

VALIDATION OF ELIMINATION OF  
**LYMPHATIC FILARIASIS**  
AS A PUBLIC HEALTH PROBLEM

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## ABBREVIATIONS

ADL	adenolymphangitis
Ag	antigenaemia
EPIRF	Epidemiological Data Reporting Form
EU	evaluation unit
GPELF	Global Programme to Eliminate Lymphatic Filariasis
IU	implementation unit
JRF	Joint Reporting Form
JRSM	Joint Request for Selected Medicines
LF	lymphatic filariasis
MDA	mass drug administration
Mf	microfilaraemia
MMDP	morbidity management and disability prevention
NTD	neglected tropical disease
PCT	preventive chemotherapy and transmission control
RDRG	Regional Dossier Review Group
RPRG	Regional Programme Review Group
TAS	Transmission Assessment Survey
WHO	World Health Organization

## VALIDATION OF ELIMINATION OF LYMPHATIC FILARIASIS AS A PUBLIC HEALTH PROBLEM

### Terminology

10 In 1997, the Fiftieth World Health Assembly adopted resolution WHA50.29 on the elimination of lymphatic filariasis as a public health problem.<sup>1</sup> Preliminary guidance from WHO printed in 2011 referred to “verification” as the official process by which the achievements of the Global Programme to Eliminate Lymphatic Filariasis (GPELF) would be confirmed. For the sake of harmonization, the terminology now used for elimination of lymphatic filariasis as a public health problem is “validation”.

In 2015, the WHO Strategic and Technical Advisory Group for Neglected Tropical Diseases endorsed standardized processes for confirming and acknowledging success for all neglected tropical diseases targeted for eradication, elimination of transmission, or elimination as a public health problem.<sup>2</sup>

### Use of these standard operating procedures

20 These standard operating procedures are intended for use when a Member State wishes to request validation of national elimination of lymphatic filariasis as a public health problem following implementation of interventions to achieve the aims of the Global Programme.

### Technical indicators of elimination of lymphatic filariasis as a public health problem

30 The elimination aims of GPELF are two-fold:

1. *Stop the spread of infection through mass drug administration (MDA)*

- a. In all areas where lymphatic filariasis is endemic, levels of infection must be reduced below a target threshold at which transmission is considered not sustainable before stopping MDA. The transmission assessment survey (TAS) is a robust, practical epidemiological survey designed to measure whether areas have reduced infection levels below elimination thresholds. The TAS thresholds are documented in detail elsewhere and summarized in *Annex 1*.<sup>3</sup> The first elimination milestone for a country is for 100% of endemic areas to pass TAS and stop MDA (TAS1).
- b. Next, a country must demonstrate sustained reduction of infection below the threshold. Current WHO guidance suggests that TAS be repeated 2 years after stopping MDA (TAS2) and again at least 4 years after MDA stops (TAS3). A country meets the validation criteria if 100% of endemic areas pass a third and final TAS conducted no earlier than 4 years after MDA stops.

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<sup>1</sup> Resolution WHA50.29. Elimination of lymphatic filariasis as a public health problem. In: Fiftieth World Health Assembly, Geneva, 5–14 May 1997. Resolutions and decisions, annexes. Geneva: World Health Organization; 1997 ([http://www.who.int/neglected\\_diseases/mediacentre/WHA\\_50.29\\_Eng.pdf](http://www.who.int/neglected_diseases/mediacentre/WHA_50.29_Eng.pdf), accessed January 2017).

<sup>2</sup> Generic framework for control, elimination and eradication of neglected tropical diseases. Geneva: World Health Organization; 2016 ([http://www.who.int/neglected\\_diseases/resources/WHO\\_HTM\\_NTD\\_2016.6/en/](http://www.who.int/neglected_diseases/resources/WHO_HTM_NTD_2016.6/en/), accessed January 2017).

<sup>3</sup> Monitoring and epidemiological assessment of mass drug administration for eliminating lymphatic filariasis: a manual for national elimination programmes. Geneva: World Health Organization; 2011 ([http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484_eng.pdf), accessed January 2017).

2. *Alleviate suffering by managing morbidity and preventing further disability*

Provision of services will decrease morbidity and help to reduce and prevent disability. A country claiming to have achieved elimination of lymphatic filariasis as a public health problem is requested to document:<sup>4</sup>

- a. In all endemic areas, the number of patients with lymphoedema and hydrocele (reported or estimated) by implementation unit or similar health administrative unit. This allows proper planning for the provision of services.
- b. In all areas of known patients (100% geographical coverage),<sup>5</sup> the availability of the recommended minimum package of care.
- c. In select designated facilities, the readiness and quality of available services.

### **Preparation and submission of dossier**

40 Previous guidance on the process for elimination, as described in *Training in monitoring and epidemiological assessment of mass drug administration for eliminating lymphatic filariasis*<sup>6</sup> has been revised to standardize processes across neglected tropical diseases (NTDs). Member States seeking official acknowledgement from WHO as having met the criteria for elimination of lymphatic filariasis as a public health problem should submit a dossier to the Organization documenting the measures taken and the evidence supporting the claim.

50 Member States should reference the WHO dossier template (*Annex 2*) for guidance and ensure that the information presented meets the minimum necessary criteria to support the claim.

60 If desired, Member States may request feedback on the draft country dossier from the Regional Programme Review Group (RPRG) through the WHO Regional Office before official submission.

70 The Member State should submit the completed dossier (one hard copy and one electronic copy) to the WHO Country Office for the attention of the WHO Representative. The Country Office should acknowledge receipt of the dossier to the Member State, and forward it to the focal point for lymphatic filariasis in the WHO Regional Office. The WHO Regional Office should then notify the Department of Control of Neglected Tropical Diseases at WHO headquarters.

*Annex 3* contains some frequently asked questions to assist countries in preparing dossiers to document the elimination of lymphatic filariasis as a public health problem.

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<sup>4</sup> Global Programme to Eliminate Lymphatic Filariasis: WHO working group on morbidity management and disability prevention. Meeting report 2014. Geneva: World Health Organization; 2014.

