The Role of Bed Net Usage and Lymphatic Filariasis Transmission in Kenya

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An abstract of

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Abstract

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Background: Mass Drug Administration (MDA) has been the main strategy used for the elimination of lymphatic filariasis (LF) and is conducted annually in endemic areas. However, current research supports that bed net usage can prevent transmission of LF even after a lapse of MDA implementation. This study examines LF infection rates in Kenya after a lapse of MDA and compares the infection rates with bed net usage rates in ten villages from five implementation units (IUs) in coastal Kenya where LF is endemic, thereby assessing the impact of bed net usage during the absence of MDA.

Methods: The Kenya Medical Research Institute (KEMRI) conducted cross-sectional surveys in five counties (IUs) using ten sentinel sites (ten villages) as the units of analysis. LF prevalence was determined using a rapid antigen test known as immunochromatographic card test (ICT) which detects *Wuchereria bancrofti* infections. A bed net usage questionnaire was administered, and participants' responses were captured electronically using Open Data Kit for android-based smartphones.

Key Findings: The study population was 2,996 comprised of 1,392 children under the age of 15 and 1,604 adults between the age of 16 and 100. LF prevalence of 1.18% was found in the combined population examined in the five implementation units (IUs), which is considered significant. The highest LF prevalence of 6.25% was found in Lamu County, and the second highest prevalence of 0.88% was found in Kilifi County. The lowest bed net usage was in the villages of Ndau at 74.38% and Mwadimu at 74.83%, and these two villages had the highest LF infection rates.

Conclusion: The study showed evidence that bed net usage plays a significant role in the reduction of LF transmission. Usage of bed nets as a vector control method has been shown to be effective in the control and elimination of LF transmission. This augmentative vector control is an alternative where MDAs are not always possible or have lapsed. Nets are still efficacious and necessary, even where MDAs are possible. It is therefore critical to have vector control management strategies in place that ensure the integration of MDA and augmentative vector control. Integration of MDAs and vector control strategies such as bed net usage will ensure long-term elimination goals and make the 2020 LF elimination target date a reality.

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List of acronyms and definition of terms

CDC	Centers for Disease Control and Prevention
DEC	Diethylcarbamazine Citrate
GAHI	Global Atlas of Helminths Infections
GPELF	Global Program to Eliminate Lymphatic Filariasis
HBM	Health Belief Model
ICT	Immunochromatographic Test
ITNs	Insecticide-treated bed nets
KEMRI	Kenya Medical Research Institute
LF	Lymphatic Filariasis
LF Elimination	The elimination of LF transmission
Mf	Microfilaria
MDA	Mass Drug Administration
NPELF	National Programme for the Elimination of Lymphatic Filariasis
NTD	Neglected Tropical Disease
WHO	World Health Organization

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Chapter 1: Introduction

Despite significant gains in the fight against Neglected Tropical Diseases (NTDs) such as lymphatic filariasis (LF), the tragedy continues. This study attempts to document Kenya's efforts to eliminate LF and the different strategies used for control and prevention of the disease. The study will look at LF infection rates in five implementation units (IUs) in the coastal area of Kenya and correlate the rates with the usage of bed nets by adults and children. The review will inform policy on the distribution of bed nets and assess whether or not bed nets could be distributed during mass drug administration (MDA).

The Purpose of this Research

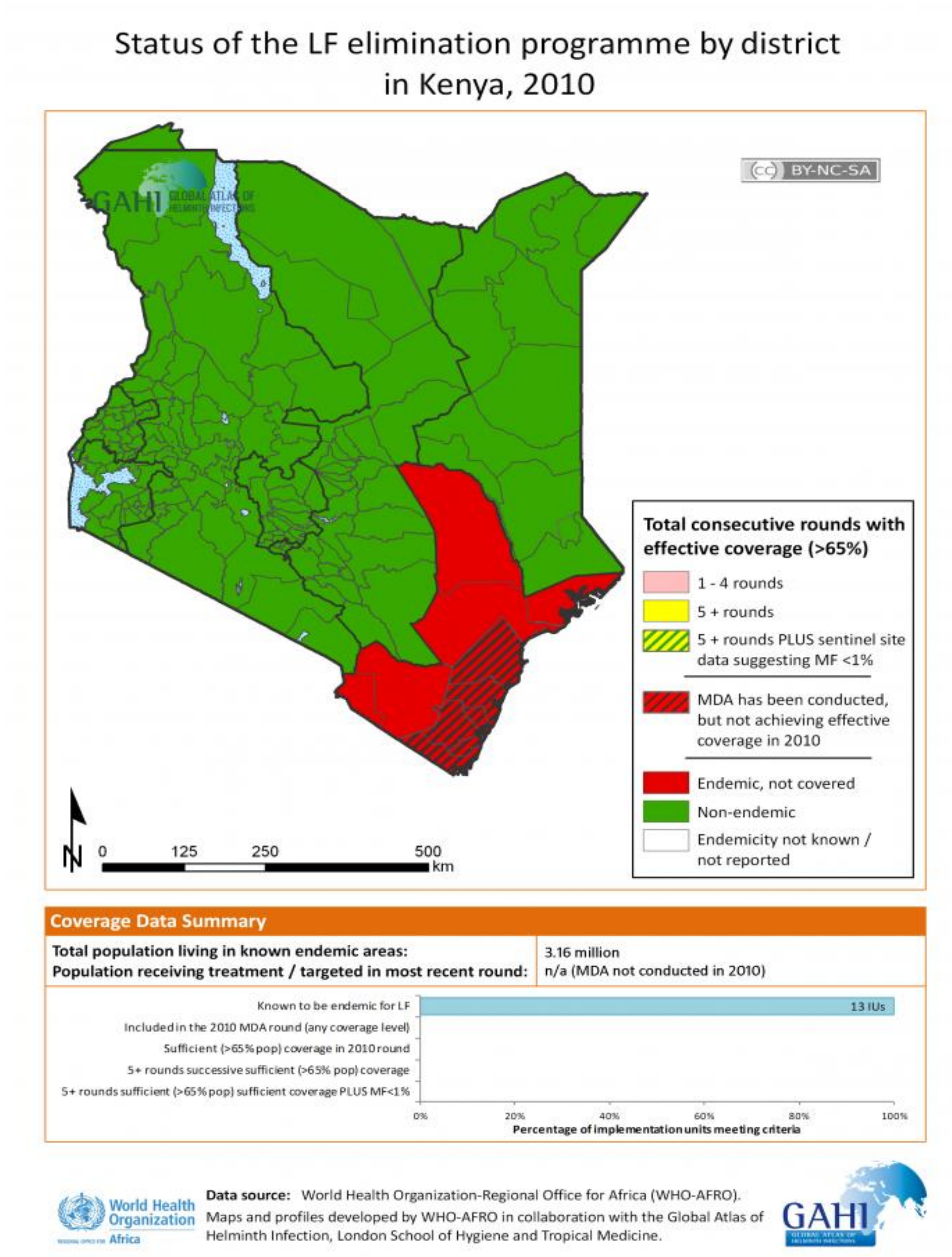
A study was conducted by the Kenya Medical Research Institute (KEMRI) in 2015 in the coastal Kenya to assess the transmission of lymphatic filariasis (LF) using a combination of diagnostic approaches and integrating assessments of co-endemic infections. Mass Drug Administration (MDA), the main strategy for the elimination of LF, is conducted annually in endemic areas, but Kenya has had financial constraints resulting in the interruption of annual MDA. The World Health Organization (WHO) recommends the following drug regimens: 1) once-yearly treatment with a single dose of albendazole plus either ivermectin or diethylcarbamazine citrate (DEC) and 2) exclusive use of table and cooking salt fortified with DEC for 1-2 years (WHO, n.d.). The Kenya National Programme for Elimination of Lymphatic Filariasis (NPELF) intended to resume the annual treatment (MDA) in 2015. The KEMRI study was critical for collecting infection data on current infection status in some selected sentinel sites in the LF endemic region before treatment or the annual MDA was resumed. One of the components of the study was the inclusion of a questionnaire (see Appendix 1) regarding bed net usage by the target population. Research has shown that insecticide-treated bed nets not only reduce the transmission of malaria but LF as well (Blackburn et al., 2006). This study will examine the role of bed nets in the transmission of lymphatic filariasis in coastal Kenya and will document any correlation between usage of bed nets and LF infection rates. Data for the study were collected by the Kenya Medical Research Institute (KEMRI) based in Nairobi, Kenya.

Problem Statement

Lymphatic Filariasis (LF), a parasitic disease and also known as elephantiasis, is a major public health problem in many tropical and sub-tropical areas of Asia, Africa, the Western Pacific, and parts of the Americas (WHO, n.d.). LF is transmitted by mosquitoes and is a disabling and disfiguring disease. It is a disease of poverty that can afflict the infected people with physiological pain, as well as psychological pain, social stigma, and it causes an economic burden to families and affected communities. Ninety percent of LF infections globally and all LF in Africa are caused by *Wuchereria bancrofti*, thread like worms that live in the lymphatic vessels (WHO, 2015). The World Health Organization states that over 120 million people worldwide suffer from lymphatic filariasis and 40 million are disfigured and incapacitated (WHO, 2015). WHO reports that one-third of the infected population live in Africa.

In Kenya, LF is mainly found in coastal rural areas where access to health care is inadequate (Wamae, et al., 2001). Moreover, Wamae, et al. state it is estimated that *all* people living in the coastal regions of Kenya are at risk of LF infection. The total population living in the endemic area is about 3.16 million (GAHI, 2010). The Kenya National Programme for Elimination of Lymphatic Filariasis (NPELF) was started in 2002 with an aim to interrupt transmission of LF infection through annual mass drug administration (MDA) of at risk populations. The first MDA for LF was launched in Kilifi District, Kenya in 2002 (Njenga et al., 2011). However, the NPELF in Kenya has not had much success scaling up MDAs due to lack of funding. Therefore, it is important to include other preventive measures such as bed nets that have shown to reduce LF infections. Many areas where malaria and LF are co-endemic use insecticide-treated bed nets (ITNs) to combat the diseases. A study done by Reimer et al. in Papua New Guinea concluded that insecticide-treated bed nets are an effective vector control strategy for *W. bancrofti* elimination in areas where anopheline mosquitoes transmit the parasite (Reimer et al., 2013). The Kenyan map below shows that only a small section of the endemic coastal region in Kenya has had MDAs. The majority if the endemic area has yet to have full coverage with MDAs. This clearly shows the importance of the necessity of other possible interventions to the vector, and why this study has significance in showing what the potential benefits of bed nets that could reach the entire endemic population could be.

