



SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL
COLLEGE

DEPARTMENT OF PUBLIC HEALTH

Ethiopian Field Epidemiology Laboratory Training Program (EFELTP)

Compiled Body of Work in Field Epidemiology

By:

Desta Birhane (BSc)

THE COMPILED BODY OF WORK SUBMITTED TO THE
DEPARTMENT OF PUBLIC HEALTH, IN PARTIALFULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF MASTER'S OF
PUBLIC HEALTH IN FIELD EPIDEMIOLOGY

February, 2018

ETHIOPIA

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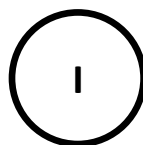
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As members of the Board of Examiners of the final body of work with thesis open defense, we certify that we have read and evaluated the body of work with thesis prepared by Desta Birhane Tesfay under the title “Desta compiled body of work” and recommencement for the degree of Master of Public Health in Field Epidemiology.

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Table of Contents

Acknowledgements:.....	III
List of Acronyms and Abbreviations:	XX
List of Tables:	XXV
List of Figures:	XXVII
List of Annex:	XXVIII
Executive summary:.....	XXIX
1. Chapter One: Outbreak Investigation.....	1
1.1. Introduction.....	2
1.1.1. Background	2
1.1.2. Statement of the problem	4
1.2. Objectives:	5
1.2.1. General objective:	5
1.2.2. Specific objective:.....	5
1.3. Methods:	6
1.3.1. Study Area	6
1.3.2. Study design:.....	7
1.3.3. Source population:	7
1.3.4. Study population:	7
1.3.4.1. Inclusion criteria	7
1.3.4.2. Exclusion criteria	7
1.3.5. Sample size determination	8
1.3.6. Sampling technique.....	8
1.3.7. Data collection	8
1.3.9. Data analysis	9
1.3.10. Ethical Consideration.....	10

1.3.11. Operational definition	10
1.3.12. Dissemination of findings to woreda	10
1.4. Result	11
1.4.1. Descriptive Outbreak investigation.....	11
1.4.1. Public health intervention:	15
1.4.2. Analytical result:.....	15
1.5. Discussion:.....	17
1.6. Conclusion:	18
1.7. Recommendation	18
1.8. Reference:	19
Annex 1: Questionnaire for assessment of AWD outbreak	20
2. Chapter Two: Surveillance Data Analysis Report	24
2.1. Introduction.....	25
2.1.1. Back ground of the Study area.....	27
2.1.2. Rationale of the study	28
2.2. Objectives	29
2.2.1. General objective	29
2.2.2. Specific objectives	29
2.3. Method and Material.....	30
2.3.1. Study Period.....	30
2.3.2. Study population	30
2.3.3. Study design.....	30
2.3.4. Data collection method	30
2.3.5. Data Analysis	30
2.3.6. Ethical consideration.....	31
2.3.7. Dissemination of findings	31

2.4. Results.....	32
2.5. Discussion	39
2.6. Conclusion:	41
2.7. Recommendations:.....	41
2.8. Reference:	42
3. Chapter Three: Evaluation of Surveillance System	45
3.1. Introduction.....	46
3.1.1. Background:.....	46
3.1.2. Rational of the study:	49
3.2. Objectives:	50
3.2.1. General objective:	50
3.2.2. Specific objective:.....	50
3.3. Methods and Materials:.....	51
3.3.1. Study area and population:.....	51
3.3.2. Study design and period:.....	52
3.3.3. Sampling method	52
3.3.4. Data collection procedure	52
3.3.5. Data analysis:	52
3.3.6. Data dissemination:.....	52
3.3.7. Ethical consideration:.....	53
3.4. Results:.....	54
3.4.1. Implementers and stakeholders:.....	54
3.4.2. Core functions of surveillance systems:.....	54
3.4.2.1. Case detection:	55
3.4.2.2. Case registration:.....	55
3.4.3.3. Case confirmation	55

3.4.3.4. Reporting:	56
3.4.3.5. Data analysis and interpretation:	56
3.4.3.6. Epidemic preparedness and response:.....	56
3.4.3.7. Feedback:	57
3.4.3. Support functions of surveillance systems:.....	57
3.4.3.1. Standards and guidelines:.....	57
3.4.3.2. Training:.....	58
3.4.3.3. Supervision:	58
3.4.3.4. Communication facilities:	58
3.4.3.5. Resources	58
3.4.4. Attribute of the surveillance system (Surveillance quality)	59
3.4.4.1. Usefulness	59
3.4.4.2. Simplicity of the system:.....	59
3.4.4.3. Acceptability of the system:.....	59
3.4.4.4. Flexibility of the surveillance system:	60
3.4.4.5. Timeliness and completeness.....	60
3.4.4.6. Sensitivity in surveillance:	60
3.4.4.7. Representativeness of the surveillance system:	60
3.5. Discussion	61
3.5.1. Limitation:.....	62
3.6. Conclusion:	62
3.7. Recommendation	63
3.8. Reference:	64
Annex 3: Surveillance system evaluation data collection tools at regional (zonal level).	65
Annex 4: Surveillance System Evaluation District (Woreda Level) Questionnaire	72
Annex 5: Surveillance System Evaluation Health Facility Questionnaire.....	78

4. Chapter Four: Health Profile Description Report	83
4.1. Introduction.....	84
4.1.1. Background of the study area.....	84
4.1.2. Rationale of the study	85
4.2. Objective	86
4.2.1. General objective	86
4.2.2. Specific objectives	86
4.3. Methods and materials	87
4.3.1. Study Period.....	87
4.3.2. Study design.....	87
4.3.4. Data collection	87
4.3.5. Data analysis	87
4.3.6. Ethical consideration.....	87
4.3.7. Dissemination of findings	88
4.4.1. Geographic and climatic conditions.....	89
4.4.2. Demography.....	89
4.4.3. Administrative structure.....	89
4.4.4. Education	89
4.4.5. Health Facilities:	90
4.4.6. Woreda Health System.....	91
4.4.6.1. Organization of woreda health office (Oregano gram)	91
4.4.6.2. Ratio of health facility and professional to population 2007 EFY (2014/2015)	92
4.4.6.3. Top causes of morbidity 2007EFY (2014/2015)	94
4.4.6.4. MCH and EPI coverage of the district 2007 EFY (2014/2015).....	95
4.4.6.5. Environmental sanitation and availability of safe drinking Water 2007 EFY (2014/2015).....	96
4.4.6.6. Endemic Diseases	96

4.4.6.7. Health sector expenditure and financing2006-2007 EFY (2014-2015)	98
4.4.6.8. Health sector Budget Distribution (2006- 2007 EFY)	98
4.4.6.9. Health Care financing /HCF/ (2006 to 2007EFY)	99
4.4.6.10. Nutrition and early warning	99
4.4.6.11. Disaster situation in woreda	99
4.5. Discussion	100
4.5.1. Challenges and Limitations	101
4.6. Conclusion	101
4.7. Recommendation	101
4.8. Reference:	102
Annex 6: Data collection tools (Checklist)	103
5. Chapter Five: Quality Manual Policy	114
5.1. Introduction.....	116
5.1.1. Background	116
5.2. Quality Policy Manual	116
5.2.1. Term and Definition.....	117
5.3. Management Requirements.....	119
5.3.1. Organization and Management Responsibility	119
A. Purpose.....	119
B. Policy.....	119
5.3.1.1. General	119
5.3.1.2. Legal entity	119
5.3.1.3. Address:	119
5.3.1.4. Working Hour	120
5.3.1.5. Vision	120
5.3.1.6. Mission.....	120

5.3.1.7. KAHGLH Values.....	120
5.3.1.8. Scope of Operations and Services.....	120
5.3.1.9. KAHGLH STRUCTURE	121
5.3.1.10. Responsibility and Authority	121
5.3.1.11. Conflict of Interest and Influences on Work.....	121
5.3.1.12. Laboratory director (Lab. Head)	122
5.3.1.13. Laboratory management	123
5.3.1.14. Quality policy.....	123
5.3.1.15. Quality objectives and planning.....	123
5.3.1.15. Confidentiality of Information	124
5.3.1.16. Quality Officer	124
5.3.1.17. Resources	124
5.3.1.18. Communication.....	125
C. Subsidiary Documents.....	125
5.4. Quality Management System	125
A. Purpose.....	125
B. Policy.....	126
5.4.1. General.....	126
5.4.2. Documentation Requirements.....	126
5.4.3. Quality manual	126
5.4.4. Quality Policy Statement	127
5.4.5. Quality Goals and Objectives	128
5.4.6. Quality Management System Description	128
5.4.7. Quality Management System Implementation.....	129
C. Subsidiary Documents.....	129
5.5. Document Control.....	129

A. Purpose.....	129
B. Policy.....	129
5.5.1. Document Identification	130
5.5.2. Document Format and Content	131
5.5.3. Document Status and Originality	132
5.5.4. Document Issue Control.....	133
5.5.5. Document Changes/Revision	134
5.5.6. Access to and Adherence to Quality System Documentation.....	134
5.5.7. Unauthorized Deviations from Quality System	135
5.5.8. Document Retention period	135
C. Subsidiary Documents.....	135
5.6. Review of Contracts.....	135
A. Purpose.....	135
B. Policy.....	136
5.6.1. Establishment of service agreements	136
5.6.2. Review of service agreements.....	136
C. Process.....	137
D. Subsidiary Documents	137
5.7. Examination by Referral Laboratories	137
A. Purpose.....	137
B. Policy.....	138
5.7.1. General.....	138
5.7.2. Selecting and evaluating referral laboratories and consultants	138
5.7.3. Provision of examination results.....	139
C. Subsidiary Documents.....	139
5.8. External Services and Supplies	139

A. Purpose.....	139
B. Policy.....	140
5.8.1. General.....	140
C. Subsidiary Documents	140
5.9. Advisory Services	141
A. Purpose.....	141
B. Policy.....	141
5.9.1. General.....	141
C. Subsidiary Documents.....	141
5.10. Resolution of Complaints.....	142
A. Purpose.....	142
B. Policy.....	142
C. Process.....	142
D. Subsidiary Documents	142
5.11. Identification & Control of Non-conformities	143
A. Purpose.....	143
B. Policy.....	143
C. Process.....	143
D. Subsidiary Documents	144
5.12. Corrective Action.....	144
A. Purpose.....	144
B. Policy.....	144
5.12.1. General.....	145
C. Process.....	147
D. Subsidiary Documents	148
5.13. Preventive Action.....	148

A. Purpose.....	148
B. Policy.....	148
C. Process.....	148
D. Subsidiary Documents	149
5.14. Continual Improvement	149
A. Purpose.....	149
B. Policy.....	150
C. Process.....	150
D. Subsidiary Documents	151
5.15. Control of Records.....	151
A. Purpose.....	151
B. Policy.....	151
C. Quality and Technical Records	152
5.15.1. Quality and Technical Records Retention Time	152
D. Subsidiary Documents	153
A. Purpose.....	153
B. Policy.....	153
5.15.2. General.....	153
5.15.3. Periodic review of requests, and suitability of procedures and sample requirements.....	154
5.15.4. Assessment of user feedback	154
5.15.5. Staff suggestions	154
5.15.6. Internal audit	154
5.15.7. Risk management.....	155
5.15.8. Quality indicators.....	155
C. Process.....	156
A. Subsidiary Documents	157

5.16. Management Review	157
A. Purpose.....	157
B. Policy.....	157
C. Process.....	157
D. Subsidiary Documents	158
5.17. Technical Requirements Policy	158
5.17.1. Personnel.....	158
A. Purpose.....	158
B. Policy.....	158
5.17.1.1. General	158
5.17.1.2. Personnel qualifications	159
5.17.1.3. Job descriptions.....	159
5.17.1.4. Personnel introduction to the organizational environment	159
5.17.1.5. Training.....	159
5.17.1.6. Competence assessment.....	159
5.17.1.7. Reviews of staff performance	160
5.17.1.8. Continuing education and professional development	160
5.17.1.9. Personnel records	160
C. Subsidiary Documents.....	161
5.17.2. Accommodation and Environmental Conditions	161
A. Purpose.....	161
B. Policy.....	161
C. Subsidiary Documents.....	163
5.17.3. Laboratory equipment, reagents and consumables	164
A. Purpose.....	164
B. Policy.....	164

5.17.4. Pre-Examination Processes	169
A. Purpose.....	169
B. Policy.....	170
C. Subsidiary Documents.....	175
5.17.5. Examination Processes.....	175
A. Purpose.....	175
B. Policy.....	175
C. Subsidiary Documents.....	179
5.17.6. Ensuring Quality of Examination Results.....	179
A. Purpose.....	179
B. Policy.....	180
5.6.6.1. General.....	180
5.6.6.2. Quality control	180
5.6.6.3. Inter laboratory comparisons	181
C. Subsidiary Documents.....	182
5.18. Post Examination Processes.....	183
A. Purpose.....	183
B. Policy.....	183
5.18.1. Review of results.....	183
5.18.2. Storage, retention and disposal of clinical samples	184
C. Subsidiary Documents.....	184
5.19. Reporting of Results	184
A. Purpose.....	184
B. Policy.....	184
5.19.1. General.....	184
5.19.2. Report attributes.....	185

5.19.3. Report content.....	185
C. Subsidiary Documents.....	187
5.20. Release of Result.....	187
5.20.1. Purpose.....	187
5.20.2. Policy	187
5.20.3. General.....	187
5.20.4. Automated selection and reporting of results.....	188
5.20.5. Revised reports.....	188
D. Subsidiary Documents	189
5.21. . Laboratory information management.....	189
5.21.1. Purpose.....	189
5.21.2. Policy	189
5.21.3. General.....	189
5.21.4. Authorities and responsibilities.....	190
5.21.5. Information system management	190
A. Subsidiary Documents	191
Annex 7: Organogram.....	192
Annex 8: Quality Policy Manual	193
Annex 9: Declaration:	194
6. Chapter Six: Thesis	195
Abstract:	195
6.1. Introduction.....	196
6.1.1. Background:.....	196
6.1.2. Statement of the problem in immunization	198
6.1.3. Rational of the study	198
6.2. Literature review:.....	200

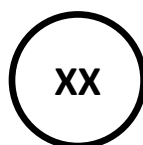
6.2.1. Immunization coverage Globally, Africa and Ethiopia	200
6.2.2. Factors affecting complete immunization.....	201
6.3. Objectives:	203
6.3.1. General objective	203
6.3.2. Specific objectives	203
6.4. Methods and materials	204
6.4.1. Study area and period.....	204
6.4.2. Study design.....	204
6.4.3. Source population	204
6.4.4. Study population	204
6.4.5. Study unit.....	204
6.4.6. Sample size determination	204
6.4.7. Sampling procedure	205
6.4.8. Data Collection Procedure	206
6.4.9. Data quality control.....	206
6.4.10. Inclusion criteria	207
6.4.11. Exclusion criteria	207
6.4.12. Study variables.....	207
6.4.12.1. Dependent variable (outcome variable)	207
6.4.12.2. Independent variable	207
6.4.13. Data processing and analysis	207
6.4.14. Ethical clearance	207
6.4.15. Dissemination of the study finding	208
6.4.16. Operational definitions.....	208
6.5. Results.....	210
6.5.1. Descriptive part of the results	210

6.5.1.1. Socio- demographic characteristic of the Primary guardians of children 12-23 months, Mekelle Town, Northern Ethiopia	210
6.5.1.2. Health service availability and related characteristics of respondents	212
6.5.1.3. Characteristics of immunization status among children aged 12-13 months, Mekelle Town, Northern Ethiopia, 2017	213
6.5.1.5. Knowledge assessment of children caretakers' age 12-23 month in Mekelle Town, Tigray Northern Ethiopia, 2017:.....	215
6.5.2. Analysis part of the results.....	217
6.5.2.1. Binary Logistic Regression Analysis:.....	217
6.5.2.2. Multivariate logistic regression analysis.....	218
6.6. Discussion.....	221
6.7. Conclusion	223
6.9. Reference:	224
Annex 10: Questionnaires in English Version.....	226
Annex 11: Map of mekelle Town	232
Annex 12: From 2007-2012EC shows mekelle population number by age category.....	233
Annex 13: Data Collection Tool infant immunization card.....	234
7. Chapter Seven: Scientific Manuscripts for Peer Reviewed Journals	235
Authors:	235
Abstract:	235
7.1. Introduction.....	236
7.2. Methods and materials:	237
7.3. Results.....	240
7.3.1. Multivariate logistic regression analysis.....	243
7.4. Discussion.....	244
7.5. Reference:	247

8.	Chapter Eight: Abstracts for Scientific Presentation	253
9.	Chapter Nine: Other Additional Laboratory Works Two SOP and One Laboratory Narrative Report	254

List of Acronyms and Abbreviations:

AFP	Acute Flaccid Paralysis
AIDS	Acquired Immune-Deficiency Syndrome
ANC	Antenatal Care
AOR	Adjusted odds ratio
ARF	Action Registry Form
ART	Anti-Retroviral Treatment
AWD	Acute watery diarrhea
CBN	Community Based
CBR	Crude Birth Rate
CCO	Clinical chief executive
CCS	Country cooperation strategy
CDC	Communicable disease control
CDR	Crude Death Rate
CEN	European Committee for Standardization
CEO	Chief executive officer
CFR	Case Fatality Rate
CHT	Chart
CI	Confidence interval
CMR	Child Mortality Rate
COR	Crud odds ratio
CSA	Central Statistical Agency
CTC	Cholera Treatment Center
CVDPV	Vaccine Derived Polio Virus



EFET	Ethiopian Field Epidemiology Training Program
EFETP	Ethiopia Field Epidemiology Training program
EFY	Ethiopia fiscal year
ENAO	Ethiopian National Accreditation Office
ENHS	Environmental Health Science
EOS	Enhanced Outreach Strategy
EPHI	Ethiopia Public Health Institution
EPI	Extended Program On Immunization
F	File
FDEs	Food and drink establishment
FDRE	Federal democratic of Ethiopia
FMoH	Federal ministry of health
GDP	Growth and transformation
GR	Growth Rate
HEW	Health Extension Worker
HIV	Human Immune-Deficiency Virus
HOA	Horn Of Africa
HSDP	Health sector development program
IAF	Investigation action form
IAR	Investigation, Action and Resolution
ICSH	International Council for Standardization in Hematology
IMR	Infant Mortality Rate
IPLS	Integrated Pharmaceuticals Logistic System
ISH	International Society of Hematology

ISO	International organization for Standardization
ISTH	International Society of Thrombosis and Hemostasis
ITN	Insecticide Treated Net
IUBMB	International Union of Biochemistry and Molecular Biology
IUIS	International Union of Immunological Societies
IUMS	International Union of Microbiological Societies
IUPAC	International Union of Pure and Applied Chemistry
JA	Job Aid
JD	Job Description
KAHGLH	Kahsay Abera Humera General Hospital Laboratory
KEMRK	Kenya Medical Research Institution
KPI	Key Performance Indicators
LIM	Laboratory Information Management
LIS	All lab sections
LQM	Laboratory Quality Management
LRS	Laboratory reception section
MCH	Maternal And Child Health
MDG	Millennium development goal
MMR	Maternal Mortality Rate
MOPV3	Monovalent Vaccine
MR	Management Review
NA-AFP	Non Acute Flaccid Paralysis
NIDS	National Immunization Days
NMR	Neonatal Mortality Rate

NPEV	Non polio entero virus
OPD	Out Patient Department
OPV	Oral Polio Vaccination
OPV	Oral Polio Vaccine
ORP	Oral rehydration point
OTP	Outpatient Therapeutic Program
PEI	Polio Eradication Initiative
PF	Plasmodium Falciparum
PHC	Primary health care
PHEM	Public Health Emergency Management
PICT	Provided Initiated Counseling And Testing
PLWHIV	Peoples Living With HIV/AIDS
PMTCT	Prevention Mother To Child Transmission
PNC	Postnatal Care
PNMR	Post-Neonatal Mortality Rate
PT	Proficiency Test
PTB	Pulmonary Tuberculosis
PV	Plasmodium Vivax
QC	Quality Control
QM	Quality officer
QPM	Quality Policy Manual
RDT	Rapid Diagnostic Test
RDT	Rapid diagnostic test
RP	Responsible Person

RX	Treatment
SARI	Severe Acute Respiratory Infection
SIAS	Supplementary Immunization Activates
SPHMMC	St.paul's hospital millennium medical college
SR. NO	Serial Number
TB	Tuberculosis
TBA	Traditional Birth Attendant
TFU	Therapeutic Feeding Unit
TOPV	Trivalent Oral Poliovirus Vaccine
TRHB	Water , hygiene and sanitation
TSF	Therapeutic Supplementary Feeding
TT	Tetanus Toxoid
URTI	Upper Respiratory Track
VCT	Voluntary Counseling And Testing
WASH	Public health emergency management
WHO	World health organization
WK.	Week
WPV	Wild Polio Virus

List of Tables:

Table 1: Socio-demographic information of cases and control, Warder Woreda, Somalia, Ethiopia 2009 EFY.....	12
Table 2 : Respondents and same factors of acute watery diarrhea warder woreda, Somalia regions	14
Table 3: AWD data Crude odds ratio Analysis, Warder Woreda, Somalia Region, Ethiopia, 2009 EFY..	15
Table 4: AWD adjusted odds ratio Analysis, Warder Woreda, Somalia Region, Ethiopia, 2009 EFY.....	16
Table 5: Tigray Region explanation.....	27
Table 6: Distribution of AFP cases by age and sex, in Tigray, Ethiopia, 2011-2015.....	32
Table 7: Distribution of AFP cases by different indicators, 2011-2015 Tigray, Ethiopia.....	33
Table 8 : Frequency of AFP cases by final classification from 2011-2015, Tigray, Ethiopia.....	35
Table 9: Distribution of AFP cases by Zonal sate and final classification, 2011-2015, Tigray Ethiopia.....	36
Table 10: Vaccination Status of AFP suspected Cases by age & dose category, Tigray, Ethiopia, 2011-2015	38
Table 11: Education and school Health	90
Table 12: Types and number of health institution in woreda Addisu Gebeya Addis Ababa Ethiopia 2007E.C	92
Table 13: Man power of Addisu Gebeya district health office and health facility in 2007EFY (2014/2015)	92
Table 14: Ratio of Gov. Health facility and professional to population 2007 EFY (2014/2015).....	92
Table 15: Top ten leading causes of total OPD visit (morbidity) in 2007 EFY (2014/2015).....	93
Table 16: Top ten leading causes of OPD visit (morbidity) female category in 2007 EFY (2014/2015)	94
Table 17: Top ten leading causes of OPD visit (morbidity) male category in 2007 EFY (2014/2015).....	94
Table 18: MCH and EPI coverage of the district 2007 EFY (2014/2015).....	95
Table 19: Environmental sanitation and availability of safe drinking Water 2007 EFY (2014/2015)	96
Table 20: URTI prevention and control program of 2007 EFY (2014/2015).....	96
Table 21: Prevalence of TB/Leprosy: 2007 EFY (2014/2015)	97
Table 22: HIV/AIDS IN 2007 EFY (2014/2015).....	98
Table 23: Health sector expenditure and financing2006-2007 EFY (2014-2015)	98
Table 24: Health sector Budget Distribution (2006- 2007 EFY)	98
Table 25: Health Care financing /HCF/ (2006 to 2007 EFY)	99
Table 26 : Socio- demographic characteristic of the Primary guardians of children 12-23 months, Mekelle Town, Northern Ethiopia	211

Table 27: Health service related characteristics of Primary Guardians of children aged 12-23 months, Mekelle Town, Northern Ethiopia, 2017	212
Table 28: Characteristics of immunization status among children aged 12-13 months, Mekelle Town, Northern Ethiopia, 2017.....	213
Table 29: Immunization related Questions by recall history respondents.....	214
Table 30 : Knowledge assessment of children caretakers' age 12-23 month in Mekelle Town, Tigray Northern Ethiopia, 2017:	216
Table 31 : Bi-variate and Multivariate analysis of immunization status among children 12-23 age months live in Mekelle town, Northern Ethiopia, 2017.....	219
Table 32 : Socio- demographic characteristic of the Primary guardians of children 12-23 months, Mekelle Town, Northern Ethiopia	249
Table 33: Health service related characteristics of Primary Guardians of children aged 12-23 months, Mekelle Town, Northern Ethiopia, 2017	250
Table 34: Characteristics of children immunization status by each type immunization mekelle town 2017	251
Table 35 : Bi-varaiat and Multivariate analysis in 12-23age month children immunization status related variables	252
:	

List of Figures:

Figure 1: Map of warder woreda	6
Figure 2: Epi curve for AWD outbreak, warder woreda, Ethiopia, 2009	11
Figure 3: AWD case fatality rate by warder kebele, Ethiopia, 2009 EFY	12
Figure 4: Map of Warder Woreda shows AWD case and death ratio distribution by place	13
Figure 5: Map of Tigray Region	28
Figure 6: Trend of AFP cases, in Tigray, Ethiopia by year 2011-2015	32
Figure 7: Frequency distribution of AFP cases by sex and age in Tigray Region from 2011-2015.	33
Figure 8: Frequency AFP of samples collected and total suspected cases per year, 2011-2015, Tigray Region, Ethiopia.	34
Figure 9: Distribution of AFP cases by laboratory result and final classification, 2011-2015, Tigray Ethiopia	35
Figure 10: Trend of AFP Cases by Zones, Tigray, Ethiopia, 2011-2015	37
Figure 11: Number of AFP suspected cases by Woredas, Tigray, Ethiopia, 2011-2015.	37
Figure 12: Number of AFP suspected case vaccinated at list one dose by zone, in Tigray, Ethiopia, 2011-2015	38
Figure 13: Map of mekelle zone	51
Figure 14: standards and guidelines of mekelle zone health facility and woreda office.....	57
Figure 15: Addisu Gebeya woreda map	85
Figure 16: Oregano gram of Addisu Gebeya health district	91
Figure 17: Vaccination coverage of children in Addisu Gebeya Woreda, Gulele sub city Addis Ababa, Ethiopia, 2014/15.....	95
Figure 18:- Conceptual framework for factors affecting immunization status of the children aged between 12-23 months.....	202
Figure 19: Sampling procedure from work	206
Figure 20: Map of mekelle special zone (Town)	232
Figure 21: Mekelle special zone (Town) estimated projection population from 2007-2012 EC	233
Figure 22: Infant Immunization Cared	234

List of Annex:

Annex 1: Questionnaire for assessment of AWD outbreak	20
Annex 2: AFP cases validation examination form.....	43
Annex 3: Surveillance system evaluation data collection tools at regional (zonal level).	65
Annex 4: Surveillance System Evaluation District (Woreda Level) Questionnaire	72
Annex 5: Surveillance System Evaluation Health Facility Questionnaire.....	78
Annex 6: Data collection tools (Checklist)	103
Annex 7: Organogram.....	192
Annex 8: Quality Policy Manual	193
Annex 9: Declaration:	194
Annex 10: Questionnaires in English Version.....	226
Annex 11: Map of mekelle Town	232
Annex 12: From 2007-2012EC shows mekelle population number by age category.....	233
Annex 13: Data Collection Tool infant immunization card.....	234
Annex 14: Kahsay Abera general hospital organogram	264
Annex 15: Biography.....	265

Executive summary:

This body of work is the summary of all outputs made during a two years and 4 four month field residency in the Field Epidemiology and Laboratory Training Program. These include outbreak investigations, surveillance data analysis, surveillance evaluation system, health profile description, Zonal Hospital Laboratory Quality Manual preparation, Research and other activities.

Investigation of acute watery diarrhea outbreak in Warder District of Somalia, region, Ethiopia, August 2017, was done. These investigations were conducted as part of public health response for the outbreaks. The outbreaks were described by person, place and time characteristics, possible causes or risk factors and sources of the outbreaks were identified. Public health interventions were done further control and prevention measures were implemented following the investigations.

Five years AFP data was analyzed (January, 2016 to December, 2015) in Tigray region. The routine surveillance data of AFP infection was important to identify the regions key indicator performance. So accordingly In this study the region reporting of NPAPF rate (none polio virus acute flaccid paralysis), stool adequacy rate were within range of the WHO standards. None of the cases were confirmed poliomyelitis.

Evaluation of a community based acute watery diarrhea (AWD) surveillance system of mekelle Zone, Tigray region north Ethiopia was conducted with the objective of assessing the performance and operation of the system, and identifying possible gaps. According to different woreda administrative focal person AWD was seen in areas where low water resources and population in use of holly water for drinking. In addition low work productivity because of incentive, no laboratory confirmatory, low skill of computer was seen.

According to the direction of SPHMMC I was customized one zonal hospital laboratory quality policy manual to help the hospital activity work in achieving, maintaining and improving accuracy, timeliness and reliability laboratory results. More over the laboratory build national capacities for the detection and response to public health events of international concern.

1. Chapter One: Outbreak Investigation

Title: Acute watery diarrhea outbreak, Warder Woreda Somalia Region Ethiopia, 2017

Authors: Desta Birhane, S. Tanie, A.Bekele

Abstract:

Background: Globally diarrheal disease is the third leading cause of mortality in low income countries, causing estimated 1.4million deaths in 2012. The bacterial, viral, and protozoan pathogens causing diarrheal disease are primarily transmitted via the fecal-oral route, through the consumption of fecal contaminated food and water. In Warder District response activities plan for the outbreak prepared or formulated; time schedule and indicators for achievement identified. The aim is to control the outbreak, and to identify and confirm possible risk factors.

Methods: Community based unmatched 50 cases and 100 control was used considering previous study. Data was collected by the recommended case definitions using structured questionnaire. Case sample were taken from the registration line list by using systematic random sampling system and control from community. Data was entered in to Epi info version 7.2.1.0. Descriptive was analyzed using Excel 2007 and analysis statistics with 95% confidence intervals, was used to compare risk factors. Ethical clearance will be obtained from SPHMMC and consent form will be asked willingness to the eligible people.

Result: From total 329 cases in the study, 53% of the cases were male and 77% are above five years of old. Overall Case Fatality Rate was 5.5%. The total attack rate was 6 people per 1000 population. . Peoples they know to treat the stored water were less likely risk with the diseases (AOR= 0.16 95 % CI=0.06-0.41. p.value=0.0002). People they have adequate Water for drinking and for preparing their food were preventable association with the AWD diseases with (AOR =0.34, 95% CI=0.11-0.97 p.value=0.044) than those who did not have enough water.

Conclusion and recommendation: people they had information about the disease, they have adequate water and they did know the water treatment were preventable risk of acute watery diarrhea diseases. So efforts in community awareness on the importance of AWD prevention and fulfill the importance resource like clean water and standard public and individual latrine.

Key words: Acute watery diarrhea, outbreak, warder woreda.

1.1.Introduction

1.1.1. Background

Globally diarrheal disease is the third leading cause of mortality in low income countries, causing estimated 1.4million deaths in 2012.The bacterial, viral, and protozoan pathogens causing diarrheal disease are primarily transmitted via the fecal-oral route, through the consumption of fecal contaminated food and water. Among the most important of these are rotavirus, Cryptosporidium, Escherichiacoli, Salmonella, Shigella,Campylobacterjejuni, Vibrio.cholerae, norovirus, Giardia lamblia, and Entamoebahistolytica, though the relative importance of these varies among settings, seasons, and population groups.(1)

Cholera is an intestinal infection caused by Vibrio cholerae. Cholera can be endemic, epidemic, or pandemic. Although the disease may be asymptomatic or mild, severe cholera can cause dehydration and death within hours of onset. Despite all the major advances in research, the condition still remains a challenge to the modern medical world (2)

Two serogroups of V. cholerae – O₁ and O₁₃₉ – cause outbreaks. V. cholerae O₁ causes the majority of outbreaks, while O₁₃₉ – first identified in Bangladesh in 1992 – is confined to South-East Asia(3).Non-O₁ and non-O₁₃₉ V. cholerae can cause mild diarrhea but do not generate epidemics. Recently, new variant strains have been detected in several parts of Asia and Africa. Observations suggest that these strains cause more severe cholera with higher case fatality rates. Individuals living in places with inadequate water treatment, poor sanitation, and inadequate hygiene are at a greater risk for cholera. Recent studies indicate that global warming creates a favorable environment for the bacteria (4).

An estimated 3-5 million cases and over 100,000 deaths occur each year around the world. The infection is often mild or without symptoms, but can sometimes be severe. Approximately one in 10 (5-10%) infected persons will have severe disease characterized by profuse watery diarrhea, vomiting, and leg cramps. In these people, rapid loss of body fluids leads to dehydration and shock. Without treatment, death can occur within hours(5).

The Health Cluster Situation Update released on October 2, 2016 reports, as of 1st week of October 2016, a total of 21, 217 AWD cases from over 249 affected Woredas in Ethiopia. Students and people living in remote area are at high risk of being affected by AWD in the country.(6)

Cholera is usually transmitted through faecally contaminated water or food and remains an ever-present risk in many countries. New outbreaks can occur occasionally in any part of the world where water supply, sanitation, food safety, and hygiene are inadequate. The greatest risk occurs in over-populated communities and refugee settings characterized by poor sanitation, unsafe drinking-water, and increased person-to person transmission. Because the incubation period is very short (2 hours to 5 days), the number of cases can rise extremely quickly.(3)

On March 16, 2009, Ethiopian public Health institution (EPHI) was notified by Somalia regional health bureau (RHB) about an outbreak of acute watery diarries in warder district dollo zone; the disease was characterized by acute watery, vomiting, general body weakness, dehydration, and in some patients shock. Local health office could not identify the causative (etiologic) agent. Accordingly the EPHI were mobilize technical staff to help the situation and collected samples prior to identify the case. Ten samples were tested for RDT (rapid diagnostic test) by Crystal VC rapid diagnostic test for Vibrio cholerae O1 and O139 (Span Diagnostics Limited, India). The investigation was conducted to identify the further confirmation etiologic agent by golden laboratory, root of transmission, risk factors and finally to recommend control and prevention measures.

1.1.2. Statement of the problem

Study shows that an estimated 1.1 billion people worldwide rely on water deliveries that are at high risk of fecal pollution. Moreover, nearly half the world's population lack household water access, and are at increased risk of unsafe water due to contamination during collection, storage, and use in the home. (1)

Cholera transmission is closely linked to inadequate environmental management. Typical at-risk areas include peri-urban slums, where basic infrastructure is not available, as well as camps for internally displaced persons or refugees, where minimum requirements of clean water and sanitation are not met. The consequences of a humanitarian crisis – such as disruption of water and sanitation systems, or the displacement of populations to inadequate and overcrowded camps can increase the risk of cholera transmission should the bacteria be present or introduced. (7).Cholera remains a global threat to public health and a key indicator of lack of social development. The number of cholera cases reported to WHO continues to be high. During 2013, a total of 129 064 cases were notified from 47 countries, including 2102 deaths. The discrepancy between those figures and the estimated burden of the disease is due to the fact that many cases are not recorded for due to limitations in surveillance systems and fear of trade and travel sanctions(3).

As already mentioned in the statements of the problem the Local and regional health office could not identify the causative (etiologic) agent of the acute watery diarrhea that why the EPHI send a professional to the fill the gaps to conduct the study.

1.2.Objectives:

1.2.1. General objective:

To control of the outbreak and assess possible risk factor of the AWD infection in Warder Woreda, Somalia region, Ethiopia

1.2.2. Specific objective:

To confirm the etiology of the outbreak acute watery diarrhea

To describe the outbreak by person, place and time

To identify the possible risk factor of the outbreak and commend preventive measures

1.3.Methods:

1.3.1. Study Area

Outbreak response activities were done. The sample was taken from the registration line list by using systematic random sampling system. Prospective Unmatched case control data 1:2 (50 cases and 100 controls) for the outbreak investigation was collected using structured questionnaire.

Warder Woreda is located in the south of the Regional Capital, Jigjiga 1,120 K/m far from Addis Ababa. It is situated between 6 degrees 58'N latitude and 45 degrees 20'E and at an altitude of 541 meter on average above sea level. It has border with North Donat in the East Geladi,in the west Kebridehar and in the south ,shilabo woreda. The climate is varies from seasons of summer, 9 months , to cool months of rainfall, about three months, with an overall average maximum and minimum temperature of 40⁰ and 29 degree centigrade, respectively.

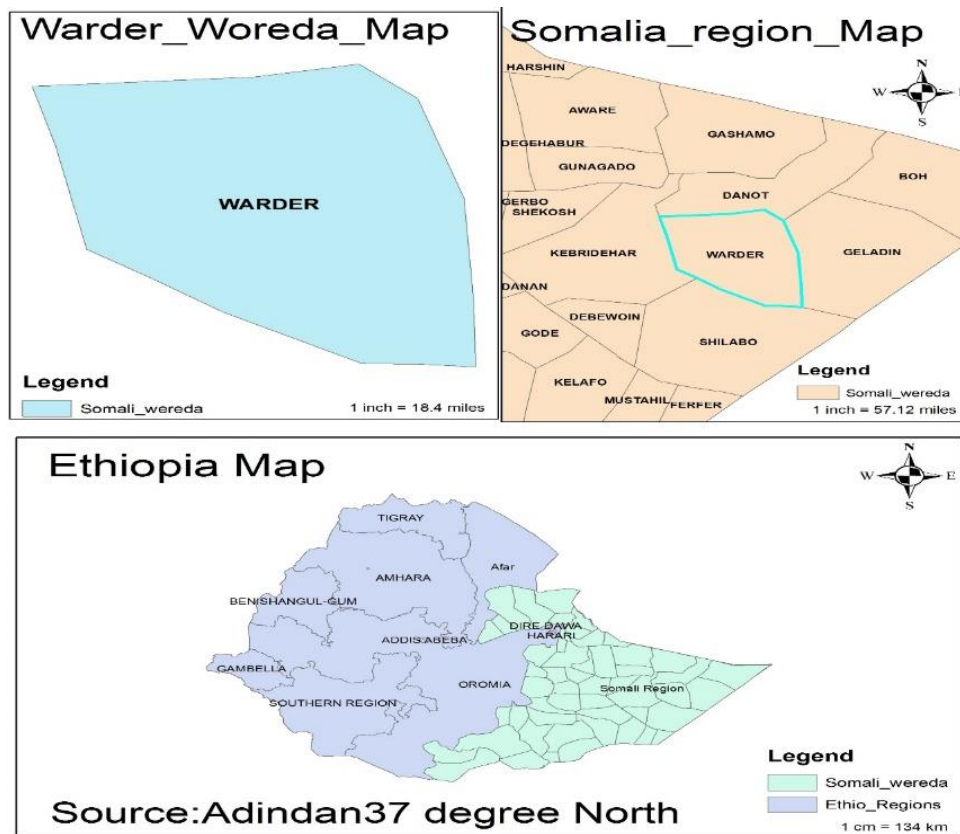


Figure 1: Map of warder woreda

Administratively Warder Woreda is one of the seven Woredas in dolo zone. It has 15 kebeles. Such as wofdug, ado, mire, kurtule, Eilalie, karloogube, eldibir, agarwayne, maiir-danbus, Walwal (warder town ,01,02,03,04) .The total population is estimated to be 58,035 of which 32,743 are male and 25,292 are females, 56.4% and 44.6% respectively.

The Woreda Health Office is responsible for both curative and preventive health care of the woreda under which there are 1 district hospital, 2 health centers and 17 health posts. Regarding health professionals currently there are a total of 50 professionals excluding hospital.

1.3.2. Study design:

Unmatched case control study design was used

1.3.3. Source population:

All population found in warder woreda Somalia region Ethiopia with in the study period.

1.3.4. Study population:

Cases: Any dwellers of Warder Woreda who had included case definition of AWD and laboratory confirmation within 04 March and 30 March 2009EFY.

Controls: Any residents of warder Woreda during the study who was a neighbor to a case in right and left direction equivalently who did not develop signs and symptoms of AWD.

1.3.4.1.Inclusion criteria

All individual included case definition and confirmed subjects who were found in the cholera treatment center (CTC) and their homes for the case selection and for control were selected from the general population especially from those who were proportionally affected kebeles.

1.3.4.2.Exclusion criteria

In the data collection time under 5 children was excluded because, in the standard national guideline clinical case definition were excluded them because majority of diarrhea due to any cause occurs in this age group. And also those who rejected to participate, comatose as well as family members from the same house hold for control.

1.3.5. Sample size determination

Unmatched case-control sample size determination to the objective with a ratio of 1:2 for cases and controls from a previous study 2014 afar Ethiopia percent of controls exposed was (34.6%) and OR (0.26) (water treatment), conventionally alpha level of 0.05 and beta of 0.20 for a power of 80% by using stat cale Epi info version 7.1. based on the following formula calculation total sample 150 was taken.

$$n_1 = \frac{r+1p^-}{r} \frac{(1+p^-)(Z\beta+Z\alpha/2)^2}{(P1+P2)^2} \quad \text{Where, } n_2=2 \times n_1 \quad r = n_2/n_1$$

$$p^- = (p_1+p_2)/(1+r)$$

Where,

n_1 =number of cases

n_2 =number of controls

$Z_{\alpha/2}$ = standard normal deviate for one-tailed test based on beta level (relates to the power level)

r =ratio of case and controls

p_1 = proportion of cases with exposure and $q_1 = 1-p_1$

p_2 = proportion of controls with exposure and $q_2 = 1-p_2$

1.3.6. Sampling technique

The sample was taken from the total case registration line list by using systematic random sampling system, the first sample selected by simple random lottery method and then, Individuals will be taken at regular intervals down the list proportionally the control also selected from the adjacent neighboring.

1.3.7. Data collection

The data was collected from the Warder Woreda community with one person guidance who know the kebeles or areas well, by using standard quantitative questioner. The questioner was pre- test in order to make standardized one day to review or collected the data from house to

houses from the study area. Socio-demographic, economic, Health/illness status, and other variables were applied to outbreak investigation.

1.3.7.1. Laboratory confirmation:

The laboratory confirmation was 10 sample from cases with the RDT and 5 case with both the RDT and with culture laboratory golden standard were confirmed positive for the type O1 vibrio cholera, facilitated the process by Somalia regional health bureau and the result was done in Ethiopian Public Health Institution (EPHI).

1.3.7.2. Case definition

Suspected case: in an area where the disease is not known to be present, a patient aged 5 Years or more develops severe dehydration or dies from acute watery diarrhea; OR In an area where there is a cholera epidemic, a patient aged 5 years or more develops acute watery diarrhea, with or without vomiting. At health post and at community levels: Any person 5 years of age or more with profuse acute watery diarrhea and vomiting.

Confirmed case: A suspected case in which *Vibrio cholerae* O1 or O139 has been isolated from their stool.

1.3.8. Variables

1.3.8.1. Dependent variable

Outcome variable AWD status

1.3.8.2. Independent variable

Socio-demographic

Economic status,

Health/illness status

Assessment of risk factors

1.3.9. Data analysis

Data entered in to Epi info version 7.2.1.0 and exported to SPSS version 21 and analyzed. Descriptive analyzed using line list by excel 2007 and analytical statistics taking crud and Adjusted odds ratio with 95% confidence intervals was calculated to compare risk factors among cases and controls. Multivariate logistic regression also used to avoid the numerous types of confounders against the dependent variables.

1.3.10. Ethical Consideration

Ethical clearance were obtained from St.paul's hospital millennium medical college department of public health, ethical committee official letter were written to EPHI/Ethiopia public health institution/,and the EPHI my field base also written a letter and given to the organization where the study was conducted. The Ethiopian public health also (EPHI) wrote a formal letter to the Somalia regional health bureau. Regarding to case and control informal verbal consent was taken from all respondents before interviews and all agreed to take part, so that collected the data by structured questioners.

1.3.11. Operational definition

Atet: people who have diarrhea more than three a day

Stored water: people stored water more than two day in container in their home

1.3.12. Dissemination of findings to woreda

Findings of the outbreak was submitted to warder woreda office, Somalia region health bureau and administrative office by soft and hard copy to use the findings for priority setting, planning & additional to initiate research also submitted to SPHMMC department of public health.

1.4.Result

1.4.1. Descriptive Outbreak investigation

From total 329 cases 53% of the cases were male and 77% are above five years of old. The first deaths were reported on 04/07/09, Most of the cases were affected on the age group of productive, mean age 22.3, and the overall Case Fatality Rate was 5.5%.The total attack rate was 6 people per 1000 population. Ten samples were tested for RDT (rapid diagnostic test) by Crystal VC rapid diagnostic test for *Vibrio cholerae* O1 and O139 and additionally five sample with both laboratory RDT and culture were confirmed vibrio cholera type O1 serotype Ogawa. The highest affected kebele were Agarwoini, followed by Wofldug, the total case 154,104 respectively, the remaining cases deserved to other kebele.

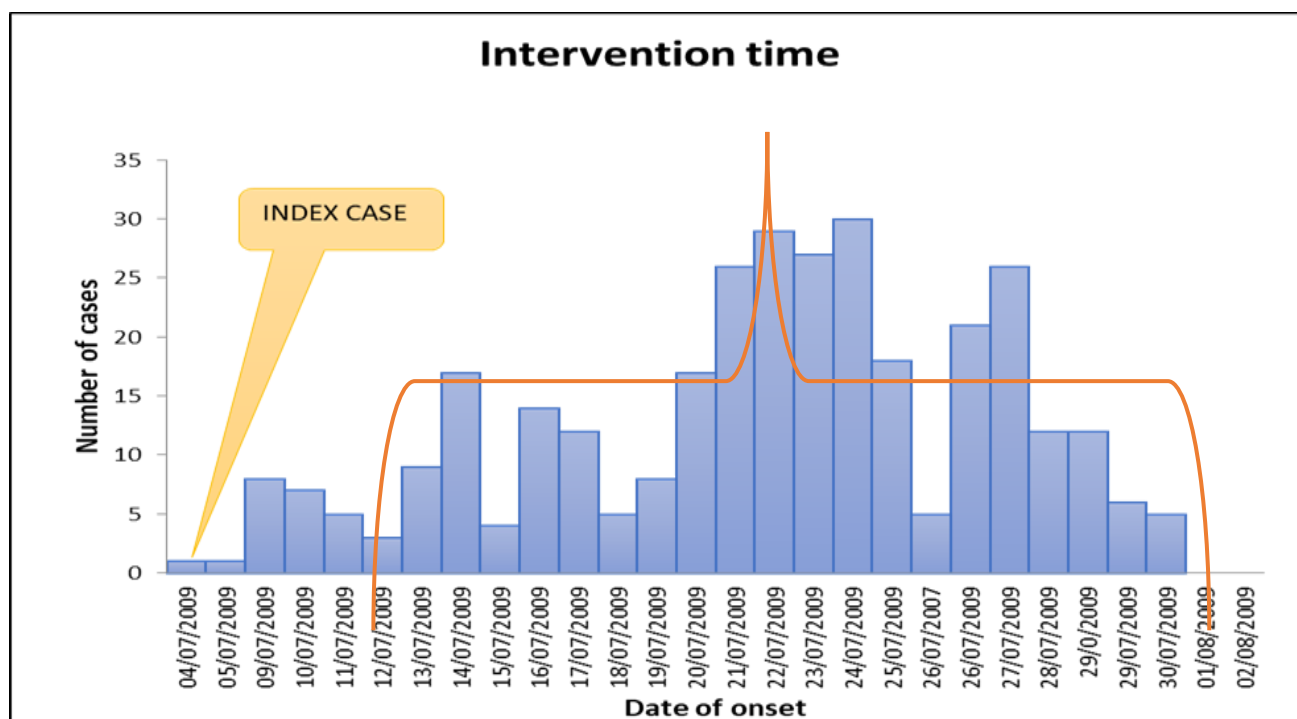


Figure 2: Epi curve for AWD outbreak, warder woreda, Ethiopia, 2009

The first early case had date of onset on 04/07/09 from geladi Woreda, Dhaqayabor kebele reported to Oduwa (Agarwoini) health post sub kebele of warder woreda. Historically, she had lived in geladi woreda present of AWD epidemic areas prior to her symptom onset and also she does have exposure to the people Oduwa sub kebele dweller neighbor warder woreda. She did

not come to health facility and she dead, this is might be due to weak surveillance activity. Her father and her brother were affected by AWD.

