

Neglected Tropical Disease Elimination Programme

National Guidelines for Lymphatic Filariasis Assessment With a Framework for Human Capacity Development



**Neglected Tropical Diseases Division
Department of Public Health
Federal Ministry of Health, Abuja, Nigeria
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FOREWORD

The target of the Federal Ministry of Health (FMOH) Nigeria is to eliminate Lymphatic Filariasis (LF) as a public health problem by 2024, and the mandate is vested in the Neglected Tropical Diseases (NTD) Division, Public Health Department of the FMOH. The road-map involves interruption of transmission with Mass Administration of Medicines (MAM), Morbidity Management and Disability Prevention (MMDP) and Integrated Vector Management. The NTD Division scaled up assessment activities towards LF elimination in Nigeria in 2018, mapping all 774 Local Government Areas (LGAs) of which 583 LGAs (75.3%) were endemic for LF and 191 LGAs (24.7%) were non-endemic. Five hundred and forty-eight (548) LGAs have received at least one (1) round of LF MAM. Eighty-Nine (89) LGAs have received 5 effective rounds of MAM, of which 30 LGAs have stopped MAM.

From 2016 through to February 2019, Pre-Transmission Assessment Survey (Pre-TAS) was conducted in 59 LGAs. A total of 46 LGAs (78%) passed while 13 LGAs (22%) failed.

The FMOH made tremendous efforts towards elimination of LF using WHO global guidelines; however, the need to have a domesticated National guideline was recognised by the National Steering Committee for NTD to address challenges peculiar to the Country. Consequently, the development of LF assessment guidelines for Nigeria was done by the NTDs Division in consultation with the LF technical working group.

The document explains the epidemiology of LF, mapping and other programme interventions, and outlines the various stages of LF programme assessments such as, Pre-Transmission Assessment Survey, Transmission Assessment Surveys, Post MAM surveillance, validation, Dossier development and verification of LF elimination. It is designed as a practical guide for assessment of LF towards elimination and will be useful to State and National LF program coordinators, the academia, Non-Governmental Development Organizations and other stakeholders supporting LF elimination programmes in Nigeria.

I wish to acknowledge the inputs of all stakeholders who contributed in various ways to the development of this guideline. I enjoin all partners and stakeholders to endeavour to ensure the successful implementation of this document.

I also reaffirm the support and commitment of the Government of Nigeria in ensuring that national and global targets are met in the elimination of LF and other Neglected Tropical Diseases in Nigeria.

Dr. Osagie Emmanuel Ehanire
Honourable Minister for Health
Federal Republic of Nigeria.
November 2019

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Dr Evelyn Ngige
Director, Public Health
Department of Public Health
Federal Ministry of Health, Nigeria
November 2019

LIST OF CONTRIBUTORS

FEDERAL MINISTRY OF HEALTH (FMOH)

| | |
|---------------------------|--|
| Dr. Evelyn Ngige | CSG1/Director Public Health, FMOH |
| Dr.Chukwuma Anyaike | CSG 1/ NC NTDs/FMOH |
| Mr. Emmanuel Davies | Deputy Director,Focal PersonNLFEP/FMOH |
| Dr.Obiageli J. Nebe | Deputy Director, NTD/FMOH |
| Dr Joel Akilah | Deputy Director, NTD/FMOH |
| Dr Nicholas Olobio | Assistant Director, NTD/FMOH |
| Mrs Perpetua Amodu-Agbi | Assistant Director, NTD/FMOH |
| Mr. FataiOyediran | Deputy Director, NTD/FMOH |
| Dr.Uzoma Nwankwo | NTD/FMOH |
| Mr. Michael Igbe | NTD/FMOH |
| Mr. OlumideFalodun | NTD/FMOH |
| Mr Celestine Njoku | NTD/FMOH |
| Mrs Maryam Abduljeleel | NTD/FMOH |
| Mrs. Lola Adeniran | NTD/FMOH |
| Mrs. Zaiyanatu Umar | NTD/FMOH |
| Mrs. Rita Urude | NTD/FMOH |
| Mrs. Audrey Nyior | NTD/FMOH |
| Ms. UnunumahEgbelu | NTD/FMOH |
| Mrs Charity Obi | NTD/FMOH |
| Dr. Chukwuemeka Makata | NTD/FMOH |
| Mrs. KehindeGaniyatBusari | NTD/FMOH |
| Mrs. Violet Njoku | NTD/FMOH |

PARTNER/NON-GOVERNMENTAL DEVELOPMENT ORGANISATION (NGDO)

| | |
|--------------------------|--------------------|
| Dr Aliyu Suleiman | WHO |
| Dr Hilary Adie | UNICEF |
| Mr Benjamin Nwobi | RTI |
| Mr Olorunsogo Samson | RTI |
| Mr Joseph Kumbur | EVIDENCE ACTION |
| Dr.AdamuSallau | THE CARTER CENTER |
| Mr. Adamani William Enan | SIGHTSAVERS |
| Dr.TeyilWamyil-Mshelia | SIGHTSAVERS |
| Mr. OsagieOmoregie | AHF |
| Mr LanreToluhi | AHF |
| Mrs Jamilalriogbe | MITOSATH |
| Mr RinpanIshaya | CBM/HANDS |
| Ms Elizabeth Ezeobebe | HKI |
| Ms MaryInAbah | 17 PLUS FOUNDATION |

ACADEMIA

| | |
|---------------------|---|
| Prof Sammy Sam-Wobo | Federal University of Agriculture Abeokuta (Consultant) |
| Prof OladeleAkogun | ModibboAdama Universityof Technology Yola (Consultant) |
| Dr Cornelius Amoke | Michael Okpara Universityof AgricultureUmudike (Consultant) |
| Dr Lawrence Usip | University of Uyo, Uyo (Consultant) |
| Dr Dung Pam | University of Jos, Jos (Consultant) |

ACRONYMS/ABBREVIATIONS

| | |
|----------|---|
| ADLA | Adenolymphangioadenitis |
| AFRO | African Regional office of WHO |
| Ag | Antigenaemia |
| Alb | Albendazole |
| AHF | Amen Health Care and Empowerment Foundation |
| CBM | ChristoffelBlinden Mission |
| CDD | Community Drug Distributor |
| CDTI | Community Directed Treatment with Ivermectin |
| CSG | Consultant Special Grade |
| DALYs | Disability Adjusted Life Years |
| DOT | Directly Observed Treatment |
| DSNO | Disease Surveillance Notification Officer |
| EPIRF | Epidemiological Data Reporting Form |
| EU | Evaluation Unit |
| FTS | Filarial Test Strip |
| FMOH | Federal Ministry of Health |
| GPELF | Global Programme to Eliminate Lymphatic Filariasis |
| GSK | Glaxo SmithKline |
| HANDS | Health And Development Support Programme |
| HKI | Helen Keller International |
| ICT | ImmunoChromatographic Test |
| IDP | Internally Displaced Persons |
| IU | Implementation Unit |
| IVM | Ivermectin |
| JAP | Joint Application Package |
| JRF | Joint Reporting Form |
| JRSM | Joint Request for Selected Medicines |
| LF | Lymphatic Filariasis |
| LGA | Local Government Area |
| MAM | Mass Administration of Medicines |
| MDP | Merck Donation Program |
| Mf | Microfilaraemia |
| MMDP | Morbidity Management and Disability Prevention |
| M&E | Monitoring and Evaluation |
| MITOSATH | Mission to Save the Helpless |
| MIS | Management Information System |
| NC | National Coordinator |
| NGDOs | Non-Governmental Developmental Organizations |
| NGOs | Non-Governmental Organizations |
| NLFEP | National Lymphatic Filariasis Elimination Programme |
| NTDs | Neglected Tropical Diseases |
| NYSC | National Youth Service Corps |
| PCR | Polymerase Chain Reaction |
| PCT | Preventive Chemotherapy |
| PHC | Primary Health Care |
| PMM | Programme Managers Meetings |
| PSC | Pyrethrum Spray Catch |
| RTI | Research Triangle Institute International |
| STH | Soil Transmitted Helminths |
| SMOH | State Ministry of Health |
| SS | Sentinel Site |
| SC | Spot Check |

UNICEF United Nations Children's Fund
RPRG Regional Programme Review Group
TAS Transmission Assessment Survey
TWG Technical Working Group
WHA World Health Assembly
WHO World Health Organization

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EXECUTIVE SUMMARY

The National Lymphatic Filariasis Elimination Programme (NLFEP) in the Neglected Tropical Diseases (NTDs) Division of the Department of Public Health, Federal Ministry of Health (FMOH), Nigeria was established in 1997 with the mandate to eliminate Lymphatic Filariasis as public health problem in accordance with the World Health Assembly (WHA) resolution 50:29 of May 1997. In the year 2000, Nigeria aligned her national programme with the WHO Global Programme to Eliminate Lymphatic Filariasis (GPELF) launched the same year-adopting the global programme guidelines as the National Programme operational document.

Following the lessons learnt from implementation of the National Lymphatic Filariasis Elimination strategies, the National Lymphatic Filariasis Elimination Programme in 2019 with technical guidance from the Lymphatic Filariasis Technical Working Group and other stakeholders developed this first national guidelines for the National Lymphatic Filariasis Elimination Programme assessments as a Nigeria specific document to address national programme implementation peculiarities that impact LF assessments.