<sup>5</sup> Progress report 2000–2009 and strategic plan 2010–2020 of the Global Programme to Eliminate Lymphatic Filariasis: halfway towards eliminating lymphatic filariasis. Geneva: World Health Organization; 2010 ([http://apps.who.int/iris/bitstream/10665/44473/1/9789241500722\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44473/1/9789241500722_eng.pdf), accessed January 2017).

<sup>6</sup> Training in monitoring and epidemiological assessment of mass drug administration for eliminating lymphatic filariasis. Geneva: World Health Organization; 2013 ([http://apps.who.int/iris/bitstream/10665/97377/1/9789241505444\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/97377/1/9789241505444_eng.pdf?ua=1), accessed January 2017).

## **Reviewing authority**

80 The dossier will be reviewed by an ad hoc regional Reviewing Authority (hereinafter referred to as the Group).

90 The objective of the 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.

100 The WHO Regional Office will be responsible for appointing and convening the Group upon the submission of country dossiers. The Group should comprise at least three members who meet the following criteria:

- a. Members should be experts on lymphatic filariasis and public health.
- b. 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.
- c. 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.

## **Review procedures**

110 Members of the Group will elect a Chair from among their number. The Chair will be responsible for chairing Group meetings; considering requests made by the Secretariat for observers to join Group meetings; coordinating and completing, with other Group members, a report on the country visit (if a visit is deemed necessary) to the Member State, before Group members depart from the country; and signing off the summary report to WHO.

120 The scope of work is as follows:

- a. A visit to the country will be undertaken for the purposes of the validation process only if there is a consensus of the 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 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 country: 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.

130 Secretariat functions will be assured by WHO throughout the process. It will:

- a. Provide the dossier and other information needed to each Group member.



- b. Organize discussions of the Group via teleconference, videoconference or face-to-face meetings, inviting observers where this is considered desirable and agreed by the Group's Chair.
- c. Specify the responsibilities and decision-making processes of the Group.
- d. Liaise with the Member State authorities 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 members.
- g. Process and permanently archive the summary report.

140 Each 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, discussing 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.
- b. Review the dossier independently, within the specified timeframe and following the directions given for this task.
- c. Discuss the dossier collectively, via video conference, teleconference or face-to-face meeting.
- d. Participate in a country visit (if deemed necessary).
- e. Review the draft summary report within the specified timeframe.

### **Processing of recommendations**

150 The following actions are taken after the 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 Regional Office to the Member State with clarification of what additional evidence is required prior to validation.
- b. If the Group recommends validation of the claim, the summary report will be forwarded by the concerned 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 the country will be provided through a letter of notification presented to the Member State by the WHO 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 lymphatic filariasis in the Global Health Observatory by WHO headquarters

### **After validation**

160 Validation implies a potentially reversible state, and all stakeholders should bear this in mind in their communications at all stages.

170 Countries should continue to conduct post-validation surveillance and ensure integration of MMDP and to health services as recommended by the Group. A commitment to continue surveillance and MMDP should be stated in the dossier.

180 Surveillance data should be reported to WHO. Where these data indicate that infection has recrudesced above elimination thresholds, WHO should be consulted on an appropriate response. 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.

190 With the agreement of the Member State and after once the Director-General has acknowledged the elimination of lymphatic filariasis as a public health problem – the dossier may be made available on the WHO website as a reference document.

200 Countries 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.

The figure below shows the five steps required to validate the elimination of lymphatic filariasis as a public health problem in a country.

### Main actions for validation of LF elimination as a public health problem



## ANNEX 1. CONSIDERATIONS FOR PROGRAMME MANAGERS

### Practical definitions

**Elimination as a public health problem** is the achievement of specific and measurable targets for infection and disease set by WHO.<sup>7</sup> When elimination is reached, continued actions are required to maintain this status. Surveillance will be required to ensure infection remains below target thresholds and to verify interruption of transmission.

In practice, **elimination of LF as a public health problem** is defined as:

1. **reduction in measurable prevalence of infection in endemic areas** below a target threshold at which further transmission is considered unlikely even in the absence of MDA.<sup>8</sup> These target thresholds are measured during TAS. However, a programme must first achieve < 1% microfilaraemia or < 2% antigenaemia among populations aged older than 5 years in sentinel and spot-check sites considered high-risk (Pre-TAS). Then, all endemic areas should pass TAS (the number of positive children is less than the critical cut-off value indicating infection is below elimination thresholds) and stop MDA. Infection must be maintained below these levels for at least 4 years after MDA has stopped. A successful TAS conducted more than 4 years after MDA meets the criteria.

Target thresholds measured during TAS by species <sup>8</sup>	
<i>Wuchereria bancrofti</i>	< 2% Ag (ICT/FTS) <i>Anopheles</i> / <i>Culex</i> vector < 1% Ag (ICT/FTS) <i>Aedes</i> vector
<i>Brugia</i> spp.	< 2% Ab (Brugia Rapid)

Ag, antigenaemia; Ab, antibody; ICT, immunochromatographic card test; FTS, Filariasis Test Strip

2. Alleviating suffering caused by the disease by ensuring the **availability of the minimum package of care** for lymphoedema and hydrocele patients. The following health services must be available within the primary care system in all areas with known patients: surgery to correct hydrocele; management of lymphoedema (health workers able to provide and teach patients self-care measures of hygiene, skin and wound-care, elevation, and exercise); and treatment for acute attacks (antibiotic treatment and symptomatic management).

**Validation** is the process of documenting the **elimination of LF as a public health problem** through a validation dossier and receiving **approval** for the achievement from WHO. The figure on page 5 identifies the five steps required for validation. Validation is not a permanent state and does not represent an end to programme activities. While some activities, such as MDA, may no longer be required, programmes should continue to undertake post-validation surveillance and ensure the minimum package of care for patients remains available within the health care system.

<sup>7</sup> Generic framework for control, elimination and eradication of neglected tropical diseases. Geneva: World Health Organization; 2016 ([http://www.who.int/neglected\\_diseases/resources/WHO\\_HTM\\_NTD\\_2016.6/en/](http://www.who.int/neglected_diseases/resources/WHO_HTM_NTD_2016.6/en/), accessed January 2017).

<sup>8</sup> Monitoring and epidemiological assessment of mass drug administration for eliminating lymphatic filariasis: a manual for national elimination programmes. Geneva: World Health Organization; 2011 ([http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484_eng.pdf), accessed January 2017).