Table 1: Socio-demographic information of cases and control, Warder Woreda, Somalia, Ethiopia 2009 EFY

Descriptive variable		Case		control		Total
		Number	%	Number	%	
Sex	male	28	56	74	74	102
	female	22	44	26	26	48
Warder kebele	Kebele 02	1	2	2	2	3
	Agarwoini	34	68	68	68	102
	Eilale	1	2	2	2	3
	Welwal	3	6	6	6	9
	Wofdugqe	11	22	22	22	33
Age group	<5	0	0	0	0	0
	5-15	13	26	16	16	39
	16-30	14	28	52	52	42
	31-45	7	14	16	16	21
	>45	16	32	16	16	48

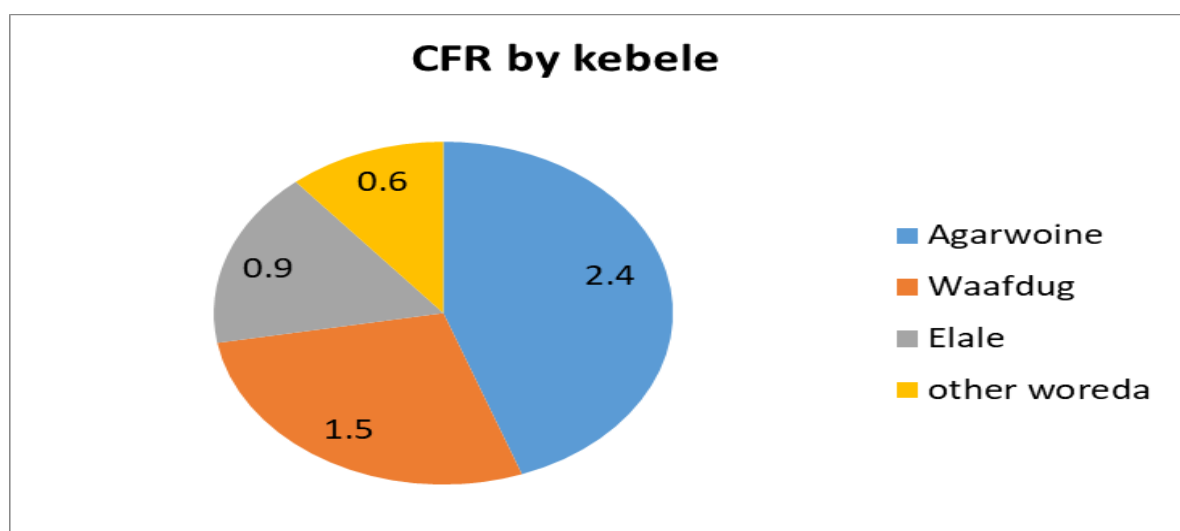


Figure 3: AWD case fatality rate by warder kebele, Ethiopia, 2009 EFY

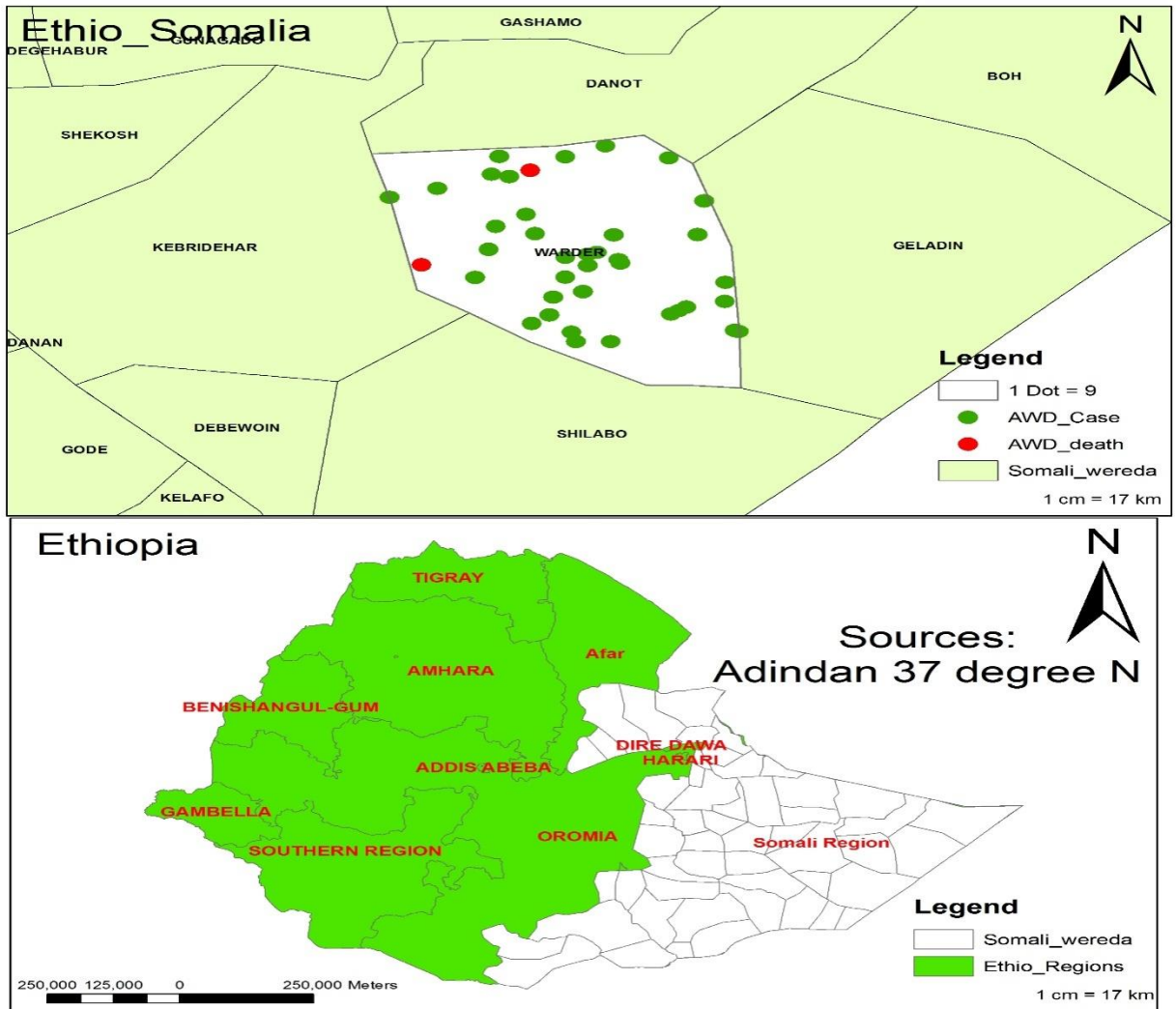


Figure 4: Map of Warder Woreda shows AWD case and death ratio distribution by place
As showed

Table 2 : Respondents and same factors of acute watery diarrhea warder woreda, Somalia regions

Variable		Frequency	Percent
Educational status	Illiterate	92	61.4
	Read and write	14	9.4
	Grade 1-4	14	9.4
	Grade 5-8	24	16
	Grade 9-10	2	1.4
	Diploma and above	2	1.4
Do use shallow water?			
	No	99	66
	Yes	51	44
Do you treat water?			
	No	95	63.4
	Yes	55	36.6
Do you use protected water?			
	No	62	41.3
	Yes	88	57.8
Do you have tanker?			
	No	145	96.6
	Yes	5	3.4
Do you eat food outside your home?			
	No	144	96
	Yes	6	4
Do you have latrine in your home?			
	No	104	69.3
	Yes	46	30.7
Do you here about atet?			
	No	86	57.3
	Yes	64	42.7

1.4.1. Public health intervention:

In collaboration with the team from FMOH and Regional Health Bureau & other NGO prepare the response actions plan that include activities monitoring and evaluation the gap, responsible bodies, time schedule and the operational cost. In such away five cases team creation (Case management and disinfection, Surveillance, logistic and resource mobilization, WaSH and Social mobilization and awareness creation) were established and the daily activity report was presented to the task force by the leaders of each thematic area. The gap and challenges are forwarded and given solution by the task force if it is above the scope of the thematic areas team. Finally the team activities are evaluated by taskforce.

1.4.2. Analytical result:

As shown in the table1 below the peoples have treated water to make safe were more likely to prevent AWD diseases than people not treated the water (COR= 0.51 ,95 % CI =0.07-0.03, P= 0.0001) and the same to that people they did have enough Water for drinking and for preparing their food were more likely preventable association compared to those who have not adequate water with the AWD diseases with (COR = 0.32 , 95% CI=0.12-0.78 p.value=0.001).additionally the risk of AWD decreases in peoples who have at home private/family latrine (COR=0.31 95% ,CI=0.13-0.73 P= 0.004).

Table 3: AWD data Crude odds ratio Analysis, Warder Woreda, Somalia Region, Ethiopia, 2009 EFY.

AWD Cases and controls	Exposu re	Case	Cont rol	COR	95% CI	P. value
Do you Treat the stored water	Yes	17	70	0.51	0.07-0.3	0.0001
	No	37	30			
Water access adequate	Yes	7	34	0.32	0.12-0.78	0.001
	No	43	66			
Do you have Latrine at home	Yes	8	38	0.31	0.13-0.73	0.004
	No	42	62			
Do you heard about Atet	Yes	10	54	0.21	0.09-0.47	0.00007
	No	40	46			
By Avoiding eating contaminated food	Yes	8	18	0.86	0.34-2.16	0.76
	No	42	82			
Transmitted by Washing hands	Yes	8	20	0.76	0.31-1.87	0.55
	No	42	80			

Transmitted by Drinking contaminated water	Yes	5	20	0.44	0.15-0.12	0.12
	No	45	80			
Transmitted by drinking treating water	Yes	2	20	6	1.3-24	0.019
	No	48	80			
Visiting health facility	Yes	18	62	0.34	0.17-0.69	0.002
	No	32	38			

Same of the knowledge about AWD like on how do you prevent the disease was removed in the multivariable analysis from further analysis due to its confounder with other variables. But some of them like peoples they know how to treat the stored water were less risk with the diseases by multivariate adjusted odds ratio (AOR= 0.1613 95% CI=0.06-0.41. p.value=0.0002).people they did have enough Water for drinking and for preparing their food were less risk with the AWD diseases such as with (AOR = 0.34 , 95% CI=0.11-0.97 p.value=0.044)than those did not have enough water, people they did have family latrine at their home also less risk with the diseases than those who did not have latrine (AOR= 0.47 ,95 % CI =0.17,1.3 , p.value =0.035).

Table 4: AWD adjusted odds ratio Analysis, Warder Woreda, Somalia Region, Ethiopia, 2009 EFY.

AWD Cases and controls	AOR (Adjusted odds ratio)	95% confidence interval	P. value
Do you Treat the stored water (Yes/No)	0.1613	0.06-0.41	0.0002
Water access adequate (Yes/No)	0.34	0.11-0.97	0.044
Latrine at home (Yes/No)	0.47	0.17-1.3	0.035
Do u heard about Atet (Yes/No)	0.17	0.06-0.47	0.0005
Transmitted by drinking treating water(Yes/No)	2.27	0.41-12.28	0.34

1.5. Discussion:

The investigation discovered that vibrio cholera sub type O1 serotype Ogawa is confirmed in warder, districts of Ethiopia Somalia region in Mar 2009EFY. The same to study has been reported in five regions, with the most populous region (Oromia) reporting cholera in five years during 2006–2011 periods. (8) Most of the cases were affected on the age group of productive, mean age 33.8, median age 29.5. This is approximately the same to the study done in Diretiyara district, Eastern Ethiopia age of the respondents ranged from 18 to 61 years, with the mean age of 37.25(7). Total 5.5 CFR were reported. The total attack rate was 6 people per 1000 population. estimated similar study Compared to the Afar region attack rate of 0.9% and case fatality rates of 4.4%(9). The national case fatality rate is the Weekly high case fatality rate (over 5%) suggests a problem with patient management review treatment routines and or supplies the health facility with treatment materials. It may also be necessary to increase the community's access to care(10).

Clinical signs symptom of AWD cases was a common practice in most peripheral health care system of the woreda; based on possible patient care and treatment was done, The laboratory confirmation was 10 sample from cases with the RDT and 5 case with both the RDT and the golden standard culture laboratory were confirmed and all became positive for the type O1 vibrio cholera, But Among the others, laboratory test were done and tested negative at national laboratories for typhus, Shigela species, Salmonella specie, Streptococcus, Staphylococcus, E.coli, species etc. Interpretation of the test results of each dipstick and according to the manufacturer's instructions and information on appropriate collection of stool specimens for culture confirmation of Vibrio cholerae and recommended isolation and identification procedures can be found in the cholera guideline.(11)

According to the data analyzed Warder Woreda has safe water coverage of only 24 % and latrine below 22% when compared with the national coverage very low. Compared to the study In Ethiopia, 60% to 80% of health problems are due to communicable diseases attributable to unsafe water supply, unhygienic and unsanitary waste management, which are directly linked to the practice of open defecation. (7)The national use of improved drinking water sources is more common among households in urban areas (97%) than among those in rural areas (57%) (12) Usage of water treatment chemicals before drinking ,people use of public or private toilet ,was

preventable association than with those who do not use. the same to the study in A fare region(9).

1.6. Conclusion:

The occurrence of the diseases were more linked to the study finding that means people who were have adequacy access water areas ,people they have public or individual latrine ,people they did know about Atet disease and they did know the function of water treatment were less risk by the acute watery diarrhea diseases. The disease was confirmed by laboratory. The water and toilet coverage was very low in the study woreda.

1.7. Recommendation

- The regional and federal water and energy work in adequate supply of safe drinking water for all the population in the woreda
- The woreda health office should teach the community and each individuals on proper waste disposal and use of toilet
- The regional and woreda health bureau should work in prevention active search case before disseminated to other area.
- Woreda Health office should be responsible to control AWD case in migration from neighboring area.

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Annex 1: Questionnaire for assessment of AWD outbreak

Questionnaire for assessment of AWD outbreak in Warder, Somalia, April 2009EFY

GPS: _____ case: _____ control: _____

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/Sub-City _____ Woreda
 Kebele _____ Sub-Kebele _____ Village

- 5) Household size _____
- 6) Head of household 1. Male 2. Female
- 7) Marital status 1. Married 2. Single C. Widowed D. divorced
- 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 starting from today? 1. Yes 2. No
(skip to part III)
- 12) If yes to question 11, 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. Muroid 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. Anti-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 _____ 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 public 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 sources _____ specify (river, rain water, spring(pump), etc)
- 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 (non-case) / 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 5. Other _____

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

2. Chapter Two: Surveillance Data Analysis Report

Title: Acute Flaccid Paralysis Surveillance data analysis in Tigray region Ethiopia.

Authors: Desta Birhane, S. Tanie, A.Bekele

Abstract:

Background: Globally estimated 350,000 Polio cases were reported in 1998 which then reduced to 223 in 2012. Ethiopia on 14 August 2013, the KEMRI (Kenya medical research institute) reported a case of WPV1 in Ethiopia, with date of onset established at 10 July 2013. The 18-month-old child is from a nomadic family, from Injiro Kebele, Geladi Woreda, Warder/Dolo zone, Somali region. The child had never been vaccinated during routine or previous polio. The aim was to determine the key indicator and five year trends in the region.

Objective: To conduct in depth review trends from EPHI secondary data of AFP surveillance in, Tigray Region, Ethiopia, from 1 January 2011 to 30 December 2015 GC.

Methods: This is a description quantitative retrospective assessment of the AFP/acute flaccid paralysis/ patients examined at EPHI from Tigray region in the year April 1 to October 24, 2016. A line list record was reviewed that fits the purpose to gather information regarding patients AFP suspected status with respect to age, sex, laboratory finding outcome. The data in EPHI for at least five years (2011-2015) reviewed as AFP suspected records as per the medical record format.

Result: According to the surveillance data analysis which include case based, line listing report, a total of n=242 AFP (range in each year n=40-57) suspected cases were reported throughout the region during 2011 -2015 G.C. none of the cases were confirmed poliomyelitis, about 60.3% (n=146) were males. The highest numbers of cases were reported during 2011 (n=57) and it was stable throughout the year.

Conclusion and recommendation: The non-polio AFP rate was 2.4/100,000 population for all the five years and the stool adequacy rate 90%. That means meeting the two key indicators of surveillance. AFP surveillance must be maintained since polio continues to circulate in other African countries and there is a risk of importation. FMOH and other partners should collaborate and strengthen regions for the improvement of AFP/polio vaccination coverage. The woreda health office and health facility should be continuing to search suspected case by strengthen stool adequacy and NPAFP with in the region.

Keywords: AFP, Polio, surveillance, Tigray

2.1. Introduction

Acute flaccid paralysis (AFP) is defined as a sudden onset of paralysis or weakness in any part of the body of a child less than 15 years of age or any person of any age (1). Polioviruses are viruses that are transmitted from person to person following excretion in feces and pharyngeal Secretions, mainly via the hand-to-hand to mouth route because the poliovirus receptor is only expressed the infectious agent (2).

Globally From an estimated 350,000 cases in 1998 then to 223 reported cases in 2012(3).The reduction is the result of the global effort to eradicate the disease(3). In 2013, only three countries (Afghanistan, Nigeria and Pakistan) remain polio-endemic(3).As long as a single child remains infected; children in all countries are at risk of contracting polio(4). Failure to eradicate polio from these last remaining strong holds could result in as many as 200,000 new cases every year within 10 years all over the world(4). In most countries, the global effort has expanded capacities to tackle other infectious diseases by building effective surveillance and immunization systems(3) .

The Horn of Africa (HoA) region is experiencing an outbreak of wild poliovirus (WPV) type 1 that started in April 2013 after a WPV importation from West Africa to the Banadir region of Somalia. Most of the cases at the start of the outbreak occurred in the Banadir region and then spread to other areas in the Central South Zone of Somalia and to neighboring areas of Kenya and Ethiopia. As of 31 October 2013, a total of 200 cases have been reported to date (180 in Somalia, 14 in Kenya and 6 in Ethiopia). These cases represent more than 60% of WPV type 1 cases reported worldwide up to November2013(3).

HoA countries have had repeated WPV outbreaks, mainly due to importations fuelled by low population immunity and massive population movements. The largest and longest occurred between 2004 and 2007, affecting Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Yemen. HoA countries were polio free between July 2011 and the beginning of the current outbreak.(3)

Ethiopia on 14 August 2013, the KEMRI (Kenya medical research institute) reported a case of WPV1 in Ethiopia, with date of onset established at 10 July 2013. The 18-month-old child is from a nomadic family, from Injiro Kebele, Geladi Woreda, Warder/Dolo zone, Somali region. The child had never been vaccinated during routine or previous polio SIAs. The AFP case was

detected on the Somalia side of the border where the child was taken for medical services, and investigation was undertaken by the Somalia polio eradication program. An additional five cases, all from Geladi and neighboring Bokh Woreda, have been confirmed. This brings the total number of WPV cases to six, with the latest date of onset established at 19 September (3).

The Polio Eradication Initiative (PEI) in Ethiopia started in 1996 following the Declaration on Polio Eradication in Africa in the same year. Since then, Ethiopia has accelerated implementation of polio eradication strategies: routine immunization, supplemental immunization activities (polio SIAs), Acute Flaccid Paralysis (AFP) surveillance, and mop-ups in areas with high risk of polio importation and undetected circulation. Based on the available data Routine Oral Polio Vaccination (OPV) coverage has increased from 52% in 2003 to 80% in 2011. The polio SIAs coverage has been above 90% using administrative and independent monitoring data. The last indigenous case of wild poliovirus (WPV) was in December 2001. However, Ethiopia suffered several WPV importations from Sudan and Somalia between 2004 and 2008. Due to implementation of high quality SIAs, improvement in routine immunization and early detection of circulations, the country has been able to contain the outbreaks. The last WPV in Ethiopia was detected in April 2008; the circulating Vaccine derived polio virus (cVDPV) detected in 2008 has stopped after November 2010. Ethiopia has maintained certification level AFP surveillance since 2004(5).

However, there is continuing risk of WPV importation from neighboring countries. Somalia, Sudan and South Sudan, which are high risk areas due to security risks affecting implementation of the EPI strategies. Despite the activities of government and including civil society organizations, surveillance in bordering regions of Ethiopia has not reached certification level NP-AFP rates or stool adequacy rates. NP-AFP rate remained unstable many times below 2.0 /100,000 individuals under 15 years of age and stool adequacy below 80%. To finish the Job of polio eradication urgently the certification level surveillance at National level must be maintained the sub national level surveillance gaps must be closed(5).

Laboratory surveillance for cVDPVs

The occurrence of cVDPV cases also highlights the need for Countries to maintain sensitive poliovirus surveillance into the foreseeable future. Laboratory-based surveillance for cVDPVs began in 1997 in the Americas, with the sequencing of the VP1 genes of poliovirus isolates from AFP cases in the region (6).Unfortunately; this approach did not provide an early warning of the

Hispaniola cVDPV outbreak because no polioviruses were isolated in the 5 years preceding the outbreak (7). Following that outbreak, intensive screening of recent poliovirus isolates for cVDPVs was initiated by laboratories within the entire WHO Global Polio Laboratory Network (8). Since 2001, all vaccine- related poliovirus isolates from AFP cases have been screened for evidence of prolonged replication or circulation (8), . Poliovirus isolates are identified according to their genetic properties by probe hybridization (9), diagnostic polymerase chain reaction (PCR) assays (7), or PCR-restriction fragment polymorphism analysis (9).

2.1.1. Back ground of the Study area

The Tigray Regional state is located in the northern part of Ethiopia with latitude of 14.0323⁰ N and longitude of 38.3166⁰ E. Tigray has a total area of 53,638Km² and an altitude with a range of 500-4000 meter above sea level. Tigray region is one of the nine regional states of federal democratic Republic , bordered by Eritrea to the north , Sudan to the west ,afar region to east ,and Amhara region to the south and south west (10)

Table 5: Tigray Region explanation

Regional Fact Sheet	
Capital city	Mekelle
Woredas	52
Kebeles	792(rural -722) (urban -70)
Total population	5,128,532
Estimated area	53,638 km ²
Population density	95.61 people per km ²
Total households	1,165,575
Average house hold Size	4.4 persons (rural 4.6)(urban 3.4)

Source: Nine years performance report on selected core indicators 1998-2006 EFY, 2006 EFY, Mekelle, Tigray.

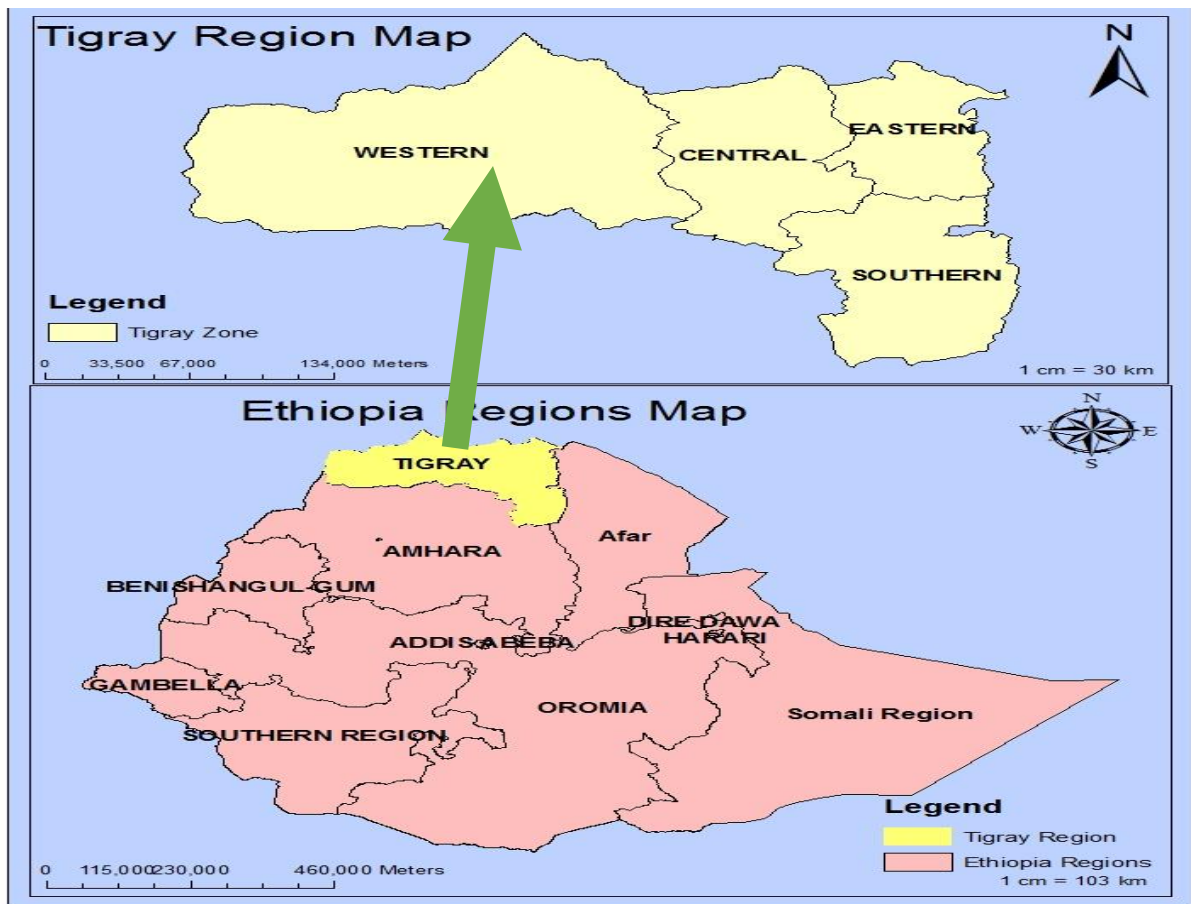


Figure 5: Map of Tigray Region

2.1.2. Rationale of the study

As already mentioned earlier the burden of AFP in the country was highly risk. so that AFP surveillance data analysis is a significant important for describing polio epidemiology. With in the different level in the region, characterize the disease burden; develop guidance to improve polio control efforts, monitoring vaccination statuses, laboratory sample adequacy, NPAFP report, trends, and evaluating the effectiveness of disease control programs and policies. Results from data analysis can generate the main public health action.

2.2.Objectives

2.2.1. General objective

- To assess in depth review from EPHI secondary data of AFP surveillance in, Tigray Region, Ethiopia, from 1 January 2011 to 30 December 2015 GC.

2.2.2. Specific objectives

- To determine the burden of AFP in under fifteen children & adult in the Tigray region.
- To compare the trend of AFP according to age, sex and year.
- To verify the two important indicators Non polio AFP and stool adequacy rate,

2.3. Method and Material

2.3.1. Study Period

The study was conducted in Tigray region, from EPHI files recorded review available data from first April 2016 to 24 October 2016.

2.3.2. Study population

All AFP case suspected which is in all age categories includes in Tigray region from January 1, 2011 to December 30, 2015.

2.3.3. Study design

This is a descriptive quantitative retrospective assessment of the records of AFP/acute flaccid paralysis patients/ examined from EPHI at Tigray region in the year, first April 2016 to 24 October 2016. I was received a line list record review format that fits the purpose to gather information regarding patients'/AFP suspected/ status with respect to age, sex, laboratory finding outcome. I was collect data in the EPHI for at least five years (2011-2015) and reviewed as AFP suspected records as per the medical record format.

2.3.4. Data collection method

The data was collected retrospective from national data pool in PHEM, EPHI. AFP/Polio cases detected and classified according to the case definition indicated below.

Suspect cases: Any child under 15 years of age with AFP or any person with paralytic illness at any age in whom the clinician Suspects poliomyelitis.

Confirmed cases: A suspected case with wild poliovirus isolation in WHO accredited laboratory stool

Epidemiological linked cases: is case which has contact with laboratory confirmed cases.

Probable poliomyelitis: any suspected case for which an alternative diagnosis is not found following clinical and epidemiological investigation.

2.3.5. Data Analysis

Acute flaccid paralysis data from line list, stool adequacy, polio suspected, compatible and cVDPV cases & NP AFP cases data variables entered and analyzed using Microsoft excel. If records were found out of range; it was re-checked with the corresponding records, accordingly correction methods was taken.

2.3.6. Ethical consideration

Ethical clearance were obtained from St.paul's hospital millennium medical college department of public health , ethical committee official letter was written to EPHI/Ethiopia public health institution/,and given to the organization where the study was conducted. After starting of the study the outcome of the study was reported to the conducted organization.

2.3.7. Dissemination of findings

Findings of AFP surveillance result was submitted to EPHI and administrative office by soft and hard copy to use the findings for priority setting, planning & initiate research also would be submitted to SPHMMC department of public health by soft and hard copy.

2.4.Results

According to the EPHI AFP surveillance data which include case based line listing report, a total of 243 (range in each year n =40-57) suspected cases were reported throughout the region during 2011 -2015 G.C. none of the cases were confirmed poliomyelitis, about 60.3% (n=146) were males and 39.6 % (n=96) were females the data was filled. The median age were 4(range 3.6 month (0.3 years)-18 year) while the mean age were 5.5 years. The highest numbers of cases were reported during 2011 (n=57) and then it was stable throughout the year. (See the figure: 2,3 & table 2 below).

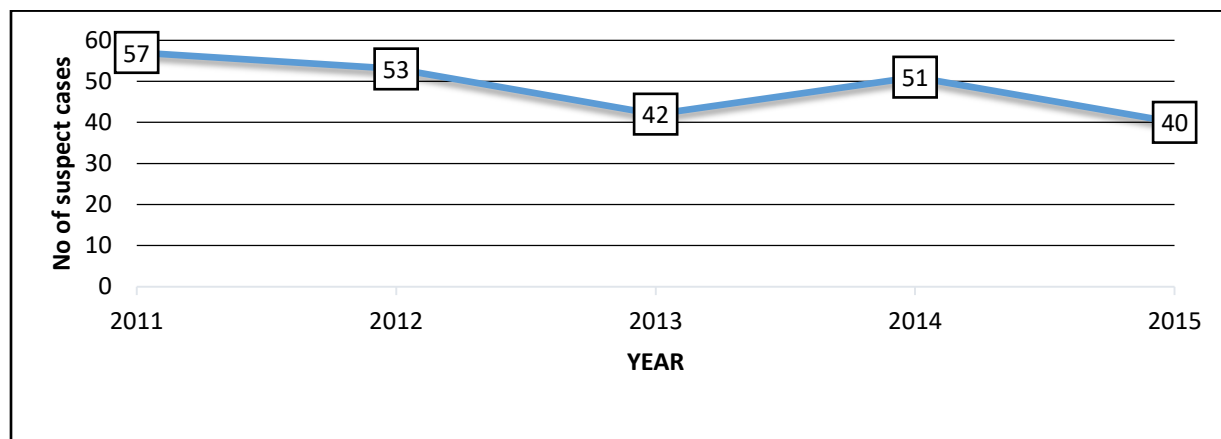


Figure 6: Trend of AFP cases, in Tigray, Ethiopia by year 2011-2015

Table 6: Distribution of AFP cases by age and sex, in Tigray, Ethiopia, 2011-2015

Row labels	Age	2011	2012	2013	2014	2015	Total
Male	<5	19	10	11	15	6	61
	5-15	11	21	17	11	16	79
	>=15	0	0	1	1	0	2
Female	<5	22	14	5	11	6	57
	5-15	5	6	6	11	11	39
	>=15	0	0	1	0	0	1
	Total	57	53	42	51	40	242

The leading sex AFP suspected cases was male with age distribution 5 to 15 n=79, while the smallest number was greater than 15 ages female n=1.

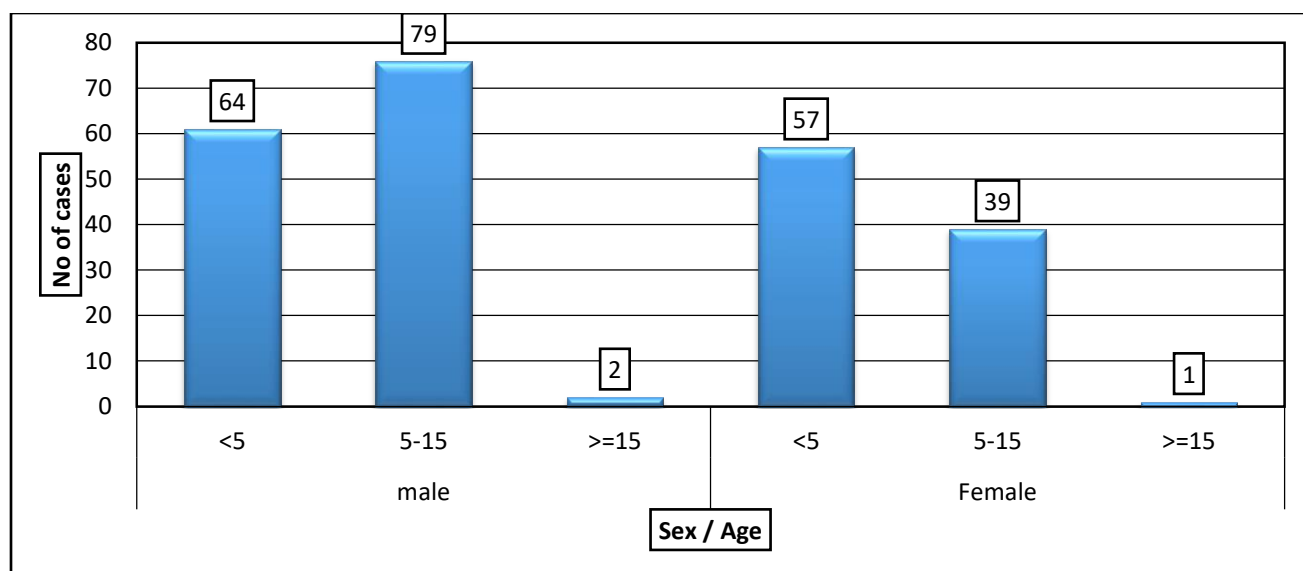


Figure 7: Frequency distribution of AFP cases by sex and age in Tigray Region from 2011-2015.

In each year the numbers of the reported AFP cases were greater than the expected number of AFP for that specific year. The stool adequacy also riches the standard.(See the Table below for detail-3).

Table 7: Distribution of AFP cases by different indicators, 2011-2015 Tigray, Ethiopia

Year	Expected AFP Case	Reported AFP case	Discarded AFP Case	Annualized NP-AFP rate (%)	VDPV	WPV case	Compatible Cases	Stool Adequacy (%)
2011	44	57	45	2.6	0	0	0	89
2012	42	53	47	2.5	0	0	0	96
2013	39	42	41	2.2	0	0	0	88
2014	39	51	49	2.6	0	0	0	90
2015	39	40	40	2.1	0	0	0	85

AFP cases (possible poliomyelitis cases) were reported immediately, be investigated within 48 hours (case-based data), and stool specimens was collected within 14 days of paralysis onset. All outbreaks should be investigated immediately. Active surveillance must be implemented in selected hospitals (also called sentinel hospitals.). So as it is shown in the above table, the

highest peak was in 2011. A total of 243 stool samples were collected and sent to the Ethiopia public health laboratory (EPHI). When compared to the annual suspected case with the highest annual proportion of samples collected was 94.4% (n=50) in 2012 followed by 87.8% (n=50) in 2011. The highest non confirmed cases of AFP were reported in 2013, 38.5% (n=5) and the least, 7.6 % (n=1) was in 2012 & 2015 (see figure 4). In each of the five year period a minimum of 40 suspected cases were reported to the central level.

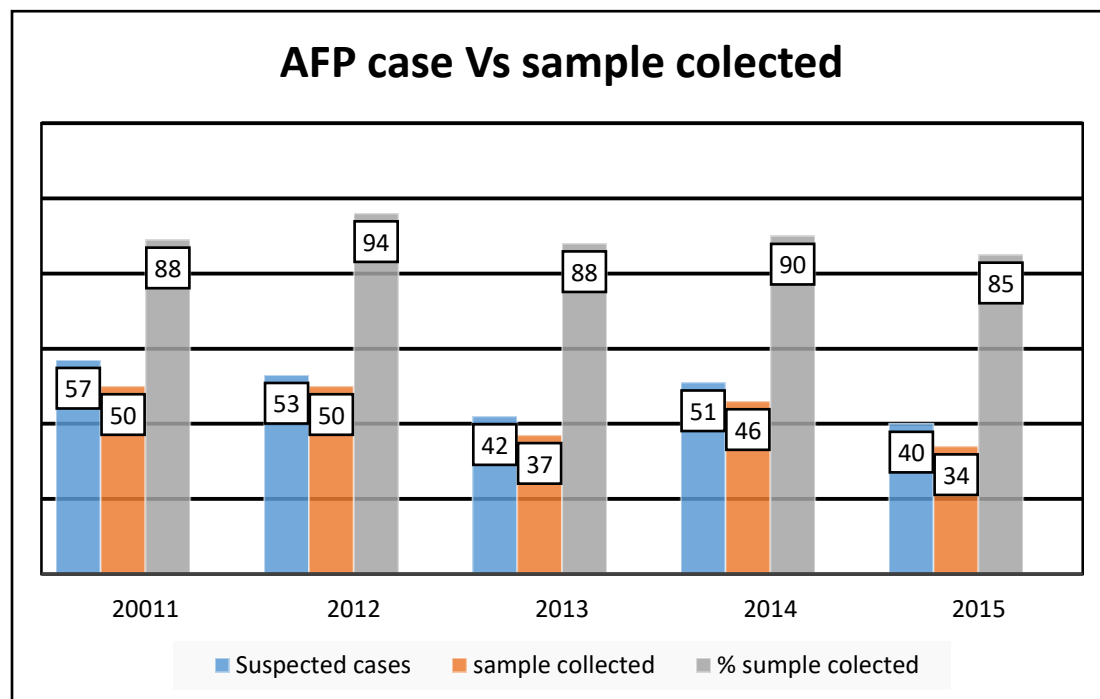


Figure 8: Frequency AFP of samples collected and total suspected cases per year, 2011-2015, Tigray Region, Ethiopia.

From the regional states there is no confirmed stool positive of their own total suspected cases. There was also no compatible cases poliomyelitis virus from 2011 to 2015 in the region.

Table 8 : Frequency of AFP cases by final classification from 2011-2015, Tigray, Ethiopia

Year	Confirmed(polio +ve)	Discarded(polio-ve)	Epi linked	Compatible	Total case
2011	0	45	0	0	57
2012	0	47	0	0	53
2013	0	41	0	0	42
2014	0	49	0	0	51
2015	0	40	0	0	40
Total	0	201	0	0	242

According to the laboratory finding, total sample perform 242, from that 201 negative, 13 suspected, 16 NPEV, 12 results not mentioned in the region in the specified period of time.

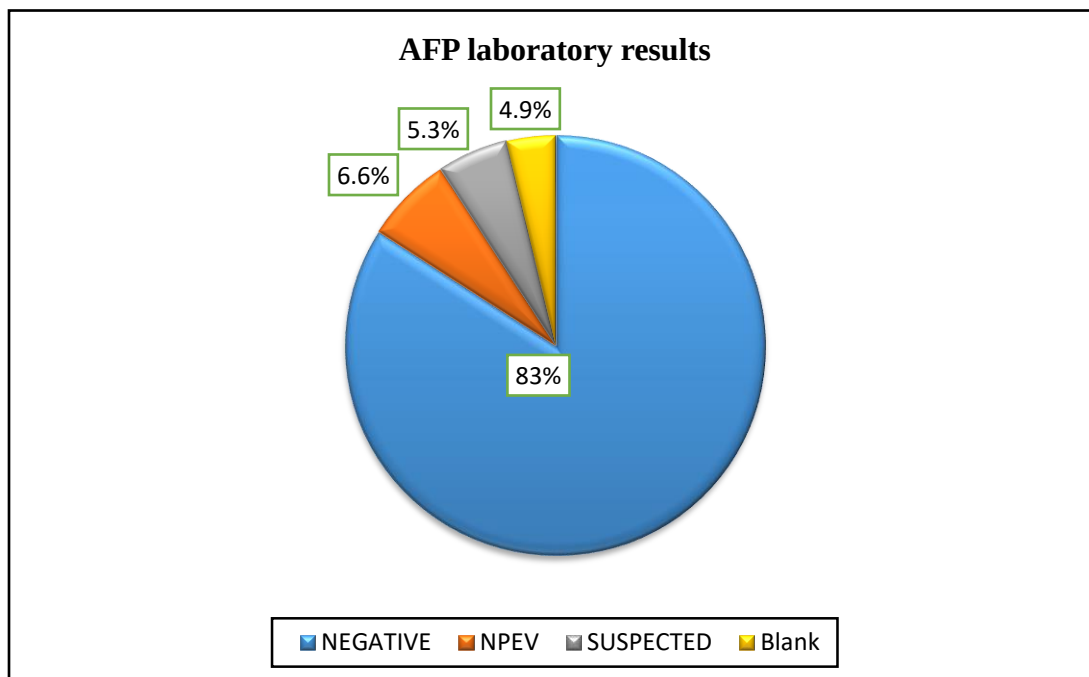


Figure 9: Distribution of AFP cases by laboratory result and final classification, 2011-2015, Tigray Ethiopia

All the Tigray region Zones /city administrations were reported suspected cases in each year except western, southern & south eastern, at least one in year the respectively.

Table 9: Distribution of AFP cases by Zonal sate and final classification, 2011-2015, Tigray Ethiopia

Province of Residence	Confirmed (polio-virus) No (%)	Discarded(polio Virus -ve) No (%)	Clinical Compatible No (%)	NPEV (%)
Western	0	13(6.4)	17 (70.2)	0
North West	0	39(19.4)	49(20.2)	4(30.7)
Central	0	52(25.8)	61(25.2)	3 (23)
Eastern	0	35(17.4)	42(17.3)	4 (30.7)
Southern	0	28(13.9)	30 (12.3)	0
Mekelle	0	13(6.4)	15 (6.1)	1 (7.6)
S.Eastern	0	14(6.9)	19 (7.8)	0
South West	0	7(3.4)	9 (3.7)	1(7.6)
Total	0	201	242	13

The trend blow shows as From the regional states, the Central zone ranked first by notifying 25.2 % (n=61) of the regional a total suspected cases during the five years period from that Adwa woreda is the highest 12 (20 %) cases. the western zone starts a report in 2014.

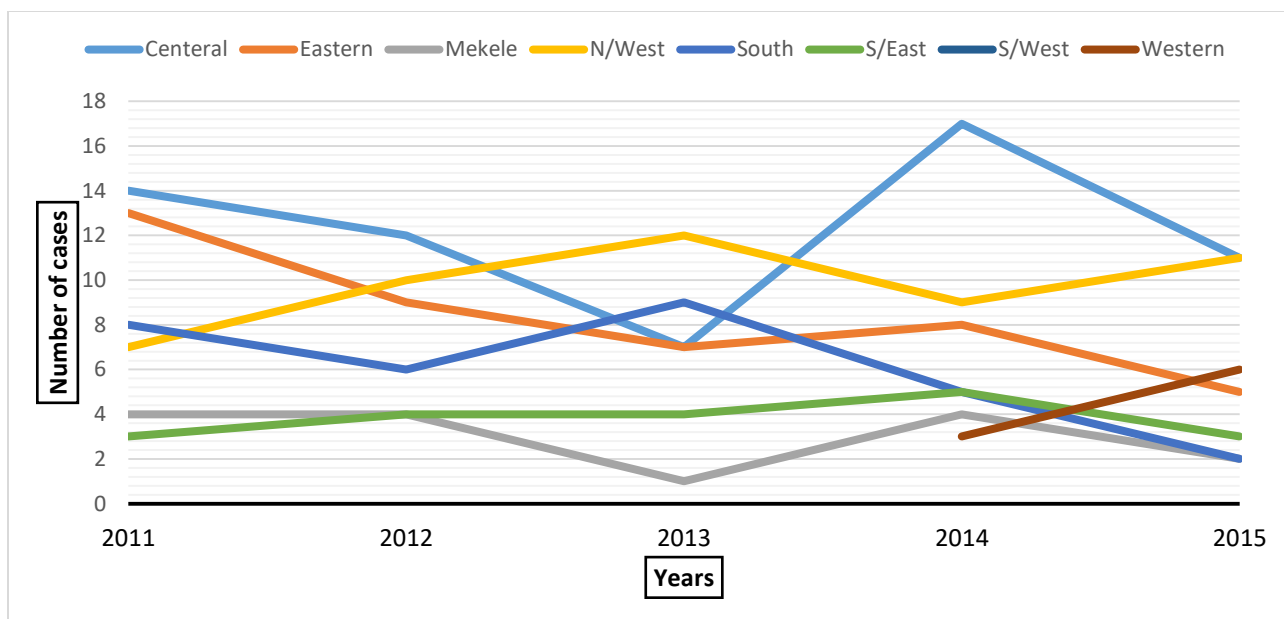


Figure 10: Trend of AFP Cases by Zones, Tigray, Ethiopia, 2011-2015

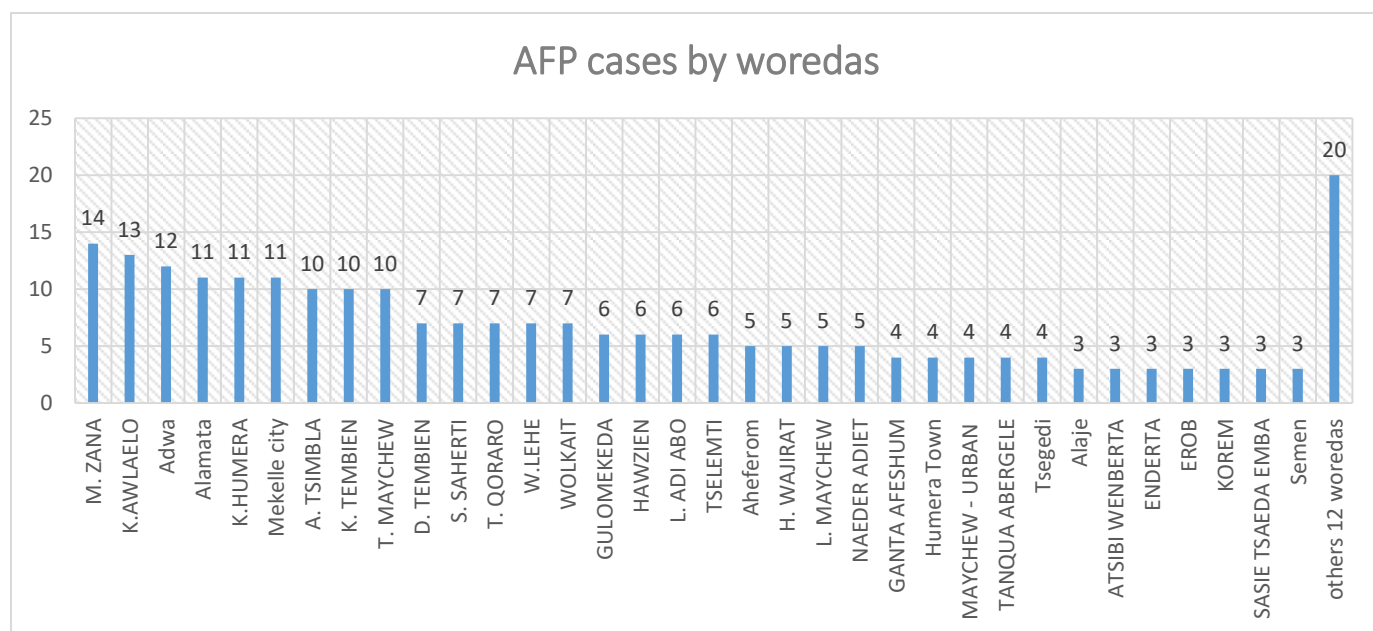


Figure 11: Number of AFP suspected cases by Woredas, Tigray, Ethiopia, 2011-2015.

The total vaccination statuses of AFP suspected cases were: 197, and also 17 were obtained vaccination below 3 doses, 180 cases were received 3dose OPV and 45 were unknown their vaccination status. Less than 1 year and Greater than 15 age year had got low vaccination (13 people) than the rest age classification. (See Table 6)

Table 10: Vaccination Status of AFP suspected Cases by age & dose category, Tigray, Ethiopia, 2011-2015

Age	< 3 Dose Number (%)	3 dose Number (%)	Unknown Vx Status
<1 Year	02 (0.8)	05 (2.0)	5 (2.0)
1 To < 5	04 (1.6)	95 (39.2)	13 (5.3)
5 To < 14	11 (4.5)	74 (30.5)	26 (10.7)
>15	0 (0.0)	6 (2.4)	01 (0.4)
Total	17	180	45

When compared the vaccination status of each zones, the highest vaccinated zone were south west & eastern Tigray respectively. South west & s/east Tigray zone were the least vaccine.