This guideline is a 58 paged document segmented into seven (7) chapters; each dealing with an aspect of the national programme in the following order:

Chapter 1: Introduction-Introduces Lymphatic Filariasis as a public health disease, providing both global and national perspectives on disease. The chapter also deals with strategies for LF elimination.

Chapter 2: Interventions- Gives insight into the components of the LF elimination strategies: Mass Administration of Medicines (MAM); Integrated Vector Management (IVM) and Morbidity Management and Disability Prevention (MMDP)

Chapter 3: Assessments- Dwells on the eligibility criteria for assessments before spelling out the guidelines for program assessments such as Pre Transmission Assessment Survey, Transmission Assessment survey, co-assessments and related field work.

Chapter4: Validation of Elimination-The process of confirming elimination of Lymphatic Filariasis as a public health problem, including dossier preparation and final verification of elimination of Lymphatic Filariasis in the country.

Chapter 5: Verification of Elimination- Guides the programme on other assessments including Post MAM Surveillance and nature of study. It equally provides insight into Morbidity Management and Disability Prevention.

Chapter 6: Human Capacity Development-Provides schedules for development of capacity of state level officers on how to use the guideline document.

Chapter 7: Training Module Content-Provides training content for human capacity development for LF assessments.

The annexures contain the relevant tools for LF assessments including:

1. LF mapping forms.
2. Pre-Transmission Assessment Survey Forms.
3. Transmission Assessment Survey forms.
4. Morbidity Management and summary form
5. Roles and responsibilities of team members for LF assessments.

6. Template for the dossier documenting elimination of Lymphatic Filariasis as public health problem.

LF assessments are conducted at different stages of elimination program to determine LF endemicity, reduction of parasite density to a level where parasite transmission is considered to be no longer sustainable; to determine if endemic areas (LGAs) may continue or stop MAM and also to monitor parasite recrudescence in areas that have passed TAS.

The NLFEP hitherto relied on the WHO Program guidelines for all its program assessments until the development of this guideline which address challenges such as minimum and maximum number of MAM rounds in an endemic area, conduct of TAS in non-contiguous LGAs that make up an Evaluation Unit. It provides guidelines for other program activities such as validation, verification and dossier development which are all important steps in LF elimination programme. It equally countenances Nigeria programme specific terms such as Mass Administration of Medicines(MAM) in lieu of the global programme use of Mass Drug Administration(MDA).

The document will guide National and State LF elimination programme coordinators and programme officers during LF programme assessments as a playbook. It will equally be very resourceful in the academia for teaching and research purposes.

**Dr. Chukwuma ANYAIKE, MD, MCommH, FWACP, DTM & H(Lond), FCAI.
Consultant Special Grade 1/National Coordinator.**

1.1 WHAT IS LYMPHATIC FILARIASIS

Lymphatic filariasis (LF) is caused by infection with threadlike worms called nematodes of the family Filarioidea: 90% of infections are caused by *Wuchereria bancrofti* and the remainder by *Brugia spp.* Humans are the exclusive host of infection with *W. bancrofti*. Although certain strains of *B. malayi* can also infect some animal species (felines and monkeys), the life cycle in these animals is perceived as epidemiologically distinct from that in humans. Male worms are about 3–4 centimetres in length, and female worms 8–10 centimetres. The male and female worms together form “nests” in the human lymphatic system. The life span of the adult worm is usually 5-6 years. The lymphatic system is an essential component of the body’s immune system. It is the network of nodes and vessels that maintain the delicate fluid balance between blood and body tissues.

Filarial infection can cause a variety of clinical manifestations, including lymphoedema of the limbs, elephantiasis, genitals (hydrocele, chylocele, and swelling of the scrotum and penis) and episodes of adenolymphangitis (ADLA), which are extremely painful and are accompanied by fever. The vast majority of infected people are asymptomatic, but virtually all of them have subclinical lymphatic damage and as many as 40% have kidney damage, with proteinuria and haematuria

Lymphatic filariasis is a painful and profoundly disfiguring disease. In communities where filariasis is transmitted, all ages are affected. While the infection may be acquired during childhood its visible manifestations may occur later in life, causing temporary or permanent disability. In endemic countries, lymphatic filariasis has a major social and economic impact with an estimated annual loss of \$1 billion and impairing economic activity up to 88%.

1.1.1 Transmission

Adult male and female worms lodge in the lymphatics. Fecund females release larvae (microfilaria) which periodically (nocturnal) circulate in the blood. Microfilaria circulating in the blood can be ingested by a mosquito during a blood meal. Microfilaria mature in the vector to become infective. The mosquitoes carrying the infective filarial (third larvae stage), then transmits to new host when feeding.

The major vectors of *W. bancrofti* are mosquitoes of the genus *Culex* (in urban and semi-urban areas), *Anopheles* (in rural areas of Africa and elsewhere) and *Aedes* (in islands of the Pacific).

The parasites of *B. malayi* are transmitted by various mosquito species of the genus *Mansonia*; in some areas, anopheline mosquitoes are responsible for transmitting infection. Brugian parasites are confined to areas of east and south Asia, notably India, Indonesia, Malaysia and Thailand.

Transmission in a community is influenced by the proportion of infected persons (prevalence), the density of microfilaria in the blood of infected persons, the density of vector mosquitoes, characteristics of the vector that affect the development of infective larvae and frequency of human-vector contact.

1.2 GLOBAL PERSPECTIVE

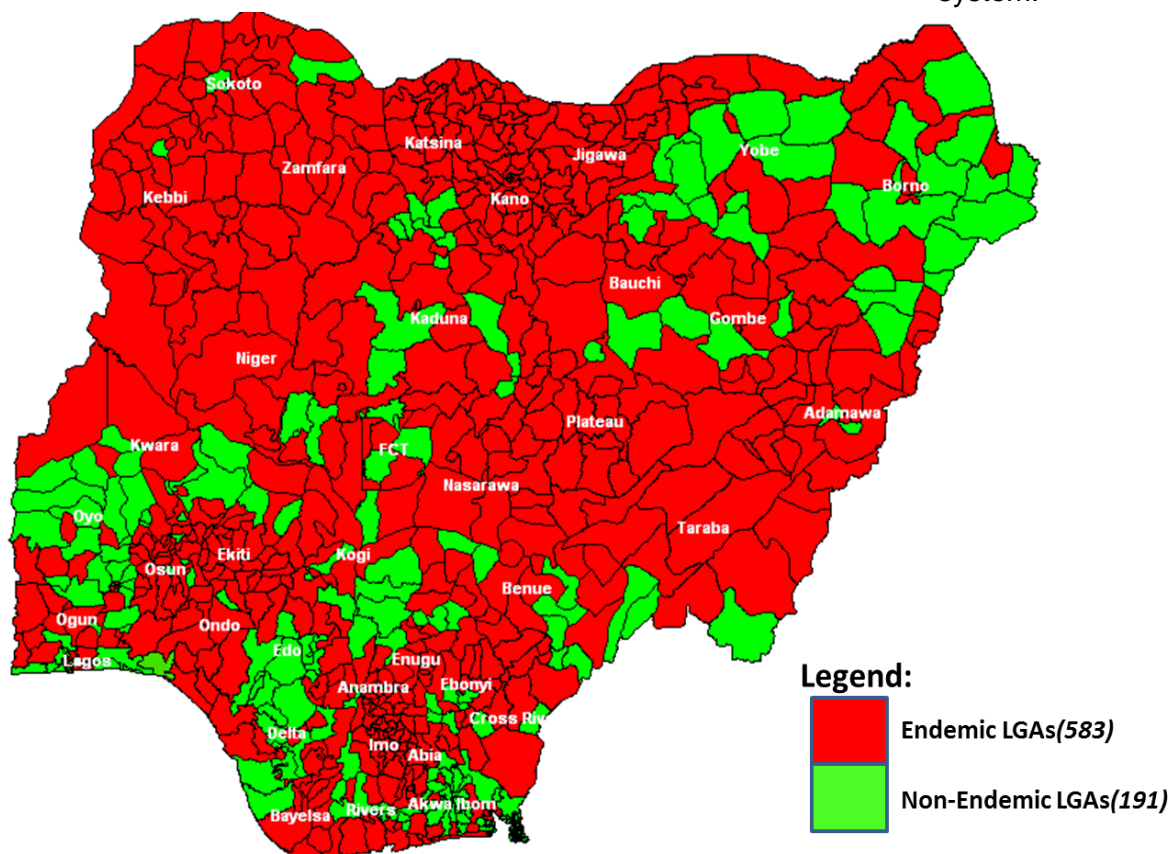
Globally, over 70 countries are endemic for LF with 946 million people at risk of infection. An estimated 120 million people in tropical and subtropical areas of the world are infected with lymphatic filariasis; of these, almost 25 million men have genital disease (most commonly hydrocele) and almost 15 million, mostly women, have lymphoedema or elephantiasis of the limbs. A recent estimation of the impact of MAM during the past 13 years suggests >96.71 million cases were prevented or cured, yet as many as 36 million cases of hydrocoele and lymphoedema remain. Of the total population requiring preventative chemotherapy, 57% live in the South-East Asia Region (9 countries) and 37% live in the African Region (35 countries).

