THE PREVALENCE AND RISK FACTORS OF ACTIVE TRACHOMA IN LAIKIPIA COUNTY, KENYA 2018

BY

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DECLARATION

Declaration by Candidate

This thesis is my original work and has not been presented for any research leading to the award of a degree in any other institution/university. No part of this thesis may be reproduced without the prior written permission of the author and/or Moi University.

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DEDICATION

I dedicate this work to me family for their continued support and words of encouragement throughout the course.

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ABSTRACT

Background: There are an estimated 1.8 million people infected with Trachoma globally, with most being in Africa due to poor water supply and poor sanitation. In Kenya, there are 7 million people living within endemic regions, and 85,000 people at risk of contracting the disease. World Health Organization (WHO) defines prevalence of active trachoma or trachoma inflammation follicular (TF) as a public health problem when the prevalence is ≥ 5% in children 1-9 years of age and has targeted to eliminate it by 2020 using the SAFE strategy. Following a baseline study conducted in Laikipia in 2007 that identified an overall TF prevalence of 9.5% with some hotspots Sub-location like Ngarendare (70.0%), Mumonyot & Ruguta (46.7%) and Kurikuri (30.0%). The study sought to estimate the prevalence and risk factors associated with Active Trachoma in Laikipia after implementation of the SAFE strategy intervention from 2007.

Methods: The study was a cross-sectional community-based study that sort to estimate the prevalence of active trachoma (TF) among children aged 1-9years and the associated risk factors. The participants were randomly selected from 30 households from each of the randomly selected 30 villages within each of the three evaluation units. Using Cochran's formula and a non-response rate of 10%, we calculated a minimum sample size of 1,000 aged 1-9 years from each evaluation unit. TF was defined as presence of five or more follicles in the upper tarsal conjunctiva and using x2.5 magnifying loupes under ample lighting, eyes were examined for signs of TF. A standardized questionnaire assessing the risk factors was administered to the household head and water and sanitation facilities observation checklist filled. Descriptive statistics analysis was done and bivariate and multivariate analysis undertaken using Odds ratio as measure of association and chi-square for statistical significance. Factors with p value <0.05 were considered statistically significant.

Results: A total of three thousand one hundred and ninety-three (3,193) aged 1-9 years were selected to participate in the study. Among all examined participants 1,625 (50.9%) were male. TF prevalence among the examined aged 1-9 years was estimated at 2.5% (n-112[95%CI 0.87- 4.8]) of whom 62 (55.4%) were male. Laikipia North EU accounted for 63(56.3%) of all the participants with TF signs. The TF signs among age 1-9 year were associated with lack of having a defecation amenities (aOR=5.64, 95%CI 3.55 – 8.95%, aOR=5.64, 95%CI 3.55 – 8.95%, P value <0.001), getting drinking water more than one hour away (aOR=3.31, 95% CI 2.27 – 4.83%, P value <0.001).

Conclusion: In all evaluation units, TF prevalence were below the WHO elimination threshold as a public health problem. Poor access to clean safe water and defecation amenities were associated with presence of active trachoma.

Recommendation: There is need to scale up community sensitization on facial cleaning, use of clean water improved sanitation and hygiene measures at the community level. As well as the county sustaining the gains made through the implementation of SAFE strategy with the hope of elimination of trachoma.

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DEFINITION OF TERMS

Active Trachoma – Chronic inflammation of the conjunctiva caused by Chlamydia trachomatis also referred to as trachoma inflammation follicular (TF) or trachoma inflammation Intense (TI). TF is the WHO recommended monitoring indicator for active trachoma.

At risk population – Population classified as having high risk to trachoma

Chlamydia Trachomatis – Bacteria that causes trachoma infection

Endemic Trachoma – Prevalence of TF among children aged 1-9 years of ≥ 5% (Endemicity of trachoma is only defined by prevalence of TF)

Household – One or more persons living in the same dwelling and share the same basic needs.

Potentially blinding Trachoma – This is trachoma that is graded as: Trachomatous Scarring (TS), Trachomatous Trichiasis (TT) and Corneal Opacity (CO). TT is the recommended monitoring indicator for potentially blinding trachoma.

SAFE – WHO strategy developed for elimination of trachoma by doing Surgery for all TT cases, administering mass Antibiotics treatment and promoting Facial cleanliness and Improving Environment

Trachoma – Eye disease (conjunctivitis) caused by Chlamydia Trachomatis spread by direct contact from infected discharge from the eyes, nose and throat

Elimination of trachoma as a public health problem is defined as:

i. Prevalence of unkown trachomatous trichiasis of <0.2% in adults aged ≥15 years
ii. Prevalence of trachomatous inflammation—follicular (TF) <5%, aged 1–9 years for at least two years in the absence of ongoing antibiotic mass treatment, in each formerly endemic district; plus
iii. The ability to identify and manage incident trachomatous trichiasis cases, using defined strategies

LIST OF ABBREVIATIONS

CHEW	Community Health Extension Workers
CHW	Community Health Workers
CIDP	County Integrated Development Plan
DALY	Disability Adjusted Life Years
DDPC	Department of Disease Prevention and Control
DHMT	District Health Management Team
DOS	Division of Ophthalmic Services
GET2020	Global Elimination of Trachoma by 2020
GTMP	Global Trachoma Mapping Project
ICTC	International Coalition for Trachoma Control
ITI	International Trachoma Initiative
KEMRI	Kenya Medical Research Institute
KNBS	Kenya Nation Bureau of statistics
KNPC	Kenya Nation Plan for Control of Trachoma
MDA	Mass Drug Administration
MOH	Ministry of Health
MU	Moi University
NGO	Non-Government Organization
NTD	Neglected Tropical Disease
OCO	Ophthalmic Clinical Officer
OSU	Ophthalmic Service Unit
TAP	Trachoma Action Plan (2011-2020)
TEO	Tetracycline Eye Ointment
TT	Trachomatous Trichiasis

TI	Trachomatous Inflammation—Intense
TF	Trachomatous Inflammation—Follicular
TS	Trachomatous Conjunctival Scarring
SAFE	Surgery, Antibiotics, Facial Cleanliness and Environmental Improvement
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Trachoma is one of the leading causes of preventable eye blindness and it is caused by a bacterial infection known as *Chlamydia trachomatis*. It is one of the Neglected Tropical Diseases (NTDs) and is spread from person to person through direct contact through discharge from infected eye and nose, through mechanical vectors like flies or by direct contact (Emerson et al, 2000).There are various serotypes of *Chlamydia trachomatis* that cause trachoma which include A, B, Ba, and C, whereas serotypes D and K cause genital infections (Thomson et al., 2007).

The World Health Organization (WHO) defines elimination of trachoma as a public health concern if unknown trachomatous trichiasis (TT) prevalence is <0.2%, trachoma inflammation follicular (TF) is <5% among aged 1-9 years for two years in absence of antibiotic and TT cases identified and managed using defined strategies (WHO, 2015). Trachoma commonly affects the low resource communities associated with scarcity of water, poor sanitation, hygiene practices and lack of awareness (Mabey et al., 2003). It still poses a great public health challenge 4with approximate 40.6 million people affected by active trachoma (Trachomatous Inflammation—Follicular) and over 1.9 million people with visual impairment accounting for 1.4% of all blindness worldwide (Mariotti et al., 2012) (Mabey et al., 2003). It is known to be endemic in 44 counties majority from Africa and Asia, responsible for 1.9 million visually impaired with approximately 142 million at risk of trachoma blindness as well as accounting for 1.4% of all blindness (WHO, 2019). It is estimated that trachoma disease burden stands at 1.3 million Disability Adjusted Life Years (DALYs) with Africa having the highest number of affected countries and disease burden (Burton et al ., 2009). During the 51st World

Health Assembly (WHA) adopted resolution to eliminate trachoma as a public health problem (WHO, 1998).