Figure 1. LF Elimination Status in Kenya (GAHI,2010)



http://www.thiswormyworld.org/maps/2012/status-of-lymphatic-filariasis-elimination-programme-in-kenya

Theoretical Framework

A growing body of research shows that public health interventions developed with an explicit theoretical framework can be more effective compared to those without a theory. Additionally, most successful public health interventions are usually based on deep knowledge of health behaviors and how these behaviors occur. It is therefore critical to design public health interventions with an understanding of key relevant behavioral theories that can impact behavior change. According to research on Behavioral & Social Science, "Theories and models help explain behavior, as well as suggest how to develop more effective ways to influence and change behavior." (Department of Health and Human Services. E-Source, n.d.). They can guide research to:

- Describe why people do or do not practice health promoting behaviors;
- Identify what information is needed to design an effective intervention strategy; and
- Provide strategies to design successful Program.

The proposed theory for this study is the Health Belief Model (HBM), a conceptual formulation for understanding why individuals do or do not engage in a wide variety of health-related actions (Janz & Becker, 1984). HBM was developed in the early 1950s to look into why people did not participate in programs to prevent disease. The model has six main constraints as outlined in table 1 (Department of Health and Human Services. e-Source, n.d.).

Table 1. Core Constructs of the Health Belief Model (adapted from the Dept. of Health and Human Services, e-Source)

CONSTRUCT	**DEFINITION**
Perceived Susceptibility	What are the chances of getting infected with lymphatic filariasis?
Perceived Severity	If I contract LF, would I suffer psychological pain, social stigma, economic burden or even death?
Perceived Benefits	Will using bed nets prevent me from LF infection, thus giving me peace of mind?
Perceived Barriers	What are the stated barriers of bed net usage?
Cues to Action	Does social mobilization encourage me to use bed nets?
Self-Efficacy	Do I know how to use a bed net?

http://www.esourceresearch.org/portals/0/uploads/documents/public/glanz_fullchapter.pdf

Purpose Statement

The purpose of this study is to assess the impact of bed nets on the control and transmission of lymphatic filariasis.

Research Hypothesis

Do lymphatic filariasis infection rates in the selected sentinel villages under this study in coastal Kenya show any correlation between the use of bed nets and LF transmission?

Research Questions:

1) What are LF infection rates among adults vs. children using bed nets?

2) Was there an added benefit of bed net usage between age groups (adults and children)?

3) What other factors may have caused one age group to have reduced rates of transmission than the other? (e.g. better compliance with use of bed nets, more receptive of education about bed nets, indoor spraying, screened windows or doors, social awareness of malaria and or LF programs, community leadership involvement, etc.)

4) Can bed nets support the elimination of LF, even when MDA programs are inconsistent or ineffective?

Conclusion:

Although current research supports that bed nets can prevent transmission of LF, there is little data published to show the effect of bed nets after a lapse of MDA implementation. This study will analyze the impact of bed nets and LF infection rates in the villages under study in an area where LF, a vector-borne disease, is co-endemic with malaria. The NPELF program in Kenya has not followed the WHO recommended MDA implementation of continuous annual MDAs for about 5 years with full geographical coverage in these villages (WHO, 2010).

Chapter 2: Background and Literature Review

Lymphatic Filariasis and Its Transmission

The World Health Organization (WHO) states that lymphatic filariasis (LF), commonly known as elephantiasis, is a neglected tropical disease which occurs when filarial parasites are transmitted to humans through a bite of infected mosquitoes that deposit larval stage parasites on human skin during a blood meal (WHO, 2015). It is one of the oldest and most debilitating neglected diseases in the world (WHO, n.d.). According to CDC, the disease is caused by microscopic, thread-like worms. Only the adult worms live in the human lymph system which maintains the body's fluid balance and fights infections (CDC, 2013). The worms form *nests* in the human lymphatic system, interfering with the network of vessels and nodes that maintain the delicate fluid balance between blood and body tissues (WHO, 2016). Microfilariae (mf) are produced by adult worms in the blood where they are picked up by mosquitoes, and when the infected mosquito bites another person, it deposits the larva worms on the person skin. CDC states that in Africa, the most common vector is *Anopheles* mosquitoes; in the Americas, it is *Culex quinquefasciatus*, and *Aedes* and *Mansonia* in the Pacific and in Asia (CDC, 2013). Some of the clinical manifestation of filarial infection include: lymphedema of the limbs, genital disease (hydrocele, chylocele, and swelling of the scrotum and penis), and extremely painful recurrent acute attacks (WHO, 2015).

LF infections occur in tropical and sub-tropical regions of the world. Infection usually occurs during childhood causing damage to the lymphatic system, but the manifestation of the disease occurs later in life. WHO states that although infection is generally acquired during childhood, the disease may take years to manifest itself, and there may not be outward clinical manifestations in many people (WHO, n.d.). LF is spread from person to person through mosquito bites. When a female mosquito seeking a blood meal bites an infected person, microscopic juvenile stages of the worms known as microfilariae circulating in the person's blood enter and infect the mosquito. In the mosquito, the microfilariae develop into infective stage that can infect another person when the mosquito looks for another blood meal to help egg development. The worms grow in the lymph vessels where they eventually develop into threadlike adult worms. The adult worms live for about 6-8 years and through mating, they release millions of microfilariae into the blood. LF infection can alter the lymphatic system and cause abnormal enlargement of body parts resulting in severe pain and disability and social stigma (WHO, 2015). Statistics from WHO show that:

- About 1.23 billion people in 73 countries worldwide are threatened by lymphatic filariasis and require preventive large-scale treatment, also known as preventive chemotherapy, to stop its spread.
- Over 120 million people are infected, with about 40 million disfigured and incapacitated by the disease.
- 25 million men suffer with genital disease.
- Over 15 million people are afflicted with lymphedema.
- Approximately 66% of those at risk live in South-East Asia, and 33% in the African region. 80% of the infected people are living in 10 countries in the world including: Bangladesh, Côte d'Ivoire, Democratic Republic of Congo, India, Indonesia, Myanmar, Nigeria, Nepal, Philippines, and the United Republic of Tanzania.

- Lymphatic filariasis can be eliminated by stopping the spread of infection through preventive chemotherapy with single doses of 2 medicines for persons living in areas where the infection is present.

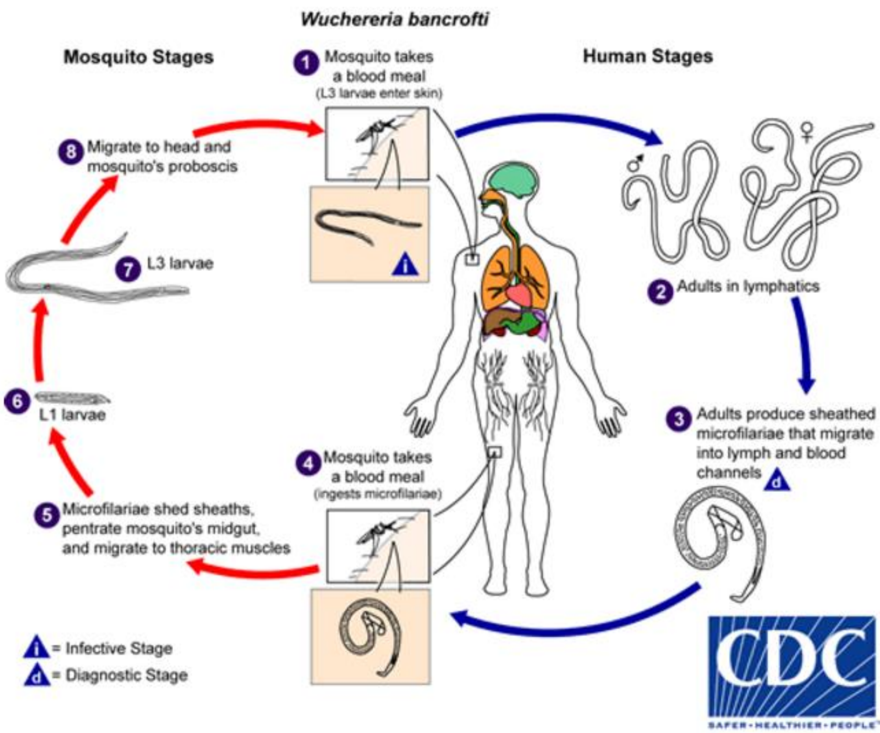
Science of Lymphatic Filariasis

There are three types of the parasite or thread-like worms that cause LF namely (WHO, 2015):

- *Wuchereria bancrofti*, which is responsible for 90% of the cases
- *Brugia malayi*, which causes most of the remainder of the cases
- *Brugia timori*, which also causes the disease.

In Africa, LF is caused by *Wuchereria bancrofti.* The worms produce millions of microfilariae (larvae) that circulate in the blood (WHO, 2015). The larvae develop from first-stage into third-stage larvae in the mosquito. Mosquitoes are infected when they ingest microfilariae in a blood meal and the lifecycle continues when an infected mosquito deposits third-stage larvae onto the skin of a human host while feeding. In about six months, the larvae grow into adult filarial worms, mate, and release microfilaria in the lymphatic vessels where they make their way into the bloodstream. If there is no intervention, the adult worms can live in the lymphatic system for about seven years and deposit millions of microfilariae. Given the inefficient lifecycle of the filarial worms, a person has to be exposed repeatedly over a very long period of time to be infected. The majority of infections can stay in the body for a long time without showing external signs of infections. However, the asymptomatic infections can still cause damage of the lymphatic system and also alter the body's immune system (WHO, 2015). The lymphatic system is a critical component of the body's immune system as it maintains the fluid balance between blood and tissues. LF infection can disrupt this balance and can cause severe pain as a result of the swelling of the legs, arms, breasts – a condition known as lymphedema – while the swelling of the scrotum is known as hydrocele. When the decreased function of the lymphatic system occurs, lymphedema patients can experience secondary bacterial infections known as adenolymphangitis attacks (ADLA) (Dreyer et al., 1999). Figure 2 shows the life cycle of *Wuchereria bancrofti.*

Figure 2. Life Cycle of Wuchereria Bancrofti.



