

Guidelines for Certifying Lymphatic Filariasis Elimination

(including Discussion of Critical Issues and Rationale)

Following from the WHO Informal Consultation on
Epidemiologic Approaches to Lymphatic Filariasis Elimination:
Initial Assessment, Monitoring, and Certification

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1. INTRODUCTION

Widespread interest in and support for a global campaign to eliminate lymphatic filariasis has developed and grown in the 1990s. In 1997 the World Health Assembly endorsed efforts to eliminate transmission of filariasis on a country by country basis (WHA resolution 50.29).

Filariasis is a disease which is endemic in communities worldwide affecting an estimated 120 million persons. Table 1 lists those countries where human filariasis has been: (i) endemic during the 1980s and 1990s, (ii) endemic or possibly endemic before 1980 but not recognized since then, (iii) sporadically reported without evidence of endemic disease. In 1998, there is still lack of knowledge about when transmission of filariasis was interrupted in many countries.

The need for certification of attainment is inherent in the goal of an elimination programme; such a need does not exist for control programmes. There must be an objective basis, according to agreed criteria, for determining whether transmission of filariasis has indeed been eliminated; the criteria must take into account the risk of importation from filariasis endemic countries. It is expected that efforts towards elimination of filariasis transmission for individual countries will be conducted until the global certification of elimination of filariasis is achieved.

In order to complete the process of certifying elimination, an independent International Commission for the Certification of Lymphatic Filariasis Elimination (ICCLFE) will be established by World Health Organization (WHO). This commission will recommend to the Organization those countries that fulfil the requirements for certification, as well as advise the Organization on criteria, procedures and progress made towards verification of absence of transmission. The commission will also designate a panel of specialists, whose members can be assigned to International Certification Teams (ICTs).

WHO, including the Regional offices, will facilitate national preparations for certification by carrying out regular visits by WHO staff, members of the designated ICT, or consultants to the country or sub-region concerned. A register will be established of countries requesting certification and also of those countries where official certification of elimination is pending. Finally WHO will also establish an official register of countries where filariasis has been eliminated, based on evaluations by the ICCLFE.

The aim of the present document is to describe the criteria for verifying the absence of filariasis transmission. In addition WHO has developed a document addressing issues of disease ascertainment, monitoring, and pre-elimination surveillance – i.e., addressing the various issues before elimination certification (see document WHO/FIL/99.195).

2. DEFINITIONS

A *lymphatic filariasis (LF) case* is defined as an individual with evidence of current infection with *Wuchereria bancrofti*, *Brugia malayi* or *Brugia timori*.

Endemic filariasis is defined as an area within a country with a prevalence of greater than or equal to 1 (locally acquired) case per 1,000 population.

Countries are classified as:

Never-endemic: No history of (or evidence for) endemic filariasis

Post-endemic: Past history of filariasis, but no evidence of transmission or new clinical disease since 1980.

Endemic: Filariasis since 1980 or current filariasis.

Local elimination is defined as a cumulative incidence rate over five years of less than 1 new case per 1000 susceptible individuals. When a country with endemic areas has achieved local elimination in all affected regions, the country can apply for certification of filariasis elimination.

Worldwide elimination of filariasis will be considered achieved when all countries have been certified as having eliminated filariasis.

3. CRITERIA FOR CERTIFICATION OF ELIMINATION

Standard criteria for certification are needed for the following reasons:

1. To ensure international credibility for the expected future claim that filariasis has been eliminated from an area.
2. To have an established and consistent mechanism for judging the success of national filariasis elimination programmes.
3. To have a standard, effective procedure to identify and eliminate any previously unknown foci of transmission.

3.1 In countries with filariasis transmission after 1980

National governments requesting certification of elimination must submit to WHO a country report (see section 4.1.2) which describes the procedures undertaken and provides evidence in support of the assertion that filariasis has been eliminated.

As a first step countries with endemic filariasis must ascertain all of the local areas in the country with endemic filariasis (see document WHO/FIL/99.195). That document also includes substantial information on monitoring elimination programmes while in progress and during the post-treatment surveillance period (up to five years after cessation of community treatment).