Kenya is a middle-income country divided into 47 counties; 12 of which are trachoma-endemic areas (CBM, 2019). These endemic areas are divided into North-West lowlands and South Central Plains, with at-risk population approximated at 7.3 million people within these areas. Majority of the areas are in the arid and semi-arid parts of the country, which are faced by major challenges like poverty, water shortage, dry and dusty environment, that are considered as a risk areas for trachoma (karimurio et al, 2006). In 2002, a trachoma prevalence study was conducted in Magadi (shompole) Kajiado County by the ophthalmology department of Nairobi University, Sight Savers International and African Medical and Research Foundation (AMREF). Although not published, the report informed the Ministry of Health of the high trachoma prevalence with TT prevalence of 70% and TF prevalence of 16.7% (Matende et al., 2003). The findings underscored the need to conduct a trachoma baseline survey across the county in areas that trachoma was suspected (Kenya NTD, 2015).The baseline surveys were conducted in the year 2004 (Kajiado, Narok, West Pokot, Baringo, Samburu and Meru), 2007 (Laikipia), 2010 (Turkana,) and 2011(Trans Mara, EastPokot, Isiolo, Marsabit and Moyale) with a TF prevalence range between 4.6% to 46.4%. From the baseline survey in Laikipia, the general prevalence of Trachomatous Inflammation Follicular (TF) was 9.5% and Trachomatous Trichiasis (TT) as 1.1%. However, some of the wards had very high prevalence and hence referred to as hot spots. Wards with TF prevalence >10% were: Ngarendare (70%), Ruguta (46.7%), Muminyot (46.7%), Kurikuri (30%), Naibor (15.9%) in Laikipia East sub-county and Olmoran (12.5%), Pesi (21.6%), Mutara (10.5%) and Maundunimeri (16.6%) in Laikipia West sub-county. Those with a prevalence of TT > 1% included; Ngarendare (16.7%), Kurikuri (3.8%), Murura

(1.4%) in Laikipia East sub-county and Thigio (7.3%), Manguo (1.3%), Mutara (4.8%), Karaba (1.6%), Maunduni Meru (1.6%) in Laikipia West sub-county (Kariumorio et al, 2007).

Trachoma is considered a water-related infectious disease that can be controlled and prevented by ensuring proper hygiene and sanitation practices (AMREF, 2004)The World Health Organization has earmarked the elimination of trachoma by the year 2020 by the use of various integrated strategies (Francis et al., 1993). These strategies were adopted in 1993 and included; use of Surgery to treat trachomatous trichiasis (TT), use of Antibiotics to treat the infection, encouraging of facial cleaning and improving the environment (SAFE strategy) (WHO,1998) .As a follow up of the baseline surveys, Kenya conducted its first impact survey in 2010 (Narok) then 2011 (Kajiado, Samburu and Laikipia) which indicated an increase in prevalence of both TT and Trachomatous Inflammation Follicular (TF) and areas that needed intervention were scaled up (Karimurio et al., 2008).

1.2 Problem Statement

Trachoma remains the second leading cause of preventable blindness globally and with over 540 million at risk of the disease worldwide (WHO, 2017) (Burton *et al.*, 2009). Trachoma contributes to a high financial burden of the affected counties which is estimated at a cost of US $ 2.9 billion globally (I.C.T.C, 2013).

Kenyans population is estimated as 47,251,449 people of which 76% live in the rural areas and less than half living below the poverty line (Burton et al., 2010). Trachoma has been highly associated with lack of basic safe water, poor sanitation, poor hygiene and lack of awareness (M.O.P.H.s, 2008). A high number burden of the disease has been noted among children aged ≤ 9 years due to the poor face hygiene, which attracts

flies that can transmit bacteria from an infected person's eye discharge. It acts as a mechanical vector with the potential to transmit these pathogens over a long distance therefore expanding the spread of various serotypes. The vector could also play a role in the transmission of trachoma strains between and within homesteads. We also hypothesize that the flies could also transmit the pathogen to animals and even abiotic surfaces or fomites (Emerson *et al.,* 2004).

In Kenya, there are approximately 650,000 people who are blind or visually impaired and trachoma accounts for 19% of all cases of blindness hence being the second leading cause of preventable blindness in the country after cataract (Fred hollows, 2019). Of the 47 counties, 12 are considered trachoma endemic area with approximately 7.3 million people at risk (Kaimuno *et al.,* 2006) with the 13th one being Garissa which still remains as a suspected trachoma county. Laikipia County is one of the arid and semiarid regions that suffer from scanty rains and water resources. Majority of the residents are nomadic pastoralist and the area is bordered by three trachoma endemic counties which are: Samburu, Baringo and Pokot. Laikipia has been identified to have some trachoma hot spots in the past with prevalence as high as high 70% for TF and 16.7% for TT (Karimurio *et al.,* 2007).

1.3 Justification of Study

Following the baseline survey conducted in Laikipia in 2007 and the impact survey in 2011, the county has been implementing the S, F&E component of the SAFE strategy. By then Laikipia County was considered as one trachoma EU, in 2012 after devolution the trachoma districts were realigned to fit the administration units which then formed the current three EU (Laikipia North, East and West). Since then, there has been no other study done to determine the trachoma burden in each of the three evaluation units

nor the progress made in trachoma elimination since the implementation of SAFE strategy with the target of elimination of trachoma in Laikipia by the year 2020.

The study was aimed to identifying the current prevalence of active trachoma and associated risk factors in Laikipia County after the implementation of the SAFE strategy as well as to enhance evidence-based programming within the countries ophthalmology department.

1.4 Research Questions

The research questions were:

- What is the prevalence of active trachoma among children aged 1-9 years in Laikipia County?
- What are the risk factors that influence trachoma infection in Laikipia County?

1.5 Objective of the Study

1.5.1 General objective

To determine prevalence and factors associated with Trachoma occurrence and transmission in Laikipia County, 2018

1.5.2 Specific objective

- To determine the prevalence of active trachoma Trachomatous Inflammation Follicular among children aged 1-9 year in Laikipia County
- To identify active trachoma associated risk factors associated within Laikipia county

1.6 Significance of the Study

The results of the study will help to inform Laikipia County health policy as well as act as a guide on the milestones achieved so far in the elimination of trachoma by 2020. It

will inform and create a better understanding to Laikipia ophthalmology department on the milestones achieved after implementation of the SAFE strategy as the county gears towards elimination of trachoma as a public health problem.

Results helped in identifying the gap and factors currently present within the community that would aid in the elimination of trachoma and enhanced community sensitization and awareness creation.

CHAPTER TWO

LITERATURE REVIEW

2.1 Trachoma Infection

Trachoma is the leading eye infectious disease and ranked second in causing preventable eye blindness worldwide (W.H.O, 2017). It's caused by *Chlamydia trachomatis* bacteria which is easily spread from person to person by contact with the infected eye and/or nasal discharge. Flies have been noted to be a great contributor to the spread of trachoma acting as mechanical vectors as reported in other studies elsewhere (Gambhir *et al.*, 2007).

The infection causes an inflammatory process on the eyelid leading to the formation of a few follicles known as trachoma folliculitis (TF). If untreated, it may result in trachomatous intensive (TI). It may appear as TF or TI, which are pronounced inflammatory processes with whitish watery discharge. If untreated or reinfection occurs continuously this may cause eyelid scarring known as trachomatous scarring-(TS). As the inner eyelid deforms it causes the lashes to turn inward scratching the cornea and referred to as trachomatous trichiasis (TT) that could lead to corneal clouding.

The *Chlamydia trachomatis* is an exclusive pathogen to human and appear as serotype A, B, Ba, and C for classic trachoma or serotype D-K for para trachoma (Copeland & Afshari, 2013).

