

WORLD HEALTH ORGANIZATION
GLOBAL PROGRAMME TO ELIMINATE
LYMPHATIC FILARIASIS

TRAINING IN MONITORING AND
EPIDEMIOLOGICAL ASSESSMENT
OF MASS DRUG ADMINISTRATION
FOR ELIMINATING LYMPHATIC
FILARIASIS

LYMPHATIC
FILARIASIS

TAS

LEARNERS' GUIDE



TRAINING IN MONITORING AND EPIDEMIOLOGICAL ASSESSMENT OF MASS DRUG ADMINISTRATION FOR ELIMINATING LYMPHATIC FILARIASIS



Effective monitoring and evaluation are necessary to achieve the goals 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. Transmission assessment survey (TAS) is designed to provide a simple, robust survey design for documenting that the prevalence of lymphatic filariasis among 6–7 year old children is below a predetermined threshold; to provide the evidence base for programme managers that MDA can be stopped; and to assure national governments that national programmes have achieved their elimination goals.

This manual is designed to teach personnel of national programmes to eliminate lymphatic filariasis, including regional and district health personnel, the essential elements of monitoring and evaluating national programmes to eliminate LF. The focus is on planning and implementing TAS as an input to decide whether to move from MDA to post-MDA surveillance.



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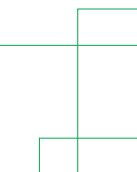
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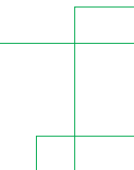


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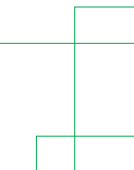
The training modules developed by Ms Kimberly Won (United States Center for Disease Control and Prevention) formed the basis for this document. Dr Aya Yajima (WHO Department of Control of Neglected Tropical Diseases) and Dr Kazuyo Ichimori (Focal Point for Lymphatic Filariasis Elimination, WHO Department of Control of Neglected Tropical Diseases) prepared the final draft.





Abbreviations

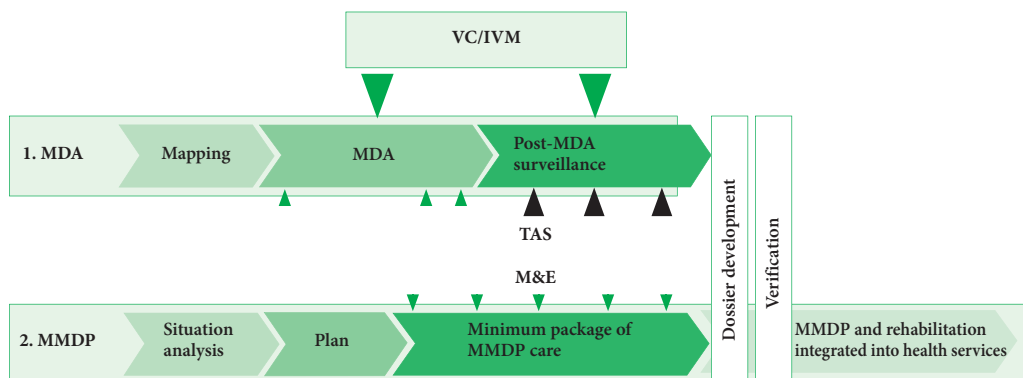
| | |
|-------|--|
| Ag | antigenaemia |
| ELISA | enzyme-linked immunosorbent assay |
| EU | evaluation unit |
| GPELF | Global Programme to Eliminate Lymphatic Filariasis |
| MDA | mass drug administration |
| Mf | microfilaraemia |
| ICT | immunochromatographic test |
| IU | implementation unit |
| PCR | polymerase chain reaction |
| RPRG | regional programme review group |
| TAS | transmission assessment survey |
| WHO | World Health Organization |



Introduction

In 1997, the Fiftieth World Health Assembly resolved to eliminate lymphatic filariasis (LF) as a public health problem. In response, the World Health Organization (WHO) established the Global Programme to Eliminate Lymphatic Filariasis (GPELF) to assist Member States in achieving this goal by 2020. The two components of the GPELF are (i) to reduce the prevalence of infection to levels at which it is assumed that transmission can no longer be sustained and (ii) to manage morbidity and prevent disability (*Figure 1*).¹

Figure 1. Two components of the Global Programme to Eliminate Lymphatic Filariasis: interrupting transmission and preventing morbidity and managing disability among people with the disease



Arrows represent epidemiological assessment recommended as part of monitoring and evaluation of the national programme. VC/IVM, vector control and integrated vector management; MDA, mass drug administration; TAS, transmission assessment survey; M&E, monitoring and evaluation; MMDP, morbidity management and disability prevention.

¹ WHO Global Programme to Eliminate Lymphatic Filariasis (GPELF) progress report 2000–2009 and strategic plan 2010–2020. (WHO/HTM/NTD/PCT/2010.6). Geneva, World Health Organization, 2010.

To eliminate LF, WHO recommends delivery of combinations of two medicines to entire populations at risk, by a strategy known as ‘mass drug administration (MDA)’. This involves four steps: mapping, MDA, post-MDA surveillance and verification of elimination.²

Effective monitoring and evaluation are necessary to achieve the goals 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. *The Progress report 2000–2009 and strategic plan 2010–2020 of the GPELF*,¹ which reviewed progress made in the first decade of the programme, highlighted the remaining challenges for the coming decade and proposed ways to reach the global goal of elimination by 2020. The milestone for 2011 was revision of WHO guidelines on interrupting transmission and conducting post-MDA surveillance. Accordingly, in 2011, WHO published a manual for monitoring and epidemiological assessment of MDA.³ 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 MDA.

Objectives of training

The manual is designed to teach the essential elements of monitoring and evaluating national programmes to eliminate LF.³ The focus is on planning and implementing TAS as an input to decide whether to move from MDA to post-MDA surveillance.

After completing the course, learners will understand:

- the elements of a TAS,
- how to plan and implement a TAS in an evaluation unit (EU), and
- the actions required after implementation of a survey.

The procedure for conducting a TAS is illustrated in *Figure 2*. The training course is designed as a 3-day workshop to present the essential elements of monitoring and evaluation in the GPELF and to prepare a plan for conducting a TAS appropriately in accordance with WHO guidelines. The modules are structured into two parts (*Table 1*): the theory behind each chapter and a practical part, which introduces recommended practices for applying the theory in the field.

² *Transmission assessment surveys in the Global Programme to Eliminate Lymphatic Filariasis. WHO position statement.* Geneva, World Health Organization, 2012.

³ *Monitoring and epidemiological assessment of mass drug administration: a manual for national elimination programmes.* Geneva, World Health Organization, 2011.

Figure 2. Procedure for conducting a transmission assessment survey and corresponding modules

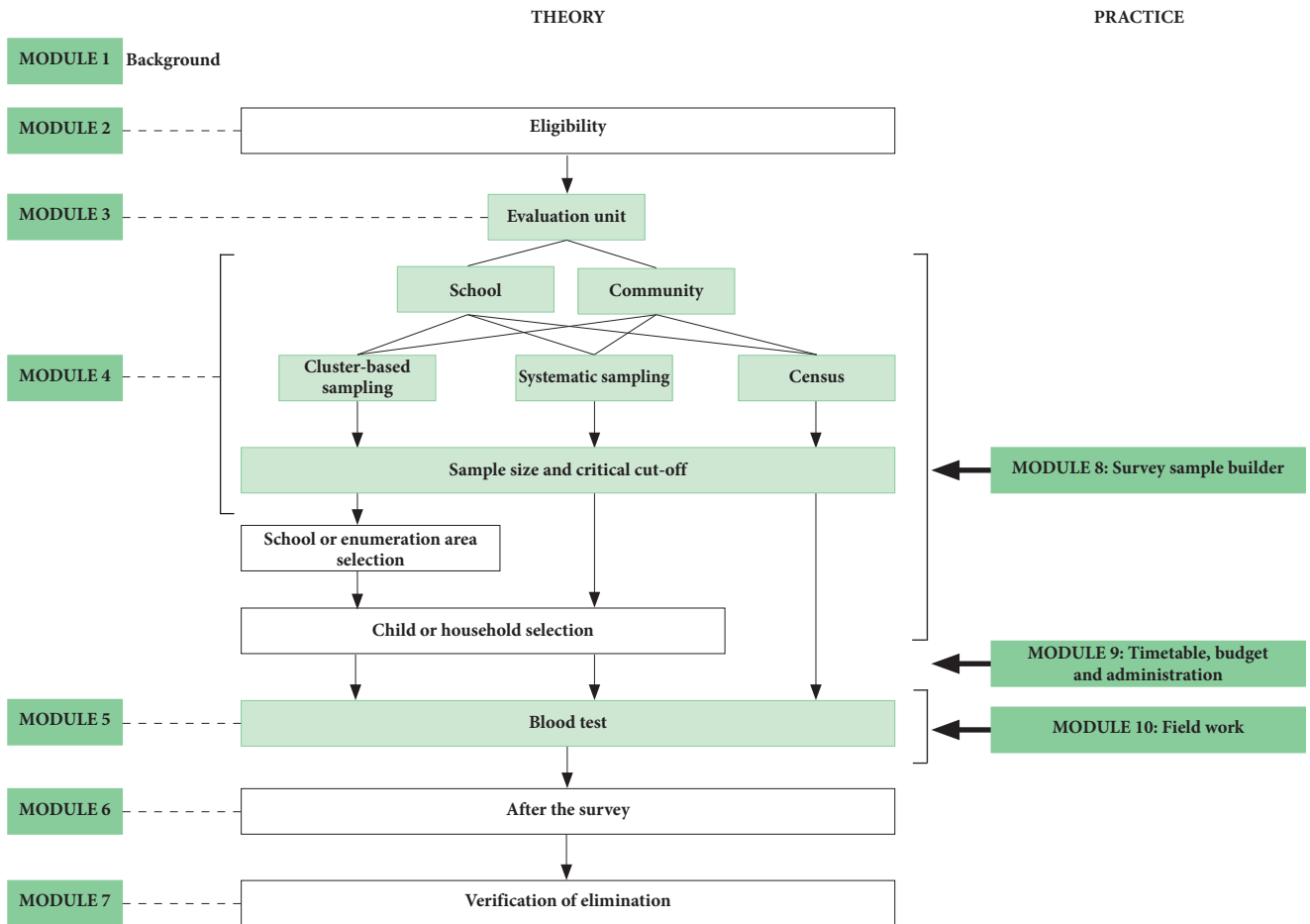


Table 1. Structure of training modules and relevant chapter of the 2011 WHO monitoring and evaluation manual

| Training module | Relevant chapter of manual | Suggested learners | |
|--|--|------------------------------|---------------------------------|
| | | National programme personnel | Subnational programme personnel |
| THEORY | | | |
| Module 1. Background | <ul style="list-style-type: none"> Chapter 1. Eliminating lymphatic filariasis Chapter 2. Recommended strategy for interrupting transmission Chapter 4. Mapping | √ | √ |
| Module 2. Eligibility for a TAS | <ul style="list-style-type: none"> Chapter 5. Monitoring coverage of mass drug administration Chapter 6. Assessing the impact of mass drug administration through sentinel and spot-check sites Chapter 7.2. When should surveys occur? | √ | √ |
| Module 3. Evaluation unit | <ul style="list-style-type: none"> Chapter 7.1. What geographical area should be used? | √ | |
| Module 4. Survey design | <ul style="list-style-type: none"> Chapter 7.3 How should the surveys be implemented? | √ | |
| Module 5. Diagnostic tests | <ul style="list-style-type: none"> Chapter 3. Diagnostic tools | √ | √ |
| Module 6. After the survey | <ul style="list-style-type: none"> Chapter 8. Implementing activities and surveillance after mass drug administration has stopped | √ | √ |
| Module 7. Verification of elimination | <ul style="list-style-type: none"> Chapter 9. Verifying the absence of transmission | √ | |
| PRACTICE | | | |
| Module 8. Survey sample builder | <ul style="list-style-type: none"> Annex 5. Detailed protocol for transmission assessment survey | √ | |
| Module 9. Timetable, budget and administration | None | √ | √ |
| Module 10. Field-work | <ul style="list-style-type: none"> Annex 5. Detailed protocol for transmission assessment survey | √ | √ |

For whom are these training modules intended?

These training modules are intended for personnel at two levels:

- personnel of national programmes to eliminate LF who are responsible for planning, implementing and reporting on TAS and for training subnational personnel. The learners should include a national programme manager, a monitoring and evaluation officer and a laboratory officer. They might also include subnational health personnel.
- regional or district health personnel who will prepare and implement field-work and report to the national programme manager.

How will this course be taught?

Presentations

Presentations in the form of lectures provide theoretical and practical information for staff of national programmes for planning and implementing TAS. Lectures are usually followed by group work or practical exercises. The slides for the modules are downloadable from http://www.who.int/lymphatic_filariasis/resources/TAS_training_materials/en. These can be used by learners for preparatory reading, as hand-outs during training and as practical resources during a survey.

Practical exercises and group work

At the end of most modules, learners are given exercises to help them gain practical experience, e.g. preparing a budget and timetable for conducting a survey and designing a survey with the 'survey sample builder'. Learners will work in small groups, ideally with colleagues from the same country, to apply the theory to their country situation. The outcomes of the practical exercises should form part of the country presentations at the end of the workshop and can also be included in the national TAS plan.

Demonstration

In module 5, 'Diagnostic tests', the preparation, use and reading of diagnostic tests will be demonstrated by the facilitators.

Role-play

In the role-play exercise, learners are asked to simulate field situations, such as playing the part of a field team in module 10. For example, they might determine the ideal work flow for a phlebotomist taking a blood sample from a child and preparing a diagnostic test or for a person reading a diagnostic test. The learners should then discuss their observations to identify the most effective organization of field-work.

Use of the learners' guide

The theoretical part of the guide, consisting of seven modules, describes the background of the GPELF, conceptual elements of monitoring and evaluation in a national programme to eliminate LF and the basic knowledge required to plan and conduct a TAS, both as a decision-making step to move from MDA to post-MDA surveillance and as a tool for post-MDA surveillance. The process of preparing a dossier for verification of elimination is also introduced.

The practical part of the guide, consisting of three modules, is designed to provide guidance and examples of approaches to logistical planning of a TAS and organization of field-work.

Learners will achieve the objectives of each module by consistently following the facilitators' instructions and by close interaction with them. The learners must have assimilated the knowledge of one unit before proceeding to the next. If they require clarification on any point, they should ask the facilitators.

Preparation

In order to obtain maximum benefit from the course, learners should arrive with information that will allow preparation of a workplan:

- Pertinent data on eligibility for conducting a TAS should be collected and entered on the 'INTRO' and 'ELIGIBILITY' worksheets of the **TAS Eligibility and Reporting Form**. These data include information on implementation units (IU), MDA coverage and sentinel site and spot-check survey results. The workplan prepared during the workshop will be for at least one EU, so data entered onto the worksheet should be for an area in which a TAS is likely to be conducted soon.
- Pertinent data for preparing a TAS should be collected and entered on the 'Sampling frame' in the 'SURVEY DESIGN' worksheet of the **TAS Eligibility and Reporting Form** for each EU. These data include the number of 6–7-year-old children and net primary school enrolment rates.
- While some of the actual costs may not be known, general estimates will help to prepare an overall budget. A **budget template** with general budget categories is provided.
- Country maps indicating endemic IUs are helpful for defining EUs and can be used for country presentations at the end of the course.
- A complete list of public and private primary schools or census enumeration areas for the area defined on the 'SURVEY DESIGN' worksheet of the TAS Eligibility and Reporting Form should be available.

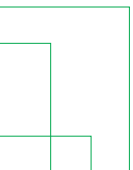
Evaluation

Evaluation of learners

In order to allow each learner to evaluate his or her progress, a test to be taken before and after training is provided (Annex 1).

Evaluation of the training

The facilitator will distribute a questionnaire to learners at the end of each day to elicit their opinions of the training. The feedback will be used to improve future training. Learners can complete the evaluation questionnaire anonymously if they wish.





■ *THEORY OF
TRANSMISSION
ASSESSMENT SURVEYS
(TAS)*

MODULE 1

Background

Learning objectives:

By the end of this module, learners should be able to answer the questions:

- What is lymphatic filariasis (LF)?
- What is the Global Programme to Eliminate LF (GPELF)?
- What is a transmission assessment survey (TAS)?
- How does a national programme report to the GPELF?

Relevant sections of *the 2011 WHO monitoring and evaluation manual*³

- Chapter 1. Eliminating lymphatic filariasis
- Chapter 2. Recommended strategy for interrupting transmission
- Chapter 4. Mapping

What is lymphatic filariasis (LF)? (slides 4–6)

LF is one of the oldest, most debilitating neglected tropical diseases. It is caused by three species of parasitic worms, *Wuchereria bancrofti*, *Brugia malayi* and *B. timori* (Figure 3), which are transmitted to humans by mosquitoes.

Figure 3. Images of microfilariae of three filarial worms in blood films stained with Giemsa, *Wuchereria bancrofti* (left), *Brugia malayi* (centre) and *B. timori* (right)



Source: www.dpd.cdc.gov/dpdx

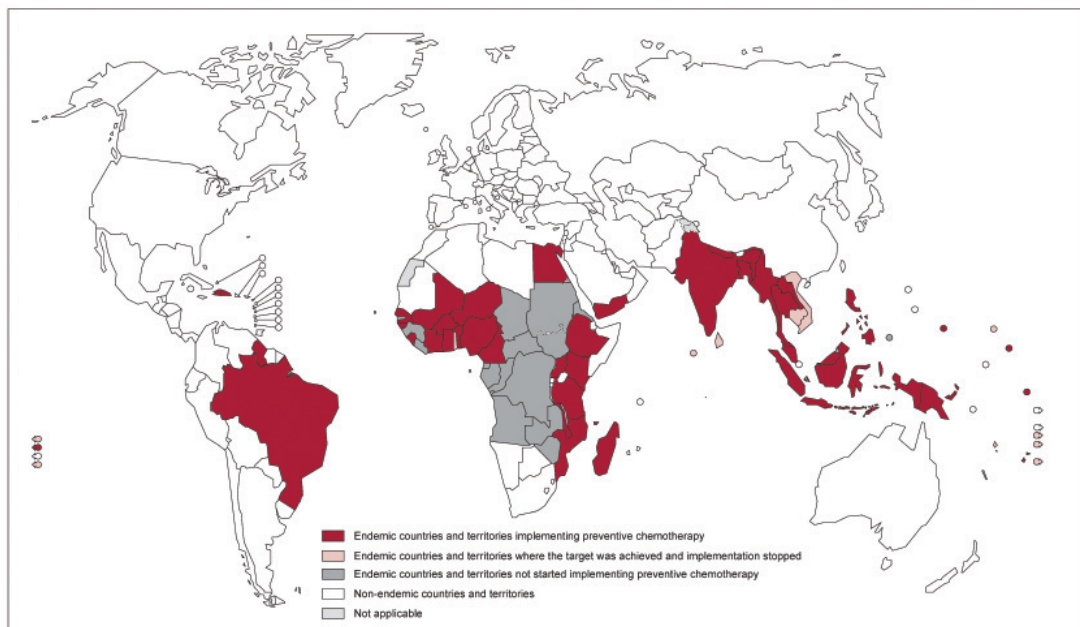
The commonest clinical manifestations are lymphoedema, which affects an estimated 15 million people, and scrotal hydrocoele, which affects 25 million men (Figure 4). Although these clinical manifestations are not often fatal, they have led to ranking of LF as one of the world's leading causes of permanent and long-term disability.¹

Figure 4. Images of lymphoedema (or elephantiasis) (left) and scrotal hydrocoele (right)



LF is currently endemic in 73 countries (Figure 5), with an estimated 1.39 billion people at risk of infection⁴.