(From CDC: http://www.cdc.gov/parasites/lymphaticfilariasis/biology_w_bancrofti.html)

Lymphatic Filariasis in Kenya

LF cases were first documented in Kenya in 1910 on Pate Island (Wamae et al., 2001). LF infection in Kenya is found in rural areas where access to health care is limited. Most of these endemic areas are in coastal Kenya where it is estimated that all people living there are at risk of LF, as they are constantly exposed to infective mosquitoes. Bancroftian filariasis is the only known type which is endemic along the Kenyan coastal districts of Kilifi, Kwale, Malindi, and Tana River (Wamae et al., 2001). Wamae et al., 2001 indicate that over 3 million people live in these endemic areas. Mass treatment (chemotherapy) with diethylcarbamazine (DEC) was started in the 1950s on Pate Island and was shown to reduce infection rates meaning that those who did not have the disease already could be prevented from becoming infected. Another control method was introduced later using ivermectin and was distributed both at regular health centers and in the community (Wamae et al., 2001). The Kenya National Programme for Elimination of Lymphatic Filariasis (NPELF) was launched in 2002 with an objective of administering MDAs in the endemic areas (Njenga et al., 2011). The program has faced some obstacles such as security instability in the endemic areas and un-sustainable funding from the Ministry of Health and other sources of funding. Therefore, it is imperative to consider other control strategies such as the insecticide-treated nets (ITNs) used for malaria control. Both malaria and LF are transmitted by the same vector making it critical to introduce the integration of vector management for both diseases.

In Kenya malaria and LF are co-endemic in the coastal areas. One of the control methods currently used for malaria is insecticide-treated nets (ITNs). There have been efforts to distribute bed nets in malaria endemic areas in order to reduce transmission. These nets are distributed by NGOs, commercial enterprises, and national programs for malaria control in Kenya. The study by Njenga et al. (2011), reports that high coverage of ITNs in the endemic areas has been associated with dramatic decline in hospital admissions due to malaria and most likely has had an impact on LF infections. Moreover, integrated vector management will result in better use of available resources by targeting multiple diseases with one intervention.

Evidence of Bed Net Usage and LF Control

Bed nets and control of diseases

Bed nets have been found to be a cost-effective method to control malaria and other mosquito-transmitted diseases such as LF. According to CDC, insecticide-treated nets (ITNs) which protect people from mosquito bites have been shown to reduce malaria (CDC, 2015). These bed nets serve as a protective barrier around a person sleeping under a bed net. CDC states that the bed nets that are treated with an insecticide are much more protective than the untreated bed nets (CDC, 2015). The treated bed nets repel mosquitoes and as a result, reduce the number of mosquitoes in the house – this results in fewer mosquito bites and fewer malaria infections. Additionally, according to CDC, in communities where there is high coverage of bed nets, the number of mosquitos, as well as the life span of the mosquito, is reduced.

Bed nets and control of lymphatic filariasis

In 2000, the World Health Organization launched the Global Program to Eliminate Lymphatic Filariasis (GPELF) with the objective of initiating activities to eliminate LF. A study by Chu et al. found that during the first eight years (2000 – 2007) of the GPELF, economic benefits were US$24 billion (Chu et al., 2010).[1] The target goal for LF elimination is 2020 (WHO, 2011).

One of the main strategies used for the interruption and prevention of LF transmission is mass drug administration (MDA). This strategy uses a combination of two filaricidal medicines (albendazole plus either diethylcarbamazine or ivermectin) delivered once-yearly to entire eligible populations in endemic areas (Ichimori et al., 2014). However, other strategies used for control of vector-borne diseases such as malaria can reduce the transmission of lymphatic filariasis in co-endemic areas, making the integration of disease control methods attractive.

Bockarie et al. state that “although significant progress in initiating MDA programs in endemic countries has been made, emerging challenges to this approach have raised questions regarding the effectiveness of using MDA alone to eliminate LF without the inclusion of supplementary vector control” (Bockarie et al., 2009). They go on to say that an integrated strategy including vector control is believed to be of potential importance as a supplement to MDAs for the control of LF. In addition, a study conducted by Sunish et al. in Tirukoilur, India found that the benefits of MDAs are sustained only with the integration of other vector control measures (Sunish et al., 2007). The inclusion of vector control can potentially reduce the time required to eliminate LF. The study done by Sunish et al. found that “vector density decreased in villages where vector control was used as an adjunct to mass drug administration and almost no infective mosquitoes were found in the small numbers still remaining” (Sunish et al., 2007). Ichimori et al. (2014) posit that vector control is recognized as a powerful tool for supplementing

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[1] These economic benefits include benefits of preventing loss of labor and income, health services for affected populations, quality of life benefits, and prevention of co-endemic diseases (WHO, 2010).

national efforts to interrupt transmission of lymphatic filariasis. They say that success of LF elimination cannot be guaranteed in all situations, and that vector control such as the use of bed nets and the elimination of mosquito breeding sites can play an important role in LF elimination during both MDA and post-MDA surveillance phases. It is evident that vector control plays an important role not only in the reduction of malaria transmission but also the reduction of LF infection. The above mentioned studies provide sufficient evidence that bed nets do affect the transmission of LF as a method of vector control.

The World Health Organization reports that in 2015, there were 214 million new cases of malaria worldwide and that the African Region accounted for 90% of these global cases (WHO, 2015). In Kenya, according to KEMRI, malaria is the leading cause of mortality and morbidity (KEMRI, 2016). One of the recommended strategies to combat this epidemic is the use of insecticide treated nets by at risk communities. This strategy will not only reduce the rates of malaria but those of LF. Therefore, the need for collaboration between the malaria and NTD programs is obvious and paramount. The Kenyan government has embraced the strategy of the distribution of bed nets to the at risk communities with an aim of providing malaria prevention interventions to 80% of the at risk population by 2017 (Kenya President's Malaria Initiative, 2015). Mass distribution of ITNs is done every three years, but scale up can be done by distributing the bed nets during the annual MDAs in LF endemic areas with the concomitant benefit towards malaria prevention. This strategy will be economical for both malaria and LF control programs, will reduce the disease burden, and will bring elimination closer in sight. Additionally, Molyneux and Nantulya (2004) state that links between control programs will result in other public health benefits such as better health and development for children and higher school attendance (Molyneux and Nantulya, 2004).

Conclusion

ITNs are important not only for the prevention of malaria but also for reducing LF infection. It is obvious that to prevent LF, mosquito bites should be avoided. The mosquitoes that carry the filarial worm normally bite between the hours of dusk and dawn making the usage of ITNs highly effective as a preventative. The ITNs are a low-cost intervention that can be used to reduce the infection of the debilitating and painful neglected disease that threatens millions of people in the tropical and sub-tropical regions of the world.

Chapter 3: Methods

Introduction

This study used data that was collected by KEMRI to evaluate bed net usage and prevalence of LF in the five counties or implementation units (IUs). Prevalence of LF was determined using a diagnostic test and LF microfilaria prevalence of 1% or higher in the population under examination will indicate that LF is a problem in the area and elimination strategies are needed. Bed net usage in the study area will be assessed using different variables such as age, gender, and household ownership of the nets.

Study Area

In Kenya, lymphatic filariasis (LF) is mainly found in the coastal region where ecological factors are suitable for its transmission. The study was conducted in five counties of the coastal region namely; Kilifi, Kwale, Lamu, Taita Taveta, and Tana River. This region has the highest LF endemicity in the country. Figure 3 shows the LF endemic coastal counties (circled in red) where the KEMRI study was conducted.

Figure 3. Map of Kenya showing the counties under study

https://commons.wikimedia.org/wiki/File:Map_showing_Counties_underthe_new_kenyan_constitution..gif

The WHO guidelines were used to select the sentinel sites above (villages in the IUs) where the KEMRI study was implemented. These guidelines for site selection state that a geographical area should have a population of at least 500 people, be in an area of high transmission, and have a stable population which is not affected by migration (WHO, 2005). For the KEMRI study under review, sentinel sites were previously selected by NPELF based on reports of LF disease and ecological factors that are known to favor transmission of the LF disease. Table 2 shows the implementation units and the sentinel sites.

Table 2. Study Implementation Units and Sentinel Sites

Implementation Unit	Sentinel Sites
Kilifi	Jaribuni, Kinarani & Masindeni
Kwale	Mwadimu, Makwenyeni & Mwaluphamba
Lamu	Ndau
Tana River	Kipini & Mikinduni
Taita Taveta	Kimorigo

Study Design

Cross-sectional surveys in five counties in the coastal region of Kenya were conducted in sentinel sites (ten villages) previously selected by the NPELF. The unit of analysis, therefore, was the sentinel site.

Ethical Consideration

The protocol for the study was reviewed and granted approval for implementation by the Scientific and Ethical Review Unit (SERU) of the Kenya Medical Research Institute (KEMRI) on March 5th, 2015 (see appendix 2). For the analysis of the data, Emory University granted an IRB exemption (see appendix 3).

Study population

The target population for this study was people residing in the 5 IUs. Ten villages were selected for the study, and they were all included in the study surveys of both LF prevalence and the usage of bed nets. Individuals eligible for this survey were male or female, aged 2 years and over. The inclusion criteria for the participants included the following:

1) The willingness of the participants to provide informed consent for self and for children

2) Residency in the study communities for at least two years

3) Age of 2 years or greater

4) Willingness of the participants to provide a blood sample (160 microliters) for LF tests.