Transmission through direct contact with nasal discharge from an infected person has also shown to be a source of infection in a study conducted in Kenya (I.C.T.C, 2013). It is strongly associated with poor personal hygiene and waste disposal that increases the number of flies, insufficient water supply, shared sleeping beddings and close

association with domestic animals like cattle (Bailey et al., 2003). Children remain the most venerable people which is mostly associated with poor hand and face hygiene (Mariotti *et al.,* 2010).

2.2 Environmental and Behavioral Factors

2.2.1 Water scarcity

Inadequate supply of clean water is a major contributor to poor hygiene and illnesses such as trachoma. Previous studies have shown that there is an association between the distance to the water source, availability of clean water and the prevalence of trachoma. The further the distance to the water source, the more likelihood of having poor hygiene and hence the more likelihood of TF. In addition, the availability of water has a big contribution on how water is used as well as the effect on sanitation and hygiene and by extension TF prevalence (Schémann *et al.,* 2002, (Dolin et al., 1997).

2.2.2 Sanitation and hygiene

Dirty hands play a major role in the transmission of the bacteria from the eye and nose discharge of an infected person to the healthy one especially among children (Gambhir et al., 2007). Frequent washing of hands and face reduce the chances of spreading the bacteria as well as attracting house flies.

Proper waste disposal and hygiene play a great role in reducing the vectors hence reduce chances of mechanical spread (Hoechsmann et al., 2001). Previous studies conducted comparing the effect of dirty face and active trachoma indicated that there is a high association (Emerson *et al.,* 2006).

2.2.3 Host flies

A high presence of flies which is highly attributed to the waste disposal and presence of domestic animals like cattle has been associated with the increase of trachoma spread and high disease prevalence (Harding-Esch et al., 2008). Reduction of fly density by proper water disposal was shown to have a reduction in trachoma transmission (Oswald *et al.,* 2017).

2.3 Trachoma Diagnosis

Trachoma is diagnosed clinically by the help of trained and qualified trachoma graders. The grader use the WHO set trachoma slide that categorizes trachoma into six grades depending on the tarsal presentation: Normal tarsal conjunctiva, Trachomatous Inflammation – Follicular (TF), Trachomatous Inflammation – Intense (TI), Trachomatous Scarring (TS), Trachomatous Trichiasis (TT) and Corneal Opacity (Thylefors *et al.,* 1987). There is laboratory test that can be used to confirm diagnosis and species identification which include molecular tools such as PCR (Bailey et al ., 1994). It is based on the structure of *Chlamydia trachomatis* major outer membrane protein (MOMP) gene. Chlamydia is an intracellular bacteria that replicates in the host cells and that's recognized by host receptors through the innate immune system that's mostly asymptomatic (Bastidas et al., 2013).

2.4 Control and Prevention

Trachoma is a preventable disease and early intervention could prevent blindness and economic loss associated to disease burden (Burton *et al.,* 2009). WHO has targeted to eliminate trachoma globally by the year 2020 (W.H.O, 2013). To help achieve this it introduced Surgery to correct the in-turned eyelashes, Antibiotic azithromycin use in

endemic regions, Face cleaning and Environmental improvement (SAFE) strategy in 1993 (W.H.O,2017).

2.5 Social-Economic Factors and Cultural Practices

Trachoma has been associated with poor communities in rural areas that have poor access to clean water and poor hygiene practices (Pashtoon *et al.*, 2004). A study in Egypt showed that lack of latrine ownership had a risk of spreading inflammatory trachoma (Courtright, 1991) . It has been being associated with overcrowding, poor hygiene and knowledge that has an effect on the health seeking behaviors (Prost *et al.*, 1989). Women and children are the most affected population compared to men (Regassa *et al.*, 2004). For a study done in Tanzania it indicated that the prevalence of trachoma was higher among the poorest communities (Evertjan *et al.*, 2011). Cultural practices and behaviors like keeping cattle within home shades has been reported to have an effect on the number of flies and hence the spread of trachoma (Bailey *et al.*, 2008).

2.6 Conceptual Framework

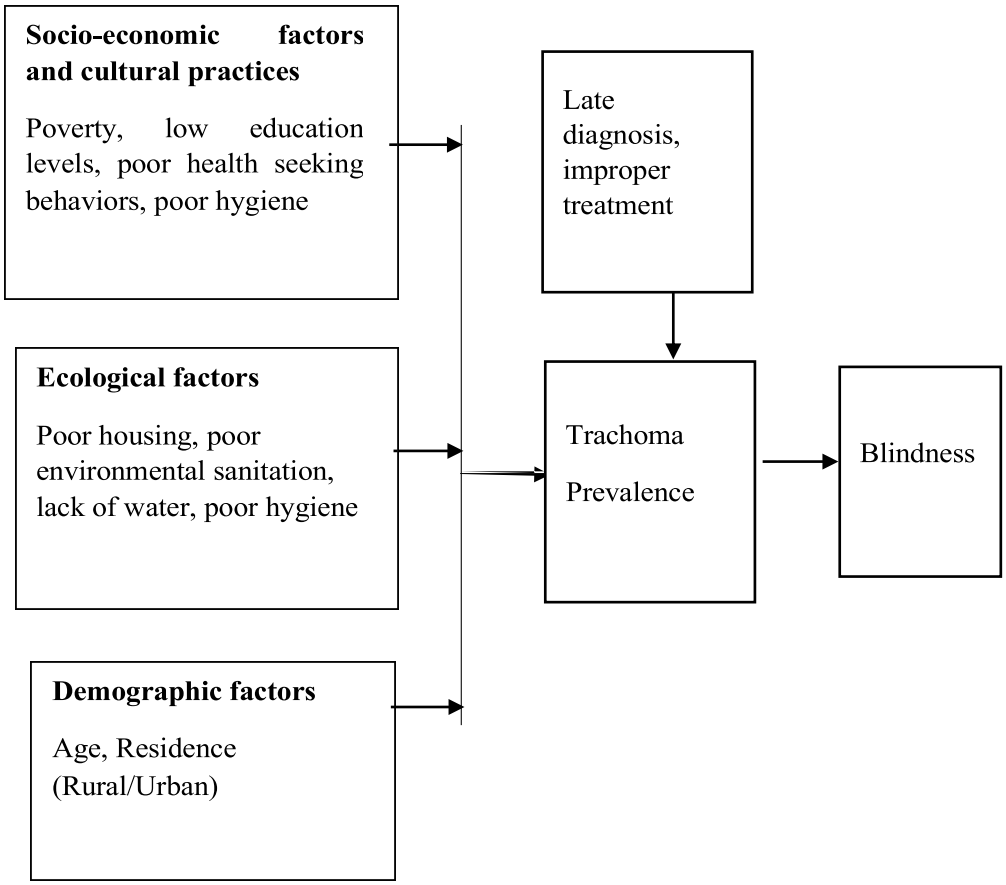

Figure 1.1: Conceptual Framework

CHAPTER THREE

METHODS

3.1 Study Site and Design

This was a community based cross-sectional study conducted in 2018 within Laikipia County, which is one of the 47 counties in Kenya. The county (figure 3.1) is located in the rift valley had a population projection of 488,190 by 2017. It is bordered by Samburu, Isiolo (North-east), Meru (East), Nyeri (South-east), Nyandarua (South-west), Nakuru (South-west) and Baringo (West) covers approximately 9,462km ^{2} and lies between 1,500m and 2,611 m above sea level. It's well known for large-scale private ranches and wildlife which cover 50% of the county as reported in the Laikipia county integrated development plan (CIDP). The county comprises of three sub-counties: Laikipia East, Laikipia West and Laikipia North and bordered by Samburu to the North, Isiolo to the North East, Meru to the East, Nyeri to the South East, Nyandarua and Nakuru to the South West and Baringo to the West (CIDP, 2012). Using the 2009 census population with the predicted inter-censual growth of 3%, the 2017 estimate for the target population for ≤9 was 138,999 (KNBS, 2009).