Figure 5. Distribution and status of preventive chemotherapy for lymphatic filariasis worldwide, 2011



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. © WHO 2012. All rights reserved

Data Source: World Health Organization
Map Production: Control of Neglected
Tropical Diseases (NTD)
World Health Organization



Global Programme to Eliminate Lymphatic Filariasis (GPELF) (slides 7 and 8)

In 1996, WHO estimated that some 120 million people worldwide were affected by LF, of whom 40 million were incapacitated by the disease.¹ In 1997, the World Health Assembly resolved to eliminate LF as a public health problem (WHA resolution 50.29), and the Global Programme to Eliminate Lymphatic Filariasis (GPELF) was launched in 2000, with the goal of global elimination by 2020 and two aims: to stop the spread of infection by interrupting transmission by mass drug administration (MDA), and to reduce the suffering caused by the disease by morbidity management and disability prevention.

The GPELF works in partnership with the ministries of health of countries endemic for LF, which are responsible for national programmes, and with donors, pharmaceutical companies, academic and research institutions, nongovernmental organizations and WHO.

⁴ The latest map of distribution and status of preventive chemotherapy for lymphatic filariasis can be downloaded from WHO Global health observatory map gallery at <http://gamapserver.who.int/mapLibrary/app/searchResults.aspx>.

Programmatic steps for interrupting transmission (slide 9)

The four programme steps recommended by the GPELF for interrupting transmission are shown in *Figure 6*:

1. **Mapping** the geographical distribution of the disease;
2. **MDA** for 5 years of more to reduce the number of parasites in the blood to levels that will prevent mosquito vectors from transmitting infection;
3. **Post-MDA surveillance** after MDA is discontinued; and
4. **Verification** of elimination of transmission.

Figure 6. Programme steps for interrupting transmission of lymphatic filariasis by mass drug administration (MDA)



Mapping (slide 10)

Mapping is conducted to determine whether active transmission is occurring and whether MDA is required.

1. Define the Implementation Unit (IU) for MDA in the country.
2. Implement mapping by:
 - a) Reviewing existing information
 - b) Conducting mapping surveys
 - *Measure antigenaemia (Ag) by immunochromatographic tests (ICT) or microfilaraemia (Mf) by blood film in older school-aged or adult populations. If the prevalence in this population is $\geq 1\%$, classify the IU as being endemic.*

MDA (slide 11)

GPELF recommends mass administration of a combination of medicines:

- diethylcarbamazine (DEC) + albendazole (in countries not co-endemic for onchocerciasis)
- ivermectin + albendazole (in countries co-endemic for onchocerciasis)

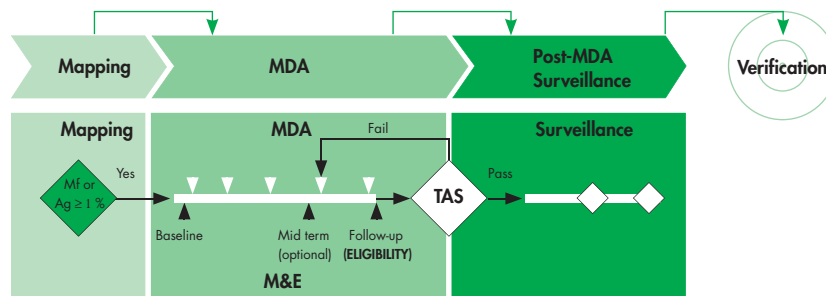
A single dose should be given annually for at least 5 years to all eligible individuals targeted in the entire endemic area.

The objective is to achieve reductions in the density of microfilariae circulating in the blood of infected individuals and in the prevalence of infection in the entire community to levels at which it is assumed that microfilariae can no longer be transmitted by mosquito vectors to new human hosts.

Monitoring and evaluation during MDA (slide 12)

Effective monitoring and evaluation are important throughout a LF elimination programme (Figure 7).

Figure 7. Steps for interrupting transmission of lymphatic filariasis by mass drug administration (MDA) as described by WHO in 2011³



Mf, microfilaraemia; Ag, antigenaemia; M&E, monitoring and evaluation; TAS, transmission assessment survey

Source: Illustrated from *Global Programme to Eliminate Lymphatic Filariasis (GPELF). Monitoring and epidemiological assessment of mass drug administration—a manual for national elimination programmes*. Geneva, World Health Organization, 2011.

- The prevalence of Mf or Ag can be used in mapping.
- During MDA, coverage is monitored at each round to determine whether the goal of at least 65% coverage of the total population was met.
- After at least five rounds of effective MDA, the impact is evaluated at sentinel and spot-check sites.
- If all the eligibility criteria are met, a transmission assessment survey (TAS) is conducted to help make a decision to stop MDA.
- TAS is repeated twice during post-MDA surveillance.

Transmission assessment survey (TAS) (slide 13)

A TAS is conducted with a standardized method, and the results help decision-makers in the national programme to move from MDA to post-MDA surveillance. Guidance is given in *Table 2*.

Table 2. Transmission assessment surveys

| Technical aspect | Guidance |
|---------------------------------|---|
| Geographical area | Evaluation unit |
| When survey should be conducted | When all the eligibility criteria are met At least 6 months after the last round of mass drug administration |
| Target population | Children aged 6–7 years |
| Diagnostic tests | <i>W. bancrofti</i> areas: ICT <i>Brugia</i> spp. areas: Brugia Rapid™ test |
| Survey design | Cluster sampling or systematic sampling in schools, the community or a census |

ICT, immunochromatographic test

Children aged 6 and 7 years are targeted because they should have been protected from infection if MDA was successful in interrupting transmission. Positive test results in this age group therefore usually indicate recent transmission.

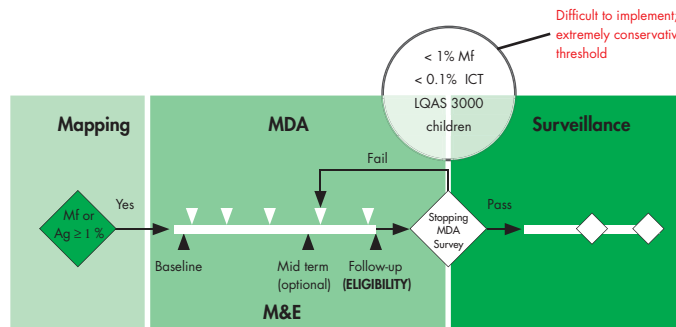
A TAS is a simplified version of the former ‘stopping-MDA survey’ protocol, which had a number of limitations.

Limitations of previous guideline (2005) (slide 14)

The differences between the two editions of the manual on monitoring and epidemiological assessment of mass drug administration (2005 and 2011) are summarized in *Annex 2*.

- An additional 5–10 sentinel and spot-check tests were required per IU.
- Antigen surveys of 2–4-year-old children were not informative in most countries.
- Lot quality assurance sampling surveys were difficult to conduct (e.g. too many schools to visit per IU to test 3000 children).
- The 1 in 3000 threshold was too conservative.

Figure 8. Steps for interrupting transmission of lymphatic filariasis by mass drug administration (MDA) in the previous monitoring and evaluation (M&E) manual



Mf, microfilaraemia; ICT, immunochromatographic test; LQAS, lot quality assessment sampling

Source: Illustrated from Monitoring and epidemiological assessment of the programme to eliminate lymphatic filariasis at implementation unit level. Geneva, World Health Organization, 2005.

Post-MDA surveillance (slide 15)

A TAS is not only important in deciding to stop MDA but is also a method recommended in post-MDA surveillance to detect recrudescence of transmission. Surveys should be repeated at least twice after MDA, at an interval of 2–3 years, to ensure that recrudescence has not occurred and that transmission can therefore be considered interrupted.

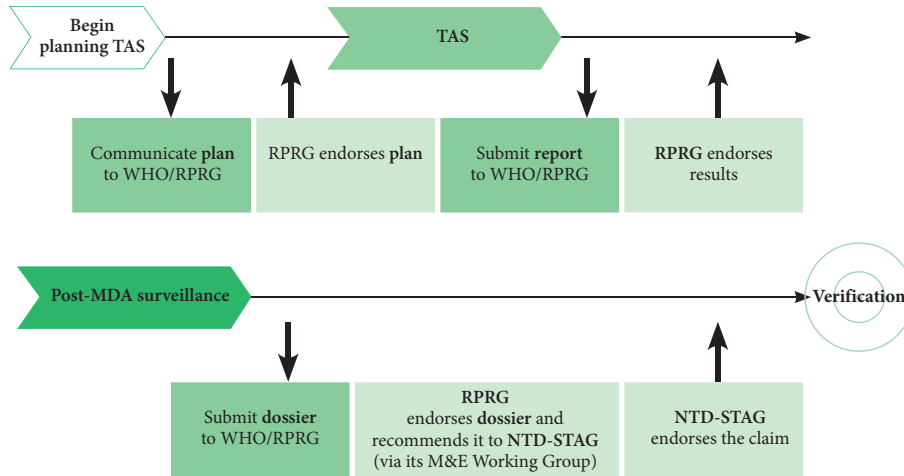
Post-MDA surveillance is discussed in module 6.

Reporting from a national programme to the GPELF (slide 16)

As a significant decision will be made on the basis of the outcome of the TAS, it must be conducted at the appropriate time and be of high quality. The national programme should inform WHO and regional programme review groups (RPRG) of plans and reports of TAS and obtain advice if necessary.

Annex 3 gives the WHO TAS Eligibility and Reporting Form that can be used for this purpose.

Figure 9. Proposed reporting and feedback mechanism between national programmes and the Global Programme for transmission assessment surveys (TAS) and post-MDA surveillance



M&E, monitoring and evaluation; RPRG, Regional Programme Review Group; WHO, World Health Organization; STAG-NTD, the Strategic and Technical Advisory Group on Neglected Tropical Diseases.

MODULE 2

Eligibility for a TAS

Learning objectives:

By the end of this module, learners should understand how to assess the eligibility of an IU for a TAS on the basis of:

- epidemiological drug coverage (programme coverage)
- prevalence of infection at sentinel sites
- prevalence of infection at spot-check sites

Relevant sections of the 2011 WHO monitoring and evaluation manual³

- Chapter 5. Monitoring coverage of mass drug administration
- Chapter 6. Assessing the impact of mass drug administration through sentinel and spot check sites
- Chapter 7.2. When should surveys occur?

Eligibility criteria for a TAS (slide 4)

Surveys require significant investments in time and money; therefore, national programmes must be as certain as possible that a survey is conducted at the appropriate time. Before a survey is planned, the following basic eligibility criteria must be met by each IU.

- **At least five rounds** of MDA were completed.
- **The epidemiological drug coverage** (programme coverage) at each round was $\geq 65\%$.
- **Sentinel sites:** The prevalence of Mf was $< 1\%$ or that of Ag was $< 2\%$ at all sites after the last effective round.
- **Spot-check sites:** The prevalence of Mf was $< 1\%$ or that of Ag was $< 2\%$ at all sites after the last effective round.

Epidemiological drug coverage (programme coverage) (slide 5)

Epidemiological drug coverage is defined as the proportion of individuals in an IU who actually ingested the medicines.

$$\text{Epidemiological drug coverage} = \frac{\text{Number of people reported to have ingested the drugs}}{\text{Total population in IU}} \times 100$$

In order to reduce the prevalence of Mf in infected individuals to the threshold below which transmission is assumed to be no longer sustainable and recrudescence is unlikely to occur even in the absence of intervention, **at least 65% of the total population in each IU must ingest the medicines for at least five rounds of MDA.** Monitoring epidemiological drug coverage at each round is therefore an essential component of programme management, which provides important information for deciding whether an IU is eligible for a TAS.

Coverage should reflect the actual compliance with intake of the medicines by the target population. Reported coverage can be verified by coverage surveys.

Sentinel and spot-check surveys (slide 6)

Blood surveys at sentinel sites are used to establish baseline infection levels and to monitor the impact of MDA on infection prevalence periodically. Once a sentinel site is selected, the same site must serve as the sentinel site throughout the programme.

Blood surveys at spot-check sites are used to confirm that the results of sentinel surveys represent the infection level in the entire IU. At least one spot-check site is selected for each sentinel site. Different spot-check sites are selected each time.

How many sentinel and spot-check sites are needed for each IU? (slide 7)

- At least one sentinel site per 1 million people in the IU
- At least one sentinel site for each IU; more sites may be selected when resources allow.

Smaller IUs may be combined and served by one sentinel site. Combined IUs should be contiguous, have similar epidemiological characteristics and should have implemented MDA at the same time. The advice of WHO and the RPRG may be required.

Characteristics of sentinel and spot-check sites (slide 8)

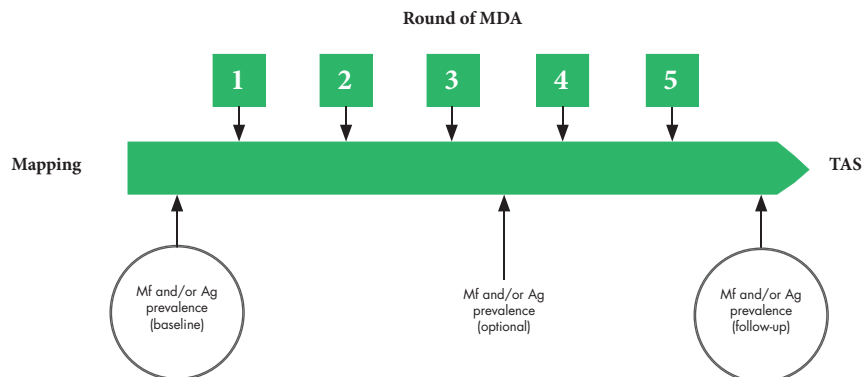
Sites with the following characteristics should be selected as sentinel and spot-check sites:

- A population of at least 500 people (so as to collect a convenience sample of at least 300 people aged > 5 years of age)
- 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 drug coverage is anticipated
- No prior MDA for onchocerciasis
- A stable population

When should surveys be conducted? (slide 9)

- Baseline survey: before first MDA
- Mid-term survey: at least 6 months after third MDA (optional); could be replaced by effective annual monitoring of coverage
- Follow-up survey: at least 6 months after fifth effective MDA to assess whether the IU is eligible for a TAS

Figure 10. Timing of sentinel site and spot-check site surveys recommended in the Global Programme



MDA, mass drug administration; TAS, transmission assessment survey; Mf, microfilariae; Ag, antigenaemia

Source: *Monitoring and epidemiological assessment of mass drug administration—a manual for national elimination programmes*. Geneva, World Health Organization, 2011.

How should surveys be implemented? (slide 10)

Target population

- Convenience sample of at least 300 people
- All members of the population in all age groups > 5 years (including pregnant women)
- If the population is too large, a part can be chosen.

Diagnostic test

- Blood film for Mf prevalence
- ICT for Ag rate if resources allow (in *W. bancrofti* areas)

Confirming eligibility to conduct a TAS (slide 11)

Before assessing the eligibility of an IU for a TAS, programme managers should compile all the necessary records and complete the 'INTRO' and 'ELIGIBILITY' worksheets of the **TAS Eligibility and Reporting Form**. The form can help to decide whether the time is appropriate to conduct a TAS.

The form should be reviewed by the WHO/RPRG before the survey is planned and implemented. The form is available in *Annex 3*.

MODULE 3

Evaluation unit

Learning objectives:

By the end of this module, learners should understand how to define a survey area, known as an evaluation unit (EU).

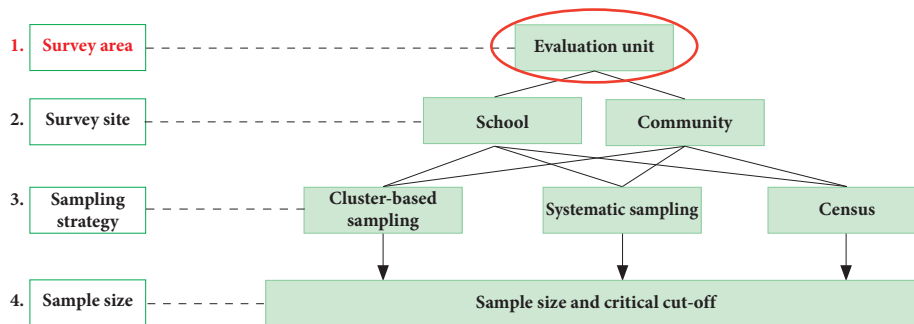
Relevant sections of the *2011 WHO monitoring and evaluation manual*³

- Section 7.1 What geographical area should be used?

Survey area for a TAS (slides 4 and 5)

If all the data from IUs confirm that they are eligible for a TAS, planning can start. The design of a TAS is determined in several steps.

Figure 11. Determining the design of a transmission assessment survey in module 3



The first step is to define the survey area (Figure 11), which is designated as an EU. It is important to recognize the difference between IUs and EUs and to define the appropriate EU:

- IU: The administrative unit in a country that is used for MDA
- EU: A study area selected for a TAS

Defining an EU (slide 6)

IUs can be combined, divided or remain the same in defining an EU. Nevertheless, all IUs in a country in which MDA is implemented will be included in a TAS.

If IUs are combined, the resulting EU should have the following characteristics:

- IUs in an EU are usually contiguous.
- All IUs in an EU should have had at least five effective rounds of MDA (i.e. covering $\geq 65\%$ of the total population) and meet all the eligibility criteria for a TAS.
- All areas in an EU should have similar epidemiological features and LF transmission dynamics (i.e. epidemiological drug coverage, baseline prevalence, Mf or Ag prevalence in sentinel and spot-check site surveys, principal LF parasites, vector abundance).
- The population should not exceed 2 million.

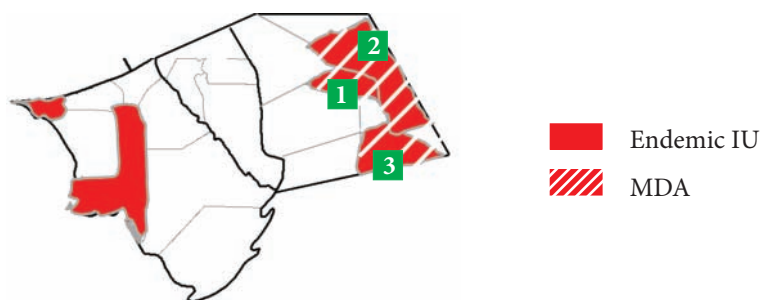
Combining IUs (slide 7)

Figure 12 shows a hypothetical situation in which combining IUs might be appropriate. The five IUs on the map (in red) are endemic; three are undergoing MDA.

Figure 12. Hypothetical situation in which combining implementation units might be appropriate

| Unit | Total population | Baseline Mf prevalence (%) | MDA coverage (%) | | | | | Sentinel site Mf prevalence (%) (after fifth round) | Spot check site Mf prevalence (%) |
|------|------------------|----------------------------|------------------|----|----|----|----|---|-----------------------------------|
| | | | #1 | #2 | #3 | #4 | #5 | | |
| 1 | 32983 | 2.1 | 81 | 69 | 79 | 76 | 76 | 0 | 0 |
| 2 | 101438 | 3.4 | 78 | 67 | 77 | 72 | 76 | 0.3 | 0.1 |
| 3 | 52138 | 2.9 | 75 | 70 | 72 | 76 | 68 | 0.1 | 0.1 |

IU, implementing unit; Mf, microfilariae; MDA, mass drug administration



All three IUs meet all the criteria for eligibility for a TAS:

- All had similar baseline Mf prevalences.
- Five effective rounds of MDA were conducted in each unit (coverage, 67–81%).
- The sentinel site Mf prevalence was < 1% in all three units after the fifth MDA round.
- The spot-check site Mf prevalence was < 1% in all three units after the fifth MDA round.