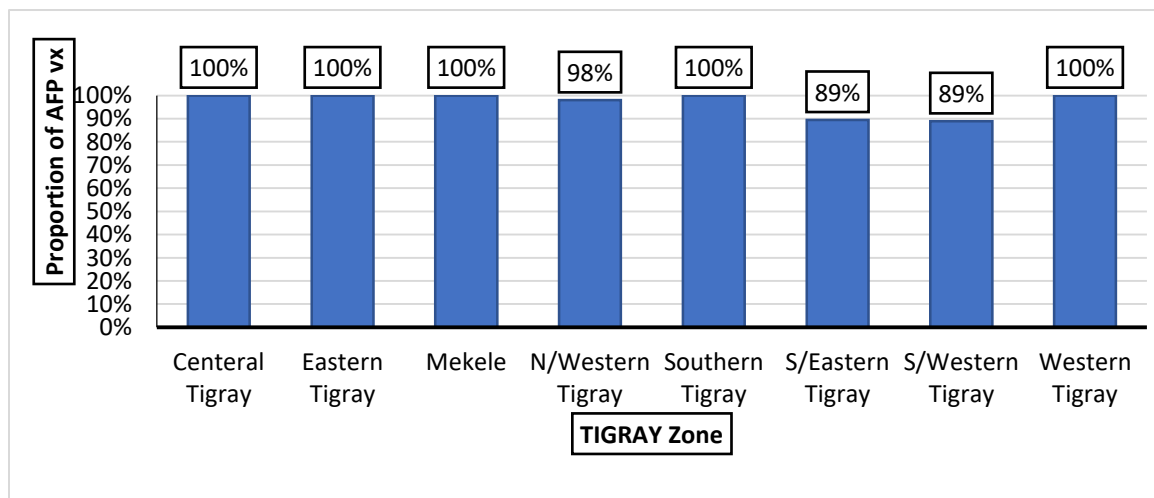


Figure 12: Number of AFP suspected case vaccinated at list one dose by zone, in Tigray, Ethiopia, 2011-2015

2.5.Discussion

Tigray region According to the EPHI AFP surveillance data which include line listing report, a total of 242 AFP suspected cases were reported throughout the region during 2011 -2015 G.C. This study on average lined with the study conducted in SNNPR Silte zone(11). About 60.3% (n=146) were males. When compute with the national finding similar cases in male 59% than female 41% (12).this could be recommended males were more suspected than female by AFP.

Tigray Regional states was experienced its first importation in December 2004 a wild poliovirus outbreak was confirmed bordering Sudan. Since then, there was no known WPV poliomyelitis. None of the five year data analysis suspected cases was confirmed poliomyelitis. Similar studies like countries, Djibouti, Eritrea, South Sudan, Sudan, Uganda and Yemen remain polio free(13). But findings showed a wild polio virus (WPV) outbreak was confirmed in the Horn of Africa Somalia Ethiopia in April 2013. Ethiopia confirmed 10 WPV cases since the onset of the outbreak; the first case has onset of paralysis on 10 July 2013; all cases have been confined to Dollo zone of Somali Region Ethiopia(14). This difference might be due to improvement polio immunization distribution in Tigray than Somalia region and weak prevention mechanism especially with the neighboring country in Somalia.

In Tigray region in each five year the numbers of the reported suspected AFP cases were greater than the expected (planed) number of AFP. In each of the five year period a minimum of 40 suspected cases were reported to the central level. Marked improvement in surveillance performance was noted at the national level similarly Tigray region the average of five year NPAFP rate was (2011-2015) 2.4 above the standard. The national<15 age NPAFP rate was 2/100,000 (5). Other Additional study Non Polio AFP rate at Tigray regional state from 2006 to 2010GC were 3.4, 2.6 2.1, 2.7and 2.9 respectively commonly higher than this study(12).This difference could be suggested that due to low clinical diagnosis of AFP and non-quality management of AFP.

A total of 217(90%) AFP suspected stool samples were collected in the study time period and sent to the Ethiopia public health laboratory (EPHI). This is still above the standard when compare with the nationally 80% Subsequently(5). Additional study was higher when compared to the study achieved in Somali region (74%), Gambella (69%) and Harar (67%). This difference could be due to the presence of awareness on AFP in the study area.

In the five year data analysis study area was a total of vaccination statuses of AFP suspected cases were low. (80% vaccinated three doses, and also 7% were obtained vaccination below 3 doses, and 13%) were unknown their vaccination status).

Less than 1 year and Greater than 15 age year had got low vaccination than the rest age classification. The result was approximately similar to the national study (27%) had obtained vaccination below 3 doses, (61%) of cases were 3 and above OPV doses and (11.4) were unknown their vaccination status(12). This shows that there was a gap in vaccination of eligible children in the region. Similar study were seen in,13 zones mostly in Oromia and Amhara regions had relatively large numbers of unimmunized children and zones in the pastoralist regions of Somali, Afar, Benshangul Gumuz and Gambella had lower coverage.(15)

According to the EPHI laboratory finding, from the total of 242 samples diagnosed, 201 negative, 13 suspected, 16 NPEV, and 12 results not mentioned in the region in the specified period of time. This study was lined with Ethiopia has maintained certification level AFP surveillance for more than 6 years. (16)

2.6.Conclusion:

The Tigray region in general the surveillance activity were satisfactory because the two mandatory issues in AFP/Acute flaccid paralysis/ surveillance system like reporting of NPAFP rate (none polio virus acute flaccid paralysis), stool adequacy rate were within range of the WHO standards. even if in presence of some criticalities in vaccination and continent of data management were needed further and more detailed sensitization, in order to obtain real structured and quick reporting, and to achieve the optimal standards recommended by the WHO both in the improvement of vaccination < 15 age children and the line listing data to fulfill the data cleanness with the goal of eradicating polio from country.

2.7.Recommendations:

The FMOH and other partners should collaborate and strengthen regions for the improvement of AFP/polio vaccination coverage. AFP surveillance system should be strengthening in the boarder of the country using diplomatic strategic among the countries is optional, especially high mobility and migration and insecurity border (Sudan, Eretria) and neighboring region with low indicator of NPAFP, vaccination and stool adequacy rate should be stay improved.

Improvement in the database management line listing for ease analysis i.e., for example all people should not verified the vaccination status & 12 samples were not filled the laboratory result (blank).

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Annex 2: AFP cases validation examination form

EPID NO: _____

I) Care seeking behavior

1. Patient's full Name _____ 2. Age ____ 3. Sex _____

4. Religion a. Islam b. Christian c. Other

5. Ethnicity _____

6. Parents educational status a. Primary b. Secondary c. Tertiary d. No formal education

7. Parents income in Birr per month a. <200 b.200-400 c.401-600 d. 601- 800 e. >800

8. Address a. Region _____ b. Zone _____ c. Woreda _____

9. Respondent's relationship with patient

a. Father b. Mother c. Guardian d. Other/Specify _____

10. Parent's Occupation

a. Farmers b. Nomads/Pastoralists c. Civil servants

d. Merchant e. Private employee f. Others/Specify _____

11. Site of paralysis: RA RL LA LL

12. Has your child taken the routine vaccination? A.Yes ____if yes no. of doses received_____ B. No ____

13. Date of onset: _____Date of notification:_____ Date of second stool: _____

14. How many days after child's paralysis did you seek help? _____

If late (>14days) why late? _____

15. What measures were taken at home?

a. Prayer b. Holy water c. Traditional treatment d. Massage

e. Nothing f. Other/Specify _____

16. Where do people in your community take their children in such types of diseases? _____

17. Where did you take the child first?

a. Health institution b. Holy water c. Traditional healer

d. Witch craft e. Prayer place f. Other / Specify _____

Mention name of the place _____

18. Distance of residence from the nearest health facility in Kms /Hrs. _____

19. Did you take the child to the nearest health institution a. Yes b. No

If No. Why not? _____

20. How many days after onset of paralysis did you take the child to health institution?
_____ Days. Mention the name of the institution_____
21. If Other than a. IN Q 17, why did you take the patient to the above-mentioned place before?
Modern health institution? _____
22. Who decided to take the patient to the mentioned place?
a. Father b. Mother c. Relatives d. Neighbors e. Other /Specify _____
23. What is your source of health related information in your surrounding?
a. Radio b. Newsletter c. Health personnel d. TV 5. Other source
e. No source of health information
24. Have you ever heard about Polio eradication and AFP surveillance? 1. Yes 2. No

3. Chapter Three: Evaluation of Surveillance System

Title: Acute Watery Diarrhea Surveillance Evaluation System, Mekelle Zone, Tigray Ethiopia

Authors: Desta Birhane, S. Tanie, A.Bekele

Abstraction:

Background: Globally, there are an estimated 2 billion cases of diarrheal diseases each year, and 1.9 million children under age 5, mostly in developing countries, die from diarrhea. Diseases like AWD are of the problem diseases throughout the Ethiopian for more than a decade. Public health Surveillance is the collection, analysis, and interpretation of information about public health. The Aim of the study is to evaluate the zonal surveillance system especially AWD public health interventions and activities.

Objective: To assess and evaluating the surveillance system mekelle zonal public health acute watery diarrhea community based surveillance.

Methods: Descriptive cross sectional study was conducted in Mekelle zone Tigray Regional State North Ethiopia from April 4 to24 April, 2017.Convenience sampling was used to select one Administrative Zone from the region based on AWD outbreak reported in 2016 EPHI. Analyzed by excels 2007, and summarize the main point.

Result: Grateful performance of the AWD standard case definition with availability of guidelines, standard case management, case registration, by all health district offices and health facility's was found improved, which helps for early detection and identification of cases for timely response and prevent further dissemination of outbreak. Some of the obstacles were also encountered like data analysis, laboratory confirmation not preformed. People in similar health facilities and health districts were lack of motivations because of employ structure and no budget line and certain resources in all level.

Conclusion and recommendation: According to the Public health Surveillance evaluation system result AWD were seen in areas low water resources and population in use of holly water. The zonal administrative should be work on improvement of availability drinking clean water, on giving health education to community, budget allocation, staff training & motivation laboratory works.

Key words: Acute watery diarrhea, zone, surveillance, evaluation

3.1.Introduction

3.1.1. Background:

AWD defines normal bowel frequency ranges from three times a day to three times a week in the normal population. Increased stooling, with stool consistency less solid than normal, constitutes a satisfactory, if somewhat imprecise, definition of diarrhea. Acute diarrhea is defined as three or more stools per day of increased form the normal, lasting for less than 14 days. If the illness persists for more than 14 days, it is called persistent. If the duration of symptoms is longer than 1 month, it is considered chronic diarrhea. Most cases of acute diarrhea are self-limited, caused by infectious agents (e.g. viruses, bacteria, parasites), and also occur following ingestion of chemicals and do not require medication unless the patient is immune compromised(1).

Globally, there are an estimated 2 billion cases of diarrheal diseases each year, and 1.9 million children under age 5, mostly in developing countries die from diarrhea(2).diarrheal diseases are major causes of morbidity, with attack rates ranging from two to twelve or more illnesses per person per year in developed and developing countries. In addition, diarrheal illnesses account for an estimated 12,600 deaths each day in children in Asia, Africa, and Latin America. The causes of diarrhea include a wide array of viruses, bacteria, and parasites, many of which have been recognized only in the last decade or two(3).

Diarrhea is more prevalent among adults who are exposed to children and non-toilet-trained infants, particularly in a daycare setting. It is also more prevalent in travelers to tropical regions, homosexual males, persons with underlying immunosuppression, and those living in non-hygienic environments who are exposed to contaminated water or foods. Women are more susceptible to travel-related diarrhea than men(1).

Diseases like AWD are of the problem diseases throughout the nation for more than a decade. AWD epidemic is becoming more frequent and dispersed to different corners of the country. Ethiopia reported in,1836 and 1850 AWD/cholera outbreak from different part of the country locally named fangalil (Med Hist,1968).In 1902,1906,1987,1993 and 1998 cases were reported (Int J Med Microbiol,2008) and the recent outbreak was in 2006,2007,2008 and 2009 G.C(4).

Ethiopia's efforts have been directed towards improving the standards of living, particularly the health of the population throughout the country. This is being implemented through a combination of strategies and approaches, which include health specific strategies, intended to influence the performance of health determinants like education, poverty reduction, and access to good sanitation and safe water (5).

Ethiopia follows a decentralized health care system, development of the preventive, promotive and curative health care delivery by public, private for profit and not-for profit players in the health sector. The country has been implementing a national health sector development plan of 20 years divided in four series of five consecutive years to ensure the attainment of national goals and MDG targets.

The Ethiopian health care delivery, organized in to three tier-system, puts the health extension program, the innovative community-based service delivery (health development army), as a center of focus for the provision of primary health care services to broad masses. Primary Health Care (PHC) potential coverage stands at 90%, reaching most of the rural areas in the country. The growing countrywide network of healthcare facilities has enhanced access to health services. The rapid expansion of both private-for-profit and not for-profit health facilities accounts for about 11% of health service coverage and this has enhanced public-private-partnerships in health. WHO Country Office Ethiopia, in line with country health policies and systems, has drafted the CCS for 2012 to 2015 which is under implementation(5).

Public health Surveillance is the collection, analysis, and interpretation of information about public health. Health officials use the information to plan, to implement and to evaluate public health interventions and activities(6).

Public health surveillance is a tool to estimate the health status and behavior of the populations served by ministries of health, ministries of finance, and donors. Because surveillance can directly measure what is going on in the population, it is useful both for measuring the need for interventions and for directly measuring the effects of interventions(7).

The right to health for every Ethiopian has been guaranteed by the 1995 Constitution of the Federal Democratic Republic of Ethiopia (FDRE), which stipulates the obligation of the state to issue policy and allocate ever increasing resources to provide public health services to all Ethiopians. The Federal Ministry of Health (FMOH) of Ethiopia has prepared a comprehensive strategic plan, the Health Sector Development Programme (HSDP), in alignment with the

national Growth and Transformation Plan (GTP). The HSDP IV covers a five year period from July 2010 to June 2015. The governance mechanisms of HSDP IV include: Joint Consultative Forum, Joint Core Coordinating Committee, joint review meetings, and an annual review meeting (5).

In order to combat with the challenges that are ever growing, the way working processes are organized and its capacities should also be changed. Based on this fact the health sector has identified Public Health Emergency Management (PHEM) as one of the core processes to be reengineered. PHEM is designed to ensure rapid detection of any public health threats, preparedness related to logistic and fund administration, and prompt response to and recovery from various public health emergencies. PHEM also the process of anticipating, preventing, preparing for, detecting, responding to, controlling and recovering from consequences of public health threats in order that health and economic impacts are minimized(8).

The FMOH/ PHEM of Ethiopia identified 20 top priority diseases which are epidemic prone, of international concern and diseases on eradication and elimination programs for surveillance activities. These diseases are monitored by a designated bodies through available means of communication- telephone, paper based reporting etc. These diseases are set to be reported as mandatory notification (which are immediately reportable) diseases and routine surveillance (which are to be reported weekly). Measles, polio, malaria, and Acute Watery Diarrhea (AWD) etc, are of among the 20 priority diseases reported as immediately and weekly reported diseases (dysentery, typhoid fever, malaria, relapsing fever, typhus). They are significant disease burdens to the public(8).

Objectives may include Detect outbreaks of AWD early; estimate how many people become sick or die; assess the size and extent of the outbreak; determine if an outbreak is spreading, and where, plan the best allocation of resources (e.g. personnel and supplies); decide whether control measures are working and to plan additional epidemiologic investigations to target control efforts(9).

Most importantly, surveillance information should be also used locally to address and resolve problems related to control of communicable diseases and to strengthen evolving programmes. Monitoring and evaluation are keys to establishing and maintaining effective and efficient surveillance and response systems(10).

According to EPHI data 2016/7 report AWD are the major diseases of the mekelle Zone with high frequency of epidemic and public health concern in the region. Mekelle zone were affected by the recent (2016/17) AWD outbreak in the region. Therefore it is endemic for AWD, and outbreaks occur with inter-epidemic period of different length the zone. Generally, the reason why studded is to use of collected data at the local level as evidence for public health decision and also evaluation of surveillance system is not done before (published) in the zone. Therefore, continuous surveillance evaluation of the disease was carried out year round, at all levels.

3.1.2. Rational of the study:

The gape of the mekelle surveillance system was seen the highest AWD outbreak in the year 2016/17 from the region as I have expressed in the background section. So Purpose of surveillance was to empower decision makers to lead and manage more effectively by providing timely, useful evidence. Increasingly, top managers in ministries of health and finance in developing plans and donor agencies are recognizing that data from effective surveillance systems are useful for targeting resources and evaluating programs in order to narrowing the gap.

3.2. Objectives:

3.2.1. General objective:

To assess the performance and operation of the system, and identifying possible gaps

3.2.2. Specific objective:

- To describe the community based integrated disease surveillance for AWD.
- To describe the purpose, operations and performance of the attributes of community based Surveillance system for AWD.
- To identify gaps and factors which is not suitable to the AWD surveillance system

3.3. Methods and Materials:

3.3.1. Study area and population:

This surveillance system evaluation was conducted in mekelle special zone, Tigray, northern Ethiopia. Mekelle is the capital city in the northern Tigray Region of Ethiopia. It is located around 780 kilometers north of the Ethiopian from capital Addis Ababa, at a latitude and longitude of $13^{\circ}29'N$ $39^{\circ}28'E$, with an elevation of 2084 meters above sea level and temperature above $18^{\circ}C$. Administratively, Mekelle is considered a Special Zone, which is divided into seven sub-cities. These are Addi-Hak'i, Ayder, Haddinet, Hawelti, Qedamay Weyyane, Kwiha, and Semien. Based on the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA), this town has a total population of 215,914 people (104,925 men and 110,989 women). Tigrigna is spoken as a first language by 95.55%, and Amharic by 3.18%; the remaining 1.27% spoke all other primary languages reported. 92.68% of the population said they were Orthodox Christians, and 6.03% were Muslim. There are 3 hospitals (1 specialized, 1 zonal & 1 district), 10 health centers (1 new). All the four districts of the Mekelle Zone are broiling areas of AWD.

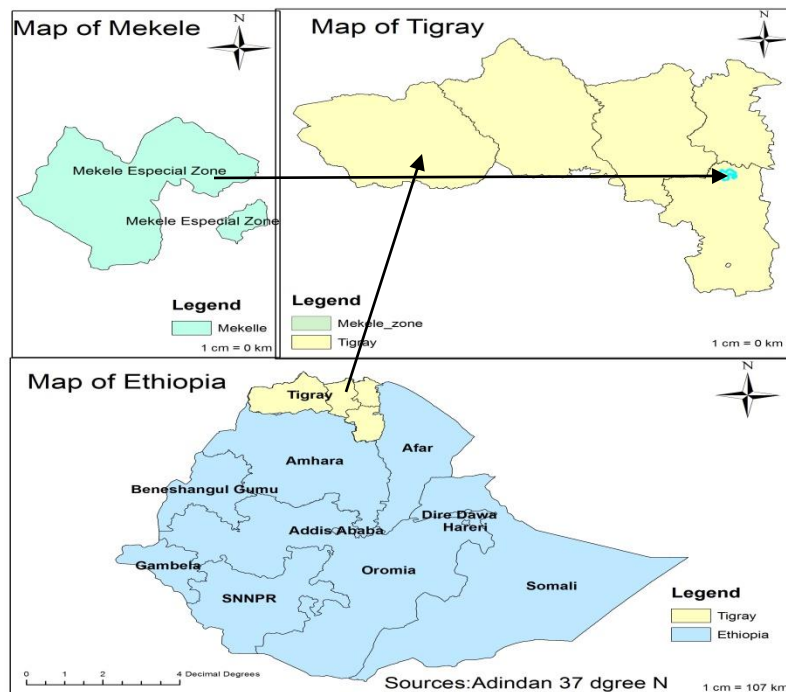


Figure 13: Map of mekelle zone

3.3.2. Study design and period:

Descriptive cross sectional study was conducted in Mekelle zone North Tigray Regional State Ethiopia from April 4 to April 24, 2017.

3.3.3. Sampling method

Convenience sampling(also known as availability sampling) was used to select one Administrative Zone since from all Tigray the region based on AWD outbreak reported data in 2016 in EPHI, there was a pick from all Tigray zone so mekelle was selected by opportuneness(convenience). In data collection four Woreda health office and five health centers, were randomly selected using lottery method for the evaluation from the total of ten health facility and seven district health offices in the total zone with no health post.

3.3.4. Data collection procedure

One public health importance disease (AWD) was considered in the evaluation of the system. The data was collected by using the check list of adapted from WHO structured questionnaires which were designed for the assessment of national communicable disease surveillance system. The data was collected using both face to face interviews with the surveillance focal person's health professional, with stakeholders, with some of the dwellers and certain observations monitored by the basic investigator as a key measure regarding mainly about core and supportive surveillance evaluation.

3.3.5. Data analysis:

Quantitative surveillance evaluation data were entered and analyzed using the Microsoft Excel and quantitative open ended questions was summarized to supplement the quantitative findings.

3.3.6. Data dissemination:

I was prepared and shared the written report of both hard and soft copies to SPHMMC department of Public Health, Tigray Regional Health Bureau (TRHB), Mekelle special Zone Health department and all visited woreda health offices, and saint Paulus Field Epidemiology Training Program mentor, resident advisors in EPHI coordinator and all stakeholder's.

3.3.7. Ethical consideration:

Ethical clearance was obtained from St.paul's hospital millennium medical college department of public health, ethical committee official letter was written to Tigray regional health bureau (TRHB) and given to the organization where the study was conducted (mekelle zone, under mekelle zone health facilities &health offices), After starting of the study the data of surveillance evaluation was collected smoothly.

3.4.Results:

3.4.1. Implementers and stakeholders:

The visited study area were discussed with the main stakeholder participating and leading the surveillance system of zones & Woredas were the public health emergency management (PHEM) process of the regional health bureau. The important surveillance levels were central, intermediate (zone /region, district) peripheral (health facility) and community level. Each of these levels were a key actors comprise formal health-service providers that were included in the surveillance system. Other stakeholders and implementers were also including the disease-specific programmes, religion influential, female affairs, public health laboratories, and public health training institutions. The roles and responsibilities of the implementers and stakeholders were supported particularly to improve quality, efficiency, and usefulness of the surveillance evaluation system. The flow of surveillance data through the system, and the dissemination and utilization of information needs were clear and known to implementers and stakeholders, and the mechanism for response were well coordinated across the different levels of surveillance.

3.4.2. Core functions of surveillance systems:

The indicators related to the core functions measure the processes and outputs from the system in the zone. The core functions include case detection, case registration, case confirmation, reporting, and data analysis and interpretation, and public health response including reports and feedback from the systems to the data providers, stakeholders and decision-makers.

Case Definition:

In all the health facility and district office that were collected data for the surveillance evaluation system was available of standard case definition.

Suspected case:

- A case of cholera should be suspected when: in an area where the disease is not known to be present, a patient aged 5 years or more develops severe dehydration or dies from acute watery diarrhea.
- In an area where there is a cholera epidemic, a patient aged 5 years or more develops acute watery diarrhea with or without vomiting.

At the health post and at community levels:

Any person 5 years of age or more with profuse acute watery diarrhea and vomiting

Confirmed case:

A suspected case in which *Vibrio cholerae* O1 or O139 has been isolated from their stool.

3.4.2.1. Case detection:

There were a formal and structured Case definitions and a functioning rumors verification system available in place used vital for case and outbreak detection in all the woreda health office and health facility. Identification of suspected cases was being done at community level, health centers or district hospitals. But investigation of suspected cases outbreaks was being done by district, zonal or regional level mainly by the IDSR focal point or the PHEM process. The regional PHEM was mainly giving technical, materials and skill human resources support when needed but not enough. Confirmation of cases was done at, regional or central level of the surveillance system but not in the lower.

At zonal level data coming from the Woredas or districts were being entered into computers, but not analyzed on the other hand at least basic information was produced. At health facility and woreda Levels except line listing of suspected cases there was no data in electronic and hard copy system and at least basic analysis was not being done.

3.4.2.2. Case registration:

All AWD cases were detected and being reported through the PHEM process at all level. The cases that could be identified in the government sector were routinely reported through the surveillance system. Although reporting of suspected AWD case is mandatory in the zone level, and there was control system to ensure that cases identified through the government sectors were appropriately registered, timely reported and investigated. Generally from the past year Sep. 2008 –January 2009, 1077 AWD cases, with 4 deaths (CFR 3.7 /1000) were registered in the study zone. The Main risk factors of the AWD were identified such as shortage of drinking water and drinking of holly waters.

3.4.3.3. Case confirmation

Case/outbreak/confirmation refers to the epidemiological and laboratory capacity for confirmation. So Capacity for case confirmation is enhanced through improved referral systems, networking and partnerships. All the health facility and health offices together have the capacity for appropriate specimen collection, packaging and transportation to the regional and central levels. Other than AWD samples were send all health facility to higher level and used of internal

and external quality control mechanisms for case confirmation which help to ensure the validity and reliability of test results. But for surprise AWD case were not confirmed in the outbreak period.

3.4.3.4. Reporting:

There was no scarcity of reporting form in the past 6 months in all visited health facilities and health offices. The weekly reporting rates of visited health facilities over the past 3 months prior to assessment were 100% (n=4/4) district health office, and 100% (n=5/5) for health centers. The overall reporting rates of the visited districts to the Zonal Health Department in 2008 EFY were 100% (n=9). All the reports were sent to the next level through hard copy and telephone. However reporting through telephone is limited in some health centers and there was no telephone services only needed hard copy. In cases of emergency the focal surveillance person uses their personal mobile phones, for which they were complaining for fee.

3.4.3.5. Data analysis and interpretation:

In the study area surveillance data was not analyzed routinely and only for information they registered the data and partially used in public Health actions. Appropriate "alert" and "epidemic" threshold, epidemiology curve by place, person, and time values were not well known including the zone for diseases with epidemic tendencies by the surveillance focal person. They were not have Capacity and skills for routine data analysis and interpretation in order to establish and maintained for epidemiological as well as laboratory data for public health priority disease response.

3.4.3.6. Epidemic preparedness and response:

In the visited study area Epidemic preparedness were implemented to the existing level of preparedness for potential epidemics and includes availability of preparedness plans, epidemic management committee with RRT (RAPID RESPONSE TEAM), with limited stockpiling, designation of isolation facilities, etc. but in all health facility and health office district were interruption in meeting of RRT and no preparedness plan even in the zone. The big problem was no budget line for epidemic preparedness not only that but also for all the surveillance structure starting from the zone to lower health posts.

3.4.3.7. Feedback:

Feedback were an important activities of all surveillance systems the visited study area. Appropriate feedback was maintained through supervisory visits, but no newsletter and bulletins performance in the zone, health facilities& district health office. The supervision was run programed by the region two times annually & the district health office quarterly to their lower administrations. But in some district health office there were a gap interruption of supervision, and not evaluated the quality of feedback provided, and the implementation of follow-up actions.

3.4.3. Support functions of surveillance systems:

3.4.3.1. Standards and guidelines:

The study health zone were have a partially (not completed) guide line in number for all surveillance priority diseases. A comprehensive surveillance case definition were defined and posted in the class room. But the problem was the standard guideline and case definition not updated included reporting format and data management tools, a description of roles and responsibilities but miss understand and interpretation of action thresholds, the expected actions by level not formal protocol followed.in the health institution other important manuals also implemented include those for outbreak investigation, for case management and infection prevention, and laboratory standard operating procedures etc.

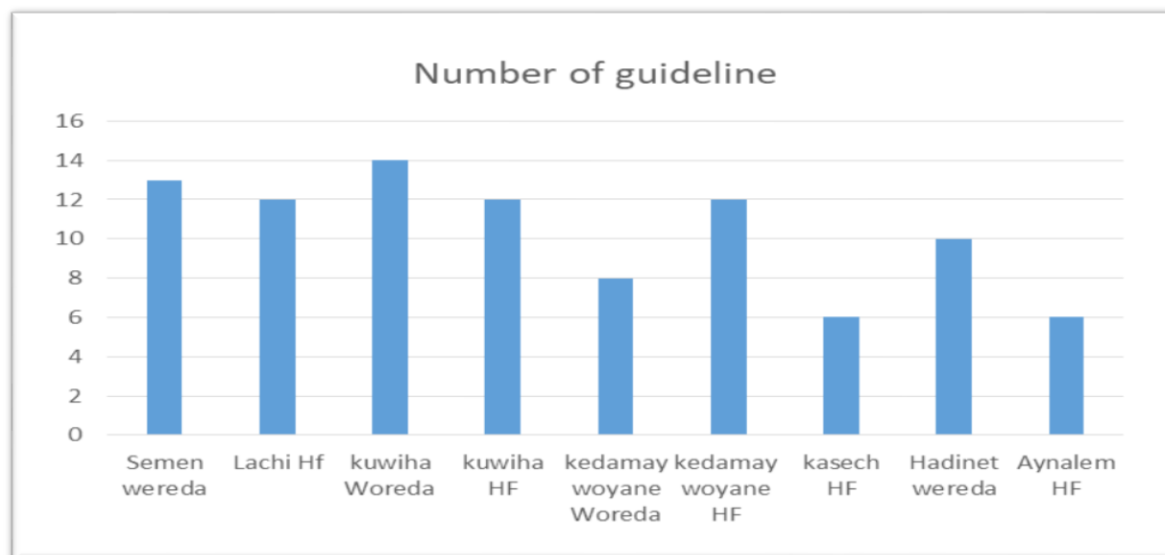


Figure 14: standards and guidelines of mekelle zone health facility and woreda office

3.4.3.2. Training:

The training in the study area were without scheduled, inadequate, and substandard in time and the Surveillance staff at different structure levels have complaining about training needs. About basic epidemiology surveillance training was only 20 % of the surveillance focal person received. There was no an assessment of identify the training needs for different categories of staff, which in chance can be used to draw up a training plan in the zone. The implementation of the training plan and the proportion of surveillance staff (epidemiology, laboratory and community resource Persons) were not trained on the different aspects of surveillance and response monitored. Evaluation and examine were not preformed, the quality, relevance, impact and cost-effectiveness of the training. Especially for the newcomer staffs were difficult in work of surveillance activities and low in productivity and motivation.

3.4.3.3. Supervision:

Supportive supervision were conducted in the different structure surveillance areas and serves numerous functions.it was needed in strengthen the capacity of staff and ensure that the right skills were used appropriately, necessary logistics in place partially , and that planned activities were implemented according to schedule. It was also necessary for each of the surveillance levels to include supervisory activities in their annual work plans. The proportion of the planned supervisory visits with check lists and feedback reports conducted by different surveillance units during the year of 2016. But Evaluation of the supervision the quality and effectiveness of the supervision were not considered and conducted by staff at the different levels of surveillance area.

3.4.3.4. Communication facilities:

Communication infrastructures in the visited study area like fax, radio call, satellite phone, computer that have modems were not available (accessible) in all the mekelle zone public health surveillance sections. This was make challenge same performance in the zone.

3.4.3.5. Resources

The visited study area where the resources for data management, communication, logistics and budget line specific for surveillance focal personnel not available at the zonal and other district health office and health facilities level. However, they used from other department (section) means shared computer, vehicle, motorcycle, telephone etc and other logistics. This make the

public health response becomes a challenge and non-productive (non-motivation) in staffs. There was also scarcity of class in most of the visited health centers were used under five clinics or emergency room as surveillance unit and the rest used OPD department for data management. The logistic and budget constraints were also observed at all the visited sites.

3.4.4. Attribute of the surveillance system (Surveillance quality)

3.4.4.1. Usefulness

The visited surveillance system delegated person were said that usefulness of surveillance quality to detect outbreaks, to estimate the magnitude of morbidity and mortality and to assess the effect of prevention and control programs. Also they were used for case detection, planning, for policy makers. so all the activities were important part on the surveillance evaluation system discovery.

3.4.4.2. Simplicity of the system:

All visited health facilities, health office and zonal health bureau agreed that the case definitions of AWD for identification of suspected cases are easy to understand and possible to apply by all level health professional. The flow of AWD data is clear and simple as it was set in the surveillance guideline and reporting forms. Moreover to fill a single AWD case based reporting format took less than 5 minutes but same times increase minutes according of the number of AWD cases. At the health facility level AWD were not confirmed by laboratory. Even for others like measles result delayed in average 10 days took time. However lack of resources like internet, computer, fax and budget line make difficult the surveillance evaluation.

3.4.4.3. Acceptability of the system:

Acceptability of the surveillance system were all willing on the surveillance staff to implement the system, and of the end users to accept and use the data generated through the system. The acceptability of the surveillance system assessed based on their active participation in surveillance system. When we looked the commitment of the reporting agents were as expected and the reporting rate of the zones and Woredas was 100% as seen over 3 months reporting. However in the visited some health facilities and in district health offices complaining of structure of employment and salaries, Because the employed staff were have a degree certificate in the health district office but their salaries were in diploma.

3.4.4.4. Flexibility of the surveillance system:

In the visited study Flexibility were used to the system adapted by customizing needs such as the removal or inclusion of additional diseases, modification of the reporting frequency, data requirement needs, etc. An early warning system of the region (zone) were customize (adapted) the reporting format in maternal and neonatal data collection reporting and also needed to be from time to time to meet additional case detection needs.

3.4.4.5. Timeliness and completeness

Timeliness of the public health surveillance is usually considered that time interval between the onset of the selected disease priority and the reporting of the event to the higher level public health agency responsible for immediate action and control effort, prevention of continued exposure or program planning. The weekly reporting rate (completeness) of the health facilities and district health offices in the zone was 100%.the visited every health facility and district health office including the zone were controlled by the standard WHO timeliness of reporting.

3.4.4.6. Sensitivity in surveillance:

Sensitivity in public health surveillance discusses to the proportion of actual cases in a population that are detected and notified through the system. Since in the visited study area the AWD case were not confirmed by laboratory to calculate the sensitivity for the public health response and outbreak investigation were challenging(not applicable) and was not analyzed.

3.4.4.7. Representativeness of the surveillance system:

The mekelle zone surveillance system especially geographical representativeness were particularly symbolic and important in an early warning system to ensure detection of outbreaks of infectious diseases.AWD surveillance that involves community health extension workers and the community itself (populations), and other private sectors were properly good coverage of the health system or presence of health facility at all kebeles, the data reported through the community based reporting system is representative of the on grassland level population under the surveillance system and can be able to show the epidemiology of the disease in the zone.

3.5. Discussion

The core and support function of the surveillance system activities of the mekelle zone were more or less done. Outbreak of AWD was occurred in the whole Woredas of mekelle zone in 2016. The total case was 1077 and with death of 4, the CFR were 3.7, attack rate 4.9 per 1000 population higher compared to the study in 2007/8(11). This might be due to low response in safe drinking water and health education to the diseases.

On the other hand, understanding of the AWD standard case definition with availability of guidelines, standard case management by all health district offices and health facility's was found well, higher than the study conducted in south Sudan.(12).this difference could be due to different study area and which helps for early detection and identification of cases for timely response and prevent further dissemination. In addition, their reporting time habit to higher level were also very high particularly helps in early warning for all the priority public health diseases. When we were looking the reporting rate system of all weekly and immediately reporting of the district and health facility was 100% including the zone this is achieved similar to the national study (8).Upon encountering events/conditions listed on the SCD (standard case definition) or getting a report from the HEW, every health care provider (especially the clinician and the lab technician) are expected to immediately (within 30 minutes) notify to the PHEM focal person or to the woreda. When and if the woreda are not accessible, notification can be done to any accessible level. Initial communication shall be made using the fastest available means of communication. but the visited study area challenges were on the surveillance data analysis, from the higher level up to community level the surveillance data analysis by time, person and place were not done and the interpretation and analysis on the epidemiological action threshold and alert threshold was missed the same to the study done in eastern Badewacho woreda, Southern Ethiopia, March, 2012(11).this could be due to data analysis by time includes the variables such as day, week, month, and year not known by the surveillance focal person because of low training and computer skill.

But the importance of “time” analysis is to detect changes in the number of cases and deaths over time. It also helps to compare the current disease trend with previous trends. It enables us to See if thresholds are reached or not (8).

In the outbreak AWD period 2016 of the mekelle zone or under the zone any other health district or health facility were not confirmed any single case by laboratory. This is the same to the study

done in south Sudan(12). In addition Confirmation of laboratory sample results other than AWD were delayed time. So they confirmed by clinical case definition only. Due to this reason the sensitivity, specificity and PPV (positive predictive value) were not done the mekelle special zone AWD in the visited study period.

Proportion of outbreaks of epidemic-prone diseases with laboratory Confirmation were important in early warning and response preparedness in the priority disease surveillance various surveillance networks and partnerships exist at country level and between countries. The laboratory network is a good example of a country-level network, while collaboration on surveillance and response activities between countries bordering one another represents inter country networking (10).

3.5.1. Limitation:

People in same health facilities and health districts were lack of motivations because even though they have the degree certificate but their employments (salaries) were in diploma. Example Kwiha and Qedamay Weyyane health district focal personnel's public health surveillance.in addition no laboratory confirmatory for AWD in order to do sensitivity, specificity and PPV. Totally in study zone data were not analyzed in epidemiologically contexts like in time, place and persons in order to help the sources of outbreak investigations.

3.6. Conclusion:

According to different woreda administrative Public health Surveillance focal person AWD were seen in areas low water resources and population in use of holly water. performance of the zonal core and supportive function of the surveillance system AWD were like standard case detection, case registration, reporting, epidemic preparedness, standards and availability guidelines, supervision, standard case management, by all health district offices and health facility's was found improved, which helps for early detection and identification of cases for timely response and prevent further dissemination of outbreak. Some of the obstacles encountered in the study area were, insufficiency of resources, low computer skills and knowledge's of staffs, no budget line and lack of motivation staffs because of structure employ, lack of scheduled necessary training were vigorously seen. Additionally laboratory activities were not included in the surveillance performance.

3.7. Recommendation

- ❖ Arrangement of the structure of employers should be give emphasizes to increase the productivity of public surveillance works.
- ❖ The central laboratories should be help to the regional laboratories in order to minimize the regional sample transport to central laboratory.
- ❖ Budget line should be underline (allocated) to help the surveillance activities in the zone and other health district office and health facility.
- ❖ Training in epidemic porn disease surveillance and post basic in epidemic management should give attention and evaluation the result.
- ❖ Accessed of Computer, telephone, fax, vehicle (motorcycle) and internet to the surveillance department should be mandatory in all level.

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Annex 3: Surveillance system evaluation data collection tools at regional (zonal level).

1. Regional /zonal level questionnaire

S.N	Questions	Coding classification
1 Identifiers:		
1.1	Interviewer name	
1.2	date	
1.3	Respondent	
1.4	Surveillance System of health facility	
1.5	District name	
1.7	Region/province	
I. Availability of a National Surveillance Manual		
1	Is there a national manual for surveillance?	A. Yes B. No C. Not applicable D. Unknown
2	If yes, describe (last update, diseases included, case definitions, surveillance and control, integrated or different for each disease):	-----
II. Case Detection and Registration		
3	Do you have standard case definitions for the Country's priority diseases like AWD?	A. Yes B. No C. Not applicable D. Unknown
4	Observed [1 to N, priority diseases] observed the standard case definition for (each priority disease)	A. Yes B. No C. Not applicable D. Unknown
III. Data reporting.		
Presence of recommended reporting forms in the country at all times over the past 6 months		
5	Is the central level responsible for providing surveillance forms to the health facilities?	A. Yes B. No C. Not applicable D. Unknown
6	If yes, have you lacked appropriate surveillance forms at any time during the last 6 months?	A. Yes B. No C. Not applicable D. Unknown
7	What are the reporting entities for the surveillance system?	a. Public health facilities b. NGO health facilities c. Military health facilities d. Private health facilities e. Others _____
8	Percent of district reports (either directly or through an intermediate level) received each reporting period at the central level during the past 3 months: Number of reports in the last 3 months compared to expected number	_____

	Weekly: /..... times the number of districts Immediately:/-----times the number of districts	
9	on time (use national deadlines) Number of weekly reports received on time: /..... times the number of districts	_____
10	Was there any report of the immediately reportable diseases in the past 1 month?	A. Yes B. No
11	If yes, with in what time is the report received after detection of the case/ diseases?	A. Less than 1 hour B. 2-24 hour C. 1-2 days D. 3-7 days E. After 1 week
12	Percent of districts that have means for reporting to next level by e-mail, telephone, fax or radio.	_____
13	Capacity to report to next level by e-mail, telephone, fax or radio: How do you report?	A. Mail B. Radio C. Fax D. Electronic E. Telephone F. Others
IV. Data analysis Does the regional level:		
14	Describe data by person (case based, outbreaks, and sentinel)? (Observed) Observed description of data by age and sex:	A. Yes B. No C. Not applicable D. Unknown
15	Describe data by place? (Observed) Observed description of data by district (tables, maps)	A. Yes B. No C. Not applicable D. Unknown
16	Describe data by time? (Observed)Observed description of data by time:	A. Yes B. No C. Not applicable D. Unknown
17	Perform trend analysis? Observe line graph of cases by time	A. Yes B. No C. Not applicable D. Unknown
18	List disease(s) for which line graph is observed	----- -----
19	Have an action threshold defined for each priority disease? Do you have an action threshold defined for AWD?	A. Yes B. No C. Not applicable D. Unknown
20	Who is responsible for the analysis of the collected data?	-----
21	How often do you analyze the collected data?	A. Daily B. Weekly C. Every 2 weeks

		D. Monthly E. Quarterly F. As needed
22	Have appropriate denominators? Observe presence of demographic data (E.g. population by district and hard to reach groups)	A. Yes B. No C. Not applicable D. Unknown
V.	Outbreak Investigation Percent of suspected outbreaks that were investigated in the past 6 months	
23	Number of outbreaks suspected in the past year:	
24	List the diseases:	_____
25	Of those, number investigated:	-----
	(Observed reports and take copies if possible) Of the investigated outbreaks in the past 1 year, percent in which risk factors were looked for:	
26	Number of outbreaks in which risk factors were looked for:	-----
	Of the investigated outbreaks in the past 1 year, percent in which findings were used for action	
27	Number of outbreaks in which findings were used for action:	
	[Observed report] Of districts that investigated an outbreak, percent that looked for risk factors	
28	Number of districts that looked for risk factors [observed in reports]	-----
	Of districts that investigated an outbreak, percent that used the data for action (action include containing outbreak, improving surveillance, community actions)	
29	Number of districts that used the data for action [observed in final report]	-----
VI.	Epidemic preparedness (relevant for epidemic prone diseases)	
30	Existence of a Regional/Zonal plan for epidemic preparedness and response	
	Observe a written plan of epidemic preparedness and response Yes No Unknown Not applicable	
31	Existence of emergency stocks of drugs, vaccines, and supplies at all times in past 1 year:	A. Yes B. No C. Not applicable D. Unknown
32	Experience of a shortage of drugs, vaccines or supplies during the most recent epidemic (or outbreak)	A. Yes B. No C. Not applicable D. Unknown
33	Existence of a standard case management protocol for AWD,	-----
	Observe the existence of a written case management protocol for at least 1 priority disease	
34	If yes, list:	-----
35	Presence of a budget line for epidemic response : Is there a budget line for epidemic response?	A. Yes B. No C. Not applicable D. Unknown
36	Existence of a regional epidemic management committee: Observed minutes (or report) of meetings of epidemic	A. Yes B. No C. Not applicable

	management committee	D. Unknown
37	Existence of a regional rapid response team for epidemics Does the country have a rapid response team for epidemic?	A. Yes B. No C. Not applicable D. Unknown
VII	Response to epidemics	
38	Ability of the regional level to respond within 48 hours of notification of most recently reported outbreak: Observe that the central level responded within 48 hours of notification of most recently reported outbreak (from written reports with trend and intervention)	A. Yes B. No C. Not applicable D. Unknown
39	Ability of the regional epidemic management committee to evaluate its preparedness and response activities: (Observed) Has epidemic management committee evaluated its preparedness and response activities during the past year (Observed written report to confirm)?	A. Yes B. No C. Not applicable D. Unknown
VII I.	Feedback	
40	Existence of a report or bulletin that is regularly produced to disseminate surveillance data: How many feedback bulletin or reports has the regional level produced in the last year?	----- ----- -----
41	Observed: Observe the presence of a report or bulletin that is regularly produced to disseminate surveillance data	A. Yes B. No C. Not applicable D. Unknown
IX.	Supervision	
42	Percent of supervisors that made the required number of supervisory visits in the past 6 months? How many supervisory visits have you made in the last 6 months? Obtained required number of visits from regional level	-----
43	The most usual reasons for not making all required supervisory visits. (Text)	----- -----
X.	Training	
44	Percent of health personnel trained in disease surveillance : What percent of your subordinate personnel have been trained in surveillance?	-----
45	Have you been trained in disease surveillance?	A. Yes B. No C. Not applicable D. Unknown
46	If yes, specify when, where, how long, by whom?	
47	Percent of health personnel that have received post-basic training in epidemic management Have you received any post-basic training in epidemic	A. Yes B. No C. Not applicable

	management?	D. Unknown
48	If yes, specify when, where, how long, by whom?	-----
49	Obtain and analyze the content of the surveillance and epidemic management training Strengths _____ Weaknesses _____ Opportunities _____ Threats _____	
XI.	Resources Percent of sites that have:	
50	Data management	A. Computer B. Printer C. Photocopier D. Statistical package E. Data manager
51	Communications	A. Telephone service B. Fax C. Radio call D. Satellite phone E. Computers that have modems
52	Budget line _____	
53	Logistics _____	
XII	Surveillance	
54	Have a functional computerized surveillance network Do you have a computerized surveillance network at this level?	A. Yes B. No C. Not applicable D. Unknown
55	Budget for surveillance Is there a budget line for surveillance in the Regional Health Bureau budget?	A. Yes B. No C. Not applicable D. Unknown
56	If yes, what is the proportion: %?	
57	Opportunities for strengthening surveillance How could surveillance be?	
XII I.	Surveillance Co-ordination	
58	Existence of focal unit for surveillance at RHB level : Observed Is there a focal unit for surveillance at the MOH central level? [Observed organogram me of MoH to confirm]	A. Yes B. No C. Not applicable D. Unknown
59	Opportunities for integration : What opportunities are there for integration of surveillance activities and functions (core activities, training, supervision, guidelines, resources etc.)?	----- ----- ----- -----

Questionnaire for Attributes and level of Usefulness:		
1	Total population under surveillance_	
2	What is the incidence / Prevalence of -----in your area/region in 2016? □ AWD cases Deaths	
I	Level of Usefulness of the Surveillance System for these selected priority diseases: Does the surveillance system help?	
1	To detect outbreaks of these selected priority diseases early?	A.Yes B.No
2	To estimate the magnitude of morbidity and mortality related to this disease, including identification of factors associated with these diseases?	A.Yes B.No
3	Permit assessment of the effect of prevention and control programs?	A.Yes B.No
4	Observed (confirmation): Interventions and diseases trends analyzed	A. Available B. Not available
II.	Describe Each System Attributes:	
i.	Simplicity:	
1	Is the case definition of AWD, Easy for case detection by all level health professionals?	A.Yes B.No
2	What are the organizations which need to receive reports of the surveillance data	
3	Do you feel that additional data collected on a case are time consuming?	A.Yes B.No
4	How long it takes to fill the format?	A. <5 minute B.10-15minuts C.>15 minutes
5	How long does it take to have laboratory confirmation of	A.AWD
ii.	Flexibility:	
1	Can the current reporting formats be used for other newly occurring health event (disease) without much difficulty?	A.Yes B.No
2	Do you think that any change in the existing procedure of case detection, reporting, and formats will be difficult to implement? Comment: _____	A.Yes B.No
iii.	Data Quality: (Completeness of the reporting forms/and validity of the recorded data)	
1	Are the data collection formats for these priority diseases clear and easy to fill for all the data collectors/ reporting sites?	A.Yes B.No
2	Are the reporting site / data collectors trained/ supervised regularly?	A.Yes B.No
3	Observed: Review the last months report of these diseases A. Average number of unknown or blank responses to variables in each of the reported forms _____ B. Percent of reports which are complete (that is with no blank or unknown responses) from the total reports _____	
iv.	Acceptability:	
1	Do you think all the reporting agents accept and well engaged to	A.Yes

	the surveillance activities?	B.No
2	If yes, how many are active participants (of the expected to)? _____	
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; i.e. no dissemination of the analysis data back to reporting facilities C. Reporting formats are difficult to understand D. Report formats are time consuming E. Other: _____	
v.	Representativeness:	
1	What is the health service coverage of the district/ zone/ region? _____%	
2	Do you think the populations under surveillance have good health seeking behavior for these diseases?	A.Yes B.No
3	Who do you think is well represented by the surveillance data?	A. the urban B. the rural
vi.	Timeliness:	A.----- B.-----
vii.	Stability:	
1	Was the new BPR restructuring affect the procedures and activities of the surveillance of these diseases?	A.Yes B.No
2	Was there lack of resources that interrupt the surveillance system?	A.Yes B.No