The **validation dossier** contains all the evidence to support the claim of achieving the elimination criteria. The dossier enables WHO to:

- validate a country's claim of LF elimination as a public health problem;
- provide feedback about necessary action to receive WHO approval.

Validation of elimination **is recognized nationally** based on review of a national dossier, but developing the dossier requires a district-by-district (or equivalent implementation unit) approach. The minimum information requested in the dossier is applicable at the IU level. The template dossier in Annex 2 identifies the minimum information requested from countries. It should be used as a guide for writing the dossier.

**Post-validation surveillance** is ongoing or periodic surveillance activities conducted after WHO acknowledgement of elimination as a public health problem, with the objectives of:

- detecting and responding to recrudescence or re-introduction of LF infection above elimination thresholds; and
- providing additional evidence to confirm elimination of transmission.

A commitment to ongoing surveillance is required at the time of submission of the dossier and ideally activities should be in place. Such surveillance activities may be a continuation of post-MDA ongoing surveillance. At this time, there are no standardized activities recommended by WHO for post-validation surveillance. Existing guidance on post-MDA ongoing surveillance is listed elsewhere.<sup>9</sup> WHO is reviewing available evidence from both research studies in progress and current country experiences to develop specific post-validation surveillance guidelines.

#### ***Data gathering for dossier preparation***

Programmes must gather data to prepare the dossier. Each section of the template dossier should be addressed and supported with presentation of programme data. A national 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:

- Ministry/Department of Health reports
- Integrated NTD database or any similar national data management system the programme utilized
- Reports submitted to WHO
  - a. LF annual report to WHO
  - b. WHO Joint Application Package Forms
    - 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 Regional Programme Review Group Meetings and Programme Managers Meetings
- WHO PCT Databank: [http://www.who.int/neglected\\_diseases/preventive\\_chemotherapy/lf/en/](http://www.who.int/neglected_diseases/preventive_chemotherapy/lf/en/)
- WHO Weekly Epidemiological Record: <http://www.who.int/wer/en/>
- Publications from research projects or surveys
- Regional publications, including official meeting reports of RPRG and PMM

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<sup>9</sup> Monitoring and epidemiological assessment of mass drug administration for eliminating lymphatic filariasis: a manual for national elimination programmes. Geneva: World Health Organization; 2011 ([http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484_eng.pdf), accessed January 2017).

- Activity reports from collaborating institutions, nongovernmental organizations, or bilateral organizations
- Patient case-reports, surveillance reports of lymphoedema and hydrocele cases
- Health facility registers
- Health facility lists
- Reports from programme evaluations, situation analysis, or consultants

Additionally, WHO has created a dossier data annex to facilitate the presentation of programme data to document in the dossier. IU specific data on endemicity, MDA, TAS and MMDP can be entered. Use of the tool is encouraged but not mandatory. This sheet is available for download here [http://www.who.int/lymphatic\\_filariasis/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filariasis/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls)

The template dossier identifies in each section where to enter corresponding data in the dossier data annex.



## LF Elimination Dossier Template: Data Annex

The purpose of this annex of the LF Elimination Dossier Template is to give countries a standardized tool for presenting the data that systematically summarizes the history and progress of the programme and the confirmation of achieving elimination of lymphatic filariasis in all the districts (or other administrative units that are defined as implementation units of the national programme) in the country.

National programmes are requested to complete the form for all the districts (or other administrative units that are defined as implementation units of the national programme) in the country, regardless of their endemicity status at the inception of the national programme. This form should be included with the dossier narrative and submitted to the World Health Organization (WHO) country office with a request for technical review.

### Structure of the form (worksheets):

<b>INTRO</b>	Contains guides on how to complete the data annex for all implementation units
<b>POPULATION</b>	Total population in each implementation unit and data source referenced
<b>MAPPING</b>	Classification of each implementation unit as endemic or non-endemic
<b>MDA</b>	History of mass drug administration (MDA) and coverage
<b>M_E</b>	Epidemiological data for each implementation unit (including baseline surveys, sentinel and spot check assessments)
<b>TAS</b>	Plan and results of TAS for each evaluation unit
<b>TAS_SURVEILLANCE</b>	Surveillance activities using TAS protocol (i.e. TAS 2 and TAS 3)
<b>MORBIDITY</b>	Burden of lymphoedema and hydrocoele and the number of facilities providing services for management of such morbidity.

### Instruction for data entry

Many of the cells on the worksheets include formulae, which are calculated automatically.

Please enter your data into the cells according to the colour code:

- White - cell is not protected. Please enter the value or text of the requested indicator.
- Yellow - cell is protected and includes name of the indicator. **No data entry required.**
- Orange - cell is not protected and includes a drop-down menu. Please select the value from the list.
- Blue - cell is protected and includes formula. **No data entry required.**

**Note: Please enter the information for all the administrative units that are defined as implementation units of the national LF elimination programme in the country, both endemic and non-endemic at the inception of the national programme.**

<b>COUNTRY</b>	<input style="width: 100%;" type="text"/>
Year of submission of the dossier	<input style="width: 100%;" type="text"/>
Is country endemic for <b>onchocerciasis (ONCHO)?</b>	<input style="width: 100%; background-color: orange;" type="text"/>
How many endemic districts (i.e. implementation units) in the country?	<input style="width: 100%;" type="text"/>
How many non-endemic districts in the country?	<input style="width: 100%;" type="text"/>
How many evaluation units were formed in the country?	<input style="width: 100%;" type="text"/>
<b>Please send this form to the following:</b>	<input type="button" value="Generate new forms"/>
WHO country office	<input type="button" value="Clear forms"/>
WHO regional office	
WHO headquarters <a href="mailto:PC_JointForms@who.int">PC_JointForms@who.int</a>	