Combining these three IUs into one EU will reduce the number of surveys from three to one and thus reduce the overall cost. If the EU fails the TAS, however, all the IUs that comprise the EU will have to continue MDA.

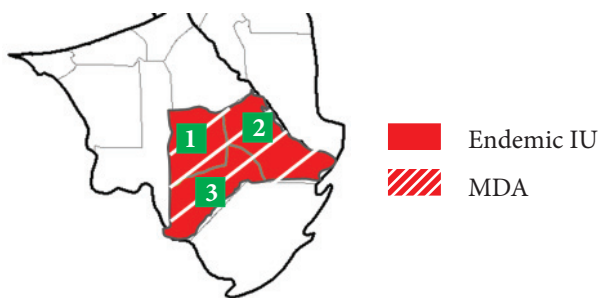
Dividing an IU (slide 8)

Figure 13 shows a hypothetical situation in which a large IU should be divided. The area shaded in red is one IU (population, 2 647 953) comprising three subdistricts (see lower table).

Figure 13. Hypothetical situation in which a large implementation unit should be divided

| Total population | Baseline Mf prevalence (%) | MDA coverage (%) | | | | | Sentinel site Mf prevalence (%) (after fifth round) | Spot check site Mf prevalence (%) |
|------------------|----------------------------|------------------|----|----|----|----|---|-----------------------------------|
| | | #1 | #2 | #3 | #4 | #5 | | |
| 2 647 953 | 2.8 | 79 | 66 | 71 | 74 | 72 | 0.2 | 0.3 |

Mf, microfilariasis; MDA, mass drug administration; IU, implementing unit



| Sub-district | Total population | Baseline Mf prevalence (%) |
|--------------|------------------|----------------------------|
| 1 | 798 234 | 1.8 |
| 2 | 989 436 | 5.4 |
| 3 | 860 283 | 1.2 |

All the eligibility criteria for a TAS have been met:

- five rounds of MDA with effective coverage and
- Mf prevalence at all sentinel and spot-check sites is < 1%.

The total population of the IU is, however, more than 2 million.

In this example, the baseline Mf prevalence in subdistrict 2 was actually higher than that in subdistricts 1 and 3. Therefore, subdistricts 1 and 3 could be combined for one assessment, and 2 could be assessed separately. Alternatively three TAS could be conducted, with one in each subdistrict.

While dividing an IU into several EUs increases the number of surveys to be conducted, it allows a more focused assessment of the situation in the IU.

Geographical area of an EU (slide 9)

Although there is no upper limit to the geographical area of an EU, combining IUs may increase the probability of missing foci of infection and might increase the logistical difficulties (e.g. transport costs).

Exercise (slide 10)

Using existing data (e.g. maps, listing of IUs, population sizes, number of MDA rounds, epidemiological drug coverage) to:

1. define an appropriate EU(s)
2. present the defined EU(s) to the group

MODULE 4

Survey design

Learning objectives:

By the end of this module, learners should understand how to determine:

- survey site
- sampling strategy
- sample size
- critical cut-off

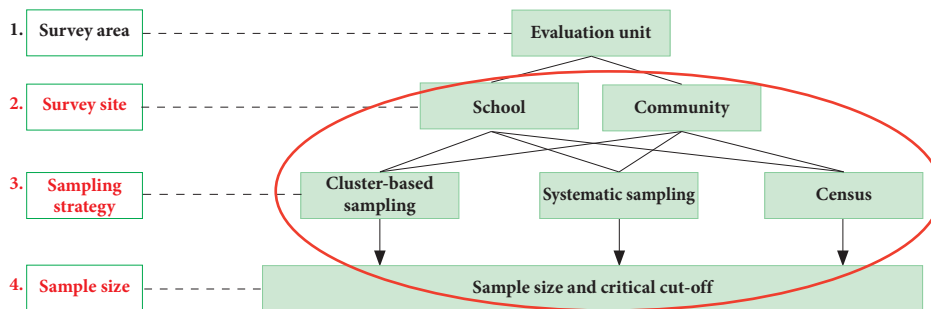
Relevant sections of the *2011 WHO monitoring and evaluation manual*³

- Section 7.3. How should the surveys be implemented?

Determining survey site, sampling strategy and sample size (slide 4, Figure 14)

Once the survey area has been defined, the next steps are to determine the survey site, sampling strategy and sample size.

Figure 14. Steps in determining the design of a transmission assessment survey in module 4



Target population (slide 5)

Target group: Children aged 6–7 years

Why? Young children should have been protected from infection if MDA was successful in interrupting transmission. Positive test results in this age group therefore usually indicate recent transmission.

- For school-based surveys:
 - All children enrolled in selected grades (usually grades 1 and 2) should be considered eligible for the survey sample.
 - Once the grade(s) have been selected for the survey, every child enrolled in that grade(s) is eligible for the survey, regardless of age. The sample may therefore include children aged 5, 8 or 9 years or more.
- For community-based household surveys:
 - All children aged 6–7 years old in the EU are eligible for inclusion.

Survey site (slide 6)

A TAS can be conducted in schools or in communities, depending on the proportion of 6- and 7-year-old children in schools.

Options:

- School/based survey
- Community based household survey

- If the net primary-school enrolment ratio in the EU is $\geq 75\%$, the survey can be conducted in schools.
 - The net school enrolment ratio should be confirmed with the ministry of education.
 - The enrolment ratios for the EU should be used, if available. Good judgement should be used if the rates in the EU vary.

- If the net primary-school enrolment ratio is $< 75\%$, a community-based household survey should be conducted.

Sampling strategy (slides 7 and 8)

After the survey site (school or community) has been selected, the next step is to determine an appropriate sampling strategy. Three options are available (*Figure 14*):

- Cluster sampling
 - A 'cluster' is a sampling unit, which in the case of a TAS is a school or enumeration area.
 - First select clusters, then systematically test only children in selected clusters.
 - Advantage: fewer sites to visit

- Systematic sampling
 - Sample children at all sites.
 - Select children to test at fixed intervals.
 - Advantage: smaller sample

- Census
 - No sampling required; test all children in target age range in all sites.

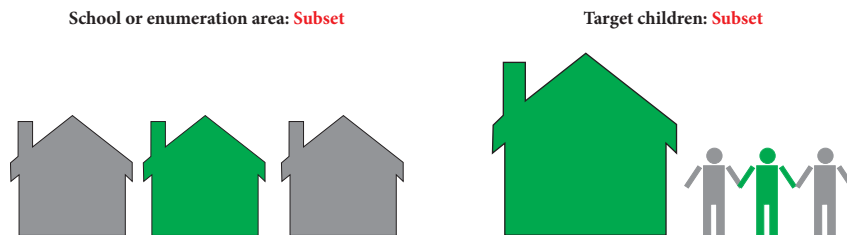
The choice of cluster or systematic sampling depends on the total number of children in the target age range (6–7 years) and the total number of clusters (schools or enumeration areas) in the EU. Census sampling should be used in areas where the target population is small.

Cluster sampling (slide 9)

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

The clusters to be visited are selected randomly (e.g. if there are 250 schools in the EU, about 30 are selected for the survey) (*Figure 15, left*). Then, children in the target age range in each cluster are selected randomly (*Figure 15, right*).

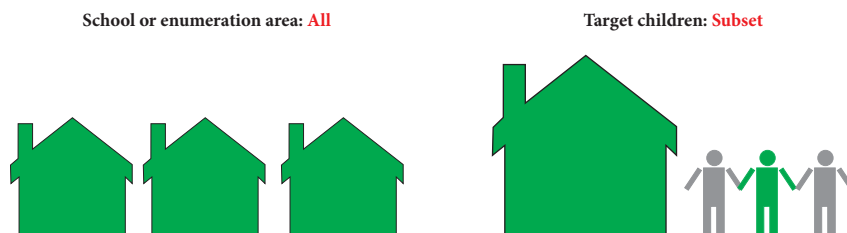
Figure 15. Conceptual diagram of cluster sampling



Systematic sampling (slide 10)

Systematic sampling is often used when the population is small to medium or there are fewer than 40 schools or enumeration area. All schools in the EU are visited (*Figure 16, left*). In each school, a subset of children are tested (*Figure 16, right*).

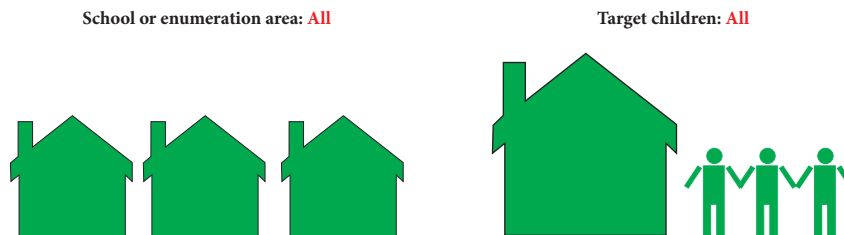
Figure 16. Conceptual diagram of systematic sampling



Census (slide 11)

A census is usually conducted when the population is small (< 400 children in areas where *Anopheles* or *Culex* is the principal vector; < 1000 children in areas where *Aedes* is the principal vector). In census sampling, all children in the target age group in the EU are tested (Figure 17).

Figure 17. Conceptual diagram of census



Algorithm for survey site and sampling strategy (slide 12)

The survey site and sampling strategy can be selected by using the algorithm on page 25 of the 2011 WHO monitoring and evaluation manual, which is reproduced in Annex 4.

Sample size (slides 13 and 14)

Once the location and sampling strategy have been determined, the target sample size for the survey should be calculated. Sample size can be calculated from either:

- Tables A.5.1 and A.5.2 of Annex 5 of the 2011 WHO monitoring and evaluation manual³ (pp. 73–74) or
- the 'survey sample builder' (see module 8).

Sample size depends on the total population of target-age children in the EU. As *Aedes* spp. are more efficient vectors, the target level of Ag is lower in these areas. As a result, the sample sizes will be larger than in areas where *Anopheles*, *Culex* or *Mansonia* is the principal vector.

In the example shown in Figure 18, the total population of children in the target age group in the EU is approximately 24 000. If the programme manager has decided to conduct cluster sampling, the target sample size for the survey will be 1 156 children of the target age group in the EU.

Figure 18. Example of sampling interval and sample size for transmission assessment and post-MDA surveillance surveys in areas where *Anopheles* or *Culex* is the principal vector. (For areas where *Aedes* is the principal vector, see Annex 4.)

| Population surveyed ^{1,2} | Sampling interval sample | Systematic sampling size (n) | Systematic sampling critical cut-off (d) | Sample size for cluster design ³ (n_cluster) | Number of clusters if cluster-sample survey is | | Cluster design critical cut-off (d_cluster) |
|------------------------------------|--------------------------|------------------------------|--|--|--|---|---|
| | | | | | school-based | a household survey | |
| <400 | 1.0 (census) | N | First integer <0.02N ⁴ | NA | NA | NA | NA |
| 400 | 1.4 | 284 | 3 | <i>Cluster-sampling not recommended. Use systematic sampling and the corresponding values of n and d</i> | | | |
| 600 | 1.6 | 365 | 4 | | | | |
| 800 | 1.8 | 438 | 5 | | | | |
| 1000 | 1.9 | 506 | 6 | | | | |
| 1200 | 2.3 | 520 | 6 | 759 | <i>Divide the sample size for cluster design by the average number of target-year children per school and round up to the nearest integer. If this integer is <30, then the number of clusters is 30.</i> | <i>Divide sample size for cluster design by the estimated average number of target-age children per EA and round up to the nearest integer. If this integer is <30, then the number of clusters is 30.</i> | 9 |
| 1400 | 2.6 | 530 | 6 | 780 | | | 9 |
| 1600 | 2.6 | 594 | 7 | 795 | | | 9 |
| 2000 | 3.3 | 606 | 7 | 891 | | | 11 |
| 2400 | 3.9 | 614 | 7 | 909 | | | 11 |
| 2800 | 4.1 | 678 | 8 | 1228 | | | 14 |
| 3200 | 4.6 | 684 | 8 | 1356 | | | 16 |
| 3600 | 5.2 | 688 | 8 | 1368 | | | 16 |
| 4000 | 5.8 | 690 | 8 | 1376 | | | 16 |
| 5000 | 7.1 | 696 | 8 | 1380 | | | 16 |
| 6000 | 7.8 | 762 | 9 | 1392 | | | 16 |
| 8000 | 10.4 | 766 | 9 | 1524 | | | 18 |
| 10 000 | 12.9 | 770 | 9 | 1532 | | | 18 |
| 14 000 | 18.0 | 774 | 9 | 1540 | | | 18 |
| 18 000 | 23.2 | 776 | 9 | 1548 | | | 18 |
| 24 000 | 30.8 | 778 | 9 | 1552 | | | 18 |
| 30 000 | 38.5 | 778 | 9 | 1556 | 18 | | |
| 40 000 | 47.5 | 842 | 10 | 1684 | 20 | | |
| 50 000 | 59.3 | 842 | 10 | 1684 | 20 | | |
| ≥50 000 | Calculate ⁵ | 846 | 10 | 1692 | 20 | | |

¹ Refers to whatever population is being surveyed, for example first and second year primary-school children or children aged 6–7 years old in the community.

² For a population size between two adjacent Ns in the table, the sampling fraction and d or d_cluster for the lower N should be used.

³ For the cluster design, the assumed design effects are 1.5 if the population size <2400, and 2.0 if the population size is ≥2400.

⁴ For example, there are a total of 300 first- and second-year primary-school children in an EU. All are tested and six are antigenaemic. The EU would fail the TAS because the proportion of children tested who are antigenaemic is 2.0%, not <2.0%. In this case, $0.02 \times N = 0.02 \times 300 = 6$. d (the first integer <6) = 5.

⁵ Divide the size of the surveyed population by 846, rounding down to the nearest tenth. For example, if the size of the survey population is 70 000, then the sampling interval is $70\,000/846=82.74$, rounded down to 82.7.

Critical cut-off (slides 15 and 16)

Critical cut-off: Threshold of infection prevalence below which transmission is assumed to be no longer sustainable and recrudescence is unlikely to occur, even in the absence of MDA.

- A TAS provides an estimate of this threshold in the EU as the number of antigen-positive or antibody-positive cases.
- If the number of positive cases is at or below the established cut-off, the EU ‘passes’, and governments can decide to stop MDA.
- If the number of positive cases is above the established cut-off, at least two more rounds of MDA should be conducted.

In the example in *Figure 19*, the critical cut-off is 18. If the total number of positive cases is 18 or fewer, a decision can be made to stop MDA. If the total number of positive cases is greater than 18, MDA should continue for at least two more rounds.

Figure 19. Example of sampling interval and sample size for transmission assessment and post-MDA surveillance surveys in areas in which *Anopheles* or *Culex* is the principal vector

| | | | | | | | |
|---------------|------------------------|-----|----|-------------|---|--|----|
| 2800 | 4.1 | 678 | 8 | 1356 | <i>for cluster design by the average number of target-year children per school and round up to the nearest integer. If this integer is <30, then the number of clusters is 30.</i> | <i>design by the estimated average number of target-age children per EA and round up to the nearest integer. If this integer is <30, then the number of clusters is 30.</i> | 16 |
| 3200 | 4.6 | 684 | 8 | 1368 | | | 16 |
| 3600 | 5.2 | 688 | 8 | 1376 | | | 16 |
| 4000 | 5.8 | 690 | 8 | 1380 | | | 16 |
| 5000 | 7.1 | 696 | 8 | 1392 | | | 16 |
| 6000 | 7.8 | 762 | 9 | 1524 | | | 18 |
| 8000 | 10.4 | 766 | 9 | 1532 | | | 18 |
| 10 000 | 12.9 | 770 | 9 | 1540 | | | 18 |
| 14 000 | 18.0 | 774 | 9 | 1548 | | | 18 |
| 18 000 | 23.2 | 776 | 9 | 1552 | | | 18 |
| 24 000 | 30.8 | 778 | 9 | 1156 | | 18 | |
| 30 000 | 38.5 | 778 | 9 | 1556 | | 18 | |
| 40 000 | 47.5 | 842 | 10 | 1684 | | 20 | |
| 50 000 | 59.3 | 842 | 10 | 1684 | | 20 | |
| ≥50 000 | Calculate ⁵ | 846 | 10 | 1692 | | 20 | |

¹ Refers to whatever population is being surveyed, for example first and second year primary-school children or children aged 6–7 years old in the community.

² For a population size between two adjacent Ns in the table, the sampling fraction and d or d_{cluster} for the lower N should be used.

³ For the cluster design, the assumed design effects are 1.5 if the population size <2400, and 2.0 if the population size is ≥2400.

⁴ For example, there are a total of 300 first- and second-year primary-school children in an EU. All are tested and six are antigenaemic. The EU would fail the TAS because the proportion of children tested who are antigenaemic is 2.0%, not <2.0%. In this case, $0.02 \times N = 0.02 \times 300 = 6$. d (the first integer <6) = 5.

⁵ Divide the size of the surveyed population by 846, rounding down to the nearest tenth. For example, if the size of the survey population is 70 000, then the sampling interval is $70\,000/846=82.74$, rounded down to 82.7.

Critical cut-off in census (slide 17)

In areas where a census is used (i.e. every child in the target age group is tested), a point prevalence of infection is calculated and forms the basis for programmatic decisions. MDA can be stopped in:

- areas of *Culex*, *Anopheles* or *Mansonia* in which the prevalence is < 2%
- in areas of *Aedes* areas in which the prevalence is < 1%.

Exercise (slide 18)

1. Using Figure 3 of the 2011 WHO monitoring and evaluation manual (p. 25), you will:
 - i. determine whether a school-based or a community-based survey is appropriate for the EU(s) defined in module 3.
 - ii. determine whether a cluster, systematic or census sampling design is appropriate.
2. Using Table A.5.1 or A.5.2 of the 2011 WHO monitoring and evaluation manual (pp. 73–74), you will:
 - i. determine the sample size required for the EU(s) defined in module 3.
 - ii. determine the critical cut-off for the survey(s).