Annex 4: Surveillance System Evaluation District (Woreda Level) Questionnaire

S.N	Questions	Coding classification
1.	Identifiers:	
1.1	Interviewer name	
1.2	date	
1.3	Respondent	
1.4	Surveillance System of health facility	
1.5	District name	
1.6	Region/province	
I	Availability of a National Surveillance Manual	
1	Is there a national manual for surveillance? Observed national surveillance manual:	A. Yes B. No C. Not applicable D. Unknown
Case confirmation		
Percent of districts that have the capacity to transport specimens to a higher level lab		
2	Does the district have the capacity to transport specimens to a higher level lab?	A. Yes B. No C. Not applicable D. Unknown
3	Percent of districts with guideline for specimen collection, handling and transportation to next level Does the district have guidelines for specimen collection, handling and transportation to the next level?	A. Yes B. No C. Not applicable D. Unknown
II	Data reporting	
Percent of sites that have forms recommended for the country for that site at all times over the past 6 months		
4	Have you lacked forms recommended for the country at any time during the last 6 months?	A. Yes B. No C. Not applicable D. Unknown
Percent of health facilities that reported each reporting period to the district level during the past 3 months:		
5	Number of reports received in the last 3 months compared to expected number Weekly: _____ /..... times the number of health facilities Immediately: _____ /.....times the number of health facilities On time (use national deadlines)	
6	Number of weekly reports submitted on time: ____ /..... times the number of health facilities	
8	Number of immediately reports submitted on time: _____ /..... times the number of health facilities	A. Mail B. Radio C. Fax D. Electronic E. Telephone F. Others

9	Strengthening reporting How can reporting be improved? _____	
III	Data analysis	
10	Percent of sites that: Describe data by person (case based, outbreaks, and sentinel) Observed description of data by age and sex	A. Yes B. No C. Not applicable D. Unknown
11	Describe data by place: Observed description of data by place (locality, village, work site etc)	A. Yes B. No C. Not applicable D. Unknown
12	Describe data by time Observed description of data by time	A. Yes B. No C. Not applicable D. Unknown
13	Perform trend analysis Observed line graph of cases by time	A. Yes B. No C. Not applicable D. Unknown
14	List _____ _____	
15	Have an action threshold for each priority disease Do you have an action threshold for any of the country priority diseases?	A. Yes B. No C. Not applicable D. Unknown
16	If yes, what is it? _____ cases _____ % increase _____ rate (Ask for 2 priority diseases) _____	
17	Have appropriate denominators Observed presence of demographic data at site (E.g. population <5 yr, population by village, total population)	A. Yes B. No C. Not applicable D. Unknown
18	Who is responsible for data analysis?	_____
19	How often do you analyze the collected data?	A. Daily B. Weekly C. Every 2 weeks D. Monthly E. Quarterly F. As needed
IV	Outbreak investigation	
20	Percent of suspected outbreaks that were investigated in the past 6 months: Number of outbreaks suspected in the past year6 months: _____ Observed Of those, number investigated (reports and take copies if possible): _____	

21	Percent of districts that have ever conducted an outbreak investigation [Number of districts assessed that have ever conducted an outbreak investigation, Number of districts assessed to obtain indicator]	_____
22	Has your district ever investigated an outbreak?	A. Yes B. No C. Not applicable D. Unknown
VI	Epidemic preparedness	
23	Percent of districts that have a plan for epidemic preparedness and response : (Observed) a written plan of epidemic preparedness and response	A. Yes B. No C. Not applicable D. Unknown
24	Percent of districts that have emergency stocks of drugs and supplies at all times in past 1 year Has the district had emergency stocks of drugs and supplies at all times in past 1 year? Observed the stocks of drugs and supplies at time of assessment	A. Yes B. No C. Not applicable D. Unknown
25	Percent of districts that experienced a shortage of drugs, vaccines or supplies during the most recent epidemic (or outbreak) Has the district experienced shortage of drugs, vaccines or supplies during the most recent epidemic (or outbreak)?	A. Yes B. No C. Not applicable D. Unknown
26	Presence of a budget line for epidemic response or access to funds for epidemic response Is there a budget line or access to funds for epidemic response?	A. Yes B. No C. Not applicable D. Unknown
27	Percent of districts that have an epidemic management committee Observed minutes (or report) of meetings of epidemic management committee	A. Yes B. No C. Not applicable D. Unknown
28	Percent of districts that have rapid response team for epidemics Does the district have a rapid response team for epidemics?	A. Yes B. No C. Not applicable D. Unknown
VII	Response	
29	Percent of sites that implemented prevention and control measures based on local data for at least one reportable disease or syndrome Has the district implemented prevention and control measures based on local data for at least one reportable disease or syndrome?	A. Yes B. No C. Not applicable D. Unknown
30	Percent of districts that responded within 48 hours of notification of most recently reported outbreak Observed that the district responded within 48 hours of notification of most recently reported outbreak (from written reports)	A. Yes B. No C. Not applicable D. Unknown
31	Percent of districts that achieved acceptable case fatality	A. Yes

	rates (e.g. Cholera) during the most recent outbreak Observed that the district achieved an acceptable case fatality rate for most recent outbreak (from outbreak report)	B. No C. Not applicable D. Unknown
32	Percent of epidemic management committees that have evaluated their preparedness and response activities during the past year Observed Has epidemic management committee evaluated their preparedness and response activities during the past year? (Observe written report to confirm)	A. Yes B. No C. Not applicable D. Unknown
VII I	Feedback	
33	Percent of sites that have written report that is regularly produced to disseminate surveillance data How much feedback written reports has the district produced in the last year? Observed the presence of a written report that is regularly produced to disseminate surveillance data (district and higher)	A. Yes B. No C. Not applicable D. Unknown
34	Percent of sites that have received a report or bulletin from a higher level during the past year on the data they have provided How many feedback bulletin or reports has the district received in the last year? Observed at least 1 report or bulletin at district from a higher level during the past year on the data they have provided	A. Yes B. No C. Not applicable D. Unknown
IX.	Supervision	
35	Percent of sites that have received a report or bulletin from a higher level during the past year on the data they have provided How many feedback bulletin or reports has the district received in the last year? Observed at least 1 report or bulletin at district from a higher level during the past year on the data they have provided	A. Yes B. No C. Not applicable D. Unknown
36	Of those supervised in the previous 6 months, percent of individuals for which the supervisor from the next higher level reviewed surveillance practices appropriate to their level Observed supervision report or any evidence for appropriate review of surveillance practices	A. Yes B. No C. Not applicable D. Unknown
37	Percent of supervisors that made the required number of supervisory visits in the past 6 months How many supervisory visits have you made in the last 6 months? _____ (Obtain required number of visits from central level)_____	
38	The most usual reasons for not making all required supervisory visits. (Text) Reason 1 _____ Reason 2 _____ Reason 3 _____	

IX.	Training	
39	Percent of health personnel (in position of responsibility) trained in disease surveillance Have you been trained in disease surveillance?	A. Yes B. No C. Not applicable D. Unknown
40	If yes, specify when, where, how long, by whom?	A. Yes B. No C. Not applicable D. Unknown
41	Proportion of districts with staff trained in surveillance and epidemic management What percent of your personnel in the district have been trained in surveillance and epidemic management?	_____
X.	Resources	
42	I. Percent of sites that have: Logistics	A. Electricity b. Bicycles c. Motor cycles d. Vehicles
43	Data management	a. Stationery b. Calculator C. computer d. printer e. statistical package
44	Communications	A. Telephone service B. Fax C. Radio call D. Satellite phone E. Computers that have modems
45	Information education and communication materials	a. Posters b. Megaphone f. screen c. Flipcharts or Image box d. VCR and TV set e. generator h. others specify g. projector(movie)
46	Hygiene and sanitation materials	a. Spray pump b. Disinfectant
XI.	Surveillance co-ordination:	
47	Existence of a surveillance co-ordination focal unit or person at district level Is there a surveillance co-ordination focal point within the district epidemic management committee?	A. Yes B. No C. Not applicable D. Unknown
XII	Satisfaction with surveillance system_____	
48	Are you satisfied with the surveillance system?	A. Yes B. No C. Not applicable D. Unknown

49	If no, how can the surveillance system be improved?	_____
XII I.	Surveillance Co-ordination	
50	Opportunities for integration What opportunities are there for integration of surveillance activities and functions (core activities, training, supervision, guidelines, resources etc?) _____ _____	

Annex 5: Surveillance System Evaluation Health Facility Questionnaire

1.1	Interviewer name	Coding classification			
1.2	Date				
1.3	Type of health facility				
1.4	Respondent				
1.5	Surveillance System of health facility				
1.6	District name				
1.7	Region/province				
1	Percent of health facilities with national surveillance manual Is there a national manual for surveillance at this site? Observed national surveillance manual:	A. Yes B. No C. Not applicable D. Unknown			
I.	Case detection and registration				
2	Percent of health facilities that have a clinical register Observed the existence of a clinical register	A. Yes B. No C. Not applicable D. Unknown			
3	Percent of health facilities that correctly register cases Observed the correct filling of the clinical register during the previous 30 days	A. Yes B. No C. Not applicable D. Unknown			
4	Percent of health facilities that have standardized case definitions for the country's priority diseases Do you have a standard case definition for: (each priority disease) AWD.	A. Yes B. No C. Not applicable D. Unknown			
5	Observed the standard case definition for: (each priority disease)	A. Yes B. No C. Not applicable D. Unknown			
6	Percent of health facilities that use standardized case definitions for the country's priority diseases Observed the respondent correctly diagnosing one of the country's priority diseases using a standard case definition	A. Yes B. No C. Not applicable D. Unknown			
	(Select one of the priority diseases in the facility's clinical register and ask how they diagnosed it — interviewer should have the standard case definition from MOH)				
II	Case confirmation				
7	Percent of health facilities that have the capacity to collect specimens (sputum stool, blood/serum and CSF) Are you able to collect sputum Stool Blood CSF at this facility?	Y	N	U	N/A
		Y	N	U	N/A
		Y	N	U	N/A
		Y	N	U	N/A
8	Observed the presence of materials required to collect Stool N/A Blood/serum N/A CSF N/A	Y	N	U	
		Y	N	U	
		Y	N	U	

9	Percent of health facilities that have the capacity to handle specimens until shipment Do you have the capacity to handle sputum, stool, blood/serum and CSF until shipment at this facility?	A. Yes B. No C. Not applicable D. Unknown
10	Observed presence of functional cold chain at health facility	A. Yes B. No C. Not applicable D. Unknown
11	Percent of health facilities that have the capacity to ship specimens to a higher level lab	
12	Observed presence of transport media for stool at health facility	A. Yes B. No C. Not applicable D. Unknown
13	Observed presence of packing materials for shipment of specimens at health facility	A. Yes B. No C. Not applicable D. Unknown
III	Data Reporting	
14	Percent of sites that have appropriate surveillance forms for that site at all times over the past 6 months Have you lacked appropriate surveillance forms at any time during the last 6 months?	A. Yes B. No C. Not applicable D. Unknown
15	Percent of sites that reported accurately cases from the registry into the summary report to go to higher level Observed that the last monthly report agreed with the register for 4 diseases (1 for each targeted group [eradication; elimination; epidemic prone; major public health importance]) a. Observed AWD	Y N U N/A
16	Percent of sites that reported each reporting period to the next higher level during the past 3 months Number of reports in the last 3 months compared to expected number Observed Weekly: /---- times the number of sites .plan_____ expected_____ Observed immediately: /----times the number of sites. plan_____ expected_____	
17	On time (use national deadlines) Observed Number of weekly reports submitted on time:-_____/_____ Observed Number of immediately reports submitted on time: ____/_____	times the number of sites times the number of sites
18	Percent of HF that have means for reporting to next level by e-mail, telephone, fax or radio How do you report?	a. Mail d. Radio b. Fax e. Electronic c. Telephone f. other specify
19	Strengthening reporting How can reporting be improved? _____	
IV.	Data analysis	
20	Percent of site that Describe data by person (outbreaks, sentinel) Observed description of data by age and sex	A. Yes B. No C. Not applicable D. Unknown
21	Describe data by place: Observed description of data by place (locality, village, work site etc)	A. Yes B. No C. Not applicable

		D. Unknown
22	Describe data by time Observed description of data by time	A. Yes B. No C. Not applicable D. Unknown
23	Perform trend analysis Observed line graph of cases by time	A. Yes B. No C. Not applicable D. Unknown
24	Have an action threshold for each priority disease Do you have an action threshold for any of the Country priority diseases?	A. Yes B. No C. Not applicable D. Unknown
25	If yes, what is it (Ask for 2 priority diseases)? _____ cases ____ % increase _____ rate	
26	Who is responsible for data analysis? _____	
27	How often do you analyze the collected data?	a. Daily d. monthly b. Weekly e. quarterly c. Every 2 weeks f. as needed
28	Have appropriate denominators Observed presence of demographic data at site (E.g. population <5 yr., population by village, total population)	A. Yes B. No C. Not applicable D. Unknown
V	Epidemic preparedness _____	
29	Percent of health facilities that have a standard case management protocol for epidemic prone diseases Observed the existence of a written case management protocol for 1 epidemic prone diseases.	A. Yes B. No C. Not applicable D. Unknown
VI.	Epidemic response _____	
30	Percent of sites that implemented prevention and control measures based on local data for at least one epidemic prone disease Has the health facility implemented prevention and control measures based on local data for at least one epidemic prone disease?	A. Yes B. No C. Not applicable D. Unknown
31	Percent of sites that achieved acceptable case fatality rates (e.g. 10% for Meningococcal CSM 1% for Cholera) during the most recent outbreak	A. Yes B. No C. Not applicable D. Unknown
VII.	Feedback	
32	Percent of sites that have received a report or bulletin from a higher level during the past year on the data they have provided How many feedback bulletin or reports has the health facility received in the last year? ____ Observed at least 1 report or bulletin at the health facility from a higher level during the past year on the data they have provided	A. Yes B. No C. Not applicable D. Unknown
33	Percent of health facilities that conducted at least semi-annual meetings with community members to discuss results of surveillance or investigation data How many meetings has this health facility conducted with the community members in the past six months? _____	A. Yes B. No C. Not applicable D. Unknown

	Observed the minutes or report of at least 1 meeting between the health facility team and the community members within the six months	
VIII.	Supervision	
34	Percent of individuals supervised in the past 6 months How many times have you been supervised in the last 6 months? _____ Observed supervision report or any evidence of supervision in last 6 months	A. Yes B. No C. Not applicable D. Unknown
35	Of those supervised in the previous 6 months, percent of individuals for which the supervisor from the next higher level reviewed surveillance practices appropriate to their level Observed supervision report or any evidence for appropriate review of surveillance practices	A. Yes B. No C. Not applicable D. Unknown
IX	Training	
36	Percent of health personnel trained in disease surveillance and epidemic management Have you been trained in disease surveillance and epidemic management?	A. Yes B. No C. Not applicable D. Unknown
37	If yes, specify when, where, how long, by whom? _____	
X	Resources	
38	Percent of sites that have Logistics	a. Electricity c. Motor cycles b. Bicycles d. Vehicles
39	Data management	a. Stationery d. Software b. Calculator e. Printer c. Computer f. Statistical package
40	Communications	a. Telephone service c. Radio call b. Fax d. Computers that have modems
41	Information education and communication materials	a. Posters e. Generator b. Megaphone f. Screen c. Flipcharts or Image box d. VCR and TV set g. Projector (Movie) h. Others
42	Hygiene and sanitation materials	a. Spray pump b. Disinfectant
43	Protection materials (list) _____	
XI	Satisfaction with surveillance system	
44	Satisfaction with the surveillance system Are you satisfied with the surveillance system?	a. Yes b. No c. Unknown d. Not applicable
45	If no, how can the surveillance system be improved? _____	

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

4. Chapter Four: Health Profile Description Report

Title: Health Profile Description Report Addisu Gebeya District, Addis Ababa, Ethiopia, 2015

Authors: Desta Birhane, S. Tanie, A.Bekele

Executive summary:

Background: Health profile description is a system of collecting, organizing and summarizing health and others health related events. It helps in prioritizing health and others health related condition occurred within the communities. The summarized data and prioritized health events are important for public health officials as well as decision makers. So the aim is to summarize the different health profiles in the district.

Objective: To assess and describe health & health related issues about health status, health indicators and to identify problems for priority setting in Addisu Gebeya district.

Methods: By cross-sectional design Health and health related data was collected from different sector offices of the district by using semi structured questionnaire, reviewing of annual reports, and observation of charts. Interviews were conducted with stakeholders and heads of different sector offices to identify the leading public health problems of the district.

Result: According to the 2007EFY census and projections, in the year 2015/16 the size of Gulele sub-city Addisu Gebeya Woreda total population were 38,501 of which 18,480 (48%) male and 20,021 (52%) female which are more than male in the sex ratio. The district health coverage was 64.9 % excluding the private clinic and health infrastructure facilities standardized major roads accessed area, fixed line call service (mobile phone network), water supply, electricity and other internet accesses were well functional. The leading cause of ten top diseases in all age category were, upper respiratory tract infection covers from the total 7765 (33.83%), among those 1883(24.2%) were pediatric (<5).

Conclusion &Recommendation: Compared to the last three years, Acute Upper Respiratory Infection, was the leading public health problem causes of Morbidity in the Woreda. Isolation of causative agent were very weak means no specific laboratory diagnosis was needed. So I recommend to the woreda health office to work strongly on prevention and care on this issue. Further more important health indicators like infant mortality crude death rate and child mortality should also be registered and documented.

Key words: Health profile, Addisu Gebeya woreda

4.1. Introduction

Health profile description is a system of collecting, organizing and summarizing health and others health related events like health vital status This includes, demographic, socio-economic, vital statistics(marriage, birth rate, death rate), political (the presence health related infrastructure, economical, cultural and others aspect of a particular geographic areas of interest. It helps to prioritizing health and others health related condition occurred within the communities(1).The summarized data and prioritized health events are important for public health officials as well as decision makers. They use it for planning, implementation and evaluation of public health programs.

The purpose of this project is to assess and describe Addisu Gebeya district health profile which was help in identifying the district's health and health related events to use it for programs planning and intervention. Addisu Gebeya district is one of the 10 districts in the Gulele Zone & found in north part of Addis Ababa. It also found 2.8 km far from the center of Addis Ababa in the Northern direction. Other unspecified infection & parasitic disease and URTI are common in the district. Due to this I have selected the district to identify the gaps since no profile description conducted before.

4.1.1. Background of the study area

Addisu Gebeya woreda is one of the 10 Woredas in Gulele sub city in Addis Ababa states of federal democratic Republic of Ethiopia and is located in northern part of the city bordered by woreda 7 to the north , woreda 10 to the west & North west ,woreda 7 to east ,and woreda 9 to the southwest and Arada sub city to the south and located around 2.8 km from Addis Ababa municipality .it covers an area of 470.81 hectares (15.09% of sub-city) .it lies at an elevation of 2,300 meters (7,500 ft) and grassland biome ,located at altitude 9°48'N longitude 38°44'E annual average temperature is 10-23 °C (18 -75 °F) , annual average rain foal 1089 mm (2)(3).

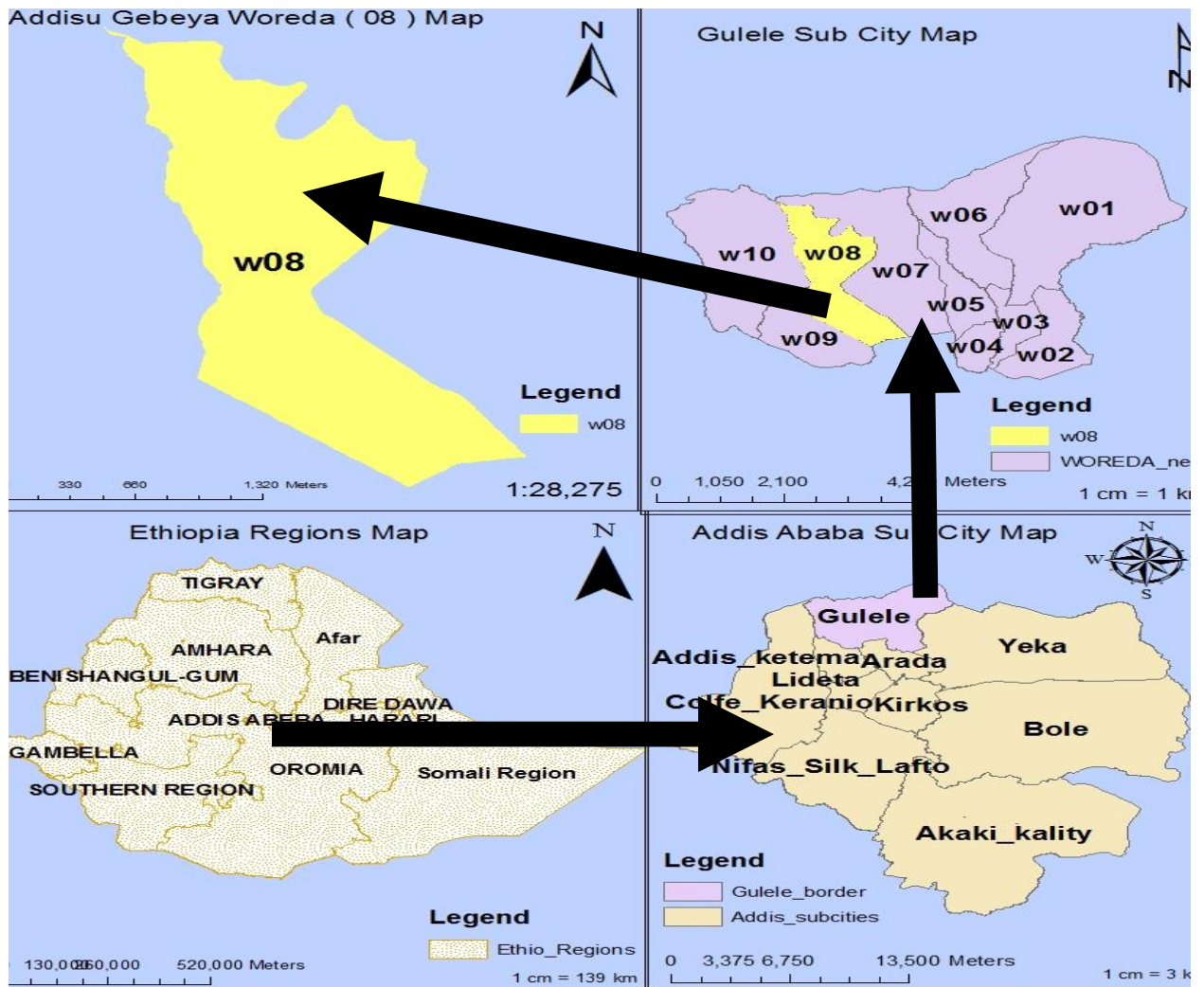


Figure 15: Addisu Gebeya woreda map

4.1.2. Rationale of the study

Describing health profile of Addisu Gebeya districts helpful to address the current gap of community health of the district, and for stakeholder's priority setting; and it is important to understand the demographic, socio-economic, morbidity and mortality and other data of the district. Health profile generates data which can be used at community level. The finding from the health profile description project was helping the district and other stakeholders for public health decision making.

4.2. Objective

4.2.1. General objective

To assess and describe health and health related issues about health status, health indicators and to identify problems for priority setting in Addisu Gebeya district.

4.2.2. Specific objectives

To assess health status and indicators of health district

To describe disease burden/magnitude and other health related events

To assess human resources of the district

To identify priority health problems setting

4.3. Methods and materials

4.3.1. Study Period

The study was conducted in Addisu Gebeya district, Gulele sub city and review available data in health offices and health institutions, health Finance, Education, Agriculture, Culture & Tourism, and Water & energy bureau, in municipality (center city) offices from 23 May to 26 June 2016G.C, review of publications and literatures about the area.

4.3.2. Study design

This is community based cross sectional quantitative prospective assessment of the health profile examined at woreda Addisu Gebeya town. A record review format (standard questioners) that fits the purpose was formulated to gather information regarding health profile status with respect to the standard. I reviewed the questioner health profiles for error correction as per the time table.

4.3.3. Sampling technique

Convenience sampling was used to select one Administrative woreda, since from all Addis Ababa administration districts have geographical homogeneity. No special sampling technique was used to collect the data since there was no sample calculation.

4.3.4. Data collection

Standard check list (tool) was used to collect the data of the woreda health profile. Interviews was conducted with relevant officers & head of the woreda health office, head of health center, education, water, woreda and health center finance and others administrative offices based on the need data collection.

4.3.5. Data analysis

The collected data was entered in to Microsoft excel, and analyzed and summarized at the woreda level. If records were found out of range; it would be re-checked with the corresponding records, accordingly correction methods was taken.

4.3.6. Ethical consideration

Ethical clearance were obtained from St. paul's hospital millennium medical college department of public health, ethical committee official letter were written to EPHI/Ethiopia public health institution/, and the EPHI my field base also written a letter and given to the organization where

the study was conducted. After starting of the study the outcome of the study was reported to the conducted organization.

4.3.7. Dissemination of findings

Findings of health profile were submitted to Addisu Gebeya woreda health and administrative office with correction action plan and by soft and hard copy to use the findings for priority setting, planning & initiate research and also were submitted to SPHMMC department of public health by soft and hard copy.

4.4. Result

4.4.1. Geographic and climatic conditions

Addisu Gebeya woreda is one of the 10 Woredas in Gulele sub city in Addis Ababa states of federal democratic Republic of Ethiopia and is located in northern part of the city bordered by woreda 7 to the north , woreda 10 to the west & North west ,woreda 7 to east ,and woreda 9 to the southwest and Arada sub city to the south and located around 2.8 km from Addis Ababa municipality .it covers an area of 470.81 hectares (15.09% of sub-city) .it lies at an elevation of 2,300 meters (7,500 ft) and grassland biome ,located at altitude 9°1'48''N longitude 38°44''E annual average temperature is 10-23 °C (18 -75 °F) , annual average rainfall 1089 mm.

4.4.2. Demography

According to the 2007EFY census and projections, in the year 2015/16 the size of Gulele sub-city Woreda 08 total population were 38,501 of which 18,480 (48%) male and 20,021 (52%) female which are more than male in the sex ratio. The age structure reflects that 662(1.7 %) were infant (<1 years old), 2757 population under 5 age (7.1 %) and 13,337 (34.6%) are women found between 15-49 age group and pregnant women are 897 (2.3) with fertility of annual population growth rate of 2.3. Ethnic group/language, religion, main income source, of woreda residence no organized data available & all Woreda population are urban resident.

4.4.3. Administrative structure

According to the latest Addis Ababa administration map Addisu Gebeya District have 7 sub Woredas, 22 sefers and 69 blocks and all are urban administrative, the district have its own council and representative of Federal Parliament, all the sectors of the managerial office are found in the woreda, the ruling party in the district is the EPRDF National Democratic Party (Ethiopian people's revolutionary democratic front) and there are other parts were participated the national election.

4.4.4. Education

Addisu Gebeya district has a total of 20 schools, 12 primary school, of which are first cycle (grade 1-4) 6 and 3 are second cycle (grade 1-8) 3 (grade 5-8) ,high school (11-12)1. In addition the district also has seven kindergartens. In 2007 EFY a total of 355,152 students excluding high school &kindergarten were enrolled to school, of which from the total 39 students school dropout ,15 students were females . For details on students profile see table.1.below.

Table 11: Education and school Health

Sr. no	Type of School	# schools	# teachers			# students	student school drop out	Total Student School Drop out	
			Male	Female	Total	Total			
1	Primary							Male	Female
	1-4	6	36	32	68	176,076	14	24	15
	5-8	3	61	36	97	1,500	25		
	1-8	3	97	68	165	177,576	0		
2	High school	1	-	-	-	-	-		
3	Others (Take note)*	KG=7							
	Total	20	194	136	330	355,152	39		

4.4.5. Health Facilities:

Concerning health facilities Gulele sub city Addisu Gebeya woreda one of the Addis Ababa standardized major roads accessed area, leading to all sub Woredas and sefers, in the district.

Regarding communication all of the health centers had fixed line call service and all health facilities had mobile phone network coverage. Regarding water supply, electricity and other internet accesses were well function.

4.4.6. Woreda Health System

4.4.6.1. Organization of woreda health office (Oregano gram)

The currently reviewed Addisu Gebeya woreda health office structure after BPR is organized in to six technical team and three supportive teams. These technical teams are curative core process, health promotion & disease prevention core process, human resources core process, plan and budgeting, financial core process, network administrative & computer maintenance.

The three supportive teams at woreda health office are the woreda health office head, supervisors and health extension workers.

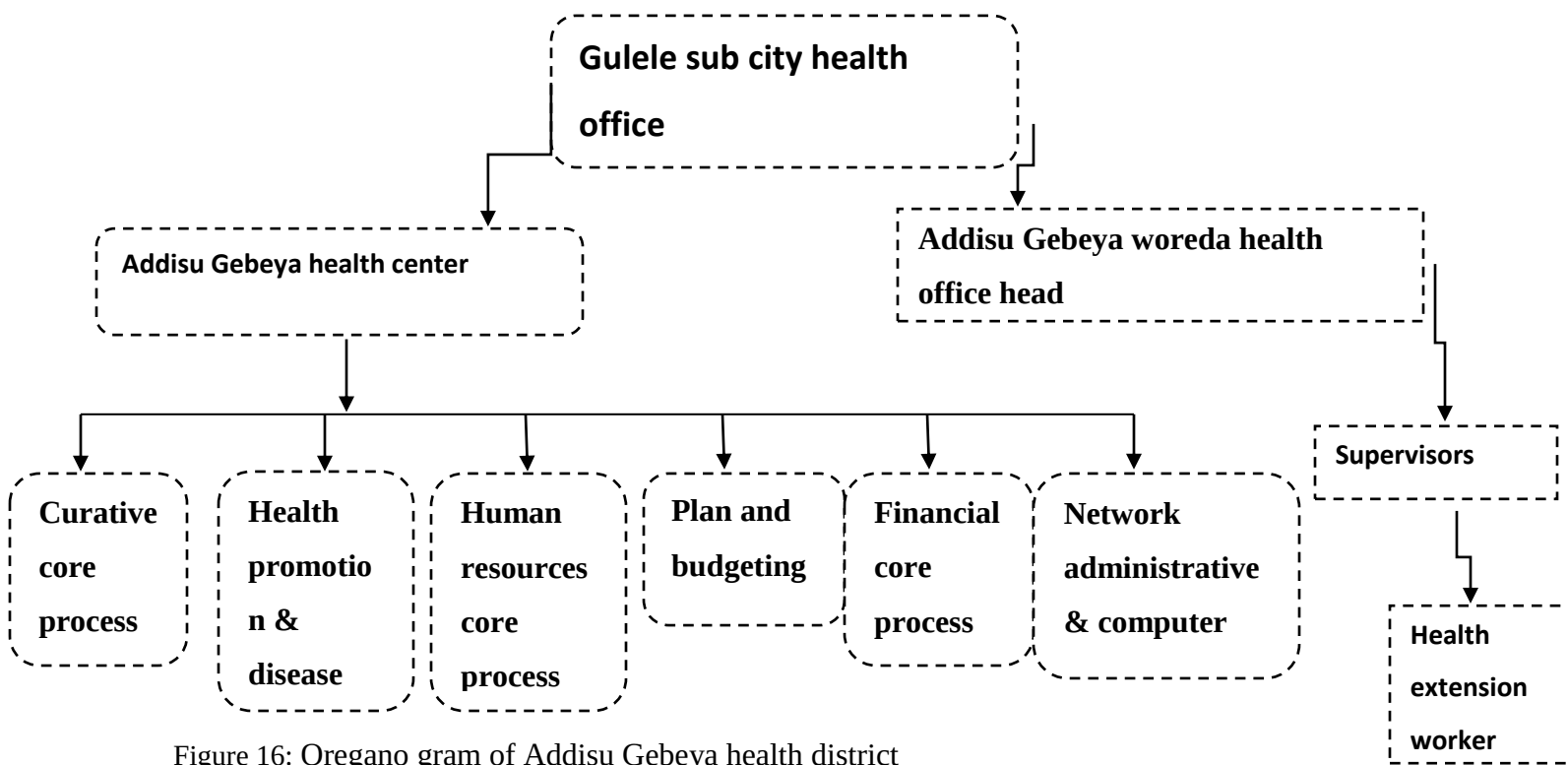


Figure 16: Oregano gram of Addisu Gebeya health district

Table 12: Types and number of health institution in woreda Addisu Gebeya Addis Ababa Ethiopia 2007E.C

Type Health Facility	Number	Standards to population
Gov. Hospital (primary)	0	1 to 60,000-100,000
Health center	1	1to15,000-25,000
Privet clinic	3	-
Pharmacy	6	-
Drag store	1	-
Diagnostic laboratory	0	-
Health posts	0	3,000-5,000

There were no government hospital but there is one health center. The population ratio to health center is 1:38,503. Health service coverage of the woreda based on the standard population to health center ratio was 64.9 % excluding the private clinic.

Table 13: Man power of Addisu Gebeya district health office and health facility in 2007EFY (2014/2015)

Sr. no	Type health professionals	Number		
		Health facility		Remark
		Government	Private	
1	Physicians	0	1	
2	Health officers	10	0	
3	Laboratory technician/technologist	5	1	
4	Pharmacy technician/Pharmacist	6	6	
5	Nurses	24	3	
6	Midwife	8	0	
7	X-Ray technician	0	0	
8	ENHS	2 nurses	0	
9	HEWs	15	0	
10	TBA	0	0	
11	Others	0	0	

4.4.6.2. Ratio of health facility and professional to population 2007 EFY (2014/2015)

Table 14: Ratio of Gov. Health facility and professional to population 2007 EFY (2014/2015)

Sr.no	Description	Ratio
1	Hospital: population	0
2	Health center: population	1:38,501
3	Health post: population	0
4	Physician: population	1:38,501
5	Health officer: population	1:3850
6	Nurse: population	1:1604
7	Midwife: population	1:4812
8	HEW: population	1:2566

Top causes of morbidity and mortality 2007EFY (2014/2015)

Table 15: Top ten leading causes of total OPD visit (morbidity) in 2007 EFY (2014/2015)

S.N	Name of cases	Total	%	Name of cases	Pediatric/ < 5 years	%
1	Acute upper respiratory infection	7765	33.8	Acute upper respiratory infection	1883	42.66
2	Other unspecified infection & parasitic disease	2139	9.32	Diarrhea (non-bloody)	704	15.95
3	Diseases of the musculoskeletal system and connective tissue	1906	8.29	Other or unspecified disease of the respiratory system	452	10.24
4	Infections of the skin and subcutaneous tissue	1900	8.26	Other unspecified infection & parasitic disease	415	9.40
5	Dyspepsia	1885	8.21	Infections of the skin and subcutaneous tissue	379	8.59
6	Diarrhea (non-bloody)	1872	8.16	Other or unspecified disease of the eye and adnexa	171	3.87
7	Urinary tract infection	1748	7.62	Acute bronchitis	112	2.54
8	Trauma (injury, fracture etc)	1512	6.59	Pneumonia	106	2.40
9	Acute febrile illness	1188	5.18	Trauma (injury, fracture etc)	100	2.27
10	Other or unspecified disease of the eye and adnexa	1040	4.45	Helminthiasis	92	2.08

4.4.6.3. Top causes of morbidity 2007EFY (2014/2015)

Table 16: Top ten leading causes of OPD visit (morbidity) female category in 2007 EFY (2014/2015)

S. N	Name of cases	Total	%
1	Acute upper respiratory infection	4150	32.74
2	Urinary tract infection	1308	10.32
3	Dyspepsia	1246	9.83
4	Other unspecified infection & parasitic disease	1160	9.15
5	Infections of the skin and subcutaneous tissue	1089	8.59
6	Diseases of the musculoskeletal system and connective tissue	1045	8.25
7	Diarrhea (non-bloody)	896	7.07
8	Acute febrile illness	702	5.57
9	Other or unspecified disease of the eye and adnexa	546	4.31
10	Trauma (injury, fracture etc)	532	4.20

Table 17: Top ten leading causes of OPD visit (morbidity) male category in 2007 EFY (2014/2015)

S. N	Name of cases	Total	%
1	Acute upper respiratory infection	3615	36.54
2	Trauma (injury, fracture etc)	980	9.90
3	Other unspecified infection & parasitic disease	979	9.89
4	Diarrhea (non-bloody)	976	9.86
5	Diseases of the musculoskeletal system and connective tissue	857	8.66
6	Dyspepsia	639	6.46
7	Other or unspecified disease of the eye and adnexa	494	4.99
8	Acute febrile illness	486	4.91
9	Urinary tract infection	440	4.45
10	typhoid fever	428	4.33

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

Table 18: MCH and EPI coverage of the district 2007 EFY (2014/2015)

Sr.no	Description	Plan	Achievement	Percent	Remark
1	ANC 1 coverage	878	703	80	
2	ANC 4 coverage	878	703	80	
3	Institutional (skilled) delivery coverage	614	303	49.3	
4	PNC coverage	658	307	46.6	
5	BCG coverage	878	686	78.1	
6	Measles vaccine	830	640	77.1	
7	OPV	830	754	90.8	
8	Penta1	830	745	89.7	
9	Penta3	830	682	82.1	
10	Full immunization coverage	830	640	77.1	
	Contraceptive acceptance rate	7780	3552	45.6	
11	TT2 coverage for pregnant	878	1133	129	
12	TT2 coverage for non-pregnant	2431	141	5.8	

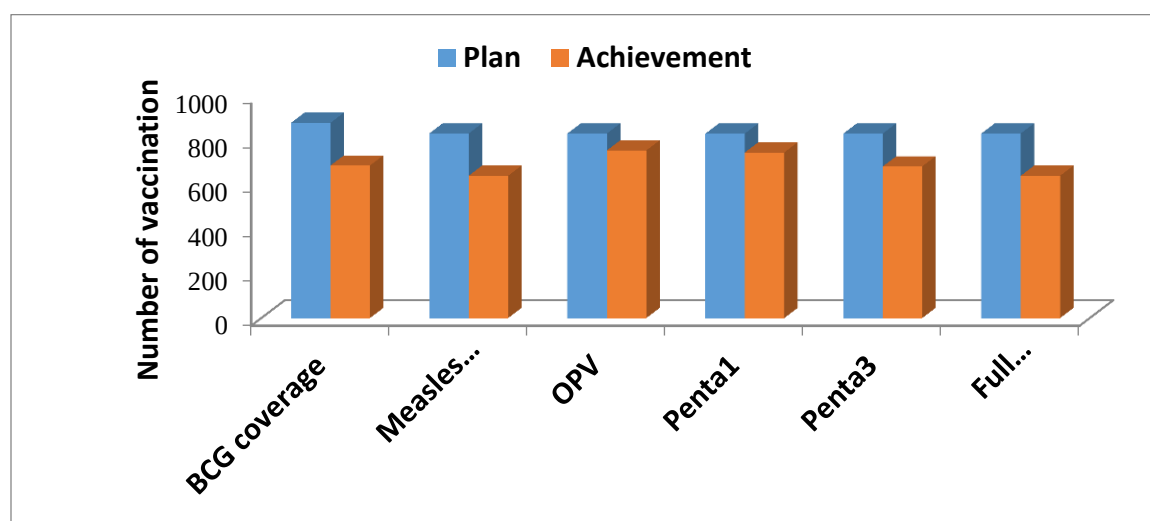


Figure 17: Vaccination coverage of children in Addisu Gebeya Woreda, Gulele sub city Addis Ababa, Ethiopia, 2014/15.

4.4.6.5. Environmental sanitation and availability of safe drinking Water 2007 EFY
(2014/2015)

Table 19: Environmental sanitation and availability of safe drinking Water 2007 EFY (2014/2015)

Sr.no	Description	Number of households (6340)	(%)
1	Latrine utilization coverage	5656	89.2
2	Number of house hold with no latrine	684	10.7
3	Safe water supply coverage	6340	100
4	Number of Kebeles accessed to safe water supply	All kebele	100

Regarding Addisu Gebeya district the environmental sanitation and availability of safe water in the year 2007 EFY reaches 89.2% and 100% respectively compared to the households.

4.4.6.6. Endemic Diseases

A. URTI prevention and control program of 2007 EFY (2014/2015)

Table 20: URTI prevention and control program of 2007 EFY (2014/2015)

Sr. no	Description	Number of population (%)	
1	Number of URTI Kebeles	All Kebeles	
2	Total no. of URTI cases per year	7765	
3	URTI Health education coverage	Not specific to URTI	
4	Percentage of URTI laboratory tested	0	
5	Case treated clinically	7765	
6	No of cases URTI in pregnant mothers	-	
7	URT Case fatality rate	<5 Age	>5Age
		0	0
8	Cases treated based on lab finding	0	0
9	Number of Vaccinated population for influenza?	0	0

NB. Death caused by URTI not registered because the severe patient were referred to nearest referral hospitals.

According to the Addisu Gebeya district health center 2007 EFY report, the leading cause of 10 top diseases in all age category were, URTI (upper respiratory tract infection) covers from the total 33.83 % (7765), among those 1883 (24.2%) were pediatric (<5). but for all patients were not laboratory confirmatory test and treated clinically only. There was also no vaccination for any one.

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

Table 21: Prevalence of TB/Leprosy: 2007 EFY (2014/2015)

Sr. No	Description	Number of cases	(%)
1	Prevalence of TB	-	0.18
2	Pulmonary TB	Smear positive	49
		Smear negative	51
3	Extra PTB	23	32
4	TB detection rate	-	49
5	TB Rx completion rate	56	77.7
6	TB cure rate	22	30.5
7	TB Rx success rate	78	108
8	TB defaulter rate	01	1.3
9	Death on TB Rx	2	2.7
10	Total TB patients screened for HIV	72	100
11	HIV prevalence rate among TB cases	19	26.3
12	Prevalence of Leprosy	0	0

So in 2007 EFY Addisu Gebeya district have total TB prevalence 0.18 means from around 2 patients Tb per 1000 population; from the total cases 32 % were Extra PTB. TB detection rate were 49 %, TB Rx completion rate 77.7% , TB cure rate 30.5% very low(national 67%) , TB Rx success rate 108 %,(national 84 %) &TB defaulter rate 1.3% respectively .

C. HIV/AIDS IN 2007 EFY (2014/2015)

Table 22: HIV/AIDS IN 2007 EFY (2014/2015)

Sr. No	Activities	Total	Remark
1	Total people screened for HIV	337	
2	VCT	250	
3	PICT	0	Shortage of test kit
4	PMTCT	15	
5	HIV Prevalence	0.06	6/10000
6	Total PLWHIV	22	
7	On ART	20	
8	No. of pregnant mothers on ART	15	
9	Pre ART	2	
10	Condom Distribution	3269 Single	
11	Health education coverage	1018 people	
12		1019	

4.4.6.7. Health sector expenditure and financing2006-2007 EFY (2014-2015)

Table 23: Health sector expenditure and financing2006-2007 EFY (2014-2015)

	Source	2006 EFY	2007 EFY
1	Total district budget (Birr)	3,975,822	4,327.750
2	Allocated to health sector (Birr)	3.581,102	3,427,750
3	Total per capital health expenditure(Birr)	394,720	900,000

4.4.6.8. Health sector Budget Distribution (2006- 2007 EFY)

Table 24: Health sector Budget Distribution (2006- 2007 EFY)

S r. n o	Health institution	2006 EFY		2007 EFY	
		Salary (birr)	Recurrent (birr)	Salary (birr)	Recurrent (birr)
1	A.G Health center	2,467,232	1,508,590	3,115,000	2,865,000
2					

*Salary = Salary + Allowance

4.4.6.9. Health Care financing /HCF/ (2006 to 2007EFY)

Table 25: Health Care financing /HCF/ (2006 to 2007 EFY)

Sr. No	Name of the Health HFs	Budget Allocated (birr)		Budget Utilized (birr)		Remark
		2006EFY	2007EFY	2006EFY	2007EFY	
1	A.G Health center	3,975,822	5,980,000	3,762,256.57	4,900,821.82	

4.4.6.10. Nutrition and early warning

According to the woreda health office termination during 2007 EFY the district was not started the specific nutritional program, but now started under five with severe malnutrition were benefited by 2008 EFY .there was no community based nutrition program, outreach therapeutic program & stabilizing center.

4.4.6.11. Disaster situation in woreda

There was no natural and manmade disaster and disease outbreak recorded in last year.

4.5. Discussion

Based on the data collected from Addisu Gebeya public health profiles, URTI, followed by, other unspecified infection & parasitic diseases; Diseases of the musculoskeletal system and connective tissue were the leading cause of outpatient visit in the district, which Total accounts for 33.83% (n=7767), (9.32 %) (n=2139), and 8.29% (n=1906) respectively of the ten top in 2007 EFY; Was higher comparing to the national coverage of 2007 EFY acute upper respiratory infection 933,949(15.6%), diarrhea 1,097,302 (8%) (4). This difference could be due to geographical and study design difference.

In Addisu Gebeya district 2007 EFY a total of 355,152 students excluding high school & kindergarten were enrolled to school, of which from the total 39 students school dropout, 15 students were females. Lower than men in Scholl drop out the reverse to the study compare to in Ethiopian gender survey of women aged 15 to 49 years in seven regions (5). This could be due to men students' needs to search work for money to help their family in the study area.

Vaccination coverage for fully vaccinated children of under one year of age was 77.1 %, which was lower than the national and regional full vaccination coverage of 2014, that was 86.5% and 95.8% respectively(6). This difference might be due to not known the advantage of vaccination and low awareness of caretaker of children's in immunization. The ANC coverage (80%) of the district is lower than the national and Addis Ababa Region in 2014, which was 98.1% and 100% respectively(6). But the institutional delivery was higher (49.3%) than the national in 2006 EFY health facility delivery, which was 41%(6). The reason could be due to effective maternal health education and quality institutional maternal delivery.

The safe water coverage of the district was 95.1% of the community, which was higher than the 2012 national coverage which was 58.2% (4). This study was lined to the study conducted in Addis Ababa urban potable water coverage (within 0.5km) was equal to 95.1%. (7) This shows the safe water distribution of Addis Ababa is equal with in the town.

Regarding TB the case detection rate of the district was 49% lower than the study of conducted 2009 national TB case detection rate (Ethiopia health sector development plan-IV) (HSDP – IV)(8) and the WHO recommendation, that was 70% (9). The district all forms of Tb prevalence were 200/100,000 in 2015 lower than the national prevalence rate 579 /100,000 in 2009 (6). This reason might be due to low Tb detection clinically isolation and laboratory microscopy in

the district. Total HIV prevalence in Addisu Gebeya woreda were 6/10,000, PLWHIV 22 and currently on ART 20 very high when compared with national study Currently HIV adult prevalence was 1.1 per 100,000 people (males=0.9 and Females=1.4). Similarly HIV incidence has also declined to 0.03 from that of 0.28 (2010) showing 89% reduction (6).The difference could be due to the increasing district false data report on HIV or due to increasing of HIV in the study district.

4.5.1. Challenges and Limitations

In Addisu Gebeya Woreda, socio-demographic by Ethnic composition, population by age category, religion and Occupational characteristics, income source were not clearly documented, and some essential health and economic indicators like Infant mortality, Child mortality, and crude death rate. Moreover, there was also difficulty to find out detailed information about financial and health service coverage of Woredas health offices.

4.6. Conclusion

This Woreda Health profile includes both previously identified health issues, and the identification of new, emerging health issues. Compared to the last three years, Acute Upper Respiratory Infection, Other unspecified infection & parasitic disease, Diseases of the musculoskeletal system and connective tissue were the three leading causes of Morbidity in the Woreda which may attribute to lack of clean drinking water, poor housing condition, poor sanitation and low public awareness of environmental health and personal hygiene practices and low coverage health education.