As one of the leading causes of global disability, LF accounts for at least 2.8 million Disability Adjusted Life Years (DALYs); this does not include significant co-morbidity of mental illness commonly experienced by patients and their caregivers.

The Global Programme for Elimination of Lymphatic Filariasis (GPELF) was launched in 2000 in response to the World Health Assembly resolution WHA50.29, which requested Member States to initiate activities to eliminate lymphatic filariasis. It aims to interrupt transmission by delivering a combination of two medicines to entire populations at risk, by mass drug administration (MDA), and to manage morbidity and prevent disability. The World Health Organization (WHO) aims to stop the spread of infection and alleviate suffering among patients. WHO recommends MDA and MMDP. The core strategy of MMDP is that suffering caused by the disease can be alleviated through a minimum recommended package of care to manage lymphedema and hydrocele, and the services should be available within primary health care systems in all areas of known patients.

1.3 NIGERIA PERSPECTIVE

The National Lymphatic Filariasis Elimination Programme (NLFEP) was established in 1997 with the mandate of eliminating LF. Nigeria has an estimated risk population of 134 million people for LF. Mapping began in Nigeria in 2000 and was completed in 2018. The result shows 583 LGAs (75.3%) to be endemic for LF while 191 LGAs (24.7%) are non-endemic for LF. There is underreporting of lymphoedema and hydrocele in the country. However, accurate data on the burden of hydrocele due to LF is not known. It is assumed that all hydroceles in endemic LGAs are due to LF. Data on this is often missed as patients report to specialist centres for surgical intervention without reporting through the National disease



Source: NLFEP, NTDs Division
Dept of Public Health, FMOH Nigeria

Figure 1: Map showing the prevalence of Lymphatic Filariasis in Nigeria

In Nigeria, the implementation unit (IU) is the Local Government Area (LGA). Implementation of MAM commenced in some endemic LGAs targeting at-risk population in the year 2000. The programme is based on annual administration of Ivermectin and Albendazole donated by Mectizan Donation Program (MDP) and GlaxoSmithKline (GSK) respectively. The medicines are administered annually for at least 5 years with the aim of achieving a 100% geographical coverage¹ and at least 65% therapeutic coverage² of the total at-risk population in every round within a period of 5-10 years (Not exceeding 10 years). In an event of an LGA not achieving five effective rounds after ten years of treatment, the National programme will conduct Pre-Transmission Assessment survey in the affected LGA. If the LGA fails then operational research should be conducted and recommendations implemented.

¹Geographical coverage – proportion of administrative units that are implementing preventive chemotherapy(PC) of all those that require to be covered by a particular PC package.

²Therapeutic coverage - proportion of individuals in an endemic country requiring preventive chemotherapy for a specific disease who have ingested the appropriate drug as part of a PC package.

Effective monitoring and evaluation are necessary to achieve the goal of LF elimination. After mass administration of medicines according to the guidelines established by WHO, programmes must be able to assess whether the interventions have succeeded in lowering the prevalence of infection to a level at which transmission is no longer likely to be sustainable. In 2011, WHO published a manual for monitoring and epidemiological assessment of MAM. The manual described a new, standardized method for measuring prevalence, the 'transmission assessment survey (TAS)', in which blood diagnostic test results are used to determine whether areas have reached a critical threshold of infection. The results of a TAS provide evidence for deciding whether to stop or continue MAM.

1.4 GLOBAL STRATEGIES FOR THE ELIMINATION OF LYMPHATIC FILARIASIS

1.4.1 Elimination strategies

Strategies for elimination include: Preventive Chemotherapy, Vector Control and Morbidity Management & Disability Prevention (MMDP).

Elimination of lymphatic filariasis is possible by interrupting the transmission cycle. Providing treatment on a large-scale to entire communities where the infection is present can stop the spread of infection. This strategy of preventive chemotherapy, called Mass Administration of Medicines (MAM), involves a combined dose of 2 medicines given annually to an entire at-risk population in the following way: a tablet of albendazole (400 mg) in combination with ivermectin (3mg) based on height (as a proxy of weight). These medicines have a limited effect on adult parasites but effectively reduce microfilariae from the bloodstream and prevent the spread of microfilaria to mosquitoes. MAM with albendazole (400 mg) alone should be given preferably twice per year to stop the spread of LF in areas where *Loa loa* is present.

Adult worms can remain viable for at least five years. Therefore, it is necessary to deliver several rounds of MAM. At least five effective rounds are recommended to reduce infections in the community to levels below a threshold at which mosquitoes are unable to continue spreading the parasites from person to person and new infections are prevented.

Vector control is supplemental to the core strategy of MAM and can enhance elimination efforts by reducing the mosquito density and preventing human-mosquito contact. Malaria control interventions such as residual spraying and sleeping under long-lasting insecticidal nets have collateral benefits in reducing transmission of LF.

Management of morbidity and disability in lymphatic filariasis is aimed at improving the quality of life of affected persons by reducing the suffering through hygiene and basic skin care practices for lymphoedema and elephantiasis, as well as surgery for hydrocele.

Below are the programmatic steps for interruption of LF transmission which Nigeria has modified and adapted.



Figure 2: Programmatic steps for interruption of LF transmission - Original source: WHO, 2017

Following the successful implementation of MAM in endemic LGAs, it becomes imperative that assessments are conducted to ascertain the level of break in transmission and morbidity burden. Therefore the domestication of WHO LF assessment guidelines will help the national programme have a uniform assessment guide and strengthen human capacity at the National and State levels. The proposed National LF assessment guidelines will serve as a tool for Stakeholders/NGDOs to justify funding support from Donors for scale down of elimination activities. The national guidelines are expected to address issues such as: remapping, contiguous LGAs that form evaluation unit (EU), timeliness, tools, study designs, re-test positives in TAS, post TAS, validation, verification, dossier, potential surveillance strategies (antifilarial antibody testing & xenomonitoring) etc.

1.5 Mapping

This is conducted to determine whether active transmission is occurring and if MAM is required. Mapping survey is done by measuring antigenaemia (Ag) using prescribed diagnostic tools (FTS) or microfilaraemia (mf) using bloodfilm in adult population between 50 and 100 persons of ages ≥ 15 years that have lived in a selected community for at least 10 years. If the prevalence in this population is $\geq 1\%$, it is classified as endemic. The criteria for selection of a community to represent LGA are based on review of existing information including sanitation and report of malaria cases.

1.6 Remapping LF

In view of the global target for LF elimination, there is need to update the baseline prevalence of all geographic areas. This should be backed with evidence on whether to proceed with intervention or not. Hence, for areas with known endemicity status, remapping is required if:

- a. Mapping was conducted later than ten years ago with no evidence of intervention
- b. Evidence from studies is in conflict with the subsisting national mapping data after due validation of such studies.

CHAPTER 2.0

INTERVENTIONS

Lymphatic Filariasis is an eliminable public health burden in Nigeria. The major approaches of interventions for LF in Nigeria are:

1. Mass administration of medicines (MAM) for prevention and interruption of transmission.
2. Integrated Vector Management (IVM).
3. Morbidity management and disability prevention (MMDP) for victims with manifestations.

2.1 Mass Administration of Medicines

The aim of MAM is to reduce the level of microfilaraemia in at risk populations so that transmission cannot be sustained, even after MAM has been stopped. In this way, transmission is interrupted. The effectiveness of MAM in reducing the prevalence and density of microfilaria in the blood is directly related to the proportion of the population that ingests the medicines every year. An effective round of MAM is $\geq 65\%$ therapeutic coverage of total at-risk population and 100% geographic coverage. The programme strives to achieve this threshold.

Mass administration of medicines started in Nigeria in year 2000 in 2 LGAs each of Plateau (Kanke and Pankshin) and Nasarawa (Akwanga and Wamba) States using the Community Directed Treatment with Ivermectin (CDTI). Community drug distributors (CDD) were selected in every endemic community by the community, trained by health workers and saddled with the task of distributing LF medicines.

2.2 Integrated Vector Management (IVM)

This is a complimentary strategy that when combined with MAM will help interrupt transmission of LF parasite in endemic LGAs especially high prevalent ones.

Integrated Vector Management (IVM) involves use of:

- Long Lasting Insecticidal Nets (LLINs)
- Indoor-residual spraying
- Larval source management
- Use of outdoor protective clothing
- Environmental modification

The Malaria-Lymphatic Filariasis co-implementation guidelines developed by the FMOH identified the need to set standards for joint delivery of interventions (LLINs and MAM) as one of its objectives,

2.3 Morbidity Management and Disability Prevention

This is aimed at reducing suffering and improving quality of life by giving patients access to minimum basic recommended packages of care.

Management of morbidity and disability in lymphatic filariasis requires a broad strategy involving simple hygiene measures starting from basic skin care, to prevention of ADL and progression of lymphoedema to elephantiasis and surgery for hydrocele (hydrocelectomy).

Furthermore, psychological and socioeconomic support should be provided for people with disabling conditions to ensure that they have equal access to rehabilitation services, education and income. The activities include promoting positive attitudes towards people with disabilities, preventing the causes of disabilities, providing education and training, supporting local initiatives, and supporting micro and macro-income-generating schemes. Others include education of families and communities, to help patients with lymphatic filariasis to fulfil their roles in society.

