



**SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE,
DEPARTMENT OF PUBLIC HEALTH
ETHIOPIAN FIELD EPIDEMIOLOGY AND LABORATORY
TRAINING PROGRAMME
COMPILED BODY OF WORKS IN FIELD EPIDEMIOLOGY**

**BY
DESALEGN BELAY, BSC**

**SUBMITTED TO THE DEPARTMENT OF PUBLIC HEALTH IN PARTIAL
FULFILLMENT FOR THE DEGREE OF MASTER OF PUBLIC HEALTH IN
FIELD EPIDEMIOLOGY**

**FEBRUARY 2018
ADDIS ABABA**



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**SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE
DEPARTMENT OF PUBLIC HEALTH**

DECLARATION FORM

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

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DEPARTMENT OF PUBLIC HEALTH GRADUATE STUDIES

FINAL BODY OF WORK WITH THESIS APPROVAL FORM

As member of the Board of Examiners of the final body of work with thesis open defense, we certify that we have read and evaluated the body of work with thesis prepared by **DESALEGN BELAY TAKELE** under the title “**PREVALENCE AND FACTORS ASSOCIATED WITH MIDDLE EAST RESPIRATORY SYNDROME-CoV IN HUMAN POPULATION OF CHIFRA WOREDA: CAMEL REARING AREA OF AFAR REGION, ETHIOPIA** ” and recommencement for the *degree of Master of Public Health in Field Epidemiology*.

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Final approval and acceptance of the body of work with thesis is contingent up on the submission of the final both hard and soft copies of the body of work with thesis to the department of public health.

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List of Abbreviations

AIDS	Acquired Immune-Deficiency Syndrome
ANC	Antenatal Care
AOR	Adjusted Odds Ratio
ART	Anti-Retroviral Treatment
CBN	Community Based Nutrition
CBR	Crude Birth Rate
CDC	Center for Disease Control and Prevention
CDR	Crude Death Rate
CHIKV	Chikungunya Virus
CMR	Child Mortality Rate
COR	Crude Odds Ratio
ECSA	West African, East/Central/South African
EFELTP	Ethiopian Field Epidemiology and Laboratory
ELISA	Enzyme Linked Immunosorbent Assay
ENHS	Environmental Health Science
EOS	Enhanced Outreach Strategy
EPHI	Ethiopian Public Health Institute
EPI	Extended Program on Immunization
GISN	Global Influenza Surveillance Network
GISRS	Global Influenza Surveillance and Response System
GR	Growth Rate
HEW	Health Extension Worker
HIV	Human Immuno-Deficiency Virus
IgG	Immunoglobulin G
ILI	Influenza-Like Illness
IMR	Infant Mortality Rate
ITN	Insecticide Treated Net
LLINs	Long Lasting Impregnated Nets
MCH	Maternal and Child Health
MERS-CoV	Middle East Respiratory Syndrome Corona Virus
ml	Milliliter
MMR	Maternal Mortality Rate
MSF	Medicines Sans Frontiers
NIL	National Influenza Laboratory
NMR	Neonatal Mortality Rate
OPD	Out Patient Department
OPV	Oral Polio Vaccine
OR	Odds Ratio

OTP	Outpatient Therapeutic Program
PF	Plasmodium Falciparum
PHEM	Public Health Emergency Management
PLWHIV	Peoples Living with HIV/AIDS
PMTCT	Prevention Mother to Child Transmission
PNC	Postnatal Care
PPV	Positive Predictive Value
PT	Provider Initiated Counseling and Testing
PTB	Pulmonary Tuberculosis
PV	Plasmodium Vivax
RHB	Regional Health Bureau
RNA	Ribonucleic Acid
rRT-PCR	Real Time Reverse Transcriptase Polymerase Chain Reaction
S1	Spike 1
SARI	Severe Acute Respiratory Infection
SD	Standard Deviation
SNNP	Southern Nations Nationalities and Peoples
SOP	Standard Operating Procedure
SPHMMC	Saint Paul Hospital Millennium Medical College
TB	Tuberculosis
TBA	Traditional Birth Attendant
TFU	Therapeutic Feeding Unit
TSF	Therapeutic Supplementary Feeding
TT	Tetanus Toxoid
UNICEF	United Nations International Children Emergency Fund
VCT	Voluntary Counseling and Testing
WHO	World Health Organization
WHO CC	World Health Organization Collaborating Centers
WK.	Week

Summary

The Ethiopian Field Epidemiology and Laboratory Training program (EFELTP) is a two years field based master's program. The field work comprises 75% of the program which is called residency.

This compiled of works has eight main sections (chapters) of which were done during the residency time of the program. These includes outbreak investigation, report of analysis of surveillance data, evaluation of the surveillance system, description of a health profile report, laboratory standard operating procedures, laboratory quality manual and research project.

The above outputs were done at Dolo Ado(Somali region), Kolfe health center (Addis Ababa), national, Kolfe Keraniyo woreda 9(Addis Ababa), Shewarobit (chapter V and VI) (Amhara region) and Chifra woreda (Afar region) respectively. All of them were done from April 2016 up to December 2017.

In order to accomplish all the above eight outputs of residency, different techniques and methods were utilized. During an outbreak investigation (chikungunya fever virus), we used laboratory confirmation to verify the outbreak and case control study was employed. We computed descriptive analysis for report of analysis of surveillance data, evaluation of the surveillance system (Influenza sentinel surveillance), and description of a health profile report using both primary and secondary data sources as appropriate. Laboratory operating procedures and laboratory quality manual (for Shewarobit health center) were prepared according to the national laboratory accreditation program using ISO 15189:2012 protocols. The research project (seroprevalence of Middle East respiratory syndrome-corona virus on human population) was done using primary data at community level and Enzyme-linked Immunosorbent assay for laboratorytesting.

CHAPTER I: OUTBREAK INVESTIGATION REPORT

CHIKUNGUNYA FEVER OUTBREAK INVESTIGATION, DOLO ADO DISTRICT, LIBEN ZONE, SOMALI REGION, ETHIOPIA, JUNE 2016

Abstract

Introduction: Chikungunya is a vector borne virus in alphaviridae family passed to humans by Aedes mosquito bite. Chikungunya virus has been transmitted by Aedes aegypti and Aedes Albopictus mosquitoes. Laboratory confirmation can be done via detection of CHIKV and anti-CHIKV antibody in blood samples. Because it is a risk group three pathogen, its containment is in biosafety level 3 facilities.

Objective: To determine factors associated with Chikungunya fever outbreak in Dolo ado district, Liben zone, Somali regional state, South-Eastern Ethiopia from June 10 to 17, 2016.

Methods: An unmatched case-control study design was used to investigate the outbreak from June 10 to 17, 2016. Epidemiological data were collected through face to face interview using structured questionnaire. Laboratory tests were performed all 17 serum samples using Real Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) technique. Results were displayed using texts, tables and graphs and statistical significance was interpreted using Odds ratio with 95% confidence interval and P value <0.05 after logistic regression was performed.

Result: In a multivariable analysis, failure to use long lasting impregnated net[AOR=14.6,(1.7-127.8), (p=0.015)], presence of Aedes mosquito larvae in water holding container during the investigation time[AOR=25.6(1.5-442.5), (p=0.025)] and travel history to Mendera (the neighboring Kenyan town) 2 weeks back from the date of onset of illness[AOR=37.3(4.3 - 321.3),(p=0.001)] were found associated with the disease. The odds of respondents who did not use bed nets while sleeping during daytime were 14.6 times more to have the disease than those who used bed nets. Basically, this finding is applicable for Aedes aegypti because it bites in the day time, and to the contrary using bed nets in a very hot weather may not be comfortable.

Conclusion: This investigation notes that Chikungunya has emerged in Ethiopia. This result reveals that we have faced a new cause of acute febrile illness. Vector control intervention, particularly, LLINs, IRS and larvicidal should be applied to halt the transmission. Continuous education should be offered for border crossing people to dress long sleeved clothes. Ministry of health should recognize the disease as public health threat and prepare guideline, intervention strategy and reporting mechanism.

Keywords: Chikungunya, Virus, Outbreak, Ethiopia

Introduction

Chikungunya is a vector borne virus in alphaviridae family passed to humans by *Aedes* mosquito bite(1). It was isolated in Tanzania where a massive outbreak with unusual illness characterized by crippling joint pain and severe fever in 1953(2). The name Chikungunya was derived from *Makonde* (a language spoken by Makonde, an ethnic group who live in southeast Tanzania and northern Mozambique) root verb *kungunyala* meaning “that which bends up”, “to become contorted”, or “to walk bent over”(3).

Chikungunya is believed to have originated from Africa and spread to islands off the eastern coast of Africa(4). The first emergence of Chikungunya was confirmed in April 2005 in southwestern Indian region, Comoros Islands which are near to the eastern coast of Mozambique(2). The virus was spread to Mayotte, Mauritius, and the French island of La Reunion. The attack rates for this outbreak in 2005 ranges from 35% to 75%. In 2006, after an apparent gap of about 32 years during which CHIKV was not detected, CHIKV disease has attacked many people in India in numerous states, suspected number of cases ultimately reaching more than 1.3 million(2)(4). The CHIKV outbreak has spread causing large outbreaks in many other countries in Southeast Asia. CHIKV was introduced into countries where it is not endemic by viremic travelers, including Italy, France, New Caledonia, Papua New Guinea, Bhutan, and Yemen(5)(4).

CHIKV was also introduced to the Americas by end of 2013. WHO reported the first local transmission of Chikungunya virus in Saint Martin, a Caribbean island(6). The rapid and explosive spread of CHIKV had caused a morbidity of about 440,000 people in more than 20 American countries, including USA’s Florida. In general, CHIKV has spread from the coast of Kenya throughout the Indian Ocean, Pacific, and Caribbean regions, causing millions of cases of disease in over 50 countries. In general, Chikungunya virus epidemics have shown cyclical trends, with inter-epidemic periods ranging from 4 to 30 years(2)(7).

Three genotypes of CHIKV, called West African, East/Central/South African (ECSA), and Asian have been defined, of which the latter two caused large outbreaks. ECSA genotype virus, which had originated from Kenya, was responsible for the epidemics on islands in the Indian Ocean. Thus, it was quite unexpected when the ongoing outbreaks in the Caribbean region were found to be due to an Asian genotype virus. Chikungunya virus has been transmitted by *Aedes aegypti* and

Aedes albopictus mosquitoes. There is evidence that ECSA strains have been adapted to *Ae. albopictus* whereas *Ae. aegypti* have greater competence for Asian strains over ECSA strains[(8)(4),(2)].

Laboratory confirmation can be done via detection of CHIKV in blood samples using enzyme linked immune-sorbent assay(ELISA), reverse transcriptase real time polymerase chain reaction (RT-PCR) , real time RT-PCR , indirect immunofluorescence assay, viral culture(virus isolation), neutralization assays, and/or haemagglutinin inhibition assays. Chikungunya virus, as it is a risk group 3 pathogen, is containment in biosafety Level 3 facilities, equipment, and operational practices for work involving infectious or potentially infectious material(9)(10). Currently, the Ethiopian public health institute arbovirus testing set up is equipped with a real time RT-PCR principle. This set up is now based at the Ethiopian national influenza laboratory where previously detected new pathogens, like Dengue and Yellow Fever Viruses, are being diagnosed. This laboratory has a capacity to detect other pathogens, such as Zika, west Nile, Cremona Congo, Rift Valley fever viruses. This investigation was done to provide a brief overview about emergence and possible risk factors of Chikungunya outbreak in Ethiopia. The Ethiopian public health institute received 10 serum specimens on June 6, 2016 and immediately deployed investigation team.

Objective

General Objective

- To describe and determine factors associated with Chikungunya virus outbreak in Dolo ado district, Liben zone, Somali regional state, South-Eastern Ethiopia

Specific Objectives

- To confirm and describe the epidemiology of Chikungunya outbreak in Dolo Ado woreda, Somali region
- To determine factors associated with the occurrence of Chikungunya outbreak in Dolo Ado woreda, Somali region

Methods and Materials

Outbreak Setting:

Dolo ado district is one of the district of Liben Zone, Somali Regional State, which is located in South-Eastern Ethiopia. It is located 1,050kms far from the capital Addis Ababa. The district has

a total population of 133,368, out of which 51% of the population was females(Source: Dolo Ado Woreda health office).

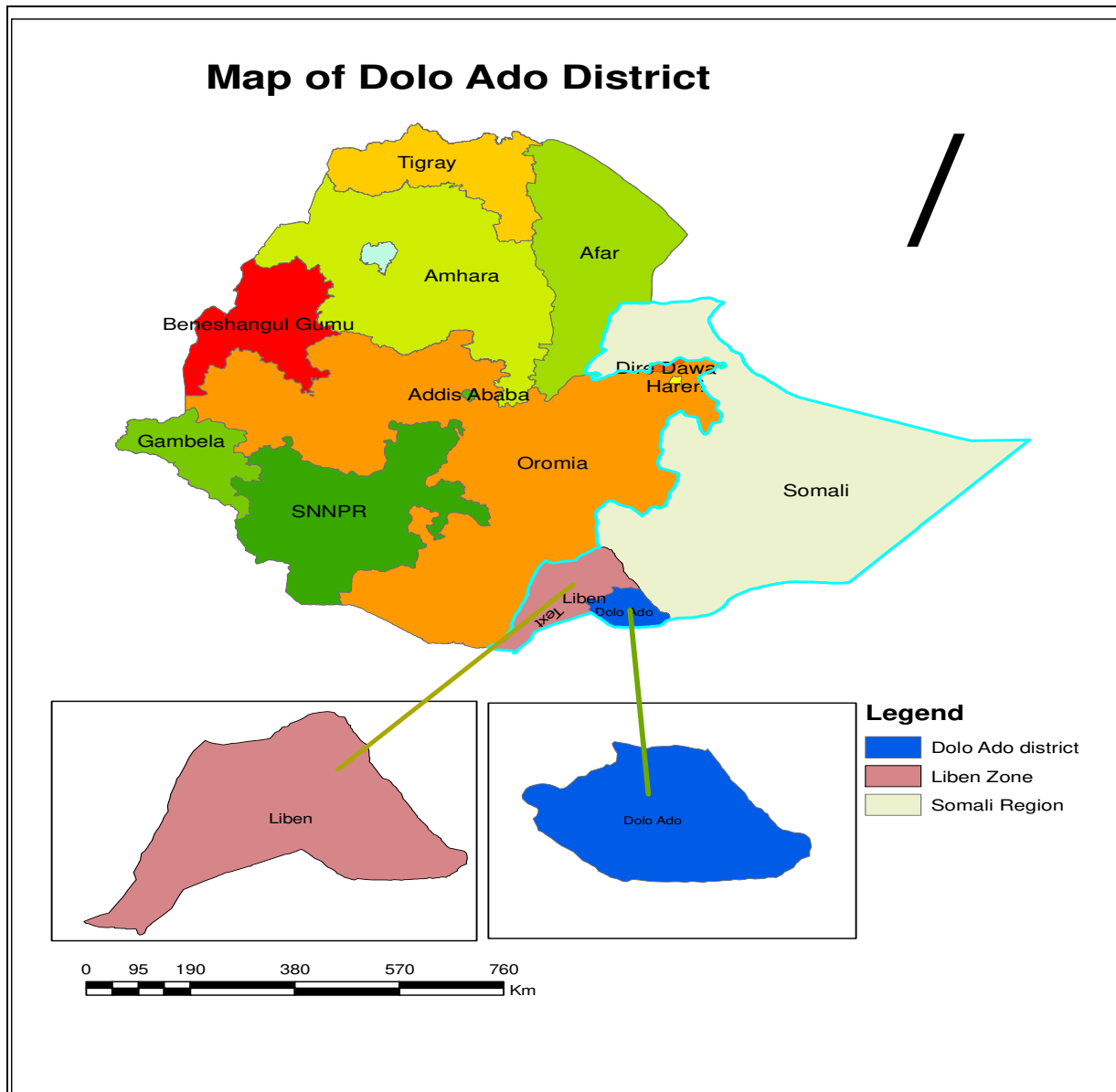


Figure 1: Map of Ethiopia Showing Dolo Ado woreda, Somali Regional State, South-Eastern Ethiopia, June 2016

Study Design and Period

An unmatched case-control study design was used to investigate the outbreak from June 10 to 17, 2016.

Source Population

All residents of Dolo Ado woreda were the source population.

Study Population

Cases and their controls were study populations.

Cases were identified by the Chikungunya case definition adapted from WHO regional office for south-east Asia that proposed by the European Centre for Disease Control (ECDC).

- **Cases:** any ill person meeting the clinical criteria
- **Controls:** were all people who do not present any sign and symptom of the illness who is neighbor of the cases.

Case Definition

Clinical criteria: Acute onset of fever $>38.5^{\circ}\text{C}$ and severe arthralgia/arthritis not explained by other medical conditions

Epidemiological criteria: Residing or having visited epidemic areas, having reported transmission within 15 days prior to the onset of symptoms (i.e. Mandera, Kenya)

Sample Size and Sampling Procedure

A total of 33 cases and 66 controls were interviewed with a ratio of 1:2 making total participants 99. Patients who were admitted in medical wards with suspected chikungunya fever and on treatment at Out Patient Departments (OPDs) during the time of data collection were included. Controls were selected randomly among the neighbors two for each case.

Data Collection

Epidemiological data were collected through face to face interview using structured questionnaire prepared in English with the help of local guides and translators and laboratory specimen was collected by the investigator. The questionnaire was divided in to three main areas covering demographic information, clinical information, laboratory specimen information, knowledge assessment and exposure information of the disease. For verifying consistency, the questionnaire was pre-tested a day before the actual data collection.

Laboratory Investigation

Serum samples were collected and transported according to the recommended cold chain to identify the cause of the unusual febrile illness. Ten serum samples were received by the national arbovirus laboratory (which is based in the national influenza laboratory) before the national investigation team was dispatched to the area of outbreak, Suftu. Additional eight specimens were taken by the investigation team and the test was done along with the first ten specimens after the laboratory has made the reagent available for the first time in the country. Laboratory

tests were performed for Dengue fever Virus and Chikungunya viruses for all 18 serum samples using Real Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) technique to identify the etiology of the existing febrile illness.

Data Analysis

The data were checked for completeness and consistency and analyzed using SPSS version 21 software. Descriptive data analysis was performed by time, person and place using Microsoft office excel sheet. Attack rate was calculated by dividing the number of cases to the population (Source: Dolo Ado Woreda Health Office). Logistic regression was also applied to determine the factors associated with Chikungunya fever disease outbreak. Results were displayed using texts, tables and graphs and statistical significance was interpreted using Odds ratio with 95% confidence interval and P value <0.05.

Ethical issues

Support letter was written to those concerned so as the national investigation team, as a public health emergency response body, can responsibly and accountably undertake the response activity at the site of the outbreak. Serum samples were collected only aiming to investigate the causative agent of the unusual febrile illness and to guide appropriate outbreak control interventions. The direction was given from EPHI, the government organization which has a full mandate to conduct epidemiological and laboratory investigation, and respond to any public health emergencies.



Figure 2: Discussion with stakeholders to respond to chikungunya fever virus outbreak, Suftu, Dolo Ado, June 2016

Result

Descriptive Epidemiology

A total of 99 individuals (33 cases and 66 controls) were interviewed. From the total respondents, 37(37.4%) were males and 62(62.6%) were females. Out of the 33 cases, 34 and 36 were males and females respectively. The median age of participants was 28 years (range from 3 to 70). From the total cases, 5(15.2%) were singles, 27(81.8%) were married and 1(3.0%). Similarly, 16(24.2%) of the controls were single, 45(68.2%) were married and 2(3.0%) were divorced/separated. Regarding occupation of the cases, 5(15.2%) were students, 8(24.2%) were daily laborers, 13(39.4%) were house wives, 2(6.1%) were merchants, 3(9.1%) were farmers and 2(6.1%) were government employees. Among the controls, 12(18.2%) were students, 5(7.6%) were daily laborers, 27(40.9%) were house wives, 8(12.1%) were merchants, 1(1.5%) were farmers and 13(19.7%) were government employees. More than half of the cases, 20(60.6%) could not read and write, 10(30.3%) have completed primary education, 2(6.1%) have completed secondary school and a person out of 33 has completed college. Whereas among the controls, 24(36.4%) could not read and write, 24(36.4%) have completed primary education, 13(19.7%) have completed secondary school and 5(7.6%) have completed college/university. The interviewees were also asked some knowledge questions regarding Chikungunya fever. Based on the interview, 14(42.4%) of the cases and 26(39.4%) of the controls have heard about Chikungunya from different sources.

Associated Factors towards Chikungunya Fever disease

The availability and use of LLINs were assessed and 54.5% of the cases have LLINs while 87.9% of the controls had access to LLINs. Among those who have LLINs, 17.6 % of the cases and 67.2% of the controls use it while sleeping. Almost all respondents had water holding containers in their houses, and larvae were identified from the water holding containers of 12(37.5%) cases and 1(1.5%) control. There was no stagnant water in that area and there is only one river, Dawa River, which is more than 200 meters from the village. Moreover, none of the respondents' house was sprayed in the last three months. In terms of close contact, 66.7 % of the cases had close contact with a person of the same complaint, while only 36.4 % of the controls had similar exposure. None of the respondents used mosquito repellent neither on their skins nor in their houses except a single case. Among the cases, 42.4% wear long sleeved clothes and 66.7% of the controls wear long sleeved clothes.

Table 1: Risk factors towards Chikungunya cases and controls, Dolo Ado District, June 2017

Characteristics	Cases n=33	Controls n=66	COR(95% CI)	P-Value
Availability of LLINs				
Yes	19(57.6%)	58(87.9%)		
No	14(42.4%)	8(12.1%)	5.3(1.9-15.1)	0.001
Utilization of LLINs				
Yes	3(9.1%)	39(59.1%)		
No	30(90.9%)	27(40.9%)	14.4(3.9-52.2)	0.000
Status of Water Holding Container				
Open	22(68.7%)	37(56.9%)		0.019
Closed	10(31.3%)	28(43.1%)	2.9(1.2-7.1)	
Presence of Larvae in Water-holding Container				
Yes	12(37.5%)	1(1.5%)	38.3(4.7-311.9)	0.001
No	20(62.5%)	64(98.5%)		
Close Contact with Ill Person in the Last 2 weeks				
Yes	22(66.7%)	24(36.4%)	3.5(1.4-8.4)	0.005
No	11(33.3%)	42(63.6%)		
Travel history to Mandera(Kenya) with in the past 2 weeks				
Yes	20(60.6%)	2(3.0%)	49.2(10.2-236.8)	0.000
No	13(39.4%)	64(97.0%)		
Type of cloths				
Long sleeved	14(42.4%)	44(66.7%)		
Short Sleeved	19(57.6%)	22(33.3%)	2.7(1.1-6.4)	0.023

In a bivariate analysis, the above factors seemed to have association with chikungunya fever disease. But, when we perform a multivariable analysis some of them hadn't have real association. Among them, utilization of LLINs ($p=0.015$), presence of *Aedes* mosquito larvae in water holding container during the investigation time ($p=0.026$) and Travel history to Mandera (the neighboring Kenyan town) with in the past 2 weeks from the date of onset of the disease($p=0.001$) were important risk factors.

Table 2: Independent predictors of Chikungunya fever disease, Dolo Ado District, June 2017

Characteristics	Case	Control	COR (95% CI)	AOR (95% CI)	P-Value for AOR
Utilization of LLINs while sleeping					
Yes	3(9.1%)	39(59.1%)	1:00	1:00	
No	30(90.9%)	27(40.9%)	14.4(3.9-52.2)	14.6(1.7-127.8)	0.015
Presence of Larvae in Water-holding Container					
Yes	12(37.5%)	1(1.5%)	38.3(4.7-311.9)	25.6(1.5-442.5)	0.025
No	20(62.5%)	64(98.5%)	1:00	1:00	
Travel history to Mandera (Kenya) with in the past 2 weeks					
Yes	20(60.6%)	2(3.0%)	49.2(10.2-236.8)	37.3(4.3 - 321.3)	0.001
No	13(39.4%)	64(97.0%)	1:00	1:00	

Discussion

First of all, this study is a case control study and hence could not determine the prevalence of Chikungunya virus in Dolo Ado woreda. Because of unavailability and shortage of diagnostic reagents, and the difficulty of the area to transport specimens easily, only limited specimens were collected relative to the large number of cases. The detection of Chikungunya virus nucleic acid, RNA, in most of the specimens by rRT-PCR can be considered as the first virological evidence of the existence of Chikungunya virus in the country's public health history.

The number of affected people in the period of outbreak is nearly equivalent with that reported in Indonesia in 2007 although the later had reported cases from multiple districts(11). The number of reported cases associated to this first outbreak is much lower than what neighboring Kenya had experienced for the first time in 2004 that attacked 13,500 people in Lamu county which represents 70 per cent of the population(12). In addition, the attack rate of the outbreak in Dolo Ado woreda was much lower than the neighboring sub-county of Kenya, Mandera, which was about 80% of the general population and 50% for the health workers according to WHO' outbreak news posted on 9 August 2016.

An outbreak of Chikungunya in Comoros in 2005 was once the cause of morbidity to 450 case per week in May 2005 and peak at the end of January 2006 (45,000 cases / week), which resulted in cumulated cases of 266.000 by end of June 2006(About 1/3 of the population has been infected)(13).in our case, all the cases were report in the month June, which resulted in a maximum number of victims of 291 cases per week at epidemiological week 26.This may be due to the smaller number of population living in Suftu and limited movements into and out of this Kebele, or prompt response in environmental management to interrupt Chikungunya transmission(14).

Knowing the genotype of Chikungunya is crucial to understand the source and linkage of the outbreak because its pathogenicity may worsen as it mutates like that in La Reunion islands(2) Unexpectedly, a new lineage, the East- Central -South African genotype, was introduced from Angola in the end of May 2014 in Feira de Santana (FSA), the second largest city in Bahia state, Brazil, where over 5,500 cases have now been reported(8). In this year, Chikungunya is reported in much number than last year (2015) in India(15). This may be the conduciveness of the environment for the spread of *Aedes* mosquito as a result of the global climate change.

The massive outbreak of Chikungunya virus which started in 2013 in the Americas has resulted in nearly 1 million cases and 71 deaths by the end of 2015(8). Although the genotyping was not done for this outbreak in Ethiopia, having no reported death due to Chikungunya is fortunate unlike could have been deaths attributed to Chikungunya outbreak in Americas by the Asian type.

On multivariable analysis, the study showed that utilization of LLINs, presence of larvae in the water holding container and previous travel to Mandera, the Kenyan town before two weeks from the interview remained associated with Chikungunya fever disease. The odds of respondents who did not use bed nets while sleeping in daytime were 14.6 times more to have the disease than those who used bed nets. Basically, this finding is applicable for *Aedes* mosquito bites in the day time, and meanwhile the respondents might have thought it shameful to respond negatively because it is not comfortable to use bed nets since the study area is very hot. Presence of larvae of *Aedes* mosquito in the water holding container of the respondents was found cause of chikungunya fever infection though effect of type of container was not studied. This association of chikungunya infection is consistent with the risk factors of chikungunya infection in Nepal(16).

We have also found a significant association between chikungunya fever disease and travel to the Kenyan town of Mandera. A case control study conducted in Malaysia showed similar risk factor for chikungunya infection (OR=3.24, 95% CI: 1.82, 5.78, $p<0.0001$)(17).

Lessons Learned

This outbreak showed us we need to be vigilant in identifying the cause of acute febrile illness cases. This will help us in building the national laboratory capacity to detect cases of unknown causes that went wrongly reported.

Conclusion and Recommendation

This investigation notes that Chikungunya has emerged in Ethiopia and there is no way that it cannot cause illness again and affect all ages and both sexes. This result reveals that we have faced a new cause of acute febrile illness. Failure to use impregnated bed nets while sleeping in daytimes, mosquito breeding in household water holding containers and movement to chikungunya affected area of Mandera, Kenya were significantly associated with the disease in multivariable analysis. Vector control intervention, particularly, LLINs, IRS and larvicidal should be applied to halt the transmission by local health office. Continuous education should be

offered for border crossing people to dress long sleeved clothes. Ministry of health should recognize the disease as public health threat and prepare guideline, intervention strategy and reporting mechanism.

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CHAPTER II: SURVEILLANCE DATA ANALYSIS REPORT

BURDEN OF INFLUENZA-LIKE ILLNESS AT KOLFE HEALTH CENTER FROM 2010-2015, ADDIS ABABA

Abstract

Introduction: Influenza is an acute viral respiratory tract disease characterized by fever, headache, myalgia, prostration (fatigue), sore throat and cough. Influenza virus has three types A, B and C. Historically in the last century, there were three recorded influenza pandemics, namely Spanish Flu of 1918, Asian flu of 1957 and Hong Kong Flu of 1968. In Ethiopia, influenza sentinel surveillance has been launched in 2008 with one ILI sentinel site (Shiromeda Health Center) and one SARI sentinel site (Yekatit 12 Hospital). However, detail catchment area specific data analysis was not collected to figure out the positivity rate, incidence and burden of ILI so as to guide the decision makers. This analysis is aimed at determining the burden and incidence of ILI at Kolfe health center and its catchment population.

Method: This descriptive data analysis was done for Kolfe Health Center's Influenza surveillance data which is nationally public health emergency management center. This data was collected from 19-30 April 2016. Descriptive statistics, like measures of dispersion and measures of central tendency are used. The health center identifies cases were identified through the use of Ethiopian Influenza Sentinel Surveillance Implementation Guideline. Written permission was obtained from the center of public health emergency management at Ethiopian Public Health Institute. Surveillance officers of Kolfe health center, national public health emergency management and field supervisor commented and feedback was obtained.

Result: Totally, 1,375 ILI visits were found registered that met the ILI case definition with age range from 1 months-80 years and no reported death from September 2010-December 2015. Among a total of 347 positives, 218(63%) were Influenza A and 129(37%) of them were Influenza B. Majority of the ILI cases were in the 15-24 year age group, 356 (26%) followed by 25-34 years which is 313(23%). No death was reported due to ILI in all age groups. Influenza like illnesses account from 5.05 % to 29.64% of outpatient visits each year from the beginning of 2010 to the end of 2015. From the total outpatient visits from 2010-2015, ILI accounts 17.53 %.

Discussion: According to this analysis, ILI occurred all year round with some peaks during February-March and around December. Influenza is known to come epidemic during winter or cold in temperate regions as opposed to what has been observed in tropical countries where it is present throughout the year often with cold season period of exacerbations. Laboratory positivity exceeded Tanzanian positivity though the latter includes severe acute respiratory infection. Both the Ethiopian and Tanzanian national influenza laboratories use same type of diagnostic technology called, rRT-PCR, and similar reagent supplies from the international reagent resource (IRR). This data analysis revealed that the influenza viruses have been circulating in Kolfe sub-city which affected both males and females of all age groups. Continuous influenza surveillance will provide a frame work for detecting and following future influenza outbreaks and pandemics.

Introduction

Influenza is an acute viral respiratory tract disease characterized by fever, headache, myalgia, prostration (fatigue), sore throat and cough. Cough is often severe and protracted with recovery in 2-7 days. Influenza is indistinguishable from other respiratory viral diseases without laboratory confirmation(1). The viruses are classified as influenza types A, B and C. Influenza type A and B viruses can cause epidemic disease in humans, and type C viruses usually cause a mild, cold-like illness. Influenza A infects multiple species, including humans, other mammals, and wild and domestic birds(2)(3).

From the molecular biology point of view, Influenza A and B viruses can be sub-typed. Influenza A viruses are sub-typed according to the antigenic and genetic nature of their surface glycoprotein; 16 hemagglutinin (HA) and 9 neuraminidase (NA) identified to date. Likewise, Influenza B viruses are sub-typed as Yamagata and Victoria. Genes encoding the surface glycoprotein of influenza A and B viruses mutate constantly leading to emergence of new strains with different antigenic characteristics. One way is through minor changes in the surface genes is ‘antigenic drift’ and this is responsible for causing annual seasonal influenza epidemics(4)(5).

Over the past two centuries, several influenza A subtypes have circulated extensively in humans: seasonal influenza viruses H1N1, H1N2 and H3N2. Another way is through “antigenic shift”, which is a major change, a sudden event that occurs through direct animal-to-human transmission, or through mixing of human influenza and animal influenza A virus genes in an intermediate host. Antigenic shift represents a major change in antigenicity; hence few individuals are protected against the new strain. If “antigenic shift” results in the creation of a novel influenza A virus that is transmissible among humans, it can lead to an influenza pandemic (6)(7). Historically in the last century, there were three recorded influenza pandemics, namely Spanish Flu of 1918, Asian Flu of 1957 and Hong Kong Flu of 1968(5)(8).

Although all of them caused substantial morbidity and mortality, especially among young adults, the Spanish Flu was the most serious took over 40 million lives worldwide. All pandemics have been due to a new influenza A subtype in humans. In 1997 an avian influenza virus (H5N1) never before seen in humans, crossed the species barrier and caused a fatal outcome in one-third of infected individuals. H5N1 one of a group of so-called highly pathogenic avian influenza

(HPAI) viruses was widely feared to cause the next influenza pandemic, but it had limited capacity for human-to-human transmission ever since it had been detected(1). In 2009 another novel influenza A virus initially believed to be of swine origin, but subsequently shown to be composed of genes from three different species, caused the first influenza pandemic of the twenty-first century influenza A(H1N1)pdm2009(6)(9).