MODULE 5

Diagnostic tests

Learning objectives:

By the end of this module, learners should understand how to:

- procure diagnostic tests
- collect blood
- prepare, conduct and interpret ICTs
- prepare, conduct and interpret Brugia Rapid™ tests

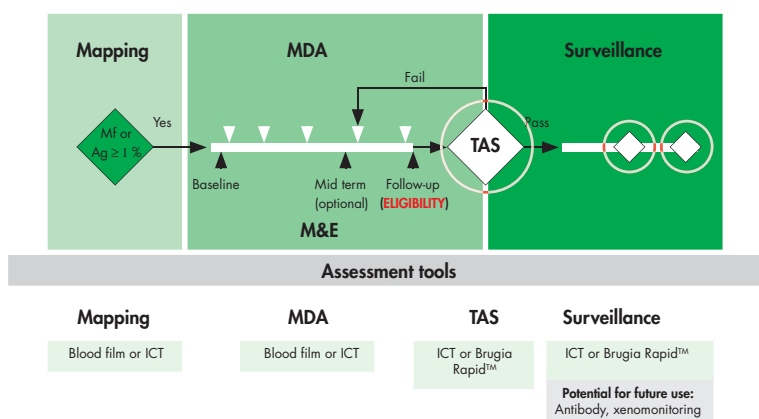
Relevant sections of the 2011 WHO monitoring and evaluation manual³

- Section 3. Diagnostic tools

Diagnostic tests for TAS (slides 4–6)

The diagnostic test selected depends on the phase of the national LF elimination programme and on the type of parasites endemic in the area (Figures 20 and 21). The ICT is recommended by the GPELF for areas in which *W. bancrofti* is endemic, the Brugia Rapid™ test for areas endemic for *Brugia* spp. and both tests for areas in which *W. bancrofti* and *Brugia* spp. are endemic, with testing evaluated separately against critical cut-off thresholds.⁵

Figure 20. Programme steps for interrupting transmission and recommended diagnostic tests



Mf, microfilariae; Ag, antigenaemia; MDA, mass drug administration; TAS, transmission assessment survey; M&E, monitoring and evaluation; ICT, immunochromatographic tests.

The ICT detects antigens from live or dead adult worms circulating in the peripheral blood that are still disintegrating, regardless of the presence of microfilariae. Positive results therefore indicate recent infection. ICTs are currently available only for *W. bancrofti*.

The Brugia Rapid™ test detects antifilarial antibodies to *B. malayi* and *B. timori*. While antibodies might persist for years after infection, detection in children is considered to indicate recent infection.

Procurement of diagnostic tests (slide 7)

- **ICT:** BinaxNow® Filariasis is manufactured by Alere, Inc. (Scarborough, Maine, USA). A “no objection certificate” is required for importation of the test devices. Positive controls can be obtained from the Filariasis Research Reagent Repository Center (www.filariasiscenter.org).
- **Brugia Rapid™ test:** manufactured by Reszon Diagnostics International (Selangor, Malaysia)

⁵ A new diagnostic test to detect antigen to *W. bancrofti* is being developed and is expected to be available in the near future (see Annex 11).

Figure 21. Diagnostic tools for lymphatic filariasis

| Field assay | Detection target |
|---------------|-----------------------|
| Blood film | Microfilariae |
| ICT | Filarial antigen |
| Brugia Rapid™ | Antifilarial antibody |



ICT, immunochromatographic tests.

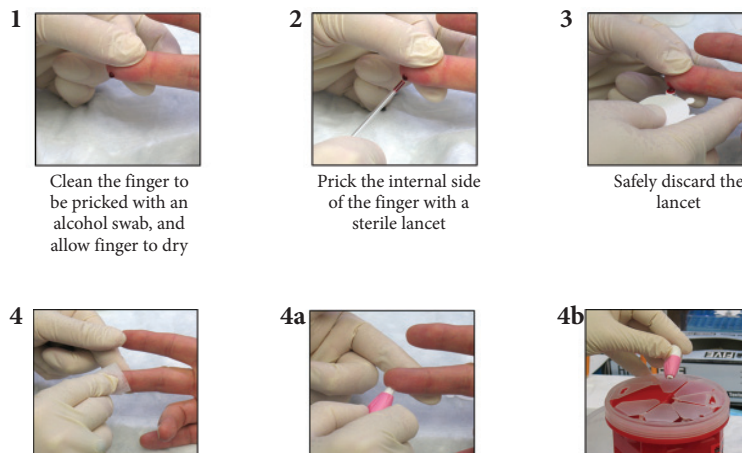
Quality control (slide 8)

Training should be conducted before a transmission assessment survey to ensure that all protocols are followed properly:

- The pouch should be opened just before use.
- Diagnostic tests should be tested with a positive control to ensure their validity.
- Diagnostic tests should be stored properly to minimize the risk for compromising their quality.
- Any indeterminate result should immediately be read by a second reader or supervisor, and the test should be repeated if necessary.

Blood collection technique (slide 9)

Figure 22. Recommended technique for collecting blood



Collect the blood (4a) into a calibrated capillary tube coated with an anticoagulant or (b) onto filter paper according to the survey method. If collecting into tubes, collect slightly more than the required volume of blood in case of clotting or spillage.

ICT (slide 10)

- Sensitive for detecting *W. bancrofti* antigen.
- Do not require laboratory equipment and can be processed quickly.
- Positive result indicates the presence of adult worm antigen.
- Adequate training is necessary to reduce interobserver variation and to reduce misreading of cards, which can lead to false-positive results.


Preparation (slide 11)

- **Storage:** Cards have a limited shelf-life at ambient temperature (3 months at 30 °C) but a longer shelf-life when stored at 4 °C (about 9 months). Cards should not be frozen.
- **Testing with a positive control:** Before a field survey is begun, two cards from each lot should be tested with a weak positive control, which can be obtained from the Filariasis Research Reagent Repository Center (www.filariasiscenter.org). With this control, the test line may be very faint. Do not use cards that give a negative result when tested with the control.
- **Transport:** A cool box is not required for transporting cards for use in the field; however, care should be taken not to expose cards to extreme heat for long periods.
- **Light:** Cards must be read under adequate lighting, as faint lines can be difficult to see. This is especially important when reading cards at night.

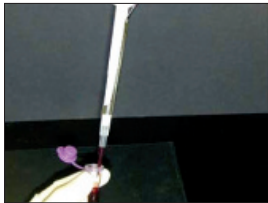
Procedure (slides 12–14)


Figure 23 Recommended procedure for immunochromatographic tests (ICTs)

- 1**

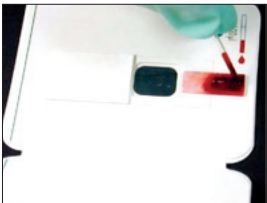


Remove card from pouch just before use.



- 2**




Collect 100 µl of blood by finger prick into a calibrated capillary tube **OR** remove 100 µl of blood from a microcentrifuge tube with a micropipette. **DO NOT** add blood directly from the finger to the card.
- 3**



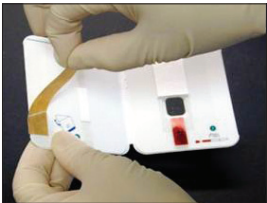
Add blood sample slowly to the white portion of the sample pad.




DO NOT add blood directly to the pink portion of the sample pad.




DO NOT close the card before the sample migrates to the pink portion of the sample pad (takes about 30 seconds after addition of blood).
- 4**



Remove adhesive liner and close card. Start timing.




It is helpful to record the starting time on the front of the card.




DO NOT read cards if the plasma has not flowed ALL the way down the strip.

If plasma fails to migrate completely past the bottom of the window, a false-positive result may be read.
- 5**



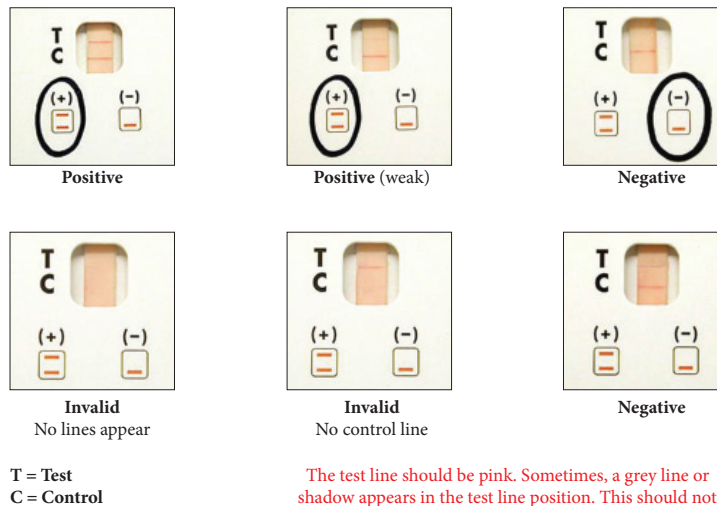
Circle the appropriate result on the front of the card to create a permanent record.



DO NOT read cards at any time other than 10 minutes, as the reading may be false-positive.

Interpretation (slide 15)

Figure 24. Interpretations of test results obtained with immunochromatographic tests (ICTs)



Brugia Rapid™ test (slide 16)


- Sensitive for detecting antibodies to *B. malayi* and *B. timori*.
- Does not require laboratory equipment and can be processed quickly.
- Positive result indicates the presence of antifilarial antibodies.


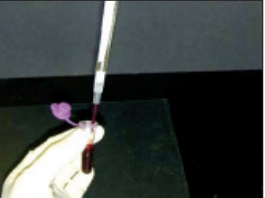
Preparation (slide 17)



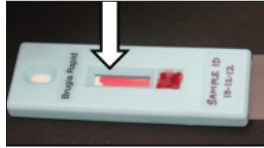
- **Storage:** The test has a shelf-life of 18 months when stored at ambient temperatures (20–25 °C); 4 °C (refrigeration) is recommended for long-term storage. The tests should **NOT** be frozen.
- **Transport:** A cool box is not required, although it is desirable, when transporting tests for use in the field. Care should be taken not to expose the tests to extreme heat for long periods.
- **Lighting:** Tests must be read under adequate lighting, as faint lines can be difficult to see. This is especially important when reading tests at night.
- The test requires 30 µl of serum or plasma or 35 µl of whole blood.

Procedure (slides 18–21)

Figure 25. Recommended procedure for Brugia Rapid™ tests

- 

Bring test cassette and chase buffer to room temperature. Remove cassette from foil pouch just before use. Label the cassette with information on the sample.
- 


Collect 35 μ l of blood by finger prick into a calibrated capillary tube OR remove 35 μ l of blood from a microcentrifuge tube with a micropipette. **DO NOT** add blood directly from the finger to the cassette.
- 





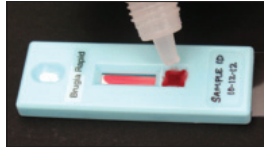
Add blood sample slowly to the square well by touching the capillary tube or pipette tip to the sloping side.

If using serum or plasma, only 30 μ l are needed.

Add one drop of chase buffer to the same square well.

If using serum or plasma, no chase buffer is required.


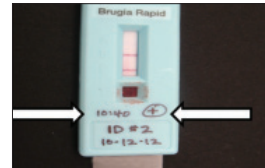
The sample will start to flow up the strip. The cassette can be tapped gently on the table to facilitate the flow. Wait until the sample has reached the blue line (A).

If the sample does not reach the blue line (A) after 4 minutes but has reached area B, proceed to the next step.
- 



When the sample has reached the blue line (A), add three drops of chase buffer to the circle well at the top of the cassette.

Add the buffer drop by drop, and allow each drop to saturate the pad before delivering the next drop.

Firmly pull the clear tab at the bottom of the cassette until you feel resistance.

After pulling the clear tab, add one drop of buffer to the square well.
- 


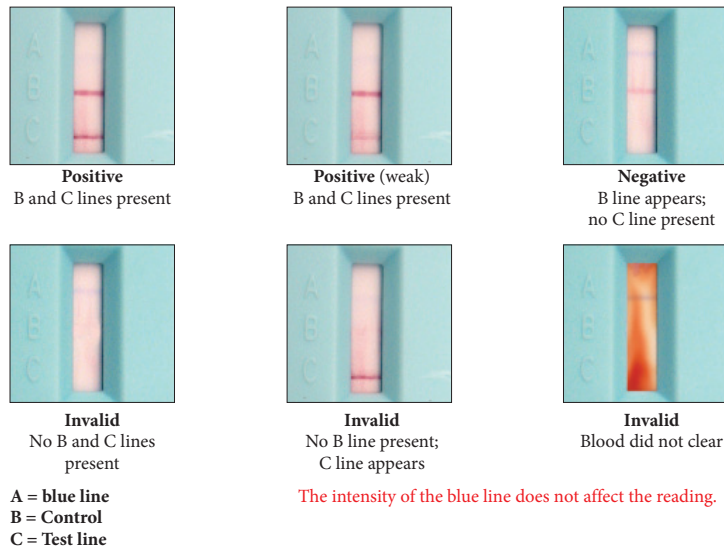
Start timing. Read test results 25 minutes after adding the final drop of buffer.

Test results for serum and plasma samples should be read after 15 minutes.

Record the start or end time on the front of the cassette. Write the appropriate result on the front of the cassette to create a permanent record.

Interpretation (slide 22)

Figure 26. Interpretations of test results obtained with the Brugia Rapid™ tests



Exercise (slide 23)

During the practical session you will:

1. Practise finger-prick blood collection.
2. Observe the use of positive controls to ensure the validity of the diagnostic test(s).
3. Practise using the diagnostic test(s) approved for transmission assessment surveys in your country.

The procedures for making blood films and interpreting them and for confirmatory testing are described in *annexes 6 and 7*.

MODULE 6

After the survey

Learning objectives:

By the end of this module, learners should understand how to:

- interpret the results of a TAS
- report to decision-makers and the GPELF
- follow up positive cases
- conduct post-MDA surveillance after MDA

Relevant sections of the 2011 WHO monitoring and evaluation manual³

- Section 8. Implementing activities and surveillance after mass drug administration has stopped

Actions required after a TAS

After the survey, programme managers should:

1. Interpret the results
2. Report to decision-makers and the GPELF
3. Follow up positive cases
4. Conduct post-MDA surveillance once MDA has stopped

Interpreting the results (slides 4 and 5)

If the number of positive results is at or below the established critical cut-off, the evaluation unit can stop mass drug administration.

- If there is still a potential focus of infection in the evaluation unit, a plan should be made to address this issue. Programme managers may decide to conduct focal treatment even though mass distribution has stopped.
- Other neglected tropical diseases, such as soil-transmitted helminthiasis or onchocerciasis, in the EU may still require control after MDA for LF has stopped. An appropriate programme should be planned to continue distribution of the necessary drugs.

If the number of positive results is greater than the established critical cut-off, the EU should continue MDA.

- At least two more rounds of MDA should be conducted before repeating the TAS.
- After two more rounds of effective MDA, the eligibility of the EU for conducting a TAS should be assessed again.

Example (slide 6)

What is the recommendation for an EU with the following characteristics and outcome of the TAS?

- Net school enrolment ratio: 78%
- Primary vector: *Culex*
- Total population of 6–7-year-old children: 18 945
- Total number of primary schools: 386
- Design of survey:
 - o Sample size: 1552
 - o Number of clusters: 38
 - o Critical cut-off: 18
- Results of TAS: 14 children positive by ICT; all positive cases in two schools

Box. Identifying reasons for 'failing' a TAS (slide 7-9)

When an EU 'fails' a TAS, it is beneficial to identify the reasons, which could include one or more of the following:

- Irregular MDA
- Inadequate epidemiological drug coverage due to distribution failures or failure to adhere to directly observed therapy
- Poor quality of generic drugs
- Population migration or previously undetected foci of infection
- Systematic non-compliance

Systematic non-compliance (slides 8 and 9) is the failure of a certain individuals to take the distributed drugs regularly during any round of MDA. These individuals may continue to constitute a reservoir of microfilariae. Even if the recommended drug coverage is achieved, systematic non-compliance may contribute to perpetuation of transmission of LF.

Systematic non-compliance can be addressed by:

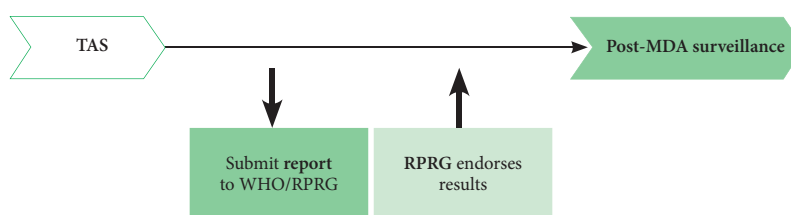
- targeted MDA designed to capture non-compliant individuals systematically,
- social mobilization strategies targeting non-compliant individuals and
- revised health education messages.

Reporting to decision-makers and the GPELF (slide 10)

Decision-makers in the country (i.e. government) should be informed of the result of a TAS in order to make an appropriate decision to stop or continue MDA. As a significant decision will be made on the basis of the outcome of the survey, national programme managers should also inform WHO and RPRG of the results and obtain advice if necessary (*Figure 27*).

The transmission assessment survey reporting form is available in *Annex 3*.

Figure 27. Proposed process of submission and review of the reporting form on the results of a transmission assessment survey (TAS) between the national programme and the Global Programme



Follow-up of positive cases (slides 11 and 12)

Positive cases should be treated with:

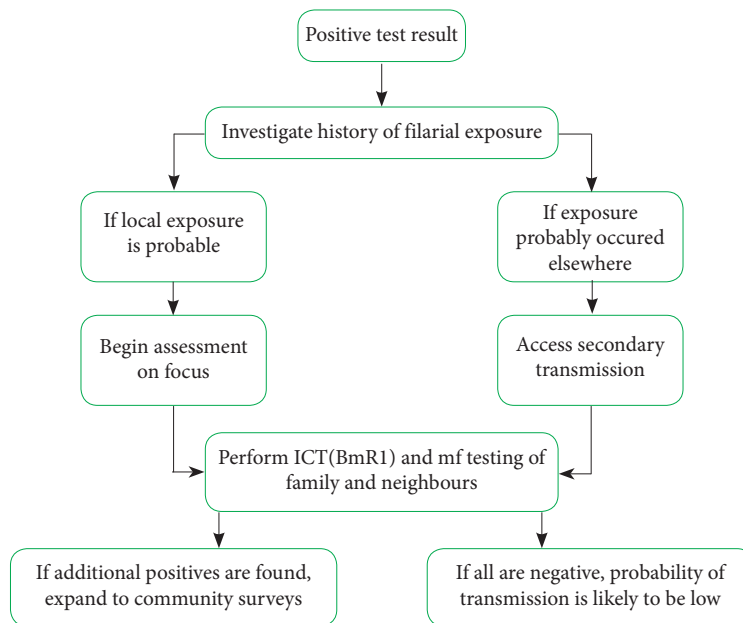
- a single dose of a combination of albendazole (400 mg) and ivermectin (150–200 µg/kg) in areas in which onchocerciasis is co-endemic; or
- a single dose of a combination of albendazole (400 mg) plus diethylcarbamazine (6 mg/kg) or diethylcarbamazine (6 mg/kg) alone for 12 days in areas where there is no onchocerciasis.

Programme managers may choose to test for Mf during the peak circulation time to follow-up positive cases.

- Residence can be ascertained to detect any significant migration in the area that could affect the impact of MDA rounds.
- This should be done before positive cases are treated.

If resources allow, programme managers should conduct follow-up surveys in communities with antigen- or antibody-positive children to obtain additional information on potential residual transmission.

Figure 28. Algorithm for following up positive test results in a transmission assessment survey



Source: *Monitoring and epidemiological assessment of mass drug administration—A manual for national elimination programmes*. Geneva, World Health Organization, 2011.

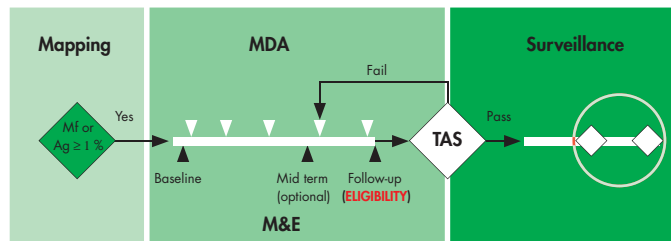
Post-MDA surveillance (slide 13)

The success of a LF elimination programme depends on careful monitoring after MDA has stopped.