MMDP must be continued in endemic communities after mass administration of medicines has stopped and after surveillance and validation of elimination as a public health problem, as chronically affected patients are likely to remain in these communities.

Furthermore in effective implementation of MMDP, using community level health facility structures will positively impact on documentation for LF validation and dossier development.

Chapter 3

ASSESSMENTS

An assessment is the systematic process of documentation using empirical data to refine programmes and improve implementation activities. The assessment of the programme is the mandate of the National office of the NTD Elimination programme in collaboration with State ministries of health and the partners.

The two major types of LF assessment are:

a. Pre-Transmission Assessment Survey (Pre-TAS)

Pre-Transmission Assessment Survey (Pre-TAS) for lymphatic filariasis is an assessment to determine whether LF infection has been reduced to a level that qualifies the LGA eligible for a Transmission Assessment Survey (TAS).

b. Transmission Assessment Survey (TAS)

TAS is an assessment used to determine whether endemic LGAs have reached a critical cut-off point of infection (a point which transmission is likely not sustainable). **It helps to determine whether to stop or continue MAM.**

Preparation for an Assessment.

In addition to the proper micro-planning for an assessment the following must be put in place:

- i. **Community Mobilization and Sensitization:** It is important that communities to be assessed are adequately mobilized and sensitized before assessment activities.
- ii. **Security:** Before embarking on assessment, security information should be obtained at State, LGA & community levels and should involve all relevant stakeholders. Adequate security measures should be provided to team members especially in known volatile areas of the country.
- iii. **Insurance:** Group insurance for team members should be provided during assessment.
- iv. Stakeholders Feedback Meeting.

3.1 Eligibility criteria for assessment survey

3.1.1 Eligibility Criteria for Pre- Transmission Assessment Survey (Pre-TAS)

To be eligible for a Pre-TAS

- a) LGAs should have achieved at least five (5) effective MAM rounds with minimum of ≥65% therapeutic coverage and 100% geographical coverage of at-risk population in each round within minimum of 5 years and maximum of 10 years.
- b) LGAs that have achieved 5 effective MAM rounds should be eligible for Pre TAS 6 months after last MAM.

3.1.2 Eligibility Criteria for Transmission Assessment Survey (TAS)

The requirements for TAS are as follows:

- a) LGAs must have passed Pre-TAS (threshold for pass is <2% antigenaemia in each site).
- b) TAS should be carried out at least 6 months after last MAM.
- c) Evaluation Unit (EU) population should not exceed two (2) million people.
- d) LGA(s) that forms an EU should have similar epidemiological characteristics and geographic proximity

3.2 Pre- Transmission Assessment Survey (Pre-TAS)

3.2.1 Definition of Sentinel and spot check sites

i. Sentinel site

A sentinel site (SS) is a previously mapped community or baseline surveyed community.

ii. Spot check site

A spot check (SC) site is another community which is not contiguous to the Sentinel site and assumed to be at high risk of continued transmission due to low MAM coverage and high vector density (high reported malaria cases).

3.2.2 Characteristics of sentinel and spot check sites

Sites with the following characteristics should be selected as sentinel and spot check sites

A stable population of at least 500 people (so as to collect a convenience sample of at least 300 people aged ≥ 5 years of age). Where the sample size is not adequate, an adjoining community should be sampled to complete the sample size.

In an area of known high transmission (i.e. high disease or parasite prevalence or vector abundance) or an area where difficulty in achieving high medicine coverage is anticipated.

- No MAM for Lymphatic filariasis and Onchocerciasis in the last six (6) months.

A sentinel site cannot be changed while the spot check site can be changed.

The sentinel and spot check sites should not be contiguous.

3.2.3 Number of sentinel and spot check sites

At least one sentinel site per 1 million people in the LGA (IU)

At least one spot check site for each LGA (IU); more sites may be selected where resources allow.

3.2.4 Threshold for Pre-TAS

<2%Ag (antigenaemia) or <1% microfilaremia

3.2.5 Target population

Community members of ages 5 years and above irrespective of gender qualify to participate voluntarily in the assessment.

3.2.6 Sample size

Collect finger prick blood samples from a minimum of 300 persons in each sentinel and spot check sites.

3.2.7 Sampling Strategy

Convenience sampling strategy: The community members gather at survey site and volunteers are randomly recruited into the survey.

3.2.8 Pass Pre TAS

Treatment should be conducted in the LGA that passes Pre TAS in the year of assessment while awaiting advice from WHO and Regional Programme Review Group (RPRG) to proceed for TAS1.

3.2.9 Fail Pre TAS

LGA that fails Pre TAS will conduct two effective rounds of treatment and repeat Pre-TAS.

Use multiple strategies during MAM (Conduct treatment in places of worship and other public places) using directly observed treatment (DOT) approach.

3.3 Transmission Assessment Survey (TAS)

3.3.1 Confirming eligibility to conduct TAS

To qualify for TAS the LGA(s) must have passed Pre TAS

TAS is conducted at least 6 months after the last round of MAM

3.3.2 Geographic area for TAS (Evaluation Unit)

An Evaluation unit is an LGA or aggregate of LGAs with similar epidemiological features, risk of ongoing transmission and geographical proximity.

Epidemiological Features: LGAs that have been mapped and are endemic for LF, have baseline information and have passed Pre-TAS.

Geographical proximity: LGA(s) that are forming an Evaluation unit should be contiguous (border each other).

Two or more non-contiguous endemic LGAs with similar epidemiological features that have passed Pre-TAS but separated by non-endemic LGAs can form an Evaluation Unit.

3.3.3 Target population:

Pupils in primary 1 and 2 in school-based surveys or six and seven year old children in community-based surveys. Children should have been protected from infection if MAM was successful in interrupting transmission. Positive test results in this age group therefore usually indicate recent transmission.

3.3.4 Survey site:

School based survey: Schools are used since the school enrolment ratio is usually above 75%. **If the school enrolment ratio is below 75%, community surveys should be implemented.**

3.3.5 Survey Sample Builder:

The Survey Sample Builder (SSB) is a Microsoft Excel tool that is used to (i) automate calculations for determining the appropriate survey design and (ii) facilitate random selection of clusters and children or households from a list of randomized numbers.

3.3.6 Sampling Strategies:

Cluster sampling strategy: This strategy is often used when the population is large or there are many schools or enumeration areas.

Systematic sampling strategy: This strategy is often used when the population is small to medium or if there are fewer than 40 schools or Enumeration Areas.

Census: This strategy is often used when the population is small.

3.3.7 Sample size:

Survey Sample Builder (SSB) determines the sample size. This depends on the population of the target age children in the EU and the sampling method used.

3.3.8 Critical cut-off:

Survey Sample Builder (SSB) generates the critical cut-off. This is a threshold of infection prevalence below which transmission is assumed to be no longer sustainable in the absence of MAM.

TAS provides an estimation of this threshold in the EU as a number of antigen positive cases.

Positive cases should be repeated to confirm the test result.

3.3.9 Sample design:

Survey Sample Builder (SSB) determines the sample design

3.3.10 Pass TAS:

EU that passes TAS 1 will treat in the LGA(s) for that year of assessment and wait for approval to stop MAM from the National office of NTDs Programme, Federal Ministry of Health.

Follow up positive case; identify cluster where the positive case resides and conduct MAM for eligible population till next TAS.

3.3.11 Fail TAS:

EU that fails TAS 1 will treat for 2 effective rounds in the LGA(s) and repeat TAS1.

The interval between TAS 1 & TAS 2 is 2 years.

3.3.12 Pass TAS 2:

EU that passes TAS 2 should wait for 2 years and conduct TAS 3.

Follow up positive case; identify cluster where the positive case resides and conduct MAM for eligible population till next TAS.

3.3.13 Fail TAS 2:

EU that fails TAS 2, the National office of NTD Programme, FMOH will require expert guidance from WHO and RPRG. The National NTD office, FMOH may conduct Operational Research (OR).

3.3.14 Pass TAS 3

EU that passes TAS 3 will maintain Post MAM surveillance until all EUs in the country pass TAS3 and are validated by WHO that LF has been eliminated as public Health problem.

Follow up positive cases and conduct MAM in the clusters, while post-MAM surveillance is ongoing.

3.3.15 Fail TAS 3:

EU that fails TAS 3, FMOH will require expert guidance from WHO and RPRG. FMOH may conduct Operational Research (OR).

3.4 Co-assessment:

An integrated approach to the control /elimination of Neglected Tropical Diseases (NTDs) is to avoid duplication of effort and reduce cost.

The LF TAS and STH Surveys should be done where there is co-endemicity using WHO approved tools. This has been well documented in WHO (2015) [Assessing the Epidemiology of STH during a TAS].

3.5 Field Work

3.5.1 Community Mobilization & Sensitization:

- Pre-assessment visits should be carried out by the State NTD team and LGA Coordinator/Education Secretary to the selected communities or schools
- Mobilization and sensitization of community and school is key to a successful implementation of Pre TAS, TAS and post surveillance.
- The purpose is to create awareness, sensitize them so as to secure their commitment and participation for a successful implementation of these assessments and informed consent from selected communities/schools should be obtained before the commencement of any assessment.

- Key messages with local contents to suit the target audience should be passed on; to avoid rumors and misconception that may jeopardize the survey.
- Appropriate communication channels such as use of town announcers, radio, television etc. should be deployed.