4.7. Recommendation

- Important health indicators like infant mortality, crude death rate and child mortality should be registered and documented in the health facility.
- Health education to the population is needed regarding environmental health, personal hygiene to prevent acute respiratory ,acute febrile illness and diarrheal disease
- To know actual coverage of health service the private clinic should submit report to woreda health office.
- The leading cases of morbidity in the district needs laboratory confirming based on prevention required.

4.8. Reference:

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Annex 6: Data collection tools (Checklist)

1. Historical Aspects of the area (if available)

- How and why the name of the district -----

- How was the district formed _____

- Any other historical aspect _____

2. 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 zone-dega-----% woynadega-----% kola-----% bereha-----%

3. 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 _____

- Annual growth rate-----

4. Population size by religion

- Orthodox _____

- Catholic _____

- Protestant _____

- Muslim _____

- Others _____

■ Ethnic composition -%-----

5. Estimated Population size by Kebeles in 2007 EFY (2014/2015)

Sr.no	Name of the Kebeles	Population size	Distance from the district town(km)
1	Kebeles 1		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			

6. Administrative setup

Total number of Kebeles: _____

Rural _____

Urban _____

District Boundaries _____

Supporting NGOs-----

7. Health status

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	

8. Man power of Addisu Gebeya district health office and health facility in 2007EFY (2014/2015)

Sr. no	Type	Number		
		No		Remark
		Government	Private	
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			

9. Ratio of health facility and professional to population 2007 EFY (2014/2015)

Sr.no	Description	Ratio
1	Hospital: population	
2	Health center: population	
3	Health post: population	
4	Physician; population	
5	Health officer: population	
6	Nurse: population	
7	Midwife: population	
8	HEW: population	

10. Health service institutions and infrastructures

	Type of institution		No of institutions	Remark
1	ሥ	With sustainable 24 hours electric power supply		
		without sustainable/ 24 hour /electric power		

		with telephone service(cable based/mobile)		
		without telephone service (cable based/mobile)		
		with piped water supply		
		Without piped water supply		
		No of hospitals with transportation facility		
2	Number of health centers	with sustainable/ 24 hour /electric power		
		without sustainable/ 24 hour /electric power		
		with telephone service (cable based/mobile)		
		without telephone service (cable based/mobile)		
		with piped water supply		
		Without piped water supply		
		No of HC with transportation road access		
3	Health posts	with sustainable/ 24 hour /electric power		
		without sustainable/ 24 hour /electric power		
		with telephone service (cable based/mobile)		
		Without telephone service (cable based/mobile)		
		with piped water supply		
		Without piped water supply		
		No of health posts with road and transportation access		

11. Top causes of morbidity and mortality 2007 EFY (2014/2015)

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

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

B. Top ten causes of admissions

Sr.no	Adult	Pediatrics
1		
2		

3		
4		
5		
6		
7		
8		
9		
10		

C. Top ten causes of deaths (mortality).

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

12. Vital statistics 2007 EFY (2014/2015)

CBR_____

CDR_____

NMR_____

PNMR_____

IMR_____

MMR_____

GR_____

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

Sr.no	Description	Coverage	Remark
1	ANC 1 coverage		
2	ANC 2 coverage		
3	Institutional (skilled) delivery coverage		
4	PNC coverage		
5	BCG coverage		
6	Measles vaccine		
7	OPV		
8	Penta1		
9	Penta3		
10	PAB		
	Full immunization coverage%		
11	Contraceptive acceptance rate		
12	TT2 coverage for pregnant		
13	TT2 coverage for non- pregnant		

14. Environmental sanitation and availability of safe drinking Water 2007 EFY (2014/2015)

Sr.no	Description	Number (%)
1	Latrine utilization coverage	
2	Number of house hold with latrine	
3	Safe water supply coverage	
4	Number of Kebeles accessed to safe water supply	

15. Endemic Diseases

D. SARI prevention and control program of 2007 EFY (2014/2015)

Sr. no	Description	Number of population (%)	
1	Number of SARI Kebeles		
2	Total no. of SARI cases per year		
3	SARI Health education coverage		
4	Percentage of SARI laboratory tested		
5	Case treated clinically		
6	No of cases SARI in pregnant mothers		
7	SARI Case fatality rate	<5 Age	>5Age
8	Cases treated based on lab finding		
9	Number of Vaccinated population for influenza?		

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

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

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

F. HIV/AIDS IN 2007 EFY (2014/2015)

Sr. No	Activities	Male	Female	Total	Remark
1	Total people screened for HIV				
2	VCT				
3	PICT				
4	PMTCT				
5	HIV Prevalence				
6	Total PLWHIV				
7	On ART				
8	No. of pregnant mothers on ART				
9	Pre ART				
10	Condom Distribution				
11	Health education coverage				
	Number of OVC				

Topics for health education-----

16. Socio economic conditions 2007 EFY (2014/2015)

Sr. no	Type of School	# schools	# teachers			# students			Female Student School Drop out
			Male	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								

*Private Schools e.g. Nursery...

17. School health activities:

- Schools with water supply_____
- Schools with functional latrines _____
- Schools with HIV/other Health clubs_____
- Literacy ratio_____
- Health education-----

A. Income

- Main source of income _____
- No. of the population committed in:
 - ✓ Agriculture _____
 - ✓ Government employee_____
 - ✓ Trade _____
 - ✓ Productivity of the land per hectare-----
 - ✓ Common products-----_
 - ✓ Husbandry _____
 - ✓ Hotel and catering _____
 - ✓ Others (specify) _____
- Yearly income per house hold_____
- GDP (during harvesting season/ meher) = -----

- GDP from irrigation=----- quintal
- Total GDP= ----- quintal
- Average income per capita _____

B. Social aspects

- Number of youth clubs_____
- Number of public libraries_____
- Others_____

C. Communication and Utilities

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

- a.** Transportation: Kebeles _____ (%)
- b.** Telecommunication: Kebeles _____ (%)
- c.** Health facility_____ (%)
- d.** Electric power: Kebeles _____ (%)

17. Health sector expenditure and financing 2003-2007 EFY (2011-2015)

	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											
6											
7											
8											

*Salary = Salary + Allowance

17.2 Health Care financing /HCF/ (_____ to _____ EFY)

Sr. No	Name of the Health HFs	Budget Allocated (birr)			Budget Utilized (birr)			Remark
		2005 EFY	2006 EFY	2007 EFY	2005 EFY	2006E FY	2007 EFY	
1								
2								
3								
4								
5								
6								
7								

18. Exempted Health services:

a/

b/

c/

d/

e/

f/

19. Disaster situation in the district 2007 EFY (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 _____

20. Nutrition intervention in Addisu Gebeya district 2007 EFY (2014/2015)

Sr.No	Type of food intervention program	
1	OTP sites	
2	TFU program	
3	TSF program	
4	CBN program	
5	EOS program	
6	Others	

No. population screened for malnutrition = children-----pregnant-----

Received therapeutic food-----

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

22. What do you think solutions of the addressed problems?

23. What are the main zoonotic diseases in the district?

A.

B.

C.

D.

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

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

5. Chapter Five: Quality Manual Policy

Title: Kahsay Abera General Hospital customized Quality Manual Policy: Humera Tigray, Ethiopia 2017.

Author: Desta Birhane

I. Revision and Amendment

Kahsay Abera Humera General Hospital Laboratory (KAHGHL) is responsible for maintain the official master copy of quality policy manual. It continues policies and list of subsidiary documents is responsible for maintaining revised and up-to-date document, however, until revision time comes, possible to amend the document using the template below. Any kind of change in this document must be indicated here and approved by authorized personnel.

A. Annual Review of Document

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

B. Version Change History/Description

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

C. Amendment

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

5.1.Introduction

5.1.1. Background

The Kahsay Abera Humera General Hospital Laboratory (KAHGLH) Quality Policy Manual shall provide an insight into the structure of Laboratories and their quality system policies and operating procedures for all the laboratory staff to carry out their job and related activities in accordance to the policies of their organization. The laboratory Quality Management (LQM) and related quality procedures shall be reviewed and revised accordingly from time to time to reflect its status. This will demonstrate that the Laboratories are competent to operate medical testing laboratory in accordance to the requirements of International organization for Standardization (ISO) 15189:2012 Medical laboratories Particular requirements for quality and competence and accreditation body/Ethiopian National Accreditation Office (ENAO) Requirements.

5.2.Quality Policy Manual

The Laboratory head is responsible for maintaining the official master copy of the KAHGLH Quality Policy Manual. The KAHGLH Quality Policy Manual consists of ISO 15189:2012 Medical laboratories Particular requirements for quality and competence Requirements and for implementation of the quality policies. KAHGLH shall prepare different type of procedures, job aids, forms, job descriptions, manuals and other documents as well as KAHGLH also will use external sources documents such as standards, guidelines, reference books etc. Annual review is coordinated by the Quality Officer.

Note

Here in the Quality Policy Manual, most of the subsidiary documents are listed under respective policy in the section of Subsidiary Document but all documents are listed at Document Master Register. In addition, Document unique ID, which is found in intervals (Example, KAHGLH/HEM/SOP5.5-001-005) at subsidiary document of Quality Policy Manual, are listed in detail with document name and unique ID at the Document Master Register.

5.2.1. Term and Definition

- Compiler: A person who gathers/complies information and or prepares documents.
- Date :time which indicate the activities performed which is recorded in the Ethiopian calendar in case of EQA feedbacks, and receiving the sample requests /tracking sheets at reception else use Gregorian Calendar.
- Document and Record Control Officer: Person who manages the documents and records of the KAHGLH
- Examination: Set of operations having the object of determining the value or characteristics of a property
- Laboratory Head: Competent person(s) with responsibility for, and authority over, a laboratory
- Measurement: set of operations having the object of determining a value of a quantity
- Post-examination processes: 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 processes :steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins
- Quality officer: Responsible for the implementation and maintenance of the Quality Management System in KAHGLH.
- Receptionist-a person who receive sample and dispatching the result. In addition, a person who receives customers.
- Referral laboratory: external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report
- Revision number: is number given for document when there is no change in the document but just to indicate that the document is revised periodically.
- Safety officer: A person who facilitates and control the implementation safe laboratory safety practice.
- Store officer: A person who manage the stock level of laboratory reagents and supplies.
- Subsidiary: It is a supportive document that helps to accomplish tasks or policy.
- 1to5 Leader: personnel who have been designated to lead 4 laboratory personnel to oversee specific technical operations of the laboratory.

- 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 measure
- Validation: is conformation through provision of objective evidence, that the requirements for specific intended use or application have been fulfilled
- Verification: is conformation through provision of objective evidence, that the specified requirements have been fulfilled.
- Version number: is a number given for document when there is a major change in the document (edition).

5.3.Management Requirements

5.3.1. Organization and Management Responsibility

A. Purpose

This document provides a description of KAHGLH in terms of its legal entity; its structure & function; its mission, vision and mandate and its delegation of responsibilities and authorities.

B. Policy

KAHGLH'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 its clients.

5.3.1.1.General

KAHGLH is responsible for the provision of diagnostic laboratory testing services for patients and specimens referred from each health facilities.

KAHGLH through its authority demonstrates and provides laboratory diagnostic services and support to:

- Provide laboratory services
- Improving and support the capacity of the laboratory
- Expand and strengthen the laboratory external quality assessment programs
- Assist a laboratory work in all the western Zone catchment area health facility.
- Above all, KAHGLH role is to enhance the quality system management.

5.3.1.2. Legal entity

The KAHGLH is a Government institution that is under the Tigray Region Health Bureau. The management ensures that the laboratories are independent from any commercial, financial or other pressures, which might adversely affect the quality of tests and test reports.

5.3.1.3. Address:

Name of Lab: Kahsay Abera Humera General Hospital Laboratory

Zone West Tigray: P.O.Box: 35

Phone No: +2510344480010/11

_Fax No: +2510344480009

Email: KAHGLHhealth@gmail.com

Tigray, Ethiopia

5.3.1.4. Working Hour

KAHGLH provide service Monday through Sunday

Regular hour: 24hours

5.3.1.5. Vision

We aspire to see one of the best hospital laboratories in Tigray Region in health service delivery system where there is no disability and death from preventable and curable disease.

5.3.1.6. Mission

- To provide quality and equitable, promoting, preventable and curative health services to the inhabitants of Tigray Region and thereby reducing morbidity and mortality due to communicable diseases and other health problems through active participation of the community and all partners.

5.3.1.7. KAHGLH Values

- User satisfying service will be our hospital culture
- Cost effective and efficient resource utilization
- We are committed to respect the health professional medical ethics
- Our organization management system is committed to transparency and accountability
- Provision of quality and result oriented service
- Partnership with stakeholders is our strategic value
- Motivated and committed staff

5.3.1.8. Scope of Operations and Services

- Microbiology Analysis
- Clinical chemistry Analysis
- Hematology analysis
- Immunohematology (CD4) Analysis
- Serology Analysis
- Parasitology Analysis
- Urinalysis Analysis etc

5.3.1.9.KAHGLH STRUCTURE

The inter-relationship of all personnel is displayed in Annex A: KAHGLH Organ-gram.

5.3.1.10. Responsibility and Authority

- 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 fulfillment of responsibilities for establishment, maintenance and continuous improvement of the Quality System the following directives are applicable:
- The Laboratory head shall be responsible for ensuring the establishment/refinement of the quality system that complies with the Quality Policy Statement and for providing the resources needed to ensure the required quality of laboratory operations. As such the Laboratory head shall fulfill the responsibilities of the designation Quality Officer as set out in ISO 15189. This responsibility may be further delegated, should the Laboratory head deem it necessary, to relevant staff member(s).
- The Quality Officer is responsible for the implementation and maintenance of the Quality Management System in KAHGLH. The role of the Quality Officer shall encompass:-
 - The scheduling and performance of annual internal audits in conjunction with selected trained technical personnel;
 - The scheduling of management review meetings;
 - The follow-up of all corrective, remedial actions and complaints; and
 - The coordination of document amendment, revision and distribution.
- The responsibilities for the Lab. Head and Quality Officer shall be designated to personnel within the laboratory during the absence of the each.
- All personnel within the laboratory shall be responsible for implementation of quality related procedures and instructions and as such are authorized to initiate an Investigation, Action & Resolution (IAR) form when a deviation from the system occurs or when a non-conformance (both technical and system based) is identified.

5.3.1.11. Conflict of Interest and Influences on Work

All personnel shall sign the KAHGLH Work Ethics Agreement (refer; KAHGLH/ALS/F4.1-004) and should attempts be made by clients, competitors, 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. (Refer KAHGLH/ALS/F4.9-001)

5.3.1.12. Laboratory director (Lab. Head)

- The laboratory shall be directed by a person with the competence and delegated responsibility for the services provided.
- The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.
- The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.
- The duties and responsibilities of the laboratory director shall be documented.
- The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfill 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;

- 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
- Plan and direct research and development, where necessary

5.3.1.13. Laboratory management

Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of Customer and those using the laboratory services.

5.3.1.14. Quality policy

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

- 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.

5.3.1.15. Quality objectives and planning

Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements and the quality objectives.

Laboratory management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.3.1.15. Confidentiality of Information

The laboratory management shall ensure confidentiality of information in the organization and all personnel within the laboratory shall be responsible for assuring of confidentiality of information. The laboratory shall define procedure for ensuring the protection of confidential information.

5.3.1.16. Quality Officer

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

- i. Ensuring that processes needed for the quality management system are established, implemented, and maintained;
 - ii. Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;
 - iii. Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.
- The Quality officer is responsible for the implementation and maintenance of the Quality Management System in KAHGLH. The role of the Quality officer shall encompass:-
 - A. The scheduling and performance of annual internal audits in conjunction with selected trained technical personnel;
 - B. The scheduling of management review meetings;
 - C. The follow-up of all corrective, remedial actions and complaints; and
 - D. The coordination of document amendment, revision and distribution in the laboratory.

5.3.1.17. Resources

- Personnel and equipment resources are planned in relation to envisaged and realized growth and expansion within the laboratory. The concept of multi-skilling shall be practiced by training of personnel for performance of tests in related fields on both an inter- and intra-laboratory basis.
- Personnel training shall be performed in accordance with the policy and procedures as prescribed in the Personnel POLICY KAHGLH/ALS/P5.1-001

- The Laboratory head shall ensure adequate supervision of staff, including trainees, by persons familiar with test methods.
- Planned replacement and expansion of capital items is scheduled in conjunction with the preparation of the operational budget for the subsequent financial year. Inputs from the Management Review are used for capital asset decisions. In addition, on-going business development may require investments into specific growth areas or projects and these investments are evaluated, motivated, and decided upon throughout the year. The decision to invest in assets is based on normal business principles of opportunity and return on investment

5.3.1.18.Communication

In general, it must be emphasized that the primary objective of the business of KAHGLH is to satisfy client requirements by supplying fit-for-purpose services and in so doing to achieve the quality objectives of the laboratory. 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 by the quality officer.

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.1-001	Procedure for Communication
KAHGLH/ALS/SOP4.1-002	Procedure for assuring of confidential information
KAHGLH / ALS/SOP4.1-003	Procedure for Conducting Staff Meeting
KAHGLH / ALS/F4.1-001	Checklist for New Staff Orientation
KAHGLH / ALS/F4.1-002	Communication Log
KAHGLH / ALS/F4.1-003	Format for Recording/Minute of Staff Meeting
KAHGLH / ALS/F4.1-004	Work Ethics Form
KAHGLH / ALS/CHT4.1-001	Organogram of KAHGLH (Annex A)

5.4. Quality Management System

A. Purpose

- This document provides the Quality Policy and Objectives of the KAHGLH together with a description of the Quality Management System that has been established in order to fulfill the Quality Policy and to meet the Objectives.

B. Policy

- KAHGLH'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 goals of the QMS by establishing a Quality Policy Statement, Quality Goals and Objectives

5.4.1. General

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

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

The laboratory shall:

- 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 these processes

5.4.2. Documentation Requirements

The quality management system documentation shall include:

- i. Statements of a quality policy
- ii. A quality manual
- iii. procedures and records required by this International Standard;
- iv. documents, and records determined by the laboratory to ensure the effective planning, operation and control of its processes;
- v. Copies of applicable regulations, standards and other normative documents.

5.4.3. Quality manual

The laboratory shall establish and maintain a quality manual that includes:

- a) the quality policy (4.1.14) or makes reference to it;
 - b) a description of the scope of the quality management system;
 - c) a presentation of the organization and management structure of the laboratory and its place in any parent organization;
 - d) a description of the roles and responsibilities of laboratory management (including the laboratory director and quality officer) for ensuring compliance with this International Standard;
 - e) a description of the structure and relationships of the documentation used in the quality management system;
 - f) The documented policies established for the quality management system and reference to the managerial and technical activities that support them.
- All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.

5.4.4. Quality Policy Statement

- KAHGLH is fully committed to the concept of third party recognition by means of accreditation of KAHGLH 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 KAHGLH'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 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 KAHGLH 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 process shall address improvements both in the Quality System and in the business processes.

5.4.5. Quality Goals and Objectives

- Kahsay Abera Humera General Hospital Laboratory is determined and committed to carry out the following quality objectives and goals:

5.4.5.15. Quality Goals

- 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

5.4.5.16. 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 evidenced 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.

5.4.6. 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 (Clause 4.2). 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 manuals) are extensive and the full set can be viewed by referring to the relevant document Master Lists (Refer Procedure for Document and record control KAHGLH/ALS/SOP4.3-001)

The QMS allows for the control of and common understanding of how activities, processes and systems are operated within KAHGLH.

5.4.7. Quality Management System Implementation

All personnel are trained in understanding the structure and operational requirements of the QMS (Refer Personnel Policy KAHGLH/ALS/P5.1) Only current documents shall be used and all obsolete documents shall be withdrawn from the laboratory (refer Procedure for Document and record control KAHGLH/ALS/SOP4.3-001).

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/JA4.2-001	Quality Management System Policies & Process (Annex B)

5.5. Document Control

A. Purpose

This document describes the means by which the documented quality system is controlled in the Kahsay Abera Humera General Hospital Laboratory (KAHGLH).

B. Policy

It is a considered policy of the KAHGLH 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.

5.5.1. 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 3.2 together with the relevant clause number from ISO 15189. The document is then prefixed by an abbreviation /KAHGLH/ to indicate that it is TRGH Lab's document and followed by three or more letters e.g. /HEM/ showing the location of the document within the organization to which the department/section belongs, next followed by one or more alphabets and number e.g. /SOP4.3/, the alphabet is indicating the type of the documents and the number is indicating the relevant ISO clause/policy and finally it will be followed with serialized number /-001/. Assembling the alphanumeric code it will be read like the following; KAHGLH/HEM/SOP4.3-00. If the document is related with all policies, no need to add ISO clause/policy number eg. KAHGLH/HEM/MN-001.

Type descriptor	Section Description
CMB	Clinical Microbiology
CCH	Clinical Chemistry
HEM	Hematology
IMH	Immunohematology
ALS	All lab sections
QAL	Quality Assurance Lab
LRS	Laboratory Reception section
LAS	Laboratory Archival section
LMS	Laboratory Mini store
RDA	Result Dispatching Area
URA	Urinalysis
PAR	Parasitology
STE	Stool Examination

- There are several document categories that are controlled under the quality system. When computer copies of such documentation are used as active documents within a laboratory, there shall be specific procedures for control, access, adherence and change to such computer files. The document categories are as follows:

Type Descriptor	Document Description	Example
QPM	Quality Policy Manual	KAHGLH/ALS/QPM-01
P	Policy	KAHGLH/ALS/P4.6
SOP	Standard operating procedure	KAHGLH/CMB/SOP4.6-001
JD	Job Description	KAHGLH/ALS/JD5.2-001
F	Forms	KAHGLH/ALS/F4.6-001
S	Standards	KAHGLH/ALS/S4.6-001or KAHGLH/ALS/S-001 if it is related to one specific policy
MAN	Manuals	KAHGLH/ALS/MAN5.3or KAHGLH/MAN/4.6-001, if it is related to one specific policy
JA	Job Aid	KAHGLH/CCM/JA5.5-001
GDL	Guideline	KAHGLH/ALS/GDL-001or KAHGLH/ALS/GDL 4.6-001, if it is related to one specific policy
CHT	Chart	KAHGLH/ALS/CHT5.2
RB	Reference Books	KAHGLH/ALS/RB4.1-001

KAHGLH documents are prepared in English language. If a document is prepared in Amharic, each Amharic Version document should include “A” with the document Unique ID at the end of serial number (Example KAHGLH/ALS/SOP5.3-001A) to indicate the Amharic Version documents. And an external document that is needed for internal use must be controlled/internalized by posting the KAHGLH’s alphanumeric document identification system.

5.5.2. Document Format and Content

5.5.2.1. Document Format

The arrangement used for P-; SOPS-; MAN-documents shall be in accordance with the format outlined in this document in terms of headers and outline. Header is outlined as follow: And header of JD-; F-; JA-; CHT is outlined as follow:

5.5.2.2. Document Content

Documents can provide both policy and process or policy alone (as in the case of the KAHGLH policy in relation to sub-contracting). In general the P-; SOP-; JD,-JA; and F- 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 contents:

Policy/Manual/Guideline-Docs	SOP-Docs	JD-Docs	Forms	JA-Docs
Purpose; Policy; Responsibility; References; Definitions; Process/guidance (however described); Subsidiary docs; Annexures	Purpose Abbreviation; Procedure; Subsidiary Docs; Reference Annexures.	Title; Department/unit; Purpose; Duties and responsibilities; Education/Qualification ; Skills/Competency; Training; Behavioral Competencies; Authority;	Forms should be formatted so as to allow the recording of evidence or data that satisfies the requirements of a P-; SOP-; or JD- as appropriate.	Purpose; Procedure; Annexure.

5.5.3. Document Status and Originality

There are two modes of ensuring that current, non-obsolete, documentation is in use with the laboratory. 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 are acceptable within KAHGLH. Both modes of control provide effective regulation over status and originality.

5.5.3.1. Status

The current status of documentation is identified by

- The revision number indicated next to front page and the version number indicated in the top right hand corner of P-; SOP; JD- , F-etc documents together with the effective date. The original document is issued as Rev No 0 and subsequent revisions are marked in sequential numerical order, e.g. 1,2, 3 etc; or
- The official edition reference which shall be an edition number or edition date (library issues, manuals, etc.).

All current KAHGLH documentation (P-; SOP-; JD-, F-; S-; JA-; MAN-; etc) shall be identified by reference to Document Master Registers (KAHGLH/LAS/F4.3-001). Each

register shall be formatted as a matrix which cross-references each document to its current status, i.e. Rev, Version No., document No. or effective date.

The Document and Record Focal person shall maintain on file the updated Document Master Register for all KAHGLH controlled documentation.

5.5.3.2. Originality

Originality of quality documents is achieved by printing the documents (P-; SOP-; JD-; JA-; S-; MAN-; F-etc) on paper with a the hospital stamp or colored imprint or logo originality of other controlled documents is achieved by controlling access to the Document Master Register.

The Quality officer shall ensure prior to the yearly Management Review that the standards, specifications and test methods used in their Laboratories are up to date and current.

5.5.4. Document Issue Control

- As soon as a new/revised document has been signed by both the Compiler and Approver, it must be distributed for implementation on the effective date. Policies, Manual, guideline and Job Description will be complied by quality officer and/or assigned person and approved by laboratory head. Likewise, other documents such as SOPs and Job Aid will be complied by technical personnel and approved by quality officer. Documents can be reviewed by quality officer, 1to5 leader or technical personnel. If necessarily, laboratory head could review documents.
- Physical distribution of documentation shall be controlled by the use of distribution lists. The control of KAHGLH quality documentation is the responsibility of the Quality officer and Document and Record Control focal person. Laboratory level documentation is the responsibility of each 1to5 leader. When a new document has been prepared or an existing document has been revised the Document and Record Control focal person shall nominate the recipients of the document on the Document Distribution List (KAHGLH/LAS/F4.3-002) ensuring that the document is available at all locations where operations essential to the effective functioning of the laboratory are performed. A copy number shall be allocated to each recipient.
- The Quality officer or Document and Record Control focal person shall ensure all nominees are issued with and have signed for receipt of the relevant document.

- It is the responsibility of all personnel to indicate receipt of documents by signing the relevant Distribution List and to immediately destroy all superseded documents. Personal signature and acceptance by each designated person on the list is therefore required.
- The Document and record Focal person shall maintain on file:
 - The original master copy of all quality documents;
 - The distribution list(s) appropriate to the document;
 - Extra copies of documents; and
 - Archive copies of obsolete MASTERS of all documents with an indication of their obsolete status.

5.5.5. Document Changes/Revision

- All personnel are responsible for quality and as such all personnel have the responsibility 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 his/her line Lab head.
- 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.
- Amendment to document is done by hand or print, pending the reissue of the amended document as soon as practicable. All amended document should be approved prior to use.
- All Quality Management System documents shall be reviewed annually.

5.5.6. 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 laboratory personnel. Copies of documents not included within the controlled document system shall not be utilized in the laboratory.

The documented Quality System is intended to satisfy the Quality Policy and ultimately the mission and organizational policy on quality. All personnel of KAHGLH shall adhere to the quality

documentation. If controlled documentation requires change or modification the procedure for requesting document changes shall be followed.

5.5.7. Unauthorized Deviations from Quality System

If an unauthorized deviation from documented procedures is identified, the Quality officer/1to5 leader 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 by organizing the possible need for retraining or disciplinary action.

5.5.8. Document Retention period

All copies of obsolete documents are archived and the retention time is defined by the nature of the documents as follows.

S.N	Name of Quality and Technical Records	Retention Time
1.	Procedure (SOPs)	5 years
2.	Manuals/ Policies	5 years
3.	Forms/Charts	5 years
6.	Job aids	5 years
5.	Job description	5 years
6.	Guideline	5 years
7.	Standards/Reference Books	Indefinite

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.3-001	Procedure for Document Preparation and Revision
KAHGLH/ALS/F4.3-001	Document Master Register
KAHGLH/ALS/F4.3-002	Document Distribution List
KAHGLH/ALS/SOP4.3-002	Procedure for Document and record control
KAHGLH/ALS/SOP4.3-003	Control procedures for electronic storage of data
KAHGLH/ALS/SOP4.3-004	Procedures for Amendment of Documents

5.6.Review of Contracts

A. Purpose

This document provides the policy, process and indicate subsidiary document (s) for review of contracts.

B. Policy

KAHGLH has policy to establish and maintain procedures for review of contracts when the laboratory enters into a contract to provide laboratory service & to get service as a referral/backup laboratory (Refer KAHGLH/ALS/SOP4.4-001). All requirements including the methods to be used, are adequately defined, documented and understood; capacity and resources of KAHGLH has to meet the requirement. KAHGLH 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.

5.6.1. Establishment of service agreements

The TRGH'S laboratory shall have documented procedures 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.
 - a) 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
 - b) The laboratory shall have the capability and resources to meet the requirements.
 - c) Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations.
 - d) Examination process selected shall be appropriate and able to meet the customers' needs
 - e) Customers and users shall be informed of deviations from the agreement that impact upon the examination results.
 - f) Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.

5.6.2. 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.

C. Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Review of request form; Method/procedure; type of sample and volume; Turnaround time; Laboratory handbook; Customers request of uncertainty of measurement and limit of detection; etc	Establishment: All inputs and activities with laboratory capacity and resource shall be evaluated and review of contract shall initiate. All contracts or arrangement must be communicated to customers. Laboratory shall determine level of uncertainty of measurement and limit of detection of test method with regard to customer's request.	Reviewed contracts through request form, lab handbook, etc must be documented and communicated with customers. Determined uncertainties of measurement and limit of detection shall be part of contracts.	Laboratory head/ Quality officer	Contract review policy and procedure available
All forms of contracts and documented; known value of measurement of uncertainty and limit of detection are identified.	Maintenance and monitoring Contract must be reviewed accordingly customers communicate on it. Ensure that the laboratory must maintain and monitor contracts. All forms of contract must be reviewed and documented.	Any improved laboratory method/test including uncertainties of measurement ; activities shall documented and contract must be reviewed accordingly and communicated effectively to customers	Quality officer	Level of customer satisfaction

D. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.4-001	Procedure for review of contract
KAHGLH/ALS/F4.4-001	Contract Review Record form
KAHGLH/ALS/SOP4.4-002	Procedure for Notification of changing the examination

5.7.Examination by Referral Laboratories

A. Purpose

This document provides the policy, guidance and subsidiary document (s) for examination of referral laboratories.

B. Policy

KAHGLH ensure 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 related disciplines. A duplicate of the laboratory report shall be retained on both patient record and in the permanent file of laboratory.

5.7.1. General

- The referring laboratory shall be responsible for ensuring that referral laboratory examination results and findings are provided to the person making the request. If the referring laboratory prepares the report, it shall include all essential of the results reported by the referral laboratory, without alterations that could affect clinical interpretation. A register shall be kept of all samples that have been referred to another laboratory.
- The laboratory shall maintain a register of all referral laboratories that it uses and name and address of the laboratory responsible for the examination result shall be provided to the user of laboratory services.

5.7.2. Selecting and evaluating referral laboratories and consultants

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

The procedure shall ensure that the following conditions are met.

- 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.

5.7.3. 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.

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.5-001	Procedure for selecting and monitoring referral lab and consultant
KAHGLH/ALS/SOP4.5-002	Procedure to Manage Interruption of service
KAHGLH/ALS/F4.5-001	Checklist for monitoring of referral lab and consultant
KAHGLH/ALS/F 4.5-002	Format for reporting/ findings from monitoring
KAHGLH/ALS/F 4.5-003	Referral Laboratories Registry Form

5.8.External Services and Supplies

A. Purpose

This document provides the policy, guidance and indicate subsidiary document (s) for external services and supplies.

B. Policy

KAHGLH has policy and procedure for selecting and use of purchased external service, equipment and consumable supplies that affect the quality if its service. The KAHGLH ensure that purchased items shall consistently meet the laboratory`s quality requirement. The KAHGLH develops procedures and criteria for inspection, acceptance/rejection and storage of consumable materials. Consumable and equipment`s items that affect the quality of service have to be verified prior to use as complying with standard specifications or requirement defined for the procedures concerned.

5.8.1. General

The KAHGLH shall have an inventory control system for supplies. The laboratory shall evaluate 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 shall be established and maintained for a period of time. This system shall include 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 shall be available for laboratory management review.

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.6-001	Procedure for purchasing and handling of Equipment, Supplies and Reagents
KAHGLH/ALS/SOP4.6-002	Verification procedure for supplies and reagents
KAHGLH/ALS/SOP4.6-003	Procedure for Inventory control
KAHGLH/ALS/F4.6-001	Supplies and Reagents Forecasting Form
KAHGLH/ALS/F4.6-002	Bin Card
KAHGLH/ALS/F4.6-003	Purchase Requisition Form
KAHGLH/ALS/F4.6-004	Facility Combined Report and Requisition Form(FCRRF)
KAHGLH/ALS/F4.6-005	Order Tracking Sheet
KAHGLH/ALS/F4.6-006	Supplies and Reagents Verification Form
KAHGLH/ALS/F4.6-007	Suppliers' list / contact person
KAHGLH/ALS/F4.6-008	Form for Retuning Unusable Supplies and Reagents
KAHGLH/ALS/F4.6-009	Internal Facility Report, Issues and Receipt Voucher (IFRIRV)
KAHGLH/ALS/JA4.6-001	Job Aid for supplies requesting from Mini Store
KAHGLH/ALS/F4.6-010	Reagent consumption log

5.9. Advisory Services

A. Purpose

To provide policy, guidance and indicating subsidiary documents for establishment of the advisory services in KAHGLH

B. Policy

KAHGLH 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 clinical staff are regularly held to ensure the best possible delivery of laboratory services and minutes are documented in the laboratory.

5.9.1. General

- The laboratory management ensures that there is a documented procedure to advise customers on choice of examinations and use of the services, including 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.
- a. The laboratory shall establish arrangements for communicating with users on the following:
- b. 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;
- c. Advising on individual clinical cases;
- d. Professional judgments on the interpretation of the results of examinations
- e. Promoting the effective utilization of laboratory services;
- f. Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.7-001	Procedure for Advisory Services
KAHGLH/LAS/F4.7-001	Catchment meeting minute form
KAHGLH/LRS/F4.7-001	Supervision checklist for sample collection site
KAHGLH/LRS/MAN4.7-001	Laboratory hand book

5.10. Resolution of Complaints

A. Purpose

To provide the policy and process 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.

B. Policy

KAHGLH's policy on complaints is to register all concerns, queries and complaints in the Compliments & 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 the laboratory policy to seek feedback on the quality of its service by surveying users on a regular basis.

C. Process

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

D. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.8-001	Procedure for conducting satisfaction survey

KAHGLH/ALS/SOP4.8-002	Procedure for Receiving and Resolution of Complaints
KAHGLH/ALS/F4.8-001	Client Satisfaction Survey Check list
KAHGLH/ALS/F4.8-002	Compliments & Complaints Register

5.11. Identification & Control of Non-conformities

A. Purpose

To provide the policy and process for the systematic investigation and resolution of non-conformities that 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.

B. Policy

KAHGLH 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 in the policy of Assuring the Quality of Examination Procedures 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

C. 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	QO	-
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).	Implemented Actions	Lab head	-

	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	Verify effectiveness of implemented actions	Non-conformity resolved	QO	Effective resolution & 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 head	-

D. Subsidiary Documents

Document Unique ID	Document Name
AARHL/ALS/SOP4.9-001	Procedure for the Identification and Control of Non-Conformities
AARHL/ALS/F4.9-001	IAR Register
AARHL/ALS/F4.9-002	Summary Occurrence & Corrective action Report Form

5.12. Corrective Action

A. Purpose

This document provides the policy, guidance, process and subsidiary documents for the initiation and implementation of corrective actions in KAHGLH. 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.

B. Policy

KAHGLH 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.

5.12.1. General

5.12.1.1. 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

i. Equipment Calibration

When corrective action is required it shall have the objective of

- Determining the effect of the non-conformance, to the specified calibration requirements, on the test activity and, where necessary, recommending to the Laboratory head to notify the relevant clients of the potential effects on such test results; and
- 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 (Refer Equipment policy: KAHGLH/ALS/P5.3).

ii. 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 shall have 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 (Refer identification and control of non-conformities policy KAHGLH/ALS/P4.9).

iii. 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 (Refer internal Audit Policy: KAHGLH/ALS/P4.14).

iv. 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 (Refer Management Review: KAHGLH/ALS/P4.15).

v. 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 Director 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 (Refer Resolution of complaint: KAHGLH/ALS/P4.8).

5.12.1.2. Cause Analysis

The following shall be used for guidance in determining the root cause of non-conformities for corrective action purposes.

i. Internally detected non-conformance

There are three general areas in the testing process in which errors may cause non-conformances:

1. Sample Handling and Preparations (refer Pre-Examination Procedure policy: KAHGLH/ALS/P5.4)
 - mislabelling;
 - 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.
2. Sample Testing (Refer Examination Procedure policy: KAHGLH/ALS/P5.5)
 - 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
3. Data Handling:(Refer Reporting of Results policy KAHGLH/ALS/P5.8)
- data transcription error; and
 - typing error.

ii. 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.

C. Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Calibration/ Verification activities; Non-conforming work; Auditing Activities; Management Review(MR) Outputs; Complaints; Preventive Action.	Initiation Since all personnel are responsible for quality they have the authority to initiate an IAF where a deficiency in a procedure or system is identified. All IAF initiated by personnel shall be forwarded to the Quality officer for investigation and registration.	Identified Corrective Action Sources	All staff	-
Identified Corrective Action Sources	Investigation All IAR shall be registered in the ARF Registry (KAHGLH/ALS/F4.11-001); investigated and corrective action determined by the Quality officer in consultation with the relevant Team Leader. The	Implemented Actions.	Quality officer & Labora tory	Improvement of the QMS in meeting client requirements as measured by the Customer

	appropriate corrective action required shall be detailed in the relevant part of the ARF. The designated responsible person shall implement the corrective action within the prescribed time.		head	Satisfaction Survey
Implemented Actions	Effectiveness Monitoring The Quality officer shall verify the implementation of the corrective action and the effectiveness of this action. Simple output verification for effectiveness is required unless the corrective action covers a process with several variable outputs and as such involves system correction. Under such circumstances, an additional audit shall be scheduled by the Quality officer to verify effectiveness of the corrective action implementation. If verification is acceptable the quality officer shall authorize the closure of the IAR. If it is not acceptable a new IAR shall be initiated		Quality officer	-

D. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.10-001	Procedure for Corrective Action

5.13. Preventive Action

A. Purpose

This document provides the policy, process and indicating subsidiary documents for the initiation and implementation of preventive actions in KAHGLH. Preventive actions are actions that are taken to prevent the occurrence of potential non-conformances.

B. Policy

KAHGLH 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.

C. Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
QC Charts; MR Reports; Internal & external	Identification: Opportunities for preventive action or potential sources of non-conformances, either technical or system based, shall be identified	Preventive Action identified	Quality officer	-

audit reports.	through: trend and risk analyses; document review; proficiency testing results; QC system; Identification by individual staff members; Auditing; and Management review.			
Identified Preventive Action	Implementation: Register each Preventive action in the Continual Improvement Register, KAHGLH/ALS /F4.12-002 Initiate an IAR in accordance with the Corrective Action procedure and attach any associated supporting documents. Cross-reference to the Continual Improvement Register, KAHGLH/ALS /F4.12-002 Investigate root cause; implement appropriate action and resolve in accordance with the IAR Process as described in the Corrective Action procedure.	Implemented Actions.	Lab head/ Quality officer	Improvement of the QMS in meeting client requirements as measured by the Customer 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.		Quality officer	-

D. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.11-001	Preventive Action procedure
KAHGLH/ALS/F4.11-001	Checklist for preventative action

5.14. Continual Improvement

A. Purpose

To provide the policy, process and indicating subsidiary for the systematic improvement of the QMS in KAHGLH

B. Policy

KAHGLH 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.

C. 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. Analyzing 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	Improve ment Opportunities identified.	Lab head	-

Improvement Opportunities	Implementation: Register each improvement opportunity in the Continual Improvement 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.	Quality officer & Lab head	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.		Quality officer	-

D.

Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/QAL/F4.12-001	Quality Indicators Form
KAHGLH/QAL/F4.12-002	Continual Improvement Register
KAHGLH/QAL/F4.12-003	Quality Improvement Planning(PDCA) Form

5.15. Control of Records

A. 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 KAHGLH.

B. Policy

KAHGLH shall ensure that all quality records and technical records are effectively identified, indexed, accessible, filed 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.

C. 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 (refer Back up procedure for all records: KAHGLH/ALS/SOP4.13-001), 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 near the change (Refer document and record control: KAHGLH/ALS/SOP4.3-00X)
- 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.

5.15.1. 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.

Note-TAT monitoring format, QC print outs, work list and result summary have been archived every month else in every six month from workstation removed.

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 and sample tracking sheet);	5 year
2.	examination results and reports;	5 years for paper based and indefinite storage on DVD and 1year on online
3.	instrument printouts;	1year
4.	examination procedures;	5 year if methods not changed
5.	laboratory work-books or sheets;	5 years
6.	accession records;	Phone log = 2years, Specimen receiving form = 5years
7.	calibration functions and conversion factors;	Indefinite
8.	quality control records;	2 years

9.	complaints and action taken;	2 years
10.	records of internal and external audits;	3 years
11.	external quality assessment records/ inter-laboratory comparisons;	2 years
12.	quality improvement records;	2 years
13.	instrument maintenance records, including internal and external calibration records;	3 years
14.	lot documentation, certificates of supplies;	2 years
15.	incident/accident records and action taken;	2 years
16.	Staff training and competency records.	2 years
17.	IAR	2 years

D. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP4.13-001	Back up procedure for electronic documents & LIS.
KAHGLH/ALS/SOP4.13-002	Procedure for Document and record archival and retrieval
KAHGLH/ALS/SOP4.13-003	Procedure for correcting mistakes and alteration of records
KAHGLH/ALS/SOP4.13-004	Procedure for Identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records
KAHGLH/ALS/F4.13-001	Job Aid for quality and technical record user access

Evaluation and Audit

A. Purpose

To provide policy, process and indicating subsidiary documents for establishment, planning and implementation of internal audit in KAHGLH

B. Policy

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.

5.15.2. General

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

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

b) Ensure conformity to the quality management system;

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

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

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

Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. The laboratory shall periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measured.

5.15.4. Assessment of user feedback

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

5.15.5. Staff suggestions

Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.

5.15.6. Internal audit

The laboratory shall conduct internal audits at planned intervals 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: 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 shall be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit programmers shall take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined and documented. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall, wherever resources permit, be independent of the activity to be audited.

The laboratory shall have 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 shall ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective action shall be taken without undue delay to eliminate the causes of the detected nonconformities.

5.15.7. Risk management

The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.

5.15.8. Quality indicators

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes. **EXAMPLE** Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports.

The process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. The indicators shall be periodically reviewed, to ensure their continued appropriateness.

The laboratory, in consultation with the users, shall establish 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.

C. Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Policy, Process, and operating procedures	Gather information using checklist Review policy, process, and operating procedures	Implementation quality management system	Quality officer, audit committee	
Equipment Calibration and maintenance and reagent/supplies	Gather information Review equipment Calibration and maintenance data Assess equipment and reagent/supplies condition	Calibrated and maintained Equipment and available reagent/supplies without interruption	Quality officer, audit committee	
Examination/test methods Validation and or verification activities	Gather information and review examination/test methods Validation and or verification data and then Compare findings with documented quality management system	Validated/verified examination methods	Quality officer, audit committee	
Records and reports	Gather records and reports Review records and reports and compare findings with documented quality management system	Reviewed records and reports	Quality officer audit committee	
Accommodation and environment condition and handling of samples	Assess accommodation and environment condition and handling of samples Review environmental control records and reports and compare findings with documented quality management system	Maintained accommodation and environment condition	Quality officer, audit committee	
Quality control verification activities	Gather records and reports of quality control Review records and reports and compare findings with documented quality management system	Well maintained Quality control system	Quality officer, audit committee	-
Proficiency testing	Review Proficiency testing results; and	Acceptable Proficiency testing	Quality officer, audit	

results;	action take for unacceptable PT results	results	committee	
Improvement Plan	Review all Improvement plan (corrective and preventive action) for their implementation and effectiveness.	Non-conformity resolved	Quality officer, audit committee	
Summary of finding	Analyze all assessment result	Compiled audit	Quality officer audit committee	Audit report

A. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/QAL/SOP4.14-001	Procedure for conducting Internal Audit
KAHGLH/QAL/F4.14-001	Internal Audit Report Form
KAHGLH/QAL/F4.14-002	Internal Audit Assessment Checklist

5.16. Management Review

A. Purpose

To provide policy, process and indicating subsidiary documents for reviewing of the Quality Management System to ensure its continued suitability and effectiveness and to introduce any necessary changes or improvements.

B. Policy

The KAHGLH manager shall evaluate and analyses 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.

C. Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Diarized Management Review (MR) meeting as	Issue notification of Management Review meeting together with Agenda (Annex A Agenda for Management Review	MR Meeting arranged. Agenda & minutes distributed to	QO	MR Meeting occurs.

scheduled from the previous MR meeting or as scheduled by the Lab head	KAHGLH/ALS/JA4.15-001);minutes of last review meeting (if applicable) & Summary Reports	participants.		
Agenda; Minutes; Summary Reports	Conduct & facilitate MR Meeting in accordance with the Agenda (Annex A Agenda for Management Review KAHGLH/ALS/JA4.15-001);	MR Plan: Goals, Objectives and Actions(ReferKAHGLH/ALS/ P4.1)	Lab Head	–
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	QO	Objectives Achieved

D. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/F4.15-001	Minute form for Management Review
KAHGLH/ALS/JA4.15-001	Agenda for Management Review (Annex C)

5.17. Technical Requirements Policy

5.17.1. Personnel

A. Purpose

This document provides the policy, guidance and indicating subsidiary documents for implementation of laboratory's human resources management in KAHGLH.

B. Policy

Human Resource Management of KAHGLH ensures the hiring of qualified personnel and the provision of well-defined job descriptions and laboratory management coordinates and/or provides orientation, training and competency assessment programs including continuing education and staff performance appraisals

5.17.1.1. General

The laboratory shall have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements.

5.17.1.2. Personnel qualifications

- Laboratory management shall document personnel qualifications for each position. The qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed.
- The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience.

5.17.1.3. Job descriptions

- The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.

5.17.1.4. Personnel introduction to the organizational environment

- The laboratory shall have 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

5.17.1.5. Training

- The laboratory shall provide training for all personnel which includes the following areas:
 - A. the quality management system;
 - B. assigned work processes and procedures;
 - C. the applicable laboratory information system;
 - D. health and safety, including the prevention or containment of the effects of adverse incidents;
 - E. ethics;
 - F. Confidentiality of patient information.
- Personnel that are undergoing training shall be supervised at all times. And the effectiveness of the training programme shall be periodically reviewed including.

5.17.1.6. Competence assessment

- The laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria and the competence assessment shall be conducted following training
- Reassessment shall take place at regular intervals. Retraining shall 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:

- i. direct observation of routine work processes and procedures, including all applicable safety practices;
 - ii. direct observation of equipment maintenance and function checks;
 - iii. monitoring the recording and reporting of examination results;
 - iv. review of work records;
 - v. assessment of problem solving skills;
 - vi. Examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples.
 - vii. 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.

5.17.1.7. 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.

5.17.1.8. 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

5.17.1.9. 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:
 - a. educational and professional qualifications;
 - b. copy of certification or license, when applicable;
 - c. previous work experience;
 - d. job descriptions;
 - e. introduction of new staff to the laboratory environment;

- f. training in current job tasks;
 - g. competency assessments;
 - h. records of continuing education and achievements;
 - i. reviews of staff performance;
 - j. reports of accidents and exposure to occupational hazards;
 - k. 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

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP5.1-001	Competency Assessment Procedure
KAHGLH/ALS/F5.1-001	Competency Assessment Checklist
KAHGLH/ALS/SOP5.1-002	Procedure for Identifying and Providing Training
KAHGLH/ALS/F5.1-002	Performance Appraisals checklist
KAHGLH/ALS/JD5.1-001	Job description
KAHGLH/ALS/F5.1-003	Personnel file Record
KAHGLH/ALS/F5.1-004	Daily Personnel Evaluation
KAHGLH/ALS/JA5.1-001	Duties on work station/work task/

5.17.2. Accommodation and Environmental Conditions

A. Purpose

To provide policy, guidance and indicating subsidiary documents for establishment of the convenient accommodation and environmental conditions for laboratory work and personnel.