Participants who were severely ill or were unwilling to give informed consent were excluded from the study.

Data Collection and Survey Questions

Data for the study were collected in October 2015, in the counties of Kilifi, Kwale, Lamu, Taita Taveta, and Tana River. The survey was conducted by four field survey teams—Taita Taveta, Kwale, Kilifi, and Tana River/Lamu. Each team consisted of two laboratory technologists/scientists, two data collectors, and a driver. Additionally, chiefs, village chairmen and two local volunteers in each selected village joined the survey teams to assist in mobilization.

- LF Prevalence:

In order to determine the prevalence of antigenemia in the blood, 100 microliter (µl) of blood was drawn from the subjects by a finger prick using a sterile disposable lancet. The blood was collected in a capillary tube and transferred to a rapid antigen test (application pad) known as immunochromatographic card test (ICT) which detects *Wuchereria bancrofti* infections. Trained laboratory scientists read all of the tests at 10 minutes, and results were recorded as positive, negative, or inconclusive. The antigen testing is the preferred method of detecting *Wuchereria bancrofti* infections (Weil et al. 1997), and the ICT tests (see ICT card diagram in Figure 4) is one of the diagnostic tools used for the diagnosis of LF prevalence. The test identifies the presence of antigens in the blood. These antigens are a marker on the presence of infection. A second blood sample (60 µl) was also collected from the same prick and preserved on filter papers for later LF serological studies. However, individuals found to be positive for circulating antigen using the ICT test were requested to provide an additional 100 µl night-time blood sample for examination of microfilariae.

Figure 4: ICT Card

The simplicity of using ICT cards for LF detection is demonstrated in these pictures. The left ICT card displays negative results for LF infection, while the right card displays positive results

(Adapted from Global Alliance to Eliminate Lymphatic Filariasis website: http://www.filariasis.org/diagnosis.html)

- Bed Net Ownership and Usage:

The bed net ownership and usage questionnaire was administered by the data collectors in Kiswahili, the common language of the counties under study. Participants' responses were captured electronically using Open Data Kit (www.opendatakit.org/) for android–based smartphones, which included in-built data quality checks to prevent errors. The survey administrators were trained on the usage of the mobile devices and the survey form uploaded in the device in advance. Data were then transferred into a server and downloaded to password protected computers by the team lead at the end of the day. Unique identifiers were used to link the bed net usage and the LF infections.

Data Analysis

A quantitative analysis was conducted for the data collected in this study. Circulating filarial antigen (CFA), which was determined using the ICT test, was expressed as a percentage of the infected population among the total number of people tested. The analyses of bed net usage was done using Microsoft Excel, and its pivot tables were used to analyze and compare the numbers of the bed net usage and the LF infections. Additionally, bed net usage was compared against age, gender, different villages, and household size.

Chapter 4. Results

The total number of people examined under this study was 2,996 in the five counties under examination. Of these, 1392 were children under the age of 15, 1604 were adults between the age of 16 and 100, and the median age was 18 years. Of the studied population, there were 1,730 (58%) female respondents and 1266 (42%) male. Overall, 1.18% ICT positives were found in the combined population examined in the five counties. These results are significant given that MDA was interrupted and not implemented annually for a period of five or more years.

Table 3 presents summaries of LF prevalence for all the five counties, while Figure 5 presents the LF prevalence by the villages in the different counties. Lamu County had the highest prevalence of 6.25%, followed by Kilifi with 0.88% prevalence and Kwale with 0.80%. Taita Taveta and Tana River had no LF positives. It is important to note that only one village in Lamu County was examined and yet the county had the highest prevalence.

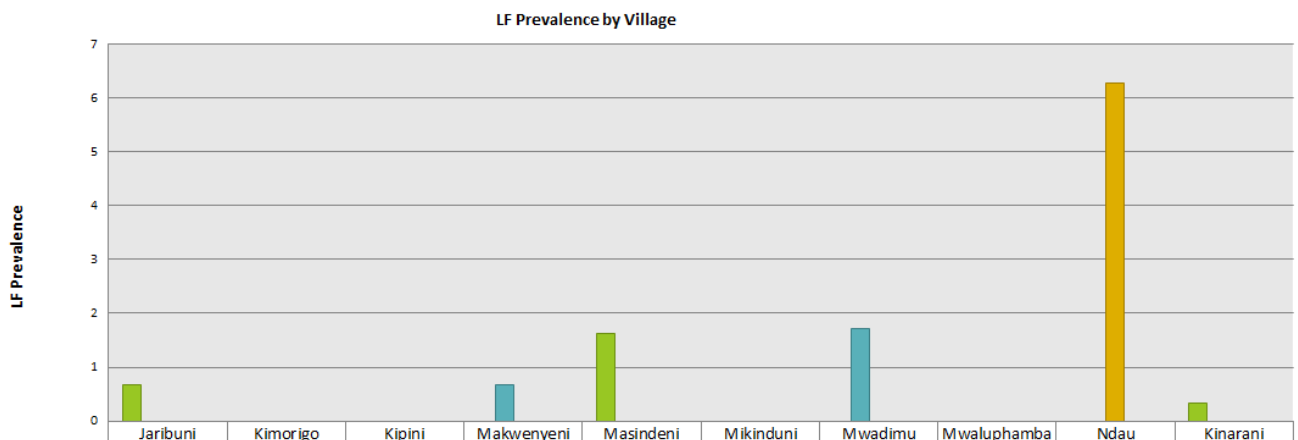
Table 3. LF Prevalence by County

County	N	No. Positive	Percent of LF Prevalence
Kilifi	911	8	0.88
Kwale	877	7	0.80
Lamu	320	20	6.25
Taita Taveta	275	0	0.00
Tana River	593	0	0.00
Total	2976	35	1.18

Prevalence by Village

Figure 5 presents LF prevalence by village. As stated above, the highest prevalence of was found in Lamu County where 320 individuals were examined and 6.27% of people examined in the village were LF positive. Since only one village in this county was examined, it would be interesting to conduct further research to determine if other villages in the County have this high prevalence and also to determine why the number was this high in comparison with other samples. Kilifi County had the second highest prevalence, and data were collected in three villages with the following prevalence: 1) 0.33% in Kinarani village, 2) 0.67% in Jaribuni village, and 3) 1.62% in Masindeni village. In Kwale County, 877 people were examined in three villages, and the prevalence was 1.72% in Mwadimu, 0.67% for Makwenyeni village and 0% for Mwaluphamba village. The two Counties of Taita Taveta (n=275) and Tana River (n=593) had zero prevalence.

Figure 5. LF Prevalence by Village



	Jaribuni	Kimorigo	Kipini	Makwenyeni	Masindeni	Mikinduni	Mwadimu	Mwaluphamba	Ndau	Kinarani
Kilifi, n=911	0.67				1.62					0.33
Kwale, n=877				0.67			1.72	0		
Lamu, n=320									6.27	
Taita Taveta, n=275		0								
Tana River, n=593			0			0				

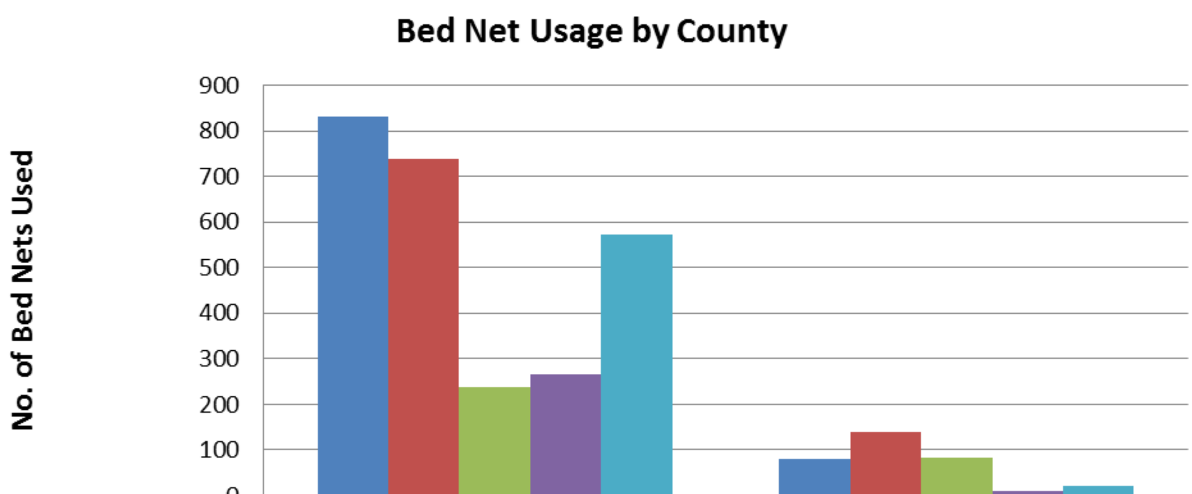
Village

Bed Net Usage by County

In order to determine if the bed nets were indeed being used, the questionnaire asked the respondents if they had slept under a bed net the previous night (see question # B2 on the questionnaire in *Appendix* 1). Figure 6 presents bed net usage by village. Out of the examined population of 2976, 329 people indicated that they did not have any bed nets. The majority of non-bed net owners were in the County of Kwale (138), followed by Kilifi (79) and Lamu with

82 non-users. When non-usage of bed nets was calculated by comparing the total number of individuals examined in the villages, Lamu had the highest non-users at 25%, followed by Kwale at 16%, and Kilifi at 9%. Additionally, the bed net usage results indicated that most households reported to have more than 2 bed nets in the household.