In these countries, elimination will be considered to have been achieved when surveys in each endemic region in the country have shown a cumulative incidence rate over five years of less than 1 new case per 1000 susceptible individuals. Because transmission of filariasis is suppressed during community treatment with antifilarial agents, and certification is of the post-treatment state, the official surveys for certification should take place not less than 5 years after cessation of community treatment. For working purposes it is recommended that, five years after cessation of community treatment, 3000

school children 5 years of age from the endemic area(s) be screened. If all test negative local elimination can be considered achieved (see Appendix Sections 1 and 6).

Confirmation of the absence of transmission in a country is judged on the basis of an assessment of:

- (i) the thoroughness and adequacy of the original ascertainment of the local areas of endemic filariasis within the country;
- (ii) the surveys and survey findings from all local areas with endemic filariasis (in order to substantiate elimination of filariasis transmission).

Records of the original ascertainment and final surveys should be compiled by the national authorities for review. In addition, documentation of elimination efforts undertaken, and other screening and surveys undertaken as part of monitoring or pre-certification surveillance (see section 4.1.2), should be compiled. These documents will then be reviewed as part of the field appraisal by an international certification team.

After provision of necessary documentation and upon satisfaction of ICCLFE that transmission has been halted in all areas of the country, the country will be officially designated as “recently-endemic: elimination certified”.

3.2 Other countries with history or possible history of filariasis transmission

In these countries certification of elimination may be granted after the provision of satisfactory documentation that no residual foci of infection exist. Countries in this group represent a wide range of situations; therefore, requirements for certification will need to be tailored to each situation, relating to the following issues:

3.2.1 A detailed description of the extent of any former endemic area(s).

3.2.2 The possible need to present findings of active case searches, conducted within the last five years, in areas which may formerly have been endemic. The results should ascertain that residual foci of infection no longer exist.

3.2.3 Countries with areas that are determined to have current filariasis transmission will subsequently need to be certified as per section 3.1.

After provision of necessary documentation and upon satisfaction of ICCLFE, a country in this category will be officially designated as “post-endemic: elimination certified”.

3.3 Countries without a history of filariasis transmission

(All other countries)

Countries that believe they should be classified as never endemic need to document to WHO that their existing public health infrastructure would have detected filariasis, if it had occurred at endemic levels. After provision of necessary documentation and upon satisfaction of WHO

(designated) reviewers, a country in this category will be officially designated as "never-endemic: elimination certified".

4. CERTIFICATION PROCEDURES

All countries should contact WHO to initiate the verification and certification process. The proposed sequence of events listed below should be kept flexible. This listing summarizes the process for certification.

- (1) All countries of the world will be encouraged to submit a formal request to WHO to certify the elimination of filariasis transmission (5 years after completion of the elimination programme for countries with currently endemic filariasis).
- (2) Such formal requests must conform with the procedures given in this document and any subsequent guidelines prepared by WHO or by the ICCLFE. In particular, the requesting countries will produce a detailed report on all ascertainment, monitoring, elimination, surveillance, and pre-certification survey activities.
- (3) WHO will designate an International Certification Team (ICT) in the case of recently endemic countries and other countries considered to potentially be at "high risk" of having filariasis foci. The ICT will have the mandate to evaluate the country report and to determine, in collaboration with the host country, the status of certification.
- (4) Countries may find it useful to designate a national committee to evaluate the report on the filariasis elimination programme before its submission to WHO. Such a committee may choose to do its own evaluation of the national programme and to give evidence before the International Certification Team (ICT).
- (5) The ICT will evaluate the likelihood that all filariasis endemic areas have been detected, review the evidence for absence of transmission for the previous five years, and make appropriate recommendations to WHO regarding approval of the claim that filariasis has been eliminated.
- (6) If certification of elimination is granted, the country will then be listed on a WHO official register of areas now verified as free of filariasis transmission.

4.1 National preparations for certification

4.1.1 Pre-Certification Activities for Endemic and Post-endemic countries

The methods employed in national preparations for certification will depend on whether the country considers itself endemic, post-endemic, or never-endemic for lymphatic filariasis.