B. Policy

KAHGLH 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. 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 legal regulations and provisions.

5.2.1 General

- The laboratory shall have 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 shall evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work.

- Where applicable, similar provisions shall be made for primary sample collection and examinations at sites other than the main laboratory premises, under the management of the laboratory.

5.2.2 Laboratory and office facilities

The laboratory management shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met.

- a. Access to areas affecting the quality of examinations is controlled. The access control should take into consideration safety, confidentiality, quality and prevailing practices.
- b. Medical Information, patient samples, and laboratory resources are safeguarded from unauthorized access.
- c. Facilities for examination allow for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.
- d. Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information. Refer Procedure for Communication: KAHGLH/ALS/SOP4.1-001
- e. 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

5.2.3 Storage facilities

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

5.2.4 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.

5.2.5 Patient sample collection facilities

The laboratory management ensures that:

- Patient sample collection facilities shall have separate reception/waiting and collection areas. Consideration shall be 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.
- Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) shall 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 shall have and maintain appropriate first aid materials for both patient and staff needs.

5.2.6 Facility maintenance and environmental conditions

The laboratory management ensures that:

- Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained.
- The laboratory shall monitor, 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. Attention shall be 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 shall be effective separation between laboratory sections in which there are incompatible activities. Procedures shall be 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 shall provide a quiet and uninterrupted work environment where it is needed

C. Subsidiary Documents

Document Unique Id	Document Name
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KAHGLH/ALS/SOP5.2-001	Procedure for environmental monitoring
KAHGLH/ALS/SOP5.2-002	Temperature monitoring Procedure for equipment's
KAHGLH/ALS/F5.2-001	Internal communication log
KAHGLH/ALS/F5.2-002	Accident reporting form
KAHGLH/ALS/F5.2-003	Log for work areas cleaning and organizing
KAHGLH/ALS/SOP5.2-003	Procedure for Segregation and disposal of waste materials
KAHGLH/ALS/F5.2-004	Format for Environment Monitoring Records
KAHGLH/ALS/F5.2-005	Refrigerator Temperature Monitoring Form
KAHGLH/ALS/MAN5.2-001	Laboratory Safety Manual
KAHGLH/ALS/CHT5.2-001	Floor design chart
KAHGLH/ALS/CHT5.2-002-004	Processes Map
KAHGLH/ALS/F5.2-006	Monthly safety inspection form
KAHGLH/ALS/F5.2-007	Fire extinguisher inspection form
KAHGLH/ALS/F5.2-008	First aid inspection form
KAHGLH/ALS/F5.2-009	Eye wash maintenance log
KAHGLH/ALS/F5.2-010	HIV exposure reporting form
KAHGLH/ALS/F5.2-011	Fire event reporting form
KAHGLH/ALS/JA5.2-001	Job Aid for Post exposure prophylaxis
KAHGLH/ALS/JA5.2-002	Instruction for Emergency Alarm using
KAHGLH/ALS/JA5.2-002A	Instruction for Emergency Alarm using (Amharic version)
KAHGLH/ALS/JA5.2-003	Instruction to Disinfect Biohazards Using Chemicals
KAHGLH/ALS/JA5.2-004	Instruction for emergency evacuation
KAHGLH/ALS/JA5.2-005	Instruction for action on bomb threat
KAHGLH/ALS/F5.2-012A	(Amharic version)

5.17.3. Laboratory equipment, reagents and consumables

A. Purpose

To provide policy, guidance and indicating subsidiary documents of laboratory equipment, reagents and consumables management for implementation of preventive maintenance program requirement, processes and procedures related to receiving equipment management, and retire/old/outdated equipment of laboratory equipment, reagents and consumables.

B. Policy

KAHGLH ensures that all laboratory equipment are installed, calibrated, maintained and used in accordance with the manufacturer's instructions and accreditation requirements. KAHGLH have consistent processes for installing, calibrating, operating, maintaining, and troubleshooting equipment, as well as for obtaining service when needed.

5.3.1 Equipment

5.3.1.1 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 shall have a documented procedure for the selection, purchasing and management of equipment.
- The laboratory shall be 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, laboratory management shall ensure that the requirements of this International Standard are met.
- The laboratory shall replace equipment as needed to ensure the quality of examination results.

5.3.1.2 Equipment acceptance testing

The laboratory management ensures that:

- The laboratory shall verify 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.
- Each item of equipment shall be uniquely labelled, marked or otherwise identified.

5.3.1.3 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.

5.3.1.4 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:
 - a. taking into account conditions of use and the manufacturer's instructions;
 - b. recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;
 - c. verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;
 - d. recording the calibration status and date of recalibration;

- e. ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;
 - f. Safeguards to prevent adjustments or tampering that might invalidate examination results.
- Metrological traceability shall be 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 may be 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 shall be applied, including but not limited 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.

5.3.1.5 Equipment maintenance and repair

- The laboratory shall have a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions.
- Equipment shall be 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 shall ensure 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 shall take 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 shall ensure that its performance is verified before being returned to laboratory use.

5.3.1.6 Equipment adverse incident reporting

- Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to the manufacturer and appropriate authorities, as required.

5.3.1.7 Equipment records

- Records shall be maintained for each item of equipment that contributes to the performance of examinations.
- These equipment records shall include, but not be limited to, the following:
 - a. identity of the equipment;
 - b. manufacturer's name, model and serial number or other unique identification;
 - c. contact information for the supplier or the manufacturer;
 - d. date of receiving and date of entering into service;
 - e. location;
 - f. condition when received (e.g. new, used or reconditioned);
 - g. manufacturer's instructions;
 - h. records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;
 - i. maintenance carried out and the schedule for preventive maintenance;
 - j. equipment performance records that confirm the equipment's ongoing acceptability for use;
 - k. Damage to, or malfunction, modification, or repair of the equipment.
- The performance records referred to in j) shall include 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 shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure

5.3.2 Reagents and consumables

5.3.2.1 General

- The laboratory shall have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.

5.3.2.2 Reagents and consumables — Reception and storage

- Where the laboratory is not the receiving facility, it shall verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.
- The laboratory shall store received reagents and consumables according to manufacturer's specifications.

5.3.2.3 Reagents and consumables — Acceptance testing

- Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before use in examinations.
- Consumables that can affect the quality of examinations shall be verified for performance before use in examinations.

5.3.2.4 Reagents and consumables — Inventory management

- The laboratory shall establish an inventory control system for reagents and consumables.
- The system for inventory control shall segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use.

5.3.2.5 Reagents and consumables — Instructions for use

- Instructions for the use of reagents and consumables, including those provided by the manufacturers, shall be readily available.

5.3.2.6 Reagents and consumables — Adverse incident reporting

- Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to the manufacturer and appropriate authorities, as required.

5.3.2.7 Reagents and consumables — Records

- Records shall be maintained for each reagent and consumable that contributes to the performance of examinations. These records shall include but not be limited to the following:
 - a. identity of the reagent or consumable;
 - b. manufacturer's name and batch code or lot number;
 - c. contact information for the supplier or the manufacturer;
 - d. date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service;
 - e. condition when received (e.g. acceptable or damaged);
 - f. manufacturer's instructions;
 - g. records that confirmed the reagent's or consumable's initial acceptance for use;

- h. Performance records that confirm the reagents or consumables ongoing 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.

C. Subsidiary Documents

Document Unique Id	Document Name
KAHGLH/IMH/SOP 5.3-001-005	Procedures for calibration & maintenance of Immunochemistry laboratory Equipment
KAHGLH/HEM/SOP 5.3-001-005	Procedures for calibration and maintenance of Haematology laboratory Equipment
KAHGLH/CCH/SOP 5.3-001-005	Procedures for calibration and maintenance of Clinical Chemistry laboratory Equipment
KAHGLH/ALS/SOP5.3-001	Procedures for acquiring & retrieving equipment
KAHGLH/ALS/F5.3-001	Format for equipment calibration record
KAHGLH/ALS/F5.3-002	Format for equipment maintenance record
KAHGLH/ALS/F5.3-003	Equipment history Recording form
KAHGLH/ALS/F 5.3-004	Non-functional Equipment Recording form
KAHGLH/ALS/F5.3-005	Equipment service contact information format
KAHGLH/IMH/JA5.3-001	Job Aid for Immunochemistry laboratory Equipment Operating
KAHGLH/HEM/ JA5.3-001-005	Job Aid for Haematology laboratory Equipment Operating
KAHGLH/CCH/ JA5.3-001-005	Job Aid for Clinical Chemistry laboratory Equipment Operating
KAHGLH/IMH/JA5.3-002	Job Aid for Facscount calibration
KAHGLH/ALS/MAN5.3-001-010	User Manual

5.17.4. Pre-Examination Processes

A. Purpose

To provide policy, guidance and indicating subsidiary documents for pre-examination processes implementation in the laboratory.

B. Policy

KAHGLH 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 sample, and the laboratory has a policy for verbal requests for examinations.

5.4.1 General

- The laboratory shall have documented procedures and information for pre-examination processes ensures the validity of the results of examinations.

5.4.2 Information for patients and users

- The laboratory shall have information available for customers of the laboratory services. The information shall include as appropriate:
 - A. the location of the laboratory;
 - B. types of clinical services offered by the laboratory including examinations referred to other laboratories;
 - C. opening hours of the laboratory;
 - D. the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values;
 - E. instructions for completion of the request form;
 - F. instruction for preparation of the patient;
 - G. instructions for patient-collected samples;
 - H. instructions for transportation of samples, including any special handling needs;
 - I. any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);
 - J. the laboratory's criteria for accepting and rejecting samples;
 - K. a list of factors known to significantly affect the performance of the examination or the interpretation of the results

- L. availability of clinical advice on ordering of examinations and on interpretation of examination results;
- M. the laboratory's policy on protection of personal information;
- N. The laboratory's complaint procedure.
- The laboratory shall have 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 (e.g. for interpreting blood transfusion), shall be explained to the patient and user.

5.4.3 Request form information

- The request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:
 - a) Patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier. Unique identification includes an alpha and/or numerical identifier such as a hospital number, or personal health number.
 - b) 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;
 - c) type of primary sample and, where relevant, the anatomic site of origin;
 - d) examinations requested;
 - e) 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.
 - f) date and, where relevant, time of primary sample collection;
 - g) 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 should be determined in discussion with the users of laboratory services.

- The laboratory shall have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic
- The laboratory shall have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time.
- The laboratory shall be willing to cooperate with users or their representatives in clarifying the user's request.

5.4.4 Primary sample collection and handling

5.4.4.1 General

- The laboratory shall have documented procedures for the proper collection and handling of primary samples.
- The documented procedures shall be 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 shall be 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 she 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 should be available and appropriate to the type of information being requested and primary sample being collected.

5.4.4.2 Instructions for pre-collection activities

The laboratory's instructions for pre-collection activities shall include the following:

- a) completion of request form or electronic request;

- b) preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);
- c) type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;
- d) special timing of collection, where needed;
- e) Clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).

5.4.4.3 Instructions for collection activities

The laboratory's instructions for collection activities shall include the following:

- a) determination of the identity of the patient from whom a primary sample is collected;
- b) 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.];
- c) instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;
- d) 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;
- e) instructions for labeling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;
- f) recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;
- g) instructions for proper storage conditions before collected samples are delivered to the laboratory;
- h) Safe disposal of materials used in the collection.

5.4.5 Sample transportation

- The laboratory's instructions for post-collection activities shall include packaging of samples for transportation.
- The laboratory shall have a documented procedure for monitoring the transportations of samples to ensure they are transported:
 - a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;

- b) within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;
- c) 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.

5.4.6 Sample reception

- The laboratory's procedure for sample reception shall ensure that the following conditions are met.
 - a) Samples are unequivocally traceable, by request and labeling, to an identified patient or site.
 - b) Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.
 - c) 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.
 - d) 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.
 - e) Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).
 - f) Where relevant, there shall be instructions for the receipt, labeling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labeling 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.

5.4.7 Pre-examination handling, preparation and storage

- The laboratory shall have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

- Laboratory procedures shall include time limits for requesting additional examinations or further examinations on the same primary sample. (Refer: Procedure for verbal requests KAHGLH/ALS/SOP5.4-002)

C. Subsidiary Documents

Document Unique Id	Document Name
KAHGLH/LRS/MAN5.4-001	Sample Collection Manual
KAHGLH/ALS/SOP5.4-001	Procedure for Sample collection, processing and storage
KAHGLH/ALS/SOP5.4-002	Procedure for verbal requests
KAHGLH/ALS/JA5.4-001	Specimen acceptance and rejection criteria
KAHGLH/LRS/F5.4-001-002	Laboratory Requesting Form
KAHGLH/LRS/F5.4-003	Worksheet for records of received samples

5.17.5. Examination Processes

A. Purpose

This document provides the policy, guidance and indicates subsidiary document(s) for examination of processes.

B. Policy

Kahsay Abera Humera General Hospital Laboratory (KAHGLH) has a policy to implement an approved examination processes 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 processes shall have unique identifiable and shall be part of document control.

5.6.5.1. Selection, verification and validation of examination processes

5.6.5.2. General

- The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded.
- The specified requirements (performance specifications) for each examination procedure shall relate 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.

5.5.1.2 Verification of examination procedures

- Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use.
- The laboratory shall obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure.
- The independent verification by the laboratory shall confirm, 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 shall be those relevant to the intended use of the examination results.
- The laboratory shall document the procedure used for the verification and record the results obtained. Staff with the appropriate authority shall review the verification results and record the review.

5.5.1.3 Validation of examination procedures

- KAHGLH shall validate examination procedures derived from the following sources:
 - a. non-standard methods;
 - b. laboratory designed or developed methods;
 - c. standard methods used outside their intended scope;
 - d. Validated methods subsequently modified.
- The validation shall be 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 should 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 quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity.
- The laboratory shall document 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 influence of such changes shall be documented and, when appropriate, a new validation shall be carried out.

5.5.1.4 Measurement uncertainty of measured quantity values

- The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement 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, e.g. changes of reagent and calibrator batches, different operators, scheduled instrument maintenance.
 - 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 shall consider measurement uncertainty when interpreting measured quantity values. Upon request, the laboratory shall 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 should calculate 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.

5.5.2 Biological reference intervals or clinical decision values

- The laboratory shall define 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 shall be 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.

5.5.3 Documentation of examination procedures

- Examination procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations.

- Any condensed document format (e.g. card files or similarly used systems) shall correspond 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:
 - a) purpose of the examination;
 - b) principle and method of the procedure used for examinations;
 - c) performance characteristics
 - d) Type of sample (e.g. plasma, serum, urine.);
 - e) patient preparation;
 - f) type of container and additives;
 - g) required equipment and reagents;
 - h) environmental and safety controls;
 - i) calibration procedures (metrological traceability);
 - j) procedural steps;
 - k) quality control procedures;
 - l) interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions;
 - m) principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values
 - n) biological reference intervals or clinical decision values;
 - o) reportable interval of examination results;
 - p) instructions for determining quantitative results when a result is not within the measurement interval;
 - q) alert/critical values, where appropriate;
 - r) laboratory clinical interpretation;
 - s) potential sources of variation;
 - t) 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.

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/CMB/SOP5.5-001-010	Procedure for clinical Microbiology tests
KAHGLH/CCH/SOP5.5-001-010	Procedure for Clinical Chemistry tests
KAHGLH/HEM/SOP5.5-001-010	Procedure for Haematology tests
KAHGLH/QAL/SOP5.5-001-010	Procedure for Serology tests
KAHGLH/IMH/SOP5.5-001	Procedure for CD3/CD4 Positive Cell Count Determination
KAHGLH/CMB/JA5.5-001-025	Job Aid for Clinical Microbiology tests
KAHGLH/CCH/JA5.5-001-010	Job Aid for Clinical Chemistry tests
KAHGLH/HEM/JA5.5-001-005	Job Aid for Haematology tests
KAHGLH/QAL/JA5.5-001-010	Job Aid for Serology test(s)
KAHGLH/IMH/JA5.5-001	Job Aid for Immuno-hematology test
KAHGLH/CMB/F5.5-001	Work Sheet for clinical Microbiology tests
KAHGLH/QAL/F5.5-001-002	Work Sheet for Serology tests
KAHGLH/CMB/SOP5.5-011	Procedure for Method Validation/Verification of Clinical Microbiology tests
KAHGLH/HEM/SOP5.5-011	Procedure for Method Validation/Verification of Haematology tests
KAHGLH/QAL/SOP5.5-011	Procedure for Method Validation/Verification of Serology tests
KAHGLH/CMB/SOP5.5-011	Procedure for Method Validation/Verification of Clinical Chemistry tests
KAHGLH/IMH/SOP5.5-002	Procedure for Method Validation/Verification of Immunohematology tests
KAHGLH/CMB/F5.5-002	Form for Method Validation/Verification of Clinical Microbiology tests
KAHGLH/HEM/F5.5-001	Form for Method Validation/Verification of Haematology test
KAHGLH/QAL/F5.5-003	Form for Method Validation/Verification of Serology tests
KAHGLH/CCH/F5.5-001	Form for Method Validation/Verification of Clinical Chemistry test
KAHGLH/IMH/F5.5-001	Form for Method Validation/Verification of Immuno-hematology test

5.17.6. Ensuring Quality of Examination Results

A. Purpose

This document provides the policy, guidance and indicating subsidiary documents for ensuring the quality of test results.

B. Policy

KAHGLH 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 (external quality assessment) (EQA) scheme such as proficiency test (PT). 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.

5.6.6.1. General

The laboratory shall ensure 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.

5.6.6.2. Quality control

5.6.6.2.1. General

The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.

5.6.6.2.2. 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.

5.6.2.3 Quality control data

The laboratory shall have 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 shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory shall also evaluate the results from patient samples that were examined after the last successful quality control event.

Quality control data shall be 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 shall be taken and recorded.

5.6.6.3. Inter laboratory comparisons

5.6.6.3.1. Participation

The laboratory shall participate 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 shall monitor the results of the inter laboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

NOTE: the laboratory should participate in inter laboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043. The laboratory shall establish 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.

Inter laboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

5.6.6.3.2. Alternative approaches

Whenever an inter laboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results. Whenever possible, this mechanism shall utilize appropriate materials.

NOTE Examples of such materials 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.

5.6.6.3.3. Analysis of inter laboratory comparison samples

The laboratory shall integrate 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 shall not communicate with other participants in the inter laboratory comparison programme about sample data until after the date for submission of the data. The laboratory shall not refer inter laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples

5.6.6.3.4. Evaluation of laboratory performance

The performance in inter laboratory comparisons shall be reviewed and discussed with relevant staff. When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff shall participate in the implementation and recording of corrective action. The effectiveness of corrective action shall be monitored. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.

5.6.6.3.5. Comparability of examination results

There shall be 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.

NOTE: 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 laboratory shall notify 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 shall document, record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be acted upon and records of actions retained.

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/IMH/SOP5.6-001	Procedure for CD ₄ in-house control
KAHGLH/IMH/SOP5.6-002	Procedure for CD ₄ quality controls out of range result

KAHGLH/HEM/SOP5.6-001	Procedure for haematology quality controls out of range result
KAHGLH/CCH/SOP5.6-001	Procedure for Clinical chemistry quality controls out of range result
KAHGLH/IMH/F5.6-001	CD ₄ Quality control monitoring Log
KAHGLH/HEM/F5.6-001	Haematology-Quality control monitoring Log
KAHGLH/CCH/F5.6-001	Clinical chemistry-Quality control monitoring Log
KAHGLH/ALS/SOP5.6-001	Procedure for graphical tools to communicate quality findings and identify trends
KAHGLH/ALS/JA5.6-001	Job aid on replicate of samples
KAHGLH/ALS/GDL5.6-001	Inter-laboratory comparison guideline
KAHGLH/ALS/SOP5.6-002	Procedure for inter-laboratory comparison
KAHGLH/CMB/JA5.5-001	Job Aid for Quality control monitoring of clinical Microbiology tests
KAHGLH/CCH/JA5.5-001	Job Aid for Quality control monitoring of Clinical Chemistry tests
KAHGLH/HEM/JA5.5-001	Job Aid for Quality control monitoring of Haematology tests
KAHGLH/QAL/JA5.5-001	Job Aid for Quality control monitoring of Serology tests
KAHGLH/IMH/JA5.5-001	Job Aid for Quality control monitoring of CD ₄ test
KAHGLH/HEM/F5.6-002	Haematology in-house control Form
KAHGLH/IMH/F5.6-002	CD ₄ in-house control Form

5.18. Post Examination Processes

A. Purpose

This document provides the policy, guidance and indicates subsidiary documents for post examination processes.

B. Policy

The laboratory shall have policy to systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results and storage of samples of the examinations.

5.18.1. Review of results

The laboratory shall have 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.

5.18.2. 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 (refer each examination procedure).

NOTE Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, pediatric examinations) may require the retention of certain samples for much longer periods than for other samples. Safe disposal of samples shall be carried out in accordance with local regulations or recommendations for waste management.

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/QAL/SOP5.7-001	Result Reviewing Procedure
KAHGLH/QAL/F5.7-001	Result Reviewing Form

5.19. Reporting of Results

A. Purpose

This document provides the policy, guidance and indicates subsidiary documents for reporting of result.

B. Policy

KAHGLH shall have policy 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.

KAHGLH shall report result within pre-defined turnaround time and special handling mechanism of “alert/critical” values must be in place. System has to place to monitor turnaround time with regards to clinical needs.

5.19.1. General

The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures. The laboratory shall

define 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 shall have a procedure to ensure the correctness of transcription of laboratory results. Reports shall include the information necessary for the interpretation of the examination results. The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care.

5.19.2. Report attributes

The laboratory shall ensure 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.

5.19.3. Report content

The report shall include, but not be limited to, the following:

- a. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;
- b. the identification of the laboratory that issued the report;
- c. identification of all examinations that have been performed by a referral laboratory;
- d. patient identification and patient location on each page;
- e. name or other unique identifier of the requester and the requester's contact details;
- f. date of primary sample collection (and time, when available and relevant to patient care);
- g. type of primary sample;
- h. measurement procedure, where appropriate;
- i. examination results reported in SI units, units traceable to SI units, or other applicable units;
- j. biological reference intervals, clinical decision values, or diagrams/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.

- k. Interpretation of results, where appropriate;

NOTE: Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.

- l. 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);
- m. identification of examinations undertaken as part of a research or development Programme and for which no specific claims on measurement performance are available;
- n. 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);
- o. date of the report, and time of release (if not contained in the report, readily available when needed);
- p. Page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.)

C. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP5.8-002	Procedure for establishing Turnaround time
KAHGLH/ALS/F5.8-001	TAT Monitoring format

5.20. Release of Result

5.20.1. Purpose

This document provides the policy, guidance and indicates subsidiary documents for release of result.

5.20.2. Policy

KAHGLH 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.

5.20.3. 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 (see 4.5)];

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 counseling may be needed. The laboratory should endeavor to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counseling.

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.

5.20.4. Automated selection and reporting of results

If the laboratory implements a system for automated selection and reporting of results, it shall establish a documented procedure to ensure that:

a) The criteria for automated selection and reporting are defined, approved, readily available and understood by the staff;

NOTE Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values.

b) The criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning;

c) There is a process for indicating the presence of sample interferences (e.g. hemolysis, icterus, lipaemia) that may alter the results of the examination;

d) There is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate;

e) Results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection.

f) There is a process for rapid suspension of automated selection and reporting.

5.20.5. Revised reports

When an original report is revised there shall be written instructions regarding the revision so that:

a) The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;

b) The user is made aware of the revision;

c) The revised record shows the time and date of the change and the name of the person responsible for the Change;

d) The original report entries remain in the record when revisions are made. (Ref ACCL/SOP5.8-

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 of such shall be kept.

D. Subsidiary Documents

Document Unique ID	Document Name
KAHGLH/ALS/SOP5.9-001	Notification procedure on “Alert” or “Critical intervals”
KAHGLH/ALS/SOP5.9-003	Procedure for distributing results including verbal, telephone, other electronic means
KAHGLH/LRS/F5.9-001	Format for interim report
KAHGLH/LRS/F5.9-002	Result distribution log
KAHGLH/ALS/SOP5.9-005	Procedure for notifying delayed examination
KAHGLH/ALS/SOP5.9-006	Procedure for corrected or amended result
KAHGLH/ALS/SOP5.9-007	Procedure for resolution of discordant result
KAHGLH/LRS/F5.9-003	Result Report Form
KAHGLH/ALS/JA5.9-001	Job aid for reporting critical results

5.21. Laboratory information management

5.21.1. Purpose

This document provides the policy, guidance and indicates subsidiary documents for laboratory information management.

5.21.2. Policy

KAHGLH shall have policy to standardize and access to laboratory data and information management. The laboratory shall define responsibilities and authorities for handling LIM. The laboratory shall have validate and verify Information system management prior to introduction of LMS.

5.21.3. General

The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user. The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

5.21.4. 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 (refer procedure KAHGLH/ALS/SPO 5.1-003).

5.21.5. Information system management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:(refer procedure KAHGLH/ALS/SPO 4.13-001).

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.

A. Subsidiary Documents

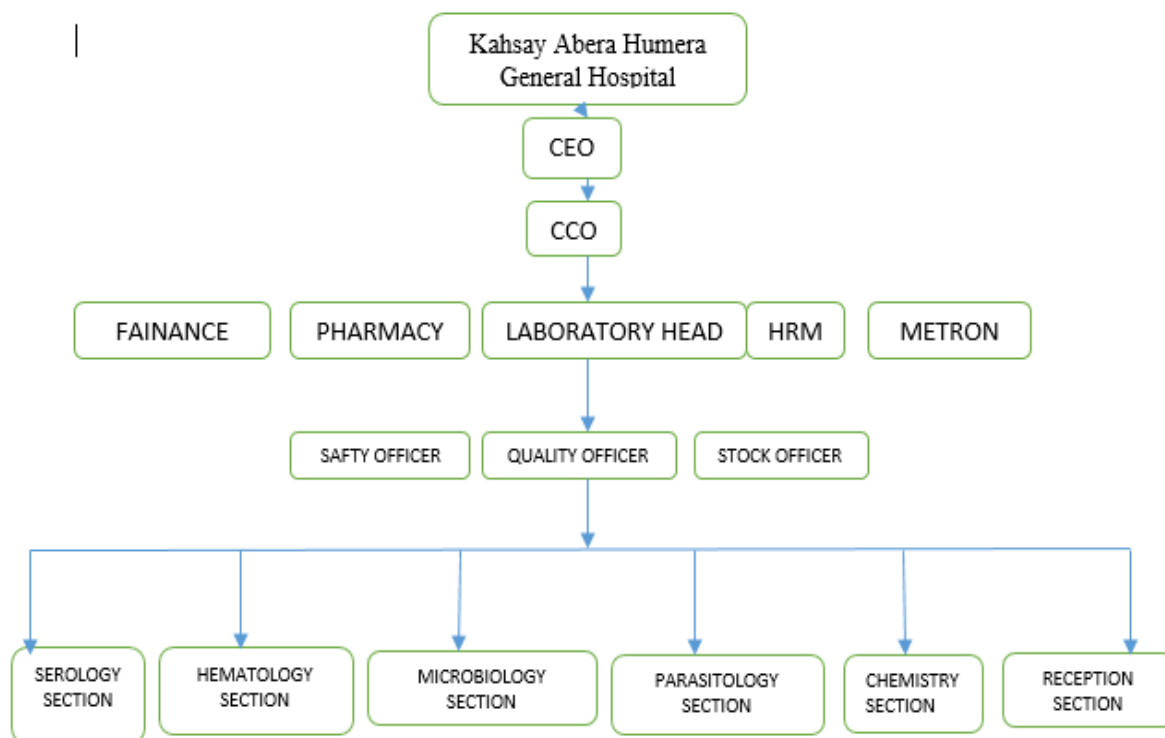
Document Unique ID	Document Name
KAHGLH/LRS/SOP5.10-001	SOP for Patient Data Entry at LIS computers
KAHGLH/ALS/F5.10-001	LIS Backup Log
KAHGLH/ALS/F5.10-002	LIS and analyzer result concordance reviewing format
KAHGLH/ALS/JA5.10-001	Job aid for How to use LIS in data entry

5.22. Reference:

- ISO 15189,2012 Medical laboratories – Particular requirements for quality and competence
- Kenya medical research institute centers for global health research, human immunodeficiency virus research laboratory quality manual, supersedes 05, version 06, 2013.
- Laboratory quality management system WHO (world health organization) 2011.

Annex 7: Organogram

Organogram of KAHGLH (KAHGLH / ALS/CHT4.1-001)



QUALITY POLICY MANUAL
FOR
TIGRAY REGION HEALTH BUREAU KAHSAY ABERA HUMERA
GENERAL HOSPITAL

Mebrahitu Assefa

01/April/2017

Prepared by

SIGNATURE

DATE

(Quality Officer Supervisor)

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01/April/2017

Reviewing authority

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DATE

(Laboratory Director)

Solomon Lema

01/April/2017

Approval authority

SIGNATURE

DATE

(Hospital Chief)

Effective Date: 01 April, 2017

Version No. 01

Document No: KAHGHL/ALS/QPM-01

Copy No. 0

Annex 9: Declaration:

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
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6. Chapter Six: Thesis

Title: Immunization coverage and Factors associated among children, Mekelle Tigray, Ethiopia

Authors: *Desta Birhane*¹, *Yemeisrach Abeje*², *Belaynehe Lulseged*³

Abstract:

Background:

Immunization is estimated to avoid between 2 and 3 million deaths globally each year. Immunization preventable diseases can affect in prolonged disabilities and can ensure a financial lost. In Ethiopian children from 12-23 ages' prevalence total immunization coverage 39 % and 16% was not taken any immunization all over the nation Ethiopia. However the aim is to assess the incomplete immunization in 12-23 age year children in the stated study area.

Objective: To assess complete immunization and factors associated with incomplete immunizations coverage in children 12-23 months in mekelle town.

Methods: Community-based cross-sectional study was conducted. The data collectors were visited at home and interviewed using pre-tested questionnaire about socio-demographic, knowledge status and other variables. Systematic random sampling technique was used. 573 samples calculated for 1st and 2nd objective after addition of design effect and 10% non-response rate by taking critical value at 95% confidence level of certainty from the actual figures for source population and power 80%. Data entered in to Epi info and analyzed by taking crud and adjusted odds ratio with 95% confidence intervals. Ethical clearance was obtained and consent form asked willingness to the eligible people.

Result: Of the 573 children, 542 (94.59%) were ever acquired one or more doses of vaccine and 31 (5.41%) had un-immunization, 69(12%) had immunized maternal recall only, about 473 (82.54%) by vaccination Card. Multivariate logistic regression analysis shows that; distance of immunization center, antenatal care, time of immunization inconvenient, concerned of immunization side effect, go to holy water after sick, variables were remained significantly associated with incomplete immunization.

Conclusion and recommendation: Overall the average complete immunization status was low. Based on the key finding there is need to increase the number of health facilities with Health workers, strengthening integrated community awareness.

Key words: immunization, mekelle town, children aged 12-23 months

6.1. Introduction

6.1.1. Background:

Global study shows approximately 45% of less than 5 age and nearly 86% of neonatal deaths occurring in developed countries. Early immunization of children and mothers had one way of intervention show reduced early child mortality. Working effectively in immunization has decrease the maternal and child mortality over the past two decade. An estimated 23 % neonatal death worldwide are infections causes and maternal under immunization (1).Immunization is one of the public health importance's to show as weather the morbidity and mortality is increased or decreased with time period and wealthy and effectively cost utilization. immunization have the power to save nearly 2 and 3 million deaths globally each year(2).

In Africa nearly three million children less than five year age dead because of children was not receive immunization.one in five children does not receive immunization due to low coverage health institution, infrastructure and lack awareness of about immunization.(3) In February 2016, minister's representativeness of African region singed agreement in immunization in Addis Ababa Ethiopia. Know a day 49 African country sing the agreement immunization. Additionally, three testimonial of support was signed by civil society organizations, religious leaders and parliamentarians to support implementation of the aid and reach every child in Africa with essential immunization.(4)

Ethiopia immunization program started 1980 with the aim of increasing 10% yearly. Though in the first 20 years very slow increment. The expansion to every health facility process has implemented in the meantime 2004 with low coverage and high dropout. so through this way Ethiopia shows an improvement in 2003 DPT coverage from 53% to 87% in 2014.even though the difference coverage among Ethiopia regions present massive.(5). between 1999 - 2013 around 15 million women age (15-49) in 62 Ethiopian regions received TT immunization in three round except Addis Ababa, Harare and dire dawa .after receiving this TT immunization the supplemental immunization activities (SIAS) assessed the high risk zones in Ethiopia in 2011 animate pre-validation assessment. so the nation to some extent validated to have eliminated neonatal tetanus (5). In EDHS 2016 all Ethiopian children from 12-23 age prevalence total immunization coverage were 39 % and 16% were not taken any immunization all over the nation(6). In early assessment of the immunization coverage show gap in from region to region

especially for those who are pastoralists persistently inequalities backward from the others. So the ministry of health collaborated with the other stack holders like UNICEF and other EPI focal were discussed on how to implement in the periphery health institutions on how to give immunization with consistency agreed and signed in julay2014. (5)

The aim of this study was to assess immunization coverage and identify factors affecting incomplete immunization among 12-23 month children, in addition to determine the socio-demographic, socioeconomic, and other factors associated with complete immunization in Tigray region, municipal of mekelle city, north Ethiopia.

6.1.2. Statement of the problem in immunization

Immunization is an important tool for children to live healthier and to eliminate or minimize the infectious diseases and also decreased approximately 2 to 3 million deaths in each year worldwide. absence of immunization in children is not only related directly to mortality and morbidity but also a big problem in economical crisis(7). Between 2000 and 2013 only measles received immunization prevents 15.6 million children globally. study shows in 2015 in every day 16,000 children less than 5 year continues to die mostly from infectious diseases globally(8).

In Africa shows numerous reasons have been given for the occurrence of lost chance for immunization in low and middle income countries. these include; health systems factors, services provider factors, child type factors, caretaker factors, cultural factors, low parental education, non-availability of immunizations, failure by facilities to immunize on all days of the week, or negative pa-rental beliefs, inappropriate health worker practices; including not opening a multi dose immunization for a small number of persons to avoid immunization wastages; and logistical problem.(9)

In Ethiopia during 2012-2016 survey shows the total less than five year age mortality 67 deaths per 1,000 children live births when compared with the previous study 2002-2006 it shows a remarkable decrement 116 deaths per 1,000 live births.so Ethiopia records a knew improvement in children death from time to time. (6).according to the 2016 EDHS study shows the whole nation age 12-23 which does not immunization at list one dose were sixteen percent. BCG, pentavalent1, polio, PCV1, rotavirus1 and measles in average from 54-81% were immunized(6).

The Tigray regional health bureau was not studded in mekelle zone about immunization status. So this is an install or baseline study to fill the gap in the factors affected incomplete immunization coverage in children age 12-23 category. In this context, understanding the risk factors for immunization is key to increase immunization and infection prevention in children.

6.1.3. Rational of the study

As clearly stated that in the statement of the problem, the prevalence of immunization and its risk of causing death is greater and common in different part in developing world especially in Ethiopia. Different reasons contribute for the deaths of children's. So, identifying immunization coverage and associated common factors with incomplete immunization support for the interest

of health planers to control the problem. So this is important to make appropriate prevention and reducing communicable diseases and deaths.

In addition to the above, little is known about risk factors of immunization in our country. Therefore, this study serves as base line information about factors associated with incomplete immunization in the country. These studies also help researchers as input for other studies which conducted on the related subject matter in the future.

6.2. Literature review:

6.2.1. Immunization coverage Globally, Africa and Ethiopia

Globally 19.5 million infants were not received immunization DPT. sixty percent of the challenges found in Angola, Brazil, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Iraq, Nigeria, Pakistan and South Africa.(10). Measles, Rota and Rubella are common infectious viruses disease which common in children. by the end of 2016 globally immunization coverage were,85% one dose, 25% and 47% respectively(10).

Even though in Africa a wonderful improvement has made in the past four decades .but still know a big challenge in children who did not take immunization in morbidity and mortality. Approximately 22 %(4.3 million) less than one year age globally not immunized are found in Africa (Democratic Republic of the Congo, Ethiopia, Nigeria and South Africa). (11) . studies in Nigeria shows about 96 percent of mothers were ANC (antenatal care) follows and 63% of the children age between 12-23 months approved immunization cards(12). WHO-UNICEF regional Africa estimated the DPT3 Africa coverage in 2014 was 77%.this is less than 60 % found in 5 countries, 90% found in 18 countries. the same to that measles also 14 countries have coverage of 90% or more; seven countries have coverage levels of less than 60%(13)." in 2014, 7.4 million infants in the WHO African region did not receive the third dose of DPT immunization, out of an annual birth cohort of 32.7 million approximately 23%"(13).

"Overall in Ethiopia 2011 EDHS, 24 percent of children age 12-23 months was fully vaccinated at the time of the survey. while this represents a 19 percent increase from the level reported in the 2005 EDHS, the percentage of children who are fully vaccinated remains far below the goal of 66 percent coverage set in the HSDP IV (MOH, 2010)" (14).study shows in rural southwestern Ethiopia, 78% of children age 12-23 had ever been immunized at least one type of immunization. however, only 37% of children age 12-23 months had received all basic recommended immunization.(15) Similar to this study in Ethiopia Somalia Jigjiga 74.6% of the children surveyed were ever vaccinated at list one dose; whereas 36.6% was fully vaccinated. the immunization coverage rate from card assessment for bacillus calmette-guérin, oral polio immunization zero, oral polio immunization one, oral polio immunization two, oral polio immunization three, and measles were not greater than approximately 25%(16).

6.2.2. Factors affecting complete immunization

In Haiti children received in supplementary immunisation activity(ASI) survey measles and rubella immunization in age category 1-4 years were lower (31%) significantly because of low educational level in caretakers.(17)

There are a lot of factors that makes immunization low coverage according to the study same of them are parents lack access because of poor quality health services, long distances or lack of money. Other may not trust vaccines or the healthcare workers who provide the immunization, or they may not understand importance for immunization due to a lack of information or false propaganda about how immunization work and the diseases they can prevent(18).Studs in low and middle income countries regular outreach immunization may improve full immunisation coverage (OR 3.09, 95% CI 1.69 to 5.67)(19). in 2014 study shows in urban Uganda Kampala only 33% of served caretaker or respondents were agreeable to receive the immunization after waiting of three or more hours(20).

In east Africa Kenya Pokot the main factor make low immunization were, place where the chilled birth, literacy level, children with in their family ($p=0.02$, $OR=1.61$.), knowledge on the immunization schedule ($p= 0.0000$, $OR= 9.04$), nomadic life style ($p= 0.0000$ $OR = 11.06$).Family income ($p= 0.0037$, $OR= 2.71$) and area of residence ($p=0.0000$, $OR = 12$) (21).

In the survey EDHS 2016 study indicates the immunization affects by mothers educational status as well as household wealth that means when the education and economic status of the Mather increases corresponding to the child immunization also increases(6).

In Ethiopia the immunization coverage were more affected by factors where in Tigray, Addis Ababa, and Diredawa administrative. Mothers who know immunization program, never married. Female children, live highlanders, Orthodox followers, single parity and first birth order, husbands' secondary education, born at health facility, mothers attended ANC and mothers who have a postnatal check-up within 2 months after birth had full vaccination coverage in the country(22).

Conceptual frame work (23)

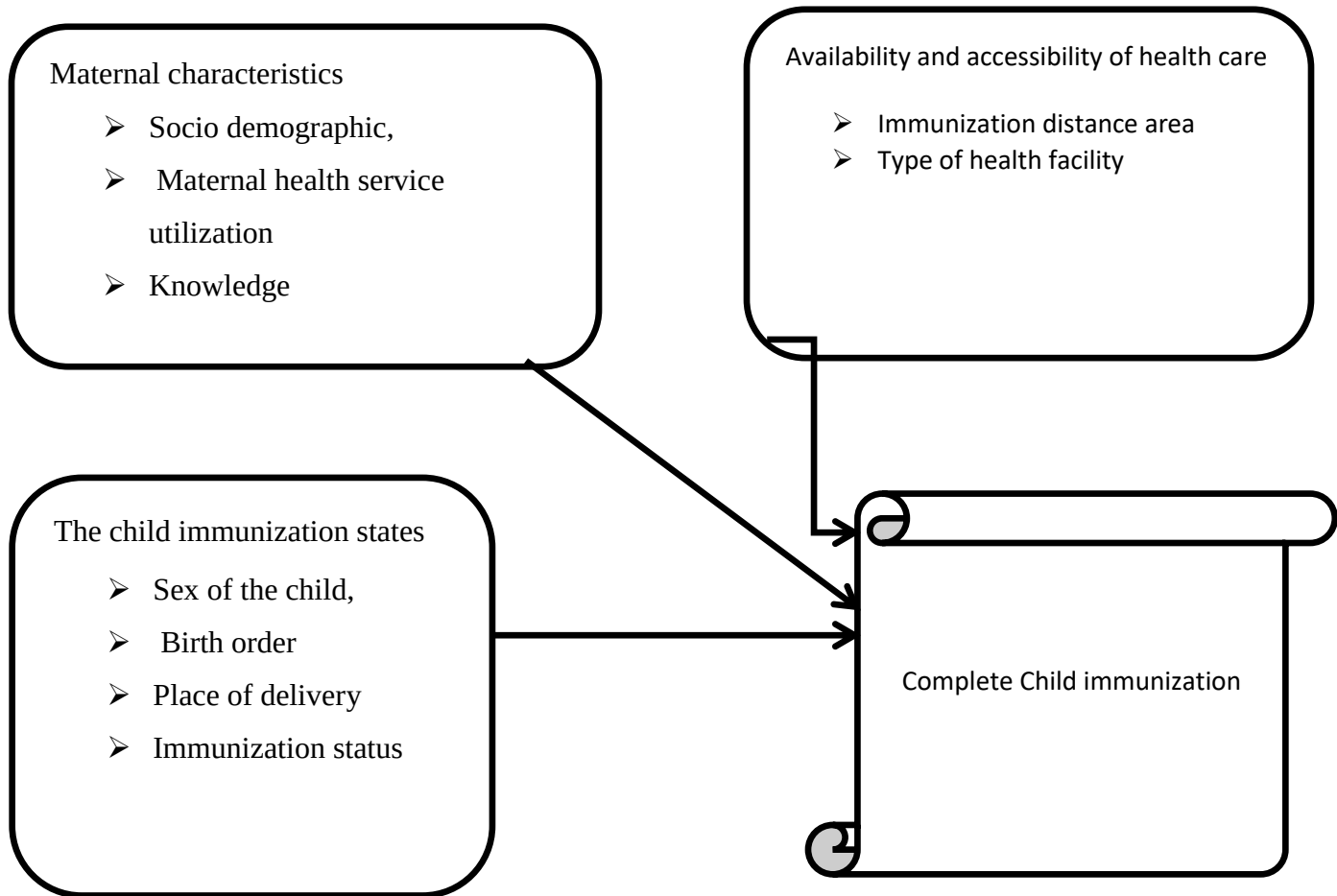


Figure 18:- Conceptual framework for factors affecting immunization status of the children aged between 12-23 months.

6.3. Objectives:

6.3.1. General objective

To assess complete immunization and associated factors with incomplete immunization among children aged 12-23 months in mekelle town, Tigray region, north Ethiopia.

6.3.2. Specific objectives

To determine the immunization coverage among children aged 12-23 months.

To identify factors associated with incomplete immunization among children aged 12-23 months.

6.4. Methods and materials

6.4.1. Study area and period

This study was conducted in Mekelle special zone, northern Ethiopia. Mekelle is the capital city in the northern Tigray region of Ethiopia. It is located around 780 kilometers north of the Ethiopian capital Addis Ababa, at a latitude and longitude of 13°29'n 39°28'e, with an elevation of 2084 meters above sea level and temperature above 18°C. Administratively, Mekelle is considered a special zone, which is divided into seven sub-cities (districts). These are Addi-Hak'i, Ayder, Haddinet, Hawelti, Qedamay Weyyane, Kwiha, and Semien. Based on the 2007 census conducted by the central statistical agency of Ethiopia (CSA), this town has a total population of 334,260 people (164,134 men and 170,110 women). (24). There are 3 hospitals (1 specialized, 1 zonal & 1 district), 10 health centers. The study was conducted from August 30, 2017 to February 30, 2018 in Mekelle town, Tigray region, north Ethiopia.

6.4.2. Study design

Community-based cross-sectional study design was conducted among children aged 12 to 23 months.

6.4.3. Source population

All children age between 12-23 months in Mekelle zone.

6.4.4. Study population

Children age between 12-23 months in selected cluster

6.4.5. Study unit

Selected children aged between 12-23 months found in individual households.

6.4.6. Sample size determination

The sample size was determined for the first objective based on sample size calculation for single population.

$$n = \frac{(Z_{\alpha/2})^2 P(1 - P)}{D^2} = 366$$

Adjust to population size (N) – if (N < 10,000), where n_0 is the calculated sample size

$$n = \frac{n_0}{1 + n_0/N} \quad n = \frac{366}{1 + 366/6653} = 346$$

Since the sample size was taken from a relatively small population ($n < 10,000$) $n = 6653$ the required minimum sample size was obtained by making adjustment using population correction

formula $n=346*1.5=519$. And also the total sample size consider the non-responding rate 10% total $n=573$.

Where,

p = proportion of children who did complete immunization (39%) (EDHS 2016)

d = margin of error = 0.05

n = minimum sample size

$Z_{\alpha/2}$ = confidence level required and $Z_{\alpha/2}$ at 95% ci = 1.96

DE=design effect is taken as 1.5 (complex cluster or multi stage design)

So the total of 573 children aged between 12-23 months was targeted for the study.

Additionally sample size was calculated for the second objectives based on sample size calculation by double population proportion, such as factors associated with incomplete immunization using Stat calc Epi info by taking previous study variable antenatal care follow up (exposed 62.9% and unexposed 37.1% $n=132$)(23). So the sample size for the first objective was the largest one 573 taken as a final sample size for this study.

6.4.7. Sampling procedure

A multistage sampling procedure was used. From the seven mekelle town woredas (mekelle special zone) three woredas cluster was selected randomly. Since those three woredas was the places where the same (homogeneous) to the others woreda was have a representative sample taken. Each district included no less than five kebeles areas within 1-5 k/m Radius of mekelle town. Each of them was have in average at least involved 206 households which have 12-23 age children.

As clearly shown below in the figure (2) all the fourteen kebele who have the eligible age group household was selected directly from the above three districts (woredas). by making sample proportion calculation against the total sample size the study unit was taken .all respondents was consider homogenous in terms of being alien to the place of study as a result immunization status areas served to have a representative sample. Households study unit from each kebele respondents was selected by systematic random sampling technique from the previous 2008 lists of health extension registration book that have eligible criteria to the study. The sampling interval was selected per each kebele example Aynalem has total 196 children in order to select 40 children needs interval 5 down the list.