## ANNEX 2. 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.

## VALIDATION DOSSIER

### 1 BACKGROUND

#### 1.1 DEMOGRAPHIC AND DEVELOPMENT CONTEXT (OPTIONAL)

- *In narrative form*, summarize (1–2 pages) the overall demographic and economic features of the country, referencing the population census, Demographic and Health Survey and other relevant documents. Where possible, provide indicators and/or maps on poverty, development, and household access to water and sanitation in both rural and urban areas. Define and quantify the administrative units in the country and explain the related health structure (total number of states, districts, etc.; State Health Bureau, District Health office).
- Refer to LF Elimination Dossier: Data Annex [http://www.who.int/lymphatic\\_filariasis/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filariasis/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls) *Worksheet INTRO and POPULATION*

#### 1.2 HEALTH SYSTEM (OPTIONAL)

- *In narrative form*, provide a brief (up to 1 page) overview of the health system, including the following:
  - o Health system structure including the delivery of primary healthcare services
  - o Major infectious diseases, neglected tropical diseases (NTDs) and any chronic diseases prevalent in the country relevant to the lymphatic filariasis (LF) elimination programme

#### 1.3 LF PROGRAMME OVERVIEW (REQUIRED)

#### BACKGROUND EPIDEMIOLOGICAL INFORMATION

- *In narrative form*, describe the LF programme in the country including the following (please reference relevant publications):
  - o Historical documentation of the disease
    - parasite species. For areas with *Brugia malayi*, discuss evidence (or lack of) for reservoir hosts for filariasis
    - description of LF vectors in the country including vector breeding habits, resting and biting behaviour, abundance and vector efficiency. If available, information on transmission levels (annual transmission potentials, vector infection and infectivity rates, etc.) may be included
    - historical evidence of clinical cases, including geographical distribution
    - coendemicity with onchocerciasis and loiasis, including maps
  - o Any interventions against LF prior to launch of current national programme

#### LF PROGRAMME STRUCTURE

- *In narrative form*, describe the LF programme in the country including the following:
  - o National programme goals and objectives, and dates of programme establishment
  - o Organizational chart and responsibilities
    - for planning and implementation of mass drug administration (MDA), supervision of the programme, and response to serious adverse events

- include the organizational chart for morbidity management and disability prevention (MMDP) activities
- How the LF programme is integrated/coordinated with NTD programmes or other health programmes, if any integration/coordination is conducted
- The data collection and management system used by the programme, including how MDA, integrated vector management, MMDP and other data and information are reported and transmitted from community to national level

## 2. DELINEATION OF ENDEMICITY

### 2.1 DATA USED TO CLASSIFY IMPLEMENTATION UNITS AS ENDEMIC OR NON-ENDEMIC (REQUIRED)

- Insert maps of endemicity, differentiating the areas that were determined to be endemic (needing MDA) and non-endemic (not needing MDA)
- *In narrative form*, describe:
  - the implementation unit (IU) used in the country and, if different, the geographical unit used for mapping; include the following information:
    - the total number of IUs (endemic and non-endemic) at the start of the programme
    - the current number of IUs and a description of any change in the total number since the start of the programme, e.g. due to redistricting
  - the methods used to determine endemicity or non-endemicity, including (if applicable) the protocol followed and sampling methodology for any surveys:
    - if the endemicity status of certain IUs was reassessed during the programme, please describe why and how the IUs were reassessed
- List endemicity status of all IUs in the country. Refer to LF Elimination Dossier: Data Annex [http://www.who.int/lymphatic\\_filariasis/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filariasis/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls) *Worksheet MAPPING*.

### 2.2 REGIONAL CONTEXT (OPTIONAL)

- *In narrative form*, briefly describe the occurrence of LF and the current status of LF elimination efforts in neighbouring countries and whether neighbouring countries are considered a risk to the achievements of the national programme.
  - Data can be found in the PCT databank ([http://www.who.int/neglected\\_diseases/preventive\\_chemotherapy/lf/en/](http://www.who.int/neglected_diseases/preventive_chemotherapy/lf/en/))
- If possible, include the status of LF in surrounding countries on the endemicity map (see section 2.1)



### 3. INTERVENTIONS FOR INTERRUPTION OF TRANSMISSION

#### 3.1 MDA (REQUIRED)

##### MDA IMPLEMENTATION

- *In narrative form*, summarize MDA activities, including a description of the following:
  - Medicine used
  - Distribution strategies
    - when, who and how delivered
    - if directly observed
    - supervision structure
  - Eligible population
  - Social mobilization strategy implemented
  - Training cascade
  - Recording and reporting
  - Medicine acquisition, quality control, repacking (if any)
  - Serious adverse events reporting and response

##### MDA COVERAGE

- *In narrative form*, provide the following information concerning MDA coverage:
  - Sources used for the denominator in reporting coverage, e.g. population projections from the national census, MDA registration, district local government population data
  - Problems with reported coverage, such as estimation of at-risk population owing to population movements, external migration
  - Activities to monitor coverage
    - if data quality assessments or coverage surveys were done, describe the protocols used and summarize the results (published studies should be referenced)
  - Response of the national programme to any evidence of systematic non-compliance
- Summarize national MDA data in the following table and list the annual MDA coverage by IU. Refer to LF Elimination Dossier: Data Annex [http://www.who.int/lymphatic\\_filaria/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filaria/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls) *Worksheet MDA*.

**Table A3.1. Summary of national MDA data, by year**

Year	Total number of IUs in the country	Number of IUs requiring PC for LF	Population requiring PC for LF	Number of IUs covered	Geographical coverage <sup>a</sup>	Total population of IUs targeted for PC for LF	Reported number of people treated	Epidemiological coverage <sup>b</sup>	National coverage <sup>c</sup>

LF, lymphatic filariasis; PC, preventive chemotherapy; a: geographical coverage = number of IUs implementing MDA / total number of IUs where MDA is required; b: epidemiological coverage = number of individuals ingesting medicine during MDA at IU level / total population of the IU; c: national coverage = number of individuals ingesting medicine during MDA in a country for a specific year / number of individuals at the national level requiring MDA; If the table contains different data from the WHO PCT databank, explain the reason for discrepancies.