The current WHO recommendations are:

- Two TAS at an interval of 2–3 years, and
- Continuous surveillance throughout the country (e.g. surveys of military recruits, blood donors, hospitalized patients), except in areas with no risk of transmission.

Figure 29. Steps in the Global Programme, with emphasis on surveillance after mass drug administration (MDA) has stopped



Mf, microfilariae; Ag, antigenaemia; M&E, mass drug administration; TAS, transmission assessment survey

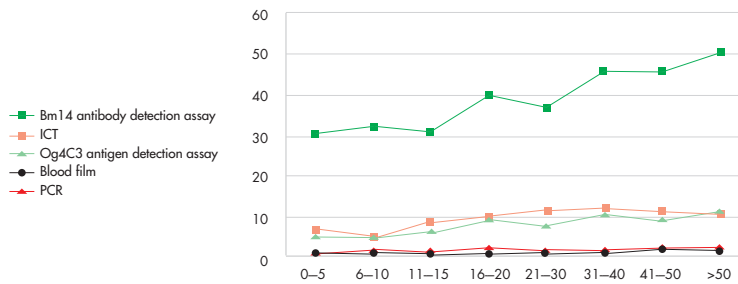
Potential future surveillance strategies (slide 14)

- Future approaches to post-MDA surveillance will be based on diagnostic tools that are not yet fully developed, standardized or validated. These include testing for antifilarial antibody and xenomonitoring.

Antifilarial antibody testing (slides 15 and 16)

- Monitoring of antibody responses might be useful for detecting any recrudescence of infection. Antibody testing can be performed on dried filter paper blood spots collected during a TAS and can be used to establish a baseline for surveillance.
- *Figure 30* shows the relative sensitivity of tests used to detect microfilariae (blood film and polymerase chain reaction [PCR]), circulating antigen (ICT and Og4C3) and antifilarial antibody (Bm14). For people of all ages, detection of antibody is significantly more sensitive than detection of either antigen or microfilariae. It could therefore be useful for post-MDA surveillance, as the presence of antifilarial antibodies is the earliest indicator of exposure.

Figure 30. Prevalence of lymphatic filariasis detected with different diagnostic tests, by age group



ICT, immunochromatographic test; PCR, polymerase chain reaction

Source: Gass K et al. A multicenter evaluation of diagnostic tools to define endpoints for programs to eliminate Bancroftian filariasis. *PLoS Neglected Tropical Diseases* 2012; 6(1):e1479.

Xenomonitoring (slide 17)

- Direct assessment of parasites in vector mosquitoes by PCR techniques may be useful for measuring parasite prevalence in humans in the same community. While xenomonitoring may be useful, however, more research is needed to develop feasible methods for sampling and testing mosquitoes.

MODULE 7

Verification of elimination

Learning objectives:

By the end of this module, learners should understand how to:

- compiling and analysing all data on LF in the country
- preparing a national dossier
- submitting the dossier to the RPRG

Relevant sections of the 2011 WHO monitoring and evaluation manual³

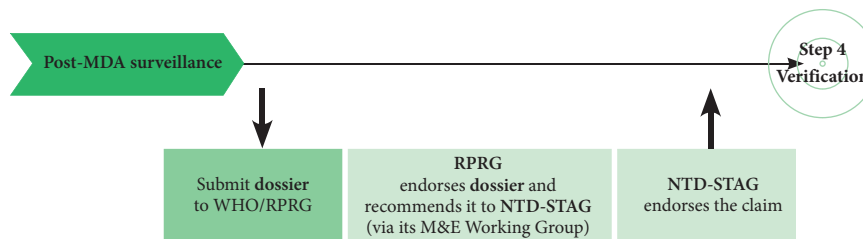
- Section 9: Verifying the absence of transmission

Process for verifying elimination (slides 4 and 5)

Verification of elimination requires the following actions by national programme managers, RPRG, WHO and the Strategic and Technical Advisory Group on Neglected Tropical Diseases (STAG-NTD):

1. The national programme for the elimination of LF compiles all data related to LF from each IU before, during and after the national programme was initiated.
2. The national programme analyses the data and prepares a national dossier.
 - Can request assistance from WHO, the RPRG or WHO collaborating centres
3. The national programme submits the dossier to the RPRG through WHO.
4. The RPRG reviews the proposal and makes a recommendation to the STAG-NTD M&E WG through WHO headquarters.
 - Can request that an expert team review the dossier and visit the country if necessary
5. The M&E WG reviews the recommendations of the RPRG and makes their recommendation to STAG-NTD.

Figure 31. Proposed process for dossier submission for verification of elimination of lymphatic filariasis



M&E, monitoring and evaluation; RPRG, Regional Programme Review Group; WHO, World Health Organization; STAG-NTD, the Strategic and Technical Advisory Group on Neglected Tropical Diseases

Dossier overview (slide 6)

A national dossier is a systematic presentation of evidence of the absence of transmission of LF **for the entire country**, containing:

- a general description
- the history of LF in the country
- interventions
- assessment of interventions
- surveillance
- additional data
- bibliography

Spatial presentation of data is encouraged, including maps of endemic and non-endemic areas and maps showing IUs and EUs.

General description (slides 7 and 8)

- Overall geographical and economic features of the country
- Health system
 - capacity to detect cases of infection
 - capacity to provide treatment for clinical cases
- Vectors
 - geographical distribution
 - feeding behaviour
 - density and competence
- Immigration patterns to and from areas endemic for LF, including other countries
- Occurrence of LF in neighbouring countries and the status of LF control or elimination in those countries

History of LF (slides 9 and 10)

- Detailed description
 - maps of past and present foci of transmission
 - review of data on prevalence and intensity of infection in humans
 - review of data on prevalence of infection in vector mosquitoes
- Clinical filarial disease
 - geographical distribution and prevalence
 - access to treatment for lymphoedema and hydrocoele
- Non-endemic areas
 - how non-endemic areas were defined
 - what surveillance there was in those areas to ensure that they remained non-endemic

Interventions (slide 11)

Details of all measures to control or interrupt transmission:

- screening, testing and treating positive cases
- MDA
- environmental and economic improvement
- vector control

Assessment of interventions (slide 12)

- Detailed description of surveys and studies conducted to evaluate the impact of interventions
 - mapping surveys
 - sentinel and spot-check sites
 - surveys for stopping MDA: “C surveys”, child transmission surveys, TAS
- Descriptions should include:
 - dates
 - sampling methods and procedures
 - diagnostic tests used
 - follow-up of positive test results

Surveillance (slides 13 and 14)

- A full review of any surveillance activities undertaken since stopping MDA and other interventions
 - post-MDA surveys, such as a TAS
 - other active surveillance activities
 - case reports of filariasis obtained through routine disease surveillance and other systems
 - complete follow-up for each positive case detected
- Evidence that adequate sampling or surveillance was conducted in all previously endemic areas and in areas that were defined as non-endemic
- Details of surveys done in cross-border areas and among immigrants from filariasis-endemic areas
- Demonstration that any positive cases detected after MDA represented isolated events not traceable to an area of active transmission

Additional data (slide 15)

Any other data to support absence of transmission, including other sources of information. This need not be in a separate section.

Bibliography (slide 16)

Articles and reports on lymphatic filariasis, its geographical distribution and interventions:

- ministry of health records
- published studies
- academic theses and dissertations

Timing (slide 17)

The dossier should be submitted only after all EUs have completed post-MDA surveillance. However, data collection and archiving should start early. Do not wait until interventions in all EUs are complete to start collecting and archiving data.

A close-up photograph of a man in a grey button-down shirt and white gloves examining a child's hand. The man is looking intently at the child's hand. In the background, a woman in a blue patterned headscarf and a child in a blue shirt are visible. The scene appears to be indoors, possibly in a community center or a clinic.

■ *PRACTICAL ASPECTS
OF TRANSMISSION
ASSESSMENT SURVEYS*

MODULE 8

Survey sample builder

Learning objectives:

By the end of this module, learners should understand how to:

- how to use the survey sample builder to:
 - determine the design of the survey
 - select random clusters and children or households
- the protocol for TAS

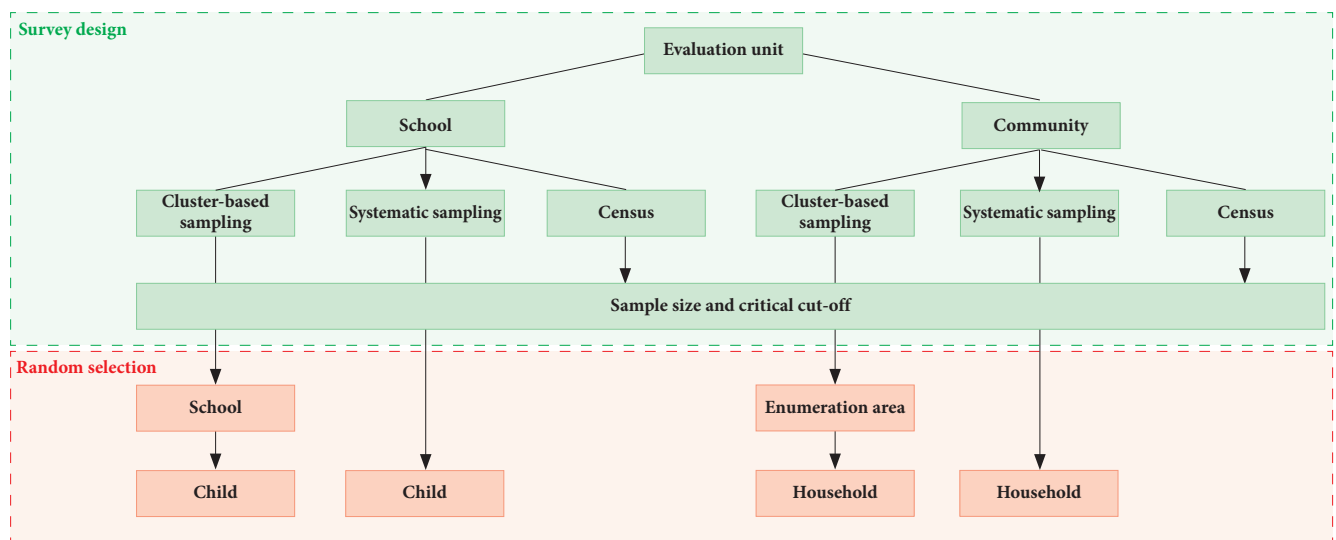
Relevant sections of the 2011 WHO monitoring and evaluation manual³

- Annex 5: Detailed protocol for a transmission assessment survey

Survey sample builder (slide 4)

The 'survey sample builder'⁶ is a Microsoft Excel-based tool that can be used to automate calculations for determining the appropriate survey design and to facilitate random selection of clusters and children or households from a list of randomized numbers (Figure 32). Use of the survey sample builder also reduces the risk for selection bias, as it ensures equal probability for selecting individuals eligible for sampling.

Figure 32. Steps in determining a survey design and random sample selection with the survey sample builder



Preparation before sample selection (slides 5 and 6)

School survey

Communicate with the ministry of education to obtain a comprehensive list of all primary schools in the defined evaluation unit.

- Ideally, the list of schools will be ordered according to geographical proximity rather than alphabetically. This will allow better geographical representation of the selected schools in the EU.

Obtain an average non-response rate for the schools in the EU, if available.

- The non-response rate gives an estimate of the non-participant rate and should include school absenteeism, refusals and inability to collect sufficient blood for diagnostic testing.
- If the non-response rate is unknown, it is recommended to estimate 10-15% non-response.

⁶ The latest version can be downloaded at <http://www.ntdsupport.org/resources/>

Community household survey

Census enumeration areas are recommended as clusters if cluster sampling is used; these are usually the smallest area for which census data are available.

Obtain a list of all the enumeration areas in the evaluation unit.

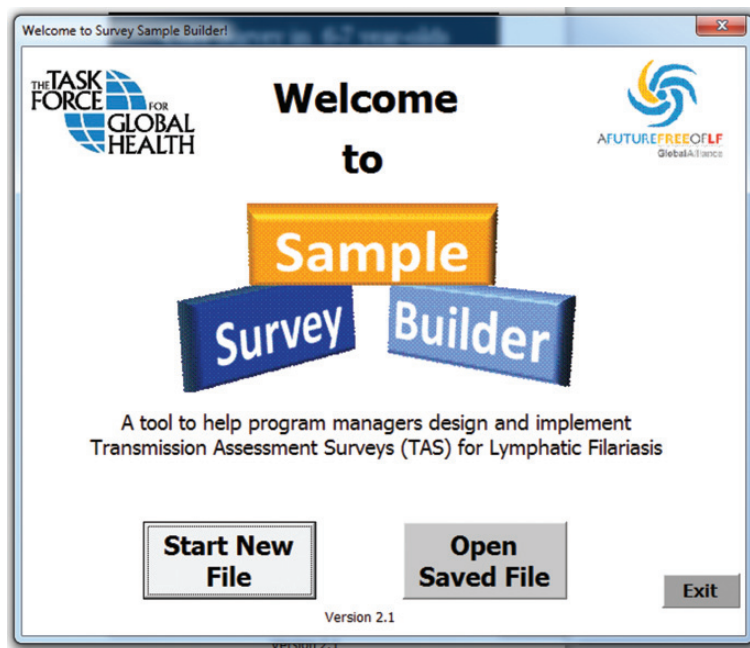
- Ideally, the enumeration areas will be listed according to geographical proximity rather than alphabetically. This will allow better geographical representation of the selected schools in the evaluation unit.

Obtain enumeration area census maps.

- These maps can often be obtained from the census department or the bureau of statistics. A fee may be charged to obtain these maps.

Determining the survey design (slides 7–10)

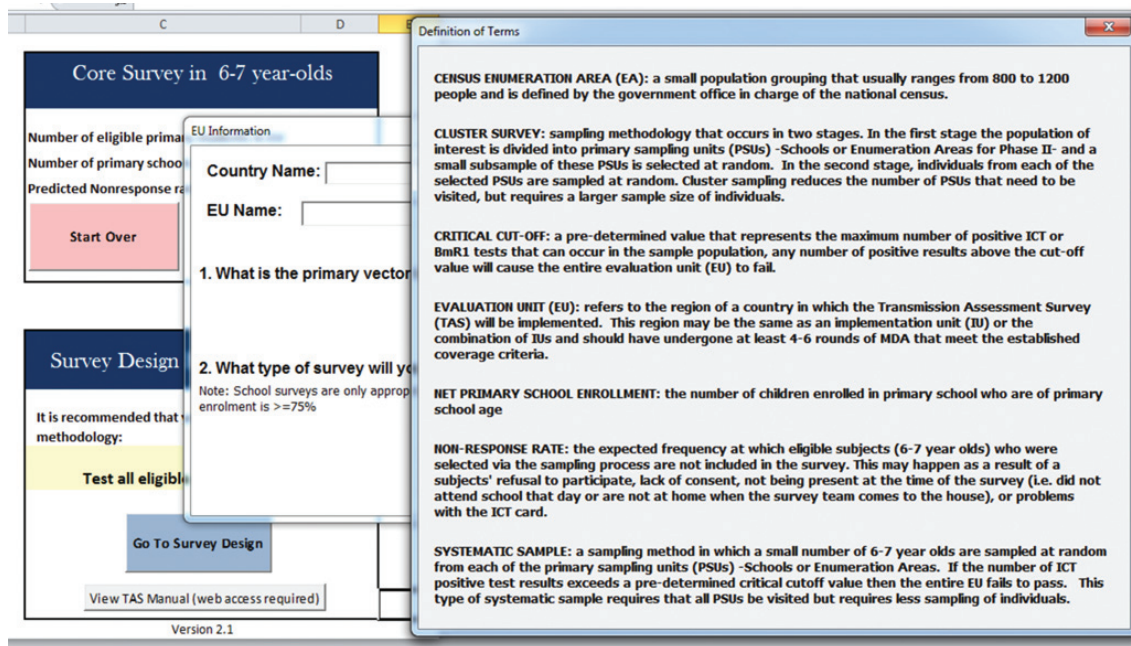
Figure 33. Screenshot of the front page of the survey sample builder



The user will be prompted to answer questions and enter information. A glossary of terms is available for terms that are unclear.

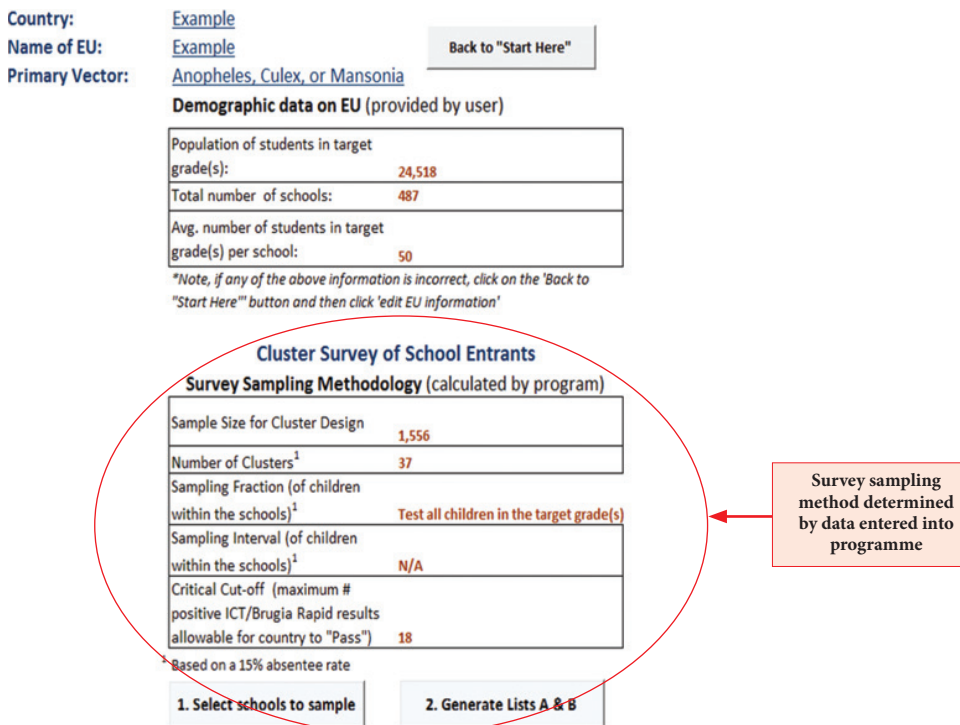
The user of the survey sample builder must know the total population of the target age group and the number of schools or enumeration areas in the EU. The choice of cluster or systematic sampling is related to cost. If the user is unsure of how to answer the question, the survey sample builder can help determine which option is more feasible for the survey.

Figure 34. Screenshot of the school survey data entry page



Once this information has been entered, the survey sample builder recommends a survey design, including the target sample size, the number of clusters needed, the sampling interval and the critical cut-off.

Figure 35. Screenshot of the survey design result page



Selecting randomized clusters and children or households (slide 11)

Depending on the survey design, clusters (schools or enumeration areas) and children or households should be selected randomly, except when census sampling is used. The survey sample builder facilitates selection by generating a list of randomized numbers.

In community sampling, once the households are selected, all the children in the target age group will be tested. In census sampling, all the children in the enumeration area will be tested (see module 5).

Selecting randomized clusters (slides 12–14)

Cluster sampling requires selection of a minimum of 30 schools or enumeration areas from which children are selected.