4.1.1.1 *Endemic countries*

Countries with endemic filariasis should carefully review the document WHO/FIL/99.195 for requirements regarding the initial assessment of filariasis, monitoring, and post-intervention surveillance.

After a period of 5 years post intervention, local elimination can be considered to have been achieved when surveys in each endemic region in the country have shown a cumulative incidence rate over five years of less than 1 new case per 1000 susceptible individuals. (Because transmission of filariasis is suppressed during community treatment with antifilarial agents, and certification is of the post-treatment state, the official surveys for certification should not take place less than 5 years after cessation of community treatment.) For working purposes, it is recommended that five years after cessation of community treatment 3000 school children 5 years of age from the endemic area(s) be screened (see Appendix Sections 1 and 6) with an appropriate screening methodology (see Appendix Section 7). Currently thick blood smears for microfilaria and antigen testing are considered to have sufficient sensitivity for use, though use of the antigen card-test might lead to some false-positive results. Those children who do test positive will then need to be further tested to determine their true status. (Note: as opposed to testing done during monitoring phases, which can be done anonymously, pre-certification testing must be linked to names so that children who test positive can be followed up.) If on follow-up testing of children with positive tests, all the positive results are reliably determined to have been false positives, then local elimination can be considered achieved.

Confirmation of the absence of transmission in a country will be judged on the basis of an assessment of:

- (i) the thoroughness and adequacy of the original ascertainment of the local areas of endemic filariasis within the country;
- (ii) the surveys and survey findings done in all local areas with endemic filariasis (in order to substantiate elimination of filariasis transmission).

Records of the original ascertainment and final surveys should be compiled by the national authorities for review. In addition, documentation of elimination efforts undertaken, and other screening and surveys undertaken as part of monitoring or pre-certification surveillance (see section 4.2 for detailed listing) should be compiled. These documents will then be reviewed as part of field appraisal by an international certification team.

4.1.1.2 Post-endemic countries

For those countries where filariasis is not thought to be currently endemic but has, or possibly has, been in the past, pre-certification activities should be tailored to maximize the detection of any indigenous filariasis transmission. One or more of the following approaches may be suitable:

- (1) Enhancing the sensitivity of case detection nationwide by promoting a high degree of public awareness of filariasis and its elimination in neighboring countries, and by stressing: (i) the importance and need of reporting cases of filariasis, (ii) the need for screening individuals at risk for filariasis;
- (2) Maintaining a register of filariasis cases and using it to: (i) note any suspected cases of infection reported or discovered during the pre-certification period, (ii) indicate that each confirmed case was either imported, by tracing the case to its origin in a filariasis endemic area, or indigenous. Ascertain that all reports were well documented;

- (3) Instituting approaches to detect asymptomatic filarial infection, which could include screening of military recruits, blood banks or other populations;
- (4) Conducting active case detection by doing surveys, perhaps on a village-by-village basis, in any areas that may have been formerly endemic; for nomadic peoples especially intensive efforts may have to be made to find and adequately screen the population.
- (5) For countries with a substantial population of migrants from endemic countries, determine level of infection in these groups and document the lack of transmission associated with them.

4.1.2 Preparation of a Country Report

Countries must submit a Country Report to the International Commission for Certification of Lymphatic Filariasis Elimination as part of the certification process. The level of detail required will vary widely from a brief document in countries which have never had filariasis (see section 3.3) to highly detailed reports needed from countries applying after a national filariasis elimination programme. Endemic countries should include all of the following information in their reports. Post-endemic countries should include at least parts 1, 2, and 5c.

- (1) An historical account of filariasis in the country;
- (2) Important background information including:
 - (a) demographic information including population distribution by geographical region
 - (b) information on significant migration patterns within the country and from filariasis endemic countries
 - (c) information on filariasis vectors and their distribution within the country;
- (3) The methodology and findings of the country's original assessment of the extent of filariasis, undertaken prior to beginning the national elimination programme;
- (4) A detailed overview of the filariasis elimination programme, including:
 - (a) a description of intervention efforts
 - (b) methodology and findings of process monitoring of community programmes for treatment coverage and compliance
 - (c) a description of education campaigns supporting community interventions;
- (5) The methodology and findings of monitoring and post-intervention surveillance for filariasis, including:
 - (a) monitoring done while community treatment programmes were in place;
 - (b) surveillance done after the cessation of community programmes and before application for certification;
 - (c) additional active or passive case detection activities undertaken (e.g. such as screening of military recruits or blood banks);

(6) The methodology and findings of surveys done for certification; if the country has set up a National Committee or group to critically examine and/or oversee programme activities, this should also include information describing work undertaken by the National Committee to ensure the effectiveness of elimination activities and accuracy of the final report.