Laikipia comprises of three evaluation unit represented by the three constituencies: Laikipia North, Laikipia West and Laikipia East. The county is semi-arid, largely rural and sparsely populated. It is one of the 12 trachoma endemic counties and has been implementing S, F & E of the SAFE strategy since 2007.

Table 3.1: Laikipia County Electoral Wards by Constituency

Name of constituency	Name of Wards	Number of Wards	2017 projected Population
Laikipia North	Mukogodo East, Mukogodo West, Segera, Sosian	4	99,792
Laikipia East	Ngobit, Tigithi, Thingithu, Nanyuki, Umande	5	137,149
Laikipia West	Olmoran, Rumuruti Township, Mithiga, Marmanet, Igwamiti, Salama	6	251,249
Total		15	488,190

Source: *Independent Electoral and Boundaries Commission, 2012*

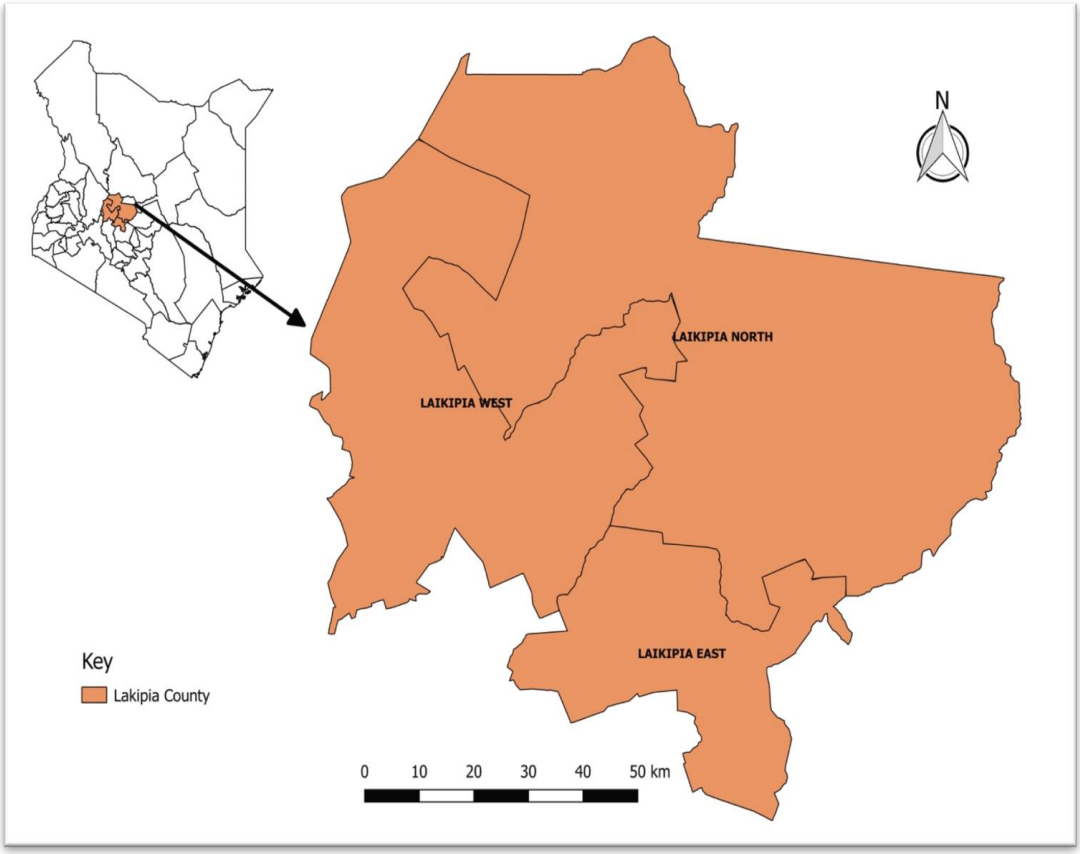

Figure 3.1: Map of Laikipia County

3.2 Study Population

Using the global trachoma task force guidelines on age inclusion for Trachoma Inflammation-Follicular (TF), the study population were selected from residents of Laikipia County aged 1 – 9 years whom were eligible to participate in study.

3.2.1 Inclusion Criteria TF participants

i Any child aged 1-9 years who is a resident of Laikipia for at least one year whose guardian consented or child assented (depending on age) to participate in the study.

3.2.2 Exclusion Criteria TF participants

i Any child aged 1-9 years who are too sick to participate at the time of the study.

ii Any child aged 1-9 years who has been treated for TF in the last one month or is on treatment for the same.

3.3 Sample Size Assumptions and Calculation

Using the single-population-proportion-for-precision(SPPP) formula as described (kirkwood et al., 2010) the following assumptions were made: a prevalence of TF of 9.5% in ages 1-9 years in Laikipia County (Karimurio et al., 2007), a margin of error of 5%, a 95% confidence interval, absolute precision of 0.20% and a design effect for cluster survey =2.63 (who, 2018) increasing the sample size to account for the cluster sampling effect , the sample size was calculated using the SPPP formula: $n=DEFF \times (z^2 \times p(1-p)/c^2) \times e$

Where:

DEFF= design effect

z= standard deviation corresponding to 95% confidence interval

p= expected prevalence

c=absolute precision

e= inflation factor to account for non-responses

A minimum number of 970 children aged 1-9 years was to be examined which was adjusted with a non-response rate inflation factor of 1.2 making the target number to be enumerated per each EU to be 1164.

3.4 Sampling Methods

Using the multistage approach in each trachoma evaluation unit (EU) (solomon et al., 2006), we determined the clusters and households. Where a sampling frame with a list of all clusters (villages) and households from all the EU's was obtained from the County office. From is a list of 30 villages were systematically selected from each of the three EU using population proportional to size (PPS) based on the in reference to the 2009 population census (K.N.B.S, 2009). In every cluster, 30 households (primary sampling unit defined as people living together and eating from the same pot) were randomly selected using simple or compact segmentation sampling based on the number of households in each segment. In cases where there were many households in a village compact segmentation was conducted. In each segment a minimum of 30 households was ensured. In which one segment was selected by listing the number of segments on a piece of paper, folding it and putting it in a hat, mixing and picking one piece. Which indicated the segment from which the households were to be selected from. While in the households, all residents aged 1-9 years who met the inclusion criteria were invited to participate and assessed for signs of TF (which are defined as presence of five or more follicles in the central part of the upper tarsal conjunctiva, each at least 0.5 mm in diameter).

3.5 Data Collection

The data collection tools were pre-tested in Baringo County (which is one of the Trachoma endemic county before the main study), where a set of standardized questionnaire regarding the participant's demographic data, trachoma and water and sanitation factors were administered among the 1-9 year guardians. All the necessary correction and restructuring of the question was done to ensure clarity. Data were collected electronically using Samsung J6 android smartphones. Consent forms were filled before the administration of the standardized questionnaires done through face to face interviews. Daily completeness and accuracy of the data was done once the data were entered. Participants were examined for TF signs by examining their eyes using x2 binocular loupe under sunlight or pen torch. Where eyelids were inverted to check for presence of follicles in the central part of the upper tarsal conjunctiva, each at least 0.5 mm in diameter (TF signs) and degree of papillary hypertrophy on the sub tarsal conjunctiva (W.H.O, 2004).

The study estimated WASH indicators which included: the source of drinking/wash water, the duration of time taken to get water, the type of defecation amenities and the availability of soap and hand washing facility at the time of visit.

3.6 Data Analysis

Data was entered electronically, cleaned and checked for completeness at the end of each day. All data was analyzed using STATA 12 software. Descriptive analysis was done and TF prevalence calculated by EU, using clinical positive cases as numerator and all examined the as denominator. Trachoma clinical signs as considered as the dependent variable while demographic (Age, sex, residence and marital status), risk factors (water availability and accessibility, sanitation and hygiene and observations

(presence of flies, children with eye discharges) as independent variables. Bivariate and multivariate analysis were undertaken to identify any association between the exposure factors and dependent variable using odds ratio as measure of association at 95% confidence interval and chi square test at as measure of significance.