1. Obtain a comprehensive list of all primary sampling units (i.e. schools, enumeration areas) in the EU.
2. Number them, preferably in order of geographical proximity as opposed to alphabetical order in order to achieve better geographical distribution.
3. Once all sampling units have been assigned a number, click the “Randomize” button.
4. Once the survey design has been determined, a list of random numbers (10, 23, 36, 49 ... in the example in *Figure 36*) is generated by the survey sample builder. Select schools or enumeration areas in the list according to these random numbers (i.e. schools numbered 10, 23, 36, 49 ...).

Figure 36. Screenshot of the cluster selection page

Directions: Obtain a comprehensive list of all the primary sampling units (i.e. Schools or EAs) in the EU and number them, preferably in order of geographic proximity. Once all sampling units have been assigned a number, double check that the values listed below are correct and click the "Randomize" button. When you are finished you can click "Return to Previous Page" to go back.

| | |
|--------------------------------------|-----|
| Total number of EAs: | 487 |
| No. of EAs (clusters) to be sampled: | 37 |

The following schools or enumeration areas have been selected for your study:

| |
|------|
| 10 |
| 23 |
| 36 |
| 49 |
| 62 |
| 76 |
| 89 |
| 102 |
| |

Randomize

[Return to Previous Page](#)

A list of random numbers can be generated to facilitate the selection of clusters to be included.

It is recommended that 5–10 additional clusters be selected for use if the sample size falls considerably short of the target after all the clusters have been surveyed. The additional clusters should be selected from a list of all remaining clusters by the same random selection process. The survey sample builder allows selection of additional clusters.

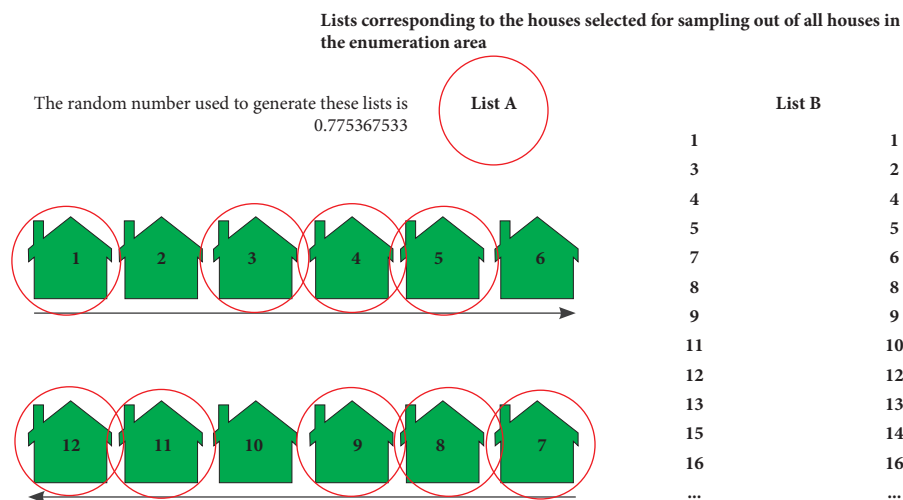
Selecting randomized children or households (slides 15 and 16)

After choosing randomized cluster or systematic sampling, the next step is random selection of children (in school-based surveys) or households (in community-based surveys), as, in many cases, not every child in a cluster will be tested.

The survey sample builder calculates the appropriate sampling interval to use and also calculates a random starting number and sampling interval (inverse of the sampling fraction) to generate two numbered lists to guide selection of schoolchildren or households. The lists are used to select the children to be tested in a school survey and the houses to be sampled in a household survey.

The survey team randomly selects one of the two lists. In the example in *Figure 37*, the team chose list A; therefore, the first, third, fourth, fifth ... house on the list will be selected.

Figure 37. Random household selection from two lists



Every 6–7-year-old child in the house should be tested. The same list should be used throughout the survey.

Sampling intervals are also listed in tables A.5.1 and A.5.2 in the 2011 monitoring and evaluation manual (pp. 73–74).

Example 1 (slides 17–20)

The following characteristics of the EU were entered into the survey sample builder to determine the appropriate design:

- Net school enrolment ratio: 78%
- Primary vector: *Culex*
- Population of students in target grades: 18 945
- Total number of primary schools: 386
- Estimated non-response rate: 15%

The survey design selected by the survey sample builder is shown in *Figure 38*

Figure 38. Screenshot of the survey design result page for example 1

Country: [Example 1](#)
 Name of EU: [Example 1](#) Back to "Start Here"
 Primary Vector: [Anopheles, Culex, or Mansonia](#)

Demographic data on EU (provided by user)

| | |
|--|---------------|
| Population of students in target grade(s): | 18,945 |
| Total number of schools: | 386 |
| Avg. number of students in target grade(s) per school: | 49 |

"Note, if any of the above information is incorrect, click on the 'Back to "Start Here"' button and then click 'edit EU information'

Cluster Survey of School Entrants

Survey Sampling Methodology (calculated by program)

| | |
|--|---|
| Sample Size for Cluster Design | 1,552 |
| Number of Clusters ¹ | 38 |
| Sampling Fraction (of children within the schools) ¹ | Test all children in the target grade(s) |
| Sampling Interval (of children within the schools) ¹ | N/A |
| Critical Cut-off (maximum # positive ICT/Brugia Rapid results allowable for country to "Pass") | 18 |

¹ Based on a 15% absentee rate

1. Select schools to sample

2. Generate Lists A & B

In this example, you will select 38 primary schools and test all children in the target grades in each selected school. If the total number of positive cases is 18 or fewer, the EU ‘passes’ the TAS. If the total number of positive cases is greater than 18, the EU ‘fails’ the TAS.

Now click “1. Select schools to sample” then the “Randomize” button in the following window for randomized cluster selection. You will obtain a list of random numbers.

If the list of primary schools is ordered in geographical proximity as below, you should visit schools 8, 18 ... (i.e. the schools highlighted in yellow on *Figure 39*) until you have tested all children in the target grades in all 38 schools.

Figure 39. Numbered list of schools ordered by geographical proximity

| | | <u>School name</u> |
|--|-----|-----------------------------|
| The following schools have been selected for your study: | | 1 Woodridge Elementary |
| | | 2 Lakeside Elementary |
| | | 3 Shadow Rock Elementary |
| | | 4 Austin Elementary |
| | | 5 Idlewood Elementary |
| | | 6 Henderson Mill Elementary |
| | | 7 Stone Mill Elementary |
| | 8 | 8 Rockland Elementary |
| | 18 | 9 Sage Elementary |
| | 29 | 10 Oak Grove Elementary |
| | 39 | 11 Brockett Elementary |
| | 49 | 12 Princeton Elementary |
| | 59 | 13 Chestnut Elementary |
| | 69 | 14 Rockbridge Elementary |
| | 79 | 15 Dresden Elementary |
| | 90 | 16 Midvale Elementary |
| | 100 | 17 Columbia Elementary |
| | 110 | 18 Pine Ridge Elementary |
| | ... | 19 Flatrock Elementary |
| | | 20 Snapfinger Elementary |
| | ... | |

Example 2 (slides 21–23)

The following characteristics of the EU were entered into the survey sample builder to determine the appropriate design:

- Net school enrolment ratio: 68%
- Primary vector: *Anopheles*
- Population of students in target grades: 23 128
- Total number of enumeration areas: 284
- Estimated non-response rate: 15%

The survey design selected by the survey sample builder is shown in *Figure 40*.

Figure 40. Screenshot of the survey design result page for example 2

Country: [Example 2](#)
Name of EU: [Example 2](#)
Primary Vector: [Anopheles, Culex, or Mansonia](#)

[Back to "Start Here"](#)

Demographic data on EU (provided by user)

| | |
|--------------------------------|--------|
| Population of 6-7 yrs: | 23,128 |
| Total number of EAs: | 284 |
| Avg. population 6-7yrs per EA: | 81 |

**Note, if any of the above information is incorrect, click on the 'Back to "Start Here"' button and then click 'edit EU information'*

Cluster Survey of Households

Survey Sampling Methodology (calculated by program)

| | |
|--|-------|
| Sample Size for Cluster Design | 1,552 |
| Number of Clusters ¹ | 30 |
| Sampling Fraction (of children within the EAs) ¹ | 0.75 |
| Sampling Interval (of children within the EAs) ¹ | 1.34 |
| Critical Cut-off (maximum # positive ICT/Brugia Rapid results allowable for country to "Pass") | 18 |

¹ Based on a 15% absentee rate

[1. Select EAs to sample](#)

 [2. Generate Lists A & B](#)

Lists of households to be selected from the clusters
(sample all children 6-7 years-old in household)

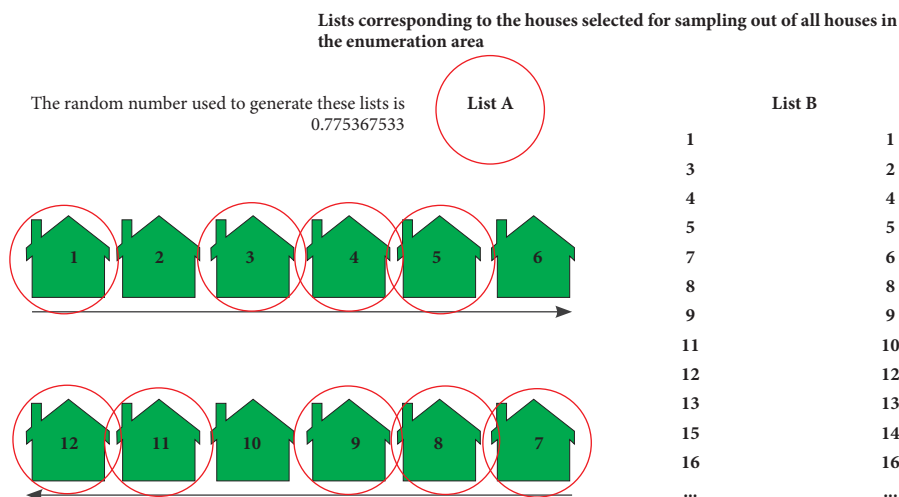
The random number used to generate these lists was:

List A
List B

In this example, you will select 30 enumeration areas as the cluster in the same way you have selected schools in *Example 1*.

If 30 enumeration areas are randomly selected with the survey sample builder, the next step is to randomly select households in each selected enumeration area. Clicking the button “2. Generate Lists A & B” will generate two lists of random numbers (*Figure 41*). The survey team will randomly select list A or B (e.g. by flipping a coin). In this example, the team chose list A; therefore, the first, third, fourth, fifth... households along the chosen route will be tested in each selected enumeration area. You will test all children in the target grades in each selected household. If the total number of positive cases is 18 or less, the EU ‘passes’ the TAS. If the total number of positive cases is above 18, the EU ‘fails’ the TAS.

Figure 41. Two lists generated by the survey sample builder for example 2 and households selected from list B (circled in red)



Example 3 (slides 24 and 25)

The following characteristics of the evaluation unit were entered into the survey sample builder to determine the appropriate design:

- Net school enrolment ratio: 95%
- Primary vector: *Aedes*
- Population of students in target grades: 2814
- Total number of primary schools: 24
- Estimated non-response rate: 15%

The survey design selected by the survey sample builder is shown in *Figure 42*.

In this example, you will select systematic sampling because the number of schools in the EU is fewer than 40. The team will visit every school, but not every child will be tested. If the total number of positive cases is 7 or fewer, the EU 'passes' the TAS. If the total number of positive cases is greater than 7, the EU 'fails' the TAS.

The children in each school who are to be tested should be randomly selected using list A or B.

Figure 42 Screenshots of the survey design result page for example 3

Country: [Example 3](#)

Name of EU: [Example 3](#)

Primary Vector: [Aedes](#)

[Back to "Start Here"](#)

Demographic data on EU (provided by user)

| | |
|--|-------|
| Population of students in target grade(s): | 2,814 |
| Total number of Schools: | 24 |
| Avg. number of students in target grade(s) per school: | 117 |

if the above information is incorrect, click on the 'Back to "Start Here"' button 'edit EU information'

Will visit every school in the evaluation unit

Systematic Sample of School Entrants

Survey Sampling Methodology (calculated by program)

| | |
|--|------|
| Sample Size for Systematic Sample | 1172 |
| Sampling fraction (children within each school) ¹ | 0.49 |
| Sampling interval (children within each school) ¹ | 2.04 |
| Critical Cut-off (maximum # positive ICT/Brugia Rapid results allowable for country to "Pass") | 7 |

¹Based on a 15% absentee rate

Protocol for TAS (slide 26)

The protocol for the TAS is as follows:

- Define EU.
- Determine survey site and sampling strategy.
- Calculate sample size.
- Prepare lists of
 - schools for a school-based survey
 - enumeration areas for a community-based survey
- Test selected children with
 - ICTs in areas endemic for *W. bancrofti*
 - Brugia Rapid™ tests in areas endemic for *Brugia* spp.
- Interpret the results on the basis of the critical cut-off.

Exercise (Slide 27)

Using population data on the EU(s) in module 3, you will use the survey sample builder to:

- define the appropriate survey design
- define the sample size needed
- define the number of sites for the survey
- define the sampling fraction
- define the sampling interval
- select the sites to include (if necessary)
- generate two lists (if necessary)

MODULE 9

Timetable, budget and administration

Learning objectives:

By the end of this module, learners should understand how to:

- preparing a timetable
- preparing a budget
- procuring supplies
- obtaining ethical clearance
- obtaining informed consent
- preparing public notification
- preparing data collection and management

Relevant sections of the 2011 WHO monitoring and evaluation manual³

None

Administrative planning and preparation (slide 3)

Once the eligibility of an EU for a TAS is confirmed, national programme managers should initiate administrative planning and preparation for the survey, including all the learning objectives of this module.

Preparing a timetable (slides 4 and 5)

The time required for planning and conducting a TAS depends largely on how long it takes to complete individual components, such as determining eligibility for the survey, obtaining ethical clearance and communicating with the ministry of education. Ample time should be allotted for collecting necessary approvals and information.

On average, the time required to conduct a TAS is 2–4 weeks for school-based surveys and 3–6 weeks for community-based surveys.

The table in *Annex 7* can be used to construct a timetable for conducting a TAS. The checklist of activities to consider in planning in *Annex 8* can also be used.

Preparing a budget (slides 6–8)

A detailed budget must be prepared before a TAS to ensure that it will be conducted as planned. Poor budget planning may result in an incomplete survey, with implications for the resources available for future activities.

The main cost categories to be taken into account are:

- Personnel
- Travel and transport
- Supplies
 - Diagnostic tests
 - Consumables
 - Shipping and customs fees
- Stationery and other office supplies
- Communication
 - Telephone
 - Internet
 - Photocopies
- Other
 - Ethical approval
 - Maps
 - Allowances for village leaders and teachers

The budget template shown in *Annex 9* can be used to estimate the required budget.

Procuring supplies (slide 9)

Ample time must be planned for procuring diagnostic tests.

- Their availability should be confirmed with the vendor before finalizing the dates for the survey.
- As diagnostic tests have a limited shelf-life, careful planning and coordination are necessary before ordering.
- The time required for tests to clear customs should be taken into account.
- Before the surveys begin, ICT cards should be tested with a weak positive control, which can be obtained from the Filariasis Research Reagent Repository Center (www.filariasiscenter.org).

Once ICT cards or Brugia Rapid™ tests are received, ideally, a cool, dry place should be used for storage. Extreme temperatures should be avoided.

Supply list (slide 10)

The box on the left in *Figure 43* lists the general core supplies needed for a survey. The time required to procure these consumables should be taken into consideration in planning. Shipping of diagnostic tests from the manufacturer often takes 6–8 weeks.

Figure 43. Supplies needed for a transmission assessment survey

Blood collection

- ICTs or Brugia Rapid™ tests
- Positive control for ICT cards
- Calibrated capillary tubes
- Gloves
- Lancets
- Cotton
- Alcohol swabs
- Sharps container
- Absorbent underpads
- Markers or pens
- Garbage bags
- Watch or timer
- Registration books or paper forms
- Clipboards
- Bags or backpacks to carry supplies and paperwork to the field
- Paper clips, rubber bands or envelopes to secure written consent forms

ADDITIONAL SUPPLIES NEEDED FOR Diagnostic tests performed at a central location:

- Blood collection tubes
- Cooler (for transporting blood samples)
- Plastic bags
- Tissue or toilet paper
- Micropipettes (P200) and pipette tips
- Rack to hold blood collection tubes
- Positive control

Performing microfilariae testing:

- Slides
- Slide folders and boxes
- Giemsa stain
- Methanol

Collecting filter paper blood spots:

- Filter paper disks
- Plastic bags
- Pencils
- Styrofoam

Treatment for positive cases:

- Diethylcarbamazine (DEC) or ivermectin plus albendazole
- Procurement of medicines should be prepared in advance of a TAS to ensure a supply of medicines to treat positive cases.*

Ethical clearance (slide 11)

Requirements for ethical clearance vary from country to country. Preparations for obtaining the necessary clearance should be made well before the start of a survey. In most countries, a TAS is considered to be an evaluation of a public health programme and is not classified as research; consequently, it does not require a full review by an ethics committee.

Informed consent (slide 12)

Requirements vary by country. Preparations for obtaining the necessary consent should be made well before the start of the survey.

The test procedures used in a transmission assessment survey are considered to carry minimal risk. If written consent or assent is required for school surveys, forms should be sent in advance to allow ample time for the return of signed forms. If only a fraction of children are to be sampled in a school survey, the children should be selected and consent for the testing obtained in advance.

Public notification (slide 13)

Once the schools or enumeration areas have been selected for the TAS, the appropriate officials should be notified about visits well before the start of the survey.

Preparation of data collection and management (slides 14 and 15)

Appropriate data management should be determined in advance of the survey. A WHO Eligibility and Reporting Form is available to standardize collection of the data needed to plan and implement a TAS. An electronic data system for reporting from the field to the national level is also available.

The necessary precautions should be taken to manage data properly to ensure that all ethical requirements are maintained. Patient identities and test results should be made available only to authorized personnel.

An example of a data collection form for a school survey is provided in *Annex 10*.

Exercise (slide 16)

In this exercise, you will estimate a timetable and budget for a TAS in the EU(s) defined in module 3, taking into consideration the survey design generated with the survey sample builder.

MODULE 10

Field work

Learning objectives:

By the end of this module, learners should understand how to:

- field team organization
- specimen collection and testing in school-based surveys
- specimen collection and testing in community-based surveys

Relevant sections of the *2011 WHO monitoring and evaluation manual*³

- Annex 5. Detailed protocol for transmission assessment surveys

Field team organization (slides 4 and 5)

Each field survey team should consist of at least three members (*Figure 44*):

- one responsible for registering children and managing supplies
- one phlebotomist and test preparer
- one test reader

Programme managers should organize field teams and designate roles before the actual field-work. Holding a training session on the survey design, blood sampling and diagnostic test procedures is highly recommended.