### 3.2 SUPPLEMENTAL INTERVENTIONS (REQUIRED)

- *In narrative form*, summarize any supplemental interventions that could have affected the transmission of LF. Interventions listed below provide some examples.
  - o Integrated vector management efforts carried out by the LF programme or other programmes, e.g. malaria, including:
    - activities conducted
    - estimated coverage of interventions (if available)
  - o Environmental or economic improvements
  - o Screening and treating persons Mf, Ag or anti-filarial antibody positive outside of MDA, including any test-and-treat activities
  - o Preventive chemotherapy for control of soil transmitted helminth infections or elimination of onchocerciasis:
    - implementation units covered (co-endemicity with LF and whether LF MDA was also conducted)
    - type of medicines distributed
    - years of implementation
    - target age group
    - whether the intervention is expected to continue in the future
  - o Distribution of DEC-fortified salt

## 4. EPIDEMIOLOGICAL MONITORING AND EVALUATION OF INTERVENTIONS

### 4.1 SENTINEL AND SPOT-CHECK SITES (REQUIRED)

- *In narrative form*, summarize sentinel and spot-check site assessments including a detailed description of:
  - o Methods for selecting sentinel and spot-check sites
  - o Protocol for selecting participants, e.g. all residents, random selection of households, convenience sample at community gathering point
  - o Diagnostic methods used
  - o Ratio of sentinel and spot-check sites per IU, per EU or per population
  - o Map of the distribution of the sentinel and spot-check sites in the IUs, if available
- List data from sentinel and spot-check sites by IU. Refer to LF Elimination Dossier: Data Annex [http://www.who.int/lymphatic\\_filariasis/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filariasis/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls) *Worksheet M\_E*.

### 4.2 SURVEYS FOR STOPPING MDA (REQUIRED)

- *In narrative form*, summarize the epidemiological surveys implemented to decide whether to stop MDA (reference any publications), including a detailed description of :
  - o Methods used, e.g. TAS, PacELF C surveys
  - o Protocol followed for selection of communities/schools and participants
  - o Composition and average population size of evaluation units (EU)
  - o Procedures for training field teams
  - o Quality control
  - o Supervision

- Protocol for follow-up of positive findings, e.g. Mf tests, entomological assessment in the village, focal community surveys, treatment of individual and family members, etc.
- Response in EUs that did not “pass” TAS or other epidemiological surveys
- Issues encountered during implementation of surveys that may have affected methods or results
- List results from TAS1 by EU indicating each IU covered. Refer to LF Elimination Dossier: Data Annex [http://www.who.int/lymphatic\\_filariasis/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filariasis/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls) *Worksheet TAS.*

## 5. SURVEILLANCE

### 5.1 CROSS-SECTIONAL SURVEYS, INCLUDING POST-MDA TAS (REQUIRED)

- *In narrative form*, summarize the epidemiological surveys implemented during post-MDA surveillance that determine LF infection levels remain below elimination targets including the following information:
  - Methods for TAS or other (clearly indicate whether the same methods were used for stopping MDA surveys, note any differences in age group or additional diagnostic tools used)
  - Protocol for response to each positive case identified
  - Description of positive cases (age range, gender, ethnic group, residence history, etc., to help determine whether cases were local or imported)
  - Separate detailed description of any surveys implemented in IUs originally classified as non-endemic
- List results from TAS2 and TAS3 by EU indicating each IU covered. Refer to LF Elimination Dossier: Data Annex
- [http://www.who.int/lymphatic\\_filariasis/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filariasis/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls) *Worksheet TAS\_SURVEILLANCE.*

### 5.2 ONGOING SURVEILLANCE (REQUIRED)

- Describe national programme commitment to sustain surveillance activities post validation
  - Description of existing plans and potential platforms for post-validation surveillance
- Summarize any ongoing surveillance activities, including a description of the following:
  - When (frequency), where (endemic and non-endemic IUs, geographical distribution of tested persons), who (teams/technician and target population) and how (sample selection, assay performed/indicator) data are collected
  - Response to positive microfilaraemia or antigenaemia cases identified
  - Profile of positive cases (age range, gender, ethnic group, residence history, etc., to help determine whether cases were local or imported)
- Annex any surveillance reports with the detailed description of the surveillance activities, results and any response taken to the dossier.

### 5.3 ENTOMOLOGICAL MONITORING (OPTIONAL)

- *In narrative form*, summarize entomological monitoring activities that occurred to look for evidence of infection in vectors, including answering the following questions:
  - Who had responsibility for implementing entomological monitoring? From what level were these activities managed and/or coordinated?
  - How were sites picked?
  - What sampling methods were used, e.g. traps, human biting?
  - (If applicable), what species of mosquito were included?
  - What methodology was used, e.g. dissection, PCR, L3 PCR?
  - Which indicators were monitored, e.g. vector infection/infectivity rate, monthly/annual transmission potential?
  - How were the results used?
  
- If applicable, annex entomological monitoring reports with the detailed description of the surveillance activities, the indicators monitored and interpretation of the results to the dossier.

## 6. MORBIDITY MANAGEMENT AND DISABILITY PREVENTION (MMDP)

### 6.1 DATA ON NUMBER OF PATIENTS WITH LYMPHOEDEMA OR HYDROCELE (REQUIRED)

- *In narrative form*, briefly describe the methodology used to identify the number of patients with lymphoedema and hydrocele, including year of estimates.
- If possible, include a map showing the prevalence of filarial clinical disease by clinical condition. Depending on burden, this could be just those IUs with cases and those IUs without cases, or IUs could be grouped by number of cases. Such information could be combined with the map showing endemicity status of IUs in section 2.1.
  