3.5.2 Planning for Assessment

There should be appropriate planning meeting with relevant stakeholders before conducting any assessment. This planning meeting must take into cognizance the security situation of the areas for assessment.

3.5.3 Training for Assessment

The National technical team should coordinate and facilitate the pre assessment training. The minimum number of days for pre TAS should be two days, TAS should be three days and other post surveillance activities should be two days.

3.5.4 Logistics management

Appropriate human and material resources should be deployed in line with the type of assessment to be conducted. Diagnostic tools e.g. FTS and materials such as: alcohol swab, lancet, gloves, data collection tools (hard copy or electronic copy), methylated spirit, table mat, cotton wool, disposable laboratory coat, digital table clock, disposable sharp container, permanent marker, waste bags, pens, hand sanitizer, bleach, etc.

3.5.4.1 Primary data forms:

The hard copy data collection tool and the electronic data capture forms will be used simultaneously as the primary sources for any assessment

3.5.4.2 Manager for electronic data platform (Smart Phones & Cloud):

Electronic data capture forms will be stored in the cloud with a Cloud Manager to maintain the captured data obtained from the field. The National focal person will have the license to access stored electronic data.

3.5.4.3 GPS Machine

GPS machine or other available devices can be used to capture coordinates of the survey sites.

3.5.4.4 Itinerary

Detailed itinerary containing schedule of activities for the assessment should be made available to all team members after the training

3.5.5 Team composition

All assessments and surveys regarding LF are planned and conducted by the National Programme based on expert advice from the LF National focal point buttressed by the current national data and prevailing guidelines. Usually, the National coordinator is the head of the National programme and responsible for the planning and implementation of all assessments and surveys. The National programme will facilitate team composition and deployment, and provide a technical lead or a designate as the case may be. The supporting

NGDO will be part of the team but in an observer role during assessments. For the roles and responsibilities of team members for LF assessments, refer to annex 5.

For Pre TAS: A team will consist of:

- Team leader
- Enumerator
- Lab. Scientist
- Lab. Technician
- Card Reader
- Electronic data manager
- Local guide
- Town announcer
- Community mobilizer
- Driver

For TAS: A team will consist of:

- Team leader
- Enumerator
- Lab. Scientist
- Card Reader
- Electronic data manager
- Local guide (Education officer/Community guide)
- Head Teacher/Community Head
- Driver

Post surveillance: A team will consist of:

- Team leader
- Enumerator
- Lab. Scientist
- Card Reader
- Electronic data manager
- Local guide
- State Epidemiologist
- Disease Surveillance Notification Officer (DSNO)
- Driver

3.5.6 Safety precaution:

- The lab scientist and technician should handle blood sample with care
- The lab scientist and technician should always wear appropriate protective safety gadgets such as: hand gloves, lab coats etc.
- All used lancets should be carefully disposed. Avoid re-use of lancet on a recruit.
- All Standard Operating Procedure (SOP) should be adhered to
- Clean up and disinfect the laboratory work environment.

3.5.7 Quality control (FTS/diagnostic tool):

- The use of control is critical to ensure quality of test kit used for assessment.
- Test each lot of diagnostic test kits with a positive control when available to ensure their validity
- Open the pouch just before use; test kits should be used immediately after opening the package.
- Store diagnostic test kits properly to minimize the risk of compromising their quality
- Confirm any indeterminate test result immediately by a second reader or team leader; repeat positive and indeterminate tests if necessary. See Table 1 below

Table 1: Procedure to confirm test results

| # | Test 1 result | Test 2 result | Test 3 result | FINAL RESULT | Treatment Needed |
|----|---------------|---------------------------|---------------------------|---------------|-------------------|
| 1 | Negative | No further testing needed | No further testing needed | Negative | No |
| 2 | Positive | Negative | No further testing needed | Inconclusive* | Yes, but optional |
| 3 | Positive | Positive | No further testing needed | Positive | Yes |
| 4 | Positive | Invalid | Positive | Positive | Yes |
| 5 | Positive | Invalid | Negative | Inconclusive* | Yes but optional |
| 6 | Positive | Invalid | Invalid | Positive | Yes |
| 7 | Positive | Invalid | Refused/Not Done | Positive | Yes |
| 8 | Positive | Refused/Not Done | No further testing needed | Positive | Yes |
| 9 | Invalid | Positive | Positive | Positive | Yes |
| 10 | Invalid | Positive | Negative | Inconclusive* | Yes but optional |
| 11 | Invalid | Positive | Invalid | Positive | Yes |
| 12 | Invalid | Positive | Refused/Not Done | Positive | Yes |
| 13 | Invalid | Negative | No further testing needed | Negative | No |
| 14 | Invalid | Invalid | No further testing needed | Inconclusive* | No |
| 15 | Invalid | Refused/Not Done | No further testing needed | Inconclusive* | No |

*Note: Individuals with inconclusive results are removed from the overall sample, and do not count towards the designated quota of individuals for a pre-TAS or TAS site.

Note: The cluster where the positive case resides should be treated till the next assessment.

3.6 Data Management

FMOH Card Reader/Electronic data manager will enter assessment data into the data forms (hard copy and electronic copy). Data editing and cleaning will be carried out before analysis but validated by the Team leader.

3.7 Data Interpretation

The interpretation of data from test results will inform the National Programme Office on level of implementation success

3.7.1 Pre TAS

If the prevalence is <2% antigenaemia, it indicates the LGA passed Pre TAS while 2% and above means the LGA failed.

3.7.2 TAS

Critical cut-off is the number of positive Filarial Test Strip (FTS) cases generated by the survey sample builder that must not be exceeded, beyond which such Evaluation Unit (EU) is considered to have failed TAS.

4.1 Validation

A framework for the control, elimination and eradication of NTDs has been developed which outlines a standardized process for reviewing and confirming the achievement of NTD roadmap targets. A process of validation will be used for formal confirmation of elimination as a public health problem. At any point in time the National Programme can request WHO for such acknowledgement with adequate evidence that elimination targets have been achieved.

Preliminary guidance from the WHO referred to “*Validation*” as the process of documenting the elimination of LF as a public health problem through a validation dossier and receiving approval for the accomplishment from WHO. Elimination of LF as a public health problem means a geographical area has achieved the measurable global targets set by WHO in relation to LF.

On the other hand, “*Verification*” is the official process by which the achievements of the Global Programme to Eliminate Lymphatic Filariasis (GPELF) to eliminate transmission of Lymphatic filariasis (LF) would be confirmed. In this case, incidence of infection caused by the specific pathogen (*Wuchereria bancrofti*) in Nigeria is reduced to < 2% Ag, with minimal risk of reintroduction, as a result of deliberate efforts.

The figure below illustrates the main steps for validation as stipulated by the WHO.



Figure 3 Validation Process

source: WHO 2017

4.2 Milestones towards validation

- Stop the spread of infection through MAM
 - Implement MAM in all endemic areas by the end of 2019 (100% geographical coverage)
 - Reduce infection below a threshold at which transmission is not sustainable in all endemic areas and stop MAM by 2024.
 - Demonstrate sustained reduction of infection below the threshold no earlier than 4 years after stopping MAM
- Alleviate suffering by managing morbidity and disability prevention (MMDP)
 - Define burden of disease (estimates of the number of patients)
 - Recommended minimum package of care available in all areas of known patients (100% geographical coverage)

4.3 Data Gathering for Dossier Preparation

State(s) must gather data to prepare the dossier. Each section of the template dossier should be addressed and supported with presentation of programme data. A State LF elimination programme should archive information throughout the history of

the programme. If such an archive is not available, the following information resources (non-inclusive) may contain supportive data required for the dossier:

- i. States' Ministry/Department of Health reports
- ii. State Integrated NTD database, NTD technical report and State logistic management information system
- iii. Reports submitted through FMOH to WHO
 - a. LF annual report to WHO
 - b. WHO Joint Application Package (JAP) consisting of Joint Reporting Form (JRF); Joint Request for Selected Medicines (JRSM); Epidemiological Data Reporting Form (EPIRF)
 - c. TAS Eligibility and Planning forms
 - d. Presentations given at State, Zonal and National NTD programme review meetings; steering committee meetings and Programme Managers Meetings (PMM).
- iv. WHO PCT Databank:
http://www.who.int/neglected_diseases/preventive_chemotherapy/lf/en/
- v. WHO Weekly Epidemiological Record: <http://www.who.int/wer/en/>
- vi. Publications from research projects or surveys
- vii. Regional publications, including official meeting reports of RPRG and PMM, activity reports from collaborating institutions, non-governmental organizations, or bilateral organizations
- viii. Patient case-reports, surveillance reports of lymphoedema and hydrocele cases
- ix. Reports from programme evaluations, situation analysis, or consultants

Additionally, WHO has created a dossier data to facilitate the presentation of programme data to document in the dossier. LGA specific data on endemicity, MAM, TAS and MMDP can be entered. Use of the tool (Annexes 1-4) is encouraged.

4.3. 1 Preparation and submission of dossier

- i. State(s) that have met the validation criteria shall submit a dossier to the National Office of the NTD Elimination Programme, FMOH for official acknowledgement from WHO that they have met the criteria for elimination of lymphatic filariasis as a public health problem.
- ii. The NTD Elimination Programme of the Federal Ministry of Health, will seek official acknowledgement from WHO for the whole country having met the criteria for elimination of LF as a public health problem. FMOH shall submit a dossier to the WHO on behalf of the State(s), documenting the measures taken and the evidence supporting the claim.
- iii. All States will reference the WHO dossier template (Annex 6) for guidance and to ensure that the information presented meets the minimum necessary criteria to support the claim.