Figure 6. Bed Net Usage by County

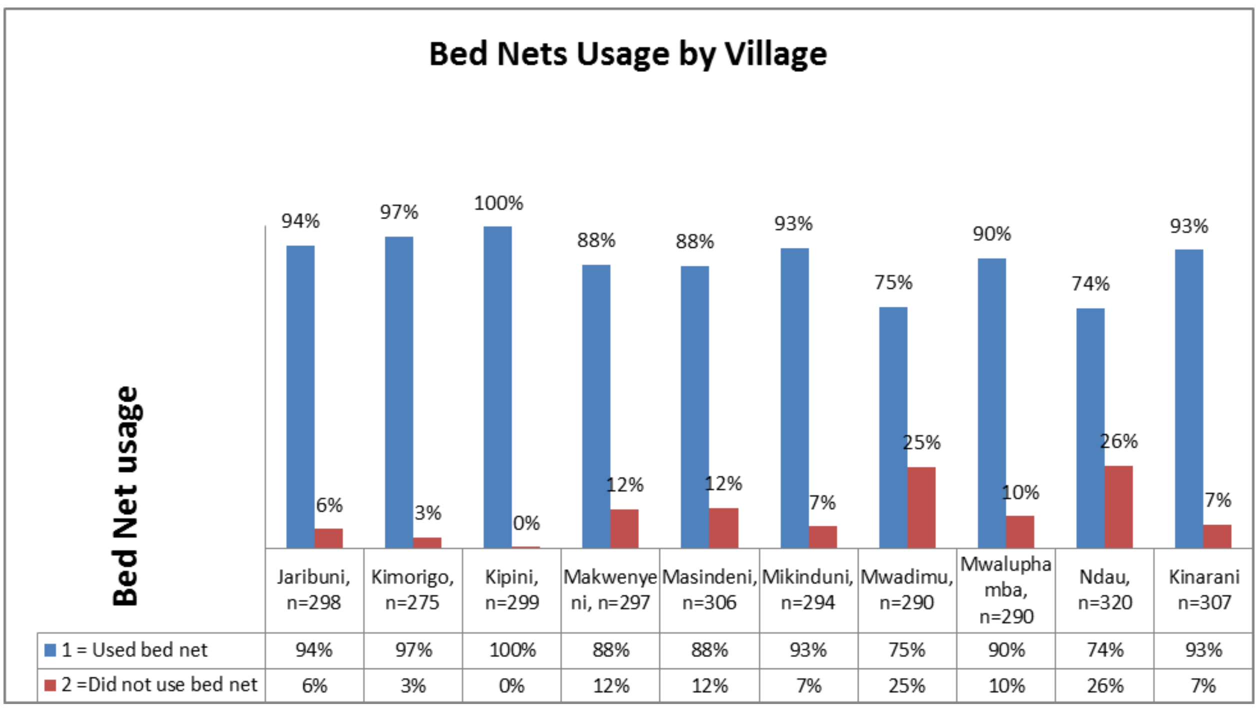


	1=Used bed nets	2= did not use bed nets
Kilifi, n=911	832	79
Kwale, n=877	739	138
Lamu, n=320	238	82
Taita Taveta, n=275	266	9
Tana River, n=593	572	21

Bed Net Usage

Overall, as shown on figure 7, usage of bed nets was high in most of the villages. The village of Kipini in Tana River County had the highest usage of bed nets at 99.76% followed by Kimorigo in Taita Taveta at 96.73%. The lowest usage was found in the villages of Ndau and Mwadimu at 74.38% and 74.83% respectively, supporting the correlation between bed net usage and infection rates – these two villages had the highest infection rates (see Figure 13 for the comparison between net usage and LF prevalence per village).

Figure 7. Bed Net Usage by Village



	Jaribuni, n=298	Kimorigo, n=275	Kipini, n=299	Makwenyeni, n=297	Masindeni, n=306	Mikinduni, n=294	Mwadimu, n=290	Mwaluphamba, n=290	Ndau, n=320	Kinarani n=307
1 = Used bed net	94%	97%	100%	88%	88%	93%	75%	90%	74%	93%
2 =Did not use bed net	6%	3%	0%	12%	12%	7%	25%	10%	26%	7%

Infection Rates by Age

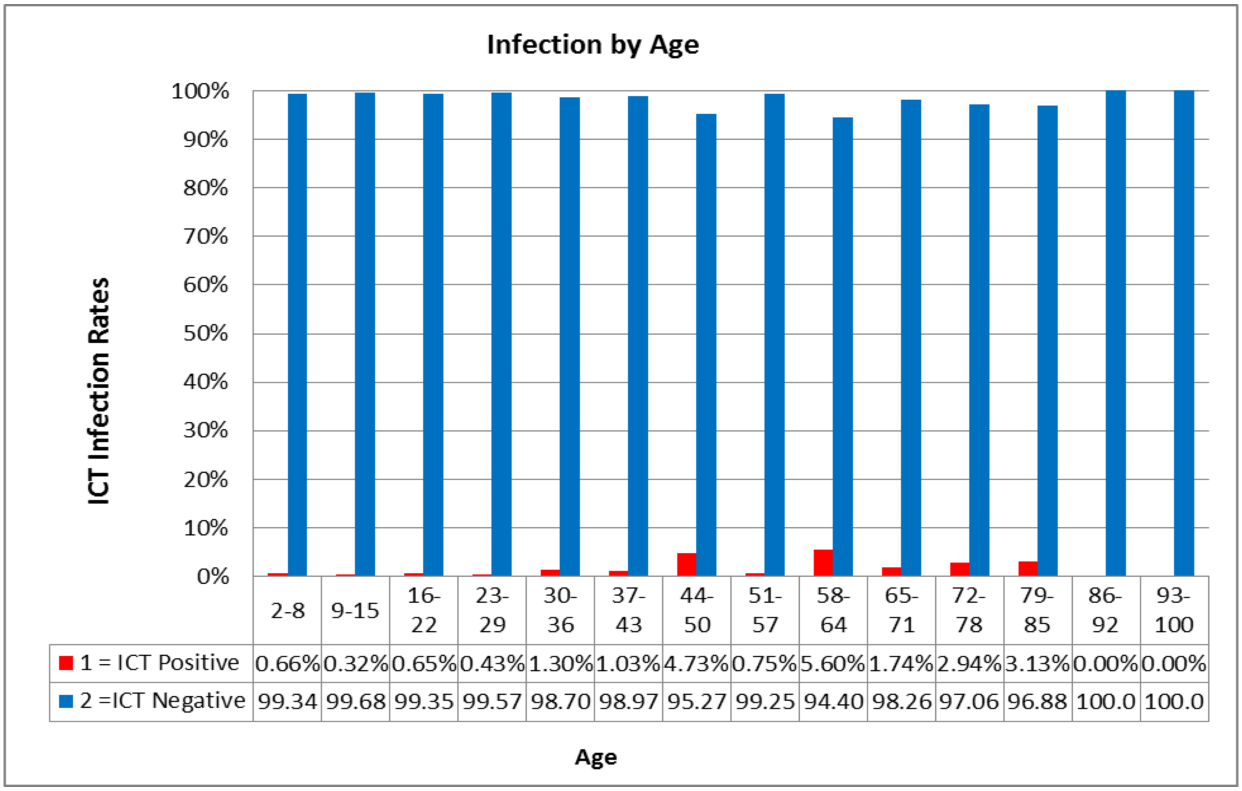
Another variable that was examined is the LF infection rate by age. Table 4 and Figure 8 show the results of this variable. The age was grouped in groups of 7 (2-8, 9-15, etc.). The highest infections were found in those between the ages of 44-85, with the highest infection in the age group of 58-64 at 5.60%. Table 4 shows the infection by age breakdown:

Table 4. LF Infection Rates by Age Group

Age Group	Percentage of LF Infection
2-8 (n=758)	0.66%
9-16,(n=634)	0.32%
16-22 (n=307)	0.65%
23-29 (n=238)	0.43%%
30-36 (n=235)	1.30%
37-43 (n=197)	1.03%
44-50 (n=169)	4.73%
51-57 (n=134)	075%
58-64 (n=127)	5.60%
65-71 (n=119)	1.74%
72-78 (n=34)	2.94%
79-85 (n=32)	3.31%
86-92 (n=9)	0.0%
93-100 (n=3)	0.00%

The age groups of 85-100 had zero infections with only 12 people being tested.