Influenza virus spreads rapidly around the world causing seasonal epidemics in temperate climates. These epidemics result in excess morbidity and mortality, especially among the very young and elderly age groups. Seasonal influenza peaks typically every year in the late fall or winter when cold weather is present, though there could be sporadic cases all year round. The reason for the seasonality is unknown but could be due to virus transmissibility resulting from favorable conditions for virus survival during the cooler seasons, or increased transmission due to indoor crowding during cold weather. Usually, the outbreak will reach its peak within 2-3 weeks and may last 5-6 weeks, although the virus may still circulate in the community for weeks before and after the onset of the outbreak. Outbreaks of Influenza are mostly spread through mass gatherings, like in traveling ships, world cup games and the hajji pilgrimages (2)(9)(10).

In Ethiopia, influenza sentinel surveillance has been launched in 2008 with one ILI sentinel site (Shiromeda Health Center) and one SARI sentinel site (Yekatit 12 Hospital). Furthermore, additional two ILI sentinel sites (Akaki Kality and Kolfe health Centers) are added in 2010. Subsequently, in 2013 SARI sentinel sites were established in four mega regional states capitals. Currently there are three ILI and Five SARI sentinel sites providing both weekly aggregated and throat swab samples. Some baseline data has been generated in all eight sentinel sites, namely Shiromeda Health Center, Yekatit 12 Hospital, Kolfe Health Center, Akaki Health Center, Adama Hospital, Adare Hospital, Felegehiwot Hospital and Mekelle Hospital. But more efforts are needed to better understand the epidemiology of influenza in the country. Presently, sentinel sites are located in Addis Ababa, Amhara, Tigray, Oromia and SNNP regions which are selected using a criteria developed to assess the convenience and feasibility of sites. Health Centers are regarded as Ili sites where as Hospitals SARI sites. Epidemiological data and clinical specimens are collected on the sentinel sited and the virological investigation is done nationally in the National Influenza Laboratory located in Ethiopian Public Health Institute. Kolfe Health Center is one of the three influenza surveillance sites of ILI since September 2010. Since then, this site

is dominant source of both epidemiological and virological data which collected some 1375 samples up to the end of 2015.

Rationale of the Data Analysis

Influenza is contagious and highly mutating virus which can cause a devastating pandemic. Influenza like illness (ILI) data has been routinely collected from Kolfe Health Center since 2010. However, detail catchment area specific data analysis was not collected to figure out the positivity rate, incidence and burden of ILI so as to guide the decision makers. Hence, this analysis will determine the burden and incidence of ILI at Kolfe health center and its catchment population. The analysis will also identify the surveillance gaps if any so as to implement corrective actions.

Objectives

General objective

- ✓ To determine the influenza positivity rate, incidence and burden of ILI at Kolfe Health Center and its catchment population

Specific objectives

- ✓ To describe the data in terms of time, place, person
- ✓ To determine influenza positivity rate among sampled ILI
- ✓ To identify the proportion of ILI among the outpatient consults at Kolfe health center
- ✓ To determine the incidence of Influenza and ILI among the Kolfe health center catchment population

Methods and Materials

Study area and period

This data analysis was done by using Kolfe Health Center's Influenza surveillance data which is nationally compiled at EPHI, PHEM. Kolfe Health Center is located in wereda 13, Kolfe keranio sub-city of Addis Ababa with a catchment population of 61,214. This data analysis was conducted from 19-30 April 2016.

Study Design

Descriptive data analysis was employed for Kolfe Health Center's Influenza Surveillance data collected from 2010-2015.

Data Type and Source

Influenza surveillance Secondary data was extracted from national data base from Public Health Management Center (PHEM), EPHI.

Identification of Cases

In influenza surveillance, cases were identified through the use of *Ethiopian Influenza Sentinel Surveillance Implementation Guideline, 2012* which is adapted from standardized case definitions developed by the WHO African Region and CDC (Technical Guidelines for Integrated Disease Surveillance and Response in the African Region, October 2010) and recommended to be used by all member states to enable comparison between different countries in the region.

Case definition for ILI:

A person, child or adult with:

- Sudden onset of fever $> 38^{\circ}\text{C}$ AND
- Cough or sore throat in the absence of other diagnoses.

A confirmed case of influenza is a case that meets the clinical case definition and is laboratory-confirmed (laboratory results must be positive for influenza virus).

Statistical Analysis

Descriptive statistical analysis was done using Microsoft Excel.

Ethical Issue

This analysis is also part of the national Influenza sentinel surveillance protocol which is endorsed by EPHI scientific and ethical review office (SERO). Furthermore, written permission was obtained from the center of public health emergency management at Ethiopian Public Health Institute.

Dissemination of the Analysis Report

Result of this data analysis was commented and feedback was obtained from surveillance officers of Kolfe health center, national public health emergency management and field supervisor.

Result

A total of 1,375 ILI visits were found registered that met the ILI case definition with age range from 1 months-80 years and no reported death from September 2010-December 2015. All 1,375

cases were sampled and tested for Influenza A (with sub-types seasonal H3 and pandemic09 H1) and Influenza B. Among a total of 347 positives, 218(63%) were Influenza A and 129(37%) of them were Influenza B.

The frequency distribution of ILI cases by time

The graph shows a strange increment from February- April, 2013 and from October-December, 2013 and 2015. The Average number of ILI Visits from 2010-2015 was 13-36 cases in each month of the years.

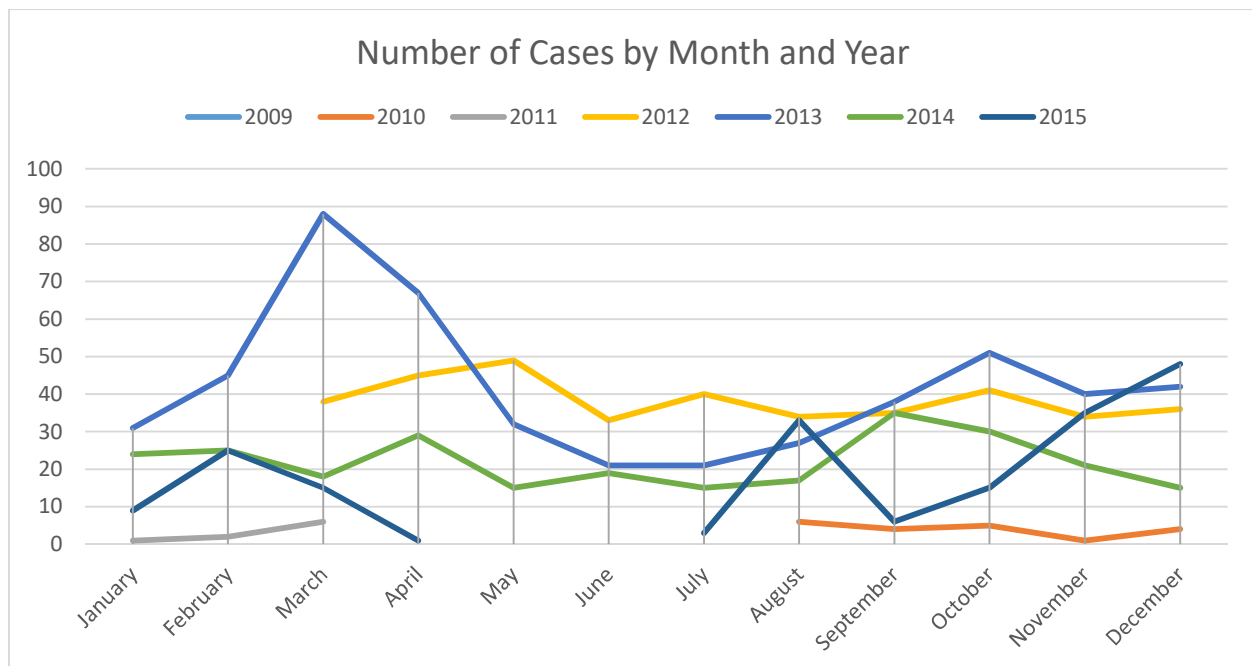


Figure 3: Seasonal trends of ILI cases, Kolfe Health Center ISS, Addis Ababa, January 2010-December 2015.

The first Influenza positive case was detected in March 2011 since the Health center had started influenza sentinel surveillance in 2010.

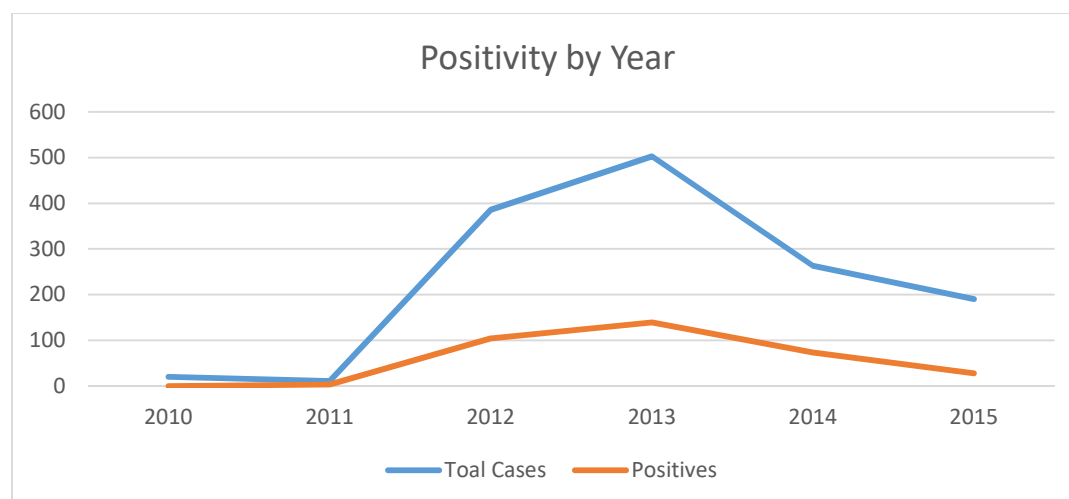


Figure 4: Positive Cases by year of Detection, Kolfe Health Center ISS, Addis Ababa, 2010- 2015.

The proportion of confirmed cases for influenza was almost similar in most of the years with an average proportion of 25 positives per year if the virus is circulating. Positivity of influenza viruses was not detected in the first two years of surveillance in the health center.

The distribution of ILI cases by person

The total of ILI cases were 357, 313. Persons aged 15-24 and 25-34 years outnumber the infection while those above 65 years were few in number relatively.

Table 3: Distribution of ILI cases by Age Group and Year, Kolfe Health Center ISS, Addis Ababa, 2010- 2015.

	2010	2011	2012	2013	2014	2015	Total
<1	4	0	1	14	5	8	33
1_4	6	1	27	51	20	47	152
5_9	3	3	50	85	35	13	189
10_14	1	3	46	67	24	21	162
15_24	3	2	107	133	81	30	357
25_34	1	1	111	90	68	42	313
35_44	1	1	29	35	21	20	107
45_54	1	0	11	16	8	5	41
55_64	0	0	4	7	1	2	14
65+	0	0	0	5	0	2	7
Grand Total	20	11	386	503	263	190	1375

Among 1369 laboratory tested cases of ILI, 804 were female and 565 were male. From 804 females, 107(13.3%) were positive for influenza type A, 81 (10.1%) positive for influenza B, 1(0.1%) was indeterminate, and the rest 611 were negative. Among the 565 male cases,

109(19.3%) were positive for influenza A, 47(8.3%) were positive for influenza B and 407(72.0%) were negative.

Table 4: Distribution of cases by gender and types of influenza virus, Kolfe Health Center ISS, Addis Ababa, March 2011-December 2015

Gender	Indeterminate	Negative	Not Tested	Type A	Type B	Grand Total
F	1	611	4	107	81	804
M	0	407	2	109	47	565
Total	1	1018	6	216	128	1369
Grand Total	1	1021	6	347		1375

Distribution of ILI cases by place of residence

Regarding Place of residence, 1268 (92%) followed by Finfine(Addis Ababa)Zuria Special Zone of Oromia region, where 26(1.9%) cases had ILI visit at Kolfe Health Center. All other cases were from Addis Ababa city. Some 37 cases had no place of residence registered on the case based format.

Table 5: Frequency of ILI cases by place of residence, Kolfe Health Center, Addis Ababa, January 2010-December 2015.

Sub-City/Zone	Number of ILI	Percent
A/Ketama	19	1.4
Akaki Kaliti	1	0.1
FifnineZuriya/Oromia	26	1.9
Gullele	8	0.6
Kirkos	1	0.1
Kok	1	0.1
Kolfe	1268	92
Lafto	5	0.4
Lidata	8	0.6
Yeka	1	0.1
Missing	37	2.7
Grand Total	1375	100

Influenza like illnesses account from 5.05 % to 29.64% of outpatient visits each year from the beginning of 2010 to the end of 2015. From the total of outpatient visits from 2010-2015, ILI accounts 17.53 % (Table 5).

Table 6: Proportion of ILI among Outpatient Consults Kolfe Health Center, Addis Ababa, January 2010-December 2015.

Year	Total ILI Cases	Total Outpatient Visits	Percentage of ILI
2010	2,338	46,306	5.05
2011	6,137	56,499	10.86
2012	15,109	50,970	29.64
2013	12,131	60,503	20.05
2014	11,446	49,947	22.92
2015	7,179	45,806	15.67
Total	54340	310031	17.53

Discussion

The aim of this study is to give a description of influenza at Kolfe Health Center at outpatient level. Majority of the ILI cases were in the 15-24 year age group, 356 (26%) followed by 25-34 years which is 313(23%). No death was reported due to ILI in all age groups. This might have happened because severe patients are referred to higher facilities for better medical care.

According to this analysis, ILI occurred all year round with some peaks during February-March and around December. This is not much different from the result of a Nigerian study of influenza epidemiology which found that influenza occurred all year round with peak levels around mid-year and that of the Kenyan study which found influenza circulation in all year round with some peaks during wet months: March-April and Oct- Nov and cold month of July(11)(12).

Influenza is known to come epidemic during winter or cold in temperate regions as opposed to what has been observed in tropical countries where it is present throughout the year often with cold season period of exacerbations(11).

During the 6 years and 4 months of influenza surveillance of Kolfe Health Center, influenza virus was found a common contributor to respiratory illness, affecting all age groups, which is similar to 30 months Tanzania national influenza sentinel surveillance that shows influenza affecting all age groups (5). This shows that influenza is a major public health concern in all ages. Since Kolfe Health Center ISS is only designated for ILI cases, it differs from the Tanzania national influenza sentinel surveillance which includes both ILI and SARI cases. The proportion of confirmed cases for influenza was almost similar in most of the years with an average proportion of 25 positives per year if the virus is circulating. Positivity of influenza viruses was not detected in the first two years of surveillance in the health center. This may perhaps be due to

the weak efforts done by the virological surveillance as it was newly established with limited resource.

Out of the total 1369 laboratory tested ILI cases, 347(25.3%) were positive for influenza that is more than the Tanzanian National Influenza sentinel surveillance with 51(7.3%) confirmed influenza cases from the total of 695 laboratory tested SARI cases. Both the Ethiopian and Tanzanian national influenza laboratories use same type of diagnostic technology called, rRT-PCR, and similar reagent supplies from the international reagent resource (IRR).

After further sub-typing of the influenza positive samples, most of the ILI cases were positive for influenza A/H3 that is 115(53%) and the rest 102(47%) was attributed to pandemic 09/H1 (swine flu A sub-type in the period of 2009-2015. Most of the confirmed cases were seen from October-December and February-April. This may be due to the cold season that can lead to an increased ILI cases which is similar to a Tanzanian study that showed majority of the cases appear from Feb,2010-Sep, 2010 and slightly from Aug-Oct,2009 (13).

Limitations and Challenges

Age classification is according to the guideline but age specific population number was not included; therefore, this study has not included age specific incidence rate. Some of the cases might not have been registered if they were referred to higher institution. Some variables like, age, sex and place of residence were missed from the data.

Conclusion

This data analysis revealed that the influenza viruses have been circulating in Kolfe subcity which affected both males and females of all age groups. Influenza is a major public health problem which affects all ages and can occur in all months of the year. It also affects both males and females of all ages.

Recommendation

Continuous influenza surveillance will provide a frame work for detecting and following future influenza outbreaks and pandemics. If all the swabbed samples are tested for other viral and bacterial pathogens in addition to influenza, Kolfe Health Center can contribute for having a clear image to predict national, regional and global burden of influenza.

This will also provide a better understanding of the epidemiology and seasonality of influenza like illnesses. It is better to increase the number of influenza sentinel surveillance sites to have

more representative population based data and burden of respiratory infections for effective intervention.

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CHAPTER III: EVALUATION OF SURVEILLANCE SYSTEM

EVALUATION OF ETHIOIAN INFUENZA SURVEILLANCE SYSTEM

Abstract

Background: Public health surveillance is an ongoing systematic collection analysis, interpretation and dissemination of data regarding a health related event for use in public health action. The Global Influenza Surveillance and Response System (GISRS) has been performing influenza virological surveillance since 1952. Ethiopia conducts influenza sentinel surveillance since 2008 in eight sites. It is carried out by Federal Ministry of Health/EPHI but little is known whether the system meets its objective. Hence, this evaluation is conducted to evaluate the sentinel surveillance attributes, purposes and its operation system.

Method: A cross-sectional descriptive study was conducted from February 15-30, 2017 in all eight Sentinel sites. Data were collected using CDC updated surveillance guideline and Interview with influenza sentinel surveillance focal persons, regional health bureau PHEM officers and national PHEM officers. Case based reports of influenza like illness and severe acute respiratory illness were also reviewed. Secondary data were collected from the national public health emergency management center based at EPHI. We analyzed and compiled the data.

Results: Not all the visited health facilities have posted the ILI and SARI cases definition. None of the sentinel sites have been reporting influenza data to their next higher level but to the national PHEM (NIL). All focal persons have responded that they are expected to do so. Data is only being analyzed by national PHEM. Supportive supervision was done this month (February, 2017) since 2014. Laboratory feedback (test result) has been provided irregularly since May 2016 by the national influenza laboratory to sentinel sites and respective regional PHEM. All of focal persons have taken training on influenza surveillance. The positive predictive value (PPV) was 21.35% (n=4922). Among a total of 5,097 case based reports from 2008-2016, 47(0.9%) age variable, 385(7.5%) temperature variable, and 103 (2%) date of specimen collection were not filled.

Conclusion: Although, focal persons are satisfied with the forms and procedures involved, they are not filling formats properly as expected and reporting regularly as scheduled neither to the national PHEM nor to the next higher level. The influenza sentinel surveillance system has proven to be useful in providing virological data used to characterize and monitor influenza trends in Ethiopia. Continuous supportive supervision should be in placed using checklist to increase the quality of data. Data should be continuously analyzed and feedback should be given periodically to health care provider and partners.

Keywords: Surveillance, Evaluation, Influenza, Ethiopia

Introduction

Public health surveillance is an ongoing systematic collection analysis, interpretation and dissemination of data regarding a health related event for use in public health action to reduce morbidity and mortality and to improve health. A communicable disease surveillance system serves two key functions; early warning of potential threats to public health and programme monitoring functions which may be disease- specific or multi-disease in nature(1). Surveillance system evaluation allows us to define whether a specific system is useful for a particular public health initiative and is achieving the overarching goals of the public health program and the data collection objectives(2). This is done for monitoring disease trends, describing natural history of diseases, identifying epidemics or new syndromes, monitoring changes in infectious agents, identifying areas for research so as eventually to reveal disease burdens and guiding the action to be taken, the health policy, planning, evaluation of health programs and the likes(3).

The Global Influenza Surveillance and Response System (GISRS), previously known as the Global Influenza Surveillance Network (GISN), has been performing influenza virological surveillance since 1952(4). This network has played a critical role in the current better understanding of global influenza virus circulation. The GISRS consists of over 130 National Influenza Centers (NICs) around the world that collect and test clinical specimens, submitting a sample of these to WHO Collaborating Centers (WHO CC) and Essential Regulatory Laboratories for further characterization(4).

In recent years, an increasing awareness has developed of the need to expand influenza surveillance and to include more epidemiological information to complement the virological data collected by GISRS. This need was formally recognized by the World Health Assembly in 2011 in Resolution 64.5 and in the adoption of the Pandemic Influenza Preparedness Framework(5).

The pandemic of 2009 uncovered several specific gaps in global influenza surveillance capacity, which compromised the assessment and monitoring of the event. The lack of a pre-existing international mechanism for sharing epidemiological data presented challenges to understanding global patterns of transmission and disease. And finally, the non-standardized approach to data collection and outbreak investigations early in the event resulted in data that was often incompletely understood outside the local context. The accumulation of historical data for influenza-associated severe respiratory disease will allow rapid comparative assessment of each influenza season and of future pandemics both locally and globally.

Public health surveillance systems play a critical role in national health management. They provide data that can be used for several purposes(6).Data disseminated by a public health surveillance system can be used for immediate public health action, program planning and evaluation, and formulating research hypotheses(7). For example, in America, Public health officials rely on the timeliness and completeness of the surveillance system data to design public policies and interventions(8).

Moreover, sentinel surveillance provides an alternative to population-based surveillance for the collection and analysis of individual patient-related information and more limited monitoring of influenza trends. Sentinel surveillance has the potential to provide more complete data about some of the epidemiologic characteristics of severe acute respiratory illness (SARI) and/or influenza like illness(ILI) at a particular sentinel surveillance site and also to determine the proportion of SARI and ILI cases which are due to influenza. One of the advantages of the sentinel surveillance approach is that it requires fewer resources by reducing the number of sites collecting laboratory specimens for influenza testing.

Ethiopia has launched influenza sentinel surveillance since 2008(9) and currently 5 SARI and 3 ILI sites are engaged in the influenza surveillance. It is carried out by Federal Ministry of Health/EPHI through a system which has support from CDC and WHO and extending from EPHI down to the sentinel site. These includes upward and down ward reporting and feedback mechanism.

Sites were selected based on availability of resources, technical capacity and number of staffs, availability of functional service for ILI/SARI for all age groups, accessibility to adequate clients and geographical proximity between SARI and ILI sites.

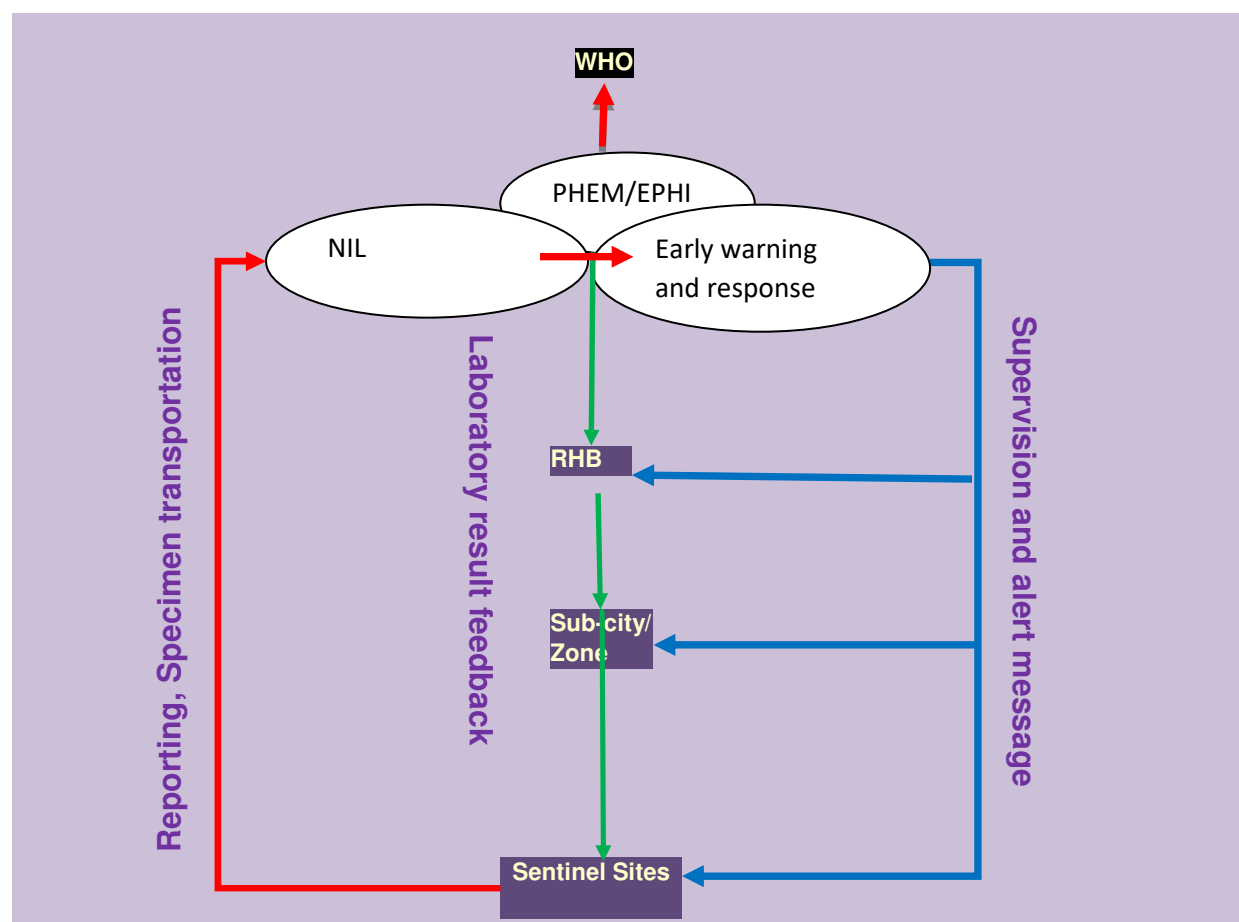


Figure 5: Ethiopian Influenza Sentinel surveillance Information Flow

Rationale for Influenza Surveillance System Evaluation

The world health organization has put a standard about periodic evaluation of influenza sentinel surveillance which states a comprehensive evaluation of the system to be done regularly, beginning one to two years after initial implementation of the surveillance system or more importantly if an expansion of the system is being considered(10). However, since the start of sentinel surveillance the system, documents showing an accomplished evaluation of the system were not found except one that was done by FELTP resident in 2012(11). Little is known whether the system meets its objective. Hence, this evaluation was conducted to evaluate the sentinel surveillance attributes, purposes and its operation system

Objectives

General Objective

- To describe and evaluate Ethiopian influenza sentinel surveillance system

Specific Objectives

- To describe the core and supportive functions of Ethiopian influenza sentinel surveillance system
- To evaluate attributes of the Ethiopian influenza sentinel surveillance system

Materials and Methods

Study Design and Area

A cross-sectional descriptive study was conducted from February 15-30, 2017 in all eight Sentinel sites. All influenza sentinel surveillance data from 2008 -2016 was included in the study. Five SARI sites (Yekatit 12, Adama, Adare, Mekelle and Felegehiwot hospitals) and three ILI sites (Shiromeda health center, Akaki health center and Kolfe health center) were included in the study.

Data Source and Collection

Primary data were collected using structured questionnaire and Interview with influenza sentinel surveillance focal persons, regional health bureau PHEM officers and national PHEM officers. Case based reports of influenza like illness and severe acute respiratory illness were also reviewed. Secondary data were collected from the national public health emergency management center based at EPHI.

Evaluation methods from Centers for Disease control and Prevention (CDC), Updated Guideline for Evaluating Public Health Surveillance Systems: Recommendation from the Guidelines working Group, MMWR July 27, 2001; 50(No. RR-13) and Communicable disease surveillance and response systems, Guide to monitoring and evaluating, WHO, 2006 were used to collect information about the surveillance system. Structured questionnaire was prepared and used to collect data about the core functions of surveillance, support functions of surveillance and attributes of surveillance system.

Case Definition

Both ILI and SARI Cases are identified using standardized case definition indicated in the Ethiopian influenza sentinel surveillance implementation guideline adopted from WHO African region which is recommended to be used by all member states to enable comparison between different countries in the region.

Case definitions for Severe Acute Respiratory Infection (SARI): Any severely ill person presenting with manifestations of acute lower respiratory infection with: history of fever or measured fever ($>38^{\circ}\text{C}$) AND Cough or sore throat AND Shortness of breath, or difficulty of breathing with or without Clinical or radiographic findings of pneumonia OR any person who died of an unexplained respiratory illness.

Case Definition for Influenza-Like Illness (ILI): A person, child or adult with: Sudden onset of fever $> 38^{\circ}\text{C}$ AND Cough or sore throat in the absence of other diagnoses.

A confirmed case of influenza is a case that meets the clinical case definition and is laboratory confirmed (laboratory results must be positive for influenza virus)

Data Analysis and Report Writing

We analyzed and compiled the data using Microsoft excel spread sheet and presented using narration and tables.

Definition of Terms

Acceptability: reflects the willingness of persons and organizations to participate in the surveillance system.

Completeness: proportion of all expected data reports that were actually submitted to the public health surveillance system.

Data Quality: reflects the completeness and validity of the data recorded in the public health surveillance system.

Flexibility: is the ability of the system to adapt to changing needs with little additional time, persons or allocated funds.

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

Sensitivity: in this report, sensitivity refers to the ability to detect outbreaks, including the ability to monitor changes in the number of cases over time.

Simplicity: refers to both its structure and ease of operation.

Timeliness: in this report reflects the elapse between date of symptom onset and date of specimen collection.

Usefulness: How helpful the system is to public health staff in taking actions as a result of interpreting and analyzing its data.

Results

Functions of Surveillance

Case Detection and Registration

During this evaluation, not all the visited health facilities have posted the cases definition of ILI and SARI but the understanding of the cases definitions by the influenza focal persons was satisfactory. The registration book was found in all sites except Adama Teaching Hospital but the handling of available registers was poor in all sites.

Reporting

There was no shortage of reporting forms in all visited sentinel sites since it is also available in soft copies. But in Adare General Hospital and Adama Teaching Hospital, computer was not functional for the influenza surveillance data management that it was intended to. All sites use similar reporting format which is incorporated in the influenza sentinel surveillance implementation guideline. None of the sentinel sites have been reporting influenza data to their next higher level but to the national PHEM (NIL). All focal persons have responded that they were expected to do so. The weekly reporting rates of the sentinel sites over the past 12 weeks prior to assessment were 50% (4/8). All the reports were sent to the National Influenza Laboratory in hard copies along with the throat swab samples.

Data Analysis and Interpretation

Although they have computer in all sentinel sites, except Adama and Adare hospitals, all influenza surveillance focal persons have never analyzed and interpreted their data routinely but only for presentations during review meetings; both case-based and aggregated. It is only analyzed by national PHEM. All of the focal persons have responded that they do not have basic computer skills.

Feedback and Supervision

Supervision and provision of feedback were assessed at national and regional levels. This assessment found that periodic supervision was not done. Supportive supervision regarding influenza surveillance was done this month (February, 2017) since 2014. Laboratory feedback (test result) has been provided irregularly since May 2016 by the national influenza laboratory to sentinel sites and respective regional PHEM.

Training

There are 14 influenza surveillance focal persons currently working in place. All of them have taken training on influenza surveillance. Including facility medical directors and regional PHEM officers, a total of 29 persons were trained on influenza surveillance in November, 2016.

Surveillance System Attributes

Usefulness

Before the beginning of influenza sentinel surveillance in Ethiopia nothing was known about influenza strains circulating in the country. Currently because of the surveillance data generated by the system, type of influenza strains, its burden and trends are being understood. A number of scientific papers were developed and presented at various national and international conferences. Sporadic pandemic influenza A (H1N1) in 2009 and seasonal influenza outbreaks in 2016 were detected by the surveillance and prompt response was instituted.

Simplicity

Participating health workers at sentinel sites were well aware of the objectives of the system. Collection of specimen and filling case based reporting format was found to be taking only 5-10 minutes. Case definition and reporting format is clear and easy to use by all level professionals. All sentinel sites focal persons were satisfied with reporting formats and easy flow of reports directly to national PHEM. The system has only few organizations involved in receiving case reports.

Flexibility

A flexible public health surveillance system can adapt to changing information needs or operating conditions with little additional time, personnel, or allocated funds. The system was found flexible; in 2009 the system was easily customized and detects pandemic influenza. The case definition by itself can also be used to detect any other respiratory infections like Middle East respiratory syndrome corona virus (MERS- CoV).

Data Quality and Completeness

Data quality reflects the completeness and validity of the data recorded in the public health surveillance system. In contrast to simplicity of the system, some important variables were in case based reports. For instance, among a total of 5,097 case based reports from 2008-2016, 47(0.9%) age variable, 385(7.5%) temperature variable, and 103 (2%) date of specimen collection variables were not filled.

Table 7: Number (percent) of variables missed during implementing influenza sentinel surveillance in Ethiopia, 2008-2016(N=5097)

Variable	Incomplete data (%)	Above Expected percentage(80%) of completeness
Age	47(0.92)	Yes
Zone	182(3.57)	Yes
Woreda	685(13.43)	Yes
Body Temperature	385(7.55)	Yes
Antiviral	557(10.93)	Yes
Date Specimen Collection	103(2.02)	Yes
Date Sent to lab	2,267(44.48)	No
Specimen Condition	181(3.55)	Yes

Acceptability

All level health personnel, especially sentinel site focal persons are happy to participate in the surveillance system. The laboratory workers in NIL have taken self-initiatives to transport specimens to laboratory from all sentinel sites of Addis Ababa twice a week. Six sentinel sites (except Adama and Adare hospitals) out of eight have dedicated a room for SARI/ILI surveillance purpose and all eight sites have assigned trained focal persons.