- List the number of known/estimated patients by IU (regardless of whether the IU required MDA)  
Refer to LF Elimination Dossier: Data Annex  
[http://www.who.int/lymphatic\\_filariasis/elimination-programme/WHO\\_LF\\_elimination\\_dossier\\_template\\_data\\_annex.xls](http://www.who.int/lymphatic_filariasis/elimination-programme/WHO_LF_elimination_dossier_template_data_annex.xls) *Worksheet MORBIDITY.*

### 6.2 AVAILABILITY OF TREATMENT FOR LYMPHOEDEMA AND HYDROCELE (REQUIRED)

- *In narrative form*, summarize existing data related to the readiness of health facilities to provide high-quality treatment for lymphoedema and hydrocele, including the following:
  - Description of where lymphoedema and adenolymphangitis (ADL) services are provided within the health system:
    - number of designated health facilities providing services for lymphoedema and ADL (*minimum recommended 1 per IU with known patients*)
  - Description of where hydrocelectomies are provided within the health system:
    - number of reference hospitals providing hydrocelectomies (*each IU with known cases should be served by at least 1 facility*)
  - Methods used to collect data on number of facilities providing services

- Number of facilities surveyed to assess quality of care for lymphoedema and ADL management and/or hydrocelectomy (*Assessment of at least 10% of designated facilities providing each service [lymphoedema management or hydrocelectomy] nationwide is preferred*)
- Methods used to collect data on quality of care
- Results of the assessments and planned programme response:
  - if using direct inspection protocol, include average scores per health facility and per indicator

**Table A6.1. National overview of facilities providing morbidity management and disability prevention services**

Indicator	Lymphoedema/ADL	Hydrocele
Number of IUs with known patients		
Number of IUs with no known patients		
Number of IUs with at least 1 facility designated to provide recommended basic package of care		
Number of patients		
Number of health facilities providing service		
Number of health facilities surveyed to assess quality of care		

ADL, adenolymphangitis

- List the number of designated facilities providing services per IU with known patients. Refer to LF Elimination Dossier: Data Annex  
<http://www.who.int/lymphatic-filariasis/elimination-programme/WHO-LF-elimination-dossier-template-data-annex.xls> *Worksheet MORBIDITY.*

## 7. SPECIAL ISSUES (OPTIONAL)

*In narrative form, please provide the following:*

- a. Description of any special circumstances that have affected the implementation, monitoring and evaluation of the programme. This could include, but is not limited to:
  - i. Stability or security issues in the country
  - ii. Immigration from LF-endemic countries
- b. Description of any effort to investigate infections and/or intervention coverage in difficult-to-reach populations (i.e. nomadic populations or seasonal workers).

## 8. RESOURCES AND PARTNERSHIPS (OPTIONAL)

- *In narrative form, briefly describe the human resources involved in implementing the programme and estimate the financial resources utilized.*
- Complete the following table to describe the partnerships of the national programme:

**Table A8.1. Role of partners in the national programme**

Partner name	Activities supported	Geographical area of support
<i>e.g. WHO</i>	<i>Financial and technical assistance for TAS</i>	<i>Region A</i>

## **9. BIBLIOGRAPHY (REQUIRED)**

Include a bibliography of all data sources used to develop this dossier, including:

- Ministry of Health records
- published studies
- academic theses and dissertations
- others

Note the key articles and reports. These should be kept on file in the national programme office.

## **10. ABBREVIATIONS (OPTIONAL)**

Provide a list of definitions for all abbreviations used in the dossier.

## ANNEX 3. FREQUENTLY ASKED QUESTIONS

Validation is a new process endorsed by the global Strategic and Technical Advisory Group for Neglected Tropical Diseases that allows WHO to officially acknowledge elimination as a public health problem. The process was applied recently to acknowledge the achievements of six countries that had submitted dossiers in 2014 and 2015. Several relevant questions have been raised by countries, partners, donors, Regional Programme Review Groups, and reviewers of the regional reviewing authorities concerning the dossier and the process. These questions are presented here in effort to facilitate understanding, improve transparency and assist programme managers of LF elimination programmes.

### ***Preparation and submission of the dossier***

- **When should a programme manager prepare the dossier?**

Answer – Data gathering and archiving should start as soon as possible and continue throughout the programme. IU level data should be updated at least annually as reports are submitted to WHO. Programme managers should consider preparation of the data for the dossier and narrative sections as soon as all endemic IUs have completed TAS1. This then allows a period of 4 years during post-MDA surveillance to document necessary data to address all components requested. The estimated start and completion date for drafting the dossier should be included in the NTD Master Plan.

- **When should a programme manager submit the dossier?**

Answer – Countries are encouraged to submit the validation dossier once all required sections listed in the template dossier have been addressed. The dossier should not be submitted before all endemic IUs have passed TAS3 or if the availability of the minimum package of care cannot be documented.

- **How long does it take to prepare a dossier?**

The amount of time required to prepare the dossier depends mostly on the availability of supporting data and the availability of a writer. At least one year may be required from an initial draft to official submission. Consider how much time will be required to gather, compile and check the necessary information starting from the beginning of the programme. Many different people within the country, including former programme staff, supporting NGOs, and WHO will likely need to be consulted. Given turnover in staff and loss of data, etc. national programmes are encouraged to start preparing a draft dossier while MDA is still ongoing, completing sections on endemicity mapping, MDA, etc. as information is available.

- **In what languages can the dossier be submitted?**

Answer – The dossier should be submitted in one of the six official working languages of the United Nations (Arabic, Chinese, English, French, Russian and Spanish). Countries should request support from WHO if translation is required.

- **How can technical support be requested for the preparation of the dossier?**

Answer – National programme managers can request WHO to provide technical support for dossier preparation. WHO will coordinate technical support for requesting countries. Preparation of the dossier takes time and may require resources for data gathering and writing. Some programmes have hired consultants to review, consolidate and organize data and to write the first draft of the narrative section. All stakeholders of the programme should be engaged in the dossier preparation.

- **How can a country get an informal review of a draft dossier prior to official submission?**

Answer – National programme managers can submit a draft dossier to WHO requesting informal feedback on a dossier. WHO will coordinate an informal review through the Regional Programme Review Group and provide feedback to enhance the dossier.

- **What if supporting data are missing?**

Answer – The programme should seek assistance from WHO if supporting data are missing. WHO has a large archive of reports submitted from countries and other files such as presentations, meeting reports, mission reports, which may be helpful for identifying the missing data. If missing data cannot be found from all available sources, there may be key informants who can provide an accurate knowledge of the setting and situation surrounding the activities for which data are missing. This should be clearly reflected in the narrative of the dossier for consideration.

### ***Processing of the dossier and acknowledgement of the achievement***

- **How long does the validation process take after submission of the dossier?**

Answer – WHO aims to coordinate the review of the dossier and provide communication (either acknowledgement or detailed reasons for postponing acknowledgement) between 6 months and 1 year from the date of submission.

- **How is the ad hoc regional reviewing authority selected?**

Answer – The regional offices of WHO are responsible for the selection of experts to review dossiers as part of a Regional Dossier Review Group that serves as the reviewing authority.