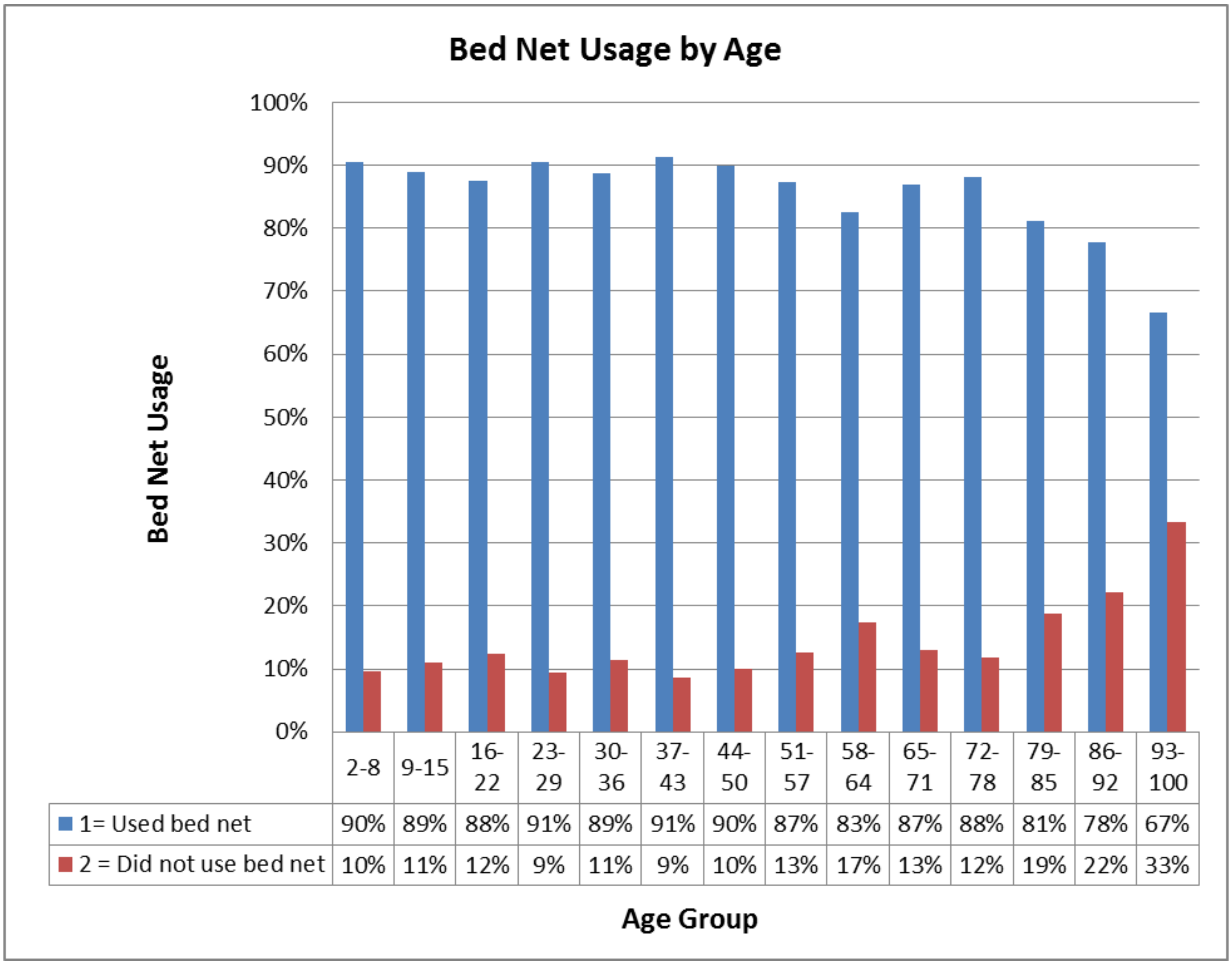
Figure 8. LF Infection by Age



Bed Net Usage by Age

Bed net usage by age was also examined. Overall, in all five counties under review, bed net usage was high. The usage rates were between 67% and 91% across the counties and among all age groups. As shown on Figure 9, the highest usage was in the age groups of 23-29 and 2-8 with 91% and 90% respectively. The lowest usage was in the 93-100 age group, at 67%. These results correlate with the infection rates by age as seen above where the age groups of 2-29 had among the lowest infection rates among the different categories.

Figure 9. Bed Net Usage by Age



Usage by Gender

In all the villages examined, the bed net usage rates for women were the same as those of men at 89%. Table 5 shows the gender breakdown and bed net usage.

Table 5. Breakdown of Bed Net Usage by Gender

	No. Examined	Used Bed Nets	Did Not Use Nets
Female	1716	89%	11%
Male	1260	89%	11%
Total	**2976**	**100%**	**100%**

Infection by Gender

ICT results showed that the infection rates for men were slightly higher than those of women. 1.35% of men were ICT positive compared to 1.05% of women (see Figure 10). Given that the net usage rates were the same, there could be other variables that are contributing to higher infection rates in men, which need to be investigated.

Figure 10. LF Infection by Gender

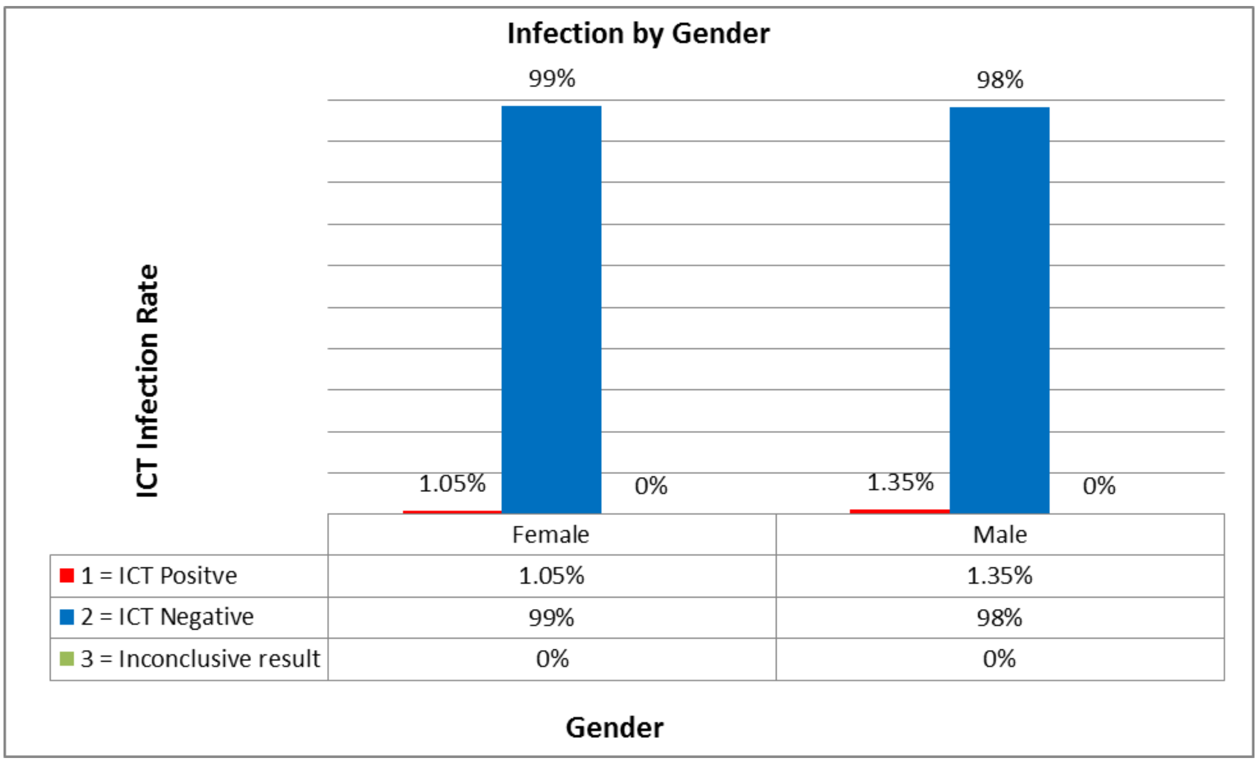
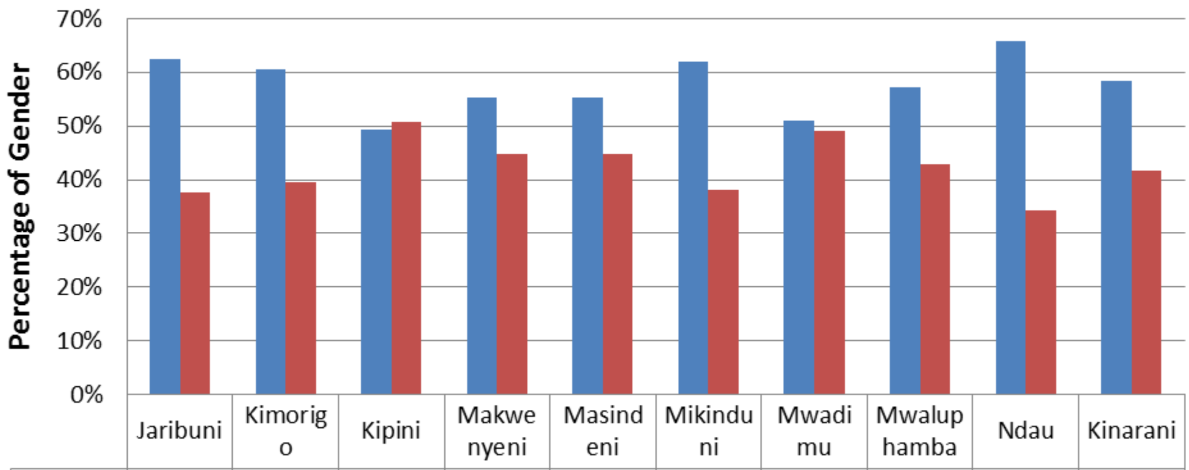


Figure 11 shows the percent graphical representation of men and women in all the villages under examination.

Figure 11. Gender Representation by Village



	Jaribuni	Kimorigo	Kipini	Makwenyeni	Masindeni	Mikinduni	Mwadimu	Mwaluphamba	Ndau	Kinarani
Female	62%	61%	49%	55%	55%	62%	51%	57%	66%	58%
Male	38%	39%	51%	45%	45%	38%	49%	43%	34%	42%

Table 6 shows LF infection numbers for women by village, while table 7 shows the men infection numbers. Overall, the infection numbers were very close with 18 females being positive and 17 men being positive. The highest number of LF infections for both groups were in the village of Ndau (Lamu County) with 11 women and 9 men being ICT positive.

Table 6. Female LF Infections by Village

Village Name	No. of ICT Positives	No. of ICT Negatives	Inconclusive Results
Jaribuni	0	186	0
Kimorigo	0	166	0
Kipini	0	146	0
Makwenyeni	2	162	0
Masindeni	2	166	1
Mikinduni	0	181	1
Mwadimu	2	146	0
Mwaluphamba	0	166	0
Ndau	11	199	0
Kinarani	1	173	5
Total	**18**	**1691**	**7**

