# 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 unitJRF 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**

In 1997, the Fiftieth World Health Assembly adopted resolution WHA50.29 on the elimination of lymphatic filariasis as a public health problem. 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

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

- 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*. 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.

(http://www.who.int/neglected\_diseases/mediacentre/WHA\_50.29\_Eng.pdf, accessed January 2017).

<sup>&</sup>lt;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

<sup>&</sup>lt;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/, accessed January 2017).

<sup>&</sup>lt;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, 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), 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

- 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.
- 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.
- 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.

<sup>&</sup>lt;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>&</sup>lt;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

<sup>(</sup>http://apps.who.int/iris/bitstream/10665/44473/1/9789241500722\_eng.pdf, accessed January 2017).

<sup>&</sup>lt;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, accessed January 2017).

### **Reviewing authority**

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

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.
  - 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

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