- **What happens after a dossier has been approved by WHO?**

Answer – WHO acknowledges the achievement of the country in a letter from the Director-General and the Regional Director to the Minister of Health. Additionally, the achievement is noted in the Weekly Epidemiological Record and the status of LF endemicity is changed in the WHO Global Health Observatory.

- **What are the next steps if acknowledgement is postponed?**

Answer – Based on the report of the dossier review group, WHO will provide feedback to the national programme to identify specific concerns and provide guidance for the steps to be taken to sufficiently address each concern. The national programme should then develop an activity plan to gather any additional evidence, revise the dossier and resubmit it for validation. Additional activities might range from amending the dossier with available data not presented in the first draft to collecting more data through additional surveys.

- **What are some reasons for a recommendation to postpone validation?**

Answer – Validation may be postponed if any of the required components of the dossier are not addressed sufficiently. Ensure that all programme data are well documented concerning endemicity and requirement of MDA, MDA coverage, sentinel monitoring, TAS implementation, number of lymphoedema and hydrocele patients, availability of MMDP services and commitment to post-validation surveillance.



### ***Classification of endemicity and requirement of MDA***

- **What evidence is needed to determine whether an IU required MDA?**

Answer – Countries should document the results of initial mapping surveys showing the proportion of persons tested who were infected. Clearly document the methodology of the surveys. If endemicity was determined based on data other than epidemiological surveys, please ensure that the data and methods are clearly presented. MDA is warranted where the proportion of persons infected is > 1% (Mf or Ag [ICT/FTS]) in any community within the implementation unit.<sup>10</sup>

- **Do all non-endemic IUs need to be remapped?**

Answer – Where the evaluation of endemicity can be clearly documented, whether at the initiation of the national LF elimination programme or later, no re-mapping of non-endemic areas is required. If any new reports/findings or changes are noted that may indicate LF transmission, then IUs originally classified as non-endemic can be remapped using a more robust sampling methodology (e.g. decision-making prevalence survey based on equal probability sampling).<sup>11</sup>

- **What if cases of lymphoedema and hydrocele have been found in an IU classified as non-endemic or not requiring MDA?**

Answer – Because clinical manifestations may occur several years after infection, the presence of clinical cases in an IU classified as non-endemic does not mean that infection is present or that transmission is ongoing. However, national LF elimination programmes should analyse data from such IUs carefully and consider whether endemicity should be re-evaluated. In addition, the national programme should ensure that care is available for patients in these IUs.

### ***TAS and other surveys to measure elimination targets***

- **What if a different survey was used to decide to stop MDA before the TAS was developed?**

Answer – In 2012, TAS was recommended by WHO for stopping MDA. Since then, efforts have been made to build capacity of all national LF elimination programmes to implement this standardized methodology. Several countries began MDA shortly after the launch of the Global Programme and stopped MDA before the development of the TAS methodology. The methods of epidemiological surveys used to determine that MDA was no longer required need to be clearly documented in the TAS section of the dossier. Programmes should indicate which surveys were the equivalent of pre-TAS sentinel and spot-check evaluations and of TAS for the decision to stop MDA.

- **What if other post-MDA surveillance surveys have been done before the development of TAS? Do additional TAS need to be implemented?**

Answer – Programmes should indicate which surveys were the equivalent of TAS for the decision to stop MDA and TAS for surveillance. The timing of the post-MDA surveillance surveys relevant to when MDA ceased needs also to be clearly presented. Additional TAS may not be needed if the methodology was robust and results support that infection remains below target threshold levels. Countries should consult WHO for assistance in such scenarios before submitting the dossier.

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<sup>10</sup> Monitoring and epidemiological assessment of mass drug administration for eliminating lymphatic filariasis: a manual for national elimination programmes. Geneva: World Health Organization; 2011 ([http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44580/1/9789241501484_eng.pdf), accessed January 2017).

<sup>11</sup> Meeting Report of the WHO Strategic and Technical Advisory Group for Neglected Tropical Diseases. Geneva, Switzerland 21-22 April 2015. Geneva: World Health Organization; 2015.



### ***Morbidity management and disability prevention***

- **Why are MMDP indicators necessary to claim elimination of LF as a public health problem?**
  - a. A significant public health burden is associated with the clinical manifestations of lymphatic filariasis, namely lymphoedema and hydrocele. This burden includes not only the clinical implications but also mental health and economic effects.
  - b. The extreme suffering of patients and the economic impact were the impetus for the Global Programme to Eliminate Lymphatic Filariasis (GPELF). Both at its inception and as the programme currently stands, addressing the suffering of patients is a key component of GPELF.
  - c. This twin pillared approach was outlined by GPELF to eliminate LF as a public health problem, including the interruption of transmission of LF as well as alleviating the suffering of affected populations through measures to control morbidity (WHA50.29<sup>12</sup>). Data supporting the implementation of activities from both pillars should be addressed in order to claim the elimination of LF as a public health problem.

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<sup>12</sup> Resolution WHA50.29. Elimination of lymphatic filariasis as a public health problem. In: Fiftieth World Health Assembly, Geneva, 5–14 May 1997. Resolutions and decisions, annexes. Geneva: World Health Organization; 1997 ([http://www.who.int/neglected\\_diseases/mediacentre/WHA\\_50.29\\_Eng.pdf](http://www.who.int/neglected_diseases/mediacentre/WHA_50.29_Eng.pdf), accessed January 2017).

- **Are estimates of patients needed for non-MDA districts? What about districts that were not included in mapping because they were deemed to not be ecologically conducive for LF transmission?**

Answer – The priority for patient estimation should occur in all historically endemic areas regardless of whether MDA was implemented. Areas with known patients include not only areas that were classified as “endemic” during LF mapping exercises but also areas that were considered to be “non-endemic” during mapping (i.e. < 1 % antigenaemia or microfilaraemia) but where there is evidence of individuals with hydrocele or lymphoedema.

- **Is the same method for patient estimation required across all districts?**

Answer – No, different methods may be used.