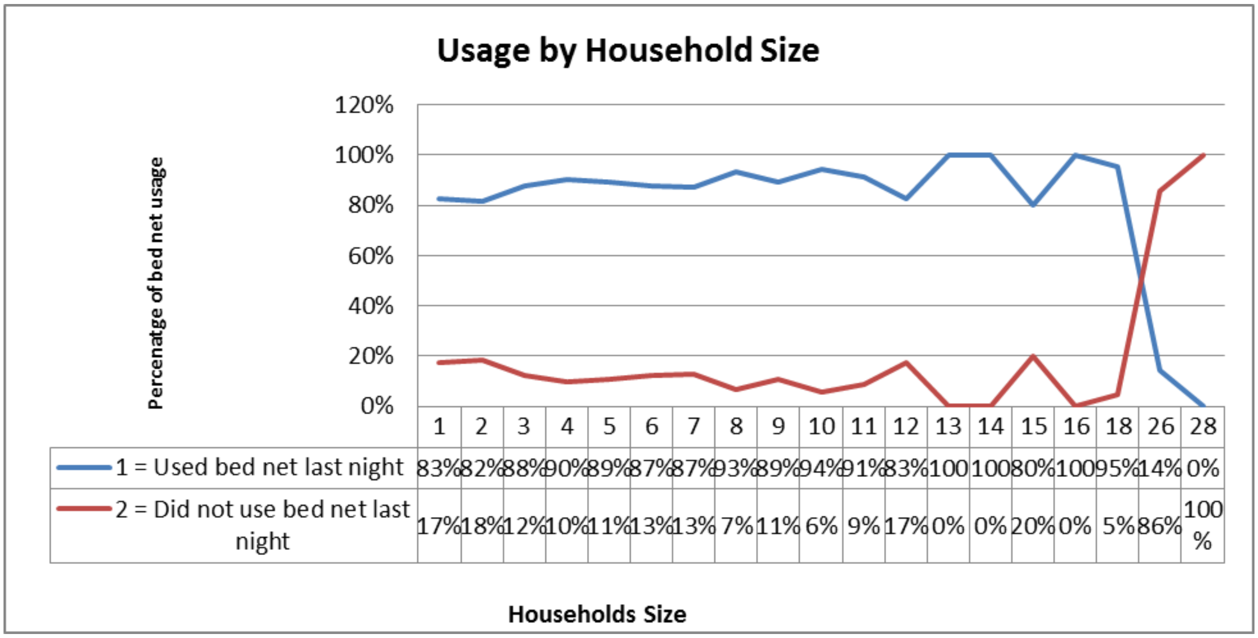
Table 7. Male LF Infections by Village

Village Name	No. of ICT Positives	No. of ICT Negatives	Inconclusive Results
Jaribuni	2	110	0
Kimorigo	0	109	0
Kipini	0	153	0
Makwenyeni	0	133	0
Masindeni	3	132	2
Mikinduni	0	112	0
Mwadimu	3	139	0
Mwaluphamba	0	124	0
Ndau	9	100	1
Kinarani	0	127	1
Total	**17**	**1239**	**4**

Bed Net Usage by Household Size

The household size ranged from 1 person to 28 persons. In these households, there was a large variability of bed net usage with ranges from 0% to 100%. Interesting, the households with the greater numbers of persons residing in them (26 and 28 persons) reported the lowest usage at 14% and 0% respectively. However, the majority of households had bed net usage ranging from 80% to 100% (see Figure 12). Further research needs to be conducted to determine why there was a greater lack of use in larger households, such as cost and sleeping arrangements (group/single). If cost was the determining factor, then another set of implications arise, such as funding requirements, etc.

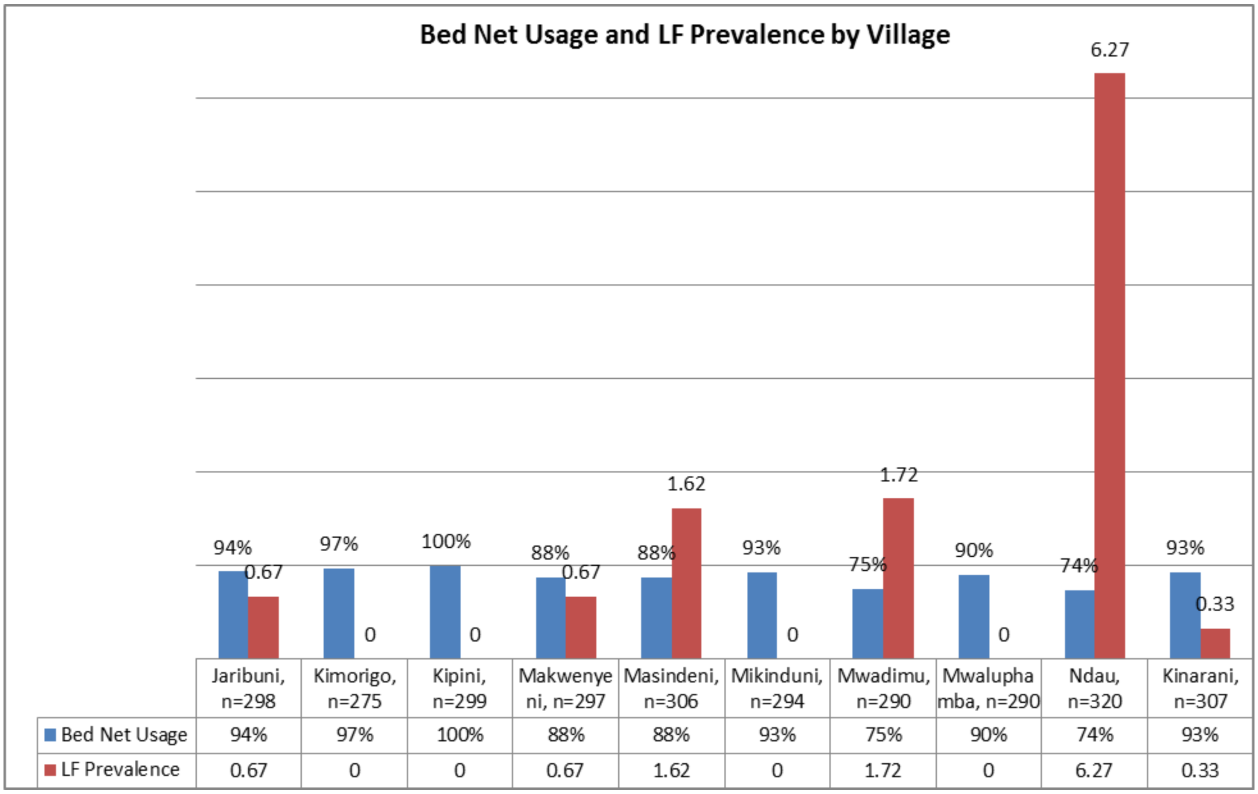
Figure 12. Bed Net Usage by Household Size



Correlation between Usage and Infection

This study supports the evidence that bed net usage reduces LF infections. As seen in Figure 13, the villages that had the lowest usage had some of the highest prevalence. This begs the question of ownership versus awareness of bed nets – whether the residents of these villages with lower bed net usage lack adequate knowledge of bed nets, or they do not fully understand the benefits of bed net usage in the prevention of LF and other vector diseases.

Figure 13. Bed Net Usage and LF Prevalence by Village



Conclusion

Data analysis shows that there is a relationship between the usage of bed nets and the reduction in infections of LF in the study region. The villages that had the lowest bed net usage had the highest LF infections, and the groups with the lowest LF infections had the highest usage of bed nets. Also, fewer infections were found in younger age groups, which may be attributed to the scale-up of bed net distribution in other programs (such as malaria) that have a special focus on children. At the same time data analysis shows that increased bed net usage may account for the lower infections. It is important to consider any factors that can cause an increase or decrease in the bed net usage—such as ease of access to the nets and more education or awareness on the benefits. This would require a separate study.

Chapter 5: Discussion

Introduction

This study highlights the impact of bed nets and the control of LF in five counties of coastal Kenya. This area has one of the greatest burdens of LF in the country. The study results show that the communities that have high rates of bed net usage have low rates of LF infections. These results can be used to advocate for the distribution of bed nets during annual MDAs, and highlight the benefits for the control of both LF and malaria.

Summary of Findings

It is evident that bed net usage plays a significant role in the reduction of the LF infections in the populations examined. Overall, the LF prevalence in most counties was low, and even two counties (Tana River and Taita Taveta) had zero prevalence. The highest prevalence (6.27) was in Lamu County. Tana River, one of the counties that had zero prevalence, had the highest bed net usage in its villages (Kipini at 99.67% and 93.20%). Additionally, Taita Taveta where only one village (Kimorigo) was examined had zero prevalence and a high usage of bed nets at 96.73%. Conversely, Lamu County which had the highest prevalence in the village of Ndau (6.27%) had the lowest rate of bed net usage at 74.38%. The second lowest usage (75%) was in Mwadimu village in Kwale County and LF prevalence there was the second highest at 1.72%. Masindeni village in Kilifi Count had 87.58% bed net usage while Mwakwenyeni village in Kwale County had 87.88% usage. The two villages had LF prevalence of 1.63 and 0.67% respectively. These results evidently show that there is a linkage between LF prevalence and bed net usage.

These results suggest that the NPELF in Kenya can take advantage of bed net distribution as an additional strategy for the control and elimination of LF. Additionally, the results from this study can be used to advocate better integration with other programs such malaria control programs. Also, the NPELF can propose to the MoH to include bed net distribution during annual MDAs. This strategy has worked well in Nigeria, where the use of long-lasting insecticidal nets along with MDA reduced infection rates to 0% in some areas, and where used alone reduced the rate from 2% to .3%. Community-directed interventions included education on net hanging, washing and use, resulting in significant improvements in these behaviors (WHO, 2012). There is every reason to believe this can be replicated in Kenya.

Another key finding was the correlation between the age groups, net usage, and LF prevalence. The age groups of 2-15 and 16-29 had less than 0.6% LF prevalence and the highest usage of bed nets at 89.77% and 88.89% respectively. Inversely, the age groups of 44-57, 58-71, and 72-85 had some of the lower net usage (88.78%, 84.65%, and 84.85%) and at the same time the highest LF positive rates at 2.97%, 3.73% and 3.03% respectively. In summary, the higher the usage of bed nets – the lower the LF infection rates.

Evaluation of bed net usage by gender indicated that women used bed nets at a higher rate than men (see Tables 6 and 7 above). At the same time, LF infection rates were slightly higher in males (1.35% ICT positives) than females (1.05% ICT Positives).

Significant differences were found between the size of the household and bed net usage. These results are not surprising given that LF is a disease of the poor, and if a household has 28 members living under one roof, it is unlikely that such households can afford the bed nets for all its members. Therefore, if these differences are attributed to the cost of the bed nets, the MoH can be lobbied to make available subsidized bed nets. This will not only increase the reduction of

LF infections but will also positively contribute to the control of other vector borne diseases such as malaria. Ownership and usage of bed nets is key to the success of vector control programs.