- iv. FMOH shall request feedback on the draft country dossier from the RPRG through the WHO Africa Regional Office before official submission. This can be submitted through the WHO Nigerian country office.
- v. Nigeria shall submit the finalised and completed dossier (one hard copy and one electronic copy) to the WHO country office in Nigeria for the attention of the WHO Representative. The WHO country Office shall acknowledge receipt of the dossier to the Member State, and forward it to the focal point for LF in the WHO Regional Office. The WHO Africa Regional Offices shall then notify the Department of Control of Neglected Tropical Diseases at WHO headquarters.

4.4 Overview of dossier

This template dossier was designed to help State and National Coordinators of NTDs to prepare LF elimination dossier with supporting evidence for presentation to WHO, requesting validation that LF has been eliminated as a public health problem. The information presented in the dossier will provide the context necessary to help reviewers understand programme achievements and supporting epidemiological evidence.

However, the minimum information necessary to support the claim of elimination as a public health problem includes the following elements:

1. Background information on the geographical area stipulated for validation
2. Delineation of endemicity with description of and supporting data on how endemic and non-endemic areas were classified as such
3. Interventions implemented to combat LF to include data on the interventions (treated population, coverage, etc.)
4. Monitoring data of the conducted interventions, including microfilaraemia and/or antigenaemia at the sentinel and spot-check sites including results from TAS from endemic areas
5. MMDP – information on reported and/or estimated number of patients with lymphoedema and hydrocele and data indicating availability and provision of the basic recommended package of care
6. Commitment for post-validation surveillance.

4.5 Reviewing Authority

- i. The dossier will be reviewed by an ad-hoc reviewing authority (hereinafter referred to as the Reviewing Group) consisting of members from WHO Africa Regional Office and other independent local experts.
- ii. The objective of the Reviewing Group is to determine whether the information contained in the dossier supports the claim of elimination as a public health problem according to the criteria outlined by WHO.

- iii. The WHO Africa Regional Office will be responsible for appointing and convening the Reviewing Group upon the submission of country dossiers. The Reviewing Group should comprise of at least three members who meet the following criteria:
 - Members should be experts on LF and public health.
 - Members should not have supported the development of the dossier under review, and should be considered independent and have no conflict of interest with regard to the statements made in the dossier.
 - Members will be invited to participate as individuals, not as representatives of an organization, institution or government. Nomination of proxies will therefore not be permitted.

4.6 Reviewing Procedure

- i. The validation will be carried out at all levels – National, State, LGA and Community; among government, partners and relevant stakeholders.
- ii. Members of the Reviewing Group will elect a Chair from among their number. The Chair will be responsible for chairing Reviewing group meetings; considering requests made by the Secretariat for observers to join Group meetings; coordinating and completing with other Reviewing Group members, a report on the visit (if a visit is deemed necessary) to the States, before group members depart; and signing off the summary report to WHO.
- iii. The scope of work of the Reviewing group is as follows:
 - a. A visit to the States will be undertaken for the purposes of the validation process only if there is a consensus of the Reviewing Group that such a visit is required.
 - b. Members will examine dossiers on a voluntary basis, independently maintaining the highest ethical standards, and declaring any conflict of interest prior to participation in collective discussions.
 - c. Members will provide written comments on the dossier to share with other members and shall clarify comments during collective discussions to develop a summary report.
 - d. Members will obtain consensus and recommend that WHO either:
 - i. Validates the claim of elimination as a public health problem; or
 - ii. Postpones such a decision until more evidence is provided in the dossier to demonstrate that elimination has occurred. In either case, the recommendation must be adequately justified.
 - e. Members will also provide a summary report of deliberations with clear recommendations including:
 - i. Conclusions, in which the Reviewing Group discusses the compliance of the data with the elimination criteria set by WHO, and expresses its opinion on whether or not to validate the claim.

- ii. Recommendations to the State(s): in case of validation, recommendations should focus on post-validation surveillance activities; in case of postponement, recommendations should focus on what steps the country should take in order to meet the elimination targets in the future, including a clear description of any reasons for postponement outlining the additional evidence needed in the dossier to be returned to the country.
- iv. Secretariat functions will be provided by WHO throughout the process. It will:
 - a. Provide the dossier and other information needed to each Reviewing Group member.
 - b. Organize discussions of the Reviewing Group via teleconference, videoconference or face-to-face meetings, inviting observers where this is considered desirable and agreed by the Reviewing Group's Chair.
 - c. Specify the responsibilities and decision-making processes of the Reviewing Group.
 - d. Liaise with the FMOH in order to obtain any additional information requested by the group.
 - e. Collate the independent reviews of group members and ensure the preparation of a summary report.
 - f. Obtain sign-off of the summary report by FMOH.
 - g. Process and permanently archive the summary report.
- v. Each Reviewing Group member will:
 - a. Keep confidential the contents of the dossier and all other information to which group members are given access, including the deliberations and recommendations of the group
 - b. Discuss them only with relevant WHO staff and other group members. Information should not be discussed directly with the Ministry of Health of the Member State, or with any other organization or person.
 - c. Review the dossier independently, within the specified timeframe and following the directions given for this task.
 - d. Discuss the dossier collectively, via video conference, teleconference or face-to-face meeting.
 - e. Participate in a country visit (if deemed necessary).
 - f. Review the draft summary report within the specified timeframe

4.7 Processing of Recommendations

The following actions will be taken after the Reviewing Group has signed off the summary report:

- a. If the group recommends postponement of validation of elimination, the summary report will be forwarded by the WHO Africa Regional Office through the WHO country office to FMOH Nigeria with clarification of what additional

evidence is required prior to validation. Following that, the FMOH will acknowledge receipt and together with the relevant stakeholders will review the submission from WHO and take necessary actions.

- b. If the Group recommends validation of the claim, the summary report will be forwarded by the WHO Regional Office with the request for acknowledgement of the achievement to WHO.
- c. At the discretion of the WHO Director-General, the official acknowledgment to Nigeria will be provided through a letter of notification presented by the WHO Africa Regional Office.
- d. Validation will be acknowledged by the following additional ways:
 - i. Reported in the disease-specific global progress update published annually in the Weekly Epidemiological Record by WHO headquarters;
 - ii. Noted by updating the status of endemicity of LF in the Global Health Observatory by WHO headquarters
- e. At the discretion of the Minister for Health, the official acknowledgment to the State(s) will be provided through a letter of notification presented by the FMOH.

4.8 After Validation

- i. Validation implies a potentially reversible state, and all stakeholders should bear this in mind in their communications at all stages.
- ii. State(s) shall continue to conduct post-validation surveillance and ensure integration of MMDP into health services as recommended by the Reviewing Group. A commitment to continue surveillance and MMDP shall be stated in the dossier.
- iii. Surveillance data shall be reported to WHO. Where these data indicate that infection has recrudesced above elimination thresholds, WHO should be consulted on an appropriate response.
- iv. Recrudescence above original elimination target thresholds will be noted by a change in endemicity status in the Global Health Observatory and in the Weekly Epidemiological Record.
- v. With the agreement of Nigeria and after the WHO Director-General has acknowledged the elimination of LF as a public health problem – the dossier may be made available on the WHO website as a reference document.

4.9 Verification of Elimination of LF

Nigeria may, at a later date, request verification of elimination of transmission, if appropriate evidence amended to the dossier demonstrates that this has occurred. Specific requirements for such verification have not yet been agreed.

Chapter 5.0 POST MAM SURVEILLANCE

Surveillance is the ongoing, systematic collection and evaluation of data describing the occurrence and spread of disease. It is the part of the programme aimed at the discovery, investigation and elimination of continuing transmission, the prevention and cure of infections, and the final substantiation of claimed absence of transmission.

5.1 Cross-Sectional Surveys, Including Post-MAM TAS

A TAS is not only important in deciding to stop MAM but is also a method recommended in post-MAM surveillance to detect recrudescence of transmission. Surveys should be repeated at least twice after MAM, at an interval of 2 years, to ensure that recrudescence has not occurred and that transmission can therefore be considered interrupted.