Sensitivity

Influenza like illness and severe acute respiratory illness outbreaks were detected in 2016 using the ILI and SARI case definitions, and prevention and control measures were taken. In this evaluation the denominator was not available to calculate sensitivity of the surveillance system. However, beside loose of case definition which is very sensitive to ILI/SARI cases, specimen tested at EPHI laboratory was also tested positive at WHO reference laboratory.

Predictive Value Positive

The positive predictive value (PPV) or the proportion of cases reported by the system that actually have influenza was 21.35% (n=4922). The capacity of the laboratory diagnostic test was periodically ensured by WHO confirmatory laboratory.

Representativeness

The ILI/SARI Sentinel surveillance is limited to only four regions and one city administration, Addis Ababa. Even though the sites were selected to represent most of the population, it is still difficult to generalize to the whole population. In the system the catchment population was not clearly defined; because of this, calculating the incidence rate was difficult.

Timeliness

Timeliness in this report reflects the elapse between date of symptom onset and date of specimen collection. In this regards, the range of the elapsed time is between two and seven days which is

exactly in line with the time indicated in the Ethiopian national influenza sentinel surveillance implementation guideline.

Discussion

Generally, this evaluation revealed that the Ethiopian ILI/SARI sentinel surveillance is on the right track to achieve its objectives. This sentinel surveillance had identified circulating influenza viruses in Ethiopia which pandemic influenza A (H1N1)2009, Seasonal influenza A (H1N1), Seasonal influenza A (H3N2) and influenza B. Seasonality and trends are also defined as in October, November and December(12). The season is not very different from Albanian influenza season(13).

Regarding the functions of surveillance system, there are gaps in reporting, data analysis and interpretation because of lack of skill from the sentinel site focal persons side. Failure to conduct periodic supportive supervision from the national and regional side might have bolded this gap. As it was stated in the influenza implementation guideline, monthly supportive supervision for sites of Addis Ababa and quarterly for others had to be done by the national PHEM/NIL and periodic supervision and feedback had to be given to sites by regional/zonal/woreda/sub-city offices(9). The sentinel surveillance was very simple; ILI/SARI focal persons at sentinel site identify eligible cases, collect throat swab samples with case based reporting format and the laboratory personnel from NIL directly receives from the sentinel site. This system is very easy for health care providers at sentinel site like Madagascar's influenza system(14).

The system has good data quality but there is a 44. 48% incomplete variable (Date specimen sent to lab) which is near to half of the total case based forms. This shows focal persons at facility level have limitations in understanding or practicing the necessity of each variable in the form. Unless this field is filled, they cannot track storage condition of the specimen.

The sentinel sites do not represent the whole population. Even the catchment population was not clearly defined. Hence to calculate incidence rate and to generalize to the whole population, the sentinel sites will need to be more expanded considering Variety of geographic location and community life style. A lack of dedicated resources from government may affect the stability of influenza sentinel surveillance. The sentinel surveillance is donor dependent; this may affect sustainability of the system. All running cost, supplies and logistics are donated by USCDC.

Conclusion

The influenza sentinel surveillance system has proven to be useful in providing virological and epidemiological data used to characterize and monitor influenza trends in Ethiopia. Generally, the staff members using the system are satisfied with the forms and procedures involved, but not all sites are reporting regularly neither to the national PHEM nor to the next higher level. The influenza sentinel surveillance system is simple, acceptable, stable, flexible and able to detect outbreaks, identify and characterize circulating influenza strains but yet to expand nationwide. Data quality is yet to be maintained.

Recommendation

Trainings should be given for sentinel site focal persons on reporting, data use and advantages of a complete data. Continuous supportive supervision should be in placed using checklist to increase the quality of data. Data should be continuously analyzed and feedback should be given periodically to health care provider and partners. Monitoring should be done as scheduled in the national influenza surveillance guideline to improve data quality.

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CHAPTER IV: HEALTH PROFILE DESCRIPTION REPORT

HEALTH PROFILE DESCRIPTION OF WOREDA 9, KOLFE KERANYO SUB-CITY, ADDIS ABABA, OCTOBER 2016

Abstract

Introduction: Health profile description is a system of collecting, organizing and summarizing health and others health related events that comprises demographic, socio-economic, vital statistics, political, economic, cultural and others aspect of a particular geographic areas of interest. This description report will help in identifying the woreda's health and health related events to use it for health programs planning and intervention. The objective of this study is to assess and describe health related issues, health indicators and to identify problems in Kolfe Keraniyo sub-city woreda 9.

Method: a descriptive cross-sectional study focusing mainly on record review was conducted for the health profile assessment of woreda 9, Kolfe Keraniyo sub city.

Result: Health coverage of the woreda is 100%, full immunization coverage of 90%. Apart from estimated 1,215 pregnant women, 1,756(>100%) pregnant women attended first antenatal care visit (ANC1) while 920(76%) attended the fourth visit. Deliveries which are attended by skilled birth personnel was 613(50%) among which 2(0.3%) were still births and 611(99.7%) were live births. There was no maternal death reported in the 2007 EFY. Oral contraceptives, injectable, implant, IUCD are contraceptive methods used in the woreda in 2007 EFY. Acute upper respiratory tract infection is the leading cause of morbidity in woreda 9 health center.

Discussion, Conclusion and Recommendation: This Woreda Health profile includes multiple issues including health care service, nutrition and education. Most of the findings from this study are complementary to the national targets of respective health problems and events. Having no dropout of student from school at secondary level is a peasant finding. TB and HIV are still public health burdens in the woreda. To know actual coverage of health service, the private clinic should submit report to woreda health office. The woreda should also be supported by the higher level government entities of data to have a modern documentation system for better planning, preparedness and public health events response.

Introduction

Health profile description is a system of collecting, organizing and summarizing health and others health related events. This includes, demographic, socio-economic, vital statistics, political, economic, cultural and others aspect of a particular geographic areas of interest. It helps

in prioritizing health and others health related condition occurred within the communities(1).The information obtained from the description will help public health officials prioritize their health planning. It is used for planning, implementation and evaluation of public health programs. The purpose of this project is to assess and describe Kolfe Woreda 9 health profile which will help in identifying the woreda's health and health related events to use it for health programs planning and intervention.

Rationale of the Description

Health profile generates data which can be used at community level. Describing health profile of Kolfe Woreda 9 has enormous advantages to briefly illustrate current gaps in the area of public health and management of man power. Using this description as a baseline, decision makers of the woreda and the city administration at large may focus on addressing gaps stepwise or think to research on the general health problem otherwise. It may also be used as an indication for setting priority health problems, understand other aspects of the community such as, demographic, social and economic. The finding of this health profile description will be disseminated to the woreda 9 health office officers after finalization of the description report.

Objective

General objective

- To assess and describe health related issues, health indicators and to identify problems

Specific Objectives

- To describe existing health related information
- To assess human resources under the health office of the woreda
- To identify priority health problems.

Methods and Materials

Study Area: Kolfe Woreda 9 is one of the 15 woredas in Kolfe sub-city of Addis Ababa administration located in the most west part of Addis Ababa. It shares boundaries with woreda 10 to the north, woreda 05 to the south, woreda 06 and 08 to the west and the ring road to the east.

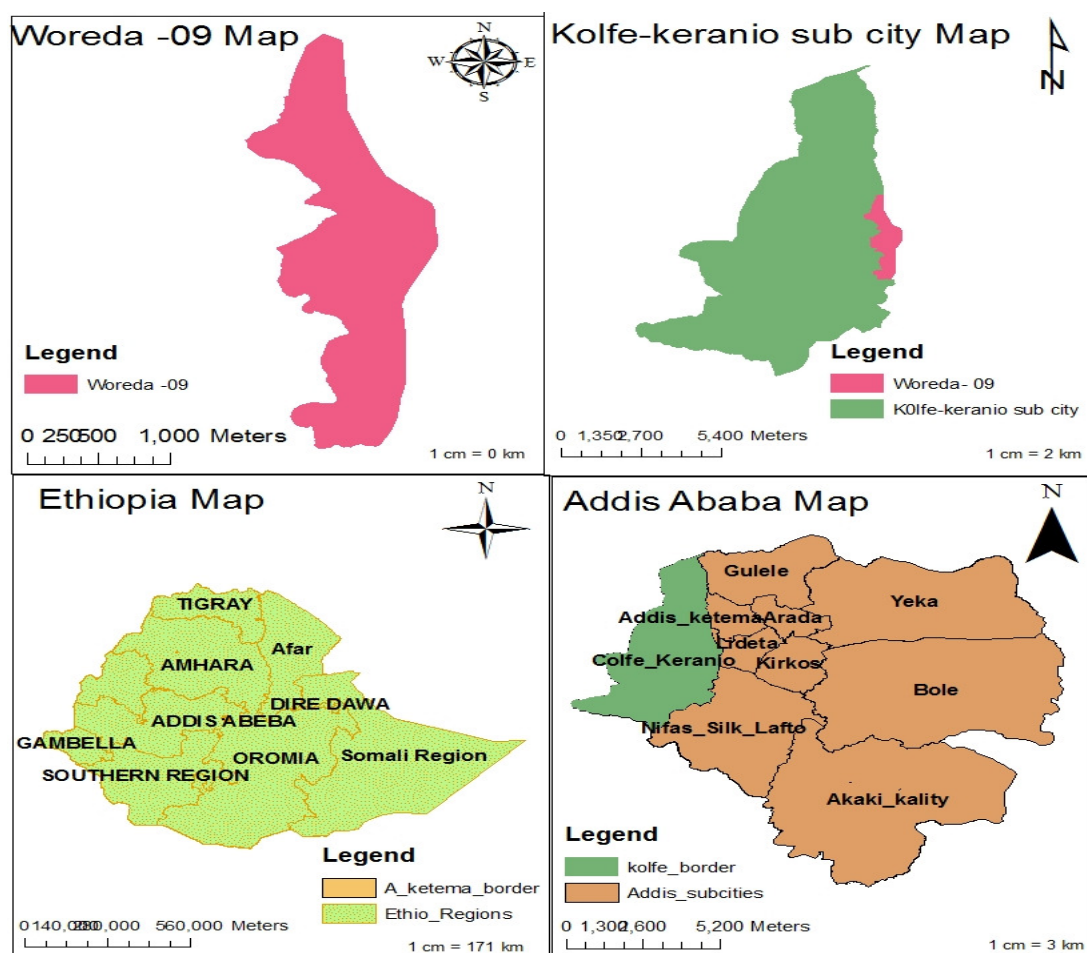


Figure 6. Map of Woreda 9, Kolfe Keraniyo Sub city, Addis Ababa, Ethiopia.

Study Design

A descriptive cross-sectional analysis was employed for this health profile description.

Study Period

This study was conducted in Kolfe Sub-City, Woreda 9, from June 1-10, 2016

Data collection

The information was collected from Kolfe Sub-City Health office, Education office, Woreda FMHACA and woreda 9 health center. The data was collected by questionnaire, face to face interviewing and reviewing available records.

Data Analysis

The collected data was analyzed using percentages, ratios, sums and ranges by MS-excel software.

Ethical Issue

The compiled document of this description was presented to kolfe woreda 9 health office and woreda 9 health center staff for their comments and is corrected and shared according to the respective comments.

Result

A) Geographic and Climatic Conditions

Kolfe Woreda 9 woreda is one of the 15 Woredas in Kolfe sub city of Addis Ababa, which is the most western part of the city, bordered by woreda 10 to the north, woreda 8 and 6 to the west, woreda 5 to the south, and completely the ring road to the east. It covers an area of 251.7 hectares. It lies at an elevation of 2,300 meters (7,500 ft.) and, located at latitude of $9^{\circ}0'10.55''$ and longitude of $38^{\circ}43'32.81''$. Annual average temperature and rain fall of the woreda is similar to that of Addis Ababa city which are $10-23^{\circ}\text{C}$ ($18-75^{\circ}\text{F}$) and 1089 mm^2 respectively. It was formerly called *Keftegna 24* under Lideta sub-city before it was integrated to Kolfe sub-city in 2000 e.c. It has a total population of 34,650.

Demographic Information

According to the 2007 EFY census and projection for in the year 2015/16 (2008 EFY), the size of Kolfe sub-city woreda 9 population is 34,650 of which 17,221 (49.7%) are male and 17,429 (50.3%) are female. The analysis of age structure of the woreda shows that 762 (2.2%) were infant (<1 years old), 2,495 (7.2 %) are under 5 years of age, 12,003 (34.6%) are women of reproductive age (15-49 years old) and estimated number of pregnancies are 797 (2.3%) with annual population growth rate of 2.3. Information about ethnic group/language, religion, main source of income of the woreda are not available. The woreda is completely urban.

Table 8 Population size of woreda 9, Kolfe Keraniyo sub-city, by Age categories, 2007 EFY

No	Population category	Number
1	Population under 1 yrs	762
2	Population under five yrs.	2,495
3	Population < 15 yrs.	8,306
5	Women 15_49 yrs. of age	12,003
6	Average household size	4.8
7	Annual population growth rate (%)	2.3%

Administrative and political structure

According to the latest Addis Ababa administration, woreda is the lowest level of administration but the woreda has its own localities called *ketena*, each having 500 households on average. This *ketenas* are designed for the purpose of health extension workers' activity. This woreda comprises 4 *ketenas*.

Woreda Health System

The currently reviewed woreda 9 health office structure 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.

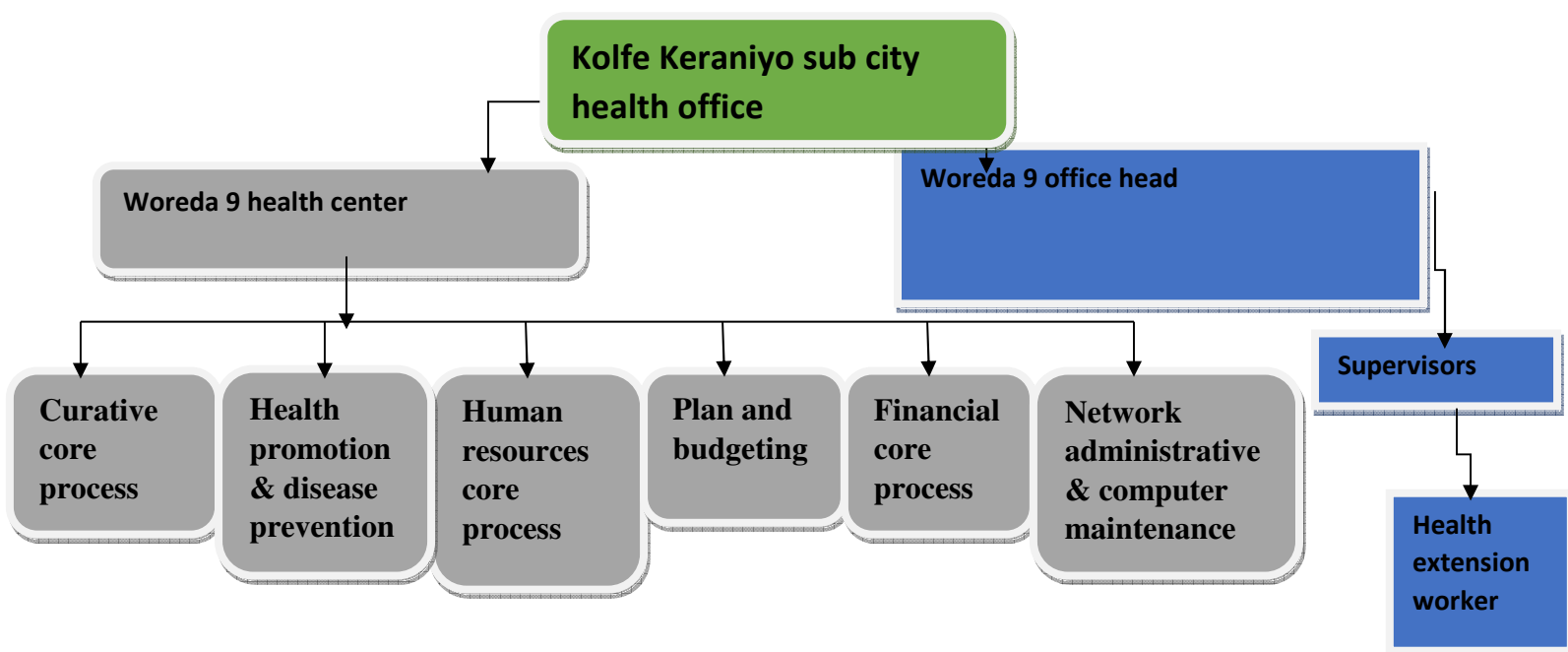


Figure 7: Organo gram of Kolfe Keraniyo sub-city Woreda 9 Health Office

B) Health Status

There is no government hospital but there is one health center. The population ratio to health center is 1:34,650. Documented information about private health institutions was not accessible in the woreda during the data collection time.

Table 9 Government Health facility professional to population Ratio, woreda 9, Kolfe Keraniyo sub-city, Addis Ababa, Ethiopia, 2008 EFY

S. No	Profession	Number	Ratio to Population
1	Physician	1	1:34,650
2	Health officer	11	1:3,150
3	Laboratory technician/technologist	7	1:4,950
4	Pharmacy technician/Pharmacist	7	1:4,950
5	Nurses	26	1:1,333
6	Midwife	11	1:3,150
7	X-Ray technician	0	0
8	ENHS	0	0
9	HEWs	10	1:3,465

Top causes of morbidity and mortality 2007EFY

Outpatient department utilization in 2007 EFY was greater than similar months of 2008EFY. 5,195 outpatients visited woreda 9 health center in the month *Nehase* which is the highest number of outpatient visit was recorded in the year. But in the same month of 2008 EFY, there were 3,052 OPD visits in the health center.

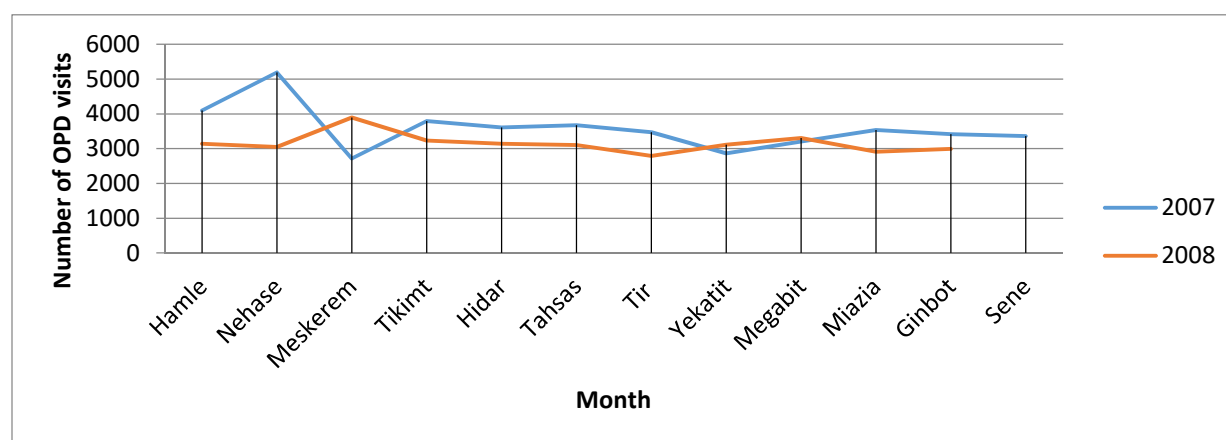


Figure 8. OPD utilization at woreda 9 health center, Kolfe Keraniyo sub-city, Addis Ababa

In 2007 EFY, 43,331 adults and 5,771 under five clients, totally 49,102, visited woreda 9 health center. The top five leading causes of morbidity for all ages are acute upper respiratory infections (33.15%), diseases of musculoskeletal system and connective tissue (11.37%), urinary tract infection (9.33%), other or unspecified infections and parasitic diseases (8.97%) and infection of the skin and subcutaneous tissue (8.58%).

Table 10 Top ten leading causes of OPD visit (morbidity) versus Number in Woreda 9, Kolfe Keraniyo sub city, Addis Ababa, Ethiopia in 2007 EFY (2014/2015)

Type of Disease	Number of Cases
Acute upper respiratory infection	5,902
Diseases of the musculoskeletal system and connective tissue	2,024
Urinary tract infection	1,661
Other or unspecified infection and parasitic diseases	1,597
Infections of the skin and subcutaneous tissue	1,528
Diarrhea (non-bloody)	1,318
Dyspepsia	1,103
Other or unspecified disease of the eye and adnexa	1,019
Other or unspecified disease of the skin and subcutaneous tissue	855
Trauma (injury, fracture etc)	796

Immunization coverage for children and women

As part of preventing and control vaccine-preventable diseases the woreda health system delivers vaccination activities for surviving children. In 2007EFY full immunization coverage of the woreda was 90%. In 2007 the immunization coverage for measles was 87% and TT2 coverage for pregnant women was 64% (n=777).

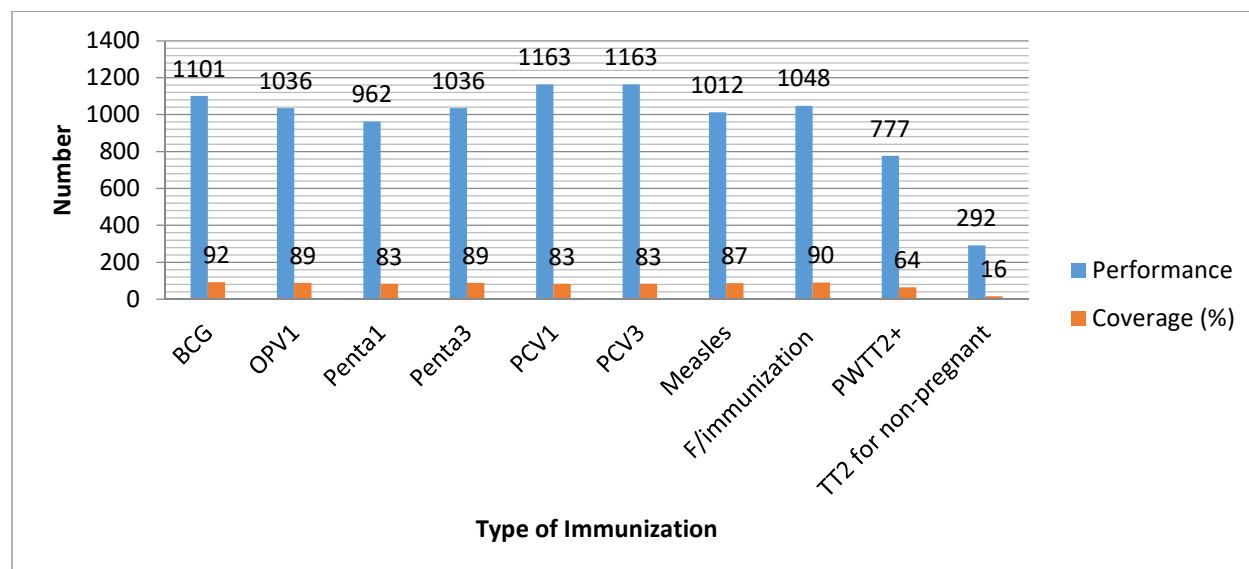


Figure 9 Immunization coverage of woreda 9, Kolfe Keraniyo, Addis Ababa, 2006-2007EFY

Maternal Health Service

There were 1,215 estimated pregnant women in 2007EFY. Among these eligible women a total of 1756(>100%) pregnant women attended first antenatal care visit (ANC1) while 920(76%) of them attended the fourth visit. Deliveries which are attended by skilled birth personnel (Nurses and Midwives) was 613(50%) among which 2(0.3%) were still births and 611(99.7%) live births. There was no maternal death reported in the 2007 EFY. 406 (33%) of women who delivered got early post natal care.

Table 11 Maternal Health Service Coverage of the district 2007 EFY (2014/2015)

Sr.no	Description	Plan	Achievement	Percentage
1	ANC 1 coverage	1215	1756	145
2	ANC 4 coverage	1215	920	76
3	Institutional (skilled) delivery coverage	1215	613	50
	Still Birth	-	2	0.3
	Live Birth	-	611	99.7
4	PNC coverage	1215	406	33
5	PMTCT	1215	1674	138

There were estimated 12,003 women in reproductive age group in 2007 EFY in the woreda. From these women 2,196 use different modern contraceptive methods; of which 1318(60%) use oral contraceptives, 200(9%) used injectable, 539(24%) used implant, 139(6%) used IUCD. Contraceptive acceptance rate was 158% in 2007.

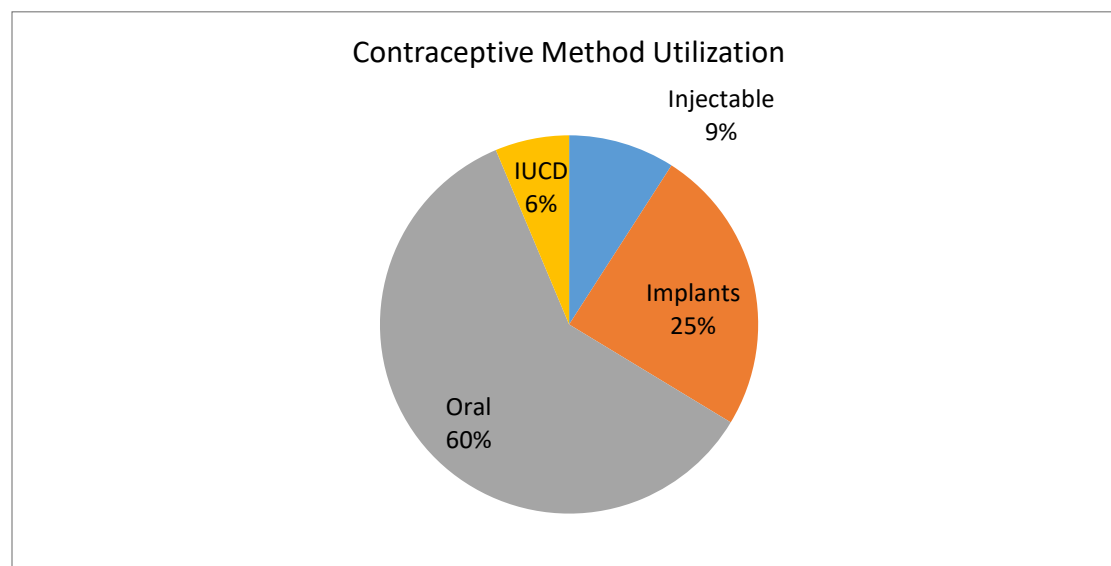


Figure 10 Contraceptive users of woreda 9, Kolfe Keraniyo sub-city, Addis Ababa, 2007EFY

Environmental Sanitation and Availability of Safe Drinking Water 2007 EFY

No documented evidence about the number of house hold with latrine and water supply was found. But both latrine and safe drinking water (pipe water), similar to other parts of Addis Ababa city, are said to be available for the residents either at household level or community (locality level).

Endemic Diseases

Tuberculosis

In 2007 EFY, there were a total of 150 TB cases, in woreda 9 which accounts TB prevalence of 0.42%. In the indicated year, 133 TB patients were screened for HIV and 33(24.8%) of them were turned positive. Among the TB cases, 38% were attributed to Extra PTB in the year. Detection rate for all forms of TB was 194 % and the cure rate was 89.7%. There were 5(2.9%) deaths due to TB in the same year.

Table 12 Prevalence of TB/Leprosy: 2007 EFY

Sr. No	Description	Number	percentage
1	Prevalence of TB	150	0.42
2	Pulmonary Smear positive	33	22
	TB Smear negative	53	36
3	Extra PTB	57	38
	Retreatment	7	4.66
4	TB detection rate All form	150	194
5	TB Rx completion rate	109	90
6	TB cure rate	44	89.7
7	TB Rx success rate	153	90
8	TB defaulter rate	2	1.8
9	Death on TB Rx	5	2.9
10	Total TB patients screened for HIV	133	88.7
11	HIV prevalence rate among TB cases	33	24.8
12	Prevalence of Leprosy	0	0

HIV/AIDS

In Kolfe Keraniyo subcity woreda 9, there are 3,018 peoples living with HIV/AIDS who are ever enrolled to care since 1999 EFY and 1,703 of them ever started ART. In 2007 EFY, 1,648 clients were screened for HIV in VCT, PITC and PMTCT departments, of these 218(13.2%) male and 1430(86.7%) were female. In the same year, 110 new HIV cases were enrolled to care, from which 5 were under 15 children. HIV prevalence was 8.7% with incidence of 317cases of HIV per 100,000populations per year. Currently 1,279 PLWHIV are receiving antiretroviral therapy.

Table 13 HIV/AIDS in 2007EFY, Woreda 9, Kolfe Keraniyo Sub-city, Addis Ababa,

Sr. No	Activities	Total		
		M	F	total
1	Total people screened for HIV	218	1430	1,648
2	VCT	101	112	213
3	PICT	117	1318	1,435
5	HIV Prevalence			8.7%
6	Total PLWHIV			3018
7	On ART(ever started)			1,703
8	Currently on ART			1,279
9	No. of pregnant mothers on ART		19	19
10	No. of pregnant mothers on Pre ART		0	0

C) Education

Kolfe woreda 9 has a total of 11 school, of which 2 are grade 1-4 only, 5 are grade 1-8, 1 is grade 5-12, 2 are grade 9-10 and 1 is grade 11-12. In 2008 EFY a total of 6,270 students were enrolled

in formal education in these schools. There were total 157 dropouts. There was no compiled data for the dropout specific to gender of students. There were no dropouts for grade 9-10 and 11-12. According to the interview made with the woreda *Education Office Head* during data collection, all schools are equipped with pipe water supply and functional latrine though the later may not be standardized as it should be. In addition to the formal education, there are 12 clubs, including Red Cross and HIV club, in all schools. The woreda has only one public library and one youth club situated in the compound of the woreda administration office.

Table 14: Education in Kolfe Keraniyo Sub city, Woreda 9, 2007EFY

Sr. no	Type of School	# schools	Number of Teachers			Number of Students			Student School Drop Out
			male	Female	total	male	female	Total	
1	Primary								
	1-4	2	11	17	28	933	970	1903	60
	5-8				0	0	0	0	
	1-8	5	59	58	117	1893	2002	3,895	97
2	Secondary								
	9-10	2	41	23	64	222	250	472	0
	11-12	1							
	9-12	-	-	-	-	-	-	-	-
	Total	10	111	98	209	3,048	3,222	6,270	157

Source: Kolfe Keraniyo woreda 9 Education Office

The most interesting activity regarding youth clubs in the woreda is that there are two physical exercise centers in the compound of two schools which are mostly functional in winter (*Kiremt*) times. The woreda has trained sport professional to give training for anyone interested to get involved in the exercise.

D) Communication and Infrastructure

Concerning health facilities, Woreda 9 is one of standardized major roads accessed areas in the in Kolfe-Keraniyo sub-city. Regarding communication the health center has fixed line call service and all health facilities have mobile phone network coverage. water supply and electricity are also well functional.

E) Health sector expenditure and financing 2003-2007 EFY.

Woreda 9 health center of Kolfe Keraniyo sub-city budget has increasing allocation from year to years. The budget allocated for next year (2009 EFY) (i.e. 14,631,150 Birr) is more than three times the budget that had been allocated for 2005 EFY(i.e. 4,355,384 Birr).

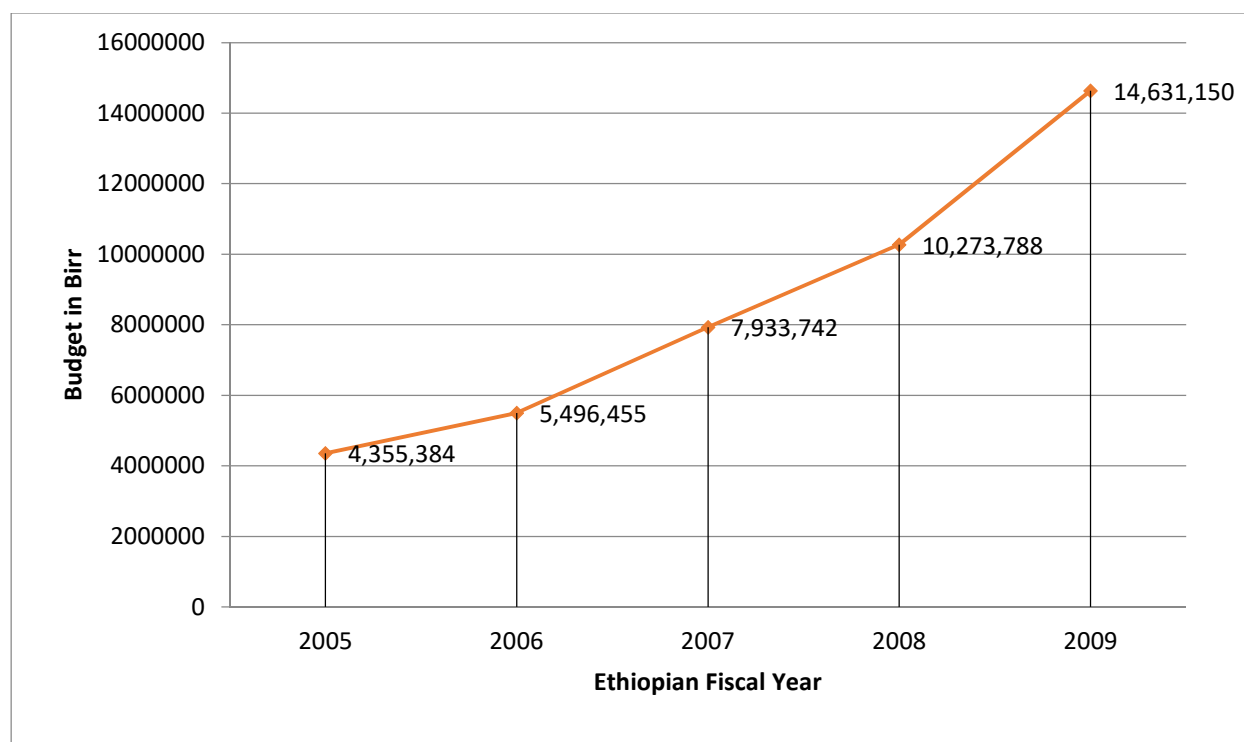


Figure 11: Amount of Budget Allocated to woreda 9 Health Center

Source: Kolfe Keraniyo woreda 9 health center finance core process

F) Nutrition and Early Warning

Regarding nutritional interventions during 2007 EFY, the district has not started the specific nutritional program, but now started for under five children with severe malnutrition by 2008 EFY. There was no community based nutrition program, outreach therapeutic program & stabilizing center. But woreda 9 health center has given severe acute malnutrition therapeutic feeding for a total of 215 adults and under 5 children. There was no natural disaster recorded in the woreda by 2007 EFY.