All factors with a p value of < 0.2 were entered into unconditional logistical regression using the backward elimination method until the final model of factors associated with trachoma infections was arrived at. Level of statistical significance were set at a p value<0.05 and significance effect of risk associated with active disease TF among the participants were determined.

3.7 Ethical Consideration

Written informed consent were obtained from all study participants guidance or parents aged ≥18years. Voluntary participation was ensured with no infringement of the participants right to seek or receive health care and were entitled to withdraw from the study at any time. Confidentiality of data collected guaranteed by the use of unique codes, key and lock cabinets with only the authorized person having access to the data. No monitory incentives were offered to the participants but findings of the study are of great benefit to the general public health.

Ethical approval was sought from Institutional Research and Ethical Committee (I.R.E.C) – Moi University IREC/2017/238 and official letter of permission was obtained from ophthalmic service units and clearance sort from the county health director for health.

CHAPTER FOUR

RESULTS

4.1 Demographic Characteristics

A total of three thousand and one hundred and ninety-three participants from the three EU's aged 1-9 years were selected to participate and examined of whom 1,625 (50.9%) were male. Laikipia North had a total of 1,126 (35.3%) of all the enrolled and examined participants.

Table 4.1: Demographic characteristics of TT and TF in Laikipia County 2018

Variables	Age group
	1-9 years (TF survey)
Sex	
Male	1,625 (50.9%)
Female	1,568 (49.1%)
Sub county	
Laikipia North	1,126 (35.3%
Laikipia East	1,037 (32.2%)
Laikipia West	1,030 (315.)
Total recruited and examined	3,193

4.2 Prevalence of Trachoma Inflammation – Follicular (TF)

Of the examined, 3,193 participants aged 1-9 years male:female ratio was approximately 1:1. The overall prevalence of TF was estimated at 2.50%, (n-112, [95% CI 0.73 - 3.94]). Among those with the active trachoma, 62(55.4%) were male, which was an approximate ration of 1:1for male:female ratio. Distribution of TF by evaluation units: Laikipia North had the highest prevalence of TF at 3.94% (n=63 [95% CI 2.18-6.33%]), followed by Laikipia West at 2.84% (n=43 [95% 0.30-6.96]) and lastly Laikipia East at 0.73% (n=6 [95%CI 0.13-1.61%]).

Table 4.2: Trachoma Folliculitis prevalence in Laikipia County

	Trachoma Inflammation Follicular prevalence
Overall participants Either right and left eye	2.5%, (n-112, [95% CI 0.73 – 3.94%])
Laikipia North EU	3.94% (n=63 [95% CI 2.18-6.33%]),
Laikipia West EU	2.8% (n=43 [95% 2.18-6.96%])
Laikipia East EU	0.73% (n=6 [95%CI 0.13-1.61%]).

4.3 Description of cases with Trachoma Inflammation – Follicular (TF) in Laikipia County, 2018

Among the 112 cases with TF,63(56.3%) were residence of Laikipia North, 43(39.4%) Laikipia west and Laikipia East accounted for 6(5.4%). Of the cases in Laikipia North, 42(66.7%) of the cases were clustered across six villages Elmokongo (14), Sieku (8), hgr picha (8), Ngiloriti, Olmalo& Lolngede 4 each. Of the cases in Laikipia West, Mathitra village accounted for 32(74.4%) while Laikipia East there were no clustering of cases noted.

The disease was not uniformly distributed across the county. Of all the TF cases identified in the study, they we in were distributed across 90 households (5.1%). Of which 71(78.9%) had one member who had TF and 19(21.9%) has two or more cases with the highest as four household members (fig 4.1).

The age distribution of the participants with TF signs was a median age of 4years (IQR 2.5years) while those with no signs of TF was a median age of 5 years, (IQR= 3-7 years)

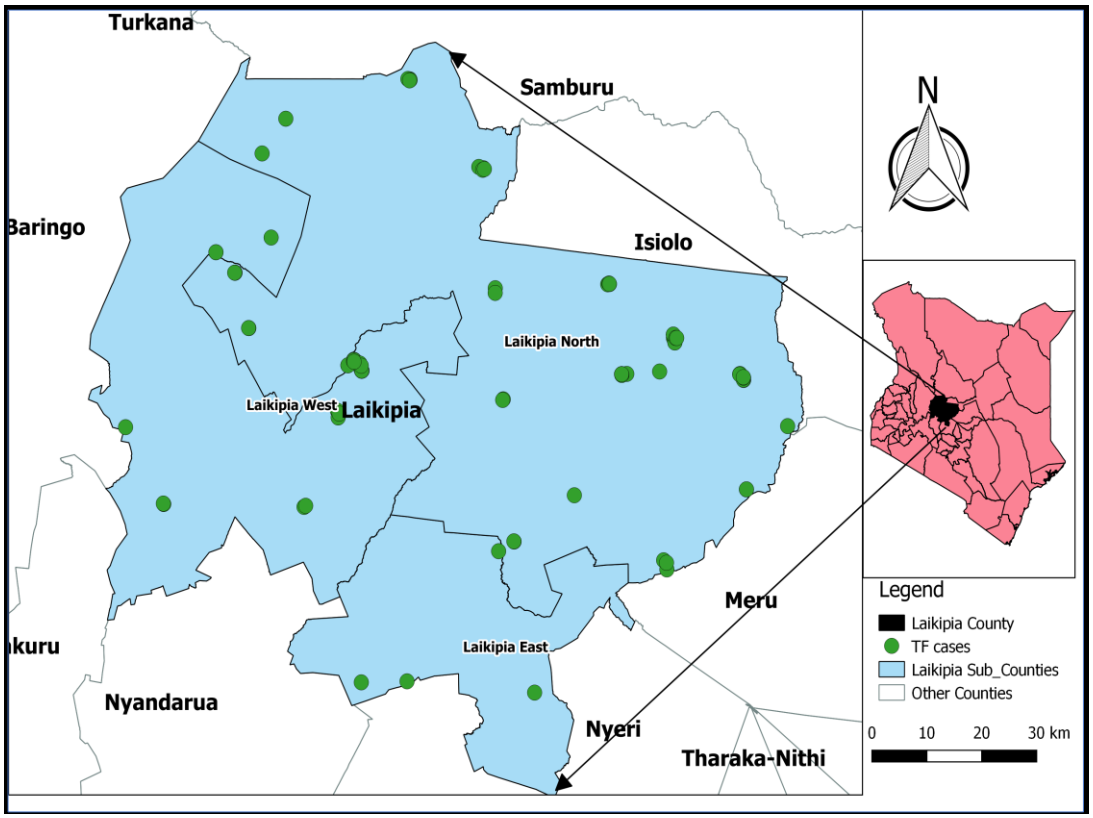

Figure 4.1: Distribution of Trachoma Inflammation Follicular case distribution by households in Laikipia County, 2018.

4.4 Water, hygiene and sanitation practices among the participants with TF

Table 4.3 Shown the different sources of wash and drinking water as reported by the 112 participants with TF. Of whom 74(66%) report surface water like rivers, dams and lakes being their main water source followed by borehole water 14 (13%), protected spring 11(10%), piped water/ public piped water each at 3(3%), water vendor/piped water into the yard each at 2(2%), Protected dug well/unprotected spring each at 1(1%). Of them, 72(64%) reported to taking more than 1hour per day to fetch water and back.