Figure 44. Field team organization for a transmission assessment survey



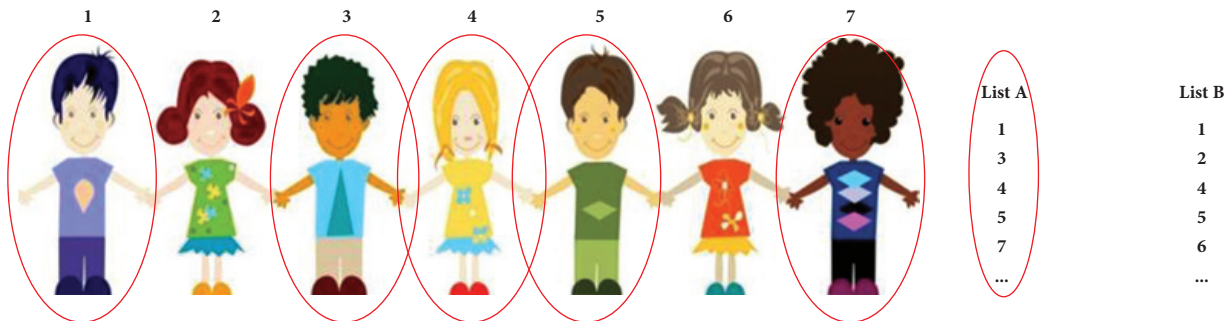
School-based surveys (slides 6–10)

This section outlines a suggested approach for specimen collection and testing in schools. Situations are different in each country, and the appropriate procedure should be determined.

1. Ensure that proper consent has been obtained. If written consent is required, forms should be sent out well in advance of the field activities to ensure maximum participation. In order to ensure a high rate of return of signed consent forms, clear, concise messages about the survey and the consent forms should be disseminated well beforehand.
2. The field team will arrive at a designated school and work with teachers, the headmaster or headmistress or school officials to gather all targeted (usually first- and second-year) children.
3. If not all children in the targeted grades are to be sampled, flip a coin to decide whether list A or list B will be used. This is necessary only if the sampling interval $\neq 1$ (i.e. not every child will be tested). Children should be lined up in sequence to be counted (*Figure 45*).

- Select children according to the numbers on the list, and continue until the next number on the list is higher than the total number of pupils in the targeted grades at the school. If the sampling interval = 1, every child in attendance should be tested.

Figure 45. Disposition of children for testing in a school-based survey



- The team should collect demographic data and blood specimens from the selected children. In most instances, diagnostic tests will be conducted and read in the field from capillary tubes. Alternatively, blood can be collected into blood collection tubes, and tests can be conducted at a central location after all the children have been sampled. If readings are done in the evening or at night, an adequate light source is essential to obtain an accurate result.
- Arrangements should be made to treat all children found to be positive by the ICT or Brugia Rapid™ tests.
- Teams should keep a record of the total numbers of children in the targeted grades who are in attendance and who are absent from each school on the day of the survey. These numbers should be compared with the numbers enrolled and the predetermined non-response rate to determine whether additional clusters will be needed as the survey progresses. If the non-response rate is lower than expected, sufficient supplies should be planned to complete the survey.
- Repeat the steps for each chosen school and additional schools (if necessary) to satisfy the target sample size.
- Even if the number of positive cases exceeds the critical cut-off point, the survey team should continue to collect information on every child in the sample to provide baseline data for interpretation of future results.

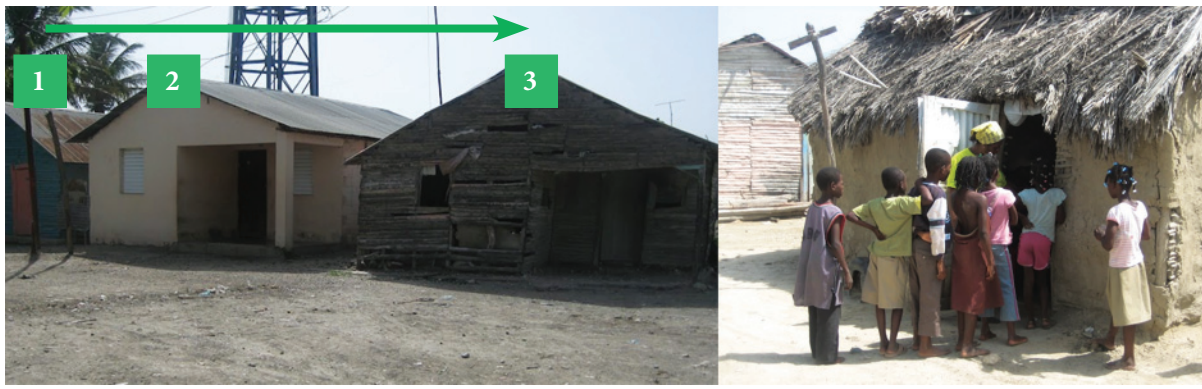
Community household surveys (slides 11–15)

If the net primary school enrolment ratio in the EU is < 75%, community-based household surveys should be conducted. Generally, community-based surveys are more expensive and time-consuming than school surveys; a community-based survey can take 3–6 weeks to conduct.

This section outlines a suggested approach of specimen collection and testing in the community setting (*Figure 46*). Situations will be different in each country, and it will be necessary to determine what best fits the situation.

1. At each selected enumeration area or community, teams should work with village officials and community health workers to estimate the number of households and plan a walking route to take them to each household. If available, sketch maps of the enumeration area can be used. The timing of the survey should be carefully planned so that children are likely to be at home (e.g. school breaks, evenings). The community should be sensitized well in advance of the start of the survey.

Figure 46. Suggested steps in a community-based household survey



Step 1: Enumerate houses. Houses can be enumerated and selected before sample collection.

Step 2: Visit houses on list A or list B. Selection continues until the next number on the list is higher than the total number of households in the enumeration area

Step 3: Test all 6–7-year-old children in the selected houses. If there are no 6–7-year-old children in the selected house, the team proceeds to the next house numbered on the list.

| List A | |
|--------|----|
| 1 | 8 |
| 3 | 10 |
| 4 | 12 |
| 6 | 15 |

2. The team should collect demographic data and blood specimens from all 6–7-year-old children in each selected household. It is recommended to collect blood samples in tubes for diagnostic testing in a laboratory or another controlled environment. This reduces the time between sample collection while moving from house to house and lowers the risk for reading error.
3. Arrangements should be made to treat people found to be positive by diagnostic tests.
4. Repeat all steps for each selected enumeration area and additional areas (if necessary) to satisfy the target sample size.
5. Even if the number of positive cases exceeds the critical cut-off point, the survey team should continue to collect information on everyone in the sample.

Data management and analysis (slide 16)

All demographic, sample, test and result data should be collected and recorded in an appropriate database management system.

Critical cut-off values are used to determine whether the level of infection has been reduced to a level at which transmission is probably not sustainable. The results of the TAS contribute to a decision to stop or continue MDA.

If a census has been used, the overall prevalence of infection will be calculated to guide the transmission assessment.

Non-respondents (slide 17)

The maximum acceptable non-response rate is 15%. At least one attempt should be made to revisit schools or houses to find non-respondents. In cluster sampling, if follow-up still results in less than the required sample size, additional clusters can be added, which can be selected before a survey with the survey sample builder. These clusters should be used only after it becomes clear that the required sample size will not be reached.

Reminder: Sample size includes only children for whom valid test results are available; it does not include absentees, refusals or children with invalid test results.

Role-playing exercise (slide 18)

During this role-playing exercise, you will set up a mock field setting, taking into account:

- the number of personnel needed for the activities
- the steps to take on arrival at the school or household
- the steps to take to set up a blood collection station at the school or household
- how to manage the selection of children (if necessary)



Annexes

Annex 1. Test to be taken by participants before and after training

1. Requirements for conducting a transmission assessment survey (TAS) include:
 - a. At least _____ rounds of effective mass drug administration (MDA)
 - b. Epidemiological drug coverage of at least _____% during each round of MDA
 - c. Sentinel site: Microfilariaemia prevalence of _____% or antigenaemia prevalence of _____%
 - d. Spot-check site: Microfilariaemia prevalence of _____% or antigenaemia prevalence of _____%
2. A TAS should be conducted at least ____ months after the most recent round of effective MDA.
3. True or false:
 - a. An evaluation unit (EU) must be the same as a MDA implementation unit (IU). _____
 - b. The total population of an EU should not exceed 2 million. _____

4. The diagnostic test used for TAS in areas endemic for:
 - a. *W. bancrofti* is _____
 - b. *Brugia* spp. is _____

5. What is the target age group for a TAS, and what is the rationale for selecting this age group?

6. The net primary school enrolment ratio must be at least _____% for a TAS to be conducted in schools.

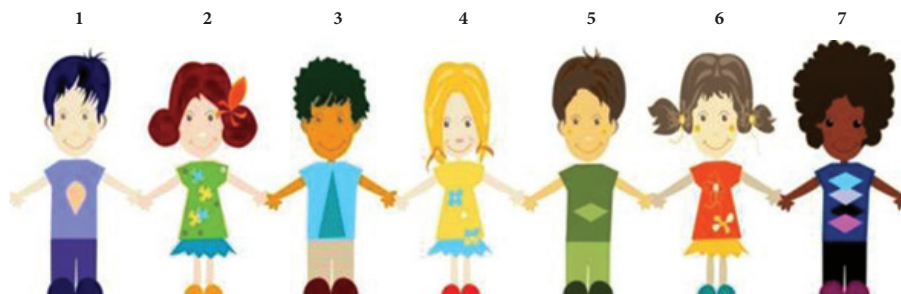
7. Identify the type of sampling strategy for:
 - a. selecting children to test in all schools per enumeration area in an EU at a fixed interval: _____ sampling
 - b. first randomly selecting clusters (schools per enumeration area) then systematically selecting children to test only in selected clusters: _____ sampling
 - c. no sampling required; test all children in target age range: _____

8. True or false: The choice of sampling strategy depends on the total population in the target age range and the total number of clusters in the EU. _____

9. In a TAS, the threshold of infection prevalence below which transmission is probably no longer sustainable even in the absence of MDA is called the _____.

10. The survey sample builder generated the following list of randomized numbers for clusters 2, 6, 8, 9 and 10. Circle the schools to visit on the list, which is ordered according to geographical proximity.
 1. Austin Elementary
 2. Dunwoody Elementary
 3. Henderson Mill Elementary
 4. Oakcliff Elementary
 5. Jolly Elementary
 6. Columbia Elementary
 7. Ashford Park Elementary
 8. Dresden Elementary
 9. Stone Mill Elementary
 10. Snapfinger Elementary

11. The survey sample builder calculated a sampling interval of 1.19 and generated list A: 1, 2, 4, 5, 6, 7. Circle the children who should be tested in this cluster.



12. In order to obtain primary school enrolment ratios for a TAS, communication is often required with the Ministry of _____.
13. The maximum acceptable non-response rate for a TAS is _____%.
14. If the number of positive results is below the established threshold, the recommendation is to _____ in the EU.
15. If the number of positive results exceeds the established threshold, the recommendation is to _____ in the EU.
16. What are the current WHO recommendations for post-MDA surveillance?

17. True or false: A dossier for verification of the interruption of lymphatic filariasis transmission can be submitted by each EU. _____.

Annex 2. Changes in editions of Monitoring and epidemiological assessment of mass drug administration—A manual for national elimination programmes between 2005 and 2011

Table A.4.2 Table of random numbers

| Item | 2005 | 2011 |
|--|---|--|
| Numbers of sentinel and spot-check sites | Two sites each per IU containing populations of < 500 people each | At least one site each per IU containing populations of < 500 people each (in order to collect at least 300 samples each) |
| Data collection times at sentinel and spot-check sites | Baseline Before third MDA Before fifth MDA | Baseline Before fourth MDA (optional) Before sixth MDA (a sixth MDA will likely be conducted in any case) |
| Measurement of clinical manifestations | Included in section on sentinel sites | Deleted |
| Geographical area for a transmission assessment survey (TAS) | Implementation unit (IU) | Evaluation unit (EU) |
| Other criteria for implementing a TAS | Prevalence of Mf is < 1% at sentinel and spot-check sites before fifth MDA In areas where <i>Wuchereria bancrofti</i> is endemic, no children aged 2–4 years test Ag-positive at sentinel and spot-check sites Prevalence of Mf is < 1% and no children aged 2–4 years test Ag-positive at 5–10 additional spot-check sites No Ag-positives in community-based LQAS cluster survey of 300 children aged 2–4 years in high-risk areas | Prevalence of Mf is < 1% at sentinel and spot-check sites after fifth MDA, with < 65% coverage of total population in each MDA |
| Design of survey | Lot quality assurance sampling survey of 3000 school entrants in IU | If the net primary school enrolment ratio is $\geq 75\%$, cluster survey or systematic sampling with LQAS analysis in schools If the net primary school enrolment ratio is < 75%, cluster survey or systematic sampling with LQAS in community |

| | | |
|-----------------------|---|--|
| Target group | School entrants (assumed to be children aged 6 years) | For a school-based survey, children in first and second years of primary school For a community-based survey, children aged 6–7 years |
| Diagnostic tests | ICT | ICT in areas where <i>W. bancrofti</i> is endemic Brugia Rapid™ test in areas where <i>Brugia</i> spp. is endemic |
| Cut-off criteria | Zero Ag-positives | In areas where <i>W. bancrofti</i> is endemic, <2% Ag where <i>Anopheles</i> or <i>Culex</i> is the principal vector ¹ In areas where <i>W. bancrofti</i> is endemic, <1% Ag where <i>Aedes</i> is the principal vector ² In areas where <i>Brugia</i> spp. are endemic, <2% Ab In areas where <i>W. bancrofti</i> and <i>Brugia</i> spp. are co-endemic, evaluate Ag and Ab results separately against cut-off points. |
| Post-MDA surveillance | Ag testing in a sample of 3000 children aged 5 years after stopping MDA | TAS carried out at approximately 2–3 years and 5–6 years after original survey Ongoing surveillance begun as early as possible |

Ab, antibody; Ag, antigenaemia; EU, evaluation unit; ICT, immunochromatographic test; IU, implementation unit; LQAS, lot quality assurance sampling; MDA, mass drug administration; Mf, Microfilaraemia; TAS, transmission assessment survey.

¹ In areas endemic for *W. bancrofti*, the prevalence of antigenaemia is always higher than that of microfilaraemia; therefore, the < 2% prevalence target for antigenaemia is used as a conservative proxy for a microfilaraemia prevalence of < 1%.

² In areas endemic for *W. bancrofti*, the prevalence of antigenaemia is always higher than that of microfilaraemia; therefore, the < 1% prevalence target for antigenaemia is used as a conservative proxy for a microfilaraemia prevalence of < 0.5%.

Annex 3. WHO TAS Eligibility and Reporting Form



TAS Eligibility and Reporting Form

The purpose of this template is to give national lymphatic filariasis elimination programme and data managers a standardized tool for systematically summarizing the eligibility of an evaluation unit (EU) for a transmission assessment survey (TAS), the survey design and the results.

National programmes are requested to complete the eligibility and survey design worksheet and submit it to the World Health Organization (WHO) before implementing the survey, so that it can be reviewed technically and the necessary support coordinated. Similarly, programmes are requested to complete and submit the results worksheet to WHO immediately after implementation. The forms can be submitted throughout the year.

Structure of the form (worksheets):

| | |
|----------------------|--|
| INTRO | This worksheet contains guides on completing the form for EUs in which a survey has been planned or implemented and for providing information on the EU and the country. |
| ELIGIBILITY | This worksheet contains information on the criteria for eligibility of an EU, such as the history of mass drug administration (MDA) coverage and the results of sentinel and spot-check surveys. |
| SURVEY DESIGN | These worksheets contain information on the design of the planned survey, such as the sampling frame, survey sites, diagnostic tools to be used, sample size, critical cut-off, estimated timetable and resources required. |
| RESULTS | This worksheet summarizes the results of the survey conducted by the EU, including the number of children surveyed, the number of positive cases identified, the non-response rate, the actual timetable and the resources used. |

Instruction for data entry

Most 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 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. |

Country and EU data

| | |
|--|----------------------|
| COUNTRY | Burkina Faso |
| Year of reporting data | 2013 |
| Name of the EU | Defra-Lena-KV |
| Number of Implementation Units (IUs) in the EU | 3 |
| Total population of the EU | 430,647 |
| Total area of the EU (km ²) | 6,000 |
| Parasite species in the EU | <i>W. bancrofti</i> |
| Predominant vector in the EU | <i>Anopheles</i> |
| Objective of TAS | Stop MDA |

Please send this form to the following:

WHO country office
WHO regional office
WHO headquarters

pctdata@who.int

Survey Design

| Information on EU | |
|---|---------------------|
| Country name | Burkina Faso |
| Year of reporting | 2013 |
| Name of EU | Defra-Lena-KV |
| Number of implementation units in the EU | 3 |
| Total population | 430647 |
| Total area (km ²) | 6000 |
| Parasite species | <i>W. bancrofti</i> |
| Predominant vector | <i>Anopheles</i> |
| Objective of transmission assessment survey | Stop MDA |

| Sampling frame | |
|---|--------|
| Net primary school enrolment rate (%) | 95% |
| Survey site location | School |
| Grade(s) with majority of 6-7 year olds | 1-3 |
| Total number of children in selected grade(s) in EU | 2,547 |
| Total number of primary schools in EU | 26 |

| Design (from 'Survey Sample Builder') | |
|---|--------|
| Survey type | Census |
| Diagnostic test | ICT |
| Target number of schools or enumeration areas | |
| Target sample size | |
| Critical cut-off value | |
| Estimated non-response rate | |
| Sampling interval | |

| Estimated timeline and resources | |
|--|--|
| Planned starting month and year | |
| Estimated number of survey days required | |
| Budgeted cost | |
| Source(s) of funding | |
| Number of ICT or Brugia Rapid tests required | |