Maps should be presented as part of the Country Report, to visualize as many as possible of the points described in the text of the report, including at least:

- (a) historical distribution of filariasis
- (b) extent of initial assessment and distribution of endemic areas
- (c) population distribution and migration patterns
- (d) distribution of filariasis vector species
- (e) areas of programme intervention
- (f) areas of monitoring and post-intervention surveillance
- (g) areas where pre-certification surveys were carried out.

4.2 Operation of International Certification Teams

International Certification Teams (ICTs) will be asked to reach one of two possible conclusions: either (i) they are satisfied that elimination has been achieved, or (ii) they are not satisfied. ICT reports will spell out reasons for their decision. The government of the country being certified should guarantee the ICT full access to all documentation of programme activities and to all parts of the country where further investigation is needed.

The timing of ICT visits to the countries and team membership will be decided by WHO in consultation with national authorities. Persons selected as team members should be able to be critical in their assessments, and their views as experts should be respected both nationally and internationally. Members should be chosen from different areas of the world so that the nature and extent of the efforts made to document the interruption of transmission may become widely known. Scientists working on filariasis and countries with elimination programmes should both be represented on ICTs so that technical expertise can be exchanged and applied to the certification process. Potential conflicts of interest, such as nomination of a national from a country under review as a member of the ICT, should be avoided. In general, contiguous formerly endemic countries should be considered and evaluated at the same time.

The principal aim of an ICT visit to a country will be to evaluate the reliability of that country's report, by interviewing health personnel and others, and by examining records at both central and peripheral levels, in order to ascertain the likelihood that filariasis transmission has been interrupted as claimed. Because team members will not usually be able to spend more than a few weeks in a country, the objective will be to assess the quality of the original ascertainment and the subsequent surveys used as the basis of applying for elimination certification. Preliminary visits by selected consultants or temporary advisers may be arranged by WHO to examine the status of documentation and to recommend any additional measures they think are indicated before the visit by the ICT.

After arrival in the country, the ICT will visit the Ministry of Health to review the country report with nationals of the host country and to be briefed by designated officials concerning the activities carried out. To facilitate visits to all epidemiologically important areas the team would divide into groups. The areas selected for visits could be (i) areas identified as potentially having been missed

in the original ascertainment, (ii) areas contiguous with affected countries, (iii) previous highly endemic areas, or (iv) areas where sporadic cases have occurred, especially if these occur in regions of the country with a weaker health infrastructure. Visits could also be undertaken to areas where surveys were done, particularly to evaluate if all areas with previous risk of transmission were adequately sampled. Regardless of the criteria for selection, team members will decide which areas, villages and health units they wish to visit.

Table 1

Countries where LF was endemic or possibly endemic in the 1980's and 1990's		
American Samoa Angola Bangladesh Benin Brazil Brunei Darussalam Burkina Faso Burundi Cambodia Cameroon Cap Vert Central African Republic Chad China Comoros Congo Cook Islands Costa Rica Côte d'Ivoire Democratic Republic of Congo Dominican Republic Egypt Equatorial Guinea Eritrea Ethiopia Fiji French Polynesia Gabon Ghana	Guam Guinea Guinea Bissau Guyana Haiti India Indonesia Iran Kenya Kiribati Laos Liberia Madagascar Malawi Malaysia Maldives Mali Marshall Islands Mauritius Micronesia Mozambique Myanmar Nepal Niger Nigeria Niue Northern Marianas Oman Pakistan	Papua New Guinea Philippines Republic of Korea Reunion Rwanda Samoa Sao Tomé & Principe Saudi Arabia Senegal Seychelles Sierra Leone Solomon Islands Somalia Sri Lanka Sudan Suriname Thailand The Gambia Togo Tonga Trinidad & Tobago Uganda United Republic of Tanzania Vanuatu Viet Nam Wallis and Futuna Yemen Zambia Zimbabwe
Countries where LF was endemic or possibly endemic before 1980 but not since then		
Antigua & Barbuda Barbados Chagos Islands Colombia Cuba Dominica French Guyana Grenada Guadeloupe Honduras	Jamaica Martinique Montserrat Nauru Nicaragua New Caledonia Panama Puerto Rico Ryukyu Islands Singapore	St Kitts & Nevis St Lucia St Vincent and the Grenadines Taiwan Tokelau Islands Tuvalu United States US Virgin Islands Venezuela
Countries with sporadic case reports of LF but probably not endemic infection		
Djibouti Palau		