Table 4.3: Source of household water and distance to and back from the water source for households with TF cases in Laikipia County

		Number	Percent (%)
Source of household water			
	Surface water (river, dam, lake, canal)	74	66.1
	Tube well/borehole	10	8.9
	Protected spring	10	8.9
	Protected dug well	6	5.4
	Piped water into yard	3	2.7
	Public tap/standpipe	3	2.7
	Water vendor	3	2.7
	Piped water into dwelling	2	1.8
	Unprotected spring	1	0.9
	Unprotected dug well	0	0
	Rainwater collection	0	0
Distance from the household to the water source (roundtrip)			
	Water source in the yard	6	5.4
	Less than 30 minutes	7	6.3
	Between 30 minutes and 1hour	27	24.1
	More than 1 hour	72	64.3

Only 27 (24%) of them had structure toilets in their households at the time of the study. Majority 67(60%) shared the same living compounds with domestic animals with poor sanitation conditions observed as well as many flies

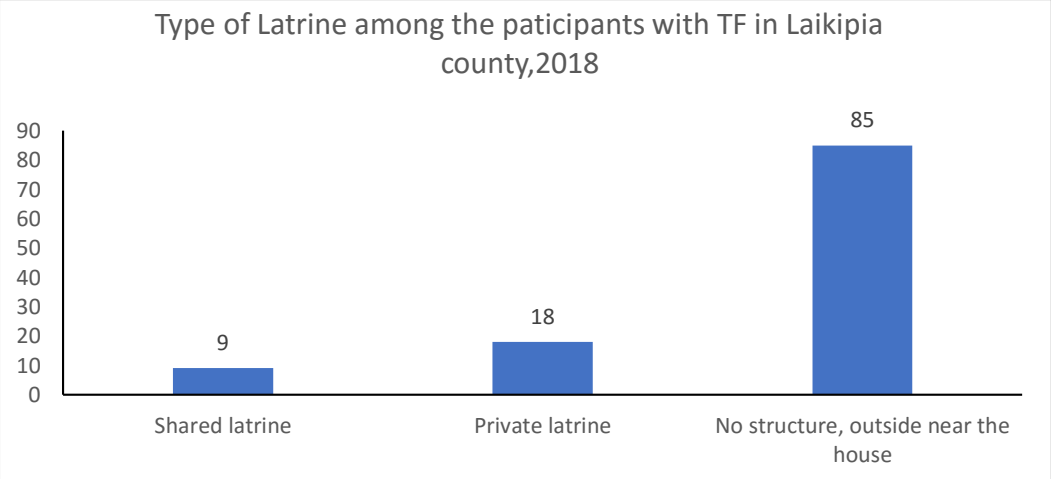

Figure 4.2: Type of latrine by household

4.5 Results of Bivariate Analysis

Table 4.3 below shows the odds ratio as a measure of association and Chi-square test used as a test of significance for analysis of association between the source of drinking water and wash water, distance taken to fetch drinking water and back, observation for type of toilet facilities at the homestead, availability of soap and water at the hand washing facility with outcome of having TF signs. Water source that was not protected, distance that took more than one hour to get water and back, Non-structured defecation facility.

Household residence getting unprotected drinking OR 8.2 (p-value <0.001) and unprotected wash water source OR 9.9 (p-value 0.001), taking more than one hour to get drinking water OR 3.1 (p-value <0.001) or wash water OR 2.9(<0.001) and with open defecation amenities OR 25 (p-value 0.001) were significantly associated with residents aged 1-9 years presenting with signs of TF (Table 4.3).

Table 2.4: Results of Bivariate analysis to evaluate the association between individual exposure factors for TF signs

	Category	TF sign present Freq (prop) n=108	Odd Ratio	P-value
Drinking water source	Exposed	84 (75%)	8.2	<0.001
	Unexposed	28 (25.%)		
Time taken to getting drinking water	>1 hour	71 (63.4%)	3.1	<0.001
	At most 1 hour	41 (36.6%)		
Type of wash water source	Exposed	86 (76.8%)	9.9	<0.001
	Unexposed	26 (23.2%)		
Time taken to get wash water	>1 hour	69 (61.6%)	2.9	<0.001
	At most 1 hour	43 (38.4%)		
Type of defecation amenities	Non-structured/outside	85 (75.9%)	25	<0.001
	Structured	27 (24.1%)		
Soap availability	No	84(75%)	8.2	<0.001
	Yes	28 (25%)		
Hand washing facility availability	No	111 (99.1%)	30	<0.001
	Yes	1 (0.9%)		

4.6 Results of Multivariate Analysis

In multivalent analysis, drinking water source (aOR= 1.17, 95% CI 0.57 – 2.44%, P value=0.666), time take to get water > one hour (aOR=2.42, 95% CI 1.17 – 5.05%, P value= 0.018), lack of private defecation amenities (aOR=2.14, 95% CI 1.05 – 4.37%, P value 0.036) were independently associated with signs of TT among adult aged ≥15 years. TF signs among age 1-9 year were associated with lack of having a defecation amenities (aOR=5.64, 95%CI 3.55 – 8.95%, P value <0.001), getting drinking water more than one hour away (aOR 3.31, 95% CI 2.27 – 4.83%, P value <0.001) while lack of soap availability (aOR=1.02, 95% CI 0.14-7.50, P value=0.97), and unprotected

drinking water source (aOR=1.73, 95% CI 1.15 – 2.59, P value=0.08) were not associated with presence of TF signs among aged 1 – 9 years.(Table 4.4)

Table 4.5: Multivariable logistic regression analysis of risk factors of TF among study participant in Laikipia County 2018

Category		Trachoma Inflammation Follicular (n=112)		
		aOR	95% CI	P-value
Drinking water source	Exposed	1.15	0.31-4.28	0.834
	Unexposed	Ref		
Time taken to get drinking water	>1 hour	2.54	0.42-15.32	0.308
	At most 1 hour	Ref		
Type of defecation amenities	Non-structured	5.22	3.12-8.75	**<0.001**
	Other	Ref		

Ref: Reference category. aOR adjusted odds ratio, CI confidence interval, NA Not applicable for Multiple logistic regression

CHAPTER FIVE

DISCUSSION

5.1 Main Findings and Interpretation

This study showed that overall TF prevalence among aged 1-9 years was 2.5% in contrast to 9.5% at baseline. Which indicates a good decline of the active trachoma after implementation of the SAFE strategy achieving the WHO targeted TF prevalence of <5% elimination threshold to consider it as no longer a public health problem. Nevertheless, to sustain the gains made over the years there is need to continue with facial cleanliness and environmental improvement.

Male were noted to be more affected elsewhere, a study done in Gale district, south Ethiopia that showed female were affected with active trachoma twice as often as males (Teshome, 2004). As well as a study in Tanzania indicating that girls had a slightly higher prevalence of active disease than boys (Courtright et al., 2004) and women whom more often are the care givers are more likely to be infected than men (Solomon et al., 2003).

Laikipia North was noted to have majority of the cases as compared to the other EU in Laikipia County which is dry, arid and more rural. There was also household clustering of TF cases in villages with the sub county. Which would suggest passing of infection among family members leaving within the same household or common environmental or social economical exposures. These agrees with similar findings from a study in Gambia (Bailey R, 1989). Some of cluster villages had TF prevalence was >10% where county targeted approach would be recommended since trachoma is a focal disease. Trachoma has been previously termed as a community clustering disease associated with individual families and not as isolated cases as was noted in a study in Tanzania

(Sheila et al., 1991). The findings will add impetus to trachoma control by identified villages that presented with TF cases and TT patient that required surgery and necessary scale up of surgical service.

5.2 Wash and Sanitation Factors

It was observed that increased assess to water resulted to improved hygiene as well reduced time taken to the water source and by so doing reduced the spread of Trachoma. Finding were consistence with other studies that show that there is reduction of TF in the community with presence on of adequate water supply (Golovaty et al., 2009). This was consistent with our findings among 1 – 9 year children living in households that fetch drinking water from unprotected dug wells, unprotected springs, and/or surface water (Exposed) had 73% increased risk of TF compared to those in the unexposed group (drink piped water, tap water, rainwater) after adjusting for the effect of other predictors in the model. Similar findings were observed among family who identified unprotected well as their primary source of water (Tielsch et al., 1988).