Results

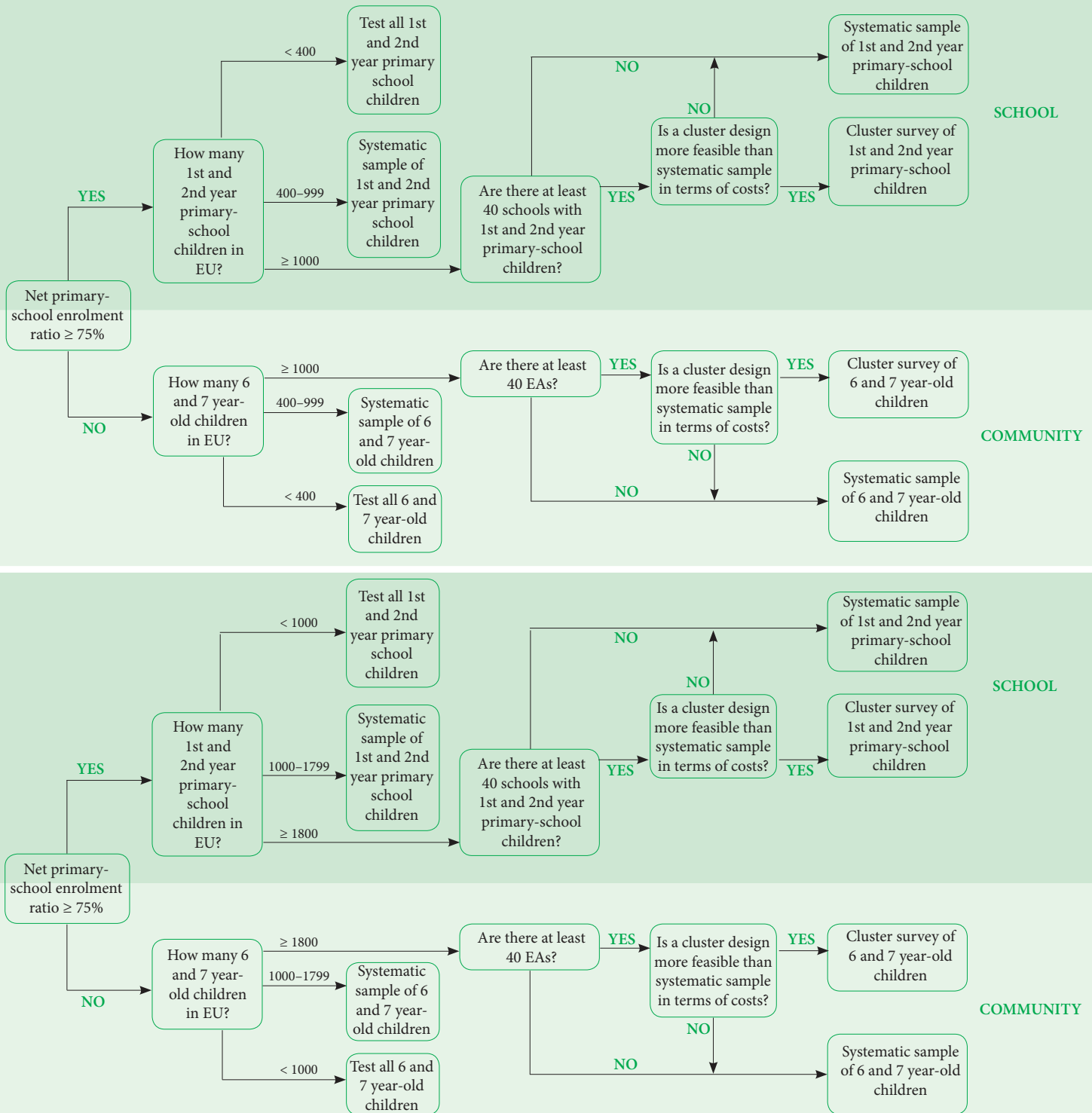
| Information on EU | |
|---|---------------------|
| Country name | Burkina Faso |
| Year of reporting | 2013 |
| Name of EU | Defra-Lena-KV |
| Number of implementation units in the EU | 3 |
| Total population | 430647 |
| Total area (km ²) | 6000 |
| Parasite species | <i>W. bancrofti</i> |
| Predominant vector | <i>Anopheles</i> |
| Objective of transmission assessment survey | Stop MDA |

| Design (from 'survey sample builder') | |
|---|--------|
| Survey site location | School |
| Survey type | Census |
| Diagnostic test | ICT |
| Target number of schools or enumeration areas | |
| Target sample size | |
| Critical cut-off value | |
| Estimated non-response rate (%) | |
| Sampling interval | |

| Results | |
|--|---------------------------------------|
| Actual number of schools or enumeration areas surveyed | |
| Actual sample size tested | <i>Positive</i> |
| | <i>Negative</i> |
| | Total tested |
| Actual non-response rate (%) | Absent (%) |
| | Refusal or no consent (%) |
| | Unable to perform diagnostic test (%) |
| | Total (%) |
| Critical cutoff decision | |

| Actual timeline and resources | |
|--|--|
| Starting month and year | |
| Number of survey days required | |
| Actual cost | |
| Source(s) of funding | |
| Number of ICT or Brugia Rapid tests used | |

Annex 4. Algorithm for choosing design of TAS in areas where Anopheles or Culex is the principal vector (above) and where Aedes is the principal vector (below)



Annex 5. Procedure for testing blood films

Used to detect microfilariae in blood in order to determine the prevalence and density of microfilariae.

Test procedure

1. Clean slide with alcohol to remove lint and oil residue, and label slide appropriately.
2. Perform a finger-prick as described in the blood collection standard operating procedure.
3. Collect 60 μ l of blood into a blood collection tube or a calibrated capillary tube.
4. Using a micropipette or capillary tube, place three parallel lines of blood (20 μ l each) along the length of the slide.



5. Air-dry the blood film thoroughly for 24–72 hours.
6. Carefully load the slides onto the staining racks. Dehaemoglobinize the blood film for approximately 5 minutes in tap water, distilled water or normal saline.
 - Dehaemoglobinization is necessary to clear the red blood cells so that the microfilariae can be visualized more easily. This is complete when the smear turns an opaque greyish-white. Caution must be exercised at this time, because the smear is fragile, and rough washing or agitation can float it off the slide. Although fixation in methanol is not absolutely necessary, it results in better staining of the microfilariae.
7. Air-dry on the staining racks.
8. Fix in methanol for 3–5 minutes.
9. Stain with Giemsa. The general rule is to stain for a time equivalent to dilution of the stain. Routinely, use a 1:50 dilution of stock Giemsa and stain for 50 minutes. If the white blood cell nuclei are properly stained, microfilariae should also be adequately stained. For Giemsa staining of films to be examined for microfilariae, the pH of the staining solution is not critical (unlike those to be examined for malaria parasites). The overall colour of the smear may range from pink to purple to blue, depending on the pH, but the microfilariae will be stained adequately regardless of colour.

10. Air-dry.
11. Examine the preparation under a microscope. Use the x 10 objective first to locate the microfilariae; then identify the filarial species under the x 40 and x 100 objectives.

Test interpretation

Microfilariae, if present, can be seen on the slide under a light microscope (with appropriate staining) (Figure 3). Care should be taken to identify filarial species correctly on the basis of morphological characteristics. Bench aids are available from WHO for correct identification of microfilariae.

Annex 6. Procedures for confirmatory testing

If resources allow, programme managers may choose to follow up positive cases. The diagnostic tests available for confirmation of positive tests include:

Dried filter paper blood spots can be used as an alternative to serum samples for diagnostic testing. They are easier to collect, store and ship and can be used for the detection of microfilariae (PCR), filarial antigen (ELISA) and antifilarial antibody (ELISA).

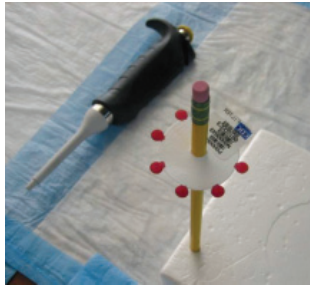
| Target | Assay | Specimen required | Where testing can be done |
|-----------------------|------------------|---|---------------------------------|
| Microfilariae | Blood films, PCR | Whole blood, dried filter paper blood spots | Locally or reference laboratory |
| Filarial antigen | Og4C3 ELISA | Serum or plasma, Dried filter paper | Reference laboratory |
| Antifilarial antibody | ELISA | Serum or plasma, dried filter paper blood spots | Reference laboratory |

Basic guidelines

To avoid cross-contamination, blood spots should be made in a central location, where they can dry completely before being stored. If blood spots are to be used for the detection of filarial DNA (PCR), the periodicity of microfilariae must be considered when collecting blood.

Test procedure

1. Label the filter disk appropriately.
2. When using TropBio filter paper, touch all six protrusions (ears) on the filter paper disk to a droplet of whole blood from a finger prick. Alternatively, touch a piece of filter paper (e.g. Whatman) to the finger to collect blood. Spotting can be done by measuring 10 µl of blood with a micropipette and adding the measured volume to each protrusion (ear), or by measuring 100 µl of blood and adding it to a piece of filter paper.
3. Completely air-dry the filter paper at room temperature for at least 2 hours; it is best to let it dry overnight.
4. When the filter paper has dried completely, place it in a small plastic bag and keep as dry as possible.



TropBio filter disk



Whatman filter paper

Storage

For short-term storage (up to 1 week): Store at 4 °C.

For longer term storage:

- Place groups of 50 disks (each in its own individual small plastic bag) into larger plastic bags.
- A silica gel desiccant can be placed into the larger bag. Make sure the small bags containing the filters are completely sealed so they do not contact the desiccant.
- Store at -20 °C.
- Dried disks packed and stored in this way can then be safely transported to the testing laboratory for up to 1 week at normal ambient temperature.

Annex 8. Checklist for planning and implementing a transmission assessment survey

| Task | Possible personnel responsible | | Relevant module |
|--|--------------------------------|------------------------|-----------------|
| | National programme | Subnational programmes | |
| Planning | | | |
| 1. Evaluation unit | | | |
| <input type="checkbox"/> Define EU | √ | | 2 and 3 |
| <input type="checkbox"/> Complete the 'INTRO' and 'ELIGIBILITY' worksheets of the TAS Eligibility and Reporting Form | √ | √ | |
| <input type="checkbox"/> Submit the TAS Eligibility and Reporting Form via WHO to RPRG | | | |
| 2. Survey design | | | |
| <input type="checkbox"/> Determine net primary school enrolment rate in the EU | √ | | 4 and 8 |
| <i>School survey (net primary school enrolment rate ≥ 75%)</i> | | | |
| <input type="checkbox"/> Determine grade(s) with majority of 6–7-year-old children | √ | | |
| <input type="checkbox"/> Obtain estimated enrolment rate(s) in selected grades from ministry of education | √ | | |
| <input type="checkbox"/> Estimate non-response rate in the EU | √ | | |
| <input type="checkbox"/> Obtain list of all primary schools in the EU, and order them by geographical proximity | √ | | |
| <input type="checkbox"/> Use the survey sample builder to randomize survey sites and to determine survey design, target sample size and critical cut-off | √ | | |
| <input type="checkbox"/> Determine actual enrolment in selected grades in the schools, and adjust survey design if necessary | √ | | |
| <i>Community survey (net primary school enrolment rate < 75%)</i> | | | |
| <input type="checkbox"/> Define administrative unit (census enumeration areas are recommended) | √ | | |
| <input type="checkbox"/> Obtain estimated no. of 6–7-year-old children in the enumeration area from census | √ | | |
| <input type="checkbox"/> Estimate non-response rate in the EU | √ | | |
| <input type="checkbox"/> Obtain list of all enumeration areas in the EU, and order them by geographical proximity | √ | | |
| <input type="checkbox"/> Use the survey sample builder to determine survey sites, survey design, target sample size and critical cut-off | √ | | |
| <input type="checkbox"/> With officials in selected enumeration areas, review estimate of 6–7-year-old children, and adjust survey design if necessary | √ | | |
| 3. Administration | | | |
| <input type="checkbox"/> Prepare a budget | √ | | 9 |
| <input type="checkbox"/> Prepare a timetable | √ | | |
| <input type="checkbox"/> Obtain ethical approval for the survey, if necessary | √ | | |
| 4. Materials | | | |
| <input type="checkbox"/> Procure diagnostic tests | √ | | 9 |
| <input type="checkbox"/> Clear diagnostic tests through customs | √ | | |

| Task | Possible personnel responsible | | Relevant module |
|---|--------------------------------|------------------------|-----------------|
| | National programme | Subnational programmes | |
| <input type="checkbox"/> Obtain and organize consumable supplies | √ | √ | |
| <input type="checkbox"/> Devise and print informed consent forms, if necessary | √ | √ | |
| <input type="checkbox"/> Coordinate with schools for distribution of informed consent forms, if necessary | √ | √ | |
| <input type="checkbox"/> Devise and print data collection forms with clear system of identifiers, or set up electronic data forms | √ | √ | |
| <input type="checkbox"/> Obtain enumeration area maps (for community-based surveys) | √ | √ | |
| 5. Field preparation | √ | | 9 |
| <input type="checkbox"/> Organize and designate roles of staff and field teams | √ | √ | |
| <input type="checkbox"/> Train staff in survey design, field procedures and diagnostic testing | √ | √ | |
| <input type="checkbox"/> Organize transport and vehicle requirements | √ | √ | |
| <input type="checkbox"/> Notify officials in schools or enumeration areas about upcoming survey | √ | √ | |
| Field work (for each school or enumeration area) | | | |
| 1. Before sampling | | | 9 |
| <input type="checkbox"/> Orient and brief survey teams, supporting staff and officers about the survey design | √ | √ | |
| <input type="checkbox"/> Ensure that consent has been obtained properly | √ | √ | |
| <input type="checkbox"/> Identify the place in the school in which sampling can be done (for school-based surveys) | √ | √ | |
| 2. Selection of participants | | | 10 |
| <i>School survey</i> | | | |
| <input type="checkbox"/> Gather all eligible children, with assistance from teachers and school officials | √ | √ | |
| <input type="checkbox"/> Record numbers of eligible children present and absent on survey day | √ | √ | |
| <input type="checkbox"/> Randomly choose one of two lists, if necessary | √ | √ | |
| <input type="checkbox"/> Line up all eligible children, and select those to survey from the list, if necessary | √ | √ | |
| <i>Community survey</i> | | | |
| <input type="checkbox"/> Review estimated population and boundaries of the enumeration area with local officials | √ | √ | |
| <input type="checkbox"/> Plan a walking route that passes each house using maps or other guides | √ | √ | |
| <input type="checkbox"/> Randomly choose one of two lists | √ | √ | |
| <input type="checkbox"/> Begin walking route, stopping at each house on list | √ | √ | |
| <input type="checkbox"/> Select all 6–7-year-old children in the houses | √ | √ | |
| <input type="checkbox"/> Record the actual number of children in each house who are present and absent on the survey day | √ | √ | |
| 3. Sampling | | | 5 and 10 |
| <input type="checkbox"/> Set up a designated area for collecting data and blood | √ | √ | |
| <input type="checkbox"/> Collect demographic data on each selected child | √ | √ | |
| <input type="checkbox"/> Collect a blood specimen from each child (in EDTA-coated tube if to be tested later at a central location) | √ | √ | |
| <input type="checkbox"/> Conduct an ICT or Brugia Rapid™ test directly in the field or send to a central location | √ | √ | |
| <input type="checkbox"/> Record results on a data collection form or in an electronic system | √ | √ | |
| 4. After sampling | | | 6 and 10 |
| <input type="checkbox"/> Clean up the sampling area | √ | √ | |
| <input type="checkbox"/> Treat or arrange for treatment of positive cases | √ | √ | |

Annex 9. Budget template

TAS Budget Template

Name of country: _____

Name of evaluation unit: _____

| Category | Unit cost | Number of unit | Number of days | Amount |
|---|-----------|----------------|----------------|----------|
| Personnel costs | | | | |
| Daily allowances for supervisors | | | | 0 |
| Daily allowances for field staff | | | | 0 |
| | | | | |
| subtotal | | | | 0 |
| Transport and fuel | | | | |
| Fuel | | | | |
| Repair and maintenance | | | | |
| Other transport | | | | |
| | | | | |
| subtotal | | | | 0 |
| Supplies and consumables | | | | |
| Diagnostic test | | | | |
| Field supplies | | | | |
| | | | | |
| subtotal | | | | 0 |
| Office supplies | | | | |
| Stationary | | | | |
| Photocopies | | | | |
| | | | | |
| subtotal | | | | 0 |
| Communication | | | | |
| Telephone and fax | | | | |
| Internet | | | | |
| | | | | |
| subtotal | | | | 0 |
| Training | | | | |
| Hall hire | | | | |
| Food | | | | |
| Miscellaneous expenses | | | | |
| | | | | |
| subtotal | | | | 0 |
| Other (specify) | | | | |
| e.g. customs fees, maps, ethical approval | | | | |
| | | | | |
| subtotal | | | | 0 |
| TOTAL BUDGET | | | | 0 |

Annex 11. Bench aid for new diagnostic test to detect antigen to *W. bancrofti*

v.1.0 (August 2013)



The Alere™ Filariasis Test Strip is a rapid diagnostic tool used for the qualitative detection of *Wuchereria bancrofti* antigen in human blood samples collected by fingerstick. Although the test is relatively simple to use, adequate training is necessary to reduce inter-observer variability and to reduce the misreading of strips.

Basic Guidelines

- Kits should be stored at 2-37°C. Test strips should NOT be frozen. The Alere™ Filariasis Test Strip kit is stable until the expiration date marked on its outer packaging when stored as specified. Kits should NOT be used past the expiration date.
- Before beginning field surveys, two strips from each lot of kits should be tested using a positive control that can be obtained from the Filariasis Research Reagent Repository Center (www.filariasiscenter.org). DO NOT use strips that are negative when tested with the control.
- When transporting strips for use in the field, a cool box is not required. However, care should be taken not to expose strips to extreme heat for prolonged periods of time.
- Strips must be read using bright unfiltered light. Faint lines can be difficult to see when lighting is not adequate. This is especially important when reading strips at night.

Test Procedure

1



Allow all kit components to equilibrate to ambient temperature (15-37°C) before testing.

Remove contents from the foil pouch just prior to use. Provided materials include one test strip, plastic work tray and fixed volume (75µL) micropipette.



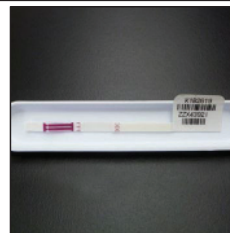
2



Strips should be handled carefully and held only at the end without the arrows. DO NOT apply pressure to the sample pad at the bottom of the strip.



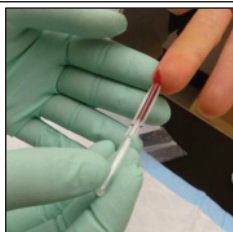
Strips should be labeled with appropriate patient identifiers. Strips can be labeled directly (A) (preferred). Alternatively, the work tray can be labeled (B).



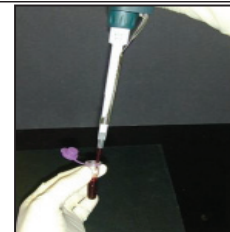
The strip should be placed in the work tray before the sample is added.

NOTE: It is advisable to secure the strip to the work tray using a sticker-type patient identifier label or tape.

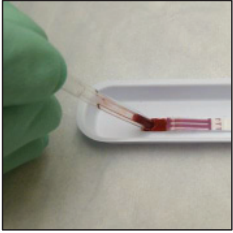
3




Collect 75µL of fingerstick blood by holding the supplied micropipette slightly above the horizontal plane. **DO NOT** squeeze the bulb end of the micropipette when collecting the sample. Alternatively, measure 75µL of anti-coagulated blood from a microcentrifuge tube using a calibrated micropipettor. **DO NOT** add blood directly from the finger to the strip.



4



Slowly add the blood sample to the lower half of the sample pad by gently squeezing the bulb.



Set a timer for 10 minutes.
NOTE: It is helpful to record the reading time on the work tray.

5

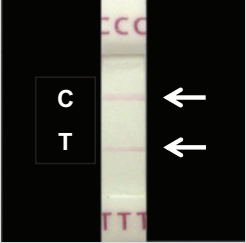


Read test results 10 minutes after the sample has been added.
NOTE: Record the appropriate result on the strip (preferred) or work tray.

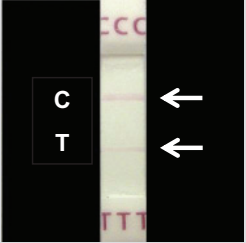


DO NOT read tests if the sample has not migrated ALL the way up the strip.

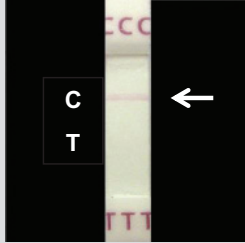
Test Interpretation



POSITIVE*
Any visible pink line in the test area should be interpreted as a positive result

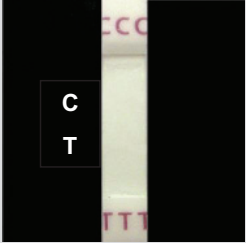


POSITIVE (weak)*
Control line only

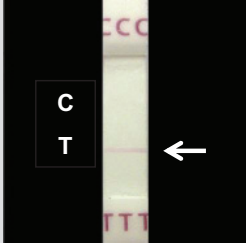


NEGATIVE*
Control line only

C = control
T = test



INVALID
No lines appear



INVALID
Test line only

**Scoring of test strips is useful but optional. Negative, 0; test line weaker than control line, 1; test line equal to control line, 2; test line stronger than control line, 3*