Discussion

Based on the data collected from Kolfe Keranyo woreda 9 health profiles, acute upper respiratory tract infection, followed by diseases of the musculoskeletal system & connective tissue, is the leading cause of outpatient visit in the woreda. It accounts for 33.15% of the outpatient visits in 2007 EFY. When we compare this figure to a health facility based study on acute respiratory infections conducted in south Gondar which was 63%, it is lower percentage. This might have happened due to the reason that the study was based on both lower and upper respiratory infections (2).

Vaccination coverage for fully vaccinated children of under one year of age was 77.1 %. This is much better than the national coverage (69%) according to a survey conducted to assess the immunization coverage in selected health facilities (3).

Regarding TB, the case detection rate of smear positive TB in the woreda was lower than the 2009 national TB case detection rate (Ethiopia health sector development plan-IV) (HSDP – IV) and the WHO recommendation, that was 70% and the district all forms of TB prevalence were 433/100,000 in 2007 EFY which is lower than the national prevalence rate 579 /100,000 in 2009.

Seventy six percent of pregnant women had at least four ANC visits in 2007 EFY in woreda 9 health center. This shows a better coverage comparative to 42% of mothers received same number of ANC visits according to the national baseline survey conducted for routine immunization improvement initiative in 2015.

The target set for the prevention and control of TB have been to achieve 85% treatment success rate and a detection rate of 70% of new smear positive TB cases. The national cure and treatment success rates are 67% and 84%, which is on track towards HSDP III target, while the case detection rate remains at 22%, far less than what was planned for HSDP III(4).

The HIV prevalence of the woreda based on the health facility data such as from VCT, PMTCT, and PITC was 8.7% which gave a total of 3,018 PLWHA in 2007EFY but very far high number as compared to the national projected prevalence that is 1.2%(5). Absence of natural disaster and very low number of severe malnutrition therapy provided in the woreda is good unless under reporting is masking the situation.

According to the district health officials, the main problems of the district are limited regular budget, shortage of medical supplies, and restriction of the most allocated budgets to programmatic activities which are not flexible and other used for other demanding activities.

Challenges and Limitations

This analysis did not represent data about private health sectors due to unavailability of document, and so it is focused on government health facilities. Occupational characteristics, vital statistics, income source and other information is not documented. Moreover, there was also difficulty to find out detailed information about health service coverage of woreda.

Conclusion

This Woreda Health profile includes multiple issues including health care service, nutrition and education. Acute upper respiratory tract infection is the leading cause of morbidity. There is no any dropout student from school at secondary level. Immunization and ANC coverage of the woreda is more than the planned number in both children and women. TB and HIV are still public health burdens in the woreda. No disaster is recorded in the years 2007 EFY.

Recommendation

Important health indicators like infant mortality, crude death rate and child mortality should also be registered and documented. Health education to the population is needed regarding environmental health and personal hygiene to prevent acute respiratory infections and other diseases. To know actual coverage of health service the private clinic should submit report to woreda health office. The woreda should also be supported by the higher level government entities and NGOs about the importance of data to have a modern documentation system for better planning, preparedness and public health events response.

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CHAPTER V: SCIENTIFIC MANUSCRIPTS AND ABSTRACTS

FACTORS ASSOCIATED WITH CHIKUNGUNYA FEVER VIRUS OUTBREAK IN ETHIOPIA, JUNE 2016

Introduction

Chikungunya is a vector borne virus in alphaviridae family passed to humans by *Aedes* mosquito bite(1). It was isolated in Tanzania where a massive outbreak with unusual illness characterized by crippling joint pain and severe fever in 1953(2). Chikungunya is believed to have originated from Africa and spread to islands off the eastern coast of Africa(4). The attack rates for this outbreak in 2005 ranges from 35% to 75%. In 2006, after an apparent gap of about 32 years during which CHIKV was not detected, CHIKV disease has attacked many people in India in numerous states, suspected number of cases ultimately reaching more than 1.3 million(2)(4). Three genotypes of CHIKV, called West African, East/Central/South African (ECSA), and Asian have been defined, of which the latter two caused large outbreaks. ECSA genotype virus, which had originated from Kenya, was responsible for the epidemics on islands in the Indian Ocean. Thus, it was quite unexpected when the ongoing outbreaks in the Caribbean region were found to be due to an Asian genotype virus. Chikungunya virus has been transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes. There is evidence that ECSA strains have been adapted to *Ae. Albopictus* whereas *Ae. aegypti* have greater competence for Asian strains over ECSA strains[8,4,2]. Chikungunya virus, as it is a risk group 3 pathogen, is containment in biosafety Level 3 facilities, equipment, and operational practices for work involving infectious or potentially infectious material(9)(10). Currently, the Ethiopian public health institute arbovirus testing set up is equipped with a real time RT-PCR principle. This set up is now based at the Ethiopian national influenza laboratory where previously detected new pathogens, like Dengue and Yellow Fever Viruses, are being diagnosed. This laboratory has a capacity to detect other pathogens, such as Zika, west Nile, Creman Congo, Rift Valley fever viruses. This investigation was done to provide a brief overview about emergence and possible risk factors of Chikungunya outbreak in Ethiopia. The Ethiopian public health institute received 10 serum specimens on June 6, 2016 and immediately deployed investigation team. The objective of the investigation was to confirm the etiologic agent, to describe and determine factors associated with Chikungunya virus outbreak in Dolo ado district, Liben zone, Somali regional state, South-Eastern Ethiopia

Methods and Materials

Dolo ado district is one of the district of Liben Zone, Somali Regional Sate, which is located in South-Eastern Ethiopia. It is located 1,050kms far from the capital Addis Ababa. The district has a total population of 133,368, out of which 51% of the population was females(Source: Dolo Ado Woreda health office). An unmatched case-control study design was used to investigate the outbreak from June 10 to 17, 2016. All residents of Dolo Ado woreda were the source population. Cases were identified by the Chikungunya case definition adapted from WHO regional office for south-east Asia that proposed by the European Centre for Disease Control (ECDC). A total of 33 cases and 66 controls were interviewed with a ratio of 1:2 making total participants 99. Acute onset of fever $>38.5^{\circ}\text{C}$ and severe arthralgia/arthritis not explained by other medical conditions was the selection criteria for cases. Controls were all people who do not present any sign and symptom of the illness who is neighbor of the cases.

Epidemiological data were collected through face to face interview using structured questionnaire prepared in English with the help of local guides and translators and laboratory specimen was collected by the investigator. Serum samples were collected. Laboratory tests were performed for Dengue fever Virus and Chikungunya viruses for all 18 serum samples using Real Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) technique to identify the etiology of the existing febrile illness. The data were checked for completeness and consistency and analyzed using SPSS version 21 software. Logistic regression was applied to determine the factors associated with Chikungunya fever disease outbreak. Results were displayed using texts, tables and graphs and statistical significance was interpreted using Odds ratio with 95% confidence interval and P value <0.05 . Support letter was written to those concerned so as the national investigation team, as a public health emergency response body, can responsibly and accountably undertake the response activity at the site of the outbreak.

Result

Descriptive Epidemiology

A total of 99 individuals (33 cases and 66 controls) were interviewed. From the total respondents, 37(37.4%) were males and 62(62.6%) were females. Out of the 33 cases, 34 and 36 were males and females respectively. The median age of participants was 28 years (range from 3 to 70). From the total cases, 5(15.2%) were singles, 27(81.8%) were married and 1(3.0%). similarly, 16(24.2%) of the controls were single, 45(68.2%) were married and 2(3.0%)

were divorced/separated. Regarding occupation of the cases, 5(15.2%) were students, 8(24.2%) were daily laborers, 13(39.4%) were house wives, 2(6.1%) were merchants, 3(9.1%) were farmers and 2(6.1%) were government employees. Among the controls, 12(18.2%) were students, 5(7.6%) were daily laborers, 27(40.9%) were house wives, 8(12.1%) were merchants, 1(1.5%) were farmers and 13(19.7%) were government employees. More than half of the cases, 20(60.6%) could not read and write, 10(30.3%) have completed primary education, 2(6.1%) have completed secondary school and a person out of 33 has completed college. Whereas among the controls, 24(36.4%) could not read and write, 24(36.4%) have completed primary education, 13(19.7%) have completed secondary school and 5(7.6%) have completed college/university. The interviewees were also asked some knowledge questions regarding Chikungunya fever. Based on the interview, 14(42.4%) of the cases and 26(39.4%) of the controls have heard about Chikungunya from different sources.

Associated Factors towards Chikungunya Fever disease

The availability and use of LLINs were assessed and 54.5% of the cases have LLINs while 87.9% of the controls had access to LLINs. Among those who have LLINs, 17.6 % of the cases and 67.2% of the controls use it while sleeping. Almost all respondents had water holding containers in their houses, and larvae were identified from the water holding containers of 12(37.5%) cases and 1(1.5%) control. There was no stagnant water in that area and there is only one river, Dawa River, which is more than 200 meters from the village. Moreover, none of the respondents' house was sprayed in the last three months. In terms of close contact, 66.7 % of the cases had close contact with a person of the same complaint, while only 36.4 % of the controls had similar exposure. None of the respondents used mosquito repellent neither on their skins nor in their houses except a single case. Among the cases, 42.4% wear long sleeved clothes and 66.7% of the controls wear long sleeved clothes.

Table 15: Factors associated with Chikungunya fever disease, Dolo Ado District, June 2017

Characteristics	Cases n=33	Controls n=66	COR(95% CI)	P-Value
Availability of LLINs				
Yes	19(57.6%)	58(87.9%)		
No	14(42.4%)	8(12.1%)	5.3(1.9-15.1)	0.001
Utilization of LLINs				
Yes	3(9.1%)	39(59.1%)		
No	30(90.9%)	27(40.9%)	14.4(3.9-52.2)	0.000
Status of Water Holding Container				
Open	22(68.7%)	37(56.9%)		0.019

Closed	10(31.3%)	28(43.1%)	2.9(1.2-7.1)	
Presence of Larvae in Water-holding Container				
Yes	12(37.5%)	1(1.5%)	38.3(4.7-311.9)	0.001
No	20(62.5%)	64(98.5%)		
Close Contact with Ill Person in the Last 2 weeks				
Yes	22(66.7%)	24(36.4%)	3.5(1.4-8.4)	0.005
No	11(33.3%)	42(63.6%)		
Travel history to Mandera(Kenya) with in the past 2 weeks				
Yes	20(60.6%)	2(3.0%)	49.2(10.2-236.8)	0.000
No	13(39.4%)	64(97.0%)		
Type of cloths				
Long sleeved	14(42.4%)	44(66.7%)		
Short Sleeved	19(57.6%)	22(33.3%)	2.7(1.1-6.4)	0.023

In a bivariate analysis, the above factors seemed to have association with chikungunya fever disease. But, when we perform a multivariable analysis some of them hadn't have real association. Among them, utilization of LLINs ($p=0.015$), presence of *Aedes* mosquito larvae in water holding container during the investigation time ($p=0.026$) and Travel history to Mandera (the neighboring Kenyan town) with in the past 2 weeks from the date of onset of the disease($p=0.001$) were important risk factors.

Table 16: Independent predictors of Chikungunya fever disease, Dolo Ado District, June 2017

Characteristics	Case	Control	COR (95% CI)	AOR (95% CI)	P-Value for AOR
Utilization of LLINs while sleeping					
Yes	3(9.1%)	39(59.1%)	1:00	1:00	
No	30(90.9%)	27(40.9%)	14.4(3.9-52.2)	14.6(1.7-127.8)	0.015
Presence of Larvae in Water-holding Container					
Yes	12(37.5%)	1(1.5%)	38.3(4.7-311.9)	25.6(1.5-442.5)	0.025
No	20(62.5%)	64(98.5%)	1:00	1:00	
Travel history to Mandera (Kenya) with in the past 2 weeks					
Yes	20(60.6%)	2(3.0%)	49.2(10.2-236.8)	37.3(4.3 - 321.3)	0.001
No	13(39.4%)	64(97.0%)	1:00	1:00	

Discussion

First of all, this study is a case control study and hence could not determine the prevalence of Chikungunya virus in Dolo Ado woreda. Because of unavailability and shortage of diagnostic reagents, and the difficulty of the area to transport specimens easily, only limited specimens were collected relative to the large number of cases. The detection of Chikungunya virus nucleic acid, RNA, in most of the specimens by rRT-PCR can be considered as the first virological evidence of the existence of Chikungunya virus in the country's public health history.

The number of affected people in the period of outbreak is nearly equivalent with that reported in Indonesia in 2007 although the later had reported cases from multiple districts(11). The number of reported cases associated to this first outbreak is much lower than what neighboring Kenya had experienced for the first time in 2004 that attacked 13,500 people in Lamu county which represents 70 per cent of the population(12). In addition, the attack rate of the outbreak in Dolo Ado woreda was much lower than the neighboring sub-county of Kenya, Mandera, which was about 80% of the general population and 50% for the health workers according to WHO' outbreak news posted on 9 August 2016.

An outbreak of Chikungunya in Comoros in 2005 was once the cause of morbidity to 450 case per week in May 2005 and peak at the end of January 2006 (45,000 cases / week), which resulted in cumulated cases of 266.000 by end of June 2006(About 1/3 of the population has been infected)(13).in our case, all the cases were report in the month June, which resulted in a maximum number of victims of 291 cases per week at epidemiological week 26.This may be due to the smaller number of population living in Suftu and limited movements into and out of this Kebele, or prompt response in environmental management to interrupt Chikungunya transmission(14).

Knowing the genotype of Chikungunya is crucial to understand the source and linkage of the outbreak because its pathogenicity may worsen as it mutates like that in La Reunion islands(2) Unexpectedly, a new lineage, the East- Central -South African genotype, was introduced from Angola in the end of May 2014 in Feira de Santana (FSA), the second largest city in Bahia state, Brazil, where over 5,500 cases have now been reported(8). In this year, Chikungunya is reported in much number than last year (2015) in India(15). This may be the conduciveness of the environment for the spread of *Aedes* mosquito as a result of the global climate change.

The massive outbreak of Chikungunya virus which started in 2013 in the Americas has resulted in nearly 1 million cases and 71 deaths by the end of 2015(8). Although the genotyping was not done for this outbreak in Ethiopia, having no reported death due to Chikungunya is fortunate unlike could have been deaths attributed to Chikungunya outbreak in Americas by the Asian type.

On multivariable analysis, the study showed that utilization of LLINs, presence of larvae in the water holding container and previous travel to Mandera, the Kenyan town before two weeks from the interviewremained associated withChikungunyafeverdisease.The odds of respondents

who did not use bed nets while sleeping in daytime were 14.6 times more to have the disease than those who used bed nets. Basically, this finding is applicable for *Aedes* mosquito bites in the day time, and meanwhile the respondents might have thought it shameful to respond negatively because it is not comfortable to use bed nets since the study area is very hot. Presence of larvae of *Aedes* mosquito in the water holding container of the respondents was found cause of chikungunya fever infection though effect of type of container was not studied. This association of chikungunya infection is consistent with the risk factors of chikungunya infection in Nepal(16).

We have also found a significant association between chikungunya fever disease and travel to the Kenyan town of Mandera. A case control study conducted in Malaysia showed similar risk factor for chikungunya infection (OR=3.24, 95% CI: 1.82, 5.78, $p < 0.0001$)(17).

Conclusion and Recommendation

This investigation notes that Chikungunya has emerged in Ethiopia and there is no way that it cannot cause illness again and affect all ages and both sexes. This result reveals that we have faced a new cause of acute febrile illness. Failure to use impregnated bed nets while sleeping in daytimes, mosquito breeding in household water holding containers and movement to chikungunya affected area of Mandera, Kenya were significantly associated with the disease in multivariable analysis. Vector control intervention, particularly, LLINs, IRS and larvicidal should be applied to halt the transmission by local health office. Continuous education should be offered for border crossing people to dress long sleeved clothes. Ministry of health should recognize the disease as public health threat and prepare guideline, intervention strategy and reporting mechanism.

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BURDEN OF INFLUENZA-LIKE ILLNESS AT KOLFE HEALTH CENTER, ADDIS ABABA, ETHIOPIA, 2010-2015- A DESCRIPTIVE ANALYSIS OF SURVEILLANCE DATA

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Abstract

Background: Influenza is an acute viral respiratory tract disease characterized by fever, headache, myalgia, prostration (fatigue), sore throat and cough. Influenza virus has three types A, B and C. Launched in 2008, Ethiopian Influenza sentinel surveillance has eight sentinel sites including Kolfe Health Center. Catchment area specific data analysis was needed to indicate the positivity rate, incidence and burden of Influenza-Like Illness (ILI). This analysis is aimed at determining the burden and incidence of ILI at Kolfe health center and its catchment population.

Method: This descriptive data analysis was done for Kolfe Health Center's Influenza surveillance data compiled at national public health emergency management. The health center identifies cases using Ethiopian Influenza Sentinel Surveillance Implementation Guideline. Written permission was obtained from the public health emergency management. Surveillance officers of Kolfe health center, national public health emergency management and field supervisor commented and feedback was obtained accordingly.

Result: Totally, 1,375 ILI visits were found registered that met the ILI case definition with age ranging from 1 months-80 years. Influenza like illnesses account from 5.05 % to 29.64% of outpatient visits each year from the beginning of 2010 to the end of 2015. From the total of outpatient visits from 2010-2015, ILI accounts 17.53 %. Among a total of 347 positives, 218(63%) were Influenza A and 129(37%) of them were Influenza B.

Conclusion: Influenza-like illness occurred all year round affecting both sexes and all ages. Continuous influenza surveillance will provide a frame work for detecting and following future influenza outbreaks and pandemics.

Keywords: Influenza Virus, Sentinel Surveillance, Ethiopia

EVALUATION OF ETHIOPIAN INFLUENZA SURVEILLANCE SYSTEM, 2017

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ABSTRACT

Background: The Global Influenza Surveillance and Response System (GISRS) has been performing influenza virological surveillance since 1952. Ethiopia conducts influenza sentinel surveillance since 2008 in eight sites. It is carried out by Ethiopian public health institute but little is known whether the system meets its objective. Hence, this evaluation is conducted to evaluate the sentinel surveillance attributes, purposes and its operation system.

Method: A cross-sectional study was employed from February 15-30, 2017 in all eight Sentinel sites. Data were collected using Centers for Disease Control and prevention updated surveillance guideline and Interview with influenza sentinel surveillance focal persons, regional health bureau officers and national officers of public health emergency management(PHEM). Case based reports of influenza like illness and severe acute respiratory illness were also reviewed. Secondary data were collected from the national public health emergency management center. We analyzed and compiled the data using Microsoft excel.

Results: Not all the visited health facilities have posted the ILI and SARI case definition. None of the sentinel sites have been reporting influenza data to their next higher level although they responded that they are expected to do so. Data is only being analyzed by national PHEM. Supportive supervision was done this month (February, 2017) since 2014. Laboratory feedback (test result) has been provided irregularly since May 2016 by the national influenza laboratory to sentinel sites and respective regional PHEM. All focal persons have taken training on influenza surveillance. The positive predictive value (PPV) was 21.35% (n=4922). Among a total of 5,097 case based reports from 2008-2016, 47(0.9%) of 4,922 age records, 385(7.5%) temperature records, and 103 (2%) dates of specimen collection records were not filled.

Conclusion: This evaluation is limited to determining sensitivity, specificity and negative predictive value. Although, focal persons are satisfied with the forms and procedures involved, they are not filling formats properly as expected and reporting regularly as scheduled neither to the national PHEM nor to the next higher level. The influenza sentinel surveillance system has proven to be useful in providing virological data used to characterize and monitor influenza trends in Ethiopia. Continuous supportive supervision should be done to increase the quality of data. Data should be continuously analyzed and feedback should be given periodically to health care provider and partners.

Key Words: Ethiopia, Evaluation, Influenza, Surveillance

CHAPTER VI: STANDARD OPERATING PROCEDURES

A) STANDARD OPERATING PROCEDURE FOR BLOOD SUGAR

Purpose	This test is intended for blood glucose meters to measure concentration of blood glucose.
Abbreviations	SOP – Standard Operating Procedures
Material and Reagents	Lancet Cotton wool Rapid blood glucose determination machine. Test strip Safety box.
Samples	Whole blood from capillary finger stick.(0.7µl)
Special Safety Precautions	Refer to the Health and Safety Guidelines for standard safety procedures.
Quality Control	Use strips high and low controls (if not available, used pooled sample). Perform control solution tests: When new vials of test strip is opened. At least once a week.
Procedure	Fully insert the test strip in to the meter with the contact bars end first. (When the strip will go no further) Obtain a blood sample of at least 0.7 microliters of blood. Hold the blood drop to the absorbent channel of the test strip until blood has completely filled the conformation window. The meter will begin to count down. After 6 seconds, the test results will appear, showing you the blood glucose test result. The last reading is automatically stored in the meter memory. Shut the meter off by removing the strip. Discard the used strip.
Result interpretation	The test result will be displayed either in milligrams per Deciliter (mg/dl) or in millimoles per liter (mmol/l).
Expected values	Before meals..... 80-120 mg/dl(4.5-6.7 mmol/l) 1-2 hr. after meals..... < 180 mg/dl(10 mmol/l) Bed time 100-140 mg/dl(5.6 -7.8 mmol/l)

Limitations	Hematocrit: below 20% or above 60% hematocrit levels can cause false results. Neonatal use: the test strips should not be used for the testing of newborns. Metabolites: reducing substances such as uric acid and ascorbic acid when occurring in expected blood concentration, or acetaminophen, dopa, methyldopa, L-dopa and tolbutamide occurring in expected blood concentration will not affect results. Lipemic effects: elevated blood triglycerides greater than 2000 mg/dl affect the result. Do not use iodoacetic acid or fluoride as a preservative for blood specimens. Use only fresh capillary whole blood. Do not use serum or plasma.
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Principle	The blood glucose test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the test strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.
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Related Procedures and Documents	Machine Manual and test strip insertion.
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Reference	1. Monica cheesbrough, second edition. District laboratory practice in tropical countries. . Part 1
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Name	Sign	Date
Prepared By: _____	_____	_____
Review By: _____	_____	_____
Approved By: _____	_____	_____
Declaration		

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

Name	Sign	Date
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____

B) STANDARD OPERATING PROCEDURE FOR KOH

10% POTASSIUM HYDROXIDE (KOH) SKIN AND NAIL

PREPARATIONS

PURPOSE

KOH preparations of skin scrapings and nail samples are used for the direct microscopic identification of fungal elements such as yeast and hyphae.

PRINCIPLE

KOH facilitates the microscopic observation of fungal elements by dissolving obscuring cellular material and debris, thus making fungal elements more visible.

INSTRUMENT, REAGENTS AND SUPPLIES

A. Instrument:

Binocular microscope with 10x and 40x objectives

Preventive maintenance should be done annually, evidenced by a dated label on the microscope.

To maintain the microscope in good working order for day-to-day use:

- Keep it covered when not in use
- Keep surfaces free from dust
- Clean objectives, lenses, eyepieces and condenser daily or as needed, using lens paper and cleaner fluids specifically designed for optical instruments
- Do not use dry lens paper, non-optical tissues or gauze

B. Reagents:

10% Potassium hydroxide (KOH) in a dropper bottle or dropper alone (Pasteur pipette)

Store at room temperature

Use until the expiration date on the bottle.

C. Supplies:

1. Alcohol wipes
2. Glass slide(s)

3. Coverslip(s)
4. Scalpel or curette

D. Personal Protective Equipment

I. Safety Glasses

2. Examination Gloves
3. Long-sleeve Lab Coat/gown

PROCEDURE

I. Specimen Collection

- A. Using two patient identifiers verify patient identity and explain procedure to the patient and/or family
- B. Observe universal precautions; wear gloves and other personal protective equipment as appropriate.

Caution: Give great care since 10% KOH is corrosive.

- C. Label clean glass slide(s) with patient name and medical record number

Skin Sample Collection:

1. Cleanse skin to be sampled with alcohol wipe to remove contaminating microorganisms.
2. If characteristic dermatophyte "ring" is present on skin, collect samples from the outer margin of the ring at its junction with normal skin. Otherwise collect samples from areas where skin appears to be scaling.
3. Use edge of glass slide or scalpel to scrape off surface skin scales. Do not use swab since the swab fibers may resemble hyphae.
4. Collect sample on labeled glass slide.
5. Apply coverslip.

Nail sample Collection:

1. Cleanse nail with alcohol wipe.
2. Using a curette or scalpel, collect nail debris on a labeled glass slide. Apply coverslip.

I. KOH Treatment

1. Check the appearance of the 10% Potassium hydroxide (KOH) solution. It should be clear with no visible contamination.
 - If the solution is clear, proceed with test.
 - If the solution is not clear, discard and obtain new solution and proceed
2. Place one drop of KOH on the glass slide containing the skin or nail specimen at the edge of the coverslip. Allow the KOH to diffuse under the coverslip.
3. Gently heat the slide using the butane lighter tethered to the microscope table. Using a pen, put light pressure on top of the coverslip to spread and separate the skin or nail material. Specimen should be flat and transparent for microscopic viewing.
4. Scan the preparation microscopically with the low power objective (10x) with reduced light, looking for fungal elements such as yeast cells and hyphae.
5. Change to the high power objective (40x) to verify fungal elements seen with the low power objective
6. Dispose of swabs and other contaminated materials in a red biohazard waste container. Slides and coverslips must be discarded in a red hard-sided sharps container.

RESULTS AND PRECAUTIONS

Yeast elements can be difficult to differentiate from cotton fibers and other debris. True hyphae crisscross epidermal cells in a random fashion and the strands are usually of a uniform diameter.

REPORTING OF RESULTS

- Report the presence or absence of yeast or hyphae.
- Document results in a designated place on the physical assessment form in the medical record.
- Date and sign result entry. Entries by supervised trainees or providers who have not completed required competency assessments must be countersigned by qualified providers who are authorized to perform the test.

LIMITATIONS OF PROCEDURE

- The KOH preparation should be set up immediately after sampling for optimal recovery of fungal elements.
- Small quantities of yeast and hyphae may be missed in the KOH preparation. Thus, failure to visualize fungal elements in the preparation does not completely exclude yeast or fungal infection.
- When fungal infection is suspected but KOH preparation is negative, samples may be sent to Ethiopian Public Health Institute Clinical Laboratory for culture. Skin and nail specimens may be kept at room temperature, but must be received in the clinical laboratory within 24 hours after collection. Use a plain, sterile, screw-capped container without media for specimen transport.

CHAPTER VII: LABORATORY QUALITY MANUAL

Revision and Amendment

Shoa Robit health centre laboratory (SRHCL) is responsible for maintaining the official master copy of quality 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.

Annual Review of Document

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

Version Change History/Description

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

Amendment

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

Introduction

Background

Shewa Robit Health Centre Laboratory (SRHCL) Quality policy Manual should provide an insight into the structure of Laboratory 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 should be reviewed and revised accordingly from time to time to reflect its status. This will demonstrate that the Laboratory's competent to operate medical testing laboratory in accordance to the requirements of International organization for Standardization (ISO) 15189: 2012 Medical laboratory — Particular requirements for quality and competence and accreditation body requirements.

Reference

The following document is referenced:

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

QUALITY POLICY MANUAL

Shoa Robit health centre laboratory (SRHCL) Quality manual should provide an insight into the structure of laboratory 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 should be reviewed and revised accordingly from time to time to reflect its status. This will demonstrate that the laboratory is competent to operate medical testing laboratory in accordance to the requirements of updated version of International organization for Standardization (ISO) 15189 medical laboratories — particular requirements for quality and competence and accreditation body requirements..

Note

Here in the Quality 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 list. In addition document unique ID, which is found in interval (Example, SRHCL-ALS- F-001) at subsidiary document of Quality manual, are listed in detail with document name and unique ID at the Document Master List.

TERM S, DEFINITION AND ABBREVIATION

Term and Definition

- **Compiler:** A person who gathers/complies information and or prepares documents.
- **Approver:** An authorized person who is responsible for documents and records approval.
- **Examination:** set of operations having the objectives of determining the value or characteristics of the property.
- **Laboratory Head:** Competent person(s) with responsibility for, and authority over, a lab.
- **Measurement:** a set of operations having the object of determining the value of the quantity.
- **Post-examination procedures:** processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples of the examinations.
- **Pre-examination procedures:** steps starting, in chronological order ,from the clinician's request and including 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 SRHCL.
- **Referral laboratory:** external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report
- **Safety officer:** A person who facilitates and control the implementation of laboratory safety practice.
- **Safety committee:** Persons who manage the activities of a laboratory safety headed by a Safety Officer.
- **Supply and inventory officer:** Responsible for managing inventory and supply control activities of SRHCL.
- **Subsidiary:** it is a supportive document that helps to accomplish tasks or policy.
- **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 change in the document(edition)

3.2 Abbreviation

AFB	Acid fast bacilli
ARF	Action Registry Form
ART	Anti-retroviral therapy
CBC	Complete blood count
CD4	Cluster of differentiation
CEN	European Committee for Standardization
CH	Checklist
EQA	External Quality Assessment
IAR	Investigation, Action and Resolution
ICSH	International Council for Standardization in Hematology
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
ISH	International Society of Hematology
ISO	International organization for Standardization
IUIS	International Union of Immunological Societies
IUPAC	International Union of Pure and Applied Chemistry
KPI	Key Performance Indicators
MR	Management Review
MGSOP	Management Standard operating Procedure
QA	Quality Assurance
QC	Quality Control
QM	Quality manual
QMS	Quality Management System
QO	Quality Officer
RP	Responsible Person
TP	Technical Procedure
SRHCL	Shoa Robit Health Center Laboratory
WHO	World Health Organization

MANAGEMENT REQUIREMENTS

Organization and Management Responsibility

Purpose

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

Policy

SRHCL'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.

General

SRHCL is responsible for the provision of diagnostic laboratory testing services for patients and specimens referring to other health facilities.

SRHCL 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 the surroundings.
- Above all, SRHCL role is to enhance the quality system management.

Legal entity

The SRHCL is a Government institution that is under Amhara Regional Health Bureau. The management ensures that the laboratory is independent from any commercial, financial or other pressures, which might adversely affect the quality of tests and test reports.

ADDRESS:

Name of Lab: ShewaRobit Health Center Laboratory

Town: ShewaRobit Kebele:

Phone No: +251-0336640075

Email: Shewarobitlab@gmail.com

ShewaRobit, Ethiopia

4.1.1. Working Hour

SRHCL Laboratory provides service 24 hours a day & seven days a week including public holidays. But for immune haematology (CD4 and CBC) perform in Regular hour:

Morning 8:00 AM - 12:00 PM Friday 8:00 AM-11:00 AM

After Noon 1:30 PM- 5:30 PM

4.1.2. Vision Statement

“To see Healthy, Productive and Prosperous People in Shoa Robit town and neighbouring woredas by providing quality laboratory services”

Mission Statement

“To protect and promote the health of the people by addressing priority public health problems, by establishing and maintaining quality laboratory management system”.

OBJECTIVES

General Objective

The objective of the laboratory is to produce accurate, reliable and timely results, achieve and maintain an effective quality management system and ensure compliance with relevant statutory and safety requirements.

Specific Objectives

- ✓ To capacitate personnel to become competent to perform assigned duties by performing regular competency assessment for all staffs 100% all time as per the policy.
- ✓ To satisfy > 90% of our customers by Laboratory service at the end of July,2018
- ✓ To provide conducive and safe working environment and create a zero incident environment/ month all time. .
- ✓ To validate processes and subject them to adequate quality control and quality assurance assessments by performing IQC 100% for all tests all time.
- ✓ To ensure equipment, supplies and services are functioning properly and/or meet required specifications thereby assures <5 days / month of equipment down and no stock outs.
- ✓ To ensure required documents and records are maintained 100% as per the required standards all time.
- ✓ To maximize the laboratory quality by giving supportive supervision to the cluster health centre laboratories every other quarter to implement QMS 100%.

VALUES

- User satisfying service is our laboratory 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 other laboratories is our strategic value

- Motivated and committed staff
- Service is our culture.

.SCOPE OF OPERATIONS AND SERVICES

Shoa Robit health centre laboratory consists of following laboratory sections providing full services:

- Reception: Phlebotomy, specimen accessioning, specimen collection and receiving
- ART laboratory
 - CD4 count
 - Haematology (Complete blood count, Haemoglobin , Haematocrit)
 - Chemistry tests(GPT,GOT,Urea,Creatinine, Cholesterol,ALP, Bilirubin total, Bilirubin direct, Triglycerides, RBS & FBS)
- Main laboratory
 - Parasitological(Blood film & Direct stool examination)
 - urinalysis tests(Chemical & Microscopic examinations)
 - Bacteriology (AFB and gram stain)
 - Serology and immunohematology (Blood grouping & Typing, Widal test, Wiaflex test, RPR, Pregnancy test, Pylori, HBSAg& HCV)
 - Viral load and Gene x-pert sample referral service
- Assuring the quality of services and EQA for Tarmaberworeda(D/sina ,Armania&Mezezo) and Kewotworeda (Abaytir, Tere&Ayaber) health facility laboratories.

Standard of Services

Shoa Robit Health Centre Laboratory provides different diagnostic services which are mentioned above based on the recommended and accepted standardized procedure. When any updated procedures and/guidelines provided which will increase of health care service, Shoa Robit health centre Laboratory uses and updates its procedure and system based on the recommended standard.

SRHCL Structure

The inter-relationship of all personnel is displayed in Annex: SRHCLOrgano-gram.

Regarding the roles, responsibilities and authorities in relation to performance outputs are described under the job descriptions. In order to give emphasis on the responsibility of all staff in relation to the operational structure, quality management system implementation and fulfil the quality system with the applicable directives.

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:

Head of Shoa Robit Health Center:

- Responsible for budget and resource allocation for proper implementation of quality management system
- Monitoring and evaluation of laboratory performance by annual management review
- Appointing of laboratory head, quality officer & delegate responsibilities
- Responsible by approving laboratory manuals, and some management SOPs prepared by HC

Laboratory Head

- Administers and supervises the technical and scientific operation of the laboratory.
- Ensures the physical and environmental conditions are appropriate for testing
- Prepares/approves job related documents
- Reviews/approves procedure manuals (SOPs) on a yearly basis.
- Conducts competency evaluation of the laboratory personnel.
- Oversees and reviews the inventory management of the laboratory.
- Oversees general quality of technical performance of laboratory personnel and competency evaluation of the laboratory personnel.
- Advises administration of personnel deficiencies, including staffing needs and requirements for personnel qualification.
- Supervises and participates in-service and continuing education to all technical personnel.
- Determines the internal auditing policy of the laboratory and must know results of internal audit outcomes to take corrective action measures.
- Propose Quality (Quality Officer), Safety (Safety Officer) and supply (supply officer).
- Respond to customer inquiries about laboratory results, and oversee that staff maintain confidentiality of patients and adhere to customer service standards of laboratory.
- Facilitate internal and external auditing program.
- Chairs and directs regular staff meetings.
- Perform other job-related duties as assigned

Quality Officer

- Implements the QA program for the laboratory.

- Prepare/review job related documents
- Maintains data to support QA program
- Monitors quality control, evaluates and documents quality control data and assure that patient results are not reported when tolerance limits are exceeded; reviews quality occurrences in compliance with the quality plan of the section; advises laboratory head of significant quality control/quality assurance issues.
- Analyses technical problems pertaining to specimen adequacy, laboratory data, and instrumentation; determine cause and rectifies problems in accordance with guidelines and procedures.
- Confirms abnormal results and result discrepancies and initiate follow-up to resolve discrepancies.
- Ensures the calibration of instruments; the performance and documentation of preventative and corrective maintenances, function checks, and repairs on instruments and equipment.
 - Ensuring that processes needed for the quality management system are established, implemented, and maintained.
 - Reviews and approves laboratory results according to standard operating procedures; report critical (panic) values or unusual results in accordance with established policy.
 - Conducts and maintains an internal audit system; develops a schedule for performing audits; coordinates the audit process; manages corrective action efforts and advises management and other staff on outcomes.
 - Assists with inventory management of supplies and assure that laboratory areas remain stocked with needed supplies.
 - Facilitates external assessments.
 - Maintains confidentiality of patients and staffs.
 - Responds to customer inquiries about laboratory results and adheres to customer service standards of laboratory.
 - Performs other job-related duties as assigned.

Safety officer

- Prepare/review job related documents
- Ensure and monitor staff adherence to the observation of safety rules and practices.
- Responsible for updating of the safety manual periodically
- Ensure that reagents and chemicals are stored properly.
- Ensure that waste material generated by the laboratory is disposed properly.
- Ensure that Personnel Protective Equipment (PPE) is available, easily accessible and utilized appropriately and consistently by all staff.

- Responsible for conducting safety inspections and audits, and safety-related meetings regularly.
- Ensure that safe laboratory practices and procedures are integrated into the basic training of employees.
- Responsible for reporting of safety hazards; i.e. ensure, where possible, that any hazard, unsafe or unhealthy situation reported by employees is removed or made harmless. If this is not possible, he/she is responsible for reporting the situation to the Laboratory head.
- Responsible for summarizing and taking corrective actions for safety related non-conformities in the laboratory.
- Responsible for conducting and re-evaluation of risk assessments.
- Responsible for maintaining documents and records, including monthly inspection reports, minutes of safety meetings, accident report forms, safety audit reports, etc.
- Chair the Safety Committee conducting safety meetings every quarter and present the inspection summary and give minutes to the laboratory head.
- Provide laboratory safety orientation to new employee; i.e. introduced to the code of practice and to local guidelines, including the health and safety manual.
- Ensure that first-aid kit is available and re-filled timely.
- Review all Safety log sheet in timely manner.
- Participate in on-job training of employees and other staff in the health center.
- Perform other job-related duties as assigned.

Supply and Inventory Officer

- To ensure proper receipt of reagent and supply in terms of quantity and quality.
- To ensure proper storage and cycling of stock.
- To ensure dispensing activities.
- To ensure inventory control system for all supplies and reagent.
- Maintain proper inventory record.
- Forecast needs for supply and reagent based on testing demand.
- Preparing monthly internal facility report and resupply.
- Review equipment, supplies and reagent specification.
- Determine when and how much to reorder (consumption and quantification).
- Inspect incoming order.
- Conduct periodically physical count and calculate monthly consumption of lab reagent and supplies.

- Inspect quality of existing inventory and disposal of expired test kits, reagents, and supplies according to the policy.
- Perform other job related activities as assigned.

Human Resources Management

Maintain confidential personnel documents and records

- Manage the recruitment and hiring of qualified laboratory personnel
- Give recognition for employee of the month/year.
- Offer continuing education opportunities

All Laboratory Staffs

- Read procedures fully before performing any tasks.
- Prepare job related documents.
- Ensure that specimens received for testing have fulfilled acceptance criteria following established procedure.
- Maintain an adequate supply of all reagents and consumables. Note date when reagents/supplies are received and opened in the “Reagent/Supplies Log Sheet”.
- Inform instrumentation troubleshooting to correct problems; refer problems appropriately to the responsible person.
- Document occurrences in compliance with the quality plan of the section; advises Quality officer of significant quality control/quality assurance issues.
- Analyse technical problems pertaining to specimen adequacy, laboratory data, and instrumentation; determine cause and rectifies problems in accordance with guidelines and procedures.
- Confirm abnormal results and result discrepancies and initiate follow-up to resolve discrepancies.
- Report laboratory test results according to standard operating procedures; report critical (panic) values or unusual results in accordance with established policy.
- Participate in in-service education programs.
- Analyse panel tests (e.g. HIV and TB).
- Participate in training of new employees and other staffs.
- Ensure the confidentiality of all patient information throughout all phases of laboratory testing.
- Process specimens for referral testing following established procedure.
- Respond to customer inquiries about laboratory results.
- Adhere to customer service standards of laboratory.

- Generate data and provide day-to-day documentation.
- Perform other job-related duties as assigned

Perform quality control and document the data and assure that patient results are not reported when tolerance limits are exceeded Needs of users

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

Quality policy

Laboratory management define the intent of its quality management system in a quality policy.

Laboratory management ensure that the quality policy:

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

Confidentiality of Information

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

Resources

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

Communication

Communication is vital for the effective performance as well as continual improvement of a Quality Management System. It is in this regard that SRHCL has put in place

Communication mechanisms that will ensure customer requirements (both internal and external) are met. All communications (outgoing and incoming) are logged or filed whichever is appropriate.

A. Supportive Documents

Document Unique ID	Document Name
SRHCL /ALS/SOP4.1-001	Procedure for Communication
SRHCL /ALS/SOP4.1-002	Procedure for assuring of confidential information
SRHCL / ALS/SOP4.1-003	Procedure for Conducting Staff Meeting
SRHCL / ALS/F4.1-001	Checklist for New Staff Orientation
SRHCL / ALS/F4.1-002	Communication Log
SRHCL / ALS/F4.1-003	Format for Recording/Minute of Staff Meeting
SRHCL / ALS/F4.1-004	Work Ethics Form
SRHCL / ALS/CHT4.1-001	Organogram of SRHCL (Annex A)
SRHCL / ALS/SOP4.1-004	Sop For Ethical Conduct
SRHCL / ALS/F4.1-005	External communication log
SRHCL / ALS/F4.1-006	Annual plan

Quality Management System

Purpose

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

Policy

- ✓ *SRHCL'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*

General

The laboratory should 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 should provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.

The laboratory should:

- ✓ 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

Documentation Requirements

The quality management system documentation should include:

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

Quality Policy manual

The laboratory establishes and maintains quality policy manual that includes:

- ✓ the quality policy (4.1.12) or makes reference to it;
- ✓ a description of the scope of the quality management system;
- ✓ a presentation of the organization and management structure of the laboratory and its place in any parent organization;
- ✓ a description of the roles and responsibilities of laboratory management (including the laboratory head and quality manager) for ensuring compliance with this International Standard;

- ✓ a description of the structure and relationships of the documentation used in the quality management system;
- ✓ The documented policies established for the quality management system and reference to the managerial and technical activities that support them.
- ✓ All laboratory staff has access to and be instructed on the use and application of the quality manual and the referenced documents.

Quality Policy Statement

- ✓ SRHCL is fully committed to the concept of third party recognition by means of accreditation of SRHCL to perform tests in a competent manner. The objective of the Quality Management System described in this document is to meet the requirements of national and international accreditation body, in so doing, to continually satisfy our clients' requirements and to meet our organization mission and vision.
- ✓ SRHCL's policy to offer, at all times, services that comply with the requirements as specified in the standard ISO 15189:2012 ; Medical Laboratory – 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 SRHCL 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 should 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 should 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 should be approached in an opportunistic manner such that any implemented actions that are taken as an underlying principle of improvement in the effectiveness and efficiency of the system. Also, the Management Review process should address improvements both in the Quality System and in the business processes.

Quality Goals

✓ ShewaRobitHealth Center Laboratory is determined and committed to carry out the following quality objectives and 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.

Quality Management System Description

The Quality Management System (QMS) is based on a series of documents that make up the Quality policy Manual. These documents contain the policies and procedures as required by ISO 15189:2012 and they are directly aligned to the relevant clauses of ISO 15189:2012 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 SRHCL/ALS/SOP4.3-001*)

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

Quality Management System Implementation

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

Supportive Documents

Document Unique ID	Document Name
SRHCL /ALS/JA4.2-001	Quality Management System Policies & Process (Annex B)
SRHCL /ALS/JA 4.2-002	Training Policy
SRHCL /ALS/JA4.2-003	IQC And EQA Policy

Document Control

Purpose

This document describes the means by which the documented quality system is controlled in ShewaRobitHealth Center Laboratory (SRHCL).

Policy

It is a considered policy of the **SRHCL** 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 should be minimized and, consequently, documented procedures should free of error 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. All SRHCL documents, records, format ,job aids....etc has written with the font style times new roman ,font size 12 ,line spacing 1.5 , for cover page and other necessarily charts ,job aids etc can be change the above listed criteria.

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, 2012. The system ensures contextualization of all documentation within the quality management system that is associated with any clause of ISO 15189,2012. 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 15189,2012. The document is then pre-fixed by an abbreviation SRHCL/ to indicate that it is SRHCL'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; SRHCL/HEM/SOP4.3-00. If the document is related with all policies, no need to add ISO clause/policy number e.g. SRHCL/HEM/MAN-001. For external document we identified by adding organization stamp and give unique ID without header and footer, e.g. SRHCL /ALS/RB4.1-001, SRHCL /ALS/GDL-001, SRHCL/ALS/TMAN-001 & SRHCL/ALS/OMAN-001. For archiving documents we identified by SRHCL /HDO/F4.3-001-.....

Type descriptor	Section Description
BAC	Bacteriology
CCH	Clinical Chemistry
HEM	Haematology
IMH	Immunohematology
ALS	All lab sections
LRS	Laboratory Reception section
LMS	Laboratory Mini store

✓ 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 should 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	SRHCL /ALS/QPM-01
P	Policy	SRHCL /ALS/P4.6
SOP	Standard operating procedure	SRHCL /BAC/SOP4.6-001
JD	Job Description	SRHCL /ALS/JD5.2-001
F	Forms	SRHCL /ALS/F4.6-001
S	Standards	SRHCL /ALS/S 4.6-001 or SRHCL /ALS/S-001 if it is

		related to one specific policy
MAN	Manuals	SRHCL /ALS/MAN5.3 or SRHCL /MAN/S 4.6-001, if it is related to one specific policy
JA	Job Aid	SRHCL /ALS/JA5.5-001
GDL	Guideline	SRHCL /ALS/GDL-001or SRHCL/ALS/GDL 4.6-001, if it is related to one specific policy
CHT	Chart	SRHCL /ALS/CHT5.2
RB	Reference Books	SRHCL /ALS/RB4.1-001

✓ SRHCL 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 SRHCL/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 SRHCL’s Alphanumeric Document Identification System Like SRHCL/ALS/RB4.1-001 (By Giving Document No In A Sequence Order).

Document Format and Content

Document Format

✓ The arrangement used for P; SOPS;JD; F;JA;CHT, MAN E,T.C documents should be in accordance with the format outlined in this document in terms of headers and outline. Header is outlined for sop, job aid , manual ,job description and others as follow:

	ShewaRobit Health Center Laboratory		
	Document No: SRHCL /	Effective date: Month& Day/Year	Ver. No: _____
	Title: _____	Revision date: Month& Day/Year	Copy No: _____
	ISO standard clauses: _____	Page No: of __	
	Section: _____		

NB:-for formats we are use copy number only use ver. no. This is the only difference.

✓ The arrangement used for P-; SOPS-; JD-; F-;JA-;CHT, MAN- etc. documents should be in accordance with the format outlined in this document in terms of outline.

4.1.2.1. Document Content

Documents can provide both policy and process. 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; Annex	Purpose Principles Material,equipment & reagents needed Procedure Quality control Calculations Interpretation Reference value Limitation of the procedure Safety precaution Clinical utility Policy And Responsibility For ManagerialSOPs Only	Title Department/unit Purpose Duties and responsibilities Education/Qualification Skills/Competency Training; Behavioural Competencies; Authority;	Forms should be formatted so as to allow the recordingof evidence or data that satisfies the requirements of a P-; SOP-; or JD- as appropriate.	Purpose; Procedure; Annexure.

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 list which is updated every time a document is superseded or revised. Both modes are acceptable within SRHCL.Both modes of control provide effective regulation over status and originality.

4.1.2.2. Status

The current status of documentation is identified by

✓ The revision date, origin date and effective date 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 document Number . The original document is issued as Version No 01 and subsequent revisions are marked in sequential numerical order, e.g. 2, 3, ---- etc; And Sub Version No indicated by sequential numerical order, like 1.1, 1.2, ... 2.1, ... etc.

✓ The official edition reference which should be an edition number or edition date (library issues, manuals, etc.).

All current SRHCL documentation (P-; SOP-; JD-, F-; S-; JA-; MAN-; etc) should be identified by reference to document master list (SRHCL /ALS/F4.3-001). Each List should be formatted as a matrix which cross-references each document to its current status, i.e. origin date, rev date, version no., document no. or effective date And Copy No.

Lab head and quality officer should maintain on file the updated document master list for all SRHCL controlled documentation.

Originality

Originality of quality documents is achieved by printing the documents (P-; SOP-; JD-; JA-; S-; MAN-; F-etc) on paper with logo Originality of other controlled documents is achieved by controlling access to the Document Master List.

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

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 manager and/or assigned person and approved by laboratory head. Likewise, other documents such as SOPs and job aid will be complied by quality manager and/or technical personnel and approved by lab head . Documents can be reviewed by quality manager or technical personnel. If necessarily, laboratory head could review documents.

✓ Physical distribution of documentation should be controlled by the use of distribution lists. The control of SRHCL quality documentation is the responsibility of the Quality

Manager. Laboratory level documentation is the responsibility of each Staffs. When a new document has been prepared or an existing document has been revised the Quality Officer should nominate the recipients of the document on the Document Distribution List (SRHCL /ALS/F4.3-001) ensuring that the document is available at all locations where operations essential to the effective functioning of the laboratory are performed. A copy number should be allocated to each recipient.

- ✓ The Quality Manager should 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.
- ✓ Laboratory head should 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.

4.1.3. 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 should 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 should 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 should be reviewed annually.

Access to and Adherence to Quality System Documentation

Controlled copies of standards and other documents should be issued to or be available for reference to laboratory personnel. Copies of documents not included within the controlled document system should not be utilized in the laboratory But We Should Give Copy No. Simply to indicate how many copy is available with this document type.

The documented Quality System is intended to satisfy the Quality Policy and ultimately the mission and organizational policy on quality. All personnel of SRHCL should adhere to the quality documentation. If controlled documentation requires change or modification the procedure for requesting document changes should be followed.

Unauthorized Deviations from Quality System

If an unauthorized deviation from documented procedures is identified, the Quality Manager should initiate an IAR. The corrective action procedure should 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.

4.1.4. Document Retention period

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

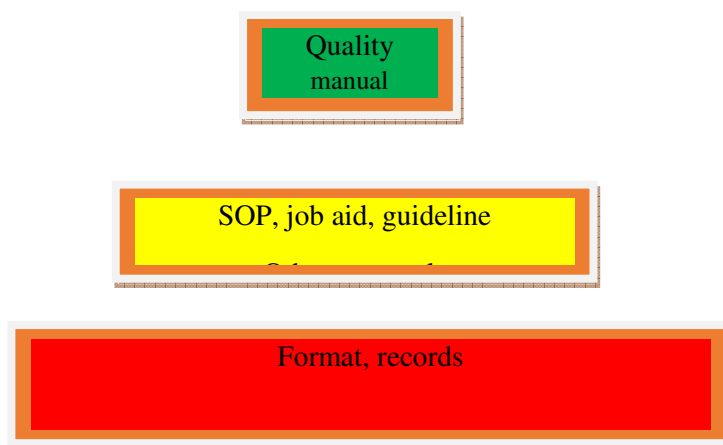
S.N	Name of Quality and Technical Records	Retention Time
1.	Procedure (SOPs)	5 years
2.	Manuals/ Policies	5 years

3.	Forms/Charts	5 years
3.	Job aids	5 years
5.	Job description	5 years
6.	Guideline	5 years
7.	Standards/Reference Books	Indefinite

Structure of documents

The quality management system of SRHCL is structured as shown in the pyramid below in figure 1.

ISO 15189:2012 regulation & guideline



A. Supportive Documents

Document Unique ID	Document Name
SRHCL /ALS/SOP4.3-001	Procedure for Document Preparation and Revision
SRHCL /ALS/F4.3-001	Document Master List
SRHCL /ALS/F4.3-002	Document Distribution List
SRHCL /ALS/SOP4.3-002	Procedure for Document and record control
SRHCL /ALS/SOP4.3-004	Procedures for Amendment of Documents
SRHCL /ALS/SOP4.3-005	Sop For Collection And Keeping Of Quality Records
SRHCL /ALS/F4.3-003	Document archived List
SRHCL/HDO/F4.3-001-_____.	Archive Documents

Review of Contracts

Purpose

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

Policy

SRHCL 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 **SRHCL/ALS/SOP4.4-001**). All requirements including the methods to be used, are adequately defined, documented and understood; capacity and resources of **SRHCL** has to meet the requirement. **SRHCL** has reviewed its capacity and resource periodically and able to determine uncertainties of measurement, limits of detection, confidence limits, etc. Customers should be informed of any deviation from the contract and same contract review process should be repeated if contract needs to be amended after work has done. Records of review should be maintained.

Establishment of service agreements

The **SRHCL**'S laboratory has documented procedures for the establishment and review of agreements for providing medical laboratory services.

- ✓ Each request accepted by the laboratory for examination(s) should be considered as an agreement.
- ✓ Agreements to provide medical laboratory services have taken into account the request, the examination and the report. The agreement should specify the information needed on the request to ensure appropriate examination and result interpretation.
- ✓ The following conditions should be met when the laboratory enters into an agreement to provide medical laboratory services.
- ✓ The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, should be defined, documented and understood
- ✓ The laboratory has the capability and resources to meet the requirements.
- ✓ Laboratory personnel have the skills and expertise necessary for the performance of the intended examinations.
- ✓ Examination process selected should be appropriate and able to meet the customers' needs
- ✓ Customers and users should be informed of deviations from the agreement that impact upon the examination results.
- ✓ Reference should be made to any work referred by the laboratory to a referral laboratory or consultant.

Review of service agreements

Reviews of agreements to provide medical laboratory services should include all aspects of the agreement.

Records of these reviews should 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 should be repeated and any amendments should be communicated to all affected parties.

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 should be evaluated and review of contact should initiate. All contracts or arrangement must be communicated to customers. Laboratory should determine level of uncertainty of measurement and limit of detection of test method with regard to customer's request.	Reviewed contacts through request form, lab handbook, etc must be documented and communicated with customers. Determined uncertainties of measurement and limit of detection should be part of contracts.	Laboratory head/ Quality Manager	Contact review policy and procedure availability
All forms of contracts and documented; knownvalue 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 mustmaintain and monitor contracts. All forms of contract must be reviewed and documented.	Any improved laboratory method/test including uncertainties of measurement ; activities should documented and contract must be reviewed accordingly and communicated effectively to customers	Quality Manager	Level of customer satisfaction

Supportive Documents

Document Unique ID	Document Name
SRHCL/SOP4.4-001	Procedure for review of contract
SRHCL/ALS/F4.4-001	Contract Review Record form

SRHCL/ALS/SOP4.4-002	Procedure for Notification of changing the examination
SRHCL/ALS/F4.4 -002	Sample ReferralForm To Backup Laboratory
SRHCL/ALS/F4.4 -003	Result Tracking Form From Back Up Laboratory
SRHCL/ALS/F4.4 -004	Calling Record Form For Backup Laboratory

Examination by Referral Laboratory

Purpose

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

Policy

SRHCL ensure that an effective documented procedure for evaluating and selecting referral laboratory 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 should be retained on both patient record and in the permanent file of laboratory.

General

- ✓ The referring laboratory should 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 should include all essential of the results reported by the referral laboratory, without alterations that could affect clinical interpretation. A register should be kept of all samples that have been referred to another laboratory.
- ✓ The laboratory should maintain a register of all referral laboratories that it uses and name and address of the laboratory responsible for the examination result should be provided to the user of laboratory services.

Selecting and Evaluating Referral Laboratory and Consultants

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

The procedure should 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 laboratory or referral consultants are competent to perform the requested examinations.
- ✓ Arrangements with referral laboratory 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 laboratory, and consultants from whom opinions are sought, is maintained.
- ✓ A results of all samples referred are kept for a pre-defined period.

Provision of examination results

- ✓ Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) should 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 should include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report should indicate which examinations were performed by a referral laboratory or consultant.
- ✓ The author of any additional remarks should be clearly identified
- ✓ Laboratory should 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 laboratory, this process should not be hindered by commercial or financial considerations.

Supportive documents

Document Unique ID	Document Name
SRHCL/ALS/SOP4.5-001	Procedure for selecting and monitoring referral lab and consultant
SRHCL/ALS/SOP4.5-002	Procedure to Manage Interruption of service
SRHCL/ALS/F4.5-001	Checklist for monitoring of referral lab and consultant
SRHCL/ALS/F 4.5-002	Format for reporting/ findings from monitoring
SRHCL/ALS/F 4.5-003	Referral laboratory registry format
SRHCL/ALS/F 4.5-004	Sample referral record format to referral laboratory
SRHCL/ALS/F 4.5-005	Result recording format result coming from referral laboratory
SRHCL/ALS/F 4.5-006	Sample reject record format by referral laboratory

External Services and Supplies

Purpose

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

A. Policy

SRHCL has policy and procedure for selecting and use of purchased external service, equipment and consumable supplies that affect the quality if its service. The SRHCL ensure that purchased items should consistently meet the laboratory`s quality requirement. The SRHCL develops procedures and criteria for inspection, acceptance/rejection and storage of consumable materials. Consumable and equipments 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.

General

The SRHCL has an inventory control system for supplies. The laboratory should evaluate suppliers of critical reagents, supplies and service that affect the quality of examinations and should maintain records of these evaluations and list those approved.

Appropriate quality records of external services, supplies and purchased products should be established and maintained for a period of time. This system should 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 should be available for laboratory management review.

B. Supportive documents

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

SRHCL/ALS/JA4.6-001	Job Aid for supplies requesting from Mini Store
SRHCL/ALS/F4.6-010	Reagent consumption log

Advisory Services

Purpose

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

Policy

SRHCL professionals should 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.

General

- ✓ The laboratory management ensures that there is a documented procedure to advice 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.
- ✓ The laboratory should establish arrangements for communicating with users on the following: (tab arrangement)
 - Advising on choice of examinations and use of the services, including required type of sample clinical indications and limitations of examination procedures and the frequency of requesting the examination;
 - Advising on individual clinical cases;
 - Professional judgments on the interpretation of the results of examinations
 - Promoting the effective utilization of laboratory services;
 - Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria

Subsidiary Documents

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

Resolution of Complaints

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.

A. Policy

SRHCL'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.

Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Client Satisfaction Survey	Issue the <i>Client Satisfaction Survey</i> 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 <i>Complaints & Compliments Register</i> . Register all scores greater than or equal to 50% and all compliments received in the <i>Complaints & Compliments Register</i> . Initiate and register an IAR in accordance with the <i>Investigation, Action & Resolution</i> process and	Complaints/ Compliments registered. IAR initiated to investigate complaints	Quality manager	Survey Results

	cross-reference each IAR to the respective complaint in the <i>Complaint's Register</i> .			
Registered complaints and IARs	Investigate the root cause of each complaint, take corrective action and resolve in accordance with the IAR Process in the <i>Corrective Action</i> 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	-

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP4.8-001	Procedure for conducting satisfaction survey
SRHCL/ALS/SOP4.8-002	Procedure for Receiving and Resolution of Complaints
SRHCL/ALS/F4.8-001A	Client Satisfaction Survey Check list
SRHCL/ALS/F4.8-002	Compliments & Complaints Register
SRHCL/ALS/F4.8-003	Feedback Notification Format Complaints

Identification & Control of Non-conformities

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.

Policy

SRHCL 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

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	QM	-
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 <i>Corrective Action</i> procedure. Verify the impact on the test results and associated test results (i.e. any test results that may have been affected in the same way, e.g. test results in a run or batch where the QC charts have been breached). If results have already been despatched to clients then inform the clients immediately by phone with follow up withdrawal and amendment of test reports in writing.	Implemented Actions	Lab head	-
Implemented Actions	Verify effectiveness of implemented actions	Non-conformity resolved	QM	Effective resolution & improvement of operations
Non-conformity resolved	Sign-off the IAR form allowing the test or examination work to resume	Resumption of conforming	Lab head	-

	with the repeat tests or examination of the effected samples	work		
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Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP4.9-001	Procedure for the Identification and Control of Non-Conformities
SRHCL/ALS/F4.9-001	IAR Register
SRHCL/ALS/F4.9-002	Summary Occurrence & Corrective action Report Form
SRHCL/ALS/F4.9-003	Root Cause Analysis Record Format

Corrective Action

Purpose

This document provides the policy, guidance, process and subsidiary documents for the initiation and implementation of corrective actions in SRHCL. This Corrective Action procedure uses the *Investigation, Action & Resolution* (IAR) process as the basis for determining root cause, implementing appropriate actions, and ensuring the effectiveness of the actions taken. The IAR system as described in this procedure is also used as the basis for resolution of Preventive Actions; Complaints; Non-Conforming work; and Continual Improvement.

Policy

SRHCL 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.

General

Identification of Corrective Action Sources

The need for corrective action may be identified through the following activities:

- Equipment calibration and verification;
- Non-conforming work;
- Auditing;
- Management review;
- Complaints

Equipment Calibration

When corrective action is required it has 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 SRHCL/ALS/P5.3*).

Non-Conforming Work (QC Outputs)

When corrective action is required the responsible staff member should initiate an IAR and forward it to the Quality Manager for follow-up and completion. The IAR has the objective of determining the cause of the non-conformance, taking the necessary action to prevent its recurrence and, where necessary, of notifying the relevant clients of possible effects on any data which may have been issued prior to the detection of the non-conformity (*Refer identification and control of non conformities policy SRHCL/ALS/P4.9*).

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 has the objective of determining the cause of the non-conformance, taking the necessary action to prevent its recurrence (*Refer internal Audit Policy: SRHCL/ALS/P4.14*).

Management review

Corrective action has 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: SRHCL/ALS/P4.15*).

Complaints

A formal corrective action should be raised for all complaints in accordance with *Complaints*. The corrective action has the following objectives:

- ✓ to determine the cause of the complaint;
- ✓ to determine if other clients are affected by the cause;

- ✓ recommending to the Laboratory head 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: SRHCL/ALS/P4.8*).

Cause Analysis

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

Internally detected non-conformance

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

- ✓ Sample Handling and Preparations (*refer Pre-Examination Procedure policy: SRHCL/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.
- ✓ Sample Testing (*Refer Examination Procedure policy: SRHCL/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
- ✓ Data Handling: (*Refer Reporting of Results policy SRHCL/ALS/P5.8*)
 - data transcription error; and

- typing error.

Externally detected non-conformities

When non-conformities are raised through complaints; second-party audits; or through external proficiency testing, the process of *Assuring the quality of test results* requires investigation in order to determine why the non-conformity was not identified by the Quality System.

Process

<i>INPUTS</i>	<i>ACTIVITIES</i>	<i>OUTPUTS</i>	<i>RP</i>	<i>KPIs</i>
<i>Calibration/ Verification activities;</i> <i>Non-conforming work;</i> <i>Auditing Activities;</i> <i>Management Review(MR) Outputs;</i> <i>Complaints;</i> <i>Preventive Action.</i>	<i>Initiation</i> <i>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 should be forwarded to the Quality Manager for investigation and registration.</i>	<i>Identified Corrective Action Sources</i>	<i>All staff</i>	<i>-</i>
<i>Identified Corrective Action Sources</i>	<i>Investigation</i> <i>All IAR should be registered in the ARF Registry (SRHCL/ALS/F4.11-001); investigated and corrective</i>	<i>Implemented Actions.</i>	<i>Quality manager & Laboratory head</i>	<i>Improvement of the QMS in meeting client requirements</i>

	<i>action determined by the Quality Manager in consultation with the relevant Team Leader. The appropriate corrective action required should be detailed in the relevant part of the ARF.</i> <i>The designated responsible person should implement the corrective action within the prescribed time.</i>			<i>as measured by the Customer Satisfaction Survey</i>
Implemented Actions	<i>Effectiveness Monitoring</i> <i>The Quality Manager should 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 should be scheduled by the Quality Manager to verify effectiveness of the corrective action implementation. If verification is acceptable the quality manager should authorize</i>		<i>Quality manager</i>	-

	<i>the closure of the IAR. If it is not acceptable a new IAR should be initiated</i>			
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Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP4.10-001	Procedure for Corrective Action
SRHCL/ALS/f4.10-001	Quality control corrective action log sheet
SRHCL/ALS/f4.10-002	SRHCL IQC Program
SRHCL/ALS/f4.10-003	Activity monitoring tools
SRHCL/ALS/f4.10-004	Discordant result correction log sheet

Preventive Action

Purpose

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

Policy

SRHCL has a policy to continually review its systems and procedures and the output data for potential sources of non-conformances so that preventive action can be applied on a pro-active basis in order to prevent the occurrence of non-conformances whenever possible.

Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
<i>QC Charts; MR Reports; Internal & external audit reports.</i>	<i>Identification: Opportunities for preventive action or potential sources of non-conformances, either technical or system based, should be identified through: trend and risk analyses;</i>	<i>Preventive Action identified</i>	<i>Quality manager</i>	-

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

<i>Actions</i>	<i>All preventive actions initiatives should be monitored for effectiveness using the IAR process. Wherever possible, the effectiveness of an improvement initiative should be evaluated and quantified.</i>		<i>manager</i>	
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Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP4.11-001	Preventive Action procedure
SRHCL/ALS/F4.11-001	Checklist for preventative action
SRHCL/ALS/F4.11-002	Preventive action log sheet

Continual Improvement

Purpose

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

Policy

SRHCL has a system of continual improvement in the laboratory. Laboratory management should 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 should participate in quality improvement activities and Laboratory management should implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care. Action plans for improvement should be developed, documented and implemented, as appropriate and evaluated the effectiveness of the Action plans.

