result Interpretation-qualitative	If malaria parasites are seen report as positive for the specific parasites seen (P.Falisparum, P Vivax, P. ovale or P. Malariae), if thick blood film is positive for malaria parasites it should be repeated in thin blood films for species identification. To report as No blood parasites Seen (NBPS) at least 100 fields (thick blood films) and 200-300 fields (thin blood films) must be screened.

Quantification of parasites	1. To quantify malaria parasites against RBCs, count the parasitized RBCs among 500-2,000 RBCs on the thin smear and express the results as % parasitemia. ***% parasitemia = (parasitized RBCs/total RBCs) × 100;*** count asexual blood stage parasites and gametocytes separately. ***2.*** To quantify malaria parasites against WBCs: on the thick smear, tally the parasites against WBCs, until you have counted 500 parasites or 1,000 WBCs ; express the results as parasites per micro liter of blood, using the WBC count if known, or otherwise assuming 8,000 WBCs per micro liter blood. ***Parasites/micro liter blood= (parasites/WBCs) × WBC count per micro liter***
Limitations	• Giemsa stained slides are difficult for species differentiation • The possibility of finding parasites in thin smeared slides is minimal • To report as no blood parasites seen (NBPS) at least 100 fields (thick smear), 200-300 fields (thin smear) must be observed • Anticoagulated blood other than EDTA inferior in the detections of blood parasites

Source of errors	• Poor smear, too thick and too thin blood films • Improper filtering of reagents

	• Long delay of smeared slides UN stained • Staining time-too long/too short • Initiation of anti-malarial drugs before blood collection • Improperly filtrations of Giemsa stain solution

Specimen rejection	• Unlabeled specimens • Insufficient patient information's on the request paper. • Wrong specimen submitted • Hemolysed specimen

Reference	• CDC: Diagnostic procedure for stool specimens (available online, http://www.dpd.cdc.gov/dpdx/HTML/DiagnosticProcedures.asp?body=Frames/Diagnostic procedures/bodydpstoolplugavi.htm • Medical laboratory manual for tropical countries, volume I second edition Monica Cheesbrough 1987. • Guideline for laboratory diagnosis of blood born parasitic disease , CLSI,2008, Volume 20

Name	**Date**	**Signature**
Prepared by: Wogayehu Workneh	may, 2017	……
Reviewed by: Lab Quality officer	May, 2017	……
Approved by: Laboratory head	May, 2017	……

Declaration

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