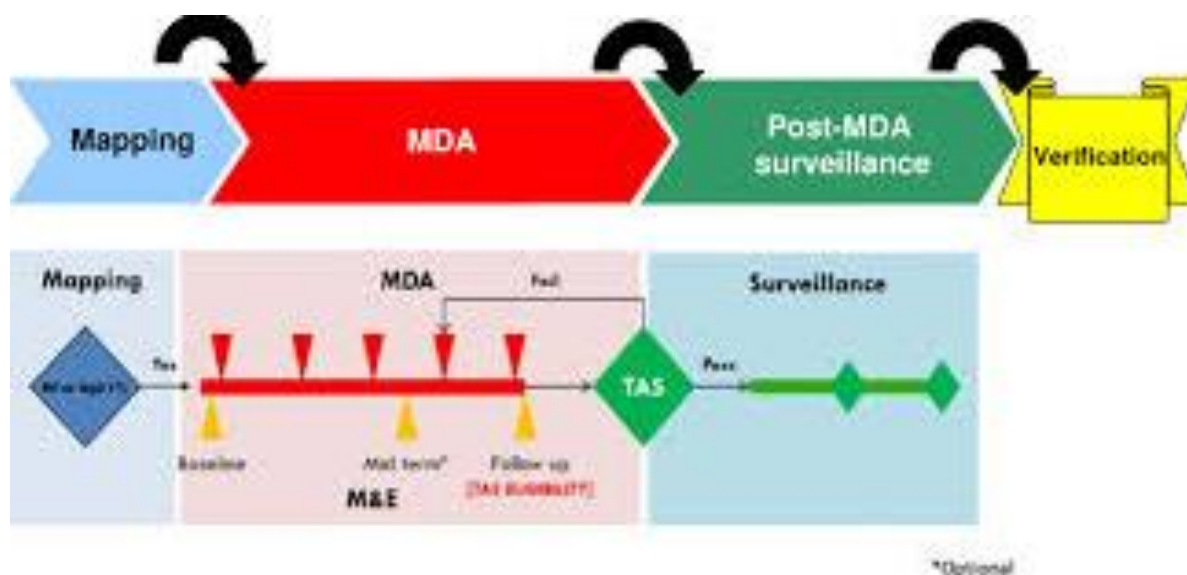


Figure 4: Steps to follow in Post MAM TAS

Source: WHO, 2017

5.2 Surveillance after MAM

This can be implemented in two ways:

- i. Periodic surveys: repeat TAS twice at interval of 2 years; and
- ii. Surveillance activities should continue after stoppage of MAM.

Other potential future surveillance strategies include antifilarial antibody testing and xenomonitoring.

5.2.1 Periodic surveys

Repeating a TAS is the best option for periodic surveys during post-MAM surveillance. Two post-MAM surveillance surveys will be conducted to evaluate

whether recrudescence has occurred. Each survey will be conducted approximately 2 years following the previous survey and should use a similar design as the original TAS.

Comparing antigen-positive or antibody-positive cases to the critical cut-off is more important than comparing differences between the first and second surveys. If the post-MAM surveillance survey results are greater than the critical cut-off point, this could be a warning that transmission has resumed. It is important to have consultation with experts in order to decide on next steps. Depending upon the level of antigenaemia or antibody detected during these surveys, additional rounds of MAM might be required. Reassessment of the MAM stopping criteria could be repeated after one or more additional rounds of MAM.

Even after MAM has stopped, National programmes will develop plans that include activities to manage morbidity and prevent disability, as well as ongoing surveillance and evaluation.

Post-MAM activities will occur in each evaluation unit as individual units stop MAM and then at a country level, once the entire country has stopped MAM. Post-MAM activities will vary according to the country situation.

The country will implement a policy of “testing and treating” for high-risk populations such as migrants. Under this policy, positive cases would be treated with ivermectin and albendazole tablets. Such cases will be followed up with repeat testing and treatment. The country will continue with vector control measures to ensure that recrudescence will not occur.

The Programme will aim to integrate post-MAM surveillance activities with those of other NTD control programmes, or integrate LF surveillance activities with population-based surveys to minimize the need for long-term resources for LF specific surveillance. This would be useful both in and between the TAS.

5.2.2 Surveillance

National programme should implement surveillance to detect new foci of transmission, collect data on infection trends in the general population and confirm the interruption of transmission. Surveillance should cover the entire country, except areas with no risk of transmission. Some of the population groups that can be surveyed include;

- Military and paramilitary recruits (during their medical check-up)
- Students (during their medical check-up or prenatal examination)
- Blood donors
- NYSC camps
- IDP camps
- Hospitalized patients.
- Migrant groups (Nomads, miners, herders, farmers, etc.)
- Pre-employment exercise

Clinical laboratories (for malaria, tuberculosis or HIV) at hospitals are encouraged to test a certain number of blood samples a month for the presence of microfilaraemia, antigenaemia, or antibodies. This information could be reported to the national programme and other disease control programmes. If any positive cases occur, they could be treated directly at the hospital, but also investigated by staff of the National programme to determine the source of infection.

5.2.3 Operational Research

Operational research (OR) is needed to evaluate critical challenges preventing stoppage of MAM and completion of elimination dossier for the submission to the WHO for validation.

The OR should address issues such as;

- i. Ineffective MAM coverage in urban, semi-urban, and hard-to-reach settings.
- ii. Unidentified isolated areas of ongoing transmission.
- iii. Low baseline prevalence and why they fail Pre-TAS.
- iv. High prevalence and why they pass Pre-TAS.
- v. Passing TAS 1 and failing TAS 2.
- vi. Passing TAS 1, TAS 2 and failing TAS 3.

5.3 Entomological Monitoring

Entomological monitoring activities should be considered to look for evidence of infection in vectors. The approaches should rely on the availability of National reference laboratories and coordinated by the National programme. Monitoring sites should be the sentinel and spot check sites in the endemic LGAs.

Sampling methods can be both or either methods listed below for capturing all mosquitoes' species (*Anopheles*, *Culex*, *Aedes* and *Mansonia*).

- Pyrethrum Spray Catch (PSC)
- Light trapping method
- Gravid traps
- Exit traps

Methods or approaches to the entomological monitoring post-MAM surveillance for *W. bancrofti*, transmission depends on the following diagnostic tools:

- i. Antibody assay reflecting exposure to infective larvae (whether or not infection is established).
- ii. Direct assessment through PCR techniques of parasites in vector mosquitoes that is xenomonitoring.

Result will advise whether transmission is interrupted or if there is recrudescence.

5.4 Morbidity Management and Disability Prevention (MMDP)

5.4.1 Data on Number of Patients with Lymphoedema or Hydrocele

The methodology to be used to identify the number of patients with lymphoedema and/or hydrocele should be active or passive search in the different States.

National programme will collect data on morbidity and disability regularly (known or estimated), once a year, depending on the local disease burden and the available human resources.

The State(s) and National Programme will verify reported morbidity cases and ensure adherence to the minimum basic care package.

WHO expects three indicators:

- i. Estimated number of lymphoedema and/or hydrocele patients by IU
- ii. Number of health facilities by IU providing services
- iii. Assessment of quality of 10% of facilities

CHAPTER 6.0 HUMAN CAPACITY DEVELOPMENT FRAMEWORK

An effective and efficient capacity development of competent State Scientists and Enumerators will be carried out to support the process. At least 10 Scientists and 10 Enumerators from each State will be trained by the National programme. The aim is to have a pool of Scientists and Enumerators that can participate at short notice.

6.1 Training

Training will be done in batches from one zone to the other. The Scientists and Enumerators will be drawn from the academia, health facilities and Ministry of Health in the State.

6.2 Training Schedule

Training will be carried out as follows:

- a) **First time Training**—all nominees will be trained in depth for the first time. It will involve theoretical and practical
- b) **Refresher training** will be shorter and will be held just before commencement of assessment in order to refresh the capacity that has already been built. It will precede field deployment. It is meant for those that will be going to the field and at the time that they will be due to leave
- c) **Expansion of training and replacement** of individuals who may have left the team.

7.0 TRAINING MODULE CONTENT

There are ten modules (Background, eligibility for a TAS, evaluation unit, survey design, diagnostic test, after the survey, verification of elimination, survey sample builder, timetable budget & administration and field work), which will be used for training and users. The content development will be done before use in two phases:

- a) Development of the content at a meeting of experts conveyed for that purpose
- b) Review and approval of the content at a meeting that is conveyed specifically for that purpose.

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**Annex 2a: LYMPHATIC FILARIASIS PRE-TRANSMISSION ASSESSMENT SURVEY
INDIVIDUAL FORM**

Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Pre-Transmission Assessment Survey

State:LGA: Village/ Community:.....

Coordinates: Lat: Long:

Survey Date: FTS Kit Lot No.: Expiry date:

Individual Form

| S/N | Name | Age | Sex | Test Result | Do you have LLIN? (Y/N) | Slept inside Net last night? (Y/N) | Length of stay in Comm. ? (yrs) | When did you take LF medicine last? (mth/yrs) | Remarks (L/H) |
|-----|------|-----|-----|-------------|-------------------------|------------------------------------|---------------------------------|---|---------------|
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*LLIN = Long Lasting Insecticide Treated Net; yrs=years, mth=months, Y=Yes, N=No, L= Lymphodema, H=Hydrocele

Name and Signature of Team leader:

Name and Signature of Lab. Scientist(s):

Annex 2b: LYMPHATIC FILARIASIS PRE-TRANSMISSION ASSESSMENT

Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Pre-Transmission Assessment Survey

Community Form

State.....

LGA.....

Community/Village.....Total Population.....

GPS: Latitude..... Longitude.....

Community/VillageLeader.....

Year and Month of Last Lymphatic Filariasis (LF) MDA.....

Number of MDA rounds for Oncho (Ivermectin).....

Number of MDA rounds for LF (Ivermectin and Albendazole)

Name of Team Leader.....

Annex 3a: CONSENT FORM FOR HEAD TEACHER/GUARDIAN

Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Transmission Assessment Survey

CONSENT FORM FOR HEAD TEACHER/GUARDIAN

Introduction

I amand I work for the Ministry of Health.