Process

<i>INPUTS</i>	<i>ACTIVITIES</i>	<i>OUTPUTS</i>	<i>RP</i>	<i>KPIs</i>
<i>Management Review; Internal</i>	<i>Identification: Continual improvement should be identified by: Reviewing and updating the Quality</i>	<i>Improvement Opportunities identified.</i>	<i>Lab head</i>	-

<i>Audit;</i> <i>Complaint & Compliments;</i> <i>Personnel & client training;</i> <i>Corrective Action;</i> <i>Preventive Action;</i> <i>External assessment</i>	<i>Policy and Procedures.</i> <i>Reviewing internal and external audit results for improvement opportunities.</i> <i>Analyzing quality data and customer survey results and using this data to set new quality objectives or modify existing ones.</i> <i>Evaluating the quality indicators of the laboratory's contribution to patient care</i> <i>Ensuring corrective and preventive actions are implemented and effective.</i> <i>Performing periodic management reviews to evaluate the system per Management Review document.</i> <i>Training opportunities for personnel & users of the laboratory</i>			
<i>Improvement Opportunities</i>	<i>Implementation:</i> <i>Register each improvement opportunity in the Continual Improvement Register.</i> <i>Initiate an IAR form for each new improvement opportunity and cross</i>	<i>Implemented Actions.</i>	<i>Quality manager & Lab head</i>	<i>Improvement of the QMS in meeting client requirements as measured by the</i>

	<i>reference to the Improvement Opportunity Register.</i> <i>Investigate root cause; implement appropriate action and resolve in accordance with the IAR Process as described in the Corrective Action procedure.</i>			<i>Customer Satisfaction Survey</i>
<i>Implemented Actions</i>	<i>Improvement Monitoring: All improvement initiatives should be monitored for effectiveness using the IAR process. Wherever possible, the effectiveness of an improvement initiative should be evaluated and quantified.</i>		<i>Quality manager</i>	-

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/F4.12-001	Quality Indicators Form
SRHCL/ALS/F4.12-002	Improvement Work Plan Form
SRHCL/ALS/F4.12-003	Quality Improvement Planning(PDCA) Form
SRHCL/ALS/F4.12-004	Continual Improvement Recording Format
SRHCL/ALS/F4.12-005	Quality review form
SRHCL/ALS/F4.12-006	Monthly quality indicator summary
SRHCL/ALS/F4.12-007	Improvement Monitoring recording format
SRHCL/ALS/sop 4.12-001	Sop for Continual Improvement

Control of Records

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 SRHCL.

Policy

SRHCL should 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 should be legible, stored securely, in confidence and easily retrievable by authorized personnel, and each type of record allocate specific retention time according to local requirements.

Quality and Technical Records

- ✓ The laboratory should 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: SRHCL/ALS/SOP4.13-001), Passwords are used determined by the laboratory management to maintain confidentiality and prevent unauthorized access and amendment of data.
- ✓ The laboratory has 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: SRHCL/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 laboratory report maintained in laboratory for next evidence and to prepare next annual and monthly plan.

Quality and Technical Records Retention Time

- ✓ *ShewaRobitHealth Center Laboratory have been 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 year else in every six month from workstation.

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.	Preventive Maintenance	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

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP4.13-002	Procedure for Document and record archival and retrieval

SRHCL/ALS/SOP4.13-003	Procedure for correcting mistakes and alteration of records
SRHCL/ALS/SOP4.13-004	Procedure for Identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records
SRHCL/ALS/F4.13-001	Job Aid for quality and technical record user access
SRHCL/ALS/SOP4.13-004	Sop for collection & keeping of quality control records

Evaluation and Audit

Purpose

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

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 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 Manager is responsible for planning and organizing the audits and audits are conducted by personnel who are qualified and preferably independent of the activity being audited.

General

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

- 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;
- Ensure conformity to the quality management system;
- Continually improve the effectiveness of the quality management system.

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

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

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

Assessment of user feedback

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

Staff suggestions

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

Internal audit

The laboratory 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.

Audits conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit program me should 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 should be defined and documented. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors should, wherever resources permit, be independent of the activity to be audited.

The laboratory has a documented procedure to define the responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records. Personnel responsible for the area being audited should ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective action should be taken without undue delay to eliminate the causes of the detected nonconformities.

Risk management

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

Quality indicators

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

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

The laboratory, in consultation with the users, should establish turnaround times for each of its examinations that reflect clinical needs. The laboratory should periodically evaluate whether or not it is meeting the established turnaround times.

Process

<i>INPUTS</i>	<i>ACTIVITIES</i>	<i>OUTPUTS</i>	<i>RP</i>	<i>KPIs</i>
<i>Policy, Process, and operating procedures</i>	<i>Gather information using checklist</i> <i>Review policy, process, and operating procedures</i>	<i>Implementation quality management system</i>	<i>Quality manager, audit committee</i>	
<i>Equipment Calibration and maintenance and reagent/supplies</i>	<i>Gather information</i> <i>Review equipment Calibration and maintenance data</i> <i>Assess equipment and reagent/supplies condition</i>	<i>Calibrated and maintained Equipments and available reagent/supplies without interruption</i>	<i>Quality manager, audit committee</i>	
<i>Examination/test</i>	<i>Gather information and review</i>	<i>Validated/verified</i>	<i>Quality</i>	

<i>methods</i> <i>Validation and</i> <i>or verificatioOn</i> <i>activities</i>	<i>examination/test methods</i> <i>Validation and or verification</i> <i>data and then</i> <i>Compare findings with</i> <i>documented quality management</i> <i>system</i>	<i>examination</i> <i>methods</i>	<i>manager,</i> <i>audit</i> <i>committee</i>	
<i>Records and</i> <i>reports</i>	<i>Gather records and reports</i> <i>Review records and reports and</i> <i>compare findings with</i> <i>documented quality management</i> <i>system</i>	<i>Reviewed records</i> <i>and reports</i>	<i>Quality</i> <i>manager,</i> <i>audit</i> <i>committee</i>	
<i>Accommodation</i> <i>and</i> <i>environment</i> <i>condition and</i> <i>handling of</i> <i>samples</i>	<i>Assess accommodation and</i> <i>environment condition and</i> <i>handling of samples</i> <i>Review environmental control</i> <i>records and reports and compare</i> <i>findings with documented quality</i> <i>management system</i>	<i>Maintained</i> <i>accommodation</i> <i>and environment</i> <i>condition</i>	<i>Quality</i> <i>manager,</i> <i>audit</i> <i>committee</i>	
<i>Quality control</i> <i>verification</i> <i>activities</i>	<i>Gather records and reports of</i> <i>quality control</i> <i>Review records and reports and</i> <i>compare findings with</i> <i>documented quality management</i> <i>system</i>	<i>Well maintained</i> <i>Quality control</i> <i>system</i>	<i>Quality</i> <i>manager,</i> <i>audit</i> <i>committee</i>	-
<i>Proficiency</i>	<i>Review Proficiency testing results;</i>	<i>Acceptable</i>	<i>Quality</i>	

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

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP4.14-001	Procedure for conducting Internal Audit
SRHCL/ALS/F4.14-001	Internal Audit Report Form
SRHCL/ALS/F4.14-002	Internal Audit Assessment Checklist
SRHCL/ALS/F4.14-003	Internal Audit finding recording format
SRHCL/ALS/F4.14-004	Internal Audit root cause analysis format
SRHCL/ALS/F4.14-005	Internal Audit Plan & Program
SRHCL/ALS/F4.14-006	Daily Quality Indicator Tracking Format
<i>SRHCL/ALS/F4.14-007</i>	internal quality monitoring sheet

Management Review

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.

Policy

The SRHCL manager should evaluate and analyse practices for introducing necessary changes or improvements to the QMS. The review should cover all of its medical services including examination and advisory services. All documented policies and relevant records should be reviewed and a list of action plans for improvements will be produced and documented.

Process

INPUTS	ACTIVITIES	OUTPUTS	RP	KPIs
Diarized Management Review (MR) meeting as scheduled from the previous MR meeting or as scheduled by the Lab head	Issue notification of Management Review meeting together with Agenda (<i>Annex A Agenda for Management ReviewSRHCL/ALS/JA4.15-001</i>); minutes of last review meeting (if applicable) & Summary Reports	MR Meeting arranged. Agenda & minutes distributed to participants.	QM	MR Meeting occurs.
Agenda; Minutes; Summary Reports	Conduct & facilitate MR Meeting in accordance with the Agenda (<i>Annex A Agenda for Management ReviewSRHCL/ALS/JA4.15-001</i>);	MR Plan: Goals, Objectives and Actions (<i>Refer SRHCL/ALS/P4.1</i>)	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	QM	Objectives Achieved

SUBSIDIARY DOCUMENTS

Document Unique ID	Document Name
SRHCL/ALS/F4.15-001	Minute form for Management Review
SRHCL/ALS/JA4.15-001	Agenda for Management Review (Annex C)
SRHCL/ALS/F4.15-002	MR Improvement Plan
SRHCL/ALS/F4.15-003	Attendance Sheet For Management Review Meeting
SRHCL/ALS/F4.15-004	SRHCL Report For Management Review Meeting
SRHCL/ALS/F4.15-005	Management Review Key Discussion Log Sheet
SRHCL/ALS/SOP 4.15-001	Sop For Management Review

TECHNICAL REQUIREMENTS POLICY

Personnel

Purpose

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

Policy

Human Resource Management of SRHCL 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

General

Laboratory has documented procedure for personnel management and maintains records for all personnel to indicate compliance with requirements.

Personnel qualifications

- Laboratory management has document personnel qualifications for each position. The qualifications should 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 has the applicable theoretical and practical background and experience.

Job descriptions

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

Personnel introduction to the organizational environment

- SRHCL has a programme to introduce/orient new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services

Training

- SRHCL provides training for all personnel which includes the following areas:
 - A. the quality management system;
 - B. assigned work processes and procedures;
 - C. New Method & New Equipment By Trained Lab Personnel
 - 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 should be supervised at all times. And the effectiveness of the training programme should be periodically reviewed including

Competence assessment

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

Reviews of staff performance

- In addition to the assessment of technical competence, the laboratory should ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.
- Staff performing reviews should receive appropriate training.

Continuing education and professional development

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

Personnel records

- Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel should be maintained.
- These records should be readily available to relevant personnel and should 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

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP5.1-001	Competency Assessment Procedure
SRHCL/ALS/F5.1-001	Competency Assessment Checklist
SRHCL/ALS/SOP5.1-002	Procedure for Identifying and Providing Training

SRHCL/ALS/F5.1-002	Performance Appraisals checklist
SRHCL/ALS/JD5.1-001	Job description
SRHCL/ALS/F5.1-003	Personnel file Record
SRHCL/ALS/F5.1-004	Daily Personnel Evaluation
SRHCL/ALS/JA5.1-001	Duties on work station
SRHCL/ALS/JA5.1-002	Orientation checklist for new staff or employ
SRHCL/ALS/F5.1-005	Staff Training Plan
SRHCL/ALS/F5.1-006	BSC for laboratory

Accommodation and Environmental Conditions

Purpose

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

Policy

SRHCL 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 has 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 statutory regulations and provisions.

5.1.1. General

- The laboratory ensures the laboratory has space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory should evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work.

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

5.1.2. Laboratory and office facilities

The laboratory management 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: SRHCL/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

5.1.3. Storage facilities

- Storage space and conditions 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 should be stored in a manner to prevent cross contamination.
- Storage and disposal facilities for dangerous materials should be appropriate to the hazards of the materials and as specified by applicable requirements.

5.1.4. Staff facilities

- The laboratory management ensures that there should 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.

5.1.5. Patient sample collection facilities

The laboratory management ensures that:

- A patient sample collection facility has separate reception/waiting and collection areas. Consideration should 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) should 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 have and maintain appropriate first aid materials for both patient and staff needs.

5.1.6. Facility maintenance and environmental conditions

The laboratory management ensures that:

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

Subsidiary Documents

Document Unique Id	Document Name
SRHCL /ALS/SOP5.2-001	Procedure for environmental monitoring
SRHCL /ALS/SOP5.2-002	Temperature monitoring Procedure for equipment's
SRHCL/ALS/F5.2-001	Internal communication log
SRHCL/ALS/F5.2-002	Accident reporting form
SRHCL/ALS/F5.2-003	Log for work areas cleaning and organizing
SRHCL/ALS/SOP5.2-003	Procedure for Segregation and disposal of waste materials
SRHCL/ALS/F5.2-004	Format for Environment Monitoring Records

SRHCL/ALS/F5.2-005	Refrigerator Temperature Monitoring Form
SRHCL/ALS/MAN5.2-001	Laboratory Safety Manual
SRHCL/ALS/CHT5.2-001	Floor design chart
SRHCL/ALS/CHT5.2-002-009	Processes Map
SRHCL/ALS/F5.2-006	Monthly safety inspection form
SRHCL/ALS/F5.2-007	Fire extinguisher inspection form
SRHCL/ALS/F5.2-008	First aid inspection form
SRHCL/ALS/F5.2-009	Eye wash maintenance log sheet
SRHCL/ALS/F5.2-010	HIV exposure reporting form
SRHCL/ALS/F5.2-011	Fire event reporting form
SRHCL/ALS/JA5.2-001	Job Aid for Post exposure prophylaxis
SRHCL/ALS/JA5.2-002	Instruction for Emergency Alarm using
SRHCL/ALS/JA5.2-002A	Instruction for Emergency Alarm using (Amharic version)
SRHCL/ALS/JA5.2-003	Instruction to Disinfect Biohazards Using Chemicals
SRHCL/ALS/JA5.2-004	Instruction for emergency evacuation
SRHCL/ALS/JA5.2-005	Instruction for action on bomb threat
SRHCL/ALS/F5.2-012A	የቆ ማሰወገጃ ስራ መከታተያ ቅጽ(Amharic version)
SRHCL/ALS/F5.2-013	Water Bath Temperature Monitoring Log Sheet
SRHCL/ALS/F5.2-014	Weekly Safety Monitoring Tools
SRHCL /ALS/SOP5.2 -004	Accommodation And Environmental Condition
SRHCL /ALS/SOP5.2 -005	Sop For Risk Management
SRHCL/ALS/F5.2-015	Temperature Review Format
SRHCL/ALS/JA5.2-005	Fire extinguisher Usage Job Aids
SRHCL /ALS/SOP5.2 -006	SOP For Laboratory Bio safety

Laboratory equipment, reagents and consumables

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.

Policy

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

5.1.7. Equipment

5.1.7.1. 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 pipette tips, glass slides, etc
- The laboratory has a documented procedure for the selection, purchasing and management of equipment.
- The laboratory should 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 should ensure that the requirements of this International Standard are met.
- The laboratory replaces equipment as needed to ensure the quality of examination results.

5.1.7.2. Equipment acceptance testing

The laboratory management ensures that:

- The laboratory verifies upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned. This requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory.
- Each item of equipment uniquely labelled, marked or otherwise identified.

5.1.7.3. Equipment instructions for use

The laboratory management ensures that:

- Equipment 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, readily available.
- The laboratory has procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

5.1.7.4. Equipment calibration and metrological traceability

- The laboratory has 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 should 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 should 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.

5.1.7.5. Equipment maintenance and repair

- The laboratory has a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions.
- Equipment should be maintained in a safe working condition and in working order. This should 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, should be used.
- Whenever equipment is found to be defective, it should be taken out of service and clearly labelled. The laboratory should ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The laboratory should examine the effect of any defects on previous examinations and institute immediate action or corrective action

- The laboratory 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 ensures that its performance is verified before being returned to laboratory use.

5.1.7.6. Equipment adverse incident reporting

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

5.1.7.7. Equipment records

- Records maintained for each item of equipment that contributes to the performance of examinations.
- These equipment records should 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) should 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 should be maintained and should be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure

5.1.8. Reagents and consumables

5.1.8.1. General

- The SRHCL has a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.

5.1.8.2. Reagents and consumables — Reception and storage

- Where the laboratory is not the receiving facility, it should 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 store received reagents and consumables according to manufacturer's specifications.

5.1.8.3. Reagents and consumables — Acceptance testing

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

5.1.8.4. Reagents and consumables — Inventory management

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

5.1.8.5. Reagents and consumables — Instructions for use

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

5.1.8.6. Reagents and consumables — Adverse incident reporting

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

5.1.8.7. Reagents and consumables — Records

- Records maintained for each reagent and consumable that contributes to the performance of examinations. These records 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 consumable's ongoing acceptance for use.

- Where the laboratory uses reagents prepared or completed in-house, the records should include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.

A. Subsidiary Documents

Document Unique Id	Document Name
SRHCL/IMH/SOP 5.3-001	SOP for BD FACSCount Preventive Maintenance
SRHCL/HEM/SOP 5.3-001-005	Procedures for calibration and maintenance of Haematology laboratory Equipment
SRHCL/CCH/SOP 5.3-001-005	Procedures for calibration and maintenance of Clinical Chemistry laboratory Equipment
SRHCL/ALS/SOP5.3-001	Procedures for acquiring & retrieving equipment
SRHCL/ALS/F5.3-001	Format for equipment calibration record
SRHCL/ALS/F5.3-002	Format for equipment maintenance record
SRHCL/ALS/F5.3-003	Equipment history Recording form
SRHCL/ALS/F 5.3-004	Non-functional Equipment Recording form
SRHCL/IMH/JA5.3-001	Job Aid for Immuno-hematology laboratory Equipment Operating
SRHCL/HEM/ JA5.3-001-005	Job Aid for Haematology laboratory Equipment Operating
SRHCL/CCH/ JA5.3-001-005	Job Aid for Clinical Chemistry laboratory Equipment Operating
SRHCL/IMH/JA5.3-002	Job Aid for Facscount calibration
SRHCL/MOD/MAN5.3-001-010	User Manual
SRHCL/ALS/F 5.3-005	Mindray Hematology Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-006	Mindray Chemistry Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-007	BD FACS Count Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-008	Blood Bank Refrigerator Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-009	Reagent Refrigerator Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-010	Microscope Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-011	Centrifuge Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-012	Genexpert Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-013	Water Bath Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-014	Distiller Apparatus Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-022	Reagent Request Form For DRHRLC For Fm Microscope

SRHCL/ALS/F 5.3-015	Laboratory supply and reagent monthly consumption summary form
SRHCL/ALS/F 5.3-016	Reagent opening recording form
SRHCL/ALS/F 5.3-017	Laboratory reagent distribution recording format
SRHCL/ALS/F 5.3-018	Expired Laboratory reagent recording format
SRHCL/ALS/F 5.3-019	Stock out Laboratory reagent recording format
SRHCL/ALS/F 5.3-020	Prepared Laboratory reagent record format
SRHCL/ALS/F 5.3-021	Maintenance review format
SRHCL/ALS/F 5.3-023	Vortex Preventive Maintenance Log Sheet
SRHCL/ALS/F 5.3-024	Equipment Inventory Record Formats
SRHCL/ALS/SOP5.3-002	SOP for Verification and Calibration of Accuracy of Pipetting Volumes
SRHCL/ALS/F 5.3-025	Digital balance Preventive Maintenance Log Sheet

Pre-Examination Processes

Purpose

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

Policy

SRHCL 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.

5.1.9. General

- The SRHCL has documented procedures and information for pre-examination processes ensures the validity of the results of examinations.

5.1.10. Information for patients and users

- The laboratory has information available for customers of the laboratory services. The information should include as appropriate:
 - a) The location of the laboratory;

- b) types of clinical services offered by the laboratory including examinations referred to other laboratory ;
 - 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 has information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant (e.g. for interpreting genetic examination results), should be explained to the patient and user.

5.1.11. Request form information

- The request form or an electronic equivalent allow space for the inclusion of, but not be limited to, the following:
 - a) Patient identification, including gender, the location/contact details of the patient, and a unique identifier. Unique identification includes an alpha and/or numerical identifier such as a medical record 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.

- a) date and, where relevant, time of primary sample collection;
- b) 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 has a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form.
- The laboratory has a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time.
- The laboratory should be willing to cooperate with users or their representatives in clarifying the user's request.

5.1.12. Primary sample collection and handling

5.1.12.1. General

- The laboratory has documented procedures for the proper collection and handling of primary samples.
- The documented procedures should 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 should be recorded and included in all documents containing examination results and should be communicated to the appropriate personnel.
- All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, vein puncture. Patients in a hospital bed should normally be given the opportunity to refuse.

- Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.
- In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.
- Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected.

5.1.12.2. Instructions for pre-collection activities

The laboratory's instructions for pre-collection activities should 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).

5.1.12.3. Instructions for collection activities

The laboratory's instructions for collection activities should 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 should be determined and communicated to the appropriate clinical staff;
- e) instructions for labelling 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.

5.1.13. Sample transportation

- The laboratory's instructions for post-collection activities should include packaging of samples for transportation.
- The laboratory has 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.

5.1.14. Sample reception

- The laboratory's procedure for sample reception should ensure that the following conditions are met.
 - a) Samples are unequivocally traceable, by request and labelling, 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 should 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 should be recorded. Whenever possible, the identity of the person receiving the sample should also be recorded.
 - e) Authorized personnel should evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).
 - f) Where relevant, there should be instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions should include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the

examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.

- All portions of the primary sample should be unequivocally traceable to the original primary sample.

5.1.15. Pre-examination handling, preparation and storage

- The laboratory has procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.
- Laboratory procedures should include time limits for requesting additional examinations or further examinations on the same primary sample. (*Refer: Procedure for verbal requests SRHCL/ALS/SOP5.4-002*)

Subsidiary Document

Document Unique Id	Document Name
SRHCL/ALS/MAN5.4-001	Sample Collection Manual
SRHCL/ALS/SOP5.4-001	Procedure for Sample collection, processing and storage
SRHCL/ALS/SOP5.4-002	Procedure for verbal requests
SRHCL/ALS/JA5.4-001	Specimen acceptance and rejection criteria
SRHCL/ALS/F5.4-001-002	Laboratory Requesting Form
SRHCL/ALS/F5.4-003	Worksheet for records of received samples
SRHCL/ALS/F5.4-004	ART Sample Receiving Log Sheet
SRHCL/TB/F5.4-005	Genexpert Sample Receiving Log Sheet
SRHCL/TB/F5.4-006	Genexpert Sample Referral Log Sheet
SRHCL/ALS/F5.4-007	Laboratory Request Form
SRHCL/ALS/JA5.4-002	Job aid for viral load sample collection
SRHCL/ALS/sop 5.4-003	Sop for verbal request
SRHCL/TB /JA5.4-003	AFB Smear Preparation Job Aid
SRHCL/TB/JA5.4-004	AFB Smear Staining Job Aid
SRHCL/BAC/SOP5.4-001	SOP For Triple Packaging
SRHCL/HEM/SOP5.4-001	<i>SOP For Specimen Collection, Handling And Transport For Haematology And CD4 Testing</i>
SRHCL/BAC/SOP5.4-002	SOP For Sputum Collection, Handling And Transportation
SRHCL/ALS/F5.4-008	Specimen referral reporting form

Examination Processes

Purpose

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

Policy

SRHCL 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 should be available and use at all time. All procedures should be documented and be available at the workstation for relevant staff. Performance specification for each examination has in place. Examination processes has unique identifiable and should be part of document control.

5.1.16. Selection, verification and validation of examination processes

5.1.16.1. General

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

5.1.16.2. Verification of examination procedures

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

5.1.16.3. Validation of examination procedures

- SRHCL 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 should 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 quantisation limit, measuring interval, diagnostic specificity and diagnostic sensitivity.
 - The laboratory has document the procedure used for the validation and record the results obtained. Staffs with the authority review the validation results and record the review.
 - When changes are made to a validated examination procedure, the influence of such changes should be documented and, when appropriate, a new validation should be carried out.

5.1.16.4. Measurement uncertainty of measured quantity values

- The laboratory determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory defines the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.
- 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 considers measurement uncertainty when interpreting measured quantity values. Upon request, the laboratory makes its estimates of measurement uncertainty available to laboratory users.

- Where examinations include a measurement step but does not report a measured quantity value, the laboratory 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.

5.1.17. Biological reference intervals or clinical decision values

- The laboratory 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 should be made and communicated to the users.
- When the laboratory changes an examination procedure or pre-examination procedure, the laboratory review associated reference intervals and clinical decision values, as applicable.

5.1.18. Documentation of examination procedures

- Examination procedures should be documented. They should 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) 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, should be subject to document control.
- In addition to document control identifiers, documentation should include, when applicable to the examination procedure, the following:
 - ✓ purpose of the examination;
 - ✓ principle and method of the procedure used for examinations;
 - ✓ performance characteristics
 - ✓ Type of sample (e.g. plasma, serum, urine...);
 - ✓ patient preparation;
 - ✓ type of container and additives;
 - ✓ required equipment and reagents;
 - ✓ environmental and safety controls;
 - ✓ calibration procedures (metrological traceability);

- ✓procedural steps;
 - ✓quality control procedures;
 - ✓interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions;
 - ✓principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values
 - ✓biological reference intervals or clinical decision values;
 - ✓reportable interval of examination results;
 - ✓instructions for determining quantitative results when a result is not within the measurement interval;
 - ✓alert/critical values, where appropriate;
 - ✓laboratory clinical interpretation;
 - ✓potential sources of variation;
 - ✓References.
- If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications should be explained to users of the laboratory services after validating the procedure.

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/BAC/SOP5.5-001-010	Procedure Bacteriology tests
SRHCL/CCH/SOP5.5-001-010	Procedure for Clinical Chemistry tests
SRHCL/HEM/SOP5.5-001-010	Procedure for Haematology tests
SRHCL/ALS/SOP5.5-001-010	Procedure for Serology tests
SRHCL/IMH/SOP5.5-001	SOP for CD4 positive cell count determination on FACSCount analyzer in single tube using CD4 Software
SRHCL/BAC/JA5.5-001-010	Job Aid for Bacteriology tests
SRHCL/CCH/JA5.5-001-010	Job Aid for Clinical Chemistry tests
SRHCL/HEM/JA5.5-001-005	Job Aid for Haematology tests
SRHCL/ALS/JA5.5-001-010	Job Aid for Serology test(s)
SRHCL/IMH/JA5.5-001	Job Aid for Immuno-haematology test
SRHCL/BAC/F5.5-001	IQC Log Sheet for Bacteriology tests
SRHCL/CHEM/F5.5-001-002	IQC log Sheet for chemistry tests
SRHCL/BAC/SOP5.5-011	Procedure for Method Validation/Verification of Bacteriology tests

SRHCL/HEM/SOP5.5-011	Procedure for Method Validation/Verification of Haematology tests
SRHCL/ALS/SOP5.5-011	Procedure for Method Validation/Verification of Serology tests
SRHCL/BAC/SOP5.5-011	Procedure for Method Validation/Verification of Clinical Chemistry tests
SRHCL/IMH/SOP5.5-002	Procedure for Method Validation/Verification of Immunohematology tests
SRHCL/BAC/F5.5-002	Form for Method Validation/Verification of Bacteriology tests
SRHCL/HEM/F5.5-001	Form for Method Validation/Verification of Haematology test
SRHCL/ALS/F5.5-003	Form for Method Validation/Verification of Serology tests
SRHCL/CCH/F5.5-001	Form for Method Validation/Verification of Clinical Chemistry test
SRHCL/IMH/F5.5-001	Form for Method Validation/Verification of Immuno-haematology test
SRHCL /URI/SOP5.5-001-005	Sop For Urinalysis Tests
SRHCL /PARA/SOP5.5-001-007	Sop For Parasitological Tests
SRHCL /PARA/JA5.5-001-010	Job Aid for Parasitological tests
SRHCL /URI /JA5.5-001-010	Job Aid for Urinalysis tests
SRHCL /SER/F5.5-001-003	IQC Log Sheet For Serological Tests
SRHCL /IMH /F5.5-001-004	IQC Log Sheet For Immuno-Haematological Tests
SRHCL /Para&Uri/F5.5-001-005	IQC Log Sheet For Parasitological &urinalysis tests
SRHCL /E-Lab/F5.5-001-006	IQC Log Sheet For E-Lab tests
SRHCL /I-Lab/F5.5-001-007	IQC Log Sheet For I-Lab tests

Ensuring Quality of Examination Results

Purpose

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

Policy

SRHCL 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 should participate in inter-laboratory comparisons (external quality assessment) (EQA) scheme such as proficiency test (PT). Laboratory should set mechanism to exchange of samples with other laboratory and monitoring of

result accordingly. There should be defined system for verifying results throughout examination procedures. Quality records should be retrievable and documented.

General

The laboratory should ensure the quality of examinations by performing them under defined conditions. Appropriate pre and post-examination processes should be implemented. The laboratory should not fabricate any results.

Quality control

5.1.18.1. General

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

Quality control materials

The laboratory use quality control materials that react to the examining system in a manner as close as possible to patient samples. Quality control materials have been 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.

Quality control data

The laboratory has a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results should be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory should also evaluate the results from patient samples that were examined after the last successful quality control event.

Quality control data has 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 should be taken and recorded.

Inter-laboratory comparisons

Participation

The laboratory 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 has 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 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 should, 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.

Alternative approaches

Whenever an inter laboratory comparison is not available, the laboratory develop other approaches and provide objective evidence for determining the acceptability of examination results. Whenever possible, this mechanism utilizes 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 laboratory ;
- Control materials that are tested daily in inter laboratory comparison programmes.

5.1.18.2. Analysis of inter laboratory comparison samples

The laboratory should 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 should be examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.

The laboratory should 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 should not refer inter laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples

5.1.18.3. Evaluation of laboratory performance

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

Comparability of examination results

There should 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 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 measure and (e.g. glucose) and when examination methods are changed.

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

Subsidiary Document

Document Unique ID	Document Name
SRHCL/IMH/SOP5.6-001	Procedure for CD ₄ in-house control
SRHCL/IMH/SOP5.6-002	Procedure for CD ₄ quality controls out of range result
SRHCL/HEM/SOP5.6-001	Procedure for haematology quality controls out of range result
SRHCL/CCH/SOP5.6-001	Procedure for Clinical chemistry quality controls out of range result
SRHCL/ALS/SOP5.6-001	Procedure for graphical tools to communicate quality findings and identify trends
SRHCL/ALS/JA5.6-001	Job aid on replicate of samples
SRHCL/ALS/SOP5.6-002	Procedure for inter-laboratory comparison
SRHCL/BAC/JA5.5-001	Job Aid for Quality control monitoring of Bacteriology tests
SRHCL/CCH/JA5.5-001	Job Aid for Quality control monitoring of Clinical Chemistry tests
SRHCL/HEM/JA5.5-001	Job Aid for Quality control monitoring of Haematology tests
SRHCL/QAL/JA5.5-001	Job Aid for Quality control monitoring of Serology tests

SRHCL/IMH/JA5.5-001	Job Aid for Quality control monitoring of CD ₄ test
SRHCL/ALS/F5.6-002-012	EQA all reporting format
SRHCL/ALS/SOP5.6-003	Sop for proficiency testing
SRHCL/ALS/SOP5.6-004	Sop for blind rechecking
SRHCL/ALS/SOP5.6-005	Sop for On-Site Evaluation For TB, HIV And Malaria Diagnosis
SRHCL/ALS/F5.6-013	Assessment Checklist For Microscopic Health Centre
SRHCL/ALS/F5.6-014	EQA assessment feedback format
SRHCL/ALS/SOP5.6-006	SOP for Quality Control for CD-4 and Haematology Analyzers

Post- Examination Processes

Purpose

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

A. Policy

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

Review of results

The laboratory has procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results. When the procedure for reviewing results involves automatic selection and reporting, review criteria established, approved and documented.

Storage, retention and disposal of clinical samples

The laboratory has a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. The laboratory should define the length of time clinical samples are to be retained. Retention time should 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. cross-match, Genexpert, paediatric examinations) may require the retention of certain samples for much longer periods than for other samples. Safe disposal of samples should be carried out in accordance with local regulations or recommendations for waste management.

Subsidiary Documents

Document Unique ID	Document Name
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SRHCL/ALS/SOP5.7-001	Result Reviewing Procedure
SRHCL/ALS/F5.7-001	Result Reviewing Form
SRHCL/ALS/F5.7-002	Result Verification Log Sheet
SRHCL/ALS/F5.7-003	Result Check Log Sheet
SRHCL/ALS/F5.7-004	Critical Result /Panic Result Recording Log Sheet
SRHCL/ALS/F5.7-005	Critical Result /Panic Result Phone Call Recording Log Sheet
SRHCL/ALS/SOP5.7-002	Sop For Reference Interval
SRHCL/ALS/SOP5.7-003	sop formeasurement uncertainty
SRHCL/ALS/F5.7-008	Sample retention format

Reporting of Results

Purpose

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

Policy

SRHCL has policy to standardize report formatting and to designate authorized personnel for reporting results. Reported results should 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.

SRHCL should 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.

General

The results of each examination should be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures. The laboratory should 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 has a procedure to ensure the correctness of transcription of laboratory results. Reports should include the information necessary for the interpretation of the examination results. The laboratory has a process for notifying the requester when an examination is delayed that could compromise patient care.

Report attributes

The laboratory should 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.

5.8.3. Report content

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

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

NOTE Under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.

- Interpretation of results, where appropriate;

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

- Other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratory, use of developmental procedure);
- identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;
- identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);

- date of the report, and time of release (if not contained in the report, readily available when needed);
- Page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.)

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP5.8-001	Procedure for establishing Turnaround time
SRHCL/ALS/F5.8-001	TAT Monitoring format
SRHCL/ALS/JA5.8 -001	Test Verification Checklist
SRHCL/ALS/F5.8 -002	Result releasing log sheet
SRHCL/ALS/ SOP5.8-002	Sop For Reporting Of Result
SRHCL/ALS/F5.8 -003	IQC Review Format
SRHCL/ALS/F5.8 -004	TAT review format

Release of Result

Purpose

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

Policy

SRHCL has documented procedures for the release of examination results and identify who may release the results and to whom. The laboratory has procedure and/or process or system for automated selection and reporting of results and revision of report.

5.9.1.General

The laboratory should establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures should 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 laboratory 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 should be followed by a written report. There should be a record of all oral results provided.

NOTE 1 for the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

NOTE 2 Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

5.9.2. Revised reports

When an original report is revised there should 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.

Results that have been made available for clinical decision making and revised should 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 should be kept.

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP5.9-001	Notification procedure on “Alert” or “Critical intervals”

SRHCL/ALS/SOP5.9-002	Procedure for distributing results including verbal, telephone, other electronic means
SRHCL/ALS/F5.9-001	Format for interim report
SRHCL/ALS/SOP5.9-003	Procedure for notifying delayed examination
SRHCL/ALS/SOP5.9-004	Procedure for corrected or amended result
SRHCL/ALS/SOP5.9-005	Procedure for resolution of discordant result
SRHCL/ALS/F5.9-002	Result Report Form
SRHCL/ALS/JA5.9-001	Job aid for reporting critical results
SRHCL/ALS/F5.9-002	Critical result reporting form

Laboratory information management

Purpose

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

Policy

SRHCL has policy to standardize and access to laboratory data and information management. The laboratory defines responsibilities and authorities for handling LIM. The laboratory has to validate and verify Information system management prior to introduction of LMS.

5.10.1. General

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

5.10.2. Authorities and responsibilities

The laboratory ensures 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 defines 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;

- Authorized the release of examination results and reports (refer procedure SRHCL/ALS/SOP 5.1-003).

5.10.3. Information system management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information should be:(refer procedure SRHCL/ALS/SOP 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.
- b) **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.
- c) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;
- d) protected from unauthorized access;
- e) safeguarded against tampering or loss;
- f) 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
- g) 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;
- h) In compliance with national or international requirements regarding data protection.

The laboratory 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 should 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 has 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 should be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.

Subsidiary Documents

Document Unique ID	Document Name
SRHCL/ALS/SOP5.10-001	SOP for Patient Data Entry at Registration Book
SRHCL/ALS/F5.10-001	Result Backup Log
SRHCL/ALS/F5.10-002	Annual Tests Performance & Plan Comparison Form
SRHCL/ALS/JA5.10-001	Job aid for How to use Registration Book in data entry
SRHCL/ALS/SOP5.10-002	Sop For LIS
SRHCL/ALS/F5.10-002	Staff/initials identification format

\6. ANNEX

Organogram of SRHCL



Quality Management System Policies & Process (SRHCL/ALS/JA4.2-001)

<i>DOC NUMBER</i>	<i>TITLE</i>
<i>4</i>	<i>Management Requirements</i>
<i>P4.1</i>	<i>Organization & Management</i>
<i>P4.2</i>	<i>Quality Management System</i>
<i>P4.3</i>	<i>Document Control</i>
<i>P4.4</i>	<i>Review of Contracts</i>
<i>P4.5</i>	<i>Examination by referral laboratory</i>
<i>P4.6</i>	<i>External Services & Supplies</i>
<i>P4.7</i>	<i>Advisory Services</i>
<i>P4.8</i>	<i>Resolution of complaints</i>
<i>P4.9</i>	<i>Identification and control of nonconformities</i>
<i>P4.10</i>	<i>Corrective action</i>
<i>P4.11</i>	<i>Preventive action</i>
<i>P4.12</i>	<i>Continual Improvement</i>
<i>P4.13</i>	<i>Quality and technical records</i>
<i>P4.14</i>	<i>Internal audits</i>
<i>P4.15</i>	<i>Management review</i>
<i>5</i>	<i>Technical Requirements</i>
<i>P5.1</i>	<i>Personnel</i>

<i>P5.2</i>	<i>Accommodation and environmental conditions</i>
<i>P5.3</i>	<i>Laboratory equipment, reagents and consumables</i>
<i>P5.4</i>	<i>Pre-examination processes</i>
<i>P5.5</i>	<i>Examination processes</i>
<i>P5.6</i>	<i>Ensuring the quality of results</i>
<i>P5.7</i>	<i>Post-examination processes</i>
<i>P5.8</i>	<i>Reporting of results</i>
<i>P5.9</i>	<i>Release of results</i>
<i>P5.10</i>	<i>Laboratory Information Management System (LIM)</i>

Agenda for Management Review (SRHCL/ALS/JA4.15-001)

<i>INSTRUCTION</i>	<i>RP</i>
<i>The management review will be conducted every twelve months</i>	<i>Quality Manager</i>
<i>Conduct and chair the MR meeting in accordance with this agenda</i>	<i>Lab head</i>
<i>Participate actively by providing inputs and resolution of discussion items</i>	<i>All staff</i>

- 1. Opening**
- 2. Attendance Register**
- 3. Matters Arising & Status of Actions From Previous Reviews**
- 4. Status of Non-Conformances; Corrective & Preventive Action**
 - ENAO Surveillance and re-assessment audits (when accredited)
 - Customer audits
 - Internal audits
 - Nature and seriousness of findings
 - Identification of issues for investigation
 - Corrective and preventive action

5. QUALITY CONTROL CHECKS

- Proficiency testing: Summary of performance
- In-house checks: Summary of compliance: Duplicates; return samples Turnaround time
- Trends and Identification of issues for investigation
- Corrective action and preventive action

6. CUSTOMER COMPLAINTS AND CUSTOMER SURVEY RESULTS

- Number of complaints
- Nature and seriousness of complaints
- Trends of complaints
- Review of Customer Survey results – Quality Indicators relating to patient care
- Identification of issues for investigation
- Corrective action and preventive action

7. STATUS OF DOCUMENTATION

- Suitability of documentation and systems
- Awareness of personnel with documentation
- Identification of issues for investigation
- Corrective action and preventive action

8. RESOURCES UTILIZATION

- Changes in volume & type of work undertaken
- Adequacy of current human resources
- Adequacy of equipment resources
- Adequacy of Procurement lead times and consumable supplies
- Training
- Identification of issues for investigation
- Corrective action and preventive action

9. EVALUATION OF SUPPLIERS

- Suitability of suppliers in meeting quality, delivery & price criteria
- Review of new suppliers
- Corrective and preventive action

10. PLAN: GOALS, OBJECTIVES AND ACTIONS

- Summary of Completeness; Suitability & Effectiveness
- Changes that could affect the Quality Management System
- Recommendation for improvement
- Allocation of responsibilities and timelines for Action

Proficiency test (PT) participation plan

Name of the test	PT provider name	Frequency	Period to be participated
CD4	QASI, Digital PT	2 times per year	Till Dec. 2018
CBC	UKNEQAS, Digital PT	2 times per year	>>
Chemistry	QASI, UKNEQAS, Digital PT	2 times per year	>>
Bacteriology, gram stain, microscope & Genexpert	Digital PT	2 times per year	>>
Blood film	QASI, UKNEQAS, Digital PT	2 times per year	>>

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	Sign	Date
7. _____	_____	_____
8. _____	_____	_____
9. _____	_____	_____
10. _____	_____	_____
11. _____	_____	_____
12. _____	_____	_____
13. _____	_____	_____
14. _____	_____	_____
15. _____	_____	_____
16. _____	_____	_____
17. _____	_____	_____

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| 18. | _____ | _____ | _____ |
| 19. | _____ | _____ | _____ |
| 20. | _____ | _____ | _____ |
| 21. | _____ | _____ | _____ |
| 22. | _____ | _____ | _____ |
| 23. | _____ | _____ | _____ |
| 24. | _____ | _____ | _____ |

CHAPTER VIII: RESEARCH PROJECT

PREVALENCE AND FACTORS ASSOCIATED WITH MIDDLE EAST RESPIRATORY SYNDROME-CoV IN HUMAN POPULATION OF CHIFRA WOREDA: CAMEL REARING AREA OF AFAR REGION, ETHIOPIA

Abstract

Background: Middle East Respiratory Syndrome (MERS) is an emerging viral zoonosis and considered as one of the major global public health threat. The infected individuals developed severe acute respiratory illness with symptoms of fever, cough, and shortness of breath. So far, 27 countries have reported human laboratory confirmed cases since 2012. Camels are considered as the probable source for zoonotic transmission of the virus. In Ethiopia, high sero and viro-prevalence of MERS-CoV has been reported in camel population; however, human case has been not yet reported. This study was done to determine the seroprevalence and associated factors of Middle East respiratory syndrome coronavirus in Chifra woreda of Afar region, Ethiopia

Methods: Random sampling technique was used at all steps and all persons above 18 years old were enrolled in selected households. Sera were tested for the presence of MERS-CoV antibodies using anti- MERS-CoV ELISA IgG kit. Result was measured at wavelength of 450 nanometers (reference between 620 and 650) and determined using ratio of extinction values (Optical density) of samples to calibrator. Samples with the extinction ratio 1.1 and above were considered positive, 0.8 and above and below 1.1 were borderline, and below 0.8 were negative

Result: Totally, 341 participants enrolled with median age of participants was 25 years (range=18-77 years). Seven (2.05%) specimens were positive, 326 (95.6%) were negative and eight (2.35%) of the specimens were found on borderline. None of the participants have used personal protective equipments while handling camels and their wastes, and none had travel history to gulf countries. From the total of 341 study participants, 329 (96.5%) had no history of chronic medical problems. In a bivariate analysis, none of our assumed risk factors were significantly associated with the presence of IgG in the participants' specimens.

Conclusion: Our study reveals that the virus has been circulating. For an emerging viral human infection, a single positivity may be considered as public health threat which makes us to say our finding has immense public health importance. This finding should be confirmed by large scale studies involving virus isolation and identification of the sequence of the virus.

Keywords: Ethiopia, Human, MERS-CoV

Introduction

Background

Middle East respiratory syndrome (MERS), which is caused by MERS-corona virus (MERS-CoV), is believed to be a zoonotic disease. The infected individuals developed severe acute respiratory illness with symptoms of fever, cough, and shortness of breath. The original source(s), route(s) of transmission to humans, and the mode(s) of human-to-human transmission have not been determined; however there is clear evidence of person-to-person transmission. The efficiency of person-to-person transmission of MERS-CoV is not well characterized but appears to be low, given the small number of confirmed cases since the discovery of the virus. As of July 2014, no evidence of sustained community transmission beyond small clusters has been reported in any country. Transmission has occurred between patients and healthcare personnel in a hospital setting. Although the exact timing and nature of exposures that result in infection is usually unknown, for those cases for which exposure is known or strongly suspected, the incubation period for laboratory confirmed cases of MERS-CoV is generally less than one week. However, in at least one case, the known exposure occurred 9 to 12 days prior to onset of illness. Further evidence in cases exposed over a range of time suggests that, at least in a minority of cases, the incubation period may exceed one week but is less than two weeks. The period of communicability for MERS-CoV is unknown at this time. Until further guidance is available, follow isolation recommendations used for SARS; persons with MERS should be isolated (for example, by not going to work or to school) until 10 days after fever has resolved, provided respiratory symptoms are absent or improving [1,2,3,4].

Middle East Respiratory Syndrome-Coronavirus (MERS-CoV) is an emerging pathogen of increasing importance. The MERS-CoV was first recognized in 2012 in Saudi Arabia as a novel Coronavirus that causes severe acute respiratory disease[5]. The infected individuals developed severe acute respiratory illness with symptoms of fever, cough, and shortness of breath. A small number of the reported cases however also had a mild respiratory illness[6].

As of May 2017, WHO has been notified of more than 1,950 laboratory-confirmed cases of infection and at least 693 deaths related to MERS-CoV. Since September 2012, 27 countries have reported cases of MERS-CoV. In total, cases have been reported from 27 countries in the Middle East, North Africa, Europe, the United States of America, and Asia. The high case fatality rate,

large distribution of the reservoir, lack of medical countermeasures, as well as the knowledge gaps in veterinary and human epidemiology, immunity and pathogenesis have placed MERS-CoV as one of the pathogens prioritized in the WHO[7,8].

Statement of the Problem

Middle East respiratory syndrome coronavirus (MERS-CoV) has been identified from camels in Egypt, Oman, Qatar and Saudi Arabia[8]. Serum samples from camels in a number of countries throughout the Middle East and African countries have been found to have antibodies to MERS-CoV[9]. Serological evidence of the early circulation of MERS-CoV in camels in African countries and established camel trade between the Middle East and Africa suggests that African countries are considered as a possible source for the establishment of MERS-CoV in Middle East. As a result, the researchers have now focused on exploring the Epidemiology of MERS-CoV in countries where camels are bred and traded, especially in eastern Africa including Ethiopia[10,11,12]. Camels are thought to play a central role in MERS epidemiology because widespread evidence of MERS-CoV-specific antibodies and virus shedding in camels was found and highly similar viruses have been detected in humans and dromedaries at the same location. The findings of these serological and molecular studies suggested that exposure to camels is one of the risk factor for infection in human [13,14,15].

A total of 2,040 laboratory-confirmed cases of Middle East respiratory syndrome-coronavirus (MERS-CoV) infection were reported to WHO since its emergence in 2012 up to 21 July 2017, 82% of whom were reported by the Kingdom of Saudi Arabia. Males above the age of 60 with underlying conditions, such as diabetes, hypertension and renal failure, are at a higher risk of severe disease and including death. To date, at least 710 individuals have died (crude CFR 34.8%) [8].

Sero-epidemiological studies have been carried out in domestic livestock (cattle, sheep, goats, horses and poultry) in the Arabian Peninsula and the Middle East, but dromedary camels were the only species from which antibodies specific to MERS-CoV have been detected. Serological evidence of MERS-CoV infection has also been demonstrated in dromedaries from Africa, including Egypt, Ethiopia, Nigeria, Tunisia, Sudan and the Canary Islands, with similarly high seroprevalence except Tunisia and Canary Islands, where adult seroprevalence was 54% and 14%, respectively[10,11,16].

The population based seroprevalence of Saudi Arabia suggests that tens of thousands of MERS-CoV infections have gone unrecognized. Of the total of 28.5 million dromedary camels worldwide, 77% are in Africa, the largest camel populations being found in Somalia (6.2 million), Sudan (4.8 million), Kenya (3 million) and Ethiopia (2.3 million)[15]. Evidences suggests that a dromedary camel was the source of MERS-CoV that infected a patient who had had close contact with the camel's nasal secretions[17]. The existence of unrecognized human infections in African or Arabian countries in the past cannot be ruled out. Resource-limited African countries that have been exposed to civil unrest, such as Somalia and Sudan, are not likely to diagnose and report diagnostically challenging infections resembling other diseases[14].

The absence of human cases in countries with high seroprevalence of MERS-CoV in camels is suggested to be associated with poor surveillance system and lack of research focus on humans to address this information gaps in the country. Therefore, this study is aimed at determining the prevalence and factors predicting the disease.

Significance of the Study

There is a growing speculation that sporadic human cases may have gone undetected since MERS-CoV is not included in list of reportable diseases in Ethiopia[19]. Since the prevalence of MERS CoV in camels is high in Ethiopia, in which Afar region is one[18], knowing the serological status of human population is crucial. However, epidemiological studies are needed to ascertain that whether MERS-CoV has been introduced into the human population of Ethiopia, particularly humans who have close contact with camels. Since the disease is now one of the global public health concerns, and might have been affecting people before, we need to know its seroprevalence in Chifra woreda of Afar region, Ethiopia. Thus, this study will help detect and understand the epidemiology of MERS in high risk human population and investigation of the role of other species including bat in the transmission pattern of the virus. It also will provide evidence to design appropriate control and prevention strategies in pastoral areas of Ethiopia.

Literature Review

In this chapter, a critical review of literatures focused specifically on prevalence of MERS CoV and associated factors will be addressed briefly.

In a study conducted in Qatar, 2% of camel farm workers, 14% of camel barn workers at an international racing track and 2 of 5 camel slaughterhouse workers were seropositive while none of 204 people with no camel contact were seropositive[15]. According to a study initiated to identify the virus in camels and to compare it genetically with human-derived MERS-CoV, camel-derived MERS-CoV sequences are clustering independently from each other, but together with the human-derived MERS-CoV sequences from the same geographical areas of Oman[19]. This shows a probable transmission of MERS-CoV from camels to humans.

A study conducted to know the risk of MERS-CoV among people who have contact with camels in Qatar detected MERS-CoV neutralizing antibodies in healthy persons who had daily occupational contact with camels but not in persons without such contact. Only limited evidence is available regarding the presence of MERS-CoV antibodies in the general human population or in specific population cohorts in the study. However, an overall seroprevalence of 0.15% was found in a cross-sectional study in Saudi Arabia, and among slaughterhouse workers, neutralizing antibodies were detected in 3.57% of the participants[9].

Community outbreaks of MERS-CoV have been recorded having transmission in same family in Saudi Arabia. In an initial report of a family cluster, four among 28 extended family members tested positive for MERS-CoV, including the index case[12].

A study was conducted to determine the epidemiology of Middle East respiratory syndrome coronavirus in hospital patients in Kingdom of Saudi Arabia. On multivariate analysis of this study, age >80 years, cardiac disease, and cancer were independently associated with mortality. In this study, compared to primary cases, mortality due to MERS-CoV was lower in household cases and healthcare workers[20]. Additionally, pilgrims attending the 2013 Hajj were also sampled with nasal swab and screened although no MERS-CoV RNA was detected in any of the 5,235 attendants[21].

A retrospective specimen was collected from patients to determine viral shedding and antibody response in 37 patients with Middle East Respiratory Syndrome Coronavirus Infection. In the analysis, all surviving patients, but only slightly more than half of all fatal cases, produced IgG and neutralizing antibodies[22]. In a cross sectional survey in Saudi Arabia, 10,009 serum

samples were collected from healthy individuals older than 15 years who attended primary health-care centers or participated in a national burden-of-disease study in all 13 provinces, shepherds and abattoir workers with occupational exposure to camels. They screened samples by recombinant ELISA and MERS-CoV seropositivity was confirmed by recombinant immunofluorescence and plaque reduction neutralization tests. Finally, Anti-MERS-CoV antibodies were confirmed in 15 (0.15%; 95% CI 0.09–0.24) of 10,009 people in six of the 13 provinces[23].

A similar cross sectional study was also conducted in Kenya to determine the seroprevalence, serum samples were collected as part of a household survey conducted during 2013–2014 in 2 eastern counties of Kenya; Garissa and Tana River. Here, 4 (0.72) in Garissa and 12 (2.13%) from Tana River were found positive by recombinant ELISA. After a confirmatory test by plaque reduction neutralization test, 2 (0.18%) of the sampled were positive[24].

So far, there is no study found that assessed the status of MERS in high risk human population, pastoralists in Ethiopia, despite the high prevalence of MERS in their camel population. Therefore, in general terms, these literatures tell us that anti-MERS-CoV antibody can be detected in the community who has close contact with camels, diseased persons with MERS-CoV, from persons who have underlying chronic illnesses.

Conceptual framework

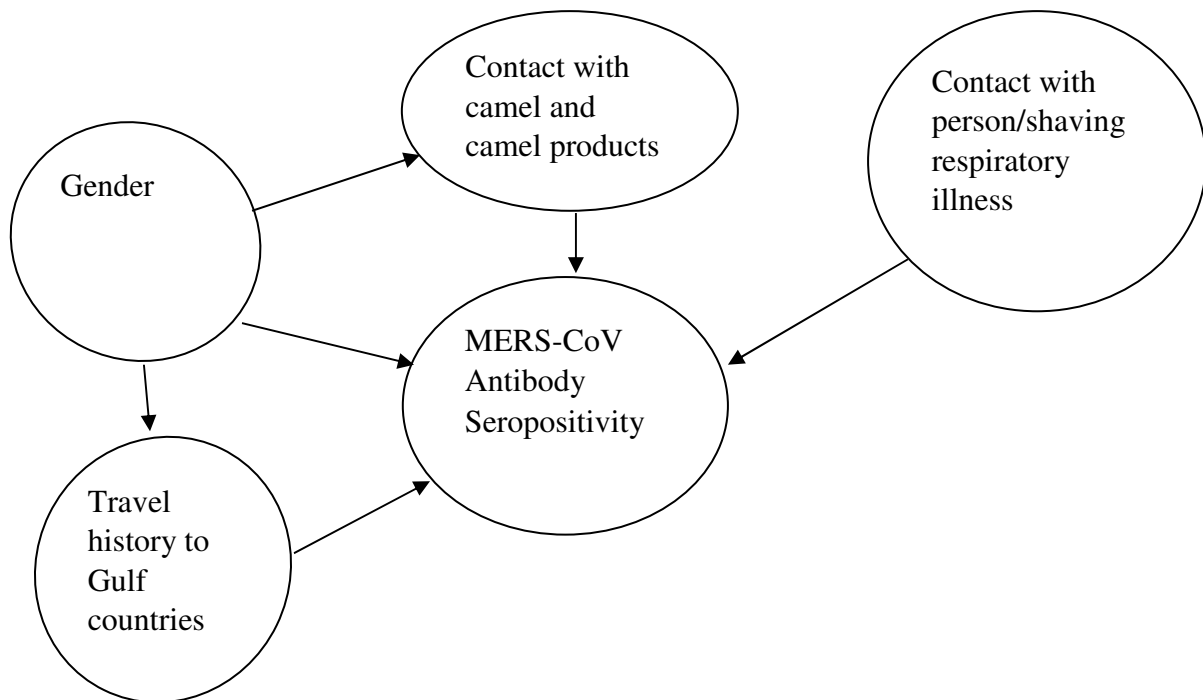


Figure 12: conceptual frame work to determine prevalence of MERS-CoV and associated factors Chifra woreda, Afar, Ethiopia, 2017

Objective

General Objective

- To determine the seroprevalence and associated factors of Middle East respiratory syndrome coronavirus in Chifra woreda of Afar region

Specific Objectives

- To determine seroprevalence of MERS-CoV in pastoral community of Chifra woreda of Afar region
- To identify associated factors for MERS-CoV seropositivity in Chifra woreda of Afar region

Methods and Materials

Study Area and Period

The study was conducted in Chifra woreda of Aar region. Chifra Woreda is one the woredas in Afar region of Ethiopia and is bordered with Ewa Woreda in the North, Ader Woreda in South, Mile and part of Dubti Woreda in the East and Habru of North Wollo and part of Bati Woreda (Werebabo) in the West[27]. It is located 665 Kilometers north of Addis Ababa along a highway to Mekelle. It has a total population of 91,078. The study was conducted from December 01 to 30, 2017.

Study Design

A community based cross-sectional study was carried out in Chifra woreda of Afar region.

Population

Source Population

All residents of Chifra woreda, Afar region, Ethiopia

Study Population

The study population were selected/sampled individuals whose age is 18 years and above living in Chifra woreda.

Inclusion and Exclusion criteria

Inclusion criteria: All individuals in selected household who possess camels, and whose age is 18 years and above was participated.

Exclusion criteria: Individuals who cannot answer questions verbally and cannot provide blood sample due to other health problems were not eligible to participate.

Sample Size Determination

The sample size was calculated using for single population proportion formula. To estimate the required sample size, a prevalence of 50% was assumed, with a required precision of 5% and an α -error of 5%. Accordingly, a total sample size of 384 is calculated for the study. The formula for single population proportion is:

$$n = \frac{1.96^2 * P (1-P)}{d^2}$$

$$n = \frac{1.96^2 * 0.5 (0.5)}{(0.05)^2}$$

$$n=384$$

Adding 10% non-response rate, the final population was supposed to be 423.

where n is the sample size without correction, $Z\alpha$ (1.96) is the percentile point relating to the required α error under the z distribution, d is the desired absolute precision, P is the expected prevalence. But due to resource limitations, we tested a total of 341 samples.

Sampling Technique and Procedure

All Kebeles in Chifra woreda were listed based on their camel population before sample collection. A simple random sampling technique was used to select each level. Then, all persons 18 years old and above in a household were enrolled.

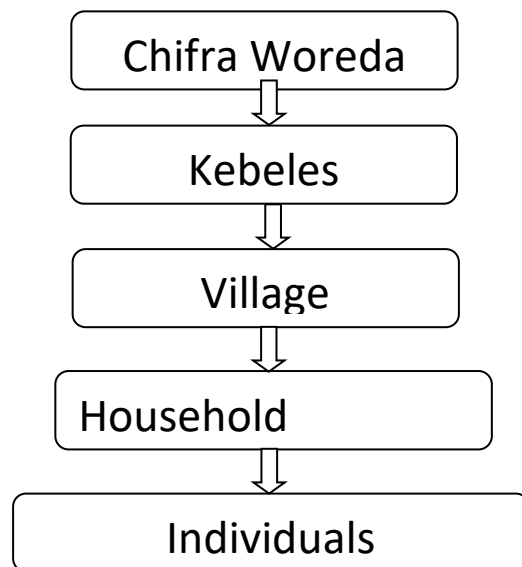


Figure 13: Schematic representation of sampling procedure, Chifra woreda, December 01-30, 2017

Study Variables

Dependent Variable: Presence of anti-MERS CoV IgG antibody in serum specimens

Independent Variables

Age, sex, occupation, travel history to gulf countries, contact with a person suffering from respiratory illness, handling of camels and their products, consumption of animal products, demographic characteristics, and, presence of underlying chronic illnesses (diabetes mellitus, hypertension, asthma, etc.)

Operational Definitions

Sero-Positive: Individuals whose serum sample is found positive for MERS COV antibodies using both screening and Confirmatory serological tests

Contact with ill person: visiting any person sick with respiratory (cough, breathing problems) in the past 6 months

Contact with camel: caring for camels, cleaning their waste, caring sick camel with nasal discharge, assist in birth, milking and drinking milk, slaughtering and eating meat and others.

Risk Factors: Presence of own camels at home and having a close contact with camels, consumption raw camel milk or a person who has a direct exposure to camel waste material, contact with a person having respiratory illness in the past six months and presence of chronic medical illnesses.

Laboratory Analysis

Type of Specimen and collection Procedure

Venous blood (2-3 ml) was drawn from the median cubital vein after applying a tourniquet 3–4 inches above the injection site and disinfected with 70% alcohol. Sterilized pre-coded serum vacutainer serum separator tubes were used. After sampling, punctured sites were bandaged using adhesive tapes. Date of collection, location, and name of person collecting the specimen were recorded.

Specimen Handling and Transportation

Sera were separated from clotted blood by centrifugation at $3,000 \times g$ for 15 minutes at nearby health centers' laboratory and stored at -20°C mobile freezer until transported to the laboratory (EPHI). Serum was separated on the date of collection by trained laboratory technologist

Specimen Analysis Procedures and interpretation

Sera were tested for the presence of MERS-CoV antibodies using anti- MERS-CoV ELISA IgG kit produced by EUROIMMUN (Germany Company). Laboratory investigation was done at EPHI (Annex 3). Result was determined using ratio of extinction values (Optical density) of samples to calibrator. Samples with the extinction ratio 1.1 and above were considered positive, 0.8 and above and below 1.1 were borderline, and below 0.8 were negative.

Test Principle of anti- MERS-CoV ELISA IgG kit:

The test kit contains micro titer strips each with 8 break-off reagent wells coated with purified S1 antigen of MERS coronavirus (MERS-CoV S1). In the first reaction step, diluted patient samples were incubated in the wells. In the case of positive samples, specific IgG would bind to the coated antigens. To detect the bound antibodies, a second incubation was carried out using an enzyme-labeled anti-human IgG (enzyme conjugate) catalyzing a color reaction.

Data Collection Tools & Procedures

To collect epidemiological data structured and pre tested questionnaire was used ([Annex 2](#)). Each questionnaire was administered by the investigator to assess the potential risk factors for Middle East Respiratory Syndrome infection in human.

Data Management and Data Analysis

Data collected was checked for completeness on the date of collection by the principal investigator. All the data collected from field were coded and entered in to SPSS version 23 by the principal investigator. Quality assurance was maintained by undertaking double data entry and all the hard copy documents are kept in locked file cabinet. SPSS version 23 was used for descriptive and analytical analyses. Descriptive analysis was calculated as counts and proportions, and presented using tables and graphs. Associations between risk factors and past infection were determined by binary logistic regression and expressed as odds ratios with 95% confidence intervals and p value <0.05 was considered as significant. Fisher exact test was also used to determine the significance for variables with a cell count of less than 5. Results were presented mainly in the form of narration, tabular summaries and a figure.

Ethical Considerations

Ethical approval for the study was obtained from the scientific and ethics review office of the Ethiopian Public health Institute and from the St Paul's Millennium Medical College. Permission for sample collection was obtained from a regional health Bureau, Chifra woreda health office and local administrative bodies. After a thorough explanation about the purpose of

the study and its benefits and potential risks to the participants in the Afar language, verbal consent was obtained before enrolment ([Annex 1](#)). All questions that arose were addressed.

Participants were clearly informed that their participation in the study is strictly voluntary, and that they can decline not to participate at any time and give no reason for withdrawal. All participants were also informed that withdrawing from this study will not affect the quality of services they receive from any health facility anywhere.

In addition, they were clearly informed that if they consent to participate in the study, 2-3 ml of blood from their arm will be collected. The subjects had been notified that samples could be shipped to external laboratories for specialized screening.

Result Dissemination

After evaluation and comment, the result of the study will be disseminated to SPHMMC department of public health, Ethiopian Public Health Institute, Afar Regional health bureau and Chifra woreda health office. The findings of the study will be published in a scientific journal as appropriate.

RESULT

Sociodemographic Characteristics

A total of 341 individuals participated in the study making a response rate of 100%. The median age of participants was 25 years (IQR=16). Among the participants, 126(36.9%) were females and 215(63.1%) were males. From a total of 313 pastoral participants, 107(34.2%) were female and 206(65.8%) were males while among 28 student participants, 19(67.9%) were females and 9(32.1%) were male students. Eighty three (24.3%) of the participants had their own camel and the rest 258(75.7%) do not own camels but live with their family who own camels.

Table 17: Demographic characteristics of the study participants, Chifra woreda, December 2017

Characteristic	Category	frequency(%)
Gender	Female	126(36.9)
	Male	215(63.1)
Age Group	<20	99(29.0)
	20-29	113(33.1)
	30-39	60(17.6)
	40-49	38(11.1)
	50-59	19(5.6)
	>=60	12(3.5)
Locality (Kebele)	Amulli	20(5.9)
	Anderkalo	46(13.5)
	Askoma	76(22.3)
	Chifra 01	45(13.2)
	Geri	15(4.4)
	Semsem	29(8.5)
	Teaboy	19(5.5)
	Wanaba	28(8.2)
	Woama	63(18.4)
Occupation	Pastoralist	313(91.8)
	Student	28(8.2)

Seroprevalence of MERS-COV

In the study area, seven [2.05% (95 % CI; 1.00-4.18)] specimens were positive, 326 [95.6% (95% CI; 92.87-97.32)] were negative and eight [2.35% (95% CI; 1.19-4.56)] of the samples were found on borderline by ELISA as indicated on figure 1 below.

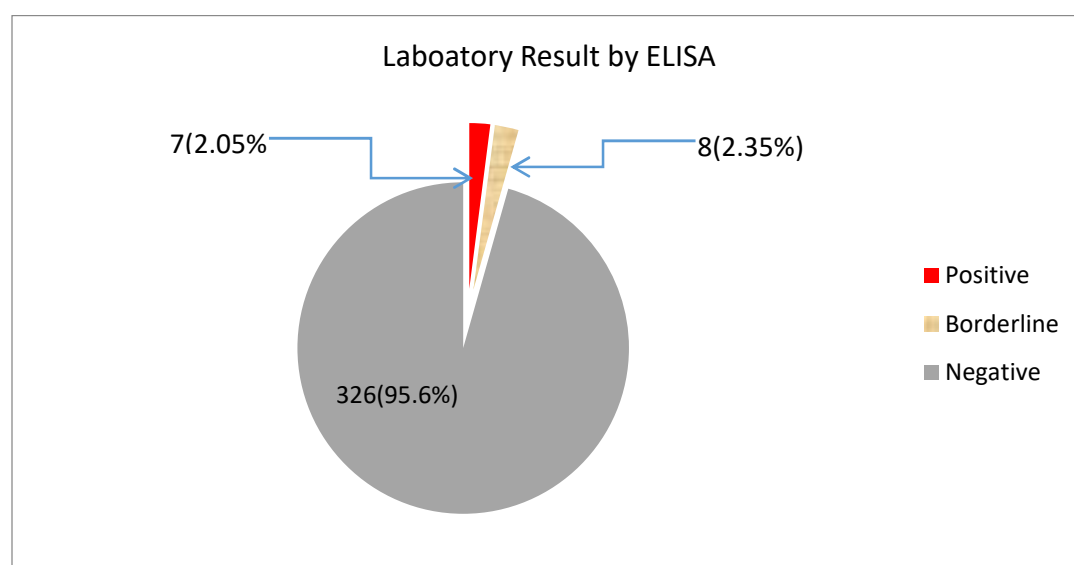


Figure 14: Distribution of results by ELISA, Chifra woreda, December 01-30, 2017

Description of Seropositive Participants

Table 18: Characteristics of the seropositive participants, Chifra woreda, Afar, December 01-30, 2017

Serial Number	Sex	Age	Occupation	Kebele	Bats around home	Chronic medical problems
1	F	44	Pastralist	Askoma	Yes	No/Don't Know
2	F	50	Pastralist	Amulli	Yes	No/Don't Know
3	M	24	Pastralist	Chifra 01	Yes	No/Don't Know
4	M	20	Pastralist	Anderkalo	Yes	No/Don't Know
5	M	29	Pastralist	Wanaba	Yes	No/Don't Know
6	M	18	Pastralist	Askoma	Yes	No/Don't Know
7	M	18	Pastralist	Anderkalo	Yes	No/Don't Know

In addition to the information illustrated in the above table (table 18), the study participants who were seropositive had the following typical exposure status.