Appendix: Discussion of Critical Issues and Rationale

Numerous assumptions, decisions and educated guesses were needed to arrive at the preceding elimination guidelines. In order to clarify the issues considered and to provide rationale for the written guidelines, the following discussion is provided.

1. WHAT IS ELIMINATION?

- *Should elimination be measured by infection or transmission parameters?*

It is clear that eliminating infection would eliminate transmission, and conversely eliminating transmission would lead, albeit more slowly, to elimination of infection. However, ascertaining a very low level of transmission was deemed to be easier than measuring a very low level of infection. To detect transmission, one needs only a geographically representative sample of susceptible individuals, but the sample could all come from a stratum of the community that is relatively easily sampled (e.g. school-entry children). In contrast, to determine the infection rate in the community would require a sample across all geographic locales and community social strata, with higher levels of effort and greater uncertainty involved.

- *Is there a threshold level below which transmission ceases?*

The evidence is not yet definitive on whether one can define a prevalence level below which transmission will cease. Reports from China indicate that following mass treatment with DEC, once prevalence is under 1%, transmission will continue to fall to zero without further intervention. However, filariasis has spontaneously rebounded in some South Pacific islands from levels reportedly lower than 1%.

A 5 year cumulative transmission rate of less than 1 new infection per 1000 susceptible individuals has been chosen as the target for filariasis elimination. This level is low enough to be compatible with either complete or soon-to-be-complete cessation of filariasis transmission, and yet it is not so low that exceptionally large numbers of tests need to be done to make the determination.

- *Given a target for global elimination, what statistical confidence (e.g. 90%, 95%, 99%) should be used to test whether the target has been reached?*

A level of 95% has been chosen as the statistical confidence one should have in reaching the determination of transmission incidence. As a practical matter, using a lot-quality-assurance statistical approach (see document WHO/FIL/99.195), this worked out to testing 3000 five year old children in each endemic area. If all 3000 test negative, one would have >95% confidence that the true 5 year cumulative incidence rate was less than 1 per 1000.

2. WHERE DOES CERTIFICATION NEED TO TAKE PLACE?

- *How will countries be placed in categories for the elimination process?*

For many countries there is a reasonable certainty that they have not had sustained transmission of filariasis in modern times. Certification for these “never-endemic” countries should be a simple process. On the other hand, “endemic” countries will need to go through the full process as outlined in the elimination certification document to ensure elimination of filariasis transmission. “Post-endemic” countries, or countries with uncertain status, will need to go through those steps necessary according to their individual circumstances to ensure the elimination of filariasis transmission. While countries are free to determine under which category (never-endemic, post-endemic, or endemic) they are applying for certification, it is the International Commission for the Certification of Lymphatic Filariasis Elimination (ICCLFE) that will determine if the evidence they have presented justifies the category under which they are applying, or if they belong in a different category. The ICCLFE will then evaluate the evidence under the category it deems to be appropriate.

- *What is the role for baseline information gathering and surveys in the elimination certification process?*

Within endemic countries it is critical that all areas with endemic filariasis be identified. Efforts to identify such areas must be done thoroughly and in accordance with the guidelines for the original assessment as described in Document WHO/FIL/99.195, since the findings of the initial assessment determine which areas need to be treated, monitored, and ultimately evaluated before applying for certification.