Children aged 1 – 9 years in households that take more than 1hour (Exposed) to reach the drinking water source had 3.3 times increased risk of having signs of TF compared to children in households that take ≤1hour (unexposed group).

Further, 1-9 years old children in households that had no toilet structure had 5.6 times increased risk of presenting with the active form of the disease as compared to children in households with private latrines. This was consistent with another study that observed increased assess to sanitation was associated with lower outcome of Trachoma (Meredith et al., 2014). It is also stated that latrine availability reduces the open defecation hence reducing the bazaar fly, *Musca sorbens* bleeding medium which is

believed to be a vector of importance in the transmission of the disease (Emerson PM, 1999).

There was no statistically significant difference in the risk of a 1 – 9-year-old child in households that did not have soap at the hand washing facility (exposed) presenting signs of TF relative to a child in households that had soaps at the hand washing facility (unexposed). The observation was similar to a study conducted in south Mexico that showed no association between presence of active trachoma and use of soap to wash hands (Taylor et al., 1985).

5.3 Study Limitations

In this study despite assessing the WASH facilities it was hard to evaluate the usage hence we focused only on availability.

There is no standardized measure for WASH indicators in relation to presence nor absence of trachoma hence difficult grouping the WASH exposure factor

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The overall prevalence in Laikipia is 2.5 % with Laikipia North recording the highest at 3.5% which is within the WHO elimination threshold and hence it no longer a public health concern.

Male were more affected and clustering of cases in households also noted among the households where TF cases lived.

Majority of the households where the TF cases lived got water from surface water like: (rivers, dam, lake and canal) and took more majority took more than one hour around trip to fetch water.

Most of the TF cases (75%) had no structured toilets with others admitting to open defecation near the house.

6.2 Recommendations

To sustain the gains there is need to continue with facial cleanliness and environmental improvement of the SAFE strategy.

There is need to scale up community advocacy on clean water accessibility and facial cleaning by the county WASH focal person as well as collaboration with WASH partners.

More community based sensitization on proper waste disposal, sanitation and hygiene measures by the county public health department. Especially in Laikipia North where majority of the cases were clustered and a targeted approach can be deployed.

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APPENDICES

Appendix I: Time Lines

	Jun 17	Jul 17	Aug 17	Sep 17	Oct 17	Nov 17	Dec 17	Jan 2018	Feb 18	Mar 18	Apr 18	May 18	Jun 18	Jul 18
Protocol development														
Contact supervisor														
Protocol Defense														
Ethical Submission														
Approval														
Data Collection														
Data analysis														
Thesis writing														
Thesis presentation														

Appendix II: Consent Form

My name is Dr. Mwatha Stephen, I am a mater's Student at Moi University doing Field Epidemiology and Laboratory Training. I am carrying out a study on the prevalence, risk factors, serotypes and vector distribution of trachoma in Laikipia County, 2017

Purpose of the study

The aim of this study is to determine the Prevalence and Risk factors for trachoma Infection among children aged 1-9 years and persons aged ≥15 years in Laikipia County. This disease is the second leading cause of preventable blindness in the world.

Study procedures

The principal investigator will first seek consent from the participants and the children's guardians. Using the set inclusion criteria will recruit guardians of children aged 1-9 years and persons ≥ 15 years old for interviews. Whereby details regarding the children and participant's demographic characteristic as well as risk factors in relation to trachoma will be collected.

Risks/discomforts

This study will interrupt the respondent's daily activity as well as consume their time.

Benefits

The study is academic with no direct benefits to the participants but results from it will go a long way to help address the health challenges facing the community. Anyone who is diagnosed with trachoma will be linked with care.

Study Costs

The study is purely voluntary and no payment will be paid to the participants.

Alternative to participation

The participants are free to refuse or even withdraw from participating and no victimization.

Confidentiality

All information will be kept confidential and unique identifiers will be used instead of participant's names. Questionnaires will be kept in a lock and key and data collected will only be accessible by authorized personnel.

Voluntariness

The exercise is purely voluntary and you're welcome to participate.

Contacts

In case of any queries or concerns, please contact Dr. Mwatha Stephen, Principle Investigator

Cell No: 0718151624; Email: dsmwatha@gmail.com

Signature ……

Relation to the child……

Thumb print/Signature of the guardian of the participant (above 18 years)

Thumb Print in here

Signature …….……

Date ……

Is the participant ≥ 18 years

Yes …… No …….

Participant Signature ……Date……

Researcher's signature …… ……Date ……

Appendix III Consent Form (Kiswahili)

Jina langu ni Dk. Mwatha Stephen, Mimi ni Mwanafunzi wa Chuo Kikuu cha Moi akifanya Epidemiology ya Field na Mafunzoya Maabara. Nina fanya utafiti juu ya kuenea kwa ugonjwa wa trachoma katika counti ya Laikipia, 2017

Kusudi la utafiti

Lengo la utafiti huu ni kuamua sababu za kuenea na hatari zinazo abatana na ujongwa wa trachoma kati ya watoto wenye umri wa miaka 1-9 na watu wenye umri wa miaka ≥15 katika countie la Laikipia. Ugonjwa huu ni sababu ya pili inayoongoza kwa upofuu na oweza kuzuiwa duniani.

Njia za kujifunza

Mpelelezi wa kanuni atakata futa kibali kutoka kwa washirikina wa lezi wa watoto.

Kutumiavigezovyakuingizwakuwekawataajiriwatotowawatotowenyeumriwamiaka 1-9 nawatu ≥ miaka 15 kwa mahojiano.

Ambapokwamaelezojuuyawatotonatabiayaidadiyawashirikiwamshirikipamojanasabab uzahatarikuhusianana trachoma zitakusanywa.

Hatari / kuchanganyikiwa

Utafiti huu utasimamisha shughuliya kila mhojiwana pia hutumia muda wako.

Faida

Utafiti huo ni wakitaaluma bila faida moja kwa moja kwa washiriki lakini matokeo kutoka kwao yata kwenda kwa muda mrefu ilikusaidia kukabiliana na changamoto za afya zinazokabili jamii. Mtu yeyote anayeambukizwa na trachoma ataunganishwa na utunzaji.

Gharama za kujifunza

Utafiti huo ni kwa hiari tu na hakuna kulipa malipo kwa washiriki.

Mbada la wakushiriki

Washiriki ni huruku kataa au hatakujiondoa kutokana na usumbufu na hakuna unyanyasaji.

Usiri

Taarifa zote zitahifadhi wa za siri na za kipekee zitatumiwa badala ya majina ya mshiriki. Maswali yata wekwa katika lock na ufunguo na data zilizo kusanywa zitapatikana tunawafanya kazi wenye mamlaka.

Kujitolea

Zoezi hili ni kwa hiari tu nauna kubali kushiriki.

Mawasiliano

Ikiwakuna maswali yoyote au wasiwasi, tafadhali wasiliana na Dk. Mwatha Stephen, Kiini cha Upeleleziwa Kanuni No: 0718151624; Barua pepe: dsmwatha@gmail.com

Sahihi ……

Uhusiano na mtoto .....

Thumb Print in here

Chapishakuchapa / Saini yamlezi wa mshiriki (Zaidi ya miaka 18)

Saini ..... Tarehe …….

Ni mshiriki ≥ miaka 18

Ndio/ la …….

Ishara ya Washiriki ..... Tarehe .....

Saini ya Mtafiti .... Tarehe .....

Appendix IV: Household Questionnaire

Identification

Cluster Number ……Household Number……Village Name ……..…

Name of Interviewer……Interview date____/_____/_____

Household Latitude (N) ……. Household Longitude (E) …….....

Socio-demographic information of parent/guardian

1. How old are you? (Years).....
2. What is your relationship with the children?
    a) Parent
    b) Guardian
3. What is your level of education?
    a) No formal education
    b) Primary
    c) Secondary
    d) College
    e) University
4. Sex
    a) Male
    b) Female
5. Age (years) …….