We are asking pupils in primary 1 and 2 in this school to participate voluntarily in this survey. S/he may be sick with lymphatic filariasis (LF) and the purpose of this study is to determine if LF is still in this area.

We will prick their fingers to collect blood sample the same way it is done at the hospital. The sample will be used for a test to see if they have the disease (LF).

Participation in this survey is voluntary. Neither parents nor teachers can compel them to participate against their wish. They reserve the right to opt out at any point in the course of the exercise.

We will educate them on the benefit of the survey and they are free to ask questions.

Do you consent to their participation in the study? Yes No

Name of School:

Name of respondent:

Sign:

Date:

Annex 3b: TRANSMISSION ASSESSMENT SURVEY INDIVIDUAL FORM

Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Transmission Assessment Survey

INDIVIDUAL FORM

| FTS Lot Number: -- | | FTS Expiry Date: | | | | Page: ----of---- | | | |
|--------------------------------------|------|------------------------------|-----|--------------|---------------------------------------|------------------|--------------------------------------|--------------------|---|
| School Name: | | Team: | | Team Leader: | | | EU: | | |
| School Code: | | Name of Head Teacher: | | | | | | | |
| Community: | | LGA: | | | State: | | | | |
| Date: | | Lat.: | | | Long.: | | | | |
| Total Number Pry 1-2 pupils present: | | | | | Total Number pry 1-2 Pupils Selected: | | | | |
| Code | Name | Consent to blood test? (Y/N) | Sex | | Age | Pry 1 / 2 | How long have you lived in this LGA? | FTS result (+/-/R) | |
| | | | M | F | | | | M | F |
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| TOTAL | | | | | | | | | |

Pry= primary; Y=Yes; N=No; M=Male; F=Female; R= Refusal; Lat. = Latitude; Long. = Longitude; EU= Evaluation Unit; +=Positive; - = Negative

Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Transmission Assessment Survey

FOLLOW-UP FORM FOR POSITIVE CASES

STATE:

EU:

LGA:

| S/N | School code | Child's name | Parent/Guardian's name & Contact | Length of Stay in the LGA | Community | Age | Sex | LF Medicines | | Do you have mosquito net? (Y/N) | Do you sleep inside mosquito net? (Y/N) |
|-----|-------------|--------------|----------------------------------|---------------------------|-----------|-----|-----|---|-------------------------------|---------------------------------|---|
| | | | | | | | | Have you ever swallowed LF medicines (Y/N)? | If Yes, how many times taken? | | |
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Y= Yes; N= No; EU= Evaluation Unit

Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Transmission Assessment Survey

HEAD TEACHER QUESTIONNAIRE

1. What is the name of this School?
2. What is the name of the Head Teacher?
3. What is the total school (Primaries 1 – 6) enrolment?
4. What is the enrolment for primaries 1 & 2?
5. Do you have a toilet system in this School? Yes or No
6. What type of toilet system do you have in this School?
7. Do you have clean water in this School? Yes or No
8. What is the source of water in this School?.....

Annex 4a: MORBIDITY MANAGEMENT AND DISABILITY REPORTING FORM

Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Annual Morbidity Management and Disability Reporting Form

STATE

REPORTING YEAR.....

| S/N | LGA | COMMUNITY (WHERE PATIENT RESIDES) | HEALTH FACILITY NEAREST TO PATIENT | PATIENT NAME | RESIDENTIAL ADDRESS/PHONE NUMBER OF PATIENT | CONDITION OF PATIENT (TICK) | | | PATIENT RECEIVING/RECEIVED CARE? (YES OR NO) | ONSET OF DISABILITY |
|-----|-----|-----------------------------------|------------------------------------|--------------|---|-----------------------------|---------------|-----------|--|---------------------|
| | | | | | | LYMPHOEDEMA | ELEPHANTIASIS | HYDROCELE | | |
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Federal Ministry of Health

Neglected Tropical Diseases Elimination Programme

Lymphatic Filariasis Morbidity Management and Disability Summary Form

Reporting Year:.....

| State name | No. of LGA in State | No. of Health Facility with patients | No. of Reported Lymphoedema patients | No. of Reported patients provided services in any one year | No. of Hydrocele patients | Cumulative hydrocele surgeries | No. of LGAs with patients | No of LGAs providing basic package of care | Years reporting data | Remarks |
|------------|---------------------|--------------------------------------|--------------------------------------|--|---------------------------|--------------------------------|---------------------------|--|----------------------|---------|
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Annex 5: ROLES AND RESPONSIBILITIES OF TEAM MEMBERS FOR LF ASSESSMENT

| ROLE | RESPONSIBILITY |
|---|---|
| Team Leader | <ul style="list-style-type: none"> - Coordinates all the survey activities of a team. - Ensures all planned activities are carried out. - Provides guidance on the survey process. - Identifies needs and provides solutions. - Chairs daily debriefing sessions. - Ensures adherence to standard procedures. - Develops checklist and ensures all logistics/materials needed daily are available and adequate including transport. - Debrief and plan for next day activity with the team members. - Perform other role assigned by the technical lead. |
| Enumerator (State NTD Officer) | <ul style="list-style-type: none"> - Provide direction to the LGA. - Provides appropriate health education when needed. - Explains purpose of the survey and obtain verbal consent/assent from the recruits/subjects. - Register recruits/subjects. - Provides unique ID to each participant. - Performs any other role assigned by the team leader. |
| Laboratory Scientist | <ul style="list-style-type: none"> - Observe recommended standard laboratory practice and biosafety. - Performs tests as prescribed. - Collect blood samples and drop on appropriate portion of the test strip. - Ensure all consumables and test kits are available, adequate and properly stored. - Performs other role assigned by the team leader |
| Laboratory Technician (State officer) | <ul style="list-style-type: none"> - Observe recommended standard laboratory practice and biosafety - Assist in collection of blood samples - Ensures proper disposal of waste materials including sharps - Performs any other role assigned by the team leader |
| Card Reader | <ul style="list-style-type: none"> - Take coordinate of survey site. - Time and read tests at 10 minutes. - Record test result. - Merge the registration and result forms before leaving survey site. - Custodian of team data. - Performs any other role assigned by the team leader. |
| Electronic data manager | <ul style="list-style-type: none"> - Takes coordinate of survey site -Registers volunteers in the electronic platform -Records test results -Transmits verified data to available data storage platform (e.g. Cloud) -Performs any other role assigned by the team leader |
| Local Guide 1 (LGA NTD coordinator/ Education) | <ul style="list-style-type: none"> - Assists the enumerator in registration of recruits/subjects. - Assists to interpret the dialect. - Assists to provide appropriate venue for the survey in the community/school - Performs any other role assigned by the team leader. |
| Local Guide 2 (FLHF Staff/Head Teacher) | <ul style="list-style-type: none"> - Leads team to selected community/school. - Assist in crowd control. - Assist to interpret the dialect. - Assist to provide appropriate venue for the survey in the community/school. - Performs any other role assigned by the team leader. |
| Community mobilizer/Town announcer | <ul style="list-style-type: none"> - Sensitizes and mobilizes survey community before and during survey - Assists in crowd control - Assists to interpret the dialect - Performs any other role assigned by the team leader |
| State Epidemiologist | <ul style="list-style-type: none"> - Assist the National programme to carry out periodic assessment of LF recrudescence in the State. -Assist the National Programme to report and follow up LF morbidities in the State |
| Disease Surveillance Notification Officer (DSNO) | <ul style="list-style-type: none"> -Report LF morbidities in the LGAs and patients that are provided basic care. - Assist the National programme to carry out periodic assessment of LF recrudescence in the LGA. |
| Observer (Supporting Partner) | <ul style="list-style-type: none"> - Provides adequate consumables/materials for the survey - Provides appropriate field vehicles for teams and technical leads. - Ensures prompt payment of all field personnel |
| Driver | <ul style="list-style-type: none"> - Ensures safe transport of team during survey - Keeps vehicle in good condition and clean - Ensures the vehicles have enough fuel for each day's work - Assists in crowd control - Assists the team in any area as may be assigned by team leader. |
| Technical lead | <ul style="list-style-type: none"> - Provides all technical requirements for the survey - Coordinates survey activity - Ensures adherence to standard operating procedure of the survey |

Annex 6: Template for the dossier documenting elimination of Lymphatic Filariasis as a public health problem

This template dossier was designed to help managers of national lymphatic filariasis programmes prepare a dossier with supporting evidence for presentation to WHO, requesting validation that lymphatic filariasis has been eliminated as a public health problem. The information presented in the dossier will provide the context necessary to help reviewers understand programme achievements and supporting epidemiological evidence. However, the minimum information necessary to support the claim of elimination as a public health problem includes the following elements:

- Description of and supporting data on how endemic and non-endemic areas were classified as such;
- Interventions implemented to combat lymphatic filariasis; data on the interventions (treated population, coverage, etc.);
- Monitoring data of the conducted interventions, including microfilaraemia and/or antigenaemia at the sentinel and spot-check sites;
- Results from transmission assessment surveys (TAS) from endemic areas;
- Reported and/or estimated number of patients with lymphoedema and (in *Wuchereria bancrofti* areas) hydrocele;
- Data indicating availability and provision of the basic recommended package of care to manage patients with lymphoedema or hydrocele;
- Commitment for post-validation surveillance.



Group photograph of the participants