The impact of bed nets in the control of vector borne diseases is becoming increasingly important not only for the national control programs but also for donor agencies and international stakeholders. Therefore, this calls for a more standardized distribution strategy and also regular impact assessments. Impact assessments are not only valuable for documenting the number of disease cases prevented, but also for informing policy changes by the MoHs and other public health decision makers.

In summary, some potential benefits for vector control through bed net usage may include: 1) suppression of filariasis transmission, 2) reducing the risk of infection from imported microfilaria from a positive person, and 3) decreasing the risk of transmission of other disease such as malaria.

Limitations

Integration efforts could potentially take time. Integration buy-in from different stakeholders such as National Programs, government authorities, donors, international organizations, and others is therefore essential. Additionally, the NTDs and other vector diseases are in countries and communities with limited resources while the burden of these diseases is enormous. Therefore, for integration to be successful, national-wide assessments of the burden of these diseases may be necessary in order to have effective integration plans and training. Again, resources may not be available for conducting these assessments if there is no commitment from the government authorities or donor community. Finally, more research may be necessary to evaluate integration programs to ensure that integration is cost-effective and that any integration challenges are addressed. For example, in Kenya the bureaucracy may slow down such efforts leading to delay in program implementation.

Implications

The use of bed nets may have contributed to significant reduction of LF infections, as evidenced by the study under review. Additionally, other research shows that the integration of vector management and in particular bed nets have shown to reduce the prevalence of LF (WHO, 2012). Integration will result in effective use of resources, thus increasing the cost-effectiveness of disease control and prevention. These resources may include transport, training, personnel, among others. Most national programs target the same communities where the diseases are co-endemic. Integration of interventions will most likely result in coordinated drug distribution and/or coordinated interventions delivery enabling the programs to use their time in the field more efficiently. Finally, the success of integration will facilitate integrated disease surveillance as the national programs move closer towards the elimination of these diseases.

Recommendations

National LF Programs must be strengthened to scale up chemotherapy treatment and the implementation of other control strategies in LF endemic areas. Additionally, great efforts should be made to ensure uninterrupted annual MDAs in endemic countries, such as Kenya, that are struggling to conduct the annual MDAs due to lack of sustained funding. The WHO recommends that MDAs be implemented and continued for a period of five years or more in order to reduce microfilaria numbers in the blood, thus preventing the vector from transmitting infection (WHO, 2010). This could potentially eradicate the disease.

The strengthening of the existing capacity and building of new capacity for integrated vector management is critical. In addition, partnerships should be forged between NTD programs and other vector-borne diseases programs.   This will ensure the integration of resources in inter-sectoral settings and promote integrated operational research which will inform future efforts of vector control in an inter-programmatic approach.

Another recommendation is the distribution of bed nets during the annual MDAs. A study in Nigeria indicated that there is no adverse effect on the distribution of nets when an annual MDA is being conducted (Blackburn et al., 2006). It is recommended that the MoH in Kenya issue guidelines of bed net distribution during LF MDA, and also guidelines for combating LF and malaria. These guidelines should be shared with all the public health officials in the co-endemic areas.

Efforts should be made to educate the target population and the community health workers who distribute the bed nets on the benefits of bed net usage. The success of the control and elimination of LF will to a certain extent depend on community awareness and involvement. When there is increased awareness of the benefits of the bed nets, it is most likely that the usage will go up, thus reducing LF transmission. Additionally, to ensure optimal MDA and bed net coverage, there should be public sharing of information about distribution and MDA dates and advocacy at the county government level—a massive public information campaign. The county health officials should ensure that information is shared using all means of communication such as TVs, radios, the Internet, village level meetings, and other settings.

Finally, political commitment is necessary to ensure the integration of LF elimination strategies. The success of full coverage of MDAs and other interventions depends on the achievement of high coverage, and this will not be possible without the commitment of national authorities in endemic countries.

Conclusion

LF is a debilitating disease that affects the poorest of the poor and results to a huge economic impact in affected areas. Research has shown that there are huge economic benefits resulting from the control of LF transmission. A study by Chu et al. found that during the first eight years (2000 -2007) of the GPELF, economic benefits were US$24 billion (Chu et al., 2010). These economic benefits include benefits of preventing loss of labor and income, health services for affected populations, quality of life benefits, and prevention of co-endemic diseases (WHO, 2010). Such benefits and health savings clearly show the importance of integrated strategies for LF control and prevention.

Although MDA can potentially eliminate LF, sustained treatment coverage may be a challenge for some endemic countries. Vector control is the only other alternative where MDAs are not possible and still efficacious and necessary, even where MDAs are possible. Usage of bed nets as a vector control method has been shown to be effective in the control and elimination of LF transmission. Therefore, it is critical to have vector control management strategies in place and ensure the integration of MDA and vector control. This integration strategy will ensure the sustainability of LF control even when annual MDAs are not regular in countries such as Kenya. Such integration will not only assist national LF elimination programs meet their annual and long-term elimination goals, but also ensure that the target date of eliminating this tragic disease of LF by 2020 is achieved.

In summary, a multi-disease control vector control strategy is essential for NTDs and other vector-borne diseases. The infrastructure for LF MDAs is already developed and has been in operation for the last few decades. This infrastructure can be used to expand the delivery of bed nets and ensure full coverage is reached especially in hard to reach and poor communities. The goal for Global Malaria Programs is to achieve universal coverage of at-risk populations (WHO, 2011) and the GPELF goal is to eliminate LF by 2020. It is, therefore, critical for malaria control programs and NTDs control programs to synergize their control efforts, thereby harmonizing their essential functions and through their coordination, maximizing the impact of their combined financial, human, and technical resources.

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Appendices

Appendix 1. KEMRI LF Survey Questionnaire

PARTICIPANT INFORMATION	
Village code: |_____|_____|_____|_____|_____|	**Village name:**
Sub-County Code: [____]____]____]	**Sub-County name:**
Participant ID |_____|_____|_____|_____|_____|____|____|____|	**Date of visit:** |____|____|/|____|____|/|____|____| ***day month year***
Participant's initials	**Date of birth** |____|____|/|____|____|/|____|____| ***day month year*** 99/99/99=Not known
Age: |_____|_____| **years**	**Gender:** ☐ **Male** ☐ **Female**
Parent/guardian's signature/mark (if child)	

HEALTH INFORMATION	
Blood sample taken: ☐ Yes ☐ No	**ICT results:** Positive ☐ Negative ☐ Invalid ☐
Thick blood slide prepared: ☐ Yes ☐ No	**MF counted:** |_____|_____|_____| mf/ 60µL
Dry blood spot (DBS) prepared: ☐ Yes ☐ No	**Filter paper stored:** ☐ Yes ☐ No

HISTORY OF PREVIOUS RESIDENCE
A1. Have you lived in this sub-County for the last 1 year? ☐ Yes ☐ No
A2. If no, what is the name of the sub-County where you lived? ______________________________
A3. For how long did you reside in the sub-County? [___|___] years

BEDNET USE
B1. Do you normally sleep under a bednet? **Read out options, only enter one answer** .... 1 = Yes; 2 = No
B2. Did you sleep under a bed net last night? **Read out options, only enter one answer** .... 1 = Yes; 2 = No
B3. What is the colour of your bed net? **Read out options, only enter one answer** .... 1 = Blue; 2 = Green; 3 = White; 4 = Red; 5 = Others........ *specify* [___________________]
B4. How many people normally reside in your household? ....[___|___]
B5. How many bednets does your household possess? ....[___|___]

END OF INTERVIEW

Please thank the participant for their cooperation and time

Appendix 2. KEMRI IRB

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

KEMRI/RES/7/3/1 **March 05, 2015**

TO: **PROF. SAMMY NJENGA (PRINCIPAL INVESTIGATOR)**
THE DIRECTOR, ESACIPAC
NAIROBI

Dear Sir,

RE: SSC PROTOCOL NO. 3018-(*RESUBMITTED-INITIAL SUBMISSION*): SEROEPIDEMIOLOGICAL ASSESSMENT OF LYMPHATIC FILARIASIS IN COASTAL KENYA: USEOF A COMBINATION OF DIAGNOSTIC APPROACHES TO MONITOR THE IMPACT OF MASS DRUG ADMINISTRATION – (*VERSION 1.2 DATED 23RD FEBRUARY, 2015*)

Reference is made to your letter dated 23rd February, 2015 and the revised documents received at the KEMRI/Scientific and Ethics Review Unit (SERU) on 24th February, 2015.

This is to inform you that the Committee notes that the issues raised at the 233rd meeting of the Expedited Review Team have been adequately addressed. Consequently, the study is granted approval for implementation effective this **5th March, 2015** for a period of one year. Please note that authorization to conduct this study will automatically expire on **March 5, 2016.** If you plan to continue data collection or analysis beyond this date, please submit an application for continuation approval to SERU by **January 22, 2016**.

You are required to submit any proposed changes to this study to SERU for review and the changes should not be initiated until written approval from SERU is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and you should advise SERU when the study is completed or discontinued.

You may embark on the study.

Yours faithfully,

EAB

PROF. ELIZABETH BUKUSI,
ACTING HEAD,
KEMRI/SCIENTIFIC AND ETHICS REVIEW UNIT

In Search of Better Health

Appendix 3. Emory IRB Exemption

Dear Waithera:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definitions of research with "human subjects" or "clinical investigation" as set forth in Emory policies and procedures and federal rules, if applicable. Specifically, this project aims to conduct secondary data analysis on a deidentified dataset. The data, provided by the Kenya Research Medical Institute, has been collected on lymphatic filariasis in coastal Kenya. You intend to compare usage of bed nets and transmission rates of lymphatic filariasis to determine correlation. No one conducting the analysis was part of the original data collection team.

Please note that this determination does not mean that you cannot publish the results. This email serves as your official determination letter. If you have questions about this issue, please contact me.

This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Carolyn Sims, MPA

Research Protocol Analyst

Institutional Review Board

Emory University

Phone: 404.727.8864

Email: carolyn.sims@emory.edu

www.irb.emory.edu