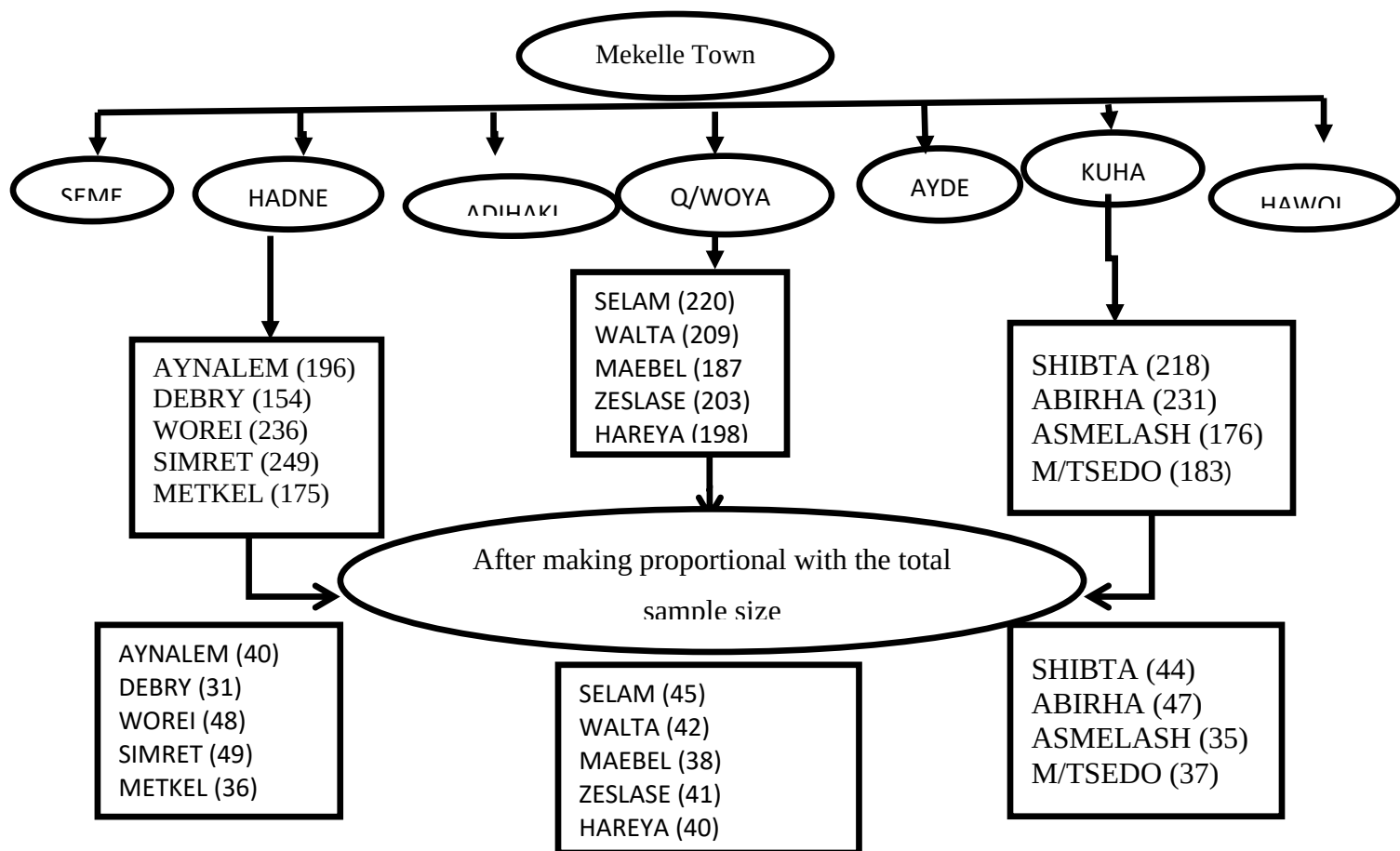


Figure 19: Sampling procedure from work

6.4.8. Data Collection Procedure

Ten health extension workers who know the kebeles or areas well with a commitment to face challenges was review or collected the data from house to houses from the eligible study units. Socio-demographic, economic, quality of immunization related questions and variables apply to immunization coverage was gathered using a structured questionnaire. A medical immunization ID card or by asking question was used to review employed to gather information.

6.4.9. Data quality control

The questionnaire used for study was adopted from Ethiopia demographic health survey (EDHS) and from the previous researches done in other places. Questionnaire was translated from English to Tigrigna and back to English as well to reaffirm consistency. Training was given to data collectors and supervisor before data collection for one day. The questionnaire was pre-

tested for 20 households in adihaki kebele other than my study kebele to see the completeness and appropriateness to the local context and as per correction was taken seriously.

6.4.10. Inclusion criteria

Children who are between 12-23 month age group

6.4.11. Exclusion criteria

Children age 12-23 month whose parents/caretakers was not willing to give consent and children whose parents/caretaker could not have immunization card or not remember the number or type of vaccine they had received.

6.4.12. Study variables

6.4.12.1. Dependent variable (outcome variable)

Immunization status

6.4.12.2. Independent variable

Socio-demographic characteristics

Time of travel to reach the nearest health facility

Maternal health care utilization

Health service availability and related characteristics of respondents

Knowledge of mothers/caretakers

6.4.13. Data processing and analysis

Data was entered into Epi info version 7.2.1.0 and analyzed using SPSS version 21. Summary statistics such as, tables, percentages, graphical techniques for descriptive and logistic regression were used to test the association between the independent and the outcome variables. All explanatory variables that will be associated with the outcome variable in bivariate analyses were included into multivariate logistic regression to avoid confounder variable, to determine factors that are significantly associated with immunization incompleteness rate. P-value of 0.05 was considered as a cut-off point for statistical significance.

6.4.14. Ethical clearance

Ethical clearance was obtained from St. Paul's hospital millennium medical college department of public health, institutional review board (IRB). The IRB reviewed the above mentioned

research proposal and made decision approved on October /04/2017. So lastly official letter was written to me the decision is valid for 12 months and given to the organization where the study was conducted TRHB (Tigray regional health bureau (mekelle zone, under mekelle zone health facilities & health offices). the consent with the people participated in the study was asked their willingness as in the annex I part expressed. After agreed the data collection was started.

6.4.15. Dissemination of the study finding

The finding was prepared and shares the written report of both hard and soft copies to St. Paul hospital millennium medical college department of public health (SPHMMC), Tigray regional health bureau (TRHB), mekelle special zone health department and all visited woreda health offices, and, resident advisors in EPHI coordinator. The finding was also being presented for different work-shops and seminars and will be published in a peer reviewed journals.

6.4.16. Operational definitions

Complete (full) immunization: the childhood immunization status once a child has received all recommended immunizations, including BCG, three doses of pentavalent, and four doses of polio and one dose measles, 3 dose Rota immunizations, 3 dose PCV by the age of 12 months as in Ethiopian context

Dropout rate (DOR): the percent of children who received the initial dose immunization (PCV, Oral Rota viruses, OPV1, pentavalent1) but not the final dose immunizations (Example: pentavalent2 or 3).

Incomplete (partial) immunization: the childhood immunization status if the child missed at least one of the recommended immunizations.

Missed opportunities: if an eligible child visited the selected health facility or outreach site but didn't receive any or all of the immunizations for which he/she is eligible.

Knowledge of immunization: If mother/caretaker has awareness about immunization and answers the question above mean score = considered as very good knowledgeable, below mean score = considered as poor knowledgeable, in the mean score = considered as moderate knowledgeable.

UN immunization: a child who does not receive any dose or type of the immunization

Measurement of distance by time = less than 10 minutes = very near distance; 16 to 30 minutes= near distance; 31 to 60 minutes = moderate distance; Greater than one hour = far distance (21)

6.5. Results

6.5.1. Descriptive part of the results

6.5.1.1. Socio- demographic characteristic of the Primary guardians of children 12-23 months, Mekelle Town, Northern Ethiopia

Of the 573 children studied 542 (94.59%) were ever took one or more doses of vaccine and 31 (5.41%) had not vaccinated at list one dose by maternal recall and immunization card checking, 69(12%) had immunized maternal/caretaker recall only. Children from these about 473 (82.54%) had vaccination card during the study. Of the 573 children studied 72% were ever took full immunization with immunization card only. Socio demographic characteristics of respondents showed that a total of 573 (with 100% response rate) were included in the study. The mean age of caregiver's and children were 28.55(min16 to max75) years, and 16.68 months, respectively. The sex distribution of children shows that 276 (48.17%) males and 297(51.83%) of were females. With regard to types of caretakers of the children, both mothers and fathers 468(81.68%), mothers 94(16.40%), father 9(1.57%) and other than parents 2(0.35%).Majority of the marital status of the caretaker indicates that 513(89.53%) were married. The educational level of caretakers 112(19.5%) had no formal education, 207(36.13%) grades1-8, and 254(44.32%) grade 9 and above.

Most of the children's mothers were 558(97.38%) attended antenatal care clinic during pregnancy and 546 (95.29%) delivered in a health facility. With regard to child birth order 232(40.49%) were born in the first,150 (26.18%) second birth order, 97(16.93%) third birth order, and 94(16.40%) greater than third birth order. Respondent children household family size indicated that 194(33.86%) first family size, 174 (30.37%) second, 87(15.18%) third family size, and 118 (20.59%) were had more than four family size. The mean children household family size was approximately 3 with minimum 1 and 9 maximum.

Majority 325 (56.72%) of these caretakers were unemployed, and 553 (96.51%) were of the Christian faith as shown in table 26.

Table 26 : Socio- demographic characteristic of the Primary guardians of children 12-23 months, Mekelle Town, Northern Ethiopia

Name of variables categories		Frequency n=573	Percent
Primary Care taker age category	16-25Age	203	35.43%
	26-40Age	360	62.83%
	> 41Age	10	1.75%
Woreda of the Primary Care taker	Hadnet	204	35.60%
	Kuha	163	28.45%
	Q/Weyyane	206	35.95%
Educational status of the Primary Care taker	Illiterate	61	10.65%
	Read and write	51	8.90%
	Grade 1-8	207	36.13%
	Grade 9-10	176	30.72%
	College and university	78	13.61%
Religion of the Primary Care taker	Muslim	20	3.49%
	Orthodox Christian	553	96.51%
Mothers Marital Status	Divorced	21	3.66%
	Married	513	89.53%
	Single	33	5.76%
	Widowed	6	1.05%
Occupation Primary Care taker	Daily laborer	65	11.34%
	Farmer	24	4.19%
	Government /privet employ	72	12.57%
	Housewife	325	56.72%
	Merchant	83	14.49%
	Others	4	0.70%
Children family size ever born	1	194	33.86%
	2	174	30.37%
	3	87	15.18%
	4	74	12.91%
	>5	44	7.67%
Birth order of children	First	232	40.49%
	Second	150	26.18%
	third	97	16.93%
	Greater than three	94	16.40%
Children who live in life	1	196	34.21%
	2	175	30.54%
	3	94	16.40%
	4	66	11.52%

	>5	42	7.33%
Have you ever had your child immunization	Yes	542	94.59%
	No	31	5.41%
Immunization with card	Yes	473	82.55%
	No	100	17.45%

6.5.1.2. Health service availability and related characteristics of respondents

The availability and accessibility of health facility for immunization was measured by presence of the service and average walking time to reach the health facility. All 100% of the respondents were reported that they had access to the health facility that provides immunization services and majority of the reported 433(75.57%) that they were more access to health center followed by hospital 116(20.24%) and the remaining 7(1.22%) in health post. Respondents walking time to reach the nearest health facilities for immunization was <10 minutes 98(17.10%), 16 to 30 minutes 323(56.37%), 31 to 60 minutes 116(20.24%), >1 hours 12(2.09%) and they did not know the time 24(4.19%). About 558(97.38%) of mothers had followed at least one ANC follow up while pregnant her last birth child. With regard to Place of mother deliver her last child, 546 (95.29%) were delivered at health institutions, 22(3.84%) at home and Privet or NGO health facility 5(0.87%). The majority of mothers of the children were 500(87.26%) immunized tetanus toxoid (TT) while pregnant (Show Table27).

Table 27: Health service related characteristics of Primary Guardians of children aged 12-23 months, Mekelle Town, Northern Ethiopia, 2017

Types of variable		Frequency	Percent
Nearest health facility for immunization	Yes	573	100.00%
Type of health facility for immunization			
Hospital	Yes	116	20.24%
	No	457	9.76%
Health center	Yes	433	75.57%
	No	140	24.43%
Health post	Yes	7	1.22%
	No	566	98.78%
Time to reach the nearest immunization center	< 10 minutes	98	17.10%
	16 to 30 minutes	323	56.37%
	31 to 60 minutes	116	20.24%
	>1 hours	12	2.09%
	I did not know	24	4.19%
Mothers ANC follow up while pregnant	Yes	558	97.38%
	No	15	2.62%

Number of ANC follow up	1	2	0.35%
	2	29	5.11%
	3	81	14.29%
	4	281	49.56%
	>5	127	22.40%
	I did not know	47	8.29%
Place of mother deliver her last child	Health facility	546	95.29%
	Home	22	3.84%
	Privet or NGO health facility	5	0.87%
Did the Mather ever immunized TT	Yes	500	87.26%
	No	73	12.73%
How many times receive TT	1	2	0.35%
	2	29	5.11%
	3	81	14.29%
	4	281	49.56%
	5	86	15.17%
	>6	21	3.70
	I did not know	47	8.29%

6.5.1.3. Characteristics of immunization status among children aged 12-13 months, Mekelle Town, Northern Ethiopia, 2017

The outcomes of each type immunization 12-23 month age children by checking vaccination card was show as follows: approximately all types of immunization were the same in dropout rate except low in OPV₀ 72% flowed Measles 79.7%. By district Children of full immunization coverage with checking cards were recorded for 26.35% Hadnet followed by kuha 24.60%, and, Qedamay Weyyane district 20.76 % (as showed inTable28).

Table 28: Characteristics of immunization status among children aged 12-13 months, Mekelle Town, Northern Ethiopia, 2017

Variable Immunization type		Frequency n=573	Percent
BCG	Yes	461	80.45%
	No	112	19.55%
OPV0	Yes	413	72.08%
	No	160	27.92%
OPV1	Yes	464	80.98%
	No	109	19.02%
OPV2	Yes	463	80.80%
	No	110	19.20%
OPV3	Yes	465	80.80%
	No	110	19.20%

DPT HepB Hib1(Pentavalent1)	Yes	466	81.33%
	No	107	18.67%
DPT HepB Hib2(Pentavalent2)	Yes	464	80.98%
	No	109	19.02%
DPT HepB Hib3(Pentavalent3)	Yes	463	80.80%
	No	110	19.20%
PCV1	Yes	465	81.15%
	No	108	18.85%
PCV2	Yes	465	81.15%
	No	108	18.85%
PCV3	Yes	461	80.45%
	No	112	19.55%
ROTA1	Yes	465	81.15%
	No	108	18.85%
ROTA2	Yes	462	80.63%
	No	111	19.37%
MEASELS	Yes	457	79.76%
	No	116	20.24%
Vitamin A	Yes	262	45.72%
	No	311	54.28%
Hadnet	Yes	151	26.35%
Kuha	Yes	141	24.60%
Qedamay Weyyane	Yes	119	20.76%

6.5.1.4. Immunization related Questions by recall history respondents

Majority of respondents they did not know the right answers weathers the child received the immunization with the right dose or not by remembering the past time. The core reasons children did not get or drop out their immunization were expressed the respondents as follow; I did not know the advantage of vaccine 109(19.02%), Being unaware of the need to return for subsequent doses 63 (10.99%) and Time of vaccination inconvenient with respondents 37(6.46%) as showmen below tables 29.

Table 29: Immunization related Questions by recall history respondents

Variables		Frequency	Percent
Child received BCG vaccine on the right hand scar	Yes	10	1.75%
	No	563	98.25%
Did your child received Polio vaccine oral drop	Yes	14	2.44%
	No	559	97.56%
How many times your child did receive polio	1	10	1.91%

vaccination	2	53	10.11%
	3	126	24.05%
	4	243	46.37%
	>5	4	0.76%
	I did not know	88	16.79%
Your child received measles vaccine at the age of 9 months on the left leg	Yes	530	92.50%
	No	31	5.41%
	I did not know	12	2.09%
Reason children did not get their immunization			
I did not know the advantage of vaccine	Yes	109	19.02%
	No	464	80.98%
Being unaware of the need to return for subsequent doses	No	510	89.01%
	Yes	63	10.99%
Did not know where and when to get vaccination	Yes	27	4.71%
	No	546	95.29%
Concerned about side effects	Yes	16	2.79%
	No	557	97.21%
Distance from the clinic was too far	Yes	31	5.41%
	No	542	94.59%
Time of vaccination inconvenient	Yes	37	6.46%
	No	536	93.54%
Shortage of vaccine	Yes	5	0.87%
	No	568	99.13%
Family problem illness of the mother lack of husband support	Yes	11	1.92%
	No	562	98.08%
Long line Waiting time	Yes	15	2.62%
	No	558	97.38%

6.5.1.5. Knowledge assessment of children caretakers' age 12-23 month in Mekelle Town, Tigray Northern Ethiopia, 2017:

Generally children guardians were have poor knowledge about immunization related questions from 4,011 questions by responding 2,751 the right answer and registered below average mean score 393. Majority of respondents were heard about immunization from health workers 220(38.39%), radio 78(13.61%), TV 74 (12%) and the remaining from other sources. The main type of information respondents get were about advantage of immunization 246 (42.93%), followed by campaign immunization 81(14.14%). Respondents knowledge on schedule of vaccination indicates

that 64(11.17%) had low knowledge on schedule of vaccination. respondent's about immunization side effects were not heard 553 (96.51%) and 20(3.49%) had the heard about immunization side effects. The majority of guardians were answers the question when start child immunization; after birth 24 hours 385(67.19%), greater than one week after birth 97(16.93%), after birth from 2 day to one week 49(8.55%), and I did not know 42(7.33%).

The majority of guardians were believed immunization of children's preventing disease 537(93.72%). Respondents level of satisfaction on immunization service showed that 484(84.47%) =Good, 51(8.90) =Medium, 29(5.0%) = I did not know, and 9 (1.57%) = No response.

Table 30 : Knowledge assessment of children caretakers' age 12-23 month in Mekelle Town, Tigray Northern Ethiopia, 2017:

Variables		Frequency	Percent
Did you get any information about immunization	Yes	291	50.79%
	No	282	49.21%
Radio	Yes	78	13.61%
	No	495	86.39%
Television	Yes	74	12.91%
	No	499	87.09%
Health worker	Yes	220	38.39%
	No	353	61.61%
From Community meeting	Yes	65	11.34%
	No	508	88.66%
1 to 5 network leader	Yes	62	10.82%
	No	511	89.18%
Health extension worker	Yes	12	2.09%
	No	561	97.91%
What kind of information did get about immunization			
Campaign vaccination	Yes	81	14.14%
	No	492	85.86%
Advantage of vaccination	Yes	246	42.93%
	No	327	57.07%
Where to get regular immunization	Yes	82	14.31%
	No	491	85.69%
Do you know the eligible age of children to get vaccine	Yes	4	0.70%
	No	569	99.30%
Vaccination schedule	Yes	64	11.17%

	No	509	88.83%
New vaccines	Yes	12	2.09%
	No	561	97.91%
In your opinion when did the child start immunization	After birth from 2 day to one week	49	8.55%
	after birth in 24 hours	385	67.19%
	Greater than one week after birth	97	16.93%
	I did not know	42	7.33%
Do you think vaccines can prevent diseases	No	1	0.17%
	Yes	537	93.72%
	I do not know	35	6.11%
Do you Heard the side effect of vaccine	Yes	20	3.49%
	No	553	6.51%
Satisfaction rate in immunizations service	Good	484	84.47%
	I do not know	29	5.06%
	Medium	51	8.90%
	No response	9	1.57%
Where did you go when the child sick			
Health facility	Yes	556	97.03%
	No	17	2.97%
Holy water	Yes	32	5.58%
	No	541	94.42%

6.5.2. Analysis part of the results

6.5.2.1. Binary Logistic Regression Analysis:

The children 12-23 month age immunization status bi-variate analysis showed that, the Sex of caretaker of children, mothers ever TT immunized, did not know the advantage of immunization, Unaware of the need to return for subsequent doses, did not know where and when to get vaccination, time of immunization inconvenient, worried of immunization side effect, confirmation of birthday, Go to health facility after sick, Go to holy water after sick, Pregnant women follow up clinic(ANC), were variables significantly associated with incomplete childhood immunization and then filtered for multivariate analysis.

Some of the Factors associated with incomplete immunization among children aged 12 – 23 months by cured Odds ratio. The odds of incomplete immunization were high for children caretaker female sex than male [(OR = 2.02; 95% CI: 0.9 – 4.3)]. Children mothers who were immunized TT during pregnant period were less times incomplete immune to their childe than those who did not immunized TT [(OR= 0.04; 95% CI: 2.03-6.21)]. Additionally children of mothers who had with immunization cared at the data collection time were preventable

association than those mothers without immunization cared [(OR = 0.01; 95% CI: 1.0 – 15.3)]. Children caretakers who were worried of side effect immunization 23.2 times more likely to be incomplete immunized compared to children caretakers who did not worried of side effect immunization [(OR=23.2(8.0-67.3)].

However most of the other variables like; Educational status of the Primary Care taker, Marital status, religion of the Primary Care taker, Occupation Primary Care taker, Children family size ever born, type of health facility for immunization, Did you get any information about immunization, religion, birth order of the children, were not associated with incomplete immunization.

6.5.2.2. Multivariate logistic regression analysis

The multivariate logistic regression analysis variables like shows that; did not know the advantage of immunization, did not know where and when to get vaccination, distance of immunization center, time of immunization inconvenient with caretaker, worried of immunization side effect, children go to holy water after sick, pregnant follow-up clinic during pregnancy time variables were stayed to be significantly associated with incomplete children immunization.

Caretaker of the children's did not know the advantage of immunization were more associated with children incomplete immunization than those caretakers who know the advantage immunization [AOR=18.17 (95% CI: 7.5 – 43.6)]. Children of guardians who did not know where and when to get vaccination were more significantly associated with incomplete immunization than those guardians who know the place and time [AOR=2.7 (95% CI: 0.75 – 10.5)]. Children who live in far distance from health institution immunization center were more likely associated with incomplete immunization than near lived. [AOR=26.1 (95% CI: 14.2 – 102.1)]. In addition mothers of the children who had time inconvenient for immunization children were more likely 5.5 times associated with immunization incompleteness than mothers had convenient time [AOR= 71.0 (95%CI: 16.8-130)].

Furthermore, Children who had go to holy water after sick were 21.4 times more likely to incomplete immunization status compared to children who were not go to holy water after sick.

[(AOR=21.4(95%CI: 4.9-92.8)]. Mothers or caretakers who were had worried of in appropriate awareness on immunization side effect were 3.4 times more likely to be their children to

incomplete immunization than mother who had not worried of immunization side effect trust. [(AOR: 3.4(95% CI: 2.8 - 6.29)]. Children who were born from mothers who had pregnancy follow-up (ANC) visit during pregnancy were less times to incomplete immunization compared to infants who were born from mothers who had not antenatal care visit during pregnancy [AOR= 0.01 (95%CI : 0.002 - 0.064)].

However variables like Mather's ever TT immunized, sex of caretakers, do you have immunization card, Unaware of the need to return for subsequent doses about in immunization, confirmation of child birthday and go to health facility after child sick were measured as the confounder in adjusted rigration.

Table 31 : Bi-variate and Multivariate analysis of immunization status among children 12-23 age months live in Mekelle town, Northern Ethiopia, 2017

Variable		Immunization Status		Cured OR (95% CI)	Adjusted OR (95% CI)
		No	Yes		
Sex	Female	21	276	2.02(0.9-4.3)	0.8(0.28-1.08)
	Male	10	266		
Mother immunized TT	Yes	15	478	0.04(2.03-6.21)	NI
	No	16	64		
Do you have immunization card	Yes	0	473	0.01(1.0 – 15.3)	NI
	No	31	69		
Did not know the advantage of immunization	Yes	23	86	18.17(7.5-43.5)	44.1(2.4 – 83.6)
	No	8	456		
Unaware of the need to return for subsequent doses	Yes	20	52	5.15(2.7-16.32)	0.29(0.02-3.2)
	No	11	490		
Did not know where and when to get vaccination	Yes	8	27	6.6(12.8-184.9)	2.7(0.75-10.4)
	No	23	515		
Distance of immunization center was far	Yes	22	33	37.7(16.7 – 88.0)	13.4(14.2 – 102.1)
	No	9	509		
Time of immunization inconvenient	Yes	13	24	15.5(6.84-35.47)	71(16.8-130)
	No	18	518		
Worried of immunization side effect	Yes	8	8	9.0(3.6-22.3)	3.4(2.8-6.29)
	No	23	534		
Heard of any information about immunization	Yes	9	20	10.6(4.3-26.0)	16.4(3.8-69.4)
	No	22	522		
Confirmation of child birthday	Yes	22	479	0.32(0.14-0.72)	1.0 (.35 -5.54)
	No	9	63		
Go to health facility after sick	Yes	27	529	0.16(0.05-0.54)	.092(.01-.50)
	No	4	13		
Go to holy water after sick	Yes	9	23	9.23(3.82-22.27)	21.4(4.9- 92.8.)

	No	22	519		
Pregnant follow up clinic	Yes	25	533	0.07(0.023-0.21)	0.01(.002 -.06)
	No	6	9		

* CI-confidence interval significant at 95%

NI-not included

6.6. Discussion

The study confirm that by checking card and recall mothers the proportion of children age 12-23 month immunization status of mekelle town were 94% ever taken at list one type of vaccine the reaming had not received any dose of immunization. The children complete immunization coverage by checking immunization cards only was 72%. So this result is very high when comparing to the national immunization coverage 39 percent of received all basic immunization and Sixteen percent had not received any vaccinations (6). Additional study complete immunization coverage in this study is higher than what was reported from Jigjiga 74.6% were ever vaccinated, 36.6% fully vaccinated and 25.4% not vaccinated at all(16).The observed variation could be due to geographical variation and health service coverage including immunization services.

The study shows that the immunization coverage among children aged 12-23 months for each immunization type by checking cards were BCG 80.55%, OPV0 72.08%, Pentavalent1 81.33%, PCV1 81.15%, Rota1 81.15%, Measles 79.76%; was fully vaccinated. The immunization coverage significantly no difference among the immunization type and the children, this could be due to no interruption immunization supply. this study coverage lower than the study conducted in Ethiopia routine EPI coverage (Penta1 87% & Measles 84%) 2014, Ethiopia (Administrative & Survey data)(5). Furthermore study WHO 2016 shows, worldwide coverage of measles, 64 % , polio 85%,PCV 42%,Rota25% (10). This markedly difference could be due to country geographical location, political and economic status, and other believes.

The dropout rate from OPV0, 72.08% to OPV3, 80.89% in the present study was 8.81% which is comparatively similar than that in other study pre urban Kenya the drop-out rate between the first and third vaccine coverage was 8.9% (25). The difference might be due to high percentage of defaulters, in OPVo lack of awareness when to start the immunization and no local health educators for reminding or distance on health institution for immunization center, and time inconvenient.

The study were identified the main factors affecting incomplete immunization coverage. Care takers where that live in far distance to reach health facility for immunization center were more likely to associate with children incomplete immunization. This study is similar with the study

conducted in east Pokot, Baringo, Kenya(21).this could be suggested that the care takers which live in distance to health facility were difficult to immunize the children.

Children care takers did not know the advantage of immunization were more likely associated with children incomplete immunization. So this study is similarly with the study conducted in Arbegona District, southern Ethiopia(26).this might be advocated that there was deficiency of health education in the community. In addition schedule of immunization health facility inconvenient time with children caretakers was more likely associated with incomplete immunization of children. this study was lined with the study conducted in South western Ethiopia (15).The reason could be certain of the children caretakers dwellers leaved in far pre urban near to mekelle town and lack of modern transportation .

Maternal health care follow-up in pregnancy time (ANC) were found preventive association in incomplete immunization children. These factors have been similarly demonstrated in Machakel Woreda, East Gojjam Zone and Ethiopia national study (27)(14). These findings advocate the need to alert women to follow health care services during pregnancy.

The study shows that children guardians or caretakers Concerned of immunization side effect were more likely to associated to children incomplete immunization than those who did not had concerned of immunization side effect. This study is the same to the study conducted in Arbegona district, southern Ethiopia, "due to fear of common vaccine side effects were at a higher risk of incomplete vaccination than children of mothers who perceived common vaccine side effects positively" (26).

Children caretakers who believe after sick go to holy water were more likely associated with child incomplete immunization than who did not go to holy water. When this study compared with the study conducted at juba teaching hospital similarly many children miss immunization in South Sudan because of the wrong believed in immunization(9).

The study limitation:

The study was cross-sectional study, so that cannot make causal inferences. In addition, some of the data was obtained from maternal recall, not all women had vaccination cards for their children. As such, the result was on mothers' report which is subject to recall bias. Furthermore in the adjusted odds ratio the gap between confidence interval and odds ratio was large because the sample size in the outcome variable in 2 x2 tables not enough.

6.7. Conclusion

Overall the average complete immunization status was low from the national immunization plan. Immunization status of children were influenced by not knowing the advantage of immunization, not knowing where and when to get vaccination, distance to health facility, caretakers time inconvenient with immunization, concerned of immunization side effect, go to holy water after sick, variables were the major factors that obstacle stayed to be significantly associated with incomplete children immunization.

6.8. Recommendation:

Based on the key finding all the basic improvement action in immunization should be done as follows:

- ❖ Strengthening national capability, regional organization and delivery of immunization programmes by FMOF and ROHB
- ❖ District health office and health facility should be improving the immunization coverage especially on those low immunization coverage by zonal and district health office manager.
- ❖ For those who distance dwellers to health facility immunization center additional health facility in surrounding should be done by regional health bureau.
- ❖ Strengthen advice on ANC (antenatal care) follow up during pregnancy should be continuing by health extension worker.
- ❖ Health extension workers should be providing awareness for mothers on immunization side effects and like negative beliefs.
- ❖ Continuous immunization Campaign by district health office also important to increase improvement on children's immunization.
- ❖ Guidance information should be important in immunization time inconvenient mothers or children caretakers to arrange their time for immunization.
- ❖ Further research has to be important.

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Annex 10: Questionnaires in English Version

1. A questionnaire for the study of immunization and associated factors among children aged 12-23 months in mekelle town, north Ethiopia, 2017.

St.paul's Millennium Medical, College, department of public health informed consent statement.

My name is_____.I was conduct a study on complete immunization and associated factors in mekelle town with sponsored SPHMMC Addis Ababa. We are interviewing randomly selected mothers and care takers that have children aged 12-23 months to assess determinant factors for immunization incomplection. For this purpose certain questions which are thought to be important was asked. You are kindly required to respond to these questions.

We want to assure you that your answers were strictly kept secret. We are also doing not keep a record of your name or address. Participation in this survey is voluntary and you have the right to refuse participation at any time or not to respond to questions that you are not willing to answer. However, your honest answers to these questions were help us in identifying determinant factors of immunization incomplection and improve immunization service in the future. We would appreciate your help in responding to these questions, and the interview was not taken more than 30 minutes. If you have any concern or question please contact me at 0920429370 tell phone number or destabirhane2015@gmail.com email address.

I have read the above description of the research project and I give my consent to participate.

Signature

Date

A. ID Number _____ GPS: _____

B. Are you willing to participate in the study? 1. Yes 2.no

C. Selected household having children age 12-23 months. 1= yes 2= no

D. Time/day / month / year of interview (etc):-----

E. Study area: - zone----- woreda/Town----- kebele-----house number-----

F. Name of data collector: _____Signature _____

Date / ____Month____2017

Part I: socio demographic			
S. N	Questions	Answers	Skip
1.	Sex of your child (12-23months years old)?	1.Male 2.FEMALE	
2.	How old is your child (12-23months years old)?	[____ ____] month	
3.	When was his/her birthday date (12-23months years old)?	[____/____/____] date /month /year	
4.	Confirm his birthday date by referring his /her birthday certificate or immunization card	1. confirmed 2. Not confirmed	
5.	What is the birth order of the child (first ;second etc)?	[____ ____]	If your answer is 1 go to question 7
6.	What is the age of the youngest child? If there is no youngest child fill 99	[_____] month	
7.	Who is the caregiver of the child mostly?	1.mother 2.father 3.both 4.other than parents	
8.	Is the caregiver gave answer for the questioner? You don't have to ask the participants	1.Yes 2. No	
9.	What is the age of the caregiver?	Year [____] 99. I don't know	
10.	What is educational status of caretaker?	1.illiterate 2.read and write 3.grade 1-8 4.grade 9-12 5.college/university	
11.	What is the religion of the Primary Caretaker?	1.Orthodox 2.Muslim 3.Protestant 4.Catholic 5.Non Religion 6. Other Christians. 7.Other _____	
12.	Mother's Marital Status	1. Single 2.Married 3. Divorced 4.Widowed	
13.	Occupation Primary Caretaker	1.Government/private institution worker 2.Merchant 3.House wife 4.Student 5.Farmer	

		6.Other	
14.	How many children do you have? (it include child who died after birth)	1. Male [] 2. female [] 3.Total[]	
15.	Children who live in life	Number[]	
Part II: Health service availability and related characteristics of respondents			
16.	Do you have nearest health facility for immunization center? (if there is no health facility write "00")	1.Yes 2.No	
17.	Where did the child get the last vaccine?	1.Hospital 2.Health center 3.Health post 4.Privet clinic 5.Campaign 5.Other 99.I don't know	
18.	How long it take to reach the nearest immunization center? If it is below 1 hour write it in minute	Minute [] HOUR [] 88.I don't know 99.I don't know if there is immunization center	
19.	Have you ever go to health facility to get a vaccine while you were pregnant?	1.Yes 2. No 99.I don't remember	→22
20.	If yes how many times?	In number. []	
21.	Where did the mother deliver her last child?	1.Home 2 Relative/Neighbor's Home 3. Health Post /Health Center/Hosp 4.Private Or Ngo Facility 5.Other Specify_____	
22.	While you take your child to health facility to get health facility other than vaccination, did your child get vaccine?	1.Yes 2.No 3.No ,because he completed all the vaccine 4.no because I didn't take the 5.child with me 99.I don't remember	
23.	Have you ever refused a vaccination for your child(Missed opportunities)	1.Yes 2.No 99.I don't remember	
24.	What were the reasons for refusing? (Please select all that apply)	1.Too much needle 2.My child was sick 3. Waiting time to get the vaccine	

		4. I don't like the health worker 5. Other 99. I don't know	
25.	Did the mother ever taken any immunization?	1. Yes 2. No	
Part III. The child immunization states			
26	Have you ever had your child immunization?	1. Yes 2. No 99. I don't know	→40
27	Do you have your child immunization cared? If the answer is yes verify by asking to show you the cared?	1. Yes 2. No 99. I don't know	→40
28	Write the date of each immunization by referring the cared (if the vaccine the child received marked but no date immunization cared write "44") a) BCG b) OPV 0 c) OPV 1 d) OPV 2 e) OPV 3 f) DPT-HepB-Hib 1 g) DPT-HepB-Hib 2 h) DPT-HepB-Hib 3 i) PCB1 j) PCB2 k) PCB 3 l) ROTA1 m) ROTA2 n) MEASELS o) Vitamin A	<u>Date/Month/Year</u> BCG OPV 0 OPV 1 OPV 2 OPV 4 DPT-HepB-Hib 1 DPT-HepB-Hib 2 DPT-HepB-Hib 3 PCB 1 PCB 2 PCB3 ROTA1 ROTA2 ROTA3 MEASELS Vitamin A	If the child completed all the vaccine skip to 30
29	Did your child get any vaccination including campaign vaccination? If the answer is yes fill from "29"	1. Yes 2. No 99. I don't know	→42
30	If the answer is yes	1. Regular vaccine 2. Campaign vaccination 99. I don't know	
	Can you list the vaccination your child received?	question 31a – 38g	
31	Did your child received BCG vaccine (on the right hand sear)?	1. Yes 2. No 99. I don't know	
32	Did your child received Polio vaccine (oral drop)?	1. Yes 2. No 99. I don't know	→34
33	How many times your child did receive polio	In numbers	

	vaccination?	99.I don't know	
34	Did you child receive penta (it will be given together with polio and on the leg)	1.Yes 2.No 99.I don't know	→36
35	How many times your child did receive penta vaccination?	In number [____] 99.I don't know	
36	Did your child receive PCV (It will be given usually together with penta and on the right leg?)	1.Yes 2.No 99.I don't know	→38
37	How many times your child did receive PCV vaccination?	In number [____] 99.I don't know	
38	Did your child receive Rota vaccine (oral drop use to prevent diarrhea)	1.Yes 2.No 99.I don't know	→40
39	How many times your child did receive Rota vaccination?	In number [____ ____] 99.I don't know	
40	Did you child receive measles vaccine at the age of 9 months (on the left arm)?	1.Yes 2.No 99.I don't know	
41	Following the participant answer and immunization card review if the child didn't get the vaccine or completed the vaccine ask the following question What are the reasons the child did not get the vaccine? (Please select all that apply)	<u>a)</u> I did not know the advantage of vaccine <u>b)</u> being unaware of the need to return for subsequent doses <u>c)</u> Did not know where and when to get vaccination <u>d)</u> Concerned about side effects <u>e)</u> Distance from the clinic was too far <u>f)</u> Time of vaccination inconvenient <u>g)</u> The health profesional was not there <u>h)</u> shortage of vaccine <u>i)</u> family problem (illnes of the mother:lack of husband support) <u>j)</u> long Waiting time <u>k)</u> other <u>l)</u> I didn't t know	
Part IV: knowledge assessment			
42	Have you ever heard the side effect of vaccine?	1.Yes 2. No	
43	Did you get any information about vaccination with in the last three months?	1. Yes 2. No	45

44	Question 44, if yes by which media do you get?	1.Radio 2.TV 3.Newspaper 4.Flier 5.Health worker 6.Community meeting 7.1 to 5 leader 8.Health extension worker 9.Nabors 10.Other _____	
45	What kind of information did you get about vaccination	1.Campaign vaccination 2.Advantage of vaccination 3.Where to get regular vaccination 4.Eligible age of children to get vaccine 5.Vaccination schedule 6.New vaccines (BCG/Rota) 7.Other 99. I don't know	
46	In your opinion, at what age children start vaccine?	[____ ____] month 99.I don't know	
47	Do you know how many times you should go to health facility for vaccination?	Number [_____] 99.I don't know	
48	Do you think vaccines can prevent diseases?	1.Yes 2.No 99.I don't know	
49	How do you rate the satisfaction you get immunization service?	1.Good 2.Medium 3.Bad 4.No Response 5. I Don't Know	
50	Where do you take your child when he/she is sick?	1.Health facility 2.Holy water 3.Herbal medicine 4.Church 88.Other 99. I don't know	

Thank you very much for your participation!

T2	End time of data collection	____:____	
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Annex 11: Map of mekelle Town

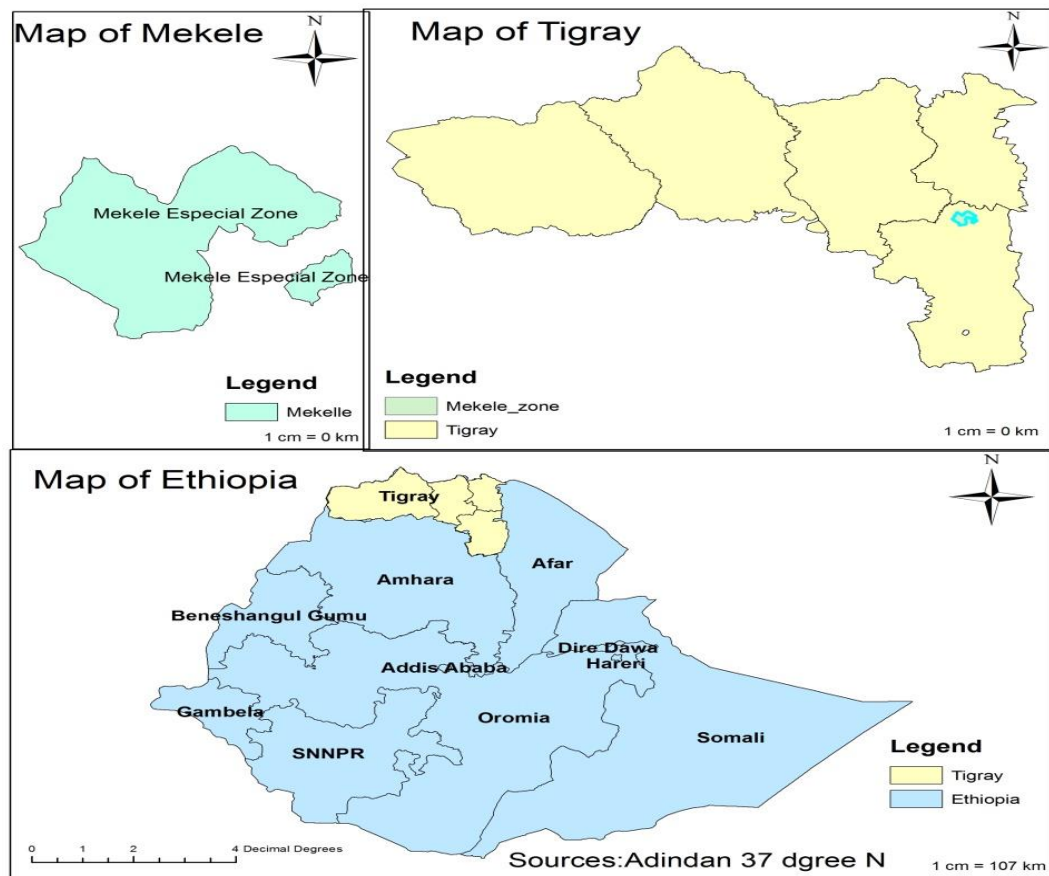


Figure 20: Map of mekelle special zone (Town)

ክብ 2007 ዓ/ም ክብ 2012 ዓ/ም ትምህርት በጊዜ ህዝብ ከተማ መቸለ ዘመናዊነት																			
ዕለ ደመ	ትኩረ 1 ዓመት	2007			2008			2009			2010			2011			2012		
		ድምር	ተባባሪ	እንስሳት	ድምር	ተባባሪ	እንስሳት	ድምር	ተባባሪ	እንስሳት	ድምር	ተባባሪ	እንስሳት	ድምር	ተባባሪ	እንስሳት	ድምር	ተባባሪ	እንስሳት
1-4	5,991	3,060	2,941	6,653	3,387	3,266	7,315	3,724	3,591	7,976	4,061	3,916	8,638	4,398	4,241	9,300	4,735	4,565	
5-9	26,655	14,589	14,066	31,820	16,200	15,620	34,986	17,812	17,174	38,152	19,424	18,728	41,318	21,036	20,281	44,483	22,647	21,836	
10-14	33,747	17,028	16,719	37,475	18,910	18,566	41,204	20,791	20,413	44,932	22,672	22,260	48,661	24,553	24,108	52,389	26,435	25,955	
15-19	39,495	19,065	20,371	43,793	21,172	22,621	48,149	23,278	24,972	52,506	25,184	27,127	56,863	27,491	29,373	61,220	29,597	31,623	
20-24	49,446	21,938	27,508	54,508	24,361	30,547	60,371	26,785	33,586	65,834	29,209	36,025	71,296	31,632	39,664	76,759	34,056	42,703	
25-29	50,339	23,942	26,297	55,901	26,587	29,314	61,467	29,232	32,230	67,024	31,877	35,146	72,585	34,522	38,063	78,147	37,168	40,979	
30-34	35,338	17,462	17,876	39,247	19,391	19,851	43,146	21,321	21,826	47,050	23,250	23,801	50,955	25,179	25,776	54,859	27,108	27,750	
35-39	22,660	11,944	10,117	24,487	13,263	11,234	26,935	14,583	12,252	29,372	15,902	13,470	31,809	17,222	14,587	34,246	18,541	15,705	
40-44	38,319	9,284	9,035	20,343	10,309	10,033	22,367	11,335	11,052	24,390	12,361	12,030	26,414	13,386	13,028	28,438	14,412	14,026	
45-49	12,968	6,575	5,433	13,313	7,302	6,011	14,637	8,028	6,600	15,962	8,725	7,207	17,286	9,481	7,805	18,611	10,208	8,407	
50-54	2,772	4,878	4,854	10,807	5,417	5,391	11,883	5,956	5,927	12,958	6,495	6,463	14,033	7,034	6,999	15,108	7,572	7,536	
55-59	3,098	3,602	4,572	8,950	4,000	4,000	9,840	4,398	5,442	10,731	4,796	5,935	11,621	5,194	6,477	12,511	5,592	6,920	
60-64	5,807	2,614	3,253	6,515	2,903	3,613	7,164	3,191	3,972	7,812	3,480	4,332	8,460	3,769	4,691	9,108	4,058	5,051	
65-69	5,738	2,244	2,254	5,826	2,492	3,124	6,295	2,740	3,656	6,974	2,988	3,986	7,552	3,236	4,317	8,131	3,483	4,647	
70-74	4,980	1,708	1,721	4,476	1,896	2,579	4,921	2,085	2,826	5,366	2,274	3,042	5,811	2,462	3,349	6,257	2,651	3,606	
75+	4,570	1,501	1,590	3,990	1,664	2,371	4,387	1,835	2,552	4,784	2,001	2,783	5,181	2,167	3,013	5,578	2,333	3,244	
ድምር	4,611	1,831	2,125	4,497															

233

Annex 13: Data Collection Tool infant immunization card

110291

Infant Immunization Card

G... 3.25

Name of Infant: Seidaw Card number: NCR 474 46312 Telenor Tawad 47444444

Age: 11/11/19 Sex: F

Date of Birth: 11/11/19 Address: Acacia Quila

Ward: Acacia

Name of Mother: Yvetelem Tefes

Ward: Acacia

Birth date (Age of mother for T1 vaccination): 24/12/08

Name of Father: Dejta Brak

Ward: Acacia

Phone: 47444444

Age	Day	Month	Year	Time	Location	Health	Notes
0-1	11	11	19	10:00	Acacia	Good	
1-2	11	11	19	10:00	Acacia	Good	
2-3	11	11	19	10:00	Acacia	Good	
3-4	11	11	19	10:00	Acacia	Good	
4-5	11	11	19	10:00	Acacia	Good	
5-6	11	11	19	10:00	Acacia	Good	
6-7	11	11	19	10:00	Acacia	Good	
7-8	11	11	19	10:00	Acacia	Good	
8-9	11	11	19	10:00	Acacia	Good	
9-10	11	11	19	10:00	Acacia	Good	
10-11	11	11	19	10:00	Acacia	Good	
11-12	11	11	19	10:00	Acacia	Good	
12-13	11	11	19	10:00	Acacia	Good	
13-14	11	11	19	10:00	Acacia	Good	
14-15	11	11	19	10:00	Acacia	Good	
15-16	11	11	19	10:00	Acacia	Good	
16-17	11	11	19	10:00	Acacia	Good	
17-18	11	11	19	10:00	Acacia	Good	
18-19	11	11	19	10:00	Acacia	Good	
19-20	11	11	19	10:00	Acacia	Good	
20-21	11	11	19	10:00	Acacia	Good	
21-22	11	11	19	10:00	Acacia	Good	
22-23	11	11	19	10:00	Acacia	Good	
23-24	11	11	19	10:00	Acacia	Good	
24-25	11	11	19	10:00	Acacia	Good	
25-26	11	11	19	10:00	Acacia	Good	
26-27	11	11	19	10:00	Acacia	Good	
27-28	11	11	19	10:00	Acacia	Good	
28-29	11	11	19	10:00	Acacia	Good	
29-30	11	11	19	10:00	Acacia	Good	
30-31	11	11	19	10:00	Acacia	Good	
31-32	11	11	19	10:00	Acacia	Good	
32-33	11	11	19	10:00	Acacia	Good	
33-34	11	11	19	10:00	Acacia	Good	
34-35	11	11	19	10:00	Acacia	Good	
35-36	11	11	19	10:00	Acacia	Good	
36-37	11	11	19	10:00	Acacia	Good	
37-38	11	11	19	10:00	Acacia	Good	
38-39	11	11	19	10:00	Acacia	Good	
39-40	11	11	19	10:00	Acacia	Good	
40-41	11	11	19	10:00	Acacia	Good	
41-42	11	11	19	10:00	Acacia	Good	
42-43	11	11	19	10:00	Acacia	Good	
43-44	11	11	19	10:00	Acacia	Good	
44-45	11	11	19	10:00	Acacia	Good	
45-46	11	11	19	10:00	Acacia	Good	
46-47	11	11	19	10:00	Acacia	Good	
47-48	11	11	19	10:00	Acacia	Good	
48-49	11	11	19	10:00	Acacia	Good	
49-50	11	11	19	10:00	Acacia	Good	
50-51	11	11	19	10:00	Acacia	Good	
51-52	11	11	19	10:00	Acacia	Good	
52-53	11	11	19	10:00	Acacia	Good	
53-54	11	11	19	10:00	Acacia	Good	
54-55	11	11	19	10:00	Acacia	Good	
55-56	11	11	19	10:00	Acacia	Good	
56-57	11	11	19	10:00	Acacia	Good	
57-58	11	11	19	10:00	Acacia	Good	
58-59	11	11	19	10:00	Acacia	Good	
59-60	11	11	19	10:00	Acacia	Good	
60-61	11	11	19	10:00	Acacia	Good	
61-62	11	11	19	10:00	Acacia	Good	
62-63	11	11	19	10:00	Acacia	Good	
63-64	11	11	19	10:00	Acacia	Good	
64-65	11	11	19	10:00	Acacia	Good	
65-66	11	11	19	10:00	Acacia	Good	
66-67	11	11	19	10:00	Acacia	Good	
67-68	11	11	19	10:00	Acacia	Good	
68-69	11	11	19	10:00	Acacia	Good	
69-70	11	11	19	10:00	Acacia	Good	
70-71	11	11	19	10:00	Acacia	Good	
71-72	11	11	19	10:00	Acacia	Good	
72-73	11	11	19	10:00	Acacia	Good	
73-74	11	11	19	10:00	Acacia	Good	
74-75	11	11	19	10:00	Acacia	Good	
75-76	11	11	19	10:00	Acacia	Good	
76-77	11	11	19	10:00	Acacia	Good	
77-78	11	11	19	10:00	Acacia	Good	
78-79	11	11	19	10:00	Acacia	Good	
79-80	11	11	19	10:00	Acacia	Good	
80-81	11	11	19	10:00	Acacia	Good	
81-82	11	11	19	10:00	Acacia	Good	
82-83	11	11	19	10:00	Acacia	Good	
83-84	11	11	19	10:00	Acacia	Good	
84-85	11	11	19	10:00	Acacia	Good	
85-86	11	11	19	10:00	Acacia	Good	
86-87	11	11	19	10:00	Acacia	Good	
87-88	11	11	19	10:00	Acacia	Good	
88-89	11	11	19	10:00	Acacia	Good	
89-90	11	11	19	10:00	Acacia	Good	
90-91	11	11	19	10:00	Acacia	Good	
91-92	11	11	19	10:00	Acacia	Good	
92-93	11	11	19	10:00	Acacia	Good	
93-94	11	11	19	10:00	Acacia	Good	
94-95	11	11	19	10:00	Acacia	Good	
95-96	11	11	19	10:00	Acacia	Good	
96-97	11	11	19	10:00	Acacia	Good	
97-98	11	11	19	10:00	Acacia	Good	
98-99	11	11	19	10:00	Acacia	Good	
99-100	11	11	19	10:00	Acacia	Good	

Figure 22: Infant Immunization Card

7. Chapter Seven: Scientific Manuscripts for Peer Reviewed Journals

Title: Immunization coverage and Factors associated with incomplete immunization among children age 12-23 month's Mekelle Tigray, north Ethiopia

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Abstract:

Background: Immunization is estimated to avoid between 2 and 3 million deaths globally each year. Immunization preventable diseases can affect in prolonged disabilities and can ensure a financial lost because of lost time at work, psychological anxiety or long-term disability care. In Ethiopian children from 12-23 ages' prevalence total immunization coverage 39 % and 16% was not taken any immunization all over the nation Ethiopia. However the aim is to assess the incomplete immunization in 12-23 age year children in the stated study area.