3. WHO WITHIN THE POPULATION NEEDS TO BE TESTED?

- *Do we need to study whole populations, or are there sentinel groups (e.g. school children) who are reasonable surrogates for the population in general and are easier to follow?*

Because exposure to infected vectors is the major over-riding risk factor for acquiring infection, and because the distribution of infected vectors is geographically determined, the primary characteristic of any sentinel population to detect transmission should be that it is geographically representative of the population. Thus, school-age children (to the extent enrolment in school is near-universal) or women of child bearing age attending clinics (to the extent that health care is widely accessible) would be populations whose exposure to transmission is representative of the communities from which they come. Limited epidemiologic evidence suggests that children *acquire* infection at a higher rate than adults; if substantiated, this would further strengthen the case for using them as sentinels for the population. It must be recognized, however, that there may be scenarios where screening children may not be the appropriate choice (e.g. studies on malaria in some regions in the Pacific have noted that children and women were more likely than men to sleep under bednets).

- *Should we repeatedly sample populations cross-sectionally – or follow specific cohorts of individuals longitudinally?*

Whether to sample a cohort of individuals repeatedly, or to do cross-sectional testing of a population repeatedly is an extremely important issue for monitoring programme progress (see document WHO/FIL/99.195). In short, the problems of tracking individuals over time in longitudinal studies must be weighed against the problems of not knowing a given individual’s prior status in cross-sectional studies. For certification of elimination, however, a cross-sectional sample of school-entry children (usually 5-7 years of age), is recommended because their prior status 5-7 years earlier (i.e. at birth) is known to be negative.

4. HOW DOES LOCAL GEOGRAPHY AFFECT CERTIFICATION?

- *What role might the local “filarial/human ecosystem” (i.e. differing combinations of vector, human demographic, climatic, and environmental variables) have on elimination criteria?*

While numerous vector, human demographic, climatic and environmental factors play significant roles in filariasis transmission, there is presently not enough known about those factors to make firm quantitative, or even qualitative, statements about them. Because further studies and the elimination efforts themselves will yield additional insights, information on these factors, to the extent known, should be submitted as part of the certification application. However, until further information shows otherwise, the elimination criteria as stated are considered applicable in all regions.

- *What is the size of local areas that should be sampled?*

There is flexibility in the size of the areas and populations to be sampled. For example, if from baseline and other information four similar areas appear to have made similar progress towards elimination, the country could choose to do four separate pre-certification surveys (sampling 3000 school entry children in each area) or could do one sample of 3000 school children drawn from all four of the areas. Either would be sufficient for certification purposes, and the second approach would be less resource intensive. The disadvantage of the second approach, however, is that the sampling frame that applies to success also applies to failure. If one infected child is found in any four of the regions – all four regions fail.

Also, while areas can be combined, it is clear that areas should only be combined if they are similar in risk for filariasis; any area with different levels of risk within it must be subdivided. The rule is that areas at highest risk of continuing transmission must be subject to the 5 year cumulative incidence of < 1 case per 1000 persons. The rigor of the testing must not be undermined by the inclusion of other areas with lower prevalence. As indicated above, it is acceptable for countries to combine several high risk areas into a single testing unit, but with the same caveat that all areas fail if the test fails (i.e. if any of the 3000 school-entry children tested is found to be infected).

- *How should certification surveys be done for small or isolated communities (including islands)?*

Small or isolated communities can be tested individually or combined as described above.

- *Do GIS techniques have a role in certifying elimination?*

The utility of GIS techniques for helping understand the nature and extent of endemic filariasis is readily apparent, and GIS will likely play an important role in surveillance and monitoring in some countries. At this time, however, no formal role is envisioned for GIS in certifying elimination.