- **No cases have been identified in some areas that were mapped as endemic and had MDA. Should the minimum package of care be required in these districts?**

Answer – The minimum package of care should be prioritized in districts with known patients. Endemic areas requiring MDA are likely to have patients with clinical disease whether reported or not to the health system. Therefore, it is preferred that the minimum package of care be available also in all areas that were mapped as endemic.

- **In some implementation units that were non-endemic and did not have MDA, we found lymphoedema or hydrocele patients. We do not know if these patients’ conditions were caused by LF. Do we still include these IUs as those that have known cases?**

Answer – Yes, basic care should be available for all lymphoedema and/or hydrocele patients from an endemic country regardless of the cause of morbidity.

- **Specifically, what activities or services are included in providing “minimum recommended care”?**

Answer – In areas of *W. bancrofti*, hydrocele surgery should be available at least at tertiary facilities. Lymphoedema management includes hygiene, care for skin and wounds, and elevation and exercises to promote lymphatic circulation. Finally, facilities should be able to provide antibiotic treatment and symptomatic management for adenolymphangitis (ADL – acute attacks).

- **What if surgical services are not available at the district/IU level?**

Answer – It is recognized that not all districts or IUs provide surgical services. At least one surgical facility should serve all IUs that have patients. If surgical services are not available at the district/IU level, then hydrocele surgery should be provided at the next health level that has consistent surgical services (e.g. regional hospital).

- **Patient estimation activities identified only a small number of hydrocele/lymphoedema patients (e.g. fewer than 5) in some districts. Must the minimum package of care be available in these areas?**

Answer – Yes, clinical services should still be available in these areas. The ultimate goal is to provide 100% geographical coverage for all known patients. It is important to note that patient estimations are likely to underestimate the true number of cases that exist in a given implementation unit and that new cases might develop over time due to the long latency period for lymphoedema and hydrocele.

- **Can services provided by nongovernmental organizations or private facilities count as designated facilities for clinical care of lymphoedema or hydrocele?**

Answer – Yes. Nongovernmental organizations and private institutions may play an important role in MMDP services. However, to promote sustainability, the capacity of public facilities should also be strengthened.

- **The national programme does not have a budget for MMDP. How can it implement MMDP activities?**

- a. The national LF elimination programme is not expected to directly implement hydrocele surgeries or lymphoedema management. These services should be available through the health care system. However, coordination, monitoring and evaluating these services do fall under the responsibility of the national LF elimination programme and will require resources. The following specific activities should be led by national LF elimination programmes:
  - i. Situation analysis including the patient estimation
  - ii. Coordination of capacity strengthening
  - iii. Monitoring and reporting of the availability of MMDP
  - iv. Readiness and quality assessment
- b. These activities can be integrated with other activities or initiatives where feasible and logical in order to use scarce resources efficiently. As countries scale down MDA activities, some funds may become available for other activities such as MMDP.
- c. Keep LF morbidity management identified as a priority for inclusion in the essential services under Universal Health Coverage and within the Sustainable Development Goals.

- **Where can I access more resources to help me complete these tasks?**

Answer – A toolkit containing various resources has been prepared to assist countries in implementation of MMDP. The toolkit is available at [http://www.who.int/lymphatic\\_filariasis/global\\_progress/managing\\_morbidity\\_preventing\\_disability\\_toolkit/en/](http://www.who.int/lymphatic_filariasis/global_progress/managing_morbidity_preventing_disability_toolkit/en/)

## **Post-validation activities**

- **What post-validation activities and surveillance should a country do?**

Answer – Even after validation has been acknowledged, activities will still be needed including surveillance for LF infection as well as ensuring care for lymphoedema and hydrocele patients. These activities should be integrated into other existing health services for sustainability.

Coordination with vector-borne disease control programmes should be established if not already part of the LF elimination programme.<sup>13</sup> Through integrated vector management, LF endemic areas should be prioritized for integration with ongoing efforts to control vectors of other diseases.

Existing ongoing surveillance activities post-MDA could serve as the foundation for post-validation surveillance. WHO recommends these surveillance activities to be specific to the setting of the country, taking advantage of existing platforms for surveillance that could include LF.<sup>14</sup> WHO is monitoring ongoing operational research to identify tools, both new diagnostic tests and standardized methods that have potential for use in post-validation surveillance, to ensure infection remains below elimination thresholds and to confirm elimination of transmission. The types of surveillance that could be implemented, but are not limited to, include:

- periodic cross-sectional surveys
- routine surveillance of target population groups
- xenomonitoring

Programmes will also have to respond to surveillance results. Such a response may include testing and treatment, additional investigations to identify areas or groups for targeted treatment. Infected persons should be treated according to national policy. The combined regimen of albendazole (400 mg) plus DEC (6 mg/kg) or ivermectin (150–200 µg/kg) currently recommended for MDA is recommended also for treatment of infected persons.<sup>15</sup> Any treatment strategies should be directly observed.

- **How should post-validation surveillance results be sent to WHO?**

Answer – Surveillance data can be submitted annually using the EPIRF ([http://www.who.int/neglected\\_diseases/preventive\\_chemotherapy/reporting/WHO\\_EPIRF\\_PC.xls](http://www.who.int/neglected_diseases/preventive_chemotherapy/reporting/WHO_EPIRF_PC.xls)) found in the joint application package. The activities and the results of activities should also be shared in meetings of Regional Programme Managers and Regional Programme Review Groups to allow discussion of the results, identification of challenges and to inform best practices in post-validation activities.

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<sup>13</sup> Integrated vector management to control malaria and lymphatic filariasis: WHO position statement. Geneva: World Health Organization; 2011 ([http://apps.who.int/iris/bitstream/10665/70817/1/WHO\\_HTM\\_NTD\\_2011.2\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/70817/1/WHO_HTM_NTD_2011.2_eng.pdf?ua=1), accessed January 2017).

<sup>14</sup> Monitoring and epidemiological assessment of mass drug administration for eliminating lymphatic filariasis: a manual for national elimination programmes. Geneva: World Health Organization; 2011.

<sup>15</sup> Lymphatic filariasis: managing morbidity and preventing disability: an aide-mémoire for national programme managers. Geneva: World Health Organization; 2013 ([http://apps.who.int/iris/bitstream/10665/85347/1/9789241505291\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/85347/1/9789241505291_eng.pdf), accessed January 2017).