Participant 1

This study participant didn't own camels and camels do not live around her house. She had no contact with camel but drinks raw camel milk. She had no respiratory illness and didn't know if she had any chronic illness.

Participant 2

This study participant owned camel and camels lived near to her house. She touched camels, had contact with sick camel and saw a camel died of illness. She used to drink raw camel milk and has been sick with respiratory illness but didn't visit a doctor.

Participant 3

This participant owned camels and those camels live near to his house. He used to touch camels daily, slaughter camels rarely (more than a month), assisted three camels during birth in the past one year before the interview, administers vaccine rarely, milk camels daily, saw camel died of illness, drink raw camel milk but never been sick with respiratory illness.

Participant 4

This study participant did not own camels but camels live around his house. He rarely touches camels, rarely slaughters camels, assisted one birth of camels in the past one year before interview, rarely administers vaccine, milks camels at most in weekly, had contact with camel, visited camel market rarely and used to drink raw camel milk.

Participant 5

This study participant did not own camels but camels live around his house. He rarely touched camels, rarely had contact with camels' waste, rarely slaughtered camels, has assisted three camel births in the past one year before the interview, rarely administered vaccine, milked camels up to weekly, had contact with sick camel, rarely visited camel market, rarely drank raw milk and was sick with respiratory illness.

Participant 6

This participant owned camels and those camels live near to his house. He rarely touched camels, rarely had contact with camels' waste, assisted in birth of three camels in the past one year before the interview, rarely administered vaccine, rarely milked camels, had contact with sick camel, had seen camel died of illness, rarely visited camel market and used to drink raw camel milk.

Participant 7

This participant owned camels and those camels live near to his house. He used to touched camels at least weekly, had contact with camel waste, assisted in birth of three camels in the past one year before the interview, rarely administered vaccine, milked camels at least weekly, had contact with sick camel, rarely visited camel market and used to drink raw camel milk.

Associated Factor Analysis

Among the participants, 160(46.9%) of them have never assisted the birth of camels while 35(10.3%) have assisted ones, 36(10.6%) have assisted twice, 13(3.8%) have assisted three times, 24(7.0%) have assisted four times and 73(24.4%) have assisted more than four times. for the past 1 year. One hundred eighty (52.8%) of the study participants have never administered vaccine for camels, 153(44.9%) have administered rarely(less than once in a month), 7(2.1%) have administered at least once a month and the rest one participant (0.3%) administered daily. None of the participants have used personal protective equipments while handling camels and their wastes, and none had no travel history to gulf countries. From the total of 341 study participants, 329 (96.5%) had history of chronic medical problems while three (0.9%) had Asthma, four (1.2%) had chronic lung disease, one(0.3%) had a combination of diabetes mellitus and hypertension, three(0.9%) kidney disease and one(0.3%) both kidney disease and hypertension. In a bivariate analysis, we found no statistically significant association between any of the risk factors and the seropositivity (table2).

Table 19: Table describing the relationship between risk factors and sero-positivity, Chifra district, Afar, December 2017

Variables	Laboratory Result by ELISA		COR(95% C.I)	P Value
	Non-Positive (%)	Positive (%)		
Age Group				
<30	205(98.09)	4(1.91)	1	
30-49	97(98.98)	1(1.02)	0.53(0.06-4.79)	0.57
>=50	32(94.12)	2(5.88)	3.20(0.56-18.21)	0.19
Total	334(97.95)	7(2.05)		
Gender				
Female	124(98.41)	2(1.59)	1	
Male	210(97.67)	5(2.33)	1.48(0.28-7.72)	0.64
Touching Camel				
No	96(98.97)	1(1.03)	1	
Yes	238(97.54)	6(2.46)	2.42(0.29-20.37)	0.68
Slaughter Camel				
No	203(98.07)	4(1.93)	1	
Yes	131(97.76)	3(2.24)	1.16(0.26-5.28)	1.00
Assist in Birth of Camels for the past 1 year				
No	158(98.75)	2(1.25)	1	
Yes	176(97.24)	5(2.76)	2.24(0.43-11.73)	0.54
Milking Camels				
No	130(98.48)	2(1.52)	1	
Yes	204(97.64)	5(2.39)	1.59(0.30-8.33)	0.87
Visit Camel Market				
No	179(98.35)	3(1.65)	1	
Yes	155(97.48)	4(2.52)	1.54(0.34-6.98)	0.86
Sickness with Respiratory Illness				
No	210(97.67)	5(2.33)	1	
Yes	124(97.41)	2(1.59)	0.68(0.13-3.54)	0.94

Discussion

Overall, this study has determined the seroprevalence of MERS-CoV and assessed expected factors leading to infection by the virus in Chifra woreda, Afar region, Ethiopia. As to the investigators' span of search, this is the first population based survey ever held on humans in Ethiopia with all its short-comings.

This study has used a similar ELISA kit with that done in Kenya and Saudi Arabia. In our study, the prevalence of seropositivity against anti MERS-CoV IgG was higher in men than in woman which fits with a similar study in Saudi Arabia. This might have happened due to the fact that men are more likely to have contact than women. The positivity prevalence (2.05%) is comparable to the two similar studies (0.15% and 1.43% for Saudi Arabia and Kenya respectively) which can also share similarities between the horn of Africa and the gulf countries due to camel trade exchange. (25),26,29].

Our study is consistent with a serological investigation conducted among slaughter house workers which showed seropositivity of 0%-5.8% although used different assay. Other seropositivity was revealed among hospitalized patients with the diagnosis of MERS-CoV infection[24,30]. So, this notes that seropositivity is resulted from the infection and meanwhile our study participants who are tested positive have been once infected with MERS-CoV. Some individuals might have been severely ill or died some time, or the infection remained asymptomatic. Due to the rapid genetic changing nature of viruses, we may face a new highly virulent type of MERS-CoV.

In a bivariate analysis, none of our assumed risk factors were significantly associated with the presence of IgG in the participants' specimens, which is to mean positivity of participants to Anti-MRS-CoV IgG antibody; revealing past infection by the virus. Some of these factors, to the contrary, for example having camels around home or farm, were found associated with evidence of infection in Saudi Arabia. Consumption of raw meet and raw milk were not associated with the positivity like ours [22,28].

Strength and Limitation of the Study

We used a validated test kit to determine the seroprevalence as mention above. But the study had several limitations. First, it was limited to strictly following WHO's two-step laboratory recommendation [28]. Second, due to the communal dwelling nature of the locality, our participants might have responded similar to the exceeding respondent. Third, due to small number of positives, we couldn't observe an association between the independent variables and seropositivity.

Conclusion

Our study reveals that the virus has been circulating in the study area and few of the population remained immunized following the infection. Although there is no cut-off point to say high or low, for an emerging viral human infection, a single positivity may be considered as public health threat which makes us to say our finding has immense public health importance.

Recommendation

Our study should be confirmed by large scale studies involving virus isolation and identification of the sequence of the virus to help for vaccine recommendation. This can be done by the ministry of health through establishing sentinel surveillance involving virological surveillance. Regional and woreda health institutions should be vigilant in identifying the causes of respiratory illnesses.

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ANNEXES

Annex 1: Consent Form for Chikungunya Outbreak Investigation

Title: Suspected Chikungunya Fever Outbreak Investigation- Dolo ado Woreda of Somali Regional state, Ethiopia, May 2016

Introduction: Hello, my name is Desalegn Belay. I am a member of Chikungunya outbreak Investigation team. Thank you for taking the time to speak with us today. We are investigating Chikungunya outbreak occurred in Dolo ado woreda of Liben Zone. We are very interested in your experiences and your point of view.

Purpose: To identify etiologic agent and assess the risk factors of Chikungunya outbreak in Dolo ado woreda of Liben Zone.

Procedure: If you agree to take part, this interview will take about 5 minutes of your time. There are two parts. First, we will ask you about demographic information of you and your family.

Confidentiality: All information collected during this study will be kept private and will only be known by the investigators.

Benefits: this information will help you and other people living in Dolo ado woreda. We will use these results to prevent and control Chikungunya fever outbreak in your woreda.

Risks: there is no risk to you from answering the questions.

Privacy: we will keep information about you private. We will not collect your name. Only the investigators will have access to the data and only for investigation purpose. We will not use any information that might identify you when we present or publish the study's results.

Payment: there is no cost to you for being a participant. The approximate time that this study will take is 5 minutes.

Participant Agreement: The project has been explained for me and my house hold members. I have been given a chance to ask questions. I feel that all my questions have been answered. Being in this study is my choice. I may change my mind and leave the study any time during the interview.

Participant Signature_____

Date_____

Name of persons obtaining consent_____

Signature of persons obtaining consent_____

Date_____

Thank For Your Cooperation!

An Investigation of Suspected CHIKV Outbreak-Dolo Ado, Somali Region, June 2016

N o.	Question	Coding Classification	Go To
1. Demographic Information Zone _____ Kebele _____ House No _____			
1.1	Respondent ID	_____	
1.2	Sex	1.Male 2.Female	
1.3	Age	_____ Years	
1.4	Marital Status	1. Single 2. Married 3. Divorced 4. Widowed 5.NA	
1.5	Educational status	1. Illiterate 2.Primary school 3. Secondary 4. College And University	
1.6	Ethnicity	1. Somali 2. Amhara 3. Oromo 4. Tigre 5. Other(specify)	
1.7	Occupation	1. Student 2. Daily laborer 3. House wife 4. Merchant 5.Farmer 6.Other(specify)	
1.8	Number of family members?	_____	
2. Clinical Information			
2.1	Respondent Classification	1. Cases 2. Controls	If Control skip to 3.1
2.2	Date of Onset	dd/mm/yyyy _____	
2.3	Sign and symptoms	1.Fever 2. Headache 3. Chill 5. Nasal Bleeding/bleeding from any part of the body 6. severe muscle and <u>joint</u> <u>pain</u> 7. Rash 8. Restlessness/lethargy 9. Abdominal pain, Nausea/vomiting	

N o.	Question	Coding Classification	Go To
2.4	Date seen at health Facility	dd/mm/yyyy _____	
2.5	Treatment	Antibiotics _____ Antiviral _____ Antipyretics _____ Ant malaria _____ Other supportive treatment _____	
3. Laboratory Specimens			
3.1	Blood Serum	1.Yes 2.No	
3.2	BF	1.Yes 2.No	
4. Knowledge towards Chikungunya Virus			
4.1	Do you hear about Chikungunya virus?	1.Yes 2.No	
4.2	If yes, what do you think the cause of Chikungunya virus?	1.Virus 2.Bacteria 3.protozoa 4.other____ 5. Don't know	
4.3	Is Chikungunya Contagious?	1.yes 2.No 3. I Don't know	
4.4	If yes, how it transmit?	1.By mosquito 2. Air droplets 3.House fly 4.Other____ 5. Don't know	
4.5	At which time mosquito bites people?	1. Night 2. Day 3.Sunrise/sunset 4. I Don't know	
4.6	Does water required for mosquito to breed?	1.Yes 2.No 3. I Don't know	
4.7	Do you know symptoms of Chikungunya?	1.Yes 2.No	
4.8	If yes what are the symptoms?	1.Fever 2. Headache 3. bleeding 4. Rash 5. Other(specify)_____	
5. Exposure			
5.1	Do you have LLINs?	1.Yes	

N o.	Question	Coding Classification	Go To
		2.No	
5.2	If Yes, do you use LLINs while sleeping in daytime?	1.Yes 2.No	
5.3	When did you get the last LLINs?	_____ Year	
5.4	Who use LLINs always?	1.Children 2.Women 3. All use equally	
5.5	Is there any water holding container in/around the house?	1. Yes 2. No	
5.6	Status of Container (observe)	1.Open 2.Closed	
5.7	Presence of larvae in the container(observe)	1.Yes 2. No	
5.8	If yes, What is the use of the container?	1. For home use 2.Other use 3. Unusable	
5.9	Is there any stagnant water around your village?	1.Yes 2.No	
5.1	If Yes, approximately distance of stagnant water from your house?	1.less than 100m 2.more than 100m	
5.1	Is your house sprayed?	1.Yes 2.No	
5.1	When was the last time that your house sprayed?	1.One month ago 2.Two months ago 3, Three months ago 4. More than three months	
5.1	Is there any river around your village?	1.Yes 2.No	
5.1	Approximately distance of the river from your house?	1.less than 100m 2.more than 100m	
5.1	Is there any person diseased in your family?	1.Yes 2.No	
5.1	If Yes, how many family members become ill?	_____	
5.1	Did you have close contact with person with same complaint within the last 1 to 2 weeks?	1.Yes 2.No	
5.1	Did you have travel history within the last two weeks?	1. Yes 2. No	
5.1	If, yes to where?	_____	
5.2	Do you use mosquito repellents on your skin?	1.Yes 2.No	
5.2	Do you use mosquito repellant in your house?	1. Yes 2. No	

N o.	Question	Coding Classification	Go To
5.2	What kind of clothes you usually wear	1. Short and T-shirts 2. Trousers/ body full dress	

THANK YOU!

Annex 2: Data Collection Tool to National Evaluate Influenza Surveillance System

Questionnaire

Introduction:

Thank you for taking time to speak with me today. My Name is Desalegn Belay. I have been working in Ethiopian Public Health Institute and now I am Field Epidemiology Resident at St Paul's Hospital Millennium Medical College. I am conducting an evaluation of Influenza like Illness and Severe Acute Respiratory Illness sentinel surveillance system and want to speak with people who are engaged in sentinel surveillance system. The aim of the evaluation is to evaluate how the system is functioning and whether the intended objectives are being met. Finally, recommendations will be forwarded all concerned bodies to improve the system.

No.	Question	Coding Classification
1. Background Information		
1.1	Region	1. Addis Ababa
1.2	Zone/Sub-city	_____ _____
1.3	Woreda	_____ _____
1.4	Name of Health Facility	_____ _____
1.5	Respondent	Name_____
1.6	Total Population	_____ _____
2. Case Detection		
2.1	Do you have influenza case definition?	1.Yes 2.No
2.2	If yes, is it posted?	1.Yes 2.No
2.3	Are all health professionals aware of it?	1.Yes 2.No

No.	Question	Coding Classification
3. Reporting		
3.1	Do you send influenza surveillance data to the next higher level?	1.Yes 2.No
3.2	How do you send the data to the next level?	_____ _____
3.3	When are you expected to send surveillance data to next higher level?	_____ _____
3.4	What kind of communication facility do you have?	_____ _____
4. Data analysis and interpretation		
4.1	Are you trained on influenza surveillance system?	1.Yes 2.No
4.2	Do you have computer?	1.Yes 2.No
4.3	Is it functional?	1.Yes 2.No
4.4	Do you have computer skill?	1.Yes 2.No
4.5	Do you analyze influenza surveillance data?	1.Yes 2.No
4.6	Do you use computer to analyze influenza surveillance data?	1.Yes 2.No
4.7	If answer for 4.6 is yes, do you describe data by time place and person?	1.Yes 2.No
4.8	Do you have denominator for data analysis?	1.Yes 2.No
4.9	Do you notify the results of your analysis to the sentinel site?	1.Yes 2.No
5. Feedback		
5.1	Do you provide Feedback to lower level?	1.Yes 2.No
5.2	How do you give your feedbacks?	1.Oral 2.Written
6. Training		
6.1	Did you take training on influenza surveillance within the last year?	1.Yes 2.No
6.2	How many staffs were trained?	_____ _____

No.	Question	Coding Classification
7. Supervision		
7.1	Do you conduct supervision?	1.Yes 2.No
7.2	If answer for 7.1 is yes, how many times did you supervise	_____ _____
7.3	How often do you supervise?	_____ _____
7.4	Do you have supervision checklist?	1.Yes 2.No
Surveillance Attribute		
8. Completeness		
8.1	Do all sentinel sites report within expected on time?	1.Yes 2.No
8.2	Are all variables completed?	1.Yes 2.No
9. Timeliness		
9.1	Does the sentinel surveillance data arrive time?	1.Yes 2.No
10. Usefulness		
10.1	Were the suspected ILI/SARI outbreaks detected early by the sentinel surveillance system?	1.Yes 2.No
10.2	Has the response initiated in a timely manner?	1.Yes 2.No
10.3	Any epidemiological investigation conducted?	1.Yes 2.No
10.4	For what purposes do you use the surveillance data?	_____ _____
11. Simplicity of the system		
11.1	Is the case definition easy?	1.Yes 2.No
11.2	Does the system allow all levels of professionals to fill data?	1.Yes 2.No
11.3	Does the system help to record and report data on time?	1.Yes 2.No
11.4	How long does it take to fill the format?	_____

No.	Question	Coding Classification

11.5	How long does it take to have laboratory confirmation?	_____ _____
12. Acceptability		
12.1	Do you believe the surveillance is important for public health intervention?	1.Yes 2.No
12.2	Did you accept the influenza surveillance system?	1.Yes 2.No
12.3	Do you think the reporting agents accept and well engaged to influenza surveillance activities?	1.Yes 2.No
12.4	If yes, how many are active participants in your health center/hospital	_____ _____
12.5	If No, what is the reason for their poor participation in the surveillance activity	_____ _____
12.6	Were all participants using the standard case definition to identify cases?	1.Yes 2.No
12.7	Were all the reporting agents send their report using the current and appropriate surveillance reporting format?	1.Yes 2.No
13. Flexibility		
13.1	Can the current reporting formats be used for other newly occurring health event (disease) without much difficulty?	1.Yes 2.No
13.2	Do you think that any change in the existing procedure of case detection and reporting format will be difficult to implement?	1.Yes 2.No
13.3	Is the system easy to add new variables?	1.Yes 2.No
13.4	Is the system easy to integrate with other systems?	1.Yes 2.No
13.5	Is the system easy to add new disease on report?	1.Yes 2.No
14. Data quality		

No.	Question	Coding Classification
14.1	Are all reported forms Complete?	1.Yes 2.No
14.2	Percentage of unknown or blank responses to variables from the total reports of 2008-2016 report	Sex ____ Age ____ Region ____ Zone ____ Woreda
14.3	Is the recorded data clear to read and understand?	1.Yes 2.No
15. Representativeness		
15.1	Was the surveillance system enabled to follow the health and health related events in the whole community?	1.Yes 2.No
16. Stability		
16.1	Was any new restructuring affected the procedures and activities of the surveillance?	1.Yes 2.No
16.2	Was there lack of resources that interrupt the surveillance system?	1.Yes 2.No
16.3	Was there any time /condition in which the surveillance is not fully operating? If yes, mention why?	1.Yes 2.No

Annex 3: Data collection tools (Checklist) for Health Profile Description

Historical Aspects of the area (if available)

How and why the name

How was the district formed _____?

Any other historical aspect _____

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-----%

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-----

Population size by religion

Orthodox_____

Catholic_____

Protestant_____

Muslim_____

Others_____

Ethnic composition -%-----

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			

Administrative setup

Total number of Kebeles(if it applies): _____

Urban_____

Supporting NGOs-----

Health status

Number of health facilities (2014/2015) 2007EFY)

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

Man power of Kolfe Woreda 9 health office and health facilities 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			

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	

Health service institutions and infrastructures

	Type of institution	No of institutions	Remark
1	Number of hospitals	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 which have vehicles	
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 which have vehicle	
3	PHC	with sustainable/ 24 hour electric power	

		without sustainable/ 24 hour electric power		
		with telephone service (cable based/mobile)		
		With out telephone service (cable based/mobile)		
		with piped water supply		
		Without piped water supply		
		No of health posts which have vehicle		

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		

Top ten causes of admissions

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

9		
10		

Top ten causes of deaths (mortality).

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

Vital statistics 2007 EFY (2014/2015)

CBR_____

CDR_____

NMR_____

PNMR_____

IMR_____

MMR_____

GR_____

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		DOR
	Full immunization coverage%		

11	Contraceptive acceptance rate		
12	TT2 coverage for pregnant		
13	TT2 coverage for non pregnant		

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	

Endemic Diseases

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 Years	>5Years
8	Cases treated based on lab finding		
9	Number of Vaccinated population for influenza?		

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

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	

HIV/AIDS IN 2007 EFY (2014/2015)

Sr. No	Activities	Male	Female	Total	Remark
1	Total number of 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	Not applicable			
9	No. of pregnant mothers Pre ART	Not applicable			
10	Condom Distribution				
11	Health education coverage				
	Number of OVC				

Topics for health education-----

Socio economic conditions 2007 EFY (2014/2015)

Education and school Health

Sr. no	Type of School	# schools	# teachers			# students			student school drop out	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...

School health activities:

Schools with water supply_____

Schools with functional latrines _____

Schools with HIV/other Health clubs_____

Literacy ratio_____

Health education-----

Income

Main source of income _____

No. of the population committed in:

Urban 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 _____

Social aspects

Number of youth clubs_____

Number of public libraries _____

Others _____

Communication and Utilities

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

Transportation: Kebeles _____ (%)

Telecommunication: Kebeles _____ (%)

Health facility _____ (%)

Electric power: Kebeles _____ (%)

17. Health Sector Expenditure and Financing 2004-2008 EFY (2012-2016)

	Source	2004EFY	2005 EFY	2006EFY	2007 EFY	2008 EFY
1	Total Woredat 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 (2004- 2008 EFY)

Sr. no	Health institution	2004 EFY		2005 EFY		2006EFY		2007 EFY		2008 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	2006 EFY	2007 EFY	
1								
2								
3								
4								
5								
6								
7								

Exempted Health services:

a/

b/

c/

d/

e/

f/

Disaster situation in the district 2007 and 2008EFY (2014/2015-2016)

Was there any disaster (natural or manmade) in the district in the last two years?

(specify) _____

Any recent disease outbreak/other public health emergency?

Yes (specify) _____

No _____

If yes cases _____ and deaths _____

Nutrition intervention in Kolfe woreda , 2007 and 2008 EFY (2014/2015-2016)

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-----

What do you think are major Health problems of woreda 9?

What do you think are solutions of the problems?

What are the main zoonotic diseases in woreda 9?

A.

B.

C.

D.

Annex 4: Participant Information Sheet and Consent Form for MERS-CoV Study

Introduction

I am _____ from St Paul's Hospital Millennium Medical College working on my Masters of Public Health in Field Epidemiology. We are doing a study to investigate whether or not the newly discovered virus, MERS-CoV, has been introduced in human population in areas where camels are reared in the country. I am now going to give you more information and invite you to be part of this study. Please ask me to stop as we go through the information if there is anything that you do not understand and I will take time to explain. You will also have time to answer questions at the end.

Purpose of the study

The novel coronavirus (MERS-CoV) which caused more than 600 deaths has been reported globally, since it was first discovered in September 2012. It is believed that the virus comes from an animal and camels are implicated to be the source of infection to human but it is not known how the virus gets from animals to humans. In Ethiopia, the presence of MERS-CoV antibody has been reported in camel population. However, there is no report on the status MERS-CoV in human population and circulating virus strain in the country. Understanding the current epidemiology of the virus at animal and human interface is critical to preventing and controlling the disease. Therefore, our study is primarily focused on people living in camel rearing areas to determine the status of MERS-CoV infection in human, to identify potential risk factors for zoonotic transmission of the virus in the country.

People in each of the study areas will be tested for the presence of antibodies against the virus, which will indicate that they have likely been infected with the virus at some time in the past. Learning about the kinds of exposures experienced by people who have had the infection may give us valuable clues about the source of the virus and the activities that result in infection. This information is extremely valuable as it will allow the responsible authorities to provide effective guidance to the public about how to reduce their risk of infection.

Type of Study

This study will involve your participation in a face to face interview that will take about 30 minutes. In addition, a small blood sample will be collected from your arm to test for signs of previous infection with the MERS-CoV. The results of blood test will only indicate previous infection and so will not be urgently shared with you. Blood specimens may be sent out of the country for testing at expert laboratories but will be coded so that only the study team can determine what specimen is yours. Blood specimens may be stored for additional testing in the future.

Voluntary Participation

Your participation in this study is entirely voluntary. It is your choice whether to participate or not. If you choose to participate, you may change your mind at any time to stop participating in this study.

Procedures

If you agree to participate, you will be asked to answer some questions about your exposures to animals and activities in an interview with myself. If you do not wish to answer any of the questions during the interview, you may say so and I will move on to the next question. No one else but me will be present unless you would like someone else to be there. The information you share is confidential, and no one else except the principal investigator and the research sponsors will access to the information documented during your interview. A blood sample will be taken from you for testing, if you do not want to give a blood sample, however, we will not proceed with the interview.

Risks

The blood collection is very low risk as only a small amount will be taken. You may experience some minor discomfort or bruising at the site of collection.

Benefits

Your participation will help us learn more about the MERS-CoV in order to plan effective measures to prevent others from being infected.

Reimbursements

You will not be provided any payment to take part in the study. But, you will be reimbursed for your working time that you spent to participate in the study.

Confidentiality

The information that we collect from this study will be kept private. Any information about you will be identified by a number on it instead of your name. It will not be shared with or given to anyone except the principal investigator and the research sponsors.

Part II: Certificate of Consent

I have understood all information contained in the information sheet and this informed consent form. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant _____

Signature of Participant _____

Date (DD/MM/YYYY) _____

Print Name of Informed consent provider _____

Signature _____

Date (DD/MM/YYYY) _____

Questionnaire for Community Based Cross-Sectional Seroprevalence Study of MERS-CoV Infection in Human Population

Contact Information of Subject

Date of interview (dd/mm/yyyy): ____/____/____ Name of interviewer: _____

Participant Name: _____ ID Number: (I/HH/V/D): _____

Residence Region: _____ Zone: _____ District: _____ Village: _____

Gender (circle one): ☐ Male ☐ Female Age: ____ Occupation: _____

1. General

1.1. How long have you lived in this area? (in years) ____ ____

1.2. Do you own animals? ☐ YES ☐ NO

1.3. What animals do you raise on your farm (check all that are there)

☐ Camels ☐ Goats ☐ Sheep ☐ Cattle ☐ Horses ☐ Donkey ☐ Chickens

1.4. Is your animals lived in/near to your house? ☐ YES ☐ NO

1.5. If not what is the address of your animals kept: _____

2. Exposure

2.1. Do you personally provide care for your camels? ☐ YES ☐ NO

2.2. On average, over the last 12 months, how often do you do the following activities?

With 1 = Never 2 = rarely (not even once a month) 3 = Monthly (at least once a month) 4 = Weekly (at least once a week) 5 = Daily

Activity	Circle the number that is closest to how frequently you perform this activity per day				
Touch animal	1	2	3	4	5
Clean Animal housing	1	2	3	4	5
Handel animal waste	1	2	3	4	5
Clean farm equipment	1	2	3	4	5
Slaughter animals	1	2	3	4	5
Assist in the birth of animals	1	2	3	4	5
Administer vaccines or medicines to animals	1	2	3	4	5

Milk animals	1	2	3	4	5
Milk Processing	1	2	3	4	5
Other	1	2	3	4	5

2.3. In the past 12 months, have you had direct contact with camels waste?

☐ YES ☐ NO

2.4. If yes, how often are you in contact with it?

☐ 1 = Never ☐ 2 = Rarely (not even once a month)
☐ 3 = Monthly (at least once a month) ☐ 4 = Weekly (at least once a week) ☐ 5 = Daily

2.5. In the last 12 months are you aware of being in contact with any sick camels?

☐ YES ☐ NO

2.6. If yes, do you know if any of the camels died of illness?

☐ YES ☐ NO

2.7. In the last 12 months have you visited a live animal market?

☐ YES ☐ NO

2.8. If yes, on average over the last 12 months, how frequently do you go to live animal markets?

☐ Rarely (not even once a month) ☐ Monthly (at least once a month)
☐ Weekly (at least once a week) ☐ Daily

2.9. Is there any cave around you area?

☐ YES ☐ NO

2.10. If yes, How far it is from your home?-----KM

2.11. Did you visit the cave ?

☐ YES ☐ NO

2.12. If yes, How often?

☐ Rarely (not even once a month) ☐ Monthly (at least once a month)
☐ Weekly (at least once a week) ☐ Daily

2.13. For what purpose do you visit the cave?_____

2.14. Have you seen Bats around your home?

☐ YES ☐ NO

2.15. Did you have contact with bats?

☐ YES ☐ NO

2.16. If yes, what type of contact? _____

3. Personal Protective Equipment and Hygiene Practices

3.1.What personal protective equipment do you usually wear when handling animals or their waste? (Check all that apply)

☐ No protective equipment used ☐ Gloves ☐ Coveralls ☐ Dust masks
☐ Boots or boot covers ☐ Respirators ☐ Eye protection (goggles, safety glasses)
☐ Others:_____

3.2. How often do you usually wash your hands while staying at the farm (check all that apply)

☐ At mealtimes ☐ Before and after each animal related task ☐ At bathroom times
☐ The beginning and end of the day ☐ Rarely

4. Human Exposure

4.1.Have you visited any person sick with respiratory (cough, breathing problems) in the last 6 months?

☐ YES ☐ NO

4.2.If yes what was your relationship to the person?

☐ Close family ☐ Extended family ☐ Friend ☐ Other_____

4.3. In the past 12 months, have you drunk raw camel milk?

☐ YES ☐ NO ☐ Don't Know

4.4. If yes, how frequently do you consume raw camel milk products?

☐ Rarely(not even once a month) ☐ Monthly (at least once a month)
☐ Weekly (at least once a week) ☐ Daily

4.5.In the past 12 months, have you eaten uncooked camel meat?

☐ YES ☐ NO ☐ Don't Know

4.6.If yes, how frequently have you eaten uncooked camel meat?

- ☐ Rarely (not even once a month) ☐ Monthly (at least once a month)
- ☐ Weekly (at least once a week) ☐ Daily

5. Medical History

5.1. Are you sick today with Fever and cough? (If yes offer to take respiratory specimens)

- ☐ YES ☐ NO

5.2. During the last 12 months have you seen a doctor for a respiratory illness (any of the following: cough, fever, runny nose, shortness of breath, rapid or shallow breathing, sore throat, vomiting after cough, or wheeze)?

- ☐ YES ☐ NO

5.3. During the last 12 months have you had to stay overnight in a hospital for a respiratory illness (any of the following: cough, fever, runny nose, shortness of breath, rapid or shallow breathing, sore throat, vomiting after cough, or wheeze)?

- ☐ YES ☐ NO

5.4. Are you currently a cigarettes smoker?

- ☐ YES ☐ NO

5.5. If yes, on average how much do you smoke?

- ☐ Not every day ☐ 1-2 times/day ☐ 3-10 times per day
- ☐ 11-20 times per day ☐ more than 20 times per day

5.6. Do you have any of the following medical problems?

Medical Problem	YES	NO	Don't Know
Diabetes			
Asthma			
Chronic Lung Disease			
Kidney Failure			
Chronic Liver Disease			
High Blood Pressure			
Cancer			
Immune Deficiency			

6. Laboratory Result

6.1. ELISA ☐ Positive ☐ Negative

Anti- MERS-CoV ELISA IgG test procedure

Preparation

Dilute sample 1:101 with sample buffer

Dilute wash buffer 1:10 with distilled water

Incubation

A, Sample Incubation

1. Transfer 100 microliters of the calibrator, positive control, negative control and diluted serum sample in to individual antigen coated micro plates. Incubate for 30 minutes at room temperature (18-25 °C)
2. Wash 3 times with diluted washing solution (450 microliters for each well in automated washer)

B, Conjugate Incubation

3. Pipette 100 microliters enzyme conjugate (peroxidase-labeled anti-human IgG) in to each micro plate wells. Incubate for 30 minutes at room temperature (18-25 °C)
4. Wash 3 times with diluted washing solution (450 microliters for each well in automated washer)

C, Substrate Incubation

5. Pipette 100 microliters chromogen/substrate solution in to each micro plate wells. Incubate for 15 minutes at room temperature (18-25 °C). protect from direct sun light

D, Stopping

6. Pipette 100 microliters of stop solution in to each micro plate wells in the same order and at the same speed as chromogen/substrate solution was introduced.

E, Measurement

7. Read at wavelength of 450 nanometers and a reference wavelength between 620 and 650 nanometers within 30 minutes of adding the stop solution. Prior to measuring, slightly shake the micro plate to insure homogeneous distribution of the solution.

Biography

The author was born on August 1986 G.C in Bahir Dar, Ethiopia. He attended his primary education at Tiss Abay primary school and high school at Ghion and Tana Haik secondary Schools. Then he joined Alemaya University (Now Haramaya) college of health sciences and graduated with Bachelor's Degree Medical Laboratory Technology in 2007.

After graduation he worked as medical laboratory technologist in Alem ketema Enat hospital, St Paul's hospital millennium medical college and Ethiopian public health institute. Then he joined SPHMMC in 2015 G.C for a postgraduate studies in FETLP lab track.