5. WHEN SHOULD CERTIFICATION TAKE PLACE?

- *Can we certify elimination while the community is being treated? If not, does there need to be a delay after treatment ceases before certifying?*

Because available anti-filarial drugs can suppress microfilaremia without eliminating adult worm infection, and because the thick blood smear (the test of infection status currently most commonly used in the field) is directly dependent on levels of microfilaremia, testing individuals while 'on treatment' would not lead to an accurate assessment of their infection status. Also, the period it takes to become microfilaraemic (and test positive) again -- if still infected after completion of treatment -- is not well known and may be as long as 1 – 3 years. Until further studies yield clarifying information with regard to the newer filarial diagnostic tests (i.e. antigen or DNA detection), for the purpose of certifying elimination, pre-certification surveys must be done at least 5 years after the completion of community treatment (based on the estimated life span of the adult *W. bancrofti*). However, countries are strongly urged to keep a post-treatment surveillance programme in place during the interval between completion of community treatment and the final pre-certification surveys. Doing surveys within this interval will allow countries to ascertain that they are indeed making the expected progress towards elimination, will identify areas where further community intervention is needed, and will maintain the programme infrastructure and presence necessary to finishing the elimination process successfully (see document WHO/FIL/99.195).

While it can be predicted that five years of broad-coverage community treatment for filariasis (as recommended), followed by 5 years of post-treatment surveillance before certification, should be an adequate period also to ensure death of adult worms (those present at the time of programme outset and those developing in the earliest years of community treatment), the evidence to support this length of time needs to be reassessed as more countries gain experience in the elimination process.

6. WHAT SAMPLING AND ANALYTIC TOOLS SHOULD BE USED FOR CERTIFICATION?

- *What is the role of cluster sampling in eradication certification?*

Cluster sampling for the original assessment, for ongoing monitoring, and for final pre-certification surveys has the principal advantage that it is a robust technique that is widely known and used in many regions of the world. The major concern, however, is its usefulness for a disease that is often focal (i.e. heterogeneous) in distribution. In such situations, the 'design effect' (in cluster sampling) becomes large, and the technique becomes less efficient (i.e. the number of persons to be tested with a cluster sampling approach can be several times that for comparable precision using a random sampling approach). Because of those concerns, cluster sampling would be useful only when the risk appeared to be homogenous throughout an area and no population list was available (or could be readily constructed) from which to draw a random sample.

- *Is there a role for over-sampling areas believed to be at highest risk for continuing transmission?*

Techniques which involve over-sampling regions at higher risk, either by a stratification method or by a technique such as adaptive cluster sampling might be useful but will require further assessment to determine their relevance for incorporation into the elimination guidelines.

- *Is Lot Quality Assurance (LQA) testing an appropriate methodology in this setting?*

Lot Quality Assurance is a technique first used in industry to determine whether a certain percentage of defectives was exceeded in a production run or shipment (i.e. a lot) of a product. It has subsequently

been used in public health, for example to evaluate disease incidence in the neonatal tetanus elimination programme. For certification of filariasis elimination the method might be most applicable for determining how many children need to be tested (and found negative) in order to be 95% certain in determinations that infection is not present in an area. The calculation that 0 of 3000 school-entry children should test negative to ascertain that the 5 year cumulative incidence of filariasis was < 1 per 1000 has been based on this methodology.

7. WHAT IS THE IMPLICATION OF OUR HAVING 'IMPERFECT TESTS'?

- *What more needs to be known about the performance of current tests, and what kinds of revisions to the elimination criteria might result from new findings?*

Conceptually the problem of imperfect sensitivities is vexing. If a test with a sensitivity of 80% is used in an area with a large population, and one wants to adequately test a certain number of people, one can correct for the 80% sensitivity of the test by sampling 25% more people, for example testing 3750 instead of 3000 children. In smaller populations, such as an island or isolated locale of 1000 people, sampling becomes problematic. (Technically, for a LQA approach one can calculate the number to sample with exact methods, using a hypergeometric distribution, but as the disease becomes rare the efficiency of sampling becomes low, with the result that calculations may give numbers to sample that are nearly the same as the total population. Screening the whole population with a more sensitive test would be the preferred approach). In the current guidelines these considerations are ignored – testing by either thick blood film or antigen card testing is recommended, and corrections for the sensitivities of each test are not suggested, though they should be.