Objective: To assess complete immunization and factors associated with incomplete immunizations coverage in children 12-23 months in mekelle town.

Methods: Community-based cross-sectional study design conducted in children aged 12 to 23 months. The data collectors were visited at home and interviewed using pre-tested questionnaire about socio-demographic, economic status and other variables. Systematic random sampling technique was used. 573 sample calculated by single proportion formula after addition of design effect and 10% non-response rate by taking critical value at 95% confidence level of certainty from the actual figures for source population and power 80%. Data entered in to Epi info version 7.2.1.0. And analyzed by taking crud and adjusted odds ratio with 95% confidence intervals. Ethical clearance was obtained and consent form asked willingness to the eligible people.

Result: Of the 573 children, 542 (94.59%) were ever acquired one or more doses of vaccine and 31 (5.41%) had not vaccinated at list one dose, 69(12%) had immunized maternal recall only, about 473 (82.54%) have vaccination Card. The multivariate logistic regression analysis shows that; distance of immunization center, antenatal care, time of immunization inconvenient, concerned of immunization side effect, go to holy water after sick, variables were remained significantly associated with incomplete children immunization.

Conclusion and recommendation: Overall the average complete immunization status was low. Based on the key finding there is need to increase the number of health facilities with Health workers, strengthening integrated community awareness.

Key words: immunization, mekelle town, children aged 12-23 months

7.1. Introduction

Global study shows approximately 45% of less than 5 age and nearly 86% of neonatal deaths occurring in developed countries. Early immunization of children and mothers had one way of intervention show reduced early child mortality. (1). Immunization is an important tool for children to live healthier and to eliminate or minimize the infectious diseases. absence of immunization in children is not only related directly to mortality and morbidity but also a big problem in economic crisis(2). immunization have the power to save nearly 2 and 3 million deaths globally each year(3).

In Africa nearly three million children less than five year age dead because of children was not receive immunization.one in five children does not receive immunization due to low coverage health institution, infrastructure and lack awareness of about immunization.(4) In February 2016, minister's representativeness of African region signed agreement in immunization in Addis Ababa Ethiopia..(5)

Ethiopia immunization program started 1980 with the aim of increasing 10% yearly. Though in the first 20 years very slow increment. So through in this way Ethiopia shows an improvement in 2003 DPT coverage from 53% to 87% in 2014.Even though the difference coverage among Ethiopia regions present massive.(6). In the study of SIA shows after receiving TT immunization the supplemental immunization activities assessed the high risk zones in Ethiopia in 2011 animate pre-validation assessment. so the nation to some extent validated to have eliminated neonatal tetanus (6). In EDHS 2016 all Ethiopian children from 12-23 age prevalence total immunization coverage were 39 % and 16% were not taken any immunization all over the nation(7). In early assessment of the immunization coverage show gap in region to region especially for those who are pastoralists persistently inequalities backward from the others. So the ministry of health collaboration with the other stack holders like UNICEF and other EPI focal were discussed on how to implement in the periphery health institutions on how to give immunization with consistency agreed and signed in julay2014. (6)

The Tigray regional health bureau was not studded in mekelle zone about immunization status. So this is baseline study to fill the gap in the factors affected incomplete immunization coverage in children age 12-23 category. So the aim is to determine the risk factors for immunization is key to increase immunization and infection prevention in children.

7.2. Methods and materials:

Study area and period:

This study was conducted in Mekelle special zone, northern Ethiopia. Mekelle is the capital city in the northern Tigray region of Ethiopia. It is located around 780 kilometers north of the Ethiopian capital Addis Ababa, at a latitude and longitude of 13°29'n 39°28'e, with an elevation of 2084 meters above sea level and temperature above 18°C. Administratively, Mekelle is considered a special zone, which is divided into seven sub-cities. These are Addi-Hak'i, Ayder, Haddinet, Hawelti, Qedamay Weyyane, Kwiha, and Semien. Based on the 2007 census conducted by the central statistical agency of Ethiopia (CSA), this town has a total population of 334,260 people (164,134 men and 170,110 women)(8). There are 3 hospitals and 10 health centers. The study was conducted from August 30, 2017 to February 30, 2018 in Mekelle, Tigray region, north Ethiopia.

Study design:

Community-based cross-sectional study design was conducted.

Sample size determination:

The sample size was determined for the first objective based on sample size calculation for single population.

$$n = \frac{(Z_{\alpha/2})^2 P(1 - P)}{D^2} = 366$$

Adjust to population size (N) –if (N<10,000), where n_0 is the calculated sample size

$$n = \frac{n_0}{1 + n_0/N} \quad n = \frac{366}{1 + 366/6653} = 346$$

Since the sample size was taken from a relatively small population ($n < 10,000$) $n = 6653$ the required minimum sample size was obtained by making adjustment using population correction formula $n = 346 * 1.5 = 519$. And also the total sample size considers the non-responding rate 10% total $n = 573$.

Where,

p = proportion of children who did complete immunization (39%) (EDHS 2016)

d = margin of error = 0.05

n = minimum sample size

$Z_{\alpha/2}$ = confidence level required and $Z_{\alpha/2}$ at 95% CI = 1.96

DE = design effect is taken as 1.5 (complex cluster or multi stage design)

So the total of 573 children aged between 12-23 months was targeted for the study.

Additionally sample size for the second objectives was calculated based on sample size calculation by double population proportion. such as factors associated with incomplete immunization using Stat calc Epi info by taking previous study variable antenatal care follow up (exposed 62.9% and unexposed 37.1% $n = 132$) (9). So the sample size for the first objective was the largest one 573 was taken as a final sample size for this study.

Sampling procedure:

A multistage sampling procedure was used. From the seven mekelle town woredas (mekelle special zone) three woredas cluster was selected randomly. Since those three woredas was the places where the same (homogeneous) to the others woreda was have a representative sample taken. Each district included no less than five kebeles areas within 1-5 k/m Radius of mekelle town. Each of them was have in average at least involved 206 households which have 12-23 age children. All the fourteen kebele who have the eligible age group household was selected directly from the above three districts (woredas). By making sample proportion calculation against the total sample size the study unit was taken. All respondents were considering homogenous in terms of being alien to the place of study as a result immunization status areas served to have a representative sample. Households study unit from each kebele respondents was selected by systematic random sampling technique from the previous 2008 lists of health extension registration book that have eligible criteria to the study. The sampling interval was selected per each kebele example Aynalem has total 196 children in order to select 40 children needs interval 5 down the list.

Date Collection Procedure:

Ten health extension workers who know the kebeles or areas well with a commitment to face challenges were collected the data from house to houses eligible study units. Socio-demographic, availability of immunization center, knowledge of caretakers related questions and variables apply to immunization coverage was gathered using a structured questionnaire. A medical immunization ID card and by asking question was used to gather information.

Data quality control:

The questionnaire used for study was adopted from Ethiopia demographic health survey (EDHS) and from the previous researches done in other places. Questionnaire was translated

from English to Tigrigna and back to English as well to reaffirm consistency. Training was given to data collectors and supervisor before data collection for one day. The questionnaire was pre-tested for 20 households in adihaki kebele other than my study kebele to see the completeness and appropriateness to the local context and as per correction was taken seriously.

Inclusion criteria:

Children who are between 12-23 month age group

Exclusion criteria:

Children ages 12-23 month whose parents/caretakers was not willing to give consent and could not have both immunizations cared and not remember the number or type of vaccine they had received.

Data processing and analysis:

Data was entering in to Epi info version 7.2.1.0 and analyzed using SPSS version 21. Summary statistics such as, tables, percentages, graphical techniques for descriptive and logistic regression were used to test the association between the independent and the outcome variables. all explanatory variables that will associated with the outcome variable in bivariate analyses was included into multivariate logistic regression to avoid confounder variable, to determine factors that are significantly associated with immunization incompleteness rate. P-value of 0.05 was considered as a cut-off point for statistical significance.

Ethical clearance:

Ethical clearance was obtained from St. Paul's hospital millennium medical college department of public health, institutional review board (IRB). The IRB reviewed the above mentioned research proposal and made decision approved on October /04/2017. So lastly official letter was written the decision is valid for 12 months and given to the organization where the study was conducted TRHB (Tigray regional health bureau (mekelle zone, under mekelle zone health facilities & health offices). the consent with the people participated in the study was asked their willingness as in the annex I part expressed. After agreed the data collection was started.

7.3. Results

Descriptive part of the results

Socio- demographic characteristic of the Primary guardians of children 12-23 months, Mekelle Town, Northern Ethiopia

Of the 573 children studied 542 (94.59%) were ever took one or more doses of vaccine and 31 (5.41%) had not vaccinated at list one dose by maternal recall and immunization card checking, 69(12%) had immunized maternal/caretaker recall only. Children from these about 473 (82.54%) had vaccination card during the study. Of the 573 children studied 72% were ever took full immunization with immunization card only. Socio demographic characteristics of respondents showed that a total of 573 (with 100% response rate) were included in the study. The mean age of caregiver's and children were 28.55(min16 to max75) years, and 16.68 months, respectively. The sex distribution of children shows that 276 (48.17%) males and 297(51.83%) of were females. With regard to types of caretakers of the children, both mothers and fathers 468(81.68%), mothers 94(16.40%), father 9(1.57%) and other than parents 2(0.35%).Majority of the marital status of the caretaker indicates that 513(89.53%) were married. The educational level of caretakers 112(19.5%) had no formal education, 207(36.13%) grades1-8, and 254(44.32%) grade 9 and above.

Most of the children's mothers were 558(97.38%) attended antenatal care clinic during pregnancy and 546 (95.29%) delivered in a health facility. With regard to child birth order 232(40.49%) were born in the first,150 (26.18%) second birth order, 97(16.93%) third birth order, and 94(16.40%) greater than third birth order. Respondent children household family size indicated that 194(33.86%) first family size, 174 (30.37%) second, 87(15.18%) third family size, and 118 (20.59%) were had more than four family size. The mean children household family size was approximately 3 with minimum 1 and 9 maximum.

Majority 325 (56.72%) of these caretakers were unemployed, and 553 (96.51%) were of the Christian faith. as shown in table 32.

Health service related characteristics of Primary Guardians of children aged 12-23 months, Mekelle Town, Northern Ethiopia, 2017

The availability and accessibility of health facility for immunization was measured by presence of the service and average walking time to reach the health facility. All 100% of the respondents were reported that they had access to the health facility that provides immunization services and majority of the reported 433(75.57%) that they were more access to health center followed by hospital 116(20.24%) and the remaining 7(1.22%) in health post. Respondents walking time to reach the nearest health facilities for immunization was <10 minutes 98(17.10%), 16 to 30 minutes 323(56.37%), 31 to 60 minutes 116(20.24%), >1 hours 12(2.09%) and they did not know the time 24(4.19%). About 558(97.38%) of mothers had followed at least one ANC follow up while pregnant her last birth child. With regard to Place of mother deliver her last child, 546 (95.29%) were delivered at health institutions, 22(3.84%) at home and Privet or NGO health facility 5(0.87%). The majority of mothers of the children were 500(87.26%) immunized tetanus toxoid (TT) while pregnant (Show Table 33).

Characteristics of immunization status among children aged 12-13 months, Mekelle Town, Northern Ethiopia, 2017:

The outcomes of each type immunization 12-23 month age children by checking vaccination card was show as follows: approximately all types of immunization were the same in dropout rate except low in OPV₀ 72% flowed Measles 79.7%. By district Children of full immunization coverage with checking cards were recorded for 26.35% Hadnet followed by kuha 24.60%, and, Qedamay Weyyane district 20.76 % (as showed inTable34).

Immunization related Questions by recall history respondents among children aged 12-13 months, Mekelle Town, Northern Ethiopia, 2017:

Majority of respondents they did not know the right answers wethears the child received the immunization with the right dose or not by remembering the past time. The core reasons children did not get or drop out their immunization were expressed the respondents as follow; I did not know the advantage of vaccine 109(19.02%), Being unaware of the need to return for subsequent doses 63 (10.99%) and Time of vaccination inconvenient with respondents 37(6.46%).

Knowledge assessment of children caretakers' age 12-23 month in Mekelle Town, Tigray Northern Ethiopia, 2017:

Majority of respondents were heard about immunization from health workers 220(38.39%), radio 78(13.61%), TV 74 (12%) and the remaining from other sources. The main type of information respondents get were about advantage of immunization 246 (42.93%), followed by campaign immunization 81(14.14%). Respondents knowledge on schedule of vaccination indicates that 64(11.17%) had low knowledge on schedule of vaccination. respondent's about immunization side effects were not heard 553 (96.51%) and 20(3.49%) had the heard about immunization side effects. The majority of guardians were answers the question when start child immunization; after birth 24 hours 385(67.19%), greater than one week after birth 97(16.93%), after birth from 2 day to one week 49(8.55%), and I did not know 42(7.33%).

The majority of guardians were believed immunization of children's preventing disease 537(93.72%). Respondents level of satisfaction on immunization service showed that 484(84.47%) =Good, 51(8.90) =Medium, 29(5.0%) = I did not know, and 9 (1.57%) = No response.

Analysis part of the results

Binary Logistic Regression Analysis:

The children 12-23 month age immunization status bi-variate analysis showed that, the Sex of caretaker of children, mothers ever TT immunized, did not know the advantage of immunization, Unaware of the need to return for subsequent doses, did not know where and when to get vaccination, time of immunization inconvenient, worried of immunization side effect, confirmation of birthday, Go to health facility after sick, Go to holy water after sick, Pregnant women follow up clinic(ANC), were variables significantly associated with incomplete childhood immunization and then filtered for multivariate analysis.

Some of the Factors associated with incomplete immunization among children aged 12 – 23 months by cured Odds ratio. The odds of incomplete immunization were high for children caretaker female sex than male [(OR = 2.02; 95% CI: 0.9 – 4.3)]. Children mothers who were immunized TT during pregnant period were less times incomplete immune to their childe than those who did not immunized TT [(OR= 0.04; 95% CI: 2.03-6.21)]. Additionally children of mothers who had with immunization cared at the data collection time were preventable association than those mothers without immunization cared [(OR = 0.01; 95% CI: 1.0 – 15.3)]. Children caretakers who were worried of side effect immunization 23.2 times more likely to be

incomplete immunized compared to children caretakers who did not worried of side effect immunization [(OR=23.2(8.0-67.3)].

However most of the other variables like; Educational status of the Primary Care taker, Marital status, religion of the Primary Care taker, Occupation Primary Care taker, Children family size ever born, type of health facility for immunization, Did you get any information about immunization, religion, birth order of the children, were not associated with incomplete immunization.

7.3.1. Multivariate logistic regression analysis

The multivariate logistic regression analysis variables like shows that; did not know the advantage of immunization, did not know where and when to get vaccination, distance of immunization center, time of immunization inconvenient with caretaker, worried of immunization side effect, children go to holy water after sick, pregnant follow-up clinic during pregnancy time variables were stayed to be significantly associated with incomplete children immunization.

Caretaker of the children's did not know the advantage of immunization were more associated with children incomplete immunization than those caretakers who know the advantage immunization [AOR=18.17 (95% CI: 7.5 – 43.6)]. Children of guardians who did not know where and when to get vaccination were more significantly associated with incomplete immunization than those guardians who know the place and time [AOR=2.7 (95% CI: 0.75 – 10.5)]. Children who live in far distance from health institution immunization center were more likely associated with incomplete immunization than near lived. [AOR=26.1 (95% CI: 14.2 – 102.1)]. In addition mothers of the children who had time inconvenient for immunization children were more likely 5.5 times associated with immunization incompleteness than mothers had convenient time [AOR= 71.0 (95%CI: 16.8-130)].

Furthermore, Children who had go to holy water after sick were 21.4 times more likely to incomplete immunization status compared to children who were not go to holy water after sick. [(AOR=21.4(95%CI: 4.9-92.8)]. Mothers or caretakers who were had worried of in appropriate awareness on immunization side effect were 3.4 times more likely to be their children to incomplete immunization than mother who had not worried of immunization side effect trust. [(AOR: 3.4(95% CI: 2.8 - 6.29)]. Children who were born from mothers who had pregnancy

follow-up (ANC) visit during pregnancy were less times to incomplete immunization compared to infants who were born from mothers who had not antenatal care visit during pregnancy [AOR= 0.01 (95%CI : 0.002 - 0.064)].

However variables like Mather's ever TT immunized, sex of caretakers, do you have immunization card, Unaware of the need to return for subsequent doses about in immunization, confirmation of child birthday and go to health facility after child sick were measured as the confounder in adjusted rigration.

The study limitation:

The study was cross-sectional study, so that cannot make causal inferences. In addition, some of the data was obtained from maternal recall, not all women had vaccination cards for their children. As such, the result was on mothers' report which is subject to recall bias. Furthermore in the adjusted odds ratio the gap between confidence interval and odds ratio was large because the sample size in the outcome variable in 2 x2 tables not enough.

7.4. Discussion

The study confirm that by checking card and recall mothers the proportion of children age 12-23 month immunization status of mekelle town were 94% ever taken at list one type of vaccine the reaming had not received any dose of immunization. The children complete immunization coverage by checking immunization cards only was 72%. So this result is very high when comparing to the national immunization coverage 39 percent of received all basic immunization and Sixteen percent had not received any vaccinations (7). Additional study complete immunization coverage in this study is higher than what was reported from Jigjiga 74.6% were ever vaccinated, 36.6% fully vaccinated and 25.4% not vaccinated at all(10).The observed variation could be due to geographical variation and health service coverage including immunization services.

The study shows that the immunization coverage among children aged 12-23 months for each immunization type by checking cards were BCG 80.55%, OPV0 72.08%, Pentavalent1 81.33%, PCV1 81.15%, Rota1 81.15%, Measles 79.76%; was fully vaccinated. The immunization coverage significantly no difference among the immunization type and the children, this could be due to no interruption immunization supply. this study coverage lower than the study conducted in Ethiopia routine EPI coverage (Penta1 87% & Measles 84%) 2014, Ethiopia (Administrative

& Survey data)(6). Furthermore study WHO 2016 shows, worldwide coverage of measles, 64 % , polio 85%,PCV 42%,Rota25% (11). This markedly difference could be due to country geographical location, political and economic status, and other believes.

The dropout rate from OPV0, 72.08% to OPV3, 80.89% in the present study was 8.81% which is comparatively similar than that in other study pre urban Kenya the drop-out rate between the first and third vaccine coverage was 8.9% (12). The difference might be due to high percentage of defaulters, in OPVo lack of awareness when to start the immunization and no local health educators for reminding or distance on health institution for immunization center, and time inconvenient.

The study were identified the main factors affecting incomplete immunization coverage. Care takers where that live in far distance to reach health facility for immunization center were more likely to associate with children incomplete immunization. This study is similar with the study conducted in east Pokot, Baringo, Kenya(13).this could be suggested that the care takers which live in distance to health facility were difficult to immunize the children.

Children care takers did not know the advantage of immunization were more likely associated with children incomplete immunization. So this study is similarly with the study conducted in Arbegona District, southern Ethiopia(14).this might be advocated that there was deficiency of health education in the community. In addition schedule of immunization health facility inconvenient time with children caretakers was more likely associated with incomplete immunization of children. this study was lined with the study conducted in South western Ethiopia (15).The reason could be certain of the children caretakers dwellers leaved in far pre urban near to mekelle town and lack of modern transportation .

Maternal health care follow-up in pregnancy time (ANC) were found preventive association in incomplete immunization children. These factors have been similarly demonstrated in Machakel Woreda, East Gojjam Zone and Ethiopia national study (16)(17). These findings advocate the need to alert women to follow health care services during pregnancy.

The study shows that children guardians or caretakers Concerned of immunization side effect were more likely to associated to children incomplete immunization than those who did not had concerned of immunization side effect. This study is the same to the study conducted in Arbegona district, southern Ethiopia, "due to fear of common vaccine side effects were at a

higher risk of incomplete vaccination than children of mothers who perceived common vaccine side effects positively" (14).

Children caretakers who believe after sick go to holy water were more likely associated with child incomplete immunization than who did not go to holy water. When this study compared with the study conducted at juba teaching hospital similarly many children miss immunization in South Sudan because of the wrong believed in immunization(18). At the end Overall the average complete immunization status was low from the plan. Some variables were factors that obstacle stayed to be significantly associated with incomplete children immunization. Strengthening the national capability, regional health, organization stockholders and delivery of immunization programmes for all children

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Table 32 : Socio- demographic characteristic of the Primary guardians of children 12-23 months, Mekelle Town, Northern Ethiopia

Name of variables categories		Frequency n=573	Percent
Primary Care taker age category	16-25Age	203	35.43%
	26-40Age	360	62.83%
	> 41Age	10	1.75%
Woreda of the Primary Care taker	Hadnet	204	35.60%
	Kuha	163	28.45%
	Q/Weyyane	206	35.95%
Educational status of the Primary Care taker	Illiterate	61	10.65%
	Read and write	51	8.90%
	Grade 1-8	207	36.13%
	Grade 9-10	176	30.72%
	College and university	78	13.61%
Religion of the Primary Care taker	Muslim	20	3.49%
	Orthodox Christian	553	96.51%
Mothers Marital Status	Divorced	21	3.66%
	Married	513	89.53%
	Single	33	5.76%
	Widowed	6	1.05%
Occupation Primary Care taker	Daily laborer	65	11.34%
	Farmer	24	4.19%
	Government /privet employ	72	12.57%
	Housewife	325	56.72%
	Merchant	83	14.49%
	Others	4	0.70%
Children family size ever born	1	194	33.86%
	2	174	30.37%
	3	87	15.18%
	4	74	12.91%
	>5	44	7.67%
Birth order of children	First	232	40.49%
	Second	150	26.18%
	third	97	16.93%
	Greater than three	94	16.40%
Children who live in life	1	196	34.21%
	2	175	30.54%
	3	94	16.40%

	4	66	11.52%
	>5	42	7.33%
Have you ever had your child immunization	Yes	542	94.59%
	No	31	5.41%
Immunization with card	Yes	473	82.55%
	No	100	17.45%

Table 33: Health service related characteristics of Primary Guardians of children aged 12-23 months, Mekelle Town, Northern Ethiopia, 2017

Types of variable		Frequency	Percent
Nearest health facility for immunization	Yes	573	100.00%
Type of health facility for immunization			
Hospital	Yes	116	20.24%
	No	457	9.76%
Health center	Yes	433	75.57%
	No	140	24.43%
Health post	Yes	7	1.22%
	No	566	98.78%
Time to reach the nearest immunization center	< 10 minutes	98	17.10%
	16 to 30 minutes	323	56.37%
	31 to 60 minutes	116	20.24%
	>1 hours	12	2.09%
	I did not know	24	4.19%
Mothers ANC follow up while pregnant	Yes	558	97.38%
	No	15	2.62%
Number of ANC follow up	1	2	0.35%
	2	29	5.11%
	3	81	14.29%
	4	281	49.56%
	>5	127	22.40%
	I did not know	47	8.29%
Place of mother deliver her last child	Health facility	546	95.29%
	Home	22	3.84%
	Privet or NGO health facility	5	0.87%
Did the Mather ever immunized TT	Yes	500	87.26%
	No	73	12.73%
How many times receive TT	1	2	0.35%
	2	29	5.11%
	3	81	14.29%
	4	281	49.56%
	5	86	15.17%

	>6	21	3.70
	I did not know	47	8.29%

Table 34: Characteristics of children immunization status by each type immunization mekelle town 2017

Variable Immunization type		Frequency n=573	Percent
BCG	Yes	461	80.45%
	No	112	19.55%
OPV0	Yes	413	72.08%
	No	160	27.92%
OPV1	Yes	464	80.98%
	No	109	19.02%
OPV2	Yes	463	80.80%
	No	110	19.20%
OPV3	Yes	465	80.80%
	No	110	19.20%
DPT HepB Hib1(Pentavalent1)	Yes	466	81.33%
	No	107	18.67%
DPT HepB Hib2(Pentavalent2)	Yes	464	80.98%
	No	109	19.02%
DPT HepB Hib3(Pentavalent3)	Yes	463	80.80%
	No	110	19.20%
PCV1	Yes	465	81.15%
	No	108	18.85%
PCV2	Yes	465	81.15%
	No	108	18.85%
PCV3	Yes	461	80.45%
	No	112	19.55%
ROTA1	Yes	465	81.15%
	No	108	18.85%
ROTA2	Yes	462	80.63%
	No	111	19.37%
MEASELS	Yes	457	79.76%
	No	116	20.24%
Vitamin A	Yes	262	45.72%
	No	311	54.28%
Hadnet	Yes	151	26.35%
Kuha	Yes	141	24.60%
Qedamay Weyyane	Yes	119	20.76%

Table 35 : Bi-variate and Multivariate analysis in 12-23 age month children immunization status related variables

Variable		Immunization Status		Crude OR (95% CI)	Adjusted OR (95% CI)
		No	Yes		
Sex	Female	21	276	2.02(0.9-4.3)	0.8(0.28-1.08)
	Male	10	266		
Mother immunized TT	Yes	15	478	0.04(2.03-6.21)	NI
	No	16	64		
Do you have immunization card	Yes	0	473	0.01(1.0 – 15.3)	NI
	No	31	69		
Did not know the advantage of immunization	Yes	23	86	18.17(7.5-43.5)	44.1(2.4 – 83.6)
	No	8	456		
Unaware of the need to return for subsequent doses	Yes	20	52	5.15(2.7-16.32)	0.29(0.02-3.2)
	No	11	490		
Did not know where and when to get vaccination	Yes	8	27	6.6(12.8-184.9)	2.7(0.75-10.4)
	No	23	515		
Distance of immunization center was far	Yes	22	33	37.7(16.7 – 88.0)	13.4(14.2 – 102.1)
	No	9	509		
Time of immunization inconvenient	Yes	13	24	15.5(6.84-35.47)	71(16.8-130)
	No	18	518		
Worried of immunization side effect	Yes	8	8	9.0(3.6-22.3)	3.4(2.8-6.29)
	No	23	534		
Heard of any information about immunization	Yes	9	20	10.6(4.3-26.0)	16.4(3.8-69.4)
	No	22	522		
Confirmation of child birthday	Yes	22	479	0.32(0.14-0.72)	1.0 (.35 -5.54)
	No	9	63		
Go to health facility after sick	Yes	27	529	0.16(0.05-0.54)	.092(.01-.50)
	No	4	13		
Go to holy water after sick	Yes	9	23	9.23(3.82-22.27)	21.4(4.9- 92.8.)
	No	22	519		
Pregnant follow up clinic	Yes	25	533	0.07(0.023-0.21)	0.01(.002 -.06)
	No	6	9		

* CI-confidence interval significant at 95%
NI-not included

8. Chapter Eight: Abstracts for Scientific Presentation

Title: Acute watery diarrhea outbreak, Warder Woreda Somalia Region Ethiopia, 2017

Authors: Desta Birhane, S. Tanie, A.Bekele

Abstract:

Background: Globally diarrheal disease is the third leading cause of mortality in low income countries, causing estimated 1.4million deaths in 2012. The bacterial, viral, and protozoan pathogens causing diarrheal disease are primarily transmitted via the fecal-oral route, through the consumption of fecal contaminated food and water. In Warder District response activities plan for the outbreak prepared or formulated; time schedule and indicators for achievement identified. The aim is to control the outbreak, and to identify and confirm possible source.

Methods: Community based unmatched 50 cases and 100 control was used considering previous study. Data was collected by the recommended case definitions using structured questionnaire. Case sample were taken from the registration line list by using systematic random sampling system and control from community. Data was entered in to Epi info version 7.2.1.0. Descriptive was analyzed using Excel 2007 and analysis statistics with 95% confidence intervals, was used to compare risk factors. Ethical clearance will be obtained from SPHMMC and consent form will be asked willingness to the eligible people.

Result: From total 329 cases in the study, 53% of the cases were male and 77% are above five years of old. Overall Case Fatality Rate was 5.5%. The total attack rate was 6 people per 1000 population. . Peoples they know to treat the stored water were less likely risk with the diseases (AOR= 0.16, 95 % CI=0.06-0.41. p.value=0.0002). People they have adequate Water for drinking and for preparing their food were preventable association with the AWD diseases with (AOR =0.34, 95% CI=0.11-0.97 p.value=0.044) than those who did not have enough water.

Conclusion and recommendation: people they had information about the disease, they have adequate water and they did know the water treatment were preventable risk of acute watery diarrhea diseases. So efforts in community awareness on the importance of AWD prevention and fulfill the importance resource like clean water and standard public and individual latrine.

Key words: Acute watery diarrhea, outbreak, warder woreda.

9. Chapter Nine: Other Additional Laboratory Works Two SOP and One Laboratory Narrative Report

I. Urine Microscopy

1. Principle

The urine microscopic examination is a method of identifying and quantifying cells, bacteria, and other materials in the sediment of centrifuged urine. This allows the practitioner to rule out or diagnose urinary tract infection and aids in the diagnosis of urinary tract or renal disease.

2. SCOPE:

The procedure is performed in the Hospital and Ambulatory settings by Medical Doctors and Nurse Practitioners who have been trained and maintain annual competency in this procedure.

3. Personnel

Licensed Medical laboratory professional

Licensed Advanced Health Practitioners

4. Reagents, Equipment and Materials

Clean plastic specimen containers

Cleansing towelettes for clean catch technique

Straight catheterization kits for catheterization

Centrifuge

Graduated, conical centrifuge tubes and caps

Plastic pipettes

Unfrosted microscope slides

Cover slips

Microscope with 10x and 40x lenses

5. Specimen

The urine specimen is collected by the patient using the "clean catch" method (See Specimen Collection Procedures), or by a nurse or provider using sterile technique catheterization of the bladder. The specimen is placed directly into a clean plastic container and labeled with two forms of patient identification. The specimen is tested immediately so it does not require storage.

6. Procedure

- 6.1. After testing urine, if necessary, with dipstick, place about 10mL in plastic conical tube labeled with patient's name and cover tube with tight fitting cover.
- 6.2.. Place tube in centrifuge and place a second tube containing equal amount of water (with tight fitting cover on) directly opposite tube with urine, to act as counter weight.
- 6.3. Centrifuge urine specimen according to manufacturer's directions. After centrifuge has stopped, remove tube and pour off the supernatant, leaving any sediment in the bottom of the tube.
- 6.4. With a plastic pipette, mix the remaining liquid and sediment and remove a few drops of the mixture. If there is no obvious sediment present, remove a few drops of urine from bottom of tube.
- 6.5. Place one drop of the sediment solution on a glass slide and cover with a cover slip.
- 6.6. Using the microscope, examine the sediment using phase contrast or bright light
- 6.7. Under low (10x) and high (40x) power, scanning several fields to obtain average numbers of formed elements.

7. Interpretation of Results

Results reported as number of identified elements per high powered (40x) field are: WBC's, RBC's, and casts. The latter need to be identified as hyaline, WBC, RBC, epithelial, fatty, or waxy casts. Samples containing crystals should be forwarded to the Clinical Laboratory for evaluation.

8. Clinical Laboratory for evaluation. Results reported as "few, moderate, or many" are: epithelial cells, bacteria, crystals, and trichomonas. Identify presence of yeast (mycelial forms or hyphae).

9. Calculations: None.

10. Reporting Results

Results should be recorded in the patient record done with the date/time the sample was collected and the name of the provider performing the examination.

11. Procedure Notes

11.1 Sediment of centrifuged urine may be on side of tube, not on bottom of tube observe first before withdrawing sediment specimen.

11.2. May need to use low light on microscope to see hyaline casts and hyphae forms of yeast fungi.

11.3. When cells are too numerous to count (over 100/HPF) report as "many full fields". Also report WBC clumps.

11.4. Grossly bloody samples should be forwarded to the Clinical Laboratory for evaluation.

12. Limitations; An inaccurate reading may be caused by one or several of the following errors made in specimen collection or technique:

12.1 Specimen not obtained by "clean catch" method and thus contains elements from sources other than the urinary tract (e.g., vaginal discharge, penile discharge).

12.2. Specimen not centrifuged long enough.

12.3. Urine extremely dilute so no sediment obtained, or not enough elements available in amount of urine tested.

12.4. Specimen not examined with proper lighting or focusing.

12.5. Microscope not functioning properly, e.g., lens dirty.

12.6. Examiner fails to recognize the elements on the slide.

Document history	Name	Date	Signature
Author	Desta Birhane	08/09/09	
Revision			
Reviewed by			
Approved by			

References:

1. CTRC. Standard Operating Procedures. 2017;1–2.
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II. Formalin stool concentration technique

1. Objective: to perform microscopic examination stool for concentration
2. Principle: The formalin-ether concentration technique is typically conducted in reference laboratories for the concurrent diagnosis of helminthes and intestinal protozoa infections in patients enrolled under the digestive syndrome by concentrating the stool sample via centrifugation, sensitivity of the microscopic detection method can be increased with the different solutions added, fecal debris is extracted into the ether phase and parasitic elements are sediment at the bottom.
3. Safety
 - Handle all samples as potentially infectious, Wear gloves during the procedure.
 - Formalin is poisonous and an irritant, while ether is flammable and presents a risk of explosion.
 - At each study site, safety precautions for handling and disposal of infectious materials should be practiced according to the laboratory safety rules of the participating hospital.
4. Materials
 - Sodium acetate
 - Acetic acid
 - 40% formaldehyde
 - 0.9% NaCl solution
 - Ether
 - Stool container
 - Centrifuge tube [15 milliliters (ml)]
 - Centrifuge stand
 - Funnel
 - Medical gauze
 - Rubber stopper
 - Spatula/ wooden stick
 - Plastic pipette
 - Microscopic slide

- Cover slip
- Light microscope
- Weighing scale

5. Samples

- ❖ Fresh stool (patient should hand in the stool the following morning after container has been distributed; please refer to the SOP for stool collection)

6. Procedures

1. Prepare the sodium acetate/acetic acid/formalin (SAF) solution by dissolving 15 grams (g) sodium acetate in a mix of 20 ml acetic acid and 40 ml 40% formaldehyde in 925 ml of water.
2. Using a weighing scale, preserve approximately 1 g of fresh stool in 10 ml of the SAF solution in a water-tight container. The stool sample should be thoroughly broken up and suspended.
3. For examination, the fixed sample is re-suspended and strained through a funnel layered with medical gauze. Rinse the container and funnel set-up with about 5 ml of SAF solution.
4. The filtrate is collected in a 15 ml tube and centrifuged at 2000 revolutions per minute (rpm) for 1 minute (min),
5. Remove the supernatant with a pipette or gently pour it out without disturbing the sediment. Add 7 ml of 0.9% NaCl to the sediment and mix with a wooden stick. Add another 3 ml of ether to the mixture.
6. Close tube with rubber stopper and shake vigorously for about 30 seconds while keeping the thumb on the stopper. Carefully remove the rubber stopper (beware of pressure build up) and centrifuge the tubes at 2000 rpm for 5 min.
7. After centrifugation, 4 layers should be detectable. Pipette out the first 3 layers of ether, detritus and NaCl (saline). The remaining sediment should be less than 1 ml. If more than 1 ml of sediment is present, repeat steps 5 and 6.
8. Mix the sediment and place a drop on a microscopic slide. Add the cover slip.
9. Examine the whole slide under a light microscope for helminthes eggs (10x objective) and for protozoa (40x objective).
7. Documentation of results

- ✓ Results should be recorded for each species separately in the hospital lab register and transcribed later in the patient request.
- ✓ Record if the test was done or not, and if the test was not done, provide a reason for not doing it.
- ✓ Record if the result is POSITIVE or NEGATIVE.
- ✓ If POSITIVE, record the name & number of helminthes eggs or protozoa and use the following semi-quantitative scheme:

Grade	Density	Parasite Distribution
0	None	No organism per low power objective slide area
1	Rare	2-5 organisms per low power objective slide area
2	Few	One organism per 5-10 high power fields
3	Moderate	From 1-2 organisms per high power field to as few as 1 organism per 2-3 fields
4	Many	More than 2 organisms in every high power field

Document history	Name	Date	Signature
Author	Desta Birhane	08/09/09	
Revision			
Reviewed by			
Approved by			

Reference:

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2. C.Kain K. Procedure Manual Mount Sinai Hospital/Toronto Medical Laboratories Shared Microbiology Service Page 18. 2017;18–24.
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III. Kahsay Abera hospital laboratory narrative report

1. Introduction

1.1. Background

Humera is a town and separate woreda in the western Tigray Regional State of Ethiopia, near the borders of Sudan and Eritrea. Located in Western Zone of the Tigray Region, this town has latitude and a longitude of 14°18'N 36°37'E.981k/m distance from Addis Ababa. Based on the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA), this town has a total population of 21,653, of whom 11,395 are men and 10,258 women; this is an increase of 14,451 over the 1994 national census. The majority of the inhabitants said they practiced Ethiopian Orthodox Christianity, with 93.18% reporting that as their religion, while 6.45% of the population was Muslim (1).

Kahsay Abera hospital is one of the twelve zonal general hospitals in Tigray region found in the western zone. The hospital is a health care institution providing patient treatment with specialized medical and nursing staff and medical equipment. The best-known type of hospital is the general hospital, which typically has an emergency department to treat urgent health problems reaching from fire and accident victims to a heart attack. And is the major health care facility in its region, with 120 numbers of beds for intensive care and additional beds for patients who need long-term care.

The laboratory has divided in to four; those are outpatient, inpatient, emergency and central laboratory.

The laboratory department provides diagnostic testing on specialized instruments to support physicians to diagnose, monitor and treat patient conditions. The Laboratory is staffed 24 hours a day 7 days a week to ensure care for the patients in our community .the laboratory has 12 lab technologists and 2 technicians .the team consists of trained healthcare professionals who work together to ensure quality results that your Health Care Provider can trust.

The hospital Quality

The laboratory is committed to good professional practice, quality of examinations, and compliance with the quality management system in order to meet regulatory requirements and ensure continuous improvement of lab processes and practices. The section of the laboratory is

exempt from the quality management system activities. The laboratory works in quality in order to be certification in accreditation.

Outpatient lab:

Services in the out patent lab include reception, hematology, and parasitology and urine analysis, microbiology.

In the reception room was done different sample collection, like blood for hematology, CD4, clinical chemistry, for serology, parasitology, glucose strip test, hemoglobin strip test, labeling sample, registration and result verification, microbiology sample collection, blood group, malaria RDT.

Hematology

Hematology is the study of blood cells (white, red and platelets). Blood is analyzed to provide accurate information for physicians who are diagnosing and monitoring patients.

In hematology section were performed peripheral blood morphology, blood film for malaria, ESR (Erythrocyte sedimentation) rate ,hematocrit (hemoglobin),serology tests such as typhoid test ,blood transfusion, hepatitis b and c ,helicobacter test strip, whale feilex for typhus, and (RPR) syphilis.

Parasitology room

Stool wet mount microscopic, as necessary concentration technique, urine analysis microscopic and chemical test.

Microbiology

The laboratory identifies bacteria (collected from swabs, tissues and fluids) that invade the body and cause infection. Once the bacteria are identified it is tested for sensitivity to a variety of antibiotics in order to help the doctor select the best treatment.

In microbiology class were performed, acid fast bacteria (zeihle- nelleson), florescent microscope, Gene xpert for micro tuberculosis, CSF meningitis, wet mounts fungus, sexually transmitted diseases (including gonorrhe).

In central laboratory:

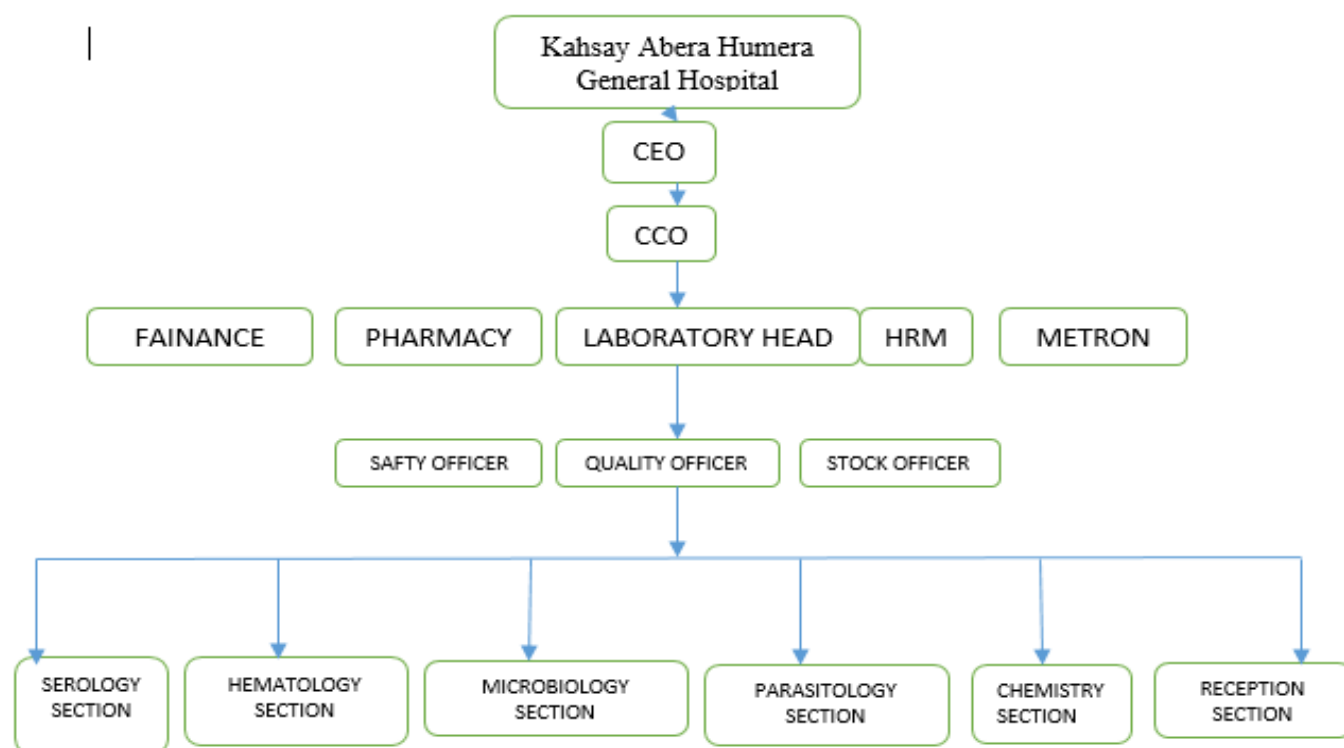
This central lab receives sample from all direction even from health centers referral because the central equipment very expensive which were not found in everywhere. The equipment like CD4 machine, CBC (complete cell count) (sysmex 21),chemistry machine(Auto lab),etc.

Objective:

The main objective of the laboratory is to coordinating and strengthening the laboratory quality system in the hospital and catchment area health centers through Provide public health services such as:

- ❖ Sample Referral diagnostic testing
- ❖ Surveillance for infectious and communicable diseases
- ❖ Outbreak investigation & Emergency response
- ❖ Participating in external and internal quality control
- ❖ Conduct supportive super vision
- ❖ By distribution stock or reagents

Annex 14: Kahsay Abera general hospital organogram



Reference:

1. From Wikipedia the free encyclopedia. <https://en.wikipedia.org/wiki/Humera>. 19 May 2017.

Annex 15: Biography

Biography: E-mail: destabirhane2015@gmail.com phone No = 0920429370

My name is Desta Birhane Tesfay and born on July 1980 G.C in Adigrat, Tigray region North Ethiopia. I was attended my primary education in Agazi school; Secondary high school in mydagame and high school in Agazi in Adigrat town. Then I was joined to Gondar University and graduated with in diploma laboratory technician in 2003 G.C.

After graduation I was employed by federal bureau of health in Humera and worked as senior laboratory technician in Kahsay Abera general hospital Humera Tigray region since September 2004 to November 2012. For the first six months I was working in different department of the laboratory latter on I have been working as the head of the laboratory and coordinating all the activity. During this time I was received several training in different laboratory techniques and procedures with related to different diseases. This includes as showmen in table below

From 2013 to 2015 as laboratory technologist position I was continue working by carry different tasks and responsibility. Since 2016 I was joined Saint Paul's hospital millennium medical college for a postgraduate studies in FETP lab track.

Name of Training	Place(Training center)	Date & Year
TB Microscopy	Mekelle University	March 28-2may 2005e.C
Laboratory Research Project Participation	Gondar University	From November 2012-June 2013G.C
Bio Safety Training	Mekelle, Axum Hotel By I-Tech.	February 1-4/2003G.C
CD4 Machine Training	Humera, Tigray, Ethiopia	April 20 th –22th 2004 G.C
Lab Automation	Adwa, Adwa Hospital.	Feb-1-10/2000G.C
Quality Assurance	Mekelle Research Laboratory	Feb-8-12/1996G.C
Visceral Leishimaniasis (Kalazar)	Kahsay Abera Hospital	4 th -5 th October 2008G.C
Laboratory Work Shop	Kenya, Nairobi	31 st of January-5 th of October
Malaria Indicator Survey(MIS-2007)	Carter Centre Ethiopia	From 1 st October-30 th December 2007G.C
Research participation(lab sample collection &	Gondar University	From November 2012-june 2013 G.C

processing)		
Epi Info Software	Ethiopia Public Health Institution(EPHI) & CDC	May 11 to 12, 2017 G.C

My References

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