Disease present

6. Is there any sign of disease?
    a) Yes
    b) No

Water and sanitation

7. Is there adequate water in your compound?
    a) Yes
    b) No
8. What is the source of your water?
    a) Piped water
    b) Public tap
    c) Borehole
    d) Protected dug well
    e) Shallow well
    f) Surface water like: dam, river or lake
    g) Protected spring
    h) Natural spring
    i) Other(specify)
9. How long does it take to get water and back?
    a) Water source at the yard
    b) Less than 30 minutes
    c) More than one hour
10. Do you have any domestic animals (cow, goats, sheep, camel, dog, and birds)?
    a) No
    b) Yes

11. If yes, where do you keep them?
    a) Living rooms
    b) In the compound
    c) Outside compound
12. What is the source of drinking water during the dry season?
    a) Piped water
    b) Public tap
    c) Borehole
    d) Protected dug well
    e) Shallow well
    f) Surface water like: dam, river or lake
    g) Protected spring
    h) Natural spring
    i) Other(specify)
13. How long does it take to get water and comeback?
    a) Less than 30minutes
    b) Between 30 minutes to 1hour
    c) More than 1hour

Personal Hygiene

14. Do you wash your hands after defecation?
    a) Yes
    b) No

15. If yes, what do you use in washing your hands?
    a) Plain water
    b) Water and soap
    c) Other(specify)
16. Is there a hand washing facility with the 15 meters from the latrine?
    a) Yes
    b) No
17. At time of visit is there soap or detergent available at the hand washing facility?
    a) Yes
    b) No
18. Do you wash your face with clean water?
    a) Yes
19. Do you wash your hands after defecation?
    a) Yes
    b) No
20. If yes, what do you use in washing your hands?
    a) Plain water
    b) Water and soap
    c) Other(specify)
21. Is there a hand washing facility with the 15 meters from the latrine?
    a) Yes
    b) No
22. At time of visit is there soap or detergent available at the hand washing facility
    a) Yes
    b) No

23. Do you wash your face with clean water?

    a) Yes

    b) No

24. If yes, how often in a week?

    a) Once

    b) Twice

    c) Other(specify)

25. If yes, what is the nature of the water you use for bathing?

    a) Flowing water

    b) Water in a basin

    c) Other(specify)

Latrines and Sanitation

26. Where do you and other adults in defecate?

    a) Private latrine

    b) Shared or public latrine

    c) Behind the house

    d) In the bushes

    e) Other(specify)

27. Are there any myths associated with use of the latrines?

    a) Yes

    b) No

If yes, what are they? …… ……

28. Observe whether there are house flies in the compound.

    a) Yes

    b) No

29. Observe whether there are house flies around children's eyes.

    a) Yes

    b) No

Appendix VI: Institutional Research and Ethical Committee Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

Reference: IREC/2017/238
Approval Number: 0003011

9th May, 2018

Stephen Mwatha,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
09 MAY 2018
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dear Mr. Mwatha,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"The Prevalence, Risk Factors and Serotypes Distribution of Trachoma in Laikipia, Kenya 2017".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 3011*** on 9th May, 2018. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 8th May, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix VII: CDC Ethical Approval

CGH HSR Tracking #: 2018-244

Request for Project Determination & Approval -- Center for Global Health (CGH)

Use this form to submit proposals to the CGH Office of the Associate Director for Science/Laboratory Science (ADS/ADLS) for research/nonresearch determination and requirements for IRB review/approval.
Approval Chain: Investigator → Branch Chief/Country Director →Division ADS → CGH Human Subjects Mailbox

☑ **New Request** ☐ **Amendment** ☐ **Laboratory Submission**

Project Title: The Prevalence, Risk Factors and Serotypes Distribution of Trachoma, Laikipia County, Kenya, 2017		Project Location/Country(ies): Kenya
CDC Principal Investigator's name and SEV#: Sara Lowther 9200	CDC Primary Contact's name and SEV# (Leave blank if same as PI):	
Division: DGHP	CDC PI or PC Email: sgl6@cdc.gov	Telephone: +254 710 602 791
Project start date (mm/dd/yyyy): 05/21/2018	Project end date (mm/dd/yyyy): 05/20/2019	

Collaborating Institutions (List other collaborating institutions in the protocol or in a separate document)

☑CoAg ☐Grant ☐contract #:	Original Award Year if CoAg:	Current Budget Year if CoAg:
Title (CoAg, Grant, or Contract): MOH coag (PEPFAR, GHSA), AFENET coag, PMI, GHSA		
Supported Institution Name: Ministry of HEalth FELTP, AFENET		
Supported Institution FWA# (if applicable):	FWA Exp. Date (if applicable):	

Check appropriate category and subcategoryy

☑ **I. Activity is NOT human subjects research. Primary intent is public health practice or a disease control activity (Check all that apply)**
- ☐ **A.** Epidemic or endemic disease control activity; if applicable, Epi-AID #
- ☐ **B.** Routine surveillance activity (e.g., disease, adverse events, injuries)
- ☑ **C.** Program evaluation activity*
- ☐ **D.** Public health program activityΩ
- ☐ **E.** Laboratory proficiency testing

* Evaluation of a new intervention for effectiveness and comparison of different interventions are research under CDC policy.
Ω e.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction and/or support; development of patient registries; needs assessments; and demonstration projects intended to assess organizational needs, management, and human resource requirements for implementation.

☐ **II. Activity is research but does NOT involve human subjects (Check all that apply)**
- ☐ **A.** Activity is research involving collection or analysis of data about health facilities or other organizations or units (NOT persons).
- ☐ **B.** Activity is research involving data or specimens from deceased persons.
- ☐ **C.** Activity is research involving unlinked or anonymous data or specimens collected for another purpose.
- ☐ **D.** Activity is research involving data or specimens from animal subjects. §

§Note: Approval by CDC Institutional Animal Care and Use Committee (IACUC) may be required for certain animal research. Institution must also have assurance with the Office of Laboratory and Animal Welfare at NIH.

☐ **III. Activity is research involving human subjects but CDC involvement does not constitute "engagement in human subject research."** CDC employees or agents will not intervene or interact with living individuals or have access to identifiable information for research purposes. Appropriate IRB or ethics committee approval is required prior to approval. **(Check all that apply)**
- ☐ **A.** This project is funded under a grant/cooperative agreement/contract award mechanism.
- ☐ **B.** CDC staff provide technical support that does not involve possession or analysis of identifiable data or interaction with participants from whom data are being collected (No CDC Supportβ).
- ☐ **C.** CDC staff are involved only in manuscript writing for a project that has closed. For the project, CDC staff did not interact with participants and were not involved with data collection (No CDC Support).
- ☐ **D.** Activity is research involving linked data, but CDC non-disclosure form 0.1375B is signed.∞

β See definition of support on page 3.
∞ CDC form 0.1375B agreement is required for all subcategories (A-D) if CDC has access to linked data. This agreement prohibits the release of identifying key to CDC investigators under any circumstances. The purposes of the planned research do not contradict the terms of consent under which the information or specimens were collected, whether that consent was documented or not documented.

☐ **IV. Activity is research involving human subjects that requires submission to CDC Human Research Protection Office (Check one)**α
- ☐ A. Full Board Review (Use forms 0.1250, 0.1370-research partners)
- ☐ B. Expedited Review (Use same forms as A above)
- ☐ C. Exemption Request¥ (Use forms 0.1250X, 0.1370-research partners)
- ☐ D. Reliance¥
  - ☐ 1. Request to allow CDC to rely on a non-CDC IRB (Use same forms as A above, plus 0.1371)
  - ☐ 2. Request to allow outside institution to rely on CDC IRB (Use same forms as A above, plus 0.1372)

α There are other types of requests not listed under category IV, e.g., continuation of existing protocol, amendment, incident reports.
¥ Exemption and reliance request is approved by CDC Human Research Protection Office (HRPO).