The problem with imperfect specificities is perhaps more tractable. Because various tests are available, individuals who are positive by the screening test can be re-tested by other methods (if there is cause to believe the results might be falsely positive). For example, even after conclusion of a community treatment programme, a pre-certification survey of 3000 school entry children that uses a test with 99.5% specificity, would be expected to yield 15 test-positive children. These positive children should be further examined using additional tests to ascertain their true status. [[No formal decision was reached on what additional tests should be done, other than that the method used should be documented for subsequent review by the International Certification Team.]]

- *What are the implications of 'test sensitivity and specificity' for certifying elimination?*

Despite substantial recent developments in this area of diagnostics there are still many unknowns. As further experience is gained with existing tests, and new tests are developed, this issue will likely need to be frequently revisited and revised.

8. CAN NON-EPIDEMIOLOGIC STUDIES HELP IN CERTIFYING ELIMINATION?

- *How might vector studies contribute to elimination certification?*

It is clear that there are important potential roles that vector studies could play in certifying elimination, particularly by offering a surrogate for testing human populations. Certainly, where suitable vectors do not exist, transmission elimination can be readily certified. However, beyond that simple situation,

there are few data available that could guide the use of measurements of vectors and their infection status as alternatives to testing people. Thus, for the present time no formal role has been assigned to vector studies in certifying elimination, though the screening of 'pools' of mosquitoes using very sensitive, specific PCR techniques offers a promising approach.

- *How might process measures of programme implementation contribute to elimination certification?* Measures of programme implementation, most notably the coverage achieved in community treatment programmes, are essential to the success of any elimination effort. Nonetheless, for purposes of elimination certification, programme measures themselves cannot substitute for measurement of the actual transmission (or lack thereof) in the population.

9. WHAT REGIONAL AND IMPORTATION ISSUES AFFECT CERTIFICATION?

- *What role might screening persons from "non-endemic" regions have in certifying elimination of filariasis?*

The use of secondary systems for routinely screening individuals from various regions of the country (e.g. screening army recruits) is attractive for several important reasons: 1) it can provide an independent system of monitoring populations from endemic areas, adding further validity to survey findings from those regions; 2) it can provide a mechanism for screening individuals from areas thought to be non-endemic, and can either help confirm that classification or identify new areas for community intervention; and 3) it can help identify areas which had only recently (since the original assessment) become endemic for filariasis, whether due to changes in local conditions or the migration of infected individuals into the area. Thus, such systems should ideally be established and described in a country's submission for elimination certification.

- *How does migration of individuals from filariasis endemic regions or countries affect elimination and certification?*

Regarding migration, a case of filariasis that occurs in an area (A) otherwise thought to free of filariasis transmission, and that could have been acquired by that individual while living in another area (B) with known filariasis transmission, can reasonably be considered not to be evidence that the area (A) has filariasis.

In order to avoid the risk that migration could contribute to re-establishing filariasis in an area previously certified as having eliminated transmission, a system of regional certification (assuming most travel of infected individuals is between contiguous countries) should be developed in order to link the certification status of neighboring countries.

10. ARE THERE CERTIFICATION ISSUES SPECIFIC TO “POST-ENDEMIC” COUNTRIES

- *What is the role of the existing national surveillance system?*

In countries with a past history of filariasis, an evaluation of the effectiveness of the routine disease reporting system will be important in determining to what extent further investigation is necessary. Such an evaluation would include: (i) evidence that filariasis is a reportable disease, (ii) the regularity and completeness with which health reporting units reported, (iii) efforts to validate the reports, (iv) records of action taken when filariasis cases were reported during the latter stages of the programme, and (v) the number and distribution of health units: primary health posts, dispensaries, health centres, hospitals etc., in the previously endemic areas.

- *Is there a need for patient registers?*

Being able to examine registers of suspected or confirmed filariasis cases, which should include the dates of testing and results, subsequent treatment and re-testing, and the person's past and present residences, would be of use to the International Certification Team. Summaries of registry data should be documented in the country report submitted as part of the application requesting certification of transmission elimination.

- *What about a “rumour” register?*

If the country does active surveillance or case finding, including public or medical education about the need for reporting, it should institute a “rumour” register which captures all reports of possible filariasis that it receives. Details of subsequent investigations and final dispositions of these possible